DEBATE ON FOODS DERIVED FROM BIOTECHNOLOGY IN CODEX ALIMENTARIUS

A Chairpersons' Experience

by

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Chair of Task Force on Foods Derived from Biotechnology from 2000 to 2003 and 2005 to 2008

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Intent of this document

The GM food issue was and continues to be controversial. The documents agreed in Codex Alimentarius are results of repeated difficult negotiations. As a consequence, to those who did not participated in the debate, certain paragraphs may be difficult to interpret. In such a situation, one may be tempted to produce guidance on interpreting the guidelines. However, such an attempt very often results in the reinterpretation of the texts and brings the issue back to the starting point.

So as not to nullify the efforts that have been made in reaching the agreements, and so as not to let the text interpreted differently from the intent when the agreement was made, it is necessary that the people understands the process that led the Task Force to the final texts. It is particularly so when these texts are translated into languages other than English, French or Spanish.

The present document is a cut-and-paste of the reports (except Introduction and Part I of Chapter 14). It is “cut-and-paste” because its intent is to provide material for studying the texts. I recall, in the Codex Alimentarius Commission one delegation very often stressed, speaking on behalf of the civil society, importance of precise reflection of the debate in the meeting report. In my view, such a document could be useful or usable only when the reports are edited so that one can follow the process of the debate.

In Codex Alimentarius, “every effort should be made to reach agreement on the adoption or amendment of standards by consensus” (from Measures to Facilitate Consensus, Codex Alimentarius Commission Procedural Manual). Arriving at consensus is never an easy task. I think the Codex Alimentarius Commission has much to learn from the past experience. I believe the present type of documentation is useful also for this purpose.

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INTRODUCTION

1. Documents produced by the Task Force

In spite of initial general skepticism, the Task Force on Food Derived from Biotechnology completed its work within the given time frame. It produced four Guidelines;

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology,
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants,
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Micro-organisms
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals.

Each guideline is annexed with Assessment of Allergenicity. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants is annexed with Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits and Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food in addition.

The Task Force greatly owes its success to good will of the delegation and scientific advice given by a series of FAO/WHO Expert Groups:

- Safety aspects of genetically modified foods of plant origin (29 May – 2 June 2000)
- Evaluation of allergenicity of genetically modified foods (22 – 25 January 2001)
- Safety assessment of foods derived from genetically modified microorganisms (24 – 28 September 2001)
- Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish (17–21 November 2003)
- Safety Assessment of Foods Derived from Recombinant-DNA Animals (26 February – 2 March 2007)

The first consultation “Safety aspects of genetically modified foods of plant origin (29 May – 2 June 2000)” was particularly important in clarifying many complex problems raised in the initial phase of the debate.

2. Concerns/ Interests Expressed in the First Meeting

In the first meeting, members and observers expressed their views on area of the work, work priorities and key concepts and definitions to be developed, which were;

- Definition/use of:
  - Substantial equivalence
  - Modern biology/recombinant DNA technique/ genetically modified organism
  - Familiarity
- Precautionary principle
- Transparency
- Traceability and Monitoring
- Analytical method including detection
- Other legitimate factors other than science

Genetically modified foods whose guidance was suggested to be developed were:

- Plants
- Microorganism
- Animals
- Animal feed
- Food additives

3. Short History of Debate on Different Topics

The following is a short summary/discussion of main topics debated during the whole Task Force sessions. See the main text for the detail. Some important topics, such as “allergenicity”, “analytical method including detection”, “labeling”, are not included in this chapter. Please see the main text.

1. Substantial Equivalence or Safety Assessment

The concept of “substantial equivalence” was first proposed by OECD as follows:

> “The concept of substantial equivalence embodies the idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or a food component that has been modified or new.” (Safety Evaluation of Foods Derived by Modern Biotechnology - Concepts and Principles, OECD, 1993, page 14).

According to this sentence, the term “substantial equivalence” is *a concept* and the “equivalence” is “equivalence for the safety” not equivalence for the nature of the products. However, in the same document, found are the following (idem, page 16):

> “if a new food or food component is found to be *substantially equivalent* to an existing food or food component, it can be treated in the same manner with respect to safety. No additional safety concerns would be expected.”

Here, “substantial equivalence” was used to indicate an *end point judgment* rather than a concept. In addition, as the sentence does not indicate on which point GM and non-GM foods should be equivalent, it could be easily misinterpreted in such a way that if a GM food is *substantially equivalent in its composition* to a conventional food, the GM food is safe. In the following sentences, the confusion of the logic is more obvious;

> “Products which are demonstrated to be substantially equivalent to an existing counterpart are regarded as being as safe as that counterpart and no further safety considerations than for the counterpart are necessary.” (Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety Rome, Italy, 30 September to 4 October 1996).

A typical reaction to the above situation is found in the following commentary that appeared in Nature (Erik Millstone, Eric Brunner and Sue Mayer, Beyond ‘substantial equivalence’ Nature, 401, 525-526, 1999)

> “The adoption of the concept of substantial equivalence by the governments of the industrialized countries signaled to the GM food industry that, as long as companies did not try to market GM foods that had a grossly different chemical composition from those of foods already on the market, their new GM products would be permitted without any safety or toxicological tests. The substantial-equivalence concept was also intended to reassure consumers, but it is not clear that it has served, or can serve, that purpose. Although toxicological and biochemical tests, and their interpretation, are notoriously problematic and contested, and are slow and expensive, they can provide information vital to consumer protection.”
>
> “GM glyphosate-tolerant soya beans (GTSBs) illustrate how the concept has been used in practice. *The chemical composition of GTSBs is, of course, different from all antecedent varieties, otherwise they would not be patentable, and would not withstand the application of herbicide glyphosate. It is quite straightforward to distinguish, in laboratory, the particular biochemical characteristics that make them different. GTSBs have, nonetheless, been deemed to be substantially equivalent to non-GM soya beans* by assuming that the known genetic and biochemical differences are toxicologically insignificant, and by focusing instead on a restricted set of composition variables, such as ……..”
>
> “Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgment masquerading as if it were scientific. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests.”

Joint FAO/WHO Expert Consultation (“Safety aspects of genetically modified foods of

plant origin", Geneva, Switzerland 29 May – 2 June 2000), while acknowledging such criticisms, clarified substantial equivalence and related issues as follows:

> **"**The Consultation acknowledged that the concept of substantial equivalence had attracted criticism. *This criticism relates, in part, to the mistaken perception that the determination of substantial equivalence was the end point of a safety assessment rather than the starting point.* Further disagreement may have arisen from reference to three outcomes of substantial equivalence discussed previously (i.e. substantially equivalent, substantially equivalent apart from defined differences, and not substantially equivalent) (FAO, 1996).
>
> Having considered the way in which the concept of substantial equivalence is currently used, and the possible use of alternative strategies, the *Consultation concluded that application of the substantial equivalence concept contributes to a robust safety assessment framework*. The Consultation was satisfied with the approach used to assess the safety of the genetically modified foods that have been approved for commercial use.
>
> It was agreed that communication of the principles involved in safety assessment could be improved. The Consultation concluded that the key message to be conveyed is that *substantial equivalence is a concept used to identify similarities and differences between the genetically modified food and a comparator with a history of safe food use which subsequently guides the safety assessment process*.
>
> The Consultation reiterated that a consideration of compositional changes was not the sole basis for determining safety. Safety can only be determined when the results of all aspects under comparison are integrated.
>
> It was recognised that *whole foods do not lend themselves to the standard safety evaluation principles (WHO 1987) used for food additives and other chemicals* and that a quantitative assessment of risk of individual whole foods from whatever source cannot be achieved. The Consultation agreed that assessing safety relative to existing foods offered the best means of assessing the safety of genetically modified foods.
>
> The Consultation *considered the issue of long term effects from the consumption of genetically modified foods and noted that very little is known about the potential long term effects of any foods.* In many cases, this is further confounded by wide genetic variability in the population, such that some individuals may have a greater predisposition to food-related effects.
>
> In this context, the Consultation acknowledged that for genetically modified foods, the pre-marketing safety assessment already gives assurance that the food is as safe as its conventional counterpart. Accordingly it was considered that the possibility of long term effects being specifically attributable to genetically modified foods would be highly unlikely. Furthermore, it was recognised that *observational epidemiological studies would be unlikely to identify any such effects against a background of undesirable effects of conventional foods*. Experimental studies, such as randomised controlled trials (RCTs), if properly designed and conducted, could be used to investigate the medium/long term effects of any foods, including genetically modified foods. Such studies could provide additional evidence for human safety, but would be difficult to conduct. In this respect, it is also important to recognise the wide variation in diets and dietary components from day to day and year to year.
>
> The Consultation was of the view that there were presently no alternative strategies that would provide a better assurance of safety for genetically modified foods than the appropriate use of the concept of substantial equivalence."

With this clarification, the Task Force agreed:

> The *concept of substantial equivalence is a key step* in the safety assessment process. However, it is not a safety assessment in itself; rather *it represents the starting point which is used to structure the safety assessment* of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart. It aids in the identification of potential safety and nutritional issues and is considered the most

> appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. *The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.* (Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants, paragraph 13)

2. Definition of foods derived from modern biotechnology

The Task Force first debated how to define the "GM foods". It considered two definitions, the one used Cartagena Protocol and the other used by Codex Committee on Food Labelling (CCFL). "Although it noted that CCFL had developed a separate definition for labeling purposes and that in general consistency between Codex texts was desirable, the Task Force was strongly of the opinion that consistency with other internationally agreed instruments, i.e., Cartagena Protocol, was critically important in this case. It recommended that CCFL give consideration to using the same definition in its work."

The Task Force had an extended discussion on the definition of "Conventional Counterpart", in particular on whether or not a genetically modified food could serve as a "conventional counterpart" for comparison purposes. Some noted that once a food derived from biotechnology had been approved and in common use for an extended period, there was no scientific reason for not using such a food as the basis for comparison. Some others pointed out that the confidence of consumers in foods derived from biotechnology depended on their being able to relate the safety of such foods to un-modified foods that had a well-established history of safe use and that the traditional unmodified food supply provided a sound baseline for this purpose.

The Task Force finally agreed to modify the definition by the inclusion of a footnote to the effect that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts. The Task Force, however, did not agree to adopt a proposed change to the Definition of Conventional Counterpart that would limit the conventional counterpart to "non-genetically modified organisms".

The agreed definition was as follows:

"Modern Biotechnology" means the application of:

(i) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(ii) Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection[4].

"Conventional Counterpart" means a related organism/variety, its components and/or products for which there is experience of establishing safety based on common use as food[5].

[4] This definition is taken from the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

[5] It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

3. Familiarity

The term “familiarity” was proposed by OECD in the document entitled “Safety considerations for Biotechnology: Scale-Up of Crop Plants (OECD. 1993)”. It was proposed as a concept guiding the environmental safety assessment of GM crop plants. The document says “familiarity is not synonymous with safety; rather it means *having enough information to be able to judge the safety* of the introduction or to indicate ways of handling the risks”. It recommends a stepwise scale-up approach noting importance of three types of “familiarity”:

(i) familiarity with the characteristics of the organism, the trait introduced, the interactions between these, and the intended application.

(ii) familiarity with the conditions and the environment into which the organisms are intended to be introduced.

(iii) familiarity with interactions among the organism, the trait and environment.

Evidently, “familiarity” does not directly concern the food safety, and the Task Force did not discuss this issue further. However, the “GM plants” have to be planted for production. For planting, developers and producers have to obtain permission from governments (and public consent, too). Therefore, how environmental risk assessment is implemented by regulators is crucial for production of “GM foods”.

The underlined part of the above paragraph “*having enough information to be able to judge the safety”* is reminiscent of “substantial equivalence”, term used in food safety. i.e., “familiarity” could be an environmental counterpart of “substantial equivalence”, which is defined as assessment of a GM food relative to its conventional counterpart for which there is experience of establishing safety based on common use as food (See above).

The environmental risk assessment of GM plants is currently done under Article 15 and Annex III of Cartagena Protocol. However, though it uses an approach quite similar to the codex’s GM food risk assessment in that it evaluates the risk of LMOs in comparison with unmodified organisms, the burden imposed on the applicants is far heavier that in case of GM foods. In Japan, for example, while clearance of GM crop plants for food safety requires 1-1.5 years, clearance for environmental safety generally requires 3-4 years (personal communication). The cost is accordingly far higher for the latter.

One difference between codex and Cartagena is that while codex uses another parameter “conventional counterpart (unmodified organism with long history of safe use)” Cartagena does not. This situation may have produced current higher barrier in environmental risk assessment, because it requires all the required information be obtained both for LMOs and the unmodified organisms simultaneously in the same location. In addition, some requested information, such as “information on biological diversity” (Annex III, paragraph 9, (h)), is difficult to obtain with authenticity even for the unmodified conventional organisms (Is such information available for potatoes in your backyard?).

Introducing the parameter “conventional counterpart” may make the environmental risk assessment more efficient and more focused on the introduced trait. It will be so at least for LMOs that have conventional counterpart(s).

4. Uncertainty and unintended effects

"The master said "Yu, shall I tell you what it is to know. To say you know when you know, and you say you do not when you do not, that is knowledge." Confucius, The Analects, Book II, 17.

"Uncertainty" was raised in connection with "precautionary principle" in CCGP and "unintended effects" in Task Force.

(1) Debate in Codex Committee on General Principles (CCGP)

CCGP, in its 14th session, noted that how to address "uncertainty" in scientific evaluation was an important issue for the risk management. Several delegations pointed out that *there was always a measure of uncertainty in the scientific evidence available, and that should not prevent necessary measures to protect public health.*

The underlined part is a claim quite similar to Article 11, 8 of Cartagena Protocol and Article 5. 7 of Agreement on SPS measures;

> "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or processing, in order to avoid or minimize such potential adverse effects." (Article 11, 8 of Cartagena Protocol)
>
> "In cases where relevant scientific evidence is insufficient, a Member may *provisionally* adopt sanitary and phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time." (Article 5. 7 of Agreement on SPS measures)

After long debate starting from 1998 and ending in 2003, CCGP agreed to the following;

> "11) Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.
>
> 23) Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.
>
> 25) The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.
>
> 40) Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para.25). (Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius)

(2) Debate in the Task Force

In the 1st session, the Task Force decided to elaborate a set of broad general principles for risk analysis of foods derived from biotechnology and a specific guidance on the risk assessment of foods derived from biotechnology. The Task Force identified “unintended effect” as one of the matters to be addressed. Therefore, it included the question below among questionnaire addressed to the FAO/WHO Expert Consultation, i.e., “What scientific approach can be used to monitor and assess possible long-term health effects or *unintended/unexpected* adverse effects?”The Expert Group’s response was as follows (extracts);

“The potential occurrence of unintended effects is not specific for the application of recombinant-DNA techniques, rather it is an inherent and general phenomenon in conventional breeding. One of the approaches to cope with this problem is to select and discard plants with unusual and undesired phenotypic and agronomic parameters already at an early stage. The practice of consecutive back-crossing is also a major procedure used to eliminate unintended effects. Only in rare cases are these approaches accompanied by analytical screening of defined constituents.

Unintended effects due to genetic modification may be subdivided into two groups: those which are "predictable" based on metabolic connections to the intended effect or knowledge of the site of insertion and those which are “unexpected”. Due to the increased precision of genetic modification compared to conventional breeding, it may become easier to predict pathways likely to be influenced by unintended effects.

The messages were:

- Unintended consequence is not specific to the recombinant-DNA techniques,
- It is not always the one “unexpected” but can be the one "predictable", and
- The GM lines with undesired traits are eliminated during the breeding.

The last message was particularly useful, because, when the Task Force started, “unintended effects” due to the random insertion of the recombinant DNA concerned many delegates. Many criticisms against GM foods disregarded the process of selection that follows the transformation of the host plant. As the selection is coupled with the genetic and phenotypic characterization, unintended events can be well characterized when the last GM product is obtained.

What was agreed by the Task Force regarding the term “unintended effects” was as follows;

14. In achieving the objective of conferring a specific target trait (intended effect) to a plant by the insertion of defined DNA sequences, additional traits could, in some cases, be acquired or existing traits could be lost or modified (unintended effects). The potential occurrence of unintended effects is not restricted to the use of in vitro nucleic acid techniques. Rather, it is an inherent and general phenomenon that can also occur in conventional breeding.–Unintended effects may be deleterious, beneficial, or neutral with respect to the health of the plant or the safety of foods derived from the plant. Unintended effects in recombinant-DNA plants may also arise through the insertion of DNA sequences and/or they may arise through subsequent conventional breeding of the recombinant-DNA plant. Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA plant would have an unexpected, adverse effect on human health.
15. Unintended effects can result from the random insertion of DNA sequences into the plant genome which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. Unintended effects may also result in the formation of new or changed patterns of metabolites. For example, the expression of enzymes at high levels may give rise to secondary biochemical effects or changes in the regulation of metabolic pathways and/or altered levels of metabolites.
16. Unintended effects due to genetic modification may be subdivided into two groups: those that are "predictable" and those that are “unexpected”. Many unintended effects are largely predictable based on knowledge of the inserted trait and its metabolic connections or of the site of insertion. Due to the expanding information on plant

genome and the increased specificity in terms of genetic materials introduced through recombinant DNA techniques compared with other forms of plant breeding, it may become easier to predict unintended effects of a particular modification. Molecular biological and biochemical techniques can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects.

17. The safety assessment of foods derived from recombinant-DNA plants involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment for unintended effects takes into account the agronomic/phenotypic characteristics of the plant that are typically observed by breeders in selecting new varieties for commercialization. These observations by breeders provide a first screen for plants that exhibit unintended traits. New varieties that pass this screen are subjected to safety assessment as described in Sections 4 and 5.

(Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants)

5. Precautionary principle

"Precautionary principle" had been debated in CCGP since 1998. However, in the first meeting of the Task Force in 2000, many delegations and observers pointed out that precautionary principles/approaches to be considered by the Task Force. Several other delegations, however, stressed that the issue of precaution should first be discussed at the Codex Committee on General Principles (CCGP). After long debate, the Task Force agreed that the precautionary approach/ principle should be dealt with as a matter of priority by the Codex Committee on General Principles (CCGP).

CCGP arrived at agreement in 2003 as follows:

Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard (Principles for risk analysis for application in the frame work of the codex alimentarius, paragraph 11).

6. Traceability and Monitoring

(1) Traceability

In the first meeting (2000), many delegations and observers identified the development of a guideline for the *monitoring and traceability* of the foods derived from biotechnology as a priority, indicating that these issues were not related only to consumer information but to consumer health protection.

However, it was noted also that the "traceability" may not be exclusive to foods derived from biotechnology and may need to be considered at a more general level. Actually, the Executive Committee noted "traceability" as a general issue confronting Codex and recommended that the Committee on General Principles consider the two aspects, i.e., SPS and TBT aspects, of traceability; it also noted the role of the Committee on Food Import and Export Inspection and Certification Systems in relation to the development of procedures for the application of traceability in food import and export inspection and certification systems.

The final solution to "traceability" was as follows:

1) CCGP defined "traceability" as:

Traceability / product tracing: the ability to follow the movement of a food through

specified stage(s) of production, processing and distribution.

2) CCFICS produced a guideline, “Principles for traceability/product tracing as a tool within a food inspection and certification system” (CAC/GL 60-2006).

(2) Monitoring

The Task Force asked the FAO/WHO expert consultation “What scientific approach can be used to monitor and assess possible long-term health effects or unintended/unexpected adverse effects?” The response was as follows:

> “The Consultation considered the issue of long-term effects from the consumption of genetically modified foods and noted that very little is known about the potential long-term effects of any foods. In many cases, this is further confounded by wide genetic variability in the population, such that some individuals may have a greater predisposition to food-related effects. Against this background, the Consultation acknowledged that for genetically modified foods, *the pre-marketing safety assessment already gives assurance that the food is as safe as its conventional counterpart.* Accordingly it was considered that the possibility of long-term effects being specifically attributable to genetically modified foods would be highly unlikely.

With the above advice, the Task Force agreed:

“Post-market monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered, on a case-by-case basis, during risk assessment and its practicability should be considered during risk management. Post-market monitoring may be undertaken for the purpose of:

A) verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects; and

B) monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.”

It is important to note that the pre-market risk assessment is the basics of the regulation of GM foods, and monitoring should be done only when it is valid and necessary.

7. Other legitimate factors

Concerning legitimate factors other than science that were relevant to the health of consumers and the promotion of fair trade practice, several delegations proposed to develop a specific guideline to take into account those factors. Ethical/religious/cultural considerations, consumer concerns/interests, food security, enforcement capacity and environmental risk were proposed as “other legitimate factors” to be considered. Other delegations meanwhile noted that CCGP was working on this issue, and that therefore the development of a guideline specific to the Task Force was not an immediate priority. (1st session)

In the 2nd session, a proposal was made again to include examples of “other legitimate factors” such as the protection of the environment, consumer choice, ethics, fair trade practices and sustainable developments. Different views were exchanged on whether other legitimate factors should be considered by the Task Force, whether or not they should be enumerated or they should be left to the discretion of the CCGP.

The Task Force recalled that its terms of reference limited its consideration to “other legitimate factors relevant to the health of consumers and the promotion of fair trade practices”. It agreed that the wording used in paragraph 2 of the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are taken into Account should be used to describe the nature of other legitimate factors and that reference would also be made to the Working Principles on Risk Analysis under development by the CCGP which would provide more detail on the application of these Statements of Principle.

The Task Force settled the argument by agreeing on the paragraph below:

16. Risk management measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, where relevant, *taking into account other legitimate factors in accordance with the general decisions of the Codex Alimentarius Commission (CAC) as well as the Codex Working Principles for Risk Analysis.* (Principles for the Risk Analysis of Foods Derived from Modern Biotechnology)

8. Low level presence of recombinant-DNA plant material in foods

When the second round of the Task Force on Foods Derived from Modern Biotechnology started, the both importers and the exporters had fully realized problems associated with "contamination" of GM crop plant material. The event was costly for the both for exporters and importers, such as, in removing the "contaminated" foods from the market. The regulatory cost was non-negligible.

In the first session of the second round (5th session of the Task Force), the Delegation of the United States proposed development of a new guideline on conduct of safety assessments of low level adventitious presence of recombinant-DNA plant materials originating from new varieties in the development or field testing stage or from older varieties coming off the market.

The Delegation of the European Community attributed a low level (adventitious) presence of unauthorized recombinant-DNA plants to differences in the approval status of recombinant-DNA plants among countries. It proposed to develop a guide line on how to deal with the situation resulting from asymmetrical approvals. It emphasized the need for establishing an international data sharing system through which member governments could obtain data regarding safety assessments of recombinant-DNA plants conducted in other countries.

These proposals were not in entire disagreement, but the approach was not the same. The US considered the application of "safety assessment" crucially important, while EU considered the data sharing crucial. The US's proposal tried to cover almost all the adventitious presence of GM material including new varieties in the development and older varieties coming off the market, while EU wanted to focus on the situation resulting from asymmetrical approvals among countries.

Some delegations wanted definition of the terms "low level" and "unauthorized". The former will invite the debate on the threshold, which would be quite difficult to negotiate. The latter relates to the different views expressed by US and EU regarding the range of GM material to be covered (See the last sentence of the preceding paragraph). Some opposed to the new work since no recombinant-DNA plants should be allowed on the market without approval by the national authority. Though the session could not reach the consensus on this issue, the US and EU expressed their willingness to work on this matter till the next meeting.

In the sixth session of the Task Force, in spite of different views expressed, the Task Force finally agreed to start a new work to develop recommendations on *performing a safety assessment* in such situations and on the *requisite data and information sharing systems*. It agreed to consider *only the recombinant-DNA plant that has already been authorized for commercialization by one or more countries*, and decided to be silent on decision as to "the level of the low level presence" applicable to the guideline, i.e., leaving the decision to the members' decision.

Though the decision as to the use of the guideline is entirely in hands of members, the guideline is important in sending out the message that the low-level presence situation can be handled by the safety assessment based on science.

FAO provided a portal in cooperation with Codex, CBD, IPPC, OIE, WHO and WTO, which provides links to SPS-related regulatory information. With this move, providing the portal with the information on GM crop plants produced and commercialized in its own territory became norm to codex members. Thus,

Codex Members shall make available to a publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline This information shall be presented in accordance with the following format:

a. name of product applicant
b. summary of application
c. country of authorization

d. date of authorization
e. scope of authorization
f. unique identifier
g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate;
h. summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline;
i. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained; and
j. contact details of the competent authority(s) responsible for the safety assessment and the product applicant. (Paragraph 28 of the agreed document)

4. Introduction to Chapters

Chapter 1: the process of establishment of the Task Force, which is documented in reports of Codex Alimentarius Commission and Executive Committee in 1997-1998.

Chapter 2: the debate in the first session of the Task Force. The main topics were on scientific uncertainty, substantial equivalence, precautionary principle, traceability, monitoring, labeling, detection and analysis of GMOs, and topics related to “other legitimate factors”. It was agreed that the issue on precaution should be handled in Codex Committee on General Principle (CCGP). See Chapter 5.

Chapter 3: the elaboration process of Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. One important but controversial issue was “traceability”. After long debate, the issue was recognized not unique to GM foods, and was transferred to CCGP and to Codex Committee on Food Inspection and Control Systems (CCFICS). See paragraphs concerning originally proposed paragraph 19 “Risk management may include traceability.” in Chapters 2 and 3, and Chapter 4.

Chapter 4: the discussion on “traceability in CCGP and CCFICS. CCGP agreed on the definition of “traceability/product tracing”, and CCFICS on a guideline “Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System”.

Chapter 5: the discussion on “precaution”. “Precaution” is finally defined as “an inherent element of risk analysis” in the paragraph 11 of the agreed document “Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius”. As I did not attend all the sessions where “precaution” was debated, this chapter needs to be redrafted by somebody else who closely followed the debate. This comment applies also to the previous chapter 4.

Chapter 6: the elaboration process of the Safety Assessment of Food Derived from Recombinant-DNA Plants. This guideline text was used as a template for guidelines on Foods Derived from Recombinant-DNA Microorganisms and Recombinant-DNA Animals. It defined the term “safety assessment” which is the core of the risk assessment of GM foods.

Chapter 7: the deliberation on the assessment of possible allergenicity. It is annexed to guidelines on food safety assessment of foods derived from recombinant-DNA plants, microorganisms and animals. As the assessment is based on amino acid sequence of the newly expressed product(s), the text is essentially the same for all these products. Decision tree approach was initially proposed but more holistic approach was adopted finally.

Chapter 8: the discussion on the analytical methods of foods derived from modern biotechnology. The working group compiled methods validated by international studies and methods reported by member countries. The continued work in CCMAS that concluded in 2020 is reproduced in this chapter.

Chapter 9: the elaboration process of guidelines for Foods Produced Using Recombinant-DNA Microorganisms. An aspect unique to this topic is “assessment of viability and residence of microorganisms in the human gastrointestinal tract”.

Chapter 10: the debate in the fifth session of the Task Force, i.e. the first meeting of the second round of the Task Force. New works proposed were recombinant DNA-animals, recombinant-DNA plants modified for nutritional or health benefits, low level (adventitious) presence of unauthorized recombinant-DNA plant materials, comparative composition analysis, plants with stacked genes, plants producing pharmaceutical or bioactive substances, post-market surveillance and foods derived from animals exposed to protection against disease through gene therapy or recombinant-DNA vaccines.

Chapter 11: the Foods Derived from Recombinant-DNA Animals. An aspect unique to this topic is use of “health status of the recombinant-DNA animal” as a criterion of food safety.

Chapter 12: the Recombinant-DNA Plant Modified for Nutritional or Health Benefits. The work was done in close collaboration with members of Codex Committee on Nutrition and Foods for Special Dietary Uses, which endorsed the final document.

Chapter 13: the Low Level Presence of Recombinant-DNA Plant Materials Resulting from Asynchronous Authorizations. The important aspect of this guideline is combination of “short-track” safety assessment and the FAO portal that provide information necessary for such an assessment.

Chapter 14: History of debate on “GM labeling”. This chapter traces the near 20 years debate on GM labeling in the codex with almost no advance. This chapter is divided into two parts, a short summary of the debate and some questions concerning this issue and compilation of the record of the debate.

Appendix 1 is an extract from the codex evaluation concerning the GM work.

Explanatory Notes

Except for chapters 5 and 6, the report/discussion part is printed in italic. Each paragraph is preceded by the session number hyphen paragraph number, i.e., if it is paragraph 10 of the 2nd session, it will be 2-10.

The texts to be discussed or those from other documents are printed in the normal letters. The agreed texts are printed in bold. For each paragraph, the originally proposed paragraph comes first followed by discussion.

Chapter 1

ESTABLISHMENT OF AD HOC TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

CONTENTS

1. DISCUSSION IN THE CODEX ALIMENTARIUS COMMISSION AND EXECUTIVE COMMITTEE

22nd Session of Codes Alimentarius Commission (1997)

178 (extract). In endorsing the general direction of the Medium-Term Plan, the Commission requested that consideration should be given to the development of standards or related texts in areas concerning foods derived from biotechnology or traits introduced into foods from biotechnology, where this scientifically justified.

45th Session of the Executive Committee of codex (1998)

18. In the programme area Food Production and Processing Systems, the Executive Committee was of the opinion that a clear statement by the Commission on the policy approach which assured the safety and nutritional aspects of food prepared from biotechnology was needed as a matter of priority. I therefore agreed in amending this programme are to include provision for consideration of a general standard for foods prepared from biotechnology.*

> **MEDIUM-TERM PLAN FOR 1998 TO 2002 Outline*
>
> *Among nine programme areas, included was*
>
> *Food production and processing systems: Establishment of principles for the use of safe technologies in food production, processing and handling including those for specific food sectors. Consideration of a general standard for foods derived from biotechnology or traits introduced into foods by biotechnology. Consideration of application of standards and related texts by small and medium-scale enterprises, especially in developing countries.*

46th Session of the Executive Committee of codex (1999)

ELABORATION OF A GENERAL STANDARD FOR FOODS DERIVED FROM BIOTECHNOLOGY

34. The Executive Committee noted that the draft Medium-Term Plan for 1998 to 2002 prepared by the Forty-fifth Session of the Executive Committee foresaw, inter alia, the consideration of a general standard for foods derived from biotechnology or traits introduced into foods by biotechnology.

35. The Executive Committee unanimously agreed to recommend to the Commission that an ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology be established to deal with this subject. It also agreed that the work should cover "safety and nutritional aspects" of foods derived from biotechnology and should be conducted in a totally transparent manner. Some Members were of the opinion that it should also cover aspects of consumer information and labelling. The Executive Committee noted that the Government of Japan had offered to host the ad hoc Task Force and appreciated the generous offer of that Government.

36. In regard to the timeframe of the Task Force to be included into the Terms of Reference, the Executive Committee unanimously agreed that the Task Force should first submit a preliminary report to the 24th Session of the Commission in 2001, and a full report in 2003. The Executive Committee also noted with satisfaction that a Joint Expert Consultation would be convened in 2000 by FAO and WHO to draft an initial text, whether a general standard, general guidelines or guidelines on specific issues, that should be scientific in nature and would be used as basis for the work of the Task Force.

37. As for the rest of the Terms of Reference the Executive Committee, having failed to reach an agreement, decided that Commission should consider the basis of the Japanese proposal in CAC/LIM 8 (1999). During the discussion the Executive Committee noted the following comments:

- *the Terms of Reference should be within the mandate of the Commission;*

- *Item 2) Objectives should include the necessity of responding to consumers' concerns regarding any risks associated with the production and processing of foods derived from biotechnology; the same should be included under item 4) Terms of reference; some Members noted, however, that the notion of consumers' concern may be outside the mandate of the Commission;*
- *co-ordination with the other Codex bodies would be essential, in particular with the Codex Committee on Food Labelling working currently on the recommendations for the labelling of foods obtained through biotechnology;*
- *it would be appropriate to link this work with that of the OECD which had been requested by the 45th Economic (G-8) Summit to study the implications of biotechnology and other aspects of food safety;*
- *existing regulatory instruments elaborated on this matter by national food safety authorities and principles and procedures recommended by FAO, WHO and other international organizations should be taken into account in the work of the Task Force;*
- *the Commission should consider which type of Codex guidance would be most appropriate.*

45. The Executive Committee was unable to consider the matters proposed for discussion under Other Business due to lack of time.

- *the response of the Codex Alimentarius Commission to the Communiqué of the 25th Economic Summit (G8 Summit) held in Cologne, Germany, on 20 June 1999, concerning biotechnology and other aspects of food safety.*

23rd Session of Codex Alimentarius Commission (1999)

12. In response to the recommendation of the 46th Session of the Executive Committee to establish an ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, the Delegation of Japan expressed its concurrence with the recommendation and its willingness to host such a Task Force if established by the Commission. The Delegation stressed the importance of establishing such a Task Force as it would provide an open forum for governments to discuss "safety and nutritional aspects" of foods derived from biotechnology in a step-by-step manner within the specific mandate and timeframe given by the 46th Session of the Executive Committee. The Commission agreed to discuss this matter under Agenda Item 12.

29. Under Production and Processing Systems, the Commission reasserted that high priority should be given to the consideration of foods derived from biotechnology and agreed to discuss further how to proceed in this area under Agenda Item 12. Recognizing that the Medium-Term Plan focused on general objectives and without prejudging the form that these considerations might take, the Commission agreed to refer to "standards, guidelines or other recommendations as appropriate". The Commission also agreed that this matter should be considered "on the basis of scientific evidence and risk analysis and having regard, where appropriate, to legitimate factors other than science relevant for the health protection of consumers and the promotion of fair trade practices in food trade", as proposed by the Delegation of the Netherlands .*

Ad Hoc Intergovernmental Codex Task Force on Foods Derived from Biotechnology

226. The Delegation of Japan introduced draft Terms of Reference for the Ad Hoc Intergovernmental Codex Task Force on Foods Derived from Biotechnology elaborated by a drafting group that had met during the Commission Session.

227. The Commission agreed to establish the Task Force to develop standards, guidelines or other recommendations on foods derived from biotechnology. It agreed also to designate the Government of Japan to be responsible for appointing the Chairperson of the Task Force in conformity with Rule IX.10 of the Commission's Rules of Procedure. The Delegation of Japan informed the Commission that the first meeting of the Task Force would be convened during the first half of the year 2000, its precise date and venue being decided following consultations with the Codex Secretariat. It was recalled that the Task Force would be open for all members and observers of the Commission.

228. Under the discussions on the Terms of Reference, some delegations mentioned that the objectives should be broadly defined while others were of the opinion they should be restricted to safety and nutrition aspects in order to meet the timeframe set down for the

Task Force. The Commission decided to adopt the Terms of Reference as drafted by the drafting group on an interim basis with the understanding that the Task Force might review them at its first meeting if required. The Terms of Reference are given in Appendix VI.

229. *The Representative of WHO informed the Commission that a Joint FAO/WHO Expert Consultation would be convened prior to the first session of the Task Force to support the work of the Task Force.*

MEDIUM-TERM PLAN FOR 1998 TO 2002: General Approach and Issues (Extract)

4. Continued priority should be given to the Commission's horizontal science-based work in the areas of food additives, contaminants, pesticide and veterinary drug residues, food hygiene, food labelling and nutrition. Consideration should be given to the development of standards in these areas for foods derived from biotechnology or traits introduced into foods by biotechnology, where this is scientifically justified. Trade-related issues between governments of food inspection and certification and determination of equivalence and appropriate methods of analysis and sampling will also remain priority areas.

MEDIUM-TERM PLAN FOR 1998 TO 2002 (modified)

Food production and processing systems: Establishment of principles for the use of safe technologies in food production, processing and handling Establishment of principles for the use of safe technologies in food production, processing and handling including those for specific food sectors. Consideration of standards, guidelines or other recommendations as appropriate for foods derived from biotechnology or traits introduced into foods by biotechnology on the basis of scientific evidence and risk analysis and having regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and the promotion of fair practices in food trade. Continued development of guidelines for food quality and safety management systems. Consideration of application of standards and related texts by small and medium-scale enterprises, especially in developing countries.

2. TERMS OF REFERENCE OF THE AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Objectives

To develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices.

Time frame

The Task Force shall complete its work within four years. The Task Force should first submit a preliminary report to the Commission in 2001, a mid-term report, where appropriate, to the Executive Committee in 2002, and a full report in 2003.

Terms of Reference

(a) To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology;

(b) To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from biotechnology; and

(c) To take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

Chapter 2

INITIAL DEBATE ON THE WORK OF TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

CONTENTS

1. INTRODUCTION

The First Session (2000)

Expert consultation

1-8. Regarding the Expert Consultation on biotechnology to be held in June 2000, delegations stressed the importance of transparency and asked further clarification on the scope of the Consultation. Representatives of FAO and WHO informed the Task Force of current discussions on further improvements in transparency of the identification and selection procedures for the expert body and that experts would be selected on the basis of their personal capacity, that the selection process would be transparent and that member Governments would be involved in the process of identification and endorsement of experts. International NGOs would also be invited to nominate potential experts. It was announced that the scope of the Consultation would be to review the current methodology on safety assessment, including the concept of substantial equivalence, and also to study the nutritional aspects of foods derived from biotechnology. It was noted that the scope would be modified in the light of discussions at the present session of the Task Force.

1-9. Attention was drawn to the recommendation of the 1996 FAO/WHO Expert Consultation that developing countries should be provided with assistance and education regarding approaches to the safety assessment of foods and food components produced by genetic modification. The Representatives of FAO and WHO reaffirmed the support of these Organizations for technical assistance to developing countries and the Task Force so noted.

Convention on Biological Diversity: Cartagena Protocol on Biodiversity

1-10. The Task Force was informed that the Protocol was adopted at the extended extraordinary session of the Conference of the Parties to the Convention in January 2000 in Montreal, Canada and would enter into force ninety days following the deposit of the fiftieth instrument of ratification. The text of the Protocol, which had not been available at the time of the preparation of the Secretariat's paper, was made available to delegations.

1-11. It was noted that the objective of the Protocol was "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

1-12. Noting that interpretation of the provisions of the Protocol was beyond the mandate of the Commission, the Task Force noted that the Protocol formed part of the international regulatory framework within which the development, adoption, acceptance and use of Codex standards had to be undertaken. The objective and provisions of the Protocol would therefore need to be taken into account during the development of appropriate Codex texts by the Task Force.

2. CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER PRINCIPLES FOR FOODS DERIVED FROM BIOTECHNOLOGY[5]

[5]CX/FBT 00/4 Part I (Brazil, Canada, Denmark, Hungary, Mexico, New Zealand, Singapore, South Africa, Switzerland, United States, ASSINSEL, Consumers International, CRN, IACFO), Part I- Add.1 (Norway, The European Community), Part I- Add.2 (Japan, Thailand, United Kingdom, United States, CIAA), Part I- Add.3 (Argentina) CX/FBT 00/4 Part II (Argentina, Brazil,

Canada, Denmark, Hungary, Singapore, South Africa, United States), Part II-Add.1(Norway, The European Community), Part II-Add.2 (Japan, Thailand, United Kingdom, United States), Part II-Add.3 (Argentina), Part II- Add.4 (Australia, Japan, Switzerland, United Kingdom), Part II-Add.5 (Switzerland), CRD6 (United States), CRD 7 and 9 (Nigeria), CRD 8 (IACFO). CX/FBT 00/4 reproduces comments and/or information submitted by Governments and international organizations in response to CL 1999/27 FBT. Part I contains comments on identification of areas of work of the Task Force, work priorities, key concepts and definitions, core principles for risk assessment, risk management and risk communication, and collection, dissemination and exchange of information. Part II contains information relating to national and regional experiences with foods derived from biotechnology. The full text of these documents, including Conference Room Documents (CRDs), may be consulted on the Codex web site at http://www.codexalimentarius.net.

1-13. Member countries and observer organizations were invited to express their views on identification of area of the work of the Task Force, work priorities, and key concepts and definitions to be developed by the Task Force. Member countries and observer organizations had been invited by means of CL 1999/27-FBT to submit their comments on these matters, and responses had been compiled in the working documents referenced for this agenda item.

Substantial Equivalence

1-14. Many delegations and observer organizations identified safety and nutrition assessment of foods derived from biotechnology as the main priority area of the work. While recognizing that the concept of the substantial equivalence was being used in safety assessment, several delegations and observer organizations stressed the need for further review of the concept and its applicability to safety assessment. Several delegations stated that risk management and especially pre-market approval were fundamental aspects of risk analysis in relation to foods derived from biotechnology. The Task Force noted the necessity to study marker genes and the potential for non-intentional and long-term health effects. Some delegations expressed the view that it would be useful to establish an international expert body that would be responsible for risk assessment.

Other legitimate Factors

1-15. Concerning legitimate factors other than science that were relevant to the health of consumers and the promotion of fair trade practice, several delegations and the observer from the European Commission proposed to develop a specific guideline to take into account those factors. Several other delegations were of the opinion that since the Codex Committee on General Principles (CCGP) was currently working on this issue, and that therefore the development of a guideline specific to the Task Force was not an immediate priority. The following factors were mentioned by some delegations as potential other legitimate factors: ethical/religious/cultural considerations, consumer concerns/interests, food security, enforcement capacity and environmental risk.*

**See Codex Alimentarius Commission Procedural Manual, Appendix General Decisions of the Commission,*

STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT(Decision of the 21st Session of the Commission, 1995) including Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle (Decision of the 24th Session of the Commission, 2001)

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the

relevant standard without necessarily preventing the decision by Codex.

Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle

• when health and safety matters are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Risk Assessment should be followed;

• other legitimate factors relevant for health protection and fair trade practices may be these factors affect the selection of risk management options and the development of identified in the risk management process, and risk managers should indicate how standards, guidelines and related texts;

• consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;

• it should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;[52]

• only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;

• the consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;

• the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;

• the integration of other legitimate factors in risk management should not create unjustified barriers to trade[53]; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

[52] Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level.

[53] According to the WTO principles, and taking into account the particular provisions of the SPS and TBT Agreements.

Precautionary Principle

1-16. Many delegations and observers also pointed out the need for addressing precautionary principles/approaches to be recommended by the Task Force. Several other delegations stressed that the issue of precaution should first be discussed at the Codex Committee on General Principles (CCGP).

Familiarity

1-17. It was also proposed that the concept of "familiarity" used in environmental risk assessment should be considered. It was noted that this concept had not previously been used by Codex and that further clarification would be needed.

Note: OECD proposed the concept of "familiarity". The following sentences are extracts from "Safety considerations for Biotechnology: Scale-Up of Crop Plants (OECD. 1993)"

General principles for safety in biotechnology (from page 8)

Risk/safety analysis

It is recognized that:

a) Risk/safety analysis is based on the characteristics of the organism, the introduced trait, the environment into which the organism is introduced, the interaction between these, and the intended application. Knowledge of and experience with any or all of these provides familiarity which plays an important role in risk/safety analysis. ….. Familiarity is not synonymous with safety; rather it means having enough information to be able to judge the safety of the introduction or to indicate ways of handling the risks. …….

Operation of the concept of stepwise development and evaluation (from pages 9-10)

Operational principles of risk/safety analysis and risk management

Several operational principles governing the stepwise development of organisms can be identified:

i) Progression through the continuum of developmental stages is based on information gathered from previous experiments, from other appropriate sources, or from empirical observations. Experiments will include observation and measurement of organisms and their impact as appropriate, in order to obtain data relevant to safety. A risk/safety analysis may indicate that a)

progression can proceed to more advanced stage; b) work should not proceed to another stage but that further work at the same stage is required, for example to accumulate data; or c)further developmental work at an even earlier stage is required.

ii) When appropriate risk/safety analysis and risk management are conducted, performance trials can be carried out at any developmental stage. Performance trials *per se* do not necessarily provide information relevant to the risk/safety analysis and risk management, but can be designed to do so.

Factors affecting the operation of the concept of stepwise development

As discussed above, progression through developmental stages is flexible and tailored to the practical situation. Factors that influence the operation of the stepwise concept include:

(i) *familiarity* with the characteristics of the organism, the trait introduced, the interactions between these, and the intended application.

(ii) *familiarity* with the conditions and the environment into which the organisms are intended to be introduced.

(iii) *familiarity* with interactions among the organism, the trait and environment.

Traceability and Monitoring

1-18. Many delegations and observers identified the development of a guideline for the monitoring and traceability of the foods derived from biotechnology as a priority, indicating that these issues were not related only to consumer information but to consumer health protection. Other delegations and observers stated that the concept of "traceability" was new to Codex and required further clarification and explanation including the implications for developing countries. It was also noted that the concept may not be exclusive to foods derived from biotechnology and may need to be considered at a more general level.

Analytical Method including Detection

1-19. The need to consider the methods of analysis, including the detection methods of genetically modified foods was also pointed out by some delegations. Several delegations were of the view that these issues also required the involvement of the Codex Committee on Food Labelling (CCFL) or the Codex Committee on Method of Analysis and Sampling (CCMAS).

Transparency

1-20. The need to develop a specific guideline on transparency and involvement of all stakeholders particularly consumers in the decision making process was emphasised by many of the delegations and observer organizations.

Definitions

1-21. Regarding key concepts and definitions, many delegations emphasised the need to establish clear definitions on several key words. The definitions of "modern biotechnology" and "substantial equivalence" were identified by many delegations and it was suggested that the Task Force refer to definitions established or to be established by other fora, e.g. the definition on modern biotechnology to be developed by the Codex Committee on Food Labelling. The words "Recombinant DNA technique" and "Genetically Modified Organism (GMO)" were also identified by several delegations and observers as possibly requiring definitions.

Which GM foods?

1-22. Among various food categories that may fall under the scope of the Task Force, many delegations and observer organizations identified genetically modified foods derived from plants, microorganism and animals in order of the priority, while others were of the opinion that these three categories should all be addressed. Animal feed and food additives were also identified. It was noted by some delegations that animal feeding would be covered by the Codex Ad Hoc Intergovernmental Task Force on Animal Feeding to be held in Denmark in June 2000.

1-23. The Task Force finally elaborated, on the basis of an aide-mémoire prepared by the Chairman, a list of subjects potentially to be dealt with in its work by summarizing the proposals made by delegations. The list is reproduced as Appendix II to this report and is considered to cover the maximum range of proposals made during discussions.

Work Plan

- General

1-24. The Task Force recognized that the time frame prescribed in its terms of reference necessitated the prioritization of its work subjects and that a considerable part of the proposed subjects were duly or partly covered by other Codex Committees or other international organizations. The Task Force recalled also that, according to its terms of reference, the Task Force should coordinate and closely collaborate with appropriate Codex Committees and take full account of existing work carried out by other international organizations. It agreed to identify those subjects that were already under discussion by other Codex subsidiary bodies or other international organizations and which therefore would not need to be considered in detail in the priority areas of the work of the Task Force. It noted that the issue of labelling was covered by the Codex Committee on Food Labelling (CCFL) and agreed that the precautionary approach/ principle should be dealt with as a matter of priority by the Codex Committee on General Principles (CCGP). The Task Force further agreed that the environmental risk was addressed by other instruments or bodies such as the Cartagena Biosafety Protocol under the Convention on Biological Diversity, the International Plant Protection Convention (IPPC) and the Commission on Genetic Resources for Food and Agriculture (CGRFA).

- Analytical Methods

1-25. For Methods (Analysis/Sampling) some delegations observed that this was primarily within the terms of reference of the Codex Committee on Methods of Analysis and Sampling (CCMAS) while others were of the opinion that the identification of methods appropriate for the detection of genetic modification should be done primarily by the Task Force. The Task Force agreed finally to include analytical methods within its work area, recognizing the use of such methods for control, monitoring and labelling purposes.

-Other Legitimate Factors

1-26. For other legitimate factors the Task Force recalled that this issue was dealt with by the Codex Committee on General Principles (CCGP) but other relevant Committees were also asked to identify legitimate factors other than science which were considered relevant for risk analysis. The Task Force noted that several factors had been proposed by delegations as such other legitimate factors but decided not to take a decision thereon at this stage, recognizing that the Task Force had not accumulated sufficient experiences on this subject.

Program of Work

1-27. Taking into account the priorities discussed above, the Task Force decided that it would proceed with the elaboration of two major texts, namely:

- *A set of broad general principles for risk analysis of foods derived from biotechnology including matters such as:*
  - *- Science-based decision-making;*
  - *- Pre-market assessment;*
  - *- Transparency;*
  - *- Post-market monitoring [including traceability]; and*
  - *- Other legitimate factors as appropriate.*
- *Specific guidance on the risk assessment of foods derived from biotechnology including such matters as:*
  - *- Food safety and nutrition;*
  - *- "Substantial equivalence";*
  - *- Potential long-term health effects; and*
  - *- Non-intentional effects.*

1-28. The Task Force agreed that in the preparation of these texts preference should be given to guidance that was applicable to all foods derived from biotechnology, however should it be necessary to prioritise the work, first priority should be given to foods of plant origin, followed by micro-organisms used directly in foods and then foods of animal origin. It was noted however, that early attention may have to be given to fish.

1-29. The Task Force also agreed that consideration should be given to the development of guidelines for transparency in decision-making and the participation of all stake-holders in the

decision-making process. It was noted that the approach of establishing over-arching general principles would allow the development of further, detailed explanatory guidelines on specific issues if these were required and if time allowed.

*1-30. It was agreed that careful attention should be paid to the development of adequate and appropriate definition**s**, drawing on definitions already developed and agreed to in other texts (such as the Cartagena Protocol) or by other bodies (such as the Codex Committee on Food Labelling).*

1-31. Concerning the issues of Traceability and Familiarity raised by several delegations, the Task Force noted that a better understanding of these concepts and their implications was required before they could be included definitively in either of the main texts to be developed. It therefore agreed that discussion papers should be prepared on these issues as soon as possible. In the meantime, any reference to these issues in the main texts under development would remain in square brackets.

1-32. The Task Force agreed that a list of available analytical methods including those for the detection or identification of foods or food ingredients derived from biotechnology should be prepared, and that this list should indicate the performance criteria for consideration. Nevertheless, there was a general consensus that the above issues had the highest priority and should be achievable within the time-frame allowed. It agreed that this programme of work should be reported to the Executive Committee for approval as new criteria and status of the validation of each method. It was further agreed that the list of methods, once finalized, should be transmitted to the Codex Committee on Methods of Analysis and Sampling for endorsement.

1-33. The Task Force recognized that the work programme outlined above was very substantial taking into account the time-limited mandate assigned by the Codex Alimentarius Commission, and that it did not cover all of the items proposed work at Step 1 of the Uniform Codex Procedure for the Elaboration of Standards and Related Texts.

1-34. Noting that finalization of its work programme would require the resolution of questions regarding labelling, the application and use of precautionary approaches, and consideration of legitimate factors other than science in decision-making, the Task Force called upon the Codex Committees on Food Labelling and on General Principles for an early resolution of these matters.

Establishment of Ad hoc Working Groups

1-35. In order to develop the programme of work as quickly as possible, the Task Force decided to establish two ad hoc Working Groups open to the participation of all Members and Observers participating in the present session and other Members and international organizations that might later indicate their interest. The first of these Working Groups, to be chaired by the Delegation of Japan, was charged with the development of the proposed draft general principles and guidelines indicated in paras. 27 and 28 above. This Working Group would also develop draft definitions. It would also review the discussion papers on traceability and familiarity if they became available in time. The Delegation of Japan indicated that it was its intention for the Working Group to meet twice before the Second Session of the Task Force, probably in July and November 2000, after which proposed draft texts would be sent to Member governments and interested international organizations for comment at Step 3.

1-36. The second ad hoc Working Group, to be chaired by the Delegation of Germany, would compile a list of appropriate analytical methods for consideration by the Task Force, together with their performance characteristics and the status of their validation. To facilitate this work it was agreed that a Circular Letter would be sent to Members and interested international organizations requesting information and that the information received would be compiled by the Delegation of Germany for review by the Working Group at a one-half day meeting to be held immediately prior to the next Session of the Task Force.

Matters Requiring Expert Advice

1-37. The Task Force welcomed the initiative of FAO and WHO to convene an Expert Consultation to support the scientific aspects of its work. In support of the programme of work outlined above, it requested advice on the five specific questions as contained in Appendix III to this report.

1-38. It requested FAO and WHO to make the results of the Consultation available as soon as

possible to all interested parties and that responses to the questions contained in Appendix III be made available to the ad hoc Working Group chaired by Japan.

3. EXTRACT FROM THE REPORT OF THE JOINT FAO/WHO CONSULTATION

Appendix III

Questions for and Answers by the 2000 FAO/WHO Expert Consultation on Foods Derived from Biotechnology to the Questions from the Codex ad hoc Intergovernmental Task Force (Presented at the second session)[1]

[1] extract from the Report of the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology: "Safety Aspect of Genetically Modified Foods of Plant Origin," WHO, 2000

1) What overarching scientific principles should be applied to the safety and nutritional assessment?

Experience throughout the world has led to the identification of a number of common scientific principles currently used in safety and nutritional assessment.

The existing food supply has a long history of safe use, even though some foods are not safe for some individuals and many foods contain substances that would present health concerns if they were present above accepted levels. Most foods derived using recombinant-DNA techniques are obtained from traditional crops that have usually been modified to exhibit one or a few well-defined traits. The knowledge and experience gained in the use of traditional crops is an important component in the safety assessment of foods derived from such plants.

Safety assessment of whole foods and many complex food ingredients requires use of an approach that differs from the strategy used to assess safety of single, well-defined chemicals, such as food additives, pesticides and contaminants. The approach for whole foods is case-by-case, based on an evaluation of multidisciplinary data and information, that is derived from, as appropriate, but is not limited to, agronomic, genetic, molecular biological, nutritional, toxicological and chemical properties. Toxicology testing in animals is not routinely employed, but when necessary based on an assessment of available data and information, tests should be designed to address specific issues.

The following issues are some of the main points considered in the evaluation: the new gene, the new protein and other food components, taking into account both intended and unintended changes in the food and steps to reduce the likelihood of adverse, unexpected effects. In specific cases, additional effects (such as antibiotic resistance) may be evaluated.

Genetically modified foods and conventional foods have many characteristics in common, and in many cases, the new food or food ingredient will be nutritionally equivalent to its conventional counterpart.

Analytical methods traditionally applied in the evaluation of food constituents such as total protein, fat, ash, fibre and micronutrients may need to be augmented with additional analyses using profiling methods to identify unexpected effects and modified nutrient profiles which may impact dietary intake and health.

Because of the potential for broad changes in nutrient levels and interactions with other nutrients as well as unexpected effects, it may be necessary in certain instances to undertake feeding tests in animals to determine outcomes that result from changes in nutrient profiles and nutrient bioavailability. Nutritional modifications which are within normal ranges of nutrient variation might require a less extensive evaluation than those outside normal ranges.

The data and information should be of a quality and quantity that would withstand scientific peer review. Safety assessment is designed to identify information on the nature and the severity of any hazards that may be present, allowing appropriate management methods to be defined.

In conclusion, safety assessment of food and food ingredients obtained using recombinant-DNA techniques does not require new scientific principles or methodology. Similar principles for the assessment of the safety and wholesomeness of genetically modified foods should be applied as practised for conventional foods. Depending on the characteristics of the genetic

modifications, specific safety and nutritional aspects are assessed.

2) What is the role, and what are the limitations, of substantial equivalence in the safety and nutritional assessment? Are there alternative strategies to substantial equivalence that should be used for the safety and nutritional assessment?

The concept of *substantial equivalence* is well established as an important component in safety assessment, and has been elaborated in several international reports. It is based on the idea that an existing organism (plant) used as food, or as a source of food, can serve as the basis for comparison when assessing the safety for human consumption of a food or a food component that has been modified or is new. There is a broad consensus that *substantial equivalence* is of value in safety assessment.

Application of the concept of substantial equivalence may lead to the identification of similarities and defined differences in the food and food ingredients. Further safety assessment will be focused on establishing the safety of the differences in the new product such that safety of the food or food ingredient can be established, relative to its comparator. The safety assessment carried out in this way does not provide an absolute safety warrant for the new product.

Another aspect of the concept of *substantial equivalence* is that it can only be applied where there is a suitable comparator. This requires that sufficient data is available or can be generated for the comparator. Where there is no comparator, *substantial equivalence* cannot be used to assess safety. In such cases, safety testing will be required based on the properties of the food concerned.

Current strategies for assessing the safety of foods derived from genetically modified plants are considered appropriate. There are presently no alternative strategies that would provide a better assurance of safety for genetically modified foods than the appropriate use of the concept of *substantial equivalence*. However, some aspects of the steps in safety assessment process could be refined to keep abreast of developments in genetic modification technology. Methodologies, such as profiling techniques, offer a means of providing a more detailed analytical comparison. However, much more developmental work would be necessary before such methods could be validated.

3) What scientific approach can be used to monitor and assess possible long-term health effects or unintended/unexpected adverse effects?

The Consultation considered that the methodologies for safety evaluation elaborated in the report are adequate to detect and evaluate any possible long-term effects of genetically modified foods.

The Consultation considered the issue of long-term effects from the consumption of genetically modified foods and noted that very little is known about the potential long-term effects of any foods. In many cases, this is further confounded by wide genetic variability in the population, such that some individuals may have a greater predisposition to food-related effects.

Against this background, the Consultation acknowledged that for genetically modified foods, the pre-marketing safety assessment already gives assurance that the food is as safe as its conventional counterpart. Accordingly it was considered that the possibility of long-term effects being specifically attributable to genetically modified foods would be highly unlikely.

An important aspect of the safety assessment is a consideration of the nature of the introduced gene product. Where there is no history of consumption of the introduced gene product or of the food, a 90-day study will probably be indicated. If such studies show evidence suggesting possible long-term effects, e.g. evidence of cell proliferation, further long-term studies would need to be considered if the development of the product was to continue.

The Consultation was of the view that monitoring to establish links between diet and disease is desirable. However, many chronic health effects are multifactorial and it was recognised that observational epidemiological studies would be unlikely to identify any such effects against a background of undesirable effects of conventional foods. Experimental studies, such as randomised controlled trials (RCTs), if properly designed and conducted, could be used to investigate the medium/long term effects of any foods, including genetically modified foods. Such studies could provide additional evidence for human safety, but would be difficult to conduct. In this respect, it is also important to recognise the wide variation in diets from day to

day and year to year.

The same problems apply to the detection of potential long-term beneficial health effects. Nevertheless, it was recognised that genetically modified foods intended to produce nutritional effects are under development for use in developed and developing countries. In such cases, a change in nutrient levels in a particular crop plant may impact overall dietary intake and it would be important to monitor changes in nutrient levels in such foods and evaluate their potential effect on nutritional and health status.

The potential occurrence of unintended effects is not specific for the application of recombinant-DNA techniques, rather it is an inherent and general phenomenon in conventional breeding. One of the approaches to cope with this problem is to select and discard plants with unusual and undesired phenotypic and agronomic parameters already at an early stage. The practice of consecutive back-crossing is also a major procedure used to eliminate unintended effects. Only in rare cases are these approaches accompanied by analytical screening of defined constituents.

Unintended effects due to genetic modification may be subdivided into two groups: those which are "predictable" based on metabolic connections to the intended effect or knowledge of the site of insertion and those which are “unexpected”. Due to the increased precision of genetic modification compared to conventional breeding, it may become easier to predict pathways likely to be influenced by unintended effects.

The comparator used to detect unintended effects should ideally be the near isogenic parental line grown under identical conditions. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The resulting natural variation should be taken into account in assessing the statistical significance of the unintended effect.

Where statistically significant unintended differences are observed, their biological significance should be assessed. This may be assisted by knowledge of the mechanisms leading to the changes. In order to assess the biological and safety relevance of an unintended effect, data on the genetically modified plant should be compared to data on other conventional varieties and literature data. If the differences exceed natural variations in traditional food crops, further assessment is required.

Present approaches to assess possible unintended effects are based, in part, on the analysis of specific components (targeted approach). In order to increase the probability of detecting unintended effects, profiling techniques are considered as useful alternatives (non-targeted approach). Profiling techniques are used at different level e.g. genomics, proteomics and metabolomics.

In the future, genetic modifications of plants are likely to be more complex perhaps involving multiple between-species transfers and this may lead to an increased chance of unintended effects. In such cases, profiling techniques may contribute to the detection of differences in a more extensive way than targeted chemical analysis but they are not yet fully developed and have certain limitations. Having detected differences using profiling techniques, their safety implications of such difficulties will still need to be considered.

4) What scientific approach can be used to assess the potential allergenicity?

An assessment of the potential allergenicity should be made for all genetically modified foods. In the assessment, the novel proteins resulting from the inserted gene should be the focus of the investigation in most cases.

An assessment of the potential allergenicity of the genetically modified food should be conducted in all cases. Possible enhancement of the inherent allergenicity of the host plant food should also be included in the assessment only when the intended effect of the genetic modification involves a significant alteration of the protein content of the food product derived from the host plant.

A decision-tree strategy should be applied in the assessment of the potential allergenicity of the novel protein(s). When the transferred gene is obtained from a source with a known history of allergenicity, the assessment should focus initially upon the immunochemical reactivity of the newly introduced protein with IgE from the blood serum of individuals with known allergies to the source of the transferred genetic material. Where necessary (in cases where no evidence of immunochemical reactivity is obtained), skin tests with extracts of the

novel protein and blinded oral food challenges with the genetically modified food should be conducted on individuals with known allergies to the source of the transferred genetic material to provide confirmation that the novel protein is not allergenic. This series of tests provides adequate evidence regarding the allergenicity (or lack thereof) of novel proteins expressed by genes obtained from known allergenic sources.

The decision-tree approach should rely upon various criteria used in combination (since no single criterion is sufficiently predictive). The current criteria include the sequence homology of the newly introduced protein to known allergens, the immunochemical reactivity of the newly introduced protein with IgE from blood serum of appropriate, allergic individuals when sequence homology is found, and the stability of the novel protein to digestion in gastric and intestinal model systems. This Consultation suggests that the incorporation of two additional criteria to the decision-tree approach when the genetic material is not known to be allergenic might be useful. The level and site of expression of the novel protein and the functional properties of the novel protein should be considered for addition to the list. These criteria taken together offer reasonable evidence that the novel protein is not allergenic, is not cross-reactive with known allergens, and has limited potential to become a food allergen. However, the development of additional criteria could offer additional confidence in the decision-tree approach. In particular, this Consultation advocated continued research on the development of a well-validated animal models for the assessment of the potential allergenicity of novel proteins from genetically modified foods. The Consultation also advocated additional research to identify allergenic proteins in food and to determine their protein sequences.

5) What scientific approach can be used to assess the possible risks arising from the use of antibiotic resistance marker genes and microorganisms?

In genetically modified plants, the product of an antibiotic resistance gene must be subjected to standard safety assessments as would be performed on any other introduced gene product. Thus the product of the antibiotic resistance gene must be assessed for toxicity and potential allergenicity.

Where antibiotic resistance marker genes are present in plants or microorganisms, the possibility of transfer of the genes to pathogenic microorganisms and possible clinical implications must be considered. Horizontal gene transfer from plants and plant products consumed as food to gut microorganisms or human cells is considered as a rare possibility, but cannot be completely discounted. The most important consideration with respect to horizontal gene transfer is the consequence of a gene being transferred and expressed in transformed cells. An important example is the transfer of antimicrobial resistance genes, if it were to occur, from genetically modified foods to gut microorganisms. Important considerations for the assessment of the consequences of the transfer and expression of this gene in transformed cells would be the clinical and veterinary importance of the antibiotic in question, the levels of natural resistance and the availability of effective alternative therapies. In general, antibiotic resistance genes used in food production that encode resistance to clinically important antibiotics should not be present in widely disseminated genetically modified organism or foods and food ingredients.

Chapter 3

PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY

CONTENTS

1. PREPARATORY DISCUSSION

The Second and the Third Sessions (2001-1002)

CONSIDERATION OF PROPOSED DRAFT GENERAL PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY AT STEP 4 (CX/FBT 01/4)

BACKGROUND

1. *The Codex* Ad Hoc *Intergovernmental Task Force on Foods Derived from Biotechnology (CTFBT) held its First Session in Chiba from 14-17 March 2000 and agreed to establish an* Ad Hoc *Working Group to develop a set of broad general principles for risk analysis of foods derived from biotechnology (ALINORM 01/34, para.35). It was understood that the Working Group, to be chaired by Japan, would also review the discussion papers on traceability and familiarity if they become available in time (ALINORM 01/34, para.35).*
2. *In June 2000, the 47th Session of the Executive Committee approved, at Step 1, the development of the text mentioned above, its precise title being still to be determined (ALINORM 01/3, para.43 and Appendix III).*

REPORT OF THE AD HOC WORKING GROUP

3. *The* Ad Hoc *Working Group met twice in Tokyo, Japan, from 5-7 July and from 30 October to 1 November 2000. The invitation was sent to all participating Members and Observers of the First Session of CTFBT as well as other Members and international organizations that indicated their interest.*

First meeting of the *Ad Hoc* Working Group, Tokyo, 5-7 July 2000

4. *Delegates from 21 Members and 16 observers attended the First Meeting of the Working Group. The Working Group reviewed a preliminary text of the Proposed Draft General Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, while, at the same time, considering the Proposed Draft Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants.*
5. *The Working Group had an in-depth discussion on the proposed draft Principles (risk analysis document) and agreed upon a number of amendments. In particular, care was taken to acknowledge the continuing work of the Codex Committee on General Principles to elaborate Codex-wide working principles of risk analysis, which, once adopted, would be equally applicable to foods derived from biotechnology. It also discussed the opportunity for including the concept of post market monitoring in the proposed draft Principles. Since no decision could be taken, it was agreed that a drafting group led by the European Community should prepare a proposal on this matter in time for the Second Meeting of the Working Group. The Working Group also reviewed a draft discussion document on the traceability of genetically modified organisms, introduced by the Delegation of France. In view of a number of points of clarification put forward by many delegations, it was agreed that France should revise the draft discussion document by giving considerations to the issues raised.*
6. *The proposed draft Principles as amended by the First Meeting of the Working Group were placed on the Codex website in July to invite comments from all interested Members and Observers.*

Second Meeting of the *Ad Hoc* Working Group, Tokyo, 30 October – 1 November 2000

7. *The Second Meeting of the* Ad Hoc *Working Group was held with the participation of delegates from 16 Members and 13 observers to review the proposed draft documents for the second time.*

8. *When considering the proposed draft Principles (risk analysis document), the Working Group agreed that the number of definitions should be kept to a minimum. It also reviewed the report and proposal of the Drafting Group led by the European Community on post market monitoring (the original report is reproduced for information in Annex 2 to the present document). The* Ad Hoc *Working Group agreed upon the wording relating to post market monitoring to be included in the proposed draft Principles. The Working Group also held a discussion session on traceability. While a proposal was made to insert a specific wording on traceability in the risk management section of the proposed draft Principles, it was agreed to include a short, square-bracketed reference to traceability (see Annex 1, para.19), in expectation of further discussion to take place at the Second Session of CTFBT, based on a revised information document on traceability to be submitted by France.*

9. *The* Ad Hoc *Working Group made a number of other amendments to the proposed draft Principles, which are attached as Annex 1 to the present document.*

2. ELABORATION OF THE TEXT

PROPOSED DRAFT GENERAL PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY, Annex 1.

TITLE

3-12: The Task Force discussed the proposals to change the title and agreed to leave it as it was. In regard to a proposal to replace the word "Modern Biotechnology" with "Genetically Modified Foods and Products derived therefrom", the Task Force, recalled that the expression "Modern Biotechnology" had been chosen in order to ensure consistency between Codex texts and the Cartagena Protocol based on the internationally-agreed definition in the Protocol. The Task Force therefore decided not to reopen this issue. In general, the Task Force decided to use the expression "Modern Biotechnology" throughout the entire document in order to maintain consistency of terminology, although several delegations expressed their preference for the use of "genetically modified".

SECTION 1 - INTRODUCTION

1. **For many foods, the level of food safety generally accepted by the society reflects the history of their safe consumption by humans. It is recognised that in many cases the knowledge required to manage the risks associated with foods has been acquired in the course of their long history of use. Foods are generally considered safe, provided that care is taken during primary production, processing, storage, handling and preparation.**

2. The hazards associated with foods are subjected to the risk analysis process of the Codex Alimentarius Commission to assess potential risks and, if necessary, to develop approaches to manage these risks. The conduct of risk analysis is guided by general decisions of the Codex Alimentarius Commissio1[1] as well as the proposed draft Codex Working Principles for Risk Analysis[2].

[1] These decisions include the *Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account* and the *Statements of principle relating to the role of food safety risk assessment* (Codex Alimentarius Commission Procedural Manual; Eleventh edition).

[2] At Step 3 in CCGP (ALINORM 01/33 APPENDIX III Report of the Fifteenth Session of the Codex Committee on General Principles).

3. While risk analysis has been used over a long period of time to address chemical hazards (e.g. residues of pesticides, contaminants, food additives and processing aids), it is being increasingly used to address microbiological hazards and nutritional factors.

2-20: The Task Force amended Paragraphs 1 and 3 to improve their clarity. In particular, it noted that existing principles for the food safety risk analysis of specific hazards had not been elaborated to take into account the risk analysis of whole foods (Paragraph 3).

➔ **3. While risk analysis has been used over a long period of time to address chemical hazards (*e.g.* residues of pesticides, contaminants, food additives and processing aids), and it is being increasingly used to address microbiological hazards and nutritional factors, the principles were not elaborated specifically for whole foods.**

4. The risk analysis approach can, in general terms, be applied to foods including foods derived from modern biotechnology. However, it is recognised that this approach must be modified when applied to a whole food rather than a discrete hazard that may be present in food.

➔ **4. The risk analysis approach can, in general terms, be applied to foods including foods derived from modern biotechnology. However, it is recognised that this approach must be modified when applied to a whole food rather than to a discrete hazard that may be present in food.**

New paragraphs 5 and 6

*In relation to **Harmonization** (paragraph 44-45 of the original draft, 2-44: the representative of WTO observed that, in the context of the SPS Agreement, Codex guidelines were to be used as the basis for national sanitary measures, presumably including risk analysis systems for foods derived from biotechnology rather than as an element of these measures, in the context of the SPS and TBT Agreements. Others preferred that these guidelines be considered only as an element of national systems. The Task Force noted that the question of the status of Codex guidelines was not specific to work of the Task Force and that deletion of the paragraph would be without consequence. 2-45: The Task Force agreed that remaining provision should be placed better under the introduction part of the Principles (where it appears as Paragraph 5) and accordingly this section was deleted/*

➔ **5. The principles presented in this document should be read in conjunction with the Codex Working Principles for Risk Analysis to which these principles are supplemental.**

➔ **6. Where appropriate, the results of a risk assessment undertaken by other regulatory authorities may be used to assist in the risk analysis and avoid duplication of work.**

SECTION 2 – SCOPE AND DEFINITIONS

7 (originally 5). The purpose of these Principles is to provide advice in undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. This document does not address environmental risks.

2-21: The Task Force agreed to specify that the Principles should be read in conjunction with the Working Principles for Risk Analysis, currently under development by the Codex Committee on General Principles (Paragraph 5).

*2-22(2): Although the Codex definition of **food** related exclusively to products for human consumption, the Task Force agreed to include a footnote to indicate that animal feed and animals fed such feed were excluded from the Scope of the Principles, except insofar that these animals had been genetically modified (i.e. all genetically modified animals would be covered).*

➔ 7. The purpose of these Principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. This document does not address environmental, other ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods[3].

[3] This document does not address animal feed and animals fed such feed insofar as these animals have been genetically

3-13: In Paragraph 7, the Task Force accepted a proposal to delete the word "other" before "ethical" in order to avoid misunderstanding that might be caused by the original formulation. Furthermore the Task Force agreed to simplify the footnote to this paragraph dealing with animal feed and animals fed such feed and to introduce the standard terminology.

➔ **7. The purpose of these Principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. This document does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods[3].**

[3] This document does not address animal feed and animals fed such feed insofar as these animals have been genetically

8 (originally 6). The definitions below apply to these Principles.

- "**Modern Biotechnology**" means the application of:

  (i). *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

  (ii). Fusion of cells beyond the taxonomic family,

  that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection[1]

- [**"Conventional Counterpart"** means a related organism/variety for which there is experience of establishing safety based on common use as food.]

[1] This definition is taken from the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

2-22, 1st sentence: In Paragraph 6, the Task Force accepted a proposal to indicate that the purpose of the Principles was to provide a framework for risk analysis, rather than to provide advice. It decided not to make a reference to intended or unintended effects other than safety and nutritional aspects in this statement of scope as these were dealt with at appropriate points in the subsequent text. On the other hand, it agreed to extend the list of factors not covered by the Principles, to cover in particular ethical factors other than safety, and the moral and socio-economic aspects of research, development, production and marketing of these foods.

*2-23: The Task Force noted that the Definition of **Modern Biotechnology** had been taken from the Cartagena Protocol on Biosafety. Although it noted that the Codex Committee on Food Labelling had developed a separate definition for labeling purposes and that in general consistency between Codex texts was desirable, the Task Force was strongly of the opinion that consistency with other internationally agreed instruments was critically important in this case. It recommended that the Codex Committee on Food Labelling give consideration to using the same definition in its work. However, some Delegations and observers were of the opinion that for labeling purposes, it may be appropriate to use terms and definitions that were easier for consumers to understand. No change was made to the definition.*

*2-24: The Task Force had an extended discussion on the definition of **Conventional Counterpart**, in particular on whether or not a genetically modified food could serve as a "conventional counterpart" for comparison purposes. Several Delegations stated that once a food derived from biotechnology had been approved and in common use for an extended period, there was no scientific reason for not using such a food as the basis for comparison. It was pointed out that the FAO/WHO Expert Consultation had stated in its reply to the Task Force on the question concerning the evaluation of unintended effects, that the comparator used to detect unintended effects should ideally be the "near isogenic parental line grown under identical conditions" which could indicate a food derived from biotechnology. Other Delegations pointed out that the confidence of consumers in foods derived from biotechnology depended on their being able to relate the safety of such foods to un-modified foods that had a well-established history of safe use and that the traditional unmodified food supply provided a sound baseline for this purpose. In their opinion, at the present time and for the foreseeable future, foods derived from biotechnology could not be considered as meeting this criterion.*

2-25: The Task Force agreed to modify the definition by the inclusion of a footnote to the effect that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts. It also modified the definition to indicate that components or products of foods could serve as a "conventional counterpart" to components or products of foods derived from biotechnology.

➔ **8. The definitions below apply to these Principles: -"Modern Biotechnology" means the application of:**

(i). *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(ii). Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection[4].

"Conventional Counterpart" means a related organism/variety, its components

and/or products for which there is experience of establishing safety based on common use as food[5].

[4] This definition is taken from the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

[5] It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

3-14: The Task Force did not agree to adopt a proposed change to the Definition of ***Conventional Counterpart*** *that would limit the conventional counterpart to "non-genetically modified organisms". It recalled the extensive debate on this issue at its last session which resulted in the present footnote to the paragraph and the indication that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.*

SECTION 3 – PRINCIPLES

9 (originally 7). The risk analysis process for foods derived from modern biotechnology should be in compliance with the Codex Working Principles for Risk Analysis[2]

2-26, 1st sentence: The Task Force agreed that the Principles should be "consistent" with the proposed draft Working Principles under development by the CCGP, rather than "in compliance" with them (Paragraph 9).

➔ **9. The risk analysis process for foods derived from modern biotechnology should be <u>consistent with</u> the Codex Working Principles for Risk Analysis[6].**

[6] At Step 3 in CCGP. (*This footnote was deleted when Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius was agreed on and incorporated in the Codex Alimentarius Commission Procedural Manual).*

RISK ASSESSMENT

10 (originally 8). Risk assessment includes a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity. The safety assessment should include a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences.

2-26, 2nd sentence: The Task Force generally agreed that the notion of "safety assessment" was characterized by an assessment of a whole food or component thereof relative to an appropriate conventional counterpart for the purpose of the identification of new or altered hazards taking into account both intended and unintended effects. In this regard, the Delegation of the United Stated noted that in the current draft there was no indication of how to proceed if a new or altered hazard was identified by the safety assessment. The Task Force agreed to amend Paragraph 10 to deal with this situation.

➔ **10. Risk assessment includes a safety assessment, which is designed to identify whether a hazard, nutritional or other safety concern is present, and if present, to gather information on its nature and severity. The safety assessment should include a comparison between the food derived from modern biotechnology and its conventional counterpart focusing on determination of similarities and differences. <u>If a new or altered hazard, nutritional or other safety concern is identified by the safety assessment, the risk associated with it should be characterized to determine its relevance to human health</u>.**

3-15: The Task Force discussed the proposal to rewrite the Paragraph 10 in such a manner to clearly separate the use of term "hazard" and "safety concern" in a different context and also to express the notion that risk assessment was an integral part of the safety assessment. The Task Force exchanged the opinions on this issue and as many delegates expressed that the safety assessment should be a part of risk assessment, finally decided not to change the present paragraph 10.

11 (originally 9). Safety assessment is characterized by:

A) undertaking an assessment relative to a similar product having a history of safe use, taking into account both intended and unintended effects;

B) identifying new or altered hazards relative to the appropriate conventional counterpart;

C) identifying changes relevant to human health in key nutrients; and

D) an assessment of a whole food or a component thereof.

2-27: The Task Force agreed to adopt a rewording of Paragraph 11 for clarity, using a proposal of the European Commission.

2-28; The Representative of WHO noted that within the present concept, safety assessment could only be conducted when an appropriate conventional counterpart existed and recommended that consideration should be given to situations where a conventional counterpart was absent, for example in the case of modified micro-organisms used in food production and processing. The Task Force recommended that this matter be considered by a future joint FAO/WHO Expert Consultation.

➔ **11. A safety assessment is characterized by <u>an assessment of a whole food or a component thereof relative to the appropriate conventional counterpart:</u>**

A) <u>taking into account both intended and unintended effects;</u>

<u>B) identifying new or altered hazards;</u>

<u>C) identifying changes, relevant to human health, in key nutrients.</u>

12 (originally 10). A pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using validated methods and analysed using appropriate statistical techniques, should be of a quality and quantity that would withstand scientific peer review.

2-21, 1st sentence: The Task Force noted that methods used for risk assessment should be scientifically sound (Paragraphs 12 and 15).

Note: Some delegates pointed out that the scientifically valid methods are not always validated).

➔ 12. A pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using <u>appropriate</u> methods and analysed using appropriate statistical techniques, should be of a quality and quantity that would withstand scientific peer review.

3-16: The Task Force agreed to insert "as appropriate" before the reference to quantity of data in Paragraph 12 in order to reflect the fact that the quantity of data in itself was not the determining factor in its scientific value.

➔ **12. A pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques, should be of a quality and, <u>as appropriate</u>, of quantity that would withstand scientific peer review.**

13 (originally 11). Risk assessment should apply to all relevant aspects of foods derived from modern biotechnology. The risk assessment approach for these foods is based on a consideration of multidisciplinary data and information taking into account the factors mentioned in the accompanying Guidelines.

1-29, 2nd sentence: The Task Force noted that risk assessment should be based on scientific data and information (Paragraph 13).

➔ 13. Risk assessment should apply to all relevant aspects of foods derived from modern biotechnology. The risk assessment approach for these foods is based on a consideration of science-based multidisciplinary data and information taking into account the factors mentioned in the accompanying Guidelines[7].

[7] Reference is made to the Proposed Draft Guideline for the Conduct of Safety Assessment of Foods Derived from Plants Obtained through Modern Biotechnology.

3-17; In Paragraph 13, the Task Force added a new reference to the "Proposed Draft Guideline for the Conduct of Food Safety Assessment for Foods Produced Using Recombinant-DNA Microorganisms" in the relevant footnote.

➔ **13. Risk assessment should apply to all relevant aspects of foods derived from modern biotechnology. The risk assessment approach for these foods is based on a consideration of science-based multidisciplinary data and information taking into account the factors mentioned in the accompanying Guidelines[6].**

[6] Reference is made to the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms.

14 (originally 12). Scientific data for risk assessment are generally obtained from a variety of sources, such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties. Data should be assessed using internationally-recognised scientific risk-based methods.

See 2-21, 1st sentence.

➔ **14. Scientific data for risk assessment are generally obtained from a variety of sources, such as the developer of the product, scientific literature, general technical information, independent scientists, regulatory agencies, international bodies and other interested parties. Data should be assessed using appropriate science-based risk assessment methods.**

15 (originally 13). Risk assessment may be based on the data and information derived from different testing procedures, provided that the procedures are effectively validated and the parameters being measured are common and comparable.

2-29, 3rd sentence: The Task Force noted that that methods used for risk assessment should be scientifically sound (Paragraphs 12 and 15); and that assessment methods need not be limited to internationally agreed methods although they should be scientifically sound and use parameters that allow comparison (Paragraph 15).

➔ 15. Risk assessment may be based on the data and information derived from different testing procedures, provided that the procedures are scientifically sound and the parameters being measured are comparable.

3-18: The Task Force agreed to modify Paragraph 15 by stressing the need to take into account all available scientific data. However, it did not adopt the proposed inclusion of the wording of "scientifically validated" after "scientifically sound" recalling that validation was covered by the principle of peer review contained in paragraph 12.

➔ **15. Risk assessment should take into account all available scientific data and information derived from different testing procedures, provided that the procedures are scientifically sound and the parameters being measured are comparable.**

RISK MANAGEMENT

16 (originally14). Risk management decisions for foods derived from modern biotechnology should be proportional, based on the outcome of the risk assessment and, where relevant, other legitimate factors[4] recognised by Codex.

[4] The Working Group recalled that work was in progress in CCGP on this matter.

2-30: The Task Force agreed that both the outcome of the risk assessment and other legitimate factors would be the basis for risk management. A proposal was made to include examples of ***other legitimate factors*** *such as the protection of the environment, consumer choice, ethics, fair trade practices and sustainable developments. Different views were exchanged on whether other legitimate factors should be considered by the Task Force, whether or not they should be enumerated or they should be left to the discretion of the CCGP. The Task Force recalled that its terms of reference limited its consideration to "other legitimate factors relevant to the health of consumers and the promotion of fair trade practices". It agreed that the wording used in paragraph 2 of the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are taken into Account should be used to describe the nature of other legitimate factors and that reference would also be made to the Working Principles on Risk Analysis under development by the CCGP which would provide more detail on the application of these Statements of Principle (Paragraph 16).*

2-31,1st sentence: For the purpose of conformity of terminology the Task Force agreed to replace the words "risk management decisions" with "risk management measures" (Paragraph 16). It also agreed that risk management measures may include conditions for marketing approvals (Paragraph 19).

➔ 16. Risk management measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, where relevant, taking into account other legitimate factors[8] in accordance with the general decisions of the Codex Alimentarius Commission (CAC) as well as the Codex Working Principles for Risk Analysis[9].

[8] The Working Group recalled that work was in progress in CCGP on this matter.

[9] See footnotes 1 and 2 above.

➔ **16. Risk management measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, where relevant, taking into account other legitimate factors in accordance with the general decisions of the Codex Alimentarius Commission (CAC) as well as the Codex Working Principles for Risk Analysis[6].**

[6] See footnotes 1

Note: After completion of Codex Working Principles for Risk Analysis, *footnotes 6 was deleted.*

17 (originally 15). It should be recognised that different risk management measures may be capable of meeting the same objective with regard to the management of risks associated with safety and nutritional impacts on human health, and are therefore equivalent.

➔ 17. It should be recognised that different risk management measures may be capable of meeting the same objective with regard to the management of risks associated with safety and nutritional impacts on human health, and therefore would be equivalent.

3-19: The Task Force agreed to modify Paragraph 17 by replacing the wording "meeting the same objective" with "achieving the same level of protection" in order to maintain a clear linkage with the SPS Agreement.

➔ **17. It should be recognised that different risk management measures may be capable of achieving the same level of protection with regard to the management of risks associated with safety and nutritional impacts on human health, and therefore would be equivalent.**

18 (originally16) **Risk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties.**

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19 (originally 17). Risk management measures may include, as appropriate, food labelling[5], post-market monitoring [and development of analytical methods for the detection or identification of foods derived from modern biotechnology].

[5]Reference is made to the work of CCFL

2-31, 2nd sentence: The Task Force also agreed that risk management measures may include conditions for marketing approvals (Paragraph 19). 2-32: The Task Force had an extended discussion concerning the need for the development of ***analytical methods for detection or identification*** *of foods derived from modern biotechnology, including the possibility of requiring that such methods be available as a condition for pre-market approval. It agreed that the wording of Paragraph 19 provided sufficient guidance in this matter by generally allowing conditions for pre-market approval and removed the square brackets surrounding this text.*

➔ 19. Risk management measures may include, as appropriate, food labelling conditions for marketing approvals, post-market monitoring and development of analytical methods for the detection or identification of foods derived from modern biotechnology.

3-20: In paragraph 19, the Task Force decided to separate the reference to risk management measures (e.g., labelling) and references the tools for the implementation and enforcement of risk management measures (e.g., development of analytical methods). It therefore decided to

create a new paragraph (after Paragraph 20) to cover these tools and made specific mention of the development of analytical methods and the provision of reference materials.

➔ **19. Risk management measures may include, as appropriate, food labelling[8], conditions for marketing approvals and post-market monitoring.**

[8]Reference is made to the CCFL in relation to the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients obtained through certain techniques of genetic modification/genetic engineering(proposed Draft Amendment to the General Standard for the Labelling of Prepacked Foods) at Step 3 of the procedures.

20 (originally 18). Post-market monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered, on a case-by-case basis, during risk assessment and risk management. Post-market monitoring would be undertaken for the purpose of:

A) verifying assumptions about the possible occurrence, impact and significance of potential human health effects identified during the risk assessment; and

B) monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.

2-33: The Task Force agreed that post-market monitoring (Paragraph 20) may be an appropriate risk management measure. Some Delegations expressed their concern about the practicability and financial implications in relation to the use of post-market monitoring. The Task Force agreed that the need and utility of post–market monitoring should be considered during risk assessment and practicably in addition during risk management. The Delegation of Thailand expressed its concern about the possibility that relying on post-market monitoring might lead to the reduction of efforts to perform efficient risk assessment for the pre-market approval of foods derived from modern biotechnology, with the subsequent release into the market of foods that were not properly tested and approved. This concern was supported by all Delegations that spoke and the Task Force agreed that the purpose of post–market monitoring should be to verify the conclusion about the absence or the possible occurrence, impact and significance of potential consumer health effects.

Note: Insertion of "the absence" in the last sentence give neutrality of monitoring, not just looking for adverse effects but rather verifying predictions.

➔ 20. Post-market monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered, on a case-by-case basis, during risk assessment and practicability in addition during risk management. Post-market monitoring may be undertaken for the purpose of:

A) verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects; and

B) monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.

After further editorial change

20. Post-market monitoring may be an appropriate risk management measure in specific circumstances. Its need and utility should be considered, on a case-by-case basis, during risk assessment and its practicability should be considered during risk management. Post-market monitoring may be undertaken for the purpose of:

A) verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects; and

B) monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.

19. [Risk management may include traceability.]

2-34: As agreed during the Adoption of the Agenda, the Delegation of France introduced its discussion paper (CX/FBT 01/6) on the issue of traceability prior to consideration of this paragraph. The Delegation stated that the issue was linked to risk management, especially in

regard to product recall, post market monitoring, the right of consumers to choose the foods that they wish to eat and also on the obligation of vendors to meet the labelling requirements applied in many countries. The Delegation noted that Traceability was defined in standard ISO 8402 in general terms as being "the ability for the retrieval of the history and use or location of an article or an activity through a registered identification".

2-35: The Delegation of France stated that within this context traceability in the food system provided mechanisms of continuous flow of relevant information that allowed the retrieval of the history and of the origin of a product at any point in the food chain, based on record keeping and documentation. The Delegation stated that traceability was less costly and more reliable than using systematic analysis of product throughout the food chain. The Delegation further noted that many aspects of traceability were common to all foods, but that because of consumer interest in foods derived from biotechnology, special consideration for the application of traceability to these foods was needed.

2-36: Many Delegations and Observer Organizations supported the conclusions of the discussion paper and recommended that reference be made to traceability in the context of Risk Management in the present document. Several of these Delegations also pointed out that traceability should be considered in the general context of risk management for all foods as it was pointed out that traceability had a role to play in post-market monitoring. Reference was made to the future identification requirements under the Cartagena Protocol for living modified organisms intended for direct use for food or feed or for processing[8].

[8]Cartagena Protocol, Article 18.2.(a): "Each Party shall take measures to require that documentation accompanying living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol."

2-37: Other Delegations were of the opinion that reference to traceability was not appropriate for inclusion in the current Principles since the issue at stake was not one of food safety risk analysis, but rather a matter of consumer choice or labelling. Although they agreed that the ability to trace defective products that had entered the food chain was an integral part of food control and risk management, it was not appropriate to require traceability for products that had received pre-market approval. Moreover, these Delegations pointed out that the cost of traceability was significant and that the economic impact of such a requirement could fall heavily on developing countries wishing to export food products. They agreed that traceability should be considered as a general issue within Codex and looked forward to the guidance of the Commission on this matter.

2-38: The Task Force noted that aspects of traceability were being treated in several other Codex Committees, notably the Codex Task Force on Animal Feeding, the Codex Committee on Fish and Fishery Products, the CCFICS, the CCFL and the Codex Committee on Food Hygiene (CCFH). It also noted that the traceability was different from the concept of "Identity Preservation (IP)". Referring to the work of ISO, the Task Force noted that in addition to the definition in ISO 8402, the Draft ISO Standard ISO/DIS 17161.2 "Guidelines on the application of ISO 9001:2000 for the food and drink industry" contained reference to traceability.

2-39: In view of the divergence of opinion surrounding the issues of traceability, an open-ended Ad Hoc Working Group, chaired by Japan, was convened to provide a further text for the consideration of the Task Force.

2-40: The Ad Hoc Working Group tabled a report indicating that the concept of traceability, a system which guarantees a continuous flow of appropriate information at all stages of placing on the market of foods, was a broad, horizontal issue and should be discussed on a Codex-wide basis. The report contained the following proposals:

- deleting paragraph 21[9]; and

- adding the following text as a footnote to the heading of Risk Management section.

It was recognized that discussion on the applicability of traceability or other equivalent

approaches as a tool in support of risk management measures is under consideration by the Codex Alimentarius Commission and its subsidiary bodies. The Task Force encouraged an early completion of this discussion.

[9]The Delegation of France expressed its reservation during the meeting of the Working Group to this proposal.

2-41: The Task Force agreed that the traceability was a broad, horizontal issue and should be discussed on a Codex-wide basis. While several Delegations supported the proposal submitted by the Ad Hoc Working Group, a large number of Delegations asked that Paragraph 21 be retained in the Proposed Draft Principles, albeit in brackets. The Task Force agreed to retain Paragraph 21 in brackets and to attach to it the footnote. The Task Force did not address further the report of Ad Hoc Working Group with respect to traceability or its meaning.

2-42: The Task Force expressed its appreciation to the Ad Hoc Working Group for its efforts in resolving this and other issues referred to it.

DISCUSSION PAPER ON TRACEABILITY (See 3. DISCUSSION PAPERS ON TRACEABILITY)

2-79. The Task Force recalled that at its 1st Session, the issue of traceability was raised by several delegations. It noted that a better understanding of this concept and its implications was required before it could be included definitively in the text on General Principles for Risk Analysis to be developed and agreed that a discussion paper should be prepared by the Delegation of France on this issue. It also agreed that, if time allowed, the paper might be considered by the ad hoc Working Group responsible for developing the first draft of the General Principles and the Guidelines on Safety Assessment.[13] A draft paper was prepared and subsequently revised following the input of several Delegations at the meetings of the Working Group. The Task Force noted that the general orientation and conclusions of the paper has been discussed in the context of the Task Force's discussion of Paragraph 21 of the proposed draft General Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (see paras. 34 to 42 above).

2-80. The Delegation of France noted that in addition to the continuing debate in the Task Force, the matter of traceability needed to be discussed at a general level within Codex since the issue was one of a horizontal nature. It stated that the most appropriate forum for such general discussions would be the CCGP, while the specific issues relating to foods derived from biotechnology should continue to be examined by the Task Force. This view was shared by many other Delegations and Observer Organizations.

2-81. The Delegation of the United States, supported by some other Delegations, stated that traceability was an important issue in the broader context, and also in many other areas, including in particular, public health. The Delegation suggested that CCFICS should be the most appropriate Codex Committee to consider this issue. It agreed that consensus was needed about the application of traceability in Codex work and noted the proposal of the CCFICS to request the advice of the Commission on how to proceed in this matter.

2-82. The Delegation of India, supported by Indonesia, stated that the concept was new to developing countries and that while the need for documentation was recognized, in view of the likely cost implications of relying solely on analytical detection of products, the implications of introducing the concept of traceability into the food system needed to be explained and carefully considered. These Delegations noted that production and marketing systems in developing countries were not the same as those of the developed countries, even though the same consumer concerns had to be met. These Delegations expressed interest in the development of equivalent systems that would meet the same objectives.

2-83. The Task Force agreed to request comments on the papers provided by the Delegations of France and the United States by means of a circular letter (see Footnote 12 above). It further agreed that these papers and the comments received would be discussed at its next session, taking into account the guidance provided by the Commission in this matter. In the meantime it agreed to inform other Codex subsidiary bodies and the Commission of the present discussion.

3-8: The Task Force noted the discussions of the Executive Committee on traceability as a general issue confronting Codex. The Secretariat paper (ALINORM 01/21. PART IV-ADD. 1) prepared for the Commission had pointed out that traceability was not new to Codex but that it*

*had not been treated in a systematic manner. The paper also pointed out that any measures requiring traceability must be justified as having a food safety objective (i.e., as an SPS measure), or having a legitimate objective as a TBT measure. The Executive Committee had generally supported the analysis and approach outlined in the Secretariat paper. The Executive Committee had recommended that the Committee on General Principles consider the two aspects of traceability referred to above, however, it had been of the opinion that first consideration should be given to the use of traceability as a risk management option in the Working Principles for Risk Analysis. The Executive Committee had also noted in particular the role of the Committee on Food Import and Export Inspection and Certification Systems in relation to the development of procedures for the application of traceability in food import and export inspection and certification systems. Although some Members of the Executive Committee had believed that a sequential approach to the development of other texts should be followed, the Executive Committee had agreed that it should be for the Committees concerned (including the Committees on General Principles, Food Import and Export Inspection and Certification Systems, Food Hygiene and Food Labelling) to undertake work as they deemed appropriate, within their respective mandates (ALINORM 03/3 PARA 31). (MATTERS REFERRED TO THE TASK FORCE BY OTHER CODEX COMMITTTEES). *See APPENDIX*

3-22: The Task Force recalled that the issue of "traceability" had been discussed at the 49th Executive Committee (see paragraph 8 above) and that consequently the issue was also under discussion in the Committee on General Principles and the Committee on Food Import and Export Inspection and Certification Systems and would probably be taken up in other Codex Committees as well.

3-23: The Delegation of Spain, speaking on behalf of the member states of EU, tabled a revised proposal as an alternative to the text of paragraph 21 that had been included in square brackets by the 2nd Session of the Task Force. The proposal outlined the situations in which traceability could be considered as a risk management option. The Delegation noted that discussions on traceability need not be restricted to its consideration within the context of Committee on General Principles. Several delegations expressed their support for this view.

3-24: The Delegation of the United States stated that the issue of traceability was not unique to foods derived from modern biotechnology, and that it would be discussed as a general issue of Codex by the Committee on General Principles and other Committees. On this basis, it should be possible to delete paragraph 21. These views were supported by several other delegations.

3-25: The Delegation of Brazil, Thailand and Indonesia expressed the view that the traceability should not be considered as a part of a mandatory system because it was mainly intended to provide information to trading partners. For this reason, paragraph 21 could be deleted. However, if traceability could be demonstrated as being useful in risk management, the practicability of its application and cost in developing countries needed to be considered.

3-26: Some NGOs observers representing consumer and environmental organizations stressed that traceability was a key risk management measure and could be specially effective for use in post-market monitoring of unintended effects and control of labelling. Other NGOs representing industry associations were of the opinion that traceback was a normal practice in industry but not specific to food derived from biotechnology. One NGO referred to the identification requirements of Article 18 of the Cartagena Protocol as having relevance to the use of traceability.

3-27: The Task Force was of the opinion that the resolution of this issue was important in order to reach a final conclusion on the text of the Draft Principles. It noted that the addition of a new paragraph after paragraph 20 (see para. 20, above) made it possible to place the question of traceability into context as one of the tools for implementation and enforcement of risk management measures, without prejudice to its use for other purposes. On this basis a compromise text was agreed to as follows.

> *"Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials; and the tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring in circumstances as indicated in paragraph 20."*

3-28: The Delegation of the Republic of Korea reserved its position in relation to the adoption of the new paragraph as its application is limited to SPS measures.

3-29: The representative of 49th Parallel noted that applications of product tracing would also need to be consistent with the provisions of the Cartagena Protocol after its entry into force. Secretariat noted that Article 18 of the Cartagena Protocol did not make direct reference to product tracing and a number of delegations stated that discussion of the Commission should not be bound to agreements that were not yet in force. Other delegations were of the opinion that Commission should take into account all other applicable international agreements. The Task Force noted that further consideration of several broader issues surrounding product tracing would continue within Codex.

DISCUSSION PAPERS ON TRACEABILITY (AGENDA ITEM 7)

3-89: The Task Force noted that it had embarked on a general discussion on Traceability at its First Session in order to provide the background for inclusion of appropriate wording in the Draft General Principles for the Risk Analysis of Foods Derived from Biotechnology. Papers prepared by the Delegations of France and the United States had been circulated for comment to assist in this regard.

3-90: In view of the compromise reached on this issue in the context of the Draft General Principles (see paras 22 to 27 above), the Task Force decided not to undertake an extended discussion on traceability at this time. It agreed however that the information obtained in response to the discussion papers should be transmitted to other relevant Codex committees to assist them in their consideration of the issue. It also agreed to have a fuller discussion at its next session, but also agreed that such a discussion should not compromise the consensus that had already been achieved in the Draft General Principles and should not lead to specific recommendations or guidelines.

RISK COMMUNICATION

22 (originally 20). Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, media and consumers.

2-42: The Task Force agreed that risk communication was essential at all phase of risk assessment and risk management and that academia should be also involved in risk communication.

➔ **22. Effective risk communication is essential at all phases of risk assessment and risk management. It is an interactive process involving all interested parties, including government, industry, academia, media and consumers.**

23 (originally 21). **Risk communication should include transparent safety assessment and management decision-making processes. These processes should be fully documented at all stages and open to public scrutiny, whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information. In particular, reports prepared on the safety assessments and other aspects of the decision-making process should be made available to all interested parties.**

24 (originally 22). Effective risk communication should include responsive consultation processes. Consultation processes should be interactive and may include consultation with existing bodies. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process.

3-30: The Task Force agreed to delete a reference to "consultation with existing bodies" in the paragraph dealing with the consultation process as this was considered to introduce redundancy in the text.

➔ **24. Effective risk communication should include responsive consultation processes. Consultation processes should be interactive. The views of all interested parties should be sought and relevant food safety and nutritional issues that are raised during consultation should be addressed during the risk analysis process.**

HARMONIZATION

[23. Relevant Codex guidelines and, where possible, other internationally agreed guidance should be used by regulatory authorities as elements of their risk analysis system for foods derived from modern biotechnology.]

[24. Where appropriate, the results of a risk assessment may assist in the risk analysis undertaken by other regulatory authorities and in avoiding duplication of work.]

2-44: The representative of WTO observed that, in the context of the SPS Agreement, Codex guidelines were to be used as the basis for national sanitary measures, presumably including risk analysis systems for foods derived from biotechnology rather than as an element of these measures, in the context of the SPS and TBT Agreements. Others preferred that these guidelines be considered only as an element of national systems. The Task Force noted that the question of the status of Codex guidelines was not specific to work of the Task Force and that deletion of the paragraph would be without consequence. 2-45: The Task Force agreed that remaining provision should be placed better under the introduction part of the Principles (where it appears as Paragraph 5) and accordingly this section was ***deleted****. **(See paragraphs 5 and 6**).*

CONSISTENCY

25. A consistent approach should be adopted to characterise and manage safety and nutritional risks associated with foods derived from modern biotechnology. The acceptable level of risk for these foods should be consistent with that for similar foods already on the market.

3-31: The Task Force exchanged opinions on a proposal of how to clearly express the necessity of maintaining consistency in the level of consumer protection against risks associated with foods, regardless whether the food is derived from biotechnology or a conventional counterpart. The Task Force reached a consensus to replace the second sentence with new formulation to state that unjustifiable differences in the level of risks between foods derived from modern biotechnology and similar foods should be avoided. In the same sentence, the Task Force also accepted a proposal to include "conventional" after "similar".

➔ **25. A consistent approach should be adopted to characterise and manage safety and nutritional risks associated with foods derived from modern biotechnology. Unjustified differences in the level of risks presented to consumers between these foods and similar conventional foods should be avoided.**

26. A transparent and well-defined regulatory framework should be provided in characterising and managing the risks associated with foods derived from modern biotechnology. This should include consistency of data requirements, assessment frameworks, acceptable level of risk, communication and consultation mechanisms and timely decision processes.

2-46: The Task Force agreed to the current wording included under this section.

CAPACITY BUILDING AND INFORMATION EXCHANGE

27. Efforts should be made to improve the capability of regulatory authorities, particularly those of developing countries, to assess and manage risks associated with foods derived from modern biotechnology or to interpret assessments undertaken by other authorities or recognised expert bodies, including access to analytical technology. Regulatory authorities, international organisations and expert bodies should facilitate exchange of information through appropriate contact points and other appropriate means.

3-47: The Task Force had requested the Ad Hoc Working Group to discuss the relationship between this Section and Paragraph 19 concerning the development and application of methods of detection and identification. It agreed to separate the two issues into separate paragraphs (Paragraphs 27 and 28) and agreed to strengthen the paragraph dealing with the exchange of information on analytical methods by making a special reference to Codex Contact Points. It also agreed that capacity building for enforcement should be referred to.

➔ **27. Efforts should be made to improve the capability of regulatory authorities, particularly those of developing countries, to assess and manage risks, <u>including enforcement,</u> associated with foods derived from modern biotechnology or to interpret assessments undertaken by other authorities or recognised expert bodies,**

<u>including access to analytical technology.</u>

New paragraph 28

3-32: The Task Force had an extended discussions on the proposals of several delegations to make specific references to the entities responsible for improving the capacity of regulatory authorities particularly in developing countries. The Task Force, noting that the present text already covered broad entities, did not agree to make explicit references in the sentence. However, based on the recognition of the importance of the capacity building for developing countries and also of the respective roles of bilateral and multilateral funding agencies as well as the technical international organizations to achieve that purpose, it agreed to add a new sentence to specify the importance of the assistance for developing countries in application of the principles with a footnote referring to the corresponding provisions of the SPS and TBT Agreements (Article 9 of SPS and Article 11 of TBT).

28. Regulatory authorities, international organisations and expert bodies and industry should facilitate through appropriate contact points including but not limited to Codex Contact Points and other appropriate means, the exchange of information including the information on analytical methods.

REVIEW PROCESSES

29 (originally 28) **Risk analysis methodology and its application should be consistent with new scientific knowledge and other information relevant to risk analysis.**

30 (originally 29). Recognising the rapid pace of development in the field of biotechnology, assessments and approvals for foods derived from modern biotechnology should be regularly reviewed to ensure that emerging scientific information is incorporated into the risk analysis.

2-48: The Delegation of the United State, while recognizing the importance of taking into account the newest scientific information for safety assessment, expressed its concern about the practicability should a routine review be required. This view was generally supported and the Task Force agreed to solve this problem by modifying Paragraph 30. An additional sentence was introduced to ensure that the assessment be reviewed to incorporate new relevant information and, if necessary, risk management measures be adapted when such information became available.

➔ 30. Recognising the rapid pace of development in the field of biotechnology, <u>the approach to safety assessments of foods derived from modern biotechnology</u> should be reviewed <u>as necessary</u> to ensure that emerging scientific information is incorporated into the risk analysis. <u>Where new scientific information relevant to a risk assessment becomes available the assessment should be reviewed to incorporate that information and, if necessary, risk management measures adapted accordingly</u>.

3-33: The Task Force agreed to make small editorial changes to the final paragraph of the Principles.

➔ **30. Recognizing the rapid pace of development in the field of biotechnology, the approach to safety assessments of foods derived from modern biotechnology should be reviewed when necessary to ensure that emerging scientific information is incorporated into the risk analysis. When new scientific information relevant to a risk assessment becomes available the assessment should be reviewed to incorporate that information and, if necessary, risk management measures adapted accordingly.**

3. DISCUSSION PAPERS ON TRACEABILITY

1. DISCUSSION PAPER ON TRACEABILITY

INTRODUCTION

At the 1st Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (CTFBT), the issue of traceability was raised by several delegations. The Task Force noted that a better understanding of this concept and its implications was required before it could be included definitively in the text (a set of broad general principles for risk analysis) to be developed. The Task Force therefore agreed that the discussion papers should

be prepared on this issue as soon as possible. In the mean time, any reference to the[se] issue[s] in the main text[s] under development would remain in square brackets (ALINORM 01/34, paras.27 and 31).

CTFBT agreed to establish an *Ad Hoc* Working Group to develop a set of broad general principles for risk analysis of foods derived from biotechnology (ALINORM 01/34, para.35). It was understood that the Working Group, to be chaired by Japan, would also review the discussion paper on traceability if it became available in time (ALINORM 01/34, para.35).

The *Ad Hoc* Working Group met twice in Tokyo, Japan, from 5-7 July and from 30 October to 1 November 2000. The First Meeting of the Working Group reviewed a draft discussion paper on traceability of genetically modified organisms, introduced by the Delegation of France. In view of a number of points of clarification put forward by many delegations, it was agreed to request France to revise the draft discussion document by giving considerations to the issues raised.

The Second Meeting of the Working Group also held a discussion session on traceability. While a proposal was made to insert a specific wording on traceability in the risk management section of the proposed draft Principles, it was agreed to include a short, square-bracketed reference to traceability, in expectation of further discussion to take place at the 2nd Session of CTFBT, based a revised information document on traceability to be submitted by France.

The present document incorporates the revised discussion paper prepared by France.

Discussion paper on the traceability of GMOs (Prepared by France)

Background

1. France was asked by the Working Group (Tokyo, 5-7 July and 30 October-1 November 2000) to review its discussion paper on traceability on the basis of the questions of the delegations in order to prepare the second session of the Task Force in Chiba (March 2001). Australia, Canada, Norway and Sweden proposed to contribute to this revised document.
2. France is very grateful to those delegations who submitted comments.

Context

3. The application of modern biotechnology to food and plants is currently the focus of intense public and political debate with particular reference to the issue of food safety. All GMOs have to undergo a comprehensive scientific assessment of risks to human health before being placed on the market. To date there have been no peer-reviewed scientific articles reporting adverse effects on human health from GMOs.
4. However, the public is concerned about their potential implications for human health and foods derived from biotechnology face a lack of confidence of consumers.
5. Consumers have the right of choice. Consequently, suppliers are seeking to meet the demand from consumers or purchasers, for information on the presence of GMOs or derivatives of GMOs in products.
6. Increasingly, producers and traders are having to meet emerging mandatory GMO-labelling requirements in certain countries, in particular the European Union, but also in Switzerland, Australia, New Zealand, Japan, Norway, etc…
7. Operators can be faced with the following factors :
   - The tolerance levels for labelling may differ among countries or still have to be decided.
   - The set of GMOs approved in different countries is not the same.
   - The existence of products of different destination on the same industrial structure.

Definition

8. Traceability is defined in standard ISO 8402 in general terms as being "*the ability for the retrieval of the history and use or location of an article or an activity through a registered identification*".
9. Traceability in the food system provides mechanisms of continuous flow of relevant information that allow the retrieval of the history and of the origin of a product at any point in the food chain. Traceability aims at limiting discontinuity of the information throughout the food supply chain.
10. This means a system of record keeping and documentation by operators that enables a retroactive tracking of the movement of a product or ingredient through the chain. Record keeping and documentation are linked to commercial transactions between operators.
11. Elements to ensure traceability include that:

- operators ensure, at each stage of the placing on the market, that relevant information is provided in the form of labelling or accompanying documentation;
- operators transmit and retain the relevant information at each stage of the placing on the market.

12. Traceability should be applicable to all food. Verifiable documentation is important since analytical tests can only be used to confirm documentation where detectable material is present. Traceability system enables to carry any kind of information which can be related to specific uses.

Uses of traceability for GMOs (*continued)*

13. The concept of traceability is currently applied in most countries, often by commercial operators (e.g., the labelling of country of origin). Existing traceability systems are based on paper or computerized documentation and/or analytical detection methods when appropriate. The transmission and retention of relevant information for a product at each stage of the placing on the market allows its identity, history and source to be traced.
14. Regarding GMOs, traceability aims at providing each agro-food business operator - from seed production to the finished product - with reliable information on the nature and genetically modified origin of the products he is delivered.
15. The system should allow all the sector operators to rely on information from the previous operator(s). In general, the following reasons for the establishment of a traceability system for GMOs can be identified:

– to possibly withdraw products if a risk to human health is established;
– to facilitate the identification and monitoring of unintended and long-term effects on human health, where appropriate;
– to assist the control of labelling;
– to facilitate the preservation of the identity of specific products.

16. Basic reasons for the establishment of such a traceability system for GMOs is food safety. However, this improvement in the fairness and transparency of transactions will facilitate the task of operators who must comply with certain regulatory or commercial requirements on the part of their customers (labelling of finished products, restrictive list of authorised GMOs, etc.).

Traceability and withdrawal of products

17. Traceability is firstly required for products derived from GMOs for the purpose of withdrawing products in the event of an unforeseen problem arising from consumption of material from GMO origin.
18. Secondly, even if pre-market approval of products derived from GMOs would normally provide for necessary safety assurance, their utilisation or purposes of use can be of different types and may be incompatible. It might appear that there is a necessity of recall measures in the event of mixture of products of different destinations.
19. Thirdly, traceability enables for targeted withdrawal based on the ability to trace back the origin or trace forward the destination. This ability limits the range of products concerned and, consequently, the scale of recall measures.

Traceability and post market monitoring

20. One of the objectives of traceability would be to facilitate monitoring of possible long-term and unintended health effects associated with particular foodstuffs. However, it is widely recognized that little is known about the long-term effects of any food, making the identification of health effects that might be unique to GM foods problematical. Post-market monitoring does not automatically prove a direct causal relationship between the occurrence of an adverse human health effect and the consumption of a particular food.
21. During the pre-market risk assessment of a food derived from GMOs, the need for post-market monitoring is normally examined on a case-by-case basis. It is generally recognized that such measures would be most useful in monitoring effects of genetically modified foods that are significantly different from their conventional counterpart.
22. In this context, traceability can be an essential component to facilitate the follow up and the vigilance that should be exercised after these products are marketed.

Traceability and labelling

23. he primary objective of food labelling is to provide relevant information to purchasers and consumers. In particular, labelling aims at facilitating consumer choice, and at protecting consumers against misleading or deceiving practices.
24. Even if traceability and labelling have different objectives they can be linked to complement one another. As an example, a traceability system could carry information to be used for labelling or in the other way, traceability for products derived from GMOs may facilitate control of labelling of such products.
25. However, it is not necessary to establish the detailed history and origin of individual GMOs to provide for a comprehensive labelling scheme. For the purpose of providing information to the final consumer it is sufficient that operators can document whether authorized GMOs have been used or not.

Traceability and Identity preservation* (*continued)

26. identity preservation (IP) is an active process where actions are taken to preserve the identity of a higher value product as it moves through the chain to a specific end market. IP systems are determined by the end user who has a particular requirement that can only be met by a system that relates the identity of the final ingredient back to some earlier stage of the chain.
27. IP systems are not applied for safety reasons, or to provide safety guarantees. Their focus is to preserve a certain specification based on an agreement between a supplier and a customer. Keeping apart or segregating raw materials is one of the consequences of applying an IP system.
28. Consumer demand for non-GM or GM free food provides an economic incentive for farmers, processors and distributors to supply such products, which require IP to be accepted by the consumer.
29. By comparison, traceability does not imply segregation while traceability does not exclude the possibility of combining several GMOs or combining GMOs and conventional products, but allows the qualitative composition of the combination to be known. In this context, traceability could facilitate the implementation of IP systems.

Implementation of traceability for GMOs

30. As expressed earlier in the document, regarding GMOs, traceability aims at providing each operator - from seed production to the finished product - with reliable information on the nature and genetically modified origin of the products he is delivered.
31. The physical support of traceability is accompanying documentation – preferably existing documentation. The "memory" of the traceability as a way to retain information is registers preferably existing registers.
32. On this base, traceability should apply to all GMOs and foods derived from GMOs, this means:
    - to products composed entirely or partly of GMOs, whatever their use, because the choice of the use, particularly regarding plant products, is not always determined beforehand;
    - to GMO derivatives intended for human and animal consumption.
33. Traceability should make it possible to find each GMO (transformation event) during the phase from the seed to the first processing. Then, from the first processing to the finished product, the aim is to follow the presence of GMO derivatives without necessarily identifying each transformation event.
34. The following information are needed, in trade and transport documents for a practical traceability systems for GMOs:
    - a clear statement indicating the presence of genetically modified organisms or of products derived from GMOs through appropriate formulations;
    - the name of each GMO present (or of the GMO combination) when non-processed products are concerned;
    - the names and particulars of the supplier and of the customer depending on the case.
35. In addition, each operator must keep an entry and exit register of GMOs or their derivatives that he has exchanged or processed, where the same statements as those mentioned above are noted.
36. The nature and form of exchanged information should be harmonised internationally.

Controls

37. Official services or operators themselves can be led to check the fairness of transaction and thus control documentation as well as reliability of the information on the documentation and the content of the product.

Documentary controls are the main controls.

38. Official control must be based on official control principles as defined in the document CAC/GL 201995 (Principles for Food Import and Export Inspection and Certification).
39. Where necessary analysis can be carried out to check the presence of GMOs or to identify a specific GMO, to confirm the reliability of information. This requires unambiguous physical detection of individual GMOs and unique DNA or protein sequences that arise as a result of the modification process. Appropriate methodology has been developed for the detection of unique DNA and protein sequences from material containing GMO but this supposes the availability of materials (primer sequences allowing identification and samples) and of harmonised analysis methods.

Cost and feasibility

40. Traceability must be based on realistic feasibility regarding its implementation procedures and cost. Little is known on the actual cost of a traceability system for GMOs as described earlier. As a contrary more information is available as it relates to the cost of IP systems or to the consequences of a non traced system in the case of recall of product.
41. As traceability has less constraints than IP systems, notably because it doesn't require segregation neither impose any obligation of analytical tests, its cost is intended to be less than the cost of IP systems.
42. Because traceability aims at reducing the scale of recall measures, its cost has also to be compared to known costs of the consequences of non targeted recall measures.

Cost of IP

43. Identity preservation (IP) systems require extra care to ensure the identity of the material from farm to end-user. The cost of an IP system is relative to the complexity and number of actors in the chain. For a product produced and sold locally costs are minimal, but with increasing product complexity, involving many suppliers and geographical origins costs of IP systems increase rapidly.
44. Any IP system reduces the flexibility an operator has in purchasing raw materials. That increases prices and the need for additional analysis on purchased goods. But there must be willingness among consumers to pay for the specific product quality associated with the IP element.
45. For that reason IP systems in practice are limited to characteristic ingredients that are « recognizable » to the consumer or a critical part of the product's identity. It must however be kept in mind that the price flexibility of most processed food products is limited.
46. An important element to establish IP systems is the technical possibility to test samples for the preserved identity (e.g. its physical or chemical contents). Random or regular tests can be carried out for the final product delivered to the consumer or the processor. To enhance the performance, control mechanisms might be applied not only to the final product but also at different stages of production and transportation.
47. Ensuring absolute purity of a food product would be prohibitively expensive in practical processing and handling chains. The principle of fixing a tolerance level (threshold) in purity standards is therefore a long-established feature for IP systems throughout the food industry. The costs of an IP system can be expected to increase with a reduction of the tolerance level.
48. Identity preservation often involves advance contracts with farmers who commit themselves to keep the crop separate during harvesting or to produce only under certain rules (quality labels, organic farming). Furthermore, seed varieties, growing specifications, chemical treatments or handling and storage requirements may be subject to specific contracts.

Cost of non traceability

49. In the case where scientific evidence highlights unforeseen effects to human health of a product, or in case of mixture of product of different destination there is an absolute need of efficient and total withdrawal of this product. In such a situation, non-traced systems for GMOs imply long, heavy and expensive analytical tests for operators and for official services. At the contrary traceability requires only to check available documentation and registers.
50. Consumer can hardly recover its confidence if the system allow only for partial withdrawal.
51. Non traced systems doesn't allow for a targeted withdrawal, and a significant part of the wide range of products concerned by the recall measures are not those products that present a risk.
52. Non traced systems impose expensive and systematic analytical tests to determine the presence of GMOs for operators who must comply with certain regulatory requirements on labelling of finished products.

Cost of traceability

53. Traceability for GMOs is based upon the transmission and retention of documentation to provide information as to the identity of individual GMOs or as to the content of product thereof.
54. Documentation accompanies already the majority of transactions to provide information with respect to the supplier, customer and transaction date as well as the nature, source, contents and amount of the product. On this basis, the costs of placing additional information in such documentation, as a mean to identify individual GMOs contained in the product or specify the presence of material derived from GMOs are expected not to be significant.
55. Incorporating additional record-keeping requirements for GMOs in the existing systems for food materials should not imply significant extra costs either, unless regular testing is required. Indeed, systematic analytical detection is expensive and has its limits. Documented follow-up within a company and upon each commercial transaction is the most informative and least expensive solution.
56. As this traceability system does not rely on a segregation system with difference to the IP system there should not be extra cost related to the dedication of industrial process structure or storage.
57. *In fine*, targeted withdrawal is economically more effective for operators and official services than non targeted withdrawal that applies to a very wide range of products not necessarily concerned.

Developing countries

58. An adequate modulation in the implementation of traceability should take into account the size of the enterprise and the financial capability of the developing countries with respect to the record keeping.

Proposal

59. It is proposed to insert the following text in the Principles for risk analysis of foods derived from modern biotechnology:

"19. Risk management may include traceability for the purpose of:

- possibly withdrawing products if a risk to human health is established;

- facilitating the identification and monitoring of unintended and long-term effects on human health, where appropriate;
- assisting the control of labelling,
- facilitating the preservation of the identity of specific products.

Operators (seed producers, farmers, processor, distributor) should implement a system which guaranty a continuous flow of appropriate information at all the stages of placing on the market of foods derived from modern biotechnology.

Traceability procedures are based on the obligation to state the following information in trade and transport documents:

- wording stating the presence of genetically modified organisms or of products derived from GMOs through appropriate formulations;
- the name of each GMO present (or of the GMO combination) when non-processed products are concerned;
- the names and particulars of the supplier and of the customer depending on the case.

In addition each operator must keep an entry and exit register of GMOs or their derivatives that he has exchanged or processed, where the same statements as those mentioned above are noted.

The nature and form of exchanged information should be harmonised internationally."

2. Comments Relating to the Discussion paper on traceability (provided by the United States)

The United States expresses it thanks to France for preparing the *Discussion Paper on Traceability of GMOs* that presents one view regarding the concept of traceability.

The United States, however, has many concerns regarding the concept of traceability.

The United States believes it is important to note the distinction between traceability and traceback. "Traceability" according to definitions of the International Standards Organization (ISO) pertains to systems for product identification in order to assure product quality. Traceability is not specifically designed to assure safety nor is it necessarily a prerequisite for assuring food safety. For food safety, the United States employs a system of "traceback" which directly addresses recall of products for food safety reasons. We believe it is important to distinguish product identification from assurances of food safety in order to avoid developing a false sense of security that food is safe just because it is labeled and traceable. For these reasons the United States prefers the use of the term traceback rather than traceability because of the term's historical usage and the public health understanding and meaning that is associated with the term.

The United believes that it is important to clearly articulate the reason for implementing a traceability program.

The United States recognizes that there is a clear role for traceback when there are public health concerns about the safety of food and note that the concept is applicable in contexts that are broader than foods derived from biotechnology. The purpose for traceback is to locate and, as necessary, remove a food or food ingredient from the marketplace when a specific public health problem has been identified. The United States does not support traceability programs that have no basis in food safety or public health protection for the reasons noted below.

The United States notes that the Discussion Paper outlines three reasons for a traceability/traceback program.

First, " to possibly withdraw products if a risk to human health is established". The United States concurs with public health as a reason, but questions the need for traceback of safe bioengineered foods because:

1. Foods derived from modern biotechnology are not inherently unsafe.

2. A complete and appropriate safety assessment is performed for all foods and food ingredients derived from modern biotechnology before they are marketed.

3. Recall of product will be the rare exception for products that were reviewed for safety before marketing.

Second, "to facilitate the identification and monitoring of unintended and long-term effects on human health, where appropriate". The United States does not support the linkage of traceability to monitoring. If monitoring is to be done, it should be determined on a case-by-case basis and should be employed only in special and exceptional cases related to human health concerns, including monitoring changes in nutrient levels. A plan for monitoring should be determined based on the specific concern associated with a particular product. It is inappropriate to require a costly and onerous traceability program for all products when the need for traceability is limited to exceptional situations and when traceability would not routinely be necessary even when some form of monitoring may be appropriate. The United States believes that a full and proper safety assessment will avoid such situations, that the occurrence of such a situation will be extremely rare and that implementing a mandatory traceability program to cover such a possibility is not cost beneficial.

Third, "to assist in the control of labeling". The United States strongly opposes traceability merely for the

purposes of labeling. The United States believes that labeling should provide important information required by the consumer. The assumption underlying the Discussion Paper's proposal appears to be that foods derived from biotechnology are inherently less safe than other foods, therefore the consumer must be informed of this fact. Such is not the case. Foods derived from biotechnology are not inherently less safe. The United States believes that setting up a costly traceability system is not justified unless there is a clear public health justification. Establishment of mandatory traceability systems "to assist in the control of labeling" of foods derived from biotechnology is not justified. The United States believes that consumer needs for information can be met by policies that permit truthful, non-misleading statements to appear on labels without imposing mandatory traceability systems with the attendant costs (which in turn will be passed on to consumers) and practical problems of implementation.

Fourth, "to facilitate the preservation of the identity of specific products." This is simply alternative wording for "identity preserved" or IP product. While the United States believes that IP systems are appropriate in certain circumstances, the United States believes that such systems relate entirely to private buyer-seller relationships and that Codex should not use this rationale as the basis for recommending mandatory traceability systems.

The United States believes that governments, particularly, should carefully examine the rationale for mandatory traceback requirements. The United States recognizes that there is a clear role for traceback when there are public health concerns. United States food safety agencies have historically used traceback as a tool within the existing food safety regulatory system to aid in the retrieving of product that may be injurious to health or is unfit for human consumption. Traceback is applied to food and feed products that are in the market place and to unsafe ingredients of these adulterated products. In the view of the United States, the need for traceback for other than public health reasons should be driven by market forces. Industry will respond to consumer interest for the need for such traceback programs resulting in the implementation of voluntary traceback mechanisms. Costs for these programs will be passed on to the consumers wishing to pay for such a service. Governments should exercise great care in mandating programs that do not clearly justify themselves with respect to the protection of the consumer.

The United States notes that Paragraph 16 of the Discussion Paper says that "the basic reasons for the establishment of such a traceability system for GMOs is food safety". The United States agrees, as noted immediately above, that traceback for food safety reasons, is justified. It is important however, to put this rationale into the proper perspective for foods derived from biotechnology. Properly conducted safety assessments, as currently being proposed in other documents under consideration by this Task Force should assure the safety of foods derived from biotechnology. As noted above, the occurrence of an unsafe food product derived from modern biotechnology should be the rare exception, not the rule. Consequently, imposing a costly mandatory traceability program as outlined in this document is, in the United States unnecessary and certainly not cost beneficial. The proposal outlined in this document essentially imposes on consumers a mandatory IP program.

The United States believes it is important to understand and be clear about how regulatory systems work to ensure a safe food supple. It is essential to ensure that food products and their ingredients are safe *before* they are placed on the market. Appropriate food safety assessment systems should be in place to accomplish this objective. Recall and traceback should be the rare exception and be required only when a significant food safety concern exists, for example the presence in a food of a bacterial pathogen at levels that can cause illness. In certain infrequent situations, monitoring systems may be appropriate to verify the scientific conclusions made in regards to the approval of a food or food ingredient and to ensure that no long term chronic adverse health effects are arising.

In regards to a number of other statements and points raised in this document.

- Paragraph 8 presents a definition for the term traceability. The United States believes this definition needs further discussion. The United States does not support the use of a registered identification system.
- The statement is made in various places in the document that traceability does not imply segregation. While this may, in some cases be true, the United States does not agree that it is true as presented in the context of this document. This document implies mandatory labeling for foods derived from biotechnology and states that all trade and transport documents should provide detailed information on the food product derived from modern biotechnology. In the United States judgment, the only way to assure that such labeling and documentation is correct is to segregate foods/food ingredients derived from biotechnology from those that are not derived from biotechnology.
- Paragraph 41 states that the costs of traceability programs as proposed in this Discussion Paper are intended to be "less than those for IP systems" since product segregation and analytical tests would not be required. For the reasons noted above, the United States does not agree with this conclusion. Additionally, The United States believes that the discussion on IP product is not germane for a discussion on traceability within the Codex context since it is purely a buyer/seller relationship and therefore need not appear in this document.
- The statement is made that "the costs of placing additional information…as a means to identify individual GMOs contained in a product or specify the presence of material derived from GMOs are not expected to be significant" since documentation already accompanies the product with respect to supplier, customer, transaction date as well as the nature, source, contents and amount of the product. The United States disagrees with this

statement. Current shipping documentation clearly does not include the special needs required to show that the food or food ingredients are derived from modern biotechnology, particularly with respect to event specific requirements.

- Further on this point, the United States believes that it is inappropriate to make any statement regarding the costs of traceability programs, particularly a statement that costs of traceability are "not expected to be significant" until a thorough and careful cost analysis is carried out of: a) the requirements for traceability as outlined in paragraphs 34 and 35 and, b) the costs of implementation and enforcement, including the availability and costs of implementing appropriate analysis as suggested in paragraph 39.
- In paragraph, 32, the statement is made that "traceability should apply to all GMOs and foods derived from GMOs. For reasons noted above, the United States does not agree with this statement.
- The United States is not clear as to the intent of paragraph 58 that relates to developing countries. If, as stated in this document, that it is important for consumers to be aware of the presence of foods and food ingredients derived from biotechnology, it would seem that this should apply to all consumers, irrespective of the country in which they are located or in which the food is produced. If food importing countries believed that traceability were necessary for consumer protection, they would require it of all exporting countries. The United States believes that the burdens and costs of establishing the kind of traceability programs envisaged in the paper would be particularly difficult for developing countries. Developing countries would also be particularly vulnerable to the adverse effects of rising food prices that would result from implementing such programs domestically or in countries that export food to them
- The United States notes that paragraph 59 proposes language that would include the use of traceability in the Principles document for the purposes presented in paragraph 15, that is for: 1) withdrawing products if a risk to human health is established; 2) facilitating the identification and monitoring of unintended and long-term effects on human health, where appropriate; 3) assisting in the control of labeling; and 4) facilitating the preservation of the identity of specific products. The United States cannot support the inclusion of this language for the reasons given above.
- ***The United States can support the inclusion of the concept of traceback in the paper so long as it related directly to public health.***
- ***The United States notes further that the concept of traceback/traceability is being raised in other Codex venues in a context that is broader than foods derived from biotechnology. The United States can be supportive of this more general discussion on traceback/traceability within Codex and believes this discussion most appropriately can be done within the Codex Committee on Food Import and Export Inspection and Certification Systems. The United States believes that it is important for Codex, and for the Task Force, to carefully and broadly evaluate the concept of traceback/traceability, before moving forward with its inclusion the Principles document, or other Codex documents.***

3. ALINORM 01/21. PART IV-ADD. 1: MATTERS ARISING FROM CODEX COMMITTEES AND TASK FORCES: TRACEABILITY , CODEX ALIMENTARIUS COMMISSION (Twenty-fourth Session, 2-7 July 2001, Geneva, Switzerland)

BACKGROUND

1. The matter of "traceability" has been raised in several Codex Committees and Task Forces with the risk that different interpretations of the meaning of "traceability" or different approaches to handling the issue within the Codex system could arise. The purpose of this paper is to bring this issue to the attention of the Commission and to propose means of dealing with it within the framework of Codex in a uniform manner.

2. "Traceability" is defined as the "ability to trace the history, application or location of an entity by means of recorded identifications"[1,2]. Traceability is closely linked with product identification. It should also be noted that traceability may relate to:

the origin of materials and parts;

the product processing history;

the distribution and location of the product after delivery.

[1]International Organization for Standardization: ISO 8402: 1994.

[2]In metrology and laboratory accreditation systems, the term *traceability* means a process whereby the indication of a measuring instrument (or a material measure) can be compared with a national standard for the measure and in question in one or more stages (International Laboratory Accrediation Conference: ILAC-G2: 1994 *Traceability*). The ISO definition also refers to this aspect of traceability. This aspect of traceability falls within the terms of reference of the Codex Committee on Methods of Analysis and Sampling, but for the purposes of this paper it will not be discussed further.

3. On the basis of this definition, it is possible to show that traceability is a recognized process in adopted Codex texts and texts under elaboration, even if the word “traceability” has not been used. In most cases it is linked to product identification and recall procedures. Examples include:

a) Adopted Texts

- Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997): Section 9.1 Lot Identification;
- Codex Code of Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979, Rev. 2-1993): Section 8.2 Record Review and Maintenance;
- Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985, Rev. 11999): Section 4.4 Name and address, Section 4.5 Country of Origin, Section 4.6 Lot Identification;
- Codex Guidelines for the Exchange of Information between Countries of Rejections of Imported Food (CAC/GL 25-1997): paragraphs 11-12 Identification of the Food Concerned and Importation Details.
- Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999)
- The Terms of Reference of the Codex *ad hoc* Intergovernmental Task Force on Animal Feeding[3].

[3]Procedural Manual of the Codex Alimentarius Commission, 11th edition, FAO/WHO, Rome 2000, p. 127.

b) Draft or Proposed Draft Texts

- Draft Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods Livestock and Livestock Products, Annex 3 (ALINORM 01/22, Appendix II);
- Proposed Draft Code of Practice for Fish and Fishery Products (ALINORM 01/18, Appendix V, Section 3.7);
- Proposed Draft Revised Code of Practice for the Processing and Handling of Quick-Frozen Foods (CL 2001/01-PFV, Section 3.6);
- Proposed Draft Code of Hygienic Practice for the Primary Production, Harvesting and Packaging of Fresh Fruits and Vegetables (ALINORM 01/13A, Appendix II): Sections 5.7 (Documentation and records) and 5.8 (Recall procedures and traceback) – also Annex II;
- Proposed Draft Guidelines for the Utilization and Promotion of Quality Assurance Systems to Meet Requirements in Relation to Food (CX/FICS 01/5, para 32);
- Proposed Draft Code of Practice on Good Animal Feeding (CX/AF 01/5); Sections *4.2. Labelling* and *4.3. Traceability and Record Keeping*);
- Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
(ALINORM 01/34A, Appendix II): the relevant paragraph in this text is in square brackets.

4. The FAO Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition (Melbourne, October 1999) accepted the suggestion that traceability was an important control factor in the production of foods[4].

[4]ALICOM 99/25: Report of the FAO Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition, Melbourne, 11 - 15 October 1999, FAO, Rome, 1999. para. 100.

5. Codex texts do not currently apply traceability to the origin of materials and parts with the exception of the Country of Origin provisions of the *General Standard for the Labelling of Pre-packaged Foods* and the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*.

6. Traceability related to product processing history is covered partially by the General Principles of Food Hygiene and in particular the Annex: Hazard Analysis and Critical Control

Point System and Guidelines for its Application. The Code of Practice for Low-Acid and Acidified Low-Acid Canned Foods also contains extensive requirements relating to traceability in product processing, as does the specific case of organically-produced foods mentioned above.

7. Within established Codex texts, traceability as it relates to the distribution and location of the product after delivery has been expressed partially in the *General Principles of Food Hygiene* and the *General Standard for the Labelling of Pre-packaged Foods*, with references to Lot Identification and the ability to recall product if necessary. At the moment, Codex texts to not require manufacturers or distributors to maintain records of onward distribution, with the exception of the *Code of Practice for Low-Acid and Acidified Low-Acid Canned Food*.

CURRENT DISCUSSIONS

8. As noted above, several Codex Committees and Task Forces have initiated work on in one or other aspects of traceability. Traceability, as a subject in itself, has been discussed by the Codex Committee on Food Import and Export Inspection and Certification Systems, the ad hoc Codex Intergovernmental Task Force on Animal Feeding and the *ad hoc* Codex Intergovernmental Task Force on Foods Derived from Biotechnology. The nature of the discussions is significantly different in each of these bodies.

9. The Codex Committee on General Principles has also discussed traceability within the context of the discussion within CCFICS[5]. During this discussion all Delegations that spoke highlighted the importance of the issue and the importance of a uniform approach to the concept and application of traceability. Individual issues that Delegations and observers believed to be important in the development of the topic included:

- The place of traceability in risk management;
- the use of traceability for product integrity, authenticity and identification;
- The use of equivalent measures;
- Practicability of traceability, and in particular the feasibility of its application in developing countries;
- Consumer confidence and information concerning the nature and origin of products;
- The possibility of using traceability for liability and redress.

[5]ALINORM 01/33A, paras 12-15.

10. At a technical level, the ad hoc Codex Intergovernmental Task Force on Animal Feeding has included specific reference to traceability in the proposed Draft Code of Practice on Good Animal Feeding, but will discuss the matter at its next session in the light of guidance from the Commission in response to the present paper[6]. The *ad hoc* Codex Intergovernmental Task Force on Foods Derived from Biotechnology has discussed traceability in the context of the Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, but has not come to a consensus on the inclusion of a reference to traceability as an element of risk management. In this regard, the Task Force has agreed to circulate a discussion paper (prepared by France) and a note (prepared by the USA) for comments[7]. At a programme or policy level, the Codex Committee on Import and Export Food Inspection and Certification Systems has agreed that within its Terms of Reference it had a responsibility to consider work in this area and that there was need for a substantive discussion of the issue at its next meeting[8]. The Codex Regional Coordinating Committee for North America and the South-West Pacific also noted that "traceability" was important in terms of food safety in general and may need to be considered more broadly by the Commission and its subsidiary bodies[9].

[6]ALINORM 01/38A, paras. 58-60. [7]ALINORM 01/34A, paras. 34-42 and 79-83. [8]ALINORM 01/30A, paras. 110-114. [9]ALINORM 01/32, para. 66.

GENERAL CONSIDERATIONS

11. According to ISO, traceability can entail high costs[10]. A decision to apply traceability should therefore be justified and the justification documented. Clearly, within the Codex context,

consideration must be given to the reasons for applying traceability for food products and the extent to which traceability is to be required as part of a food standard, code of practice, food labelling text or similar document. Such reasons must lie within the overall mandate of the Commission, namely: *To protect the health of consumers and ensure fair practices in the food trade*.

[10]ISO 9000-2:1993 Quality Assurance and Quality Management Standards – Part 2: Generic guidance for the application of ISO 9001, ISO 9002 and ISO 9003.

12. As noted above, the ISO definition states that traceability may relate to the origin of materials and parts; the product processing history; [and/or] the distribution and location of the product after delivery. However, the ISO definition of "Traceability" also states in a note that "All aspects of traceability requirements, if any, should be clearly specified, for example, in terms of period of time, point of origin or identification". The ISO definition implies that traceability may or may not be required, or may begin at a certain point within the production chain, or may end at a point before the end of the chain.

13. The extent to which traceability may be applied "to protect the health of consumers" may be considered as part of a food safety risk management decision. Such a decision would assume the ability to demonstrate the presence of a food safety risk that could be managed by a system of traceability in a manner that would achieve the Appropriate Level of Protection (ALOP) from that risk. Similarly, such a decisions would also need to take into account other measures that would achieve the same ALOP that may be less costly or may be more appropriate in a given situation. A decision to apply traceability would need therefore to specify whether it is to be applied throughout the production and distribution chain or only to some part of the chain. Such decisions may need to be specified on a case-by-case basis taking into account: i) the nature of the risk; and ii) the ability to manage the risk by the use of traceability or by other means.

14. The application of traceability "to ensure fair practices in the food trade" is probably most directly linked to the first of the General Principles set down in the *General Standard for the Labelling of Pre-packaged Foods* which reads: "Pre-packaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or is likely to create an erroneous impression regarding its character in any respect". This application reaches its fullest expression in the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*.[11] This application of traceability is closely linked to the concept of Identity Preservation (IP) and may be used to ensure the validity of other labelling claims as well.

[11]The first two aims of these guidelines contain a clear statement of "ensuring fair practices" including:

to protect consumers against deception and fraud in the market place and unsubstantiated product claims;

to protect producers of organic produce against mis-representation of other agricultural produce as being organic.

15. The use of traceability "to ensure fair practices in the food trade" correlates to the "prevention of deceptive practices" as a legitimate objective described by the WTO Agreement on Technical Barriers to Trade. A requirement of traceability in a Codex standard or related text for this purpose would therefore need to be in conformity with Article 2 of this Agreement, particularly Articles 2.2 to 2.5. Similarly to the use of traceability to protect the health of consumers, a decision to apply traceability to ensure fair practices in the food trade would need therefore to specify whether it is to be applied throughout the production and distribution chain or only to some part of the chain. However, in this case, such decisions would need to be specified on a case-by-case basis taking into account: i) the legitimate objective being fulfilled; ii) the risks that non-fulfilment would create; and iii) whether or not the legitimate objective can be addressed in a less trade-restrictive manner.

16. Traceability may also serve to meet the needs of contracting parties in fulfilling the requirements of Article 18 of the Cartagena Protocol on Biosafety in regard to living modified organisms that are intended for direct use as food or feed, or for processing and are not

intended for intentional introduction into the environment. Traceability measures that meet these requirements and at the same time meet any requirements that might be laid down in Codex standards or related texts would have the benefit of economy in their development and application.

17. In addition to the decision of whether or not to apply traceability as a means to achieve an ALOP or to fulfil a legitimate objective, there is the question of how traceability is to be applied. Specific questions to be answered are: what are the modalities to be applied, especially in regard to international food trade; what information needs to be transmitted from one regulatory authority to another, and when; how are the traceability requirements of voluntary or mandatory food quality and safety management systems to be integrated into an international regulatory framework. Consideration should also be given to its practicability and in particular the feasibility of its application in developing countries.

MATTERS FOR CONSIDERATION BY THE COMMISSION

18. The Commission may wish to take the following actions:

- Request the Codex Committee on General Principles to consider when and to what extent traceability should be considered as a risk management option within the Codex Working Principles for Risk Analysis;
- Request the Codex Committee on Food Hygiene and the Codex Committee on Food Labelling to examine whether and to what extent traceability requirements currently included in their general and specific texts may need to be strengthened; and
- Request the Codex Committee on Food Import and Export Inspection and Certification Systems to consider the modalities for the application of traceability, in particular in reference to the use of official inspection and certification requirements to ensure the integrity of traceability.

Chapter 4

DEVELOPMENT OF DOCUMENTS ON TRACEABILITY IN CODEX COMMITTEES ON GENERAL PRINCIPLE AND FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

CONTENTS

1. CODEX COMMITTEE ON GENERAL PRINCIPLES

The 16th Session (2001)

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CCFICS): Traceability

12. *The Committee was informed that the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) had discussed this issue, and that it had noted in particular that several Codex Committees and Task Forces were dealing with traceability. The CCFICS had agreed that within its Terms of Reference it had a responsibility to consider work in this area. However, the CCFICS had recommended that in view of the system-wide interest in this issue, a paper should be prepared by the Secretariat in order to obtain the Commission's guidance in this matter.*
13. *All Delegations that spoke highlighted the importance of the issue and the importance of a uniform approach to the concept and application of traceability. They welcomed the recommendation that such a paper be prepared for the Commission's consideration. Most Delegations noted the fact that the issue was being dealt with or discussed in a number of Committees or Task Forces.*
14. *Some Delegations proposed that the Committee on General Principles should have a leading role in the preparation of general guidelines or principles on traceability, with other Codex Committee providing specific guidance on its application. Other Delegations were of the opinion that it would be premature to decide what role the Committee should have before consideration of the matter by the Commission. Individual issues that Delegations and observers believed to be important in the development of the topic included:*
    - *The place of traceability in risk management;*
    - *The use of traceability for product integrity, authenticity and identification;*
    - *The use of equivalent measures;*
    - *Practicability of traceability, and in particular the feasibility of its application in developing countries;*
    - *Consumer confidence and information concerning the nature and origin of products;*
    - *The possibility of using traceability for liability and redress.*
15. *The Committee looked forward to receiving the advice of the Commission on this matter and drew attention to its role of ensuring a consistency of approach of such matters throughout the Codex system. It looked forward to contributing positively to the future development of this topic.*

The 17th Session (2002)

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES INCLUDING TRACEABILITY

GENERAL ISSUES

4. *The Delegation of the United States stressed the importance of the consideration of the Medium-Term Plan 2003-2007 and the need for member countries to provide comments. The Secretariat informed the Committee that the revised draft of the Medium-Term Plan, including the comments submitted by member countries, had been prepared and would be considered by the 50th Session of the Executive Committee.*

5. The Committee recalled the recommendations of the 49th Session of the Executive Committee concerning the consideration of traceability in Codex and noted the conclusions reached by the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology and the work undertaken by the Committee on Food Import and Export Inspection and Certification Systems (CCFICS) and other Committees in this area. The Committee took note of the comments of Uruguay concerning the need to distinguish clearly the use of traceability in risk management and other applications.

6. The Delegation of France, referring to its written comments (CRD 4) proposed that the Committee should develop a definition for the purposes of Codex as well as working principles to address this question in concerned Committees, either in a separate document or as part of other documents such as the Working Principles for Risk Analysis. The Delegation recalled that the role of the Committee was to provide guidance to Codex Committees on general issues and proposed to convene a working group, chaired by a developing country, to develop a document for this purpose.

7. Several delegations supported this proposal and pointed out that the work undertaken by CCFICS concerning traceability was focused on modalities of implementation in inspection and certification systems; other committees were also working on provisions concerning traceability in their respective areas of competence but the Committee on General Principles should address this question from a general perspective in order to ensure consistency throughout Codex.

8. *The Delegation of Brazil proposed to await the outcome of the work initiated by the CCFICS in order to avoid duplication; this would be consistent with the coordinating role of the Committee and with the recommendations of the Executive Committee that relevant Committees should undertake work as they deemed appropriate. Several delegations supported this position and stressed that the growing number of working groups established by different Codex Committees posed practical difficulties for governments, especially developing countries, and would not necessarily solve such complex issues. Some delegations also pointed out that traceability was only one of the measures applied in risk management and that it should not be addressed separately in specific guidelines or recommendations, but integrated in the work on risk analysis.*

9. *The Delegations of the United States, supported by other delegations, expressed the view that product tracing should be considered in the framework of risk management as a matter of priority, as recommended by the CCEXEC and taking into account the conclusions reached by the Codex Ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology (CTFBT) concerning risk analysis.*

10. *Other delegations and observers stressed the importance of traceability to ensure the authenticity of consumer information and proposed that the work of the Committee should not be limited to food safety aspects but should address all relevant applications of traceability.*

11. *Several delegations stated that these questions should also be examined in the light of the obligations of Members of WTO under the SPS and TBT Agreements, including consideration of alternative procedures.*

12. *The Committee could not reach a consensus on the need to create a working group but agreed to undertake work on this matter and agreed that the Secretariat should prepare a discussion paper considering how the Committee could best contribute to consideration of this issue in Codex, taking into account the work of other relevant committees, well in advance of the next session in order to allow for comments. The Secretariat was also asked to provide a draft definition for Codex use.*

13. *In reply to a question on the role of Regional Coordinating Committees, the Secretariat recalled that these Committees might wish to contribute to the debate, as agreed by the Executive Committee, and they would therefore be invited to discuss this question. The results of these discussions would be integrated into the document prepared for the Committee.*

The 18th Session (2003)

INTRODUCTION

2. The session was opened by Mr. Renaud Dutreil, Secretary of State for Small and Medium Industries, Trade, Crafts, Professions and Consumer Affairs. Mr. Dutreil welcomed the

participants and emphasized the enduring relevance of the original Codex mandate to deal with the new demands, coming from consumers' expectations, on trade, and specifically international trade, which is the focus of Codex work. He stated that the work of this committee would contribute significantly to build up consumers' confidence, by establishing a basic science-based framework, in which the protection of the consumers' health and the promotion of fair practices in the food trade could be implemented at the international level. Several issues on the agenda of this session, such as risk analysis, the code of ethics in international trade, and traceability, were directly relevant from this perspective. Mr Dutreil stated that the legitimacy of Codex standards required that the two objectives in its mandate received equal attention and be pursued in a consensus-based manner. He also noted that the work of Codex had been evaluated by its two parent organizations and the follow-up of this evaluation may require additional work from this Committee. The French government would help moving forward in this reform of Codex, by offering to organize extra plenary sessions (or working groups), as the need arose.

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY

37. *Delegations raised a number of areas of concern that needed to be addressed in the context of the document. These included: responding to potential consumers' health situations where complete scientific data were not available; traceability/product tracing within a risk management system; ensuring fair practices in the food trade within the risk analysis framework; the protection of producers' interests as well as consumers' health; and the need to ensure that these issues could not be used as a form of disguised protectionism. The Committee did not explore any of these issues in detail.*

CONSIDERATION OF TRACEABILITY/PRODUCT TRACING (Agenda Item 6)

85. *The Secretariat introduced the paper, which had been prepared on the basis of discussions that had taken place at meetings of the Regional Coordinating Committees, pursuant to the decision of the 17th Session of the Committee (ALINORM 03/33, paras. 5-13). The document contained several options that the Committee might wish to take in pursuit of this matter.*

86. *The Delegation of Switzerland provided the Committee with an overview of the status of work being carried out by the Working Group on traceability/product tracing of the Codex Committee on Food Import and Export Inspection and Certification Systems.*

87. *In relation to the text under discussion, the many delegations stated that a system of traceability/product tracing that would serve multiple purposes would most likely be costly, especially for producers and small-scale enterprises in developing countries. Most of these countries expressed their willingness to consider traceability/product tracing as a food safety risk management measure but were of the opinion that the system should not be extended to non-food safety related areas such the verification of authenticity or for labelling purposes. Many of these delegations stated that they could not support work in this area other than consideration of the definition, noting that the general ISO definition was not appropriate for Codex purposes. Several of these delegations supported the technical work currently underway in the Codex Committee on Food Import and Export Inspection and Certification Systems. Some delegations and observers supported the use of traceability/product tracing for a food safety objective (i.e. as a SPS measure) as well as for a non-food safety objective (i.e. as a TBT measure) such as for consumer information.*

88. *Many other delegations supported the elaboration of a Codex definition as well as for Codex guidelines for both purposes, taking into account the work of the Codex Committee on Food Import and Export Inspection and Certification Systems and in cooperation with the Codex Committee on Food Hygiene and the Codex Committee on Food Labelling within their respective mandates. They agreed that the use of a system of traceability/product tracing should be consistent with the provisions of the WTO SPS and TBT Agreements and be not more trade-restrictive than necessary.*

89. *Although some delegations questioned the necessity of developing a definition for traceability/product tracing, only a few delegations expressed their opposition to the development of a definition. Some delegations noted that the same terminology was used to describe very different systems.*

90. *Many delegations were of the opinion that the options contained in the Secretariat paper could form the basis of future work by the Committee in regard to the definition, guidelines for use in risk management and the determination of product origin and authenticity. Many other delegations, while supporting the need for work on a definition, did not support the need for other work. Some delegations noted that the costs of such systems should be borne by all concerned, but that certification and auditing bodies could also underwrite these systems.*

91. *A number of delegations stated that traceability/product tracing would be more difficult for developing countries to implement. Several of these delegations stated that the provisions of current Codex texts that were aimed at ensuring food safety and the protection of consumers' health were sufficient. In their opinion, even "trace-back" was not practical for developing countries where most agricultural production was on small farms. These delegations stated that economic considerations had to be taken into account and that traceability/product tracing could only be considered as an optional tool for those industries that could afford to use it.*

92. *Some delegations noted that the HACCP System required similar record-keeping and provided the tools necessary for food safety risk management. These delegations were of the opinion that it was premature to undertake work on either a definition or guidelines for traceability/product tracing before the technical work of the Committees cited above was completed. In this regard, one observer pointed out that the Codex General Principles of Food Hygiene provided adequate protection of consumers' health and already contained the elements of record-keeping that were necessary to establish a traceability/product tracing system that would be applicable to all food products throughout the food chain as pointed out in the Secretariat's paper.*

93. *Several delegations were of the opinion that that this system should only be used as a risk management option on a voluntary basis and that there should be a cost/benefit analysis before proceeding with the use of traceability/product tracing. The view was also expressed that if a cost/benefit analysis was to be carried out then the costs of not implementing the traceability system should also be analyzed. The Delegation of India, supported by several delegations, stated that traceability/product tracing should be well defined and should be applicable only to processed foods and exclude primary foods and processes. It was further stated that it should be used only for the purposes of product recall as a management option on a case-by-case basis, upon the application of strict criteria set out in paragraph 81 of the report of the FAO/WHO (Codex) Regional Coordinating Committee for Asia held in September, 2002.*

94. *Several delegations stated their view, in addition to the views noted above, that the FAO/WHO (Codex) Regional Committee for North America and the South West Pacific had noted that once a system of traceability/product tracing had been installed it could be used for various purposes.*

95. *In relation to the use of traceability/product tracing to determine the authenticity of products, several delegations stated that, although there may be such a need, this would have to be consistent with the WTO TBT Agreement. Several delegations and observers pointed out that, as an example, state-regulated systems of traceability/product tracing for the determination of product authenticity would benefit developing countries wishing to market and export "organic" foods. It was noted that such regulations were in force in some developed countries. However, many delegations stated that such a system should not be extended to the regulation of commercial "Identity Preservation".*

96. *Some delegations and observers were of the opinion that the use of traceability/product tracing for these purposes was a commercial response to consumer demand and could therefore be left to market forces to determine when and how the system should be applied, as was already the case.*

97. **Status of the Discussion** *The Committee concluded that there was sufficient support only to proceed with the development of a definition of "traceability/product tracing" for Codex purposes and agreed to establish an open-ended electronic working group under the direction of the Delegation of France to develop a draft for the consideration of the next regular session of the Committee.*

98. In view of the divergence of opinions on the other options contained in the Secretariat's paper, the Committee was unable to arrive at a consensus opinion, but agreed to keep the matter under review in the light of the ongoing work in the Codex Committee on Food Import and Export Inspection and Certification Systems.

The 20th Session (2004)

OPENING

2. The session was opened by Mr. Verdier, Assistant Cabinet Director, who welcomed participants on behalf of Mr. Christian Jacob, Delegate Minister of Small and Medium Industries, Trade, Craft, Professions and Consumers Affairs. Mr. Verdier welcomed the participants and emphasized the difficult task of Codex to protect the health of the consumers and ensure fair practices in international food trade. He underlined the importance of the work of the Codex Committee on General Principles as regards the development of the Guidelines on risk analysis for food safety, the Code of Ethics for International Trade in Food and the definition on traceability/product tracing of foodstuffs, to achieve the objectives of limiting unnecessary barriers to trade and enhancing consumers confidence. He also emphasized that on-going reforms within Codex should increase efficiency, transparency and participation in the work of the Commission. Stressing the heavy agenda of this session, Mr. Verdier wished the delegates all success in their work.

Committee on Food Import and Export Inspection and Certification Systems

9. The Committee noted that following the discussion on traceability/product tracing in the Committee on Food Import and Export Inspection and Certification Systems, a preliminary set of principles on traceability/product tracing had recently been circulated for comments and consideration by the next session of that Committee.

CONSIDERATION OF TRACEABILITY/PRODUCT TRACING (Agenda Item 6)

85. The French Secretariat recalled that the 18th Session of the Codex Committee on General Principles had established an electronic working group, open to all members and observers of Codex, under the direction of the Delegation of France, to develop a draft for the consideration of the next regular session of the Committee. The result of its work was presented in document CX/GP 04/20/6 and circulated for comments before the present session of the Committee

86. The Committee held a general discussion on the definition presented in document CX/GP 04/20/6, particularly with regard to its scope and degree of detail. Many delegations emphasized the importance of developing a Codex definition, especially in the light of the work of the Codex Committee on Food Import and Export Inspection and Certification Systems and other Codex Committees and expressed the view that the definition of traceability/product tracing should be more precise and concise and should not cover objectives or principles of specific traceability/product tracing application.

87. Some other delegations were of the view that the definition should be sufficiently broad and include such elements that would facilitate the application of the concept as a management tool and also to ensure fair practices in the food trade. It was suggested that animal feed and food producing animals should be covered by the definition, as traceability/product tracing in some cases could include them. It was also suggested by the Delegation of India that the definition should have the flexibility to exclude primary production. Some delegations, including Chile and Costa Rica, that had not sent written proposals, put forward a proposed definition of traceability/product tracing during the meeting.

88. The Committee agreed to convene an ad hoc drafting group chaired by the Delegation of France in order to proceed with the further elaboration of the definition by accommodating the views of delegations, including the written comments received.

89. On the basis of the work of the drafting group, the Committee agreed on a new definition of traceability/product tracing as follows:

Traceability / product tracing: the ability to follow the movement of a food *through specified stage(s) of production, processing and distribution.*

90. It was understood that the term "ability" should be used, as it would leave possibilities to specify the person(s)/organization(s) having this ability when guidelines for specific

applications would be drafted.

91. It was noted that the phrase "to follow the movement of" was appropriate since the use in the body of a definition words having the same root as the word to be defined was unhelpful and might result in a lack of clarity. It was also agreed not to use the verbs trace/track at this point. The phrase agreed upon already implied that the item traced has been properly identified and that the insertion of the verb "identify", as some written comments had suggested, was not needed.

92. It was noted that the inclusion of feed and food producing animals in this Codex general definition might pose difficulties. It was recognized that traceability/product tracing could cover these parts of the food chain, only in so far as, in some situations, there was an impact on the food itself and as guidelines for specific applications would so establish. It was also noted that the Codex definition of "food" only covered products for human consumption and not "feed"; that the Commission had established an ad hoc Intergovernmental Task Force on Animal Feeding; and that this Codex general definition might still be able to be used by this Task Force.

93. It was agreed to introduce some flexibility by using the wording "through specified stage(s) of" in order to take into account the specific conditions of the primary production sector in developing countries, recognizing that detailed guidelines for specific applications would have to deal with this issue.

94. The phrase "production, processing and distribution" was also chosen in order to describe succinctly the range of the operation of traceability/product tracing. It was also agreed that the term "production" could be interpreted in such a broad manner as to cover food producing animals, feed, fertilizers, pesticides, veterinary drugs, and any input of plant or animal origin, etc., if relevant for specific applications of traceability/product tracing to food.

95. The Committee expressed its appreciation to the Delegation of France for the achievement made and for its contribution to the consensus building process.

Status of the Definition of Traceability/Product tracing

96. The Committee agreed to forward the definition of Traceability / Product tracing (Appendix V) to the 27th Session of the Codex Alimentarius Commission for adoption and inclusion in the Procedural Manual.

APPENDIX V

DEFINITION OF TRACEABILITY / PRODUCT TRACING

Definition to be included in the Procedural manual

Traceability / product tracing: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution.

2. CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

The 9th Session (2001)

MATTERS REFERRED FROM OTHER CODEX COMMITTEES (Agenda Item 2)

3. The Committee was informed of matters arising from other Codex Committees, including the 47th Session of the Executive Committee of the Codex Alimentarius Commission. In addition to information provided on the consideration of "traceability" within the Codex Ad Hoc Intergovernmental Task Forces on Biotechnology and on Animal Feeding, the Committee was also informed that the recently held 6th Session of the Codex Coordinating Committee for North America and the South West Pacific (CCNASWP) "noted that traceability was important in terms of food safety in general and may need to be considered more broadly by the Commission and its subsidiary bodies".

65. The Delegation of Japan asked whether there might be linkages between the contents of this document and the issue of "traceability" to be discussed under Item 10. The delegation of Japan also enquired as to how traceability related to the work of other Codex committees.

104. The Committee reached general agreement that the elaboration of guidelines for food control emergency situations involving international trade should be undertaken in the context of CAC/GL 19-1995. It was suggested that guidelines concerning food control emergency

situations should include the consideration of:

- *final disposition of food products, including the concept of traceability and third country exports*

TRACEABILITY

110. The Delegation of Japan introduced a brief paper on the matter of traceability30 in which it noted that this issue had been referred to, or was currently being discussed by various Codex Committees including CCFICS, Committee on Fish and Fishery Products, Task Force on Animal Feeding, and the Task Force on Foods Derived from Biotechnology. It stated that the concept of traceability cut across a wide range of food issues. It further noted that, as yet, there had not been a forum under the Codex Alimentarius Commission in which a comprehensive discussion had taken place on the issue and that Codex had not yet defined the purpose and framework of this concept. The Delegation was of the opinion that due to the importance of this concept in relation to food import and export inspection and certification systems it would be an appropriate matter for the Committee to discuss. The Committee expressed its appreciation to the Delegation of Japan for raising the issue and agreed that the points raised needed to be addressed within the Codex framework.

111. At the request of the Chairperson, the Secretariat noted that different Codex Committees and Task Forces had undertaken either prior or current work related to traceability including the Committees on Food Hygiene, Food Labelling, and Food Additives and Contaminants in addition to the subsidiary bodies mentioned by Japan. The Secretariat noted that the modalities required for systems of traceability seemed to fall within the terms of reference of CCFICS whereas consideration of a Codex-wide definition of the concept would logically fall within the work of the Committee on General Principles.

112. The Representative of the European Commission stated that traceability was an instrument of risk management and as such should be considered by the Committee on General Principles. Moreover, in the opinion of the Representative, the issue was not exclusively related to food safety. For example in the area of organic foods or food claimed to be "GMO-free" it was a matter of ensuring the integrity of the product in relation to consumer confidence. Because it was such a general concept, the Representative recommended that the Committee on General Principles should establish a definition and establish general orientations.

113. The Delegation of Canada, supported by several other delegations, stated that there was a need for a general discussion paper on the status and use of the concept in which the problems, challenges and opportunities to Codex would be highlighted. The Delegation of the Republic of Korea stated that this was an important issue for food safety systems involved in international trade. The Representative of the International Association of Consumer Food Organizations proposed that consideration could be given to a "bottom up" approach, allowing a more general definition to be derived from the practical application of the concept by individual committees within their terms of reference. The Delegation of the United States was of the opinion that emphasis should be placed on the purpose and application of the concept rather than a definition. The Delegation of New Zealand was of the opinion that contemporary experience in the use of the concept at the national level should be identified and examples included in any discussion paper.

114. The Committee agreed that within its Terms of Reference it had a responsibility to consider work in this area and that there was need for a substantive discussion of the issue at its next meeting. In view of the system-wide interest and involvement in the issue, the Committee recommended that a short paper be prepared by the Secretariat for consideration by the Codex Alimentarius Commission at its next Session in order to obtain the Commission's guidance in this matter. In the meantime, the other relevant Committees and Task Forces, including the Committee on General Principles, would be informed of this recommendation.

The 10th Session (2002)

4. The Australian Secretariat also proposed the inclusion of a document on Traceability in the Context of Inspection and Certification Systems 3 and in view of the importance of this issue for the future work of the CCFICS, the Committee agreed to consider the document immediately after Agenda Item 4 (Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems) as a new

Agenda Item 4bis.

TRACEABILITY IN THE CONTEXT OF FOOD INSPECTION AND CERTIFICATION SYSTEMS *(Agenda Item 4bis)*[13]

[13] *CX/FICS 02/INF.2 and comments submitted by the USA (CRD 8)*

53. As previously decided (see para. 4), the Committee agreed to consider the information paper on Traceability in the Context of Inspection and Certification Systems prepared by the Australian Secretariat under Agenda Item 4bis.

54. The 49th Session of the Executive Committee noted that the Codex Secretariat paper on Traceability had been prepared at the specific request of the CCFICS but treated the issue as a general issue confronting Codex. The Executive Committee noted that the concept of traceability was not new to Codex but that it had not been treated in a systematic manner. The Executive Committee also supported the analysis and approach outlined in the Codex Secretariat paper, pointing out that any measures requiring traceability should be justified as either having a food safety objective (i.e., as an SPS measure) or as having a legitimate objective (i.e., as a TBT measure).

55. The Executive Committee recommended that the Codex Committee on General Principles consider these two aspects of traceability, although it was of the opinion that first consideration should be given to the use of traceability as a risk management option in the draft Working Principles for Risk Analysis. The Executive Committee also noted in particular the role of the CCFICS in relation to the development of procedures for the application of traceability in food import and export inspection and certification systems. The Executive Committee agreed that relevant Codex Committees[16] should undertake work, as they deemed appropriate, within their respective mandates. In this regard, the Committee noted the opinion expressed by the CCFH at its 34th Session that specific work on traceability as related to food hygiene was premature. The Executive Committee also welcomed the suggestion that the Chairpersons of the Committees concerned and the Secretariat should coordinate work so as to avoid a divergence of approach and asked to be kept informed of progress in this work.

[16] *Including the Codex Committees on General Principles, Food Labelling, Food Hygiene and Food Import and Export Inspection and Certification Systems.*

56. The Committee noted that the forthcoming Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology would be considering comments on traceability in the context of their work in response to CL 2001/27-FBT. The Committee was also informed of the recent decision of ISO to undertake new work on the elaboration of Traceability System in the Agriculture Food Chain – General principles for Design and Development (ISO/AWI 22519).

57. The Committee noted that the concept of "traceability" was already included in many Codex texts and was linked in most cases to product identification and recall procedures. The Committee also noted that Codex texts generally did not apply traceability to the origin of foods and ingredients although Country of Origin provisions included traceability requirements in at least two Codex texts[18].

[18] *General Codex Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985 Rev.1-1991 (amended 2001)) and Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999, Rev. 2001).*

58. The Committee noted that traceability might also be used to ensure fair practices as it correlated to the prevention of deceptive practices (e.g., organically produced food) as a legitimate objective described by the WTO Agreement on Technical Barriers to Trade. Within the Australian Secretariat's paper, traceability was described as a means to preserve the identity of the food product and according to several definitions adopted by the Commission, the concept of traceability might be considered to be included as a requirement.

59. The Committee was invited by the Australian Secretariat's paper to consider three different issues relating to traceability and inspection/certification systems:

- *Whether the existing Codex norms originating in CCFICS were adequate in relation to their applicability to traceability;*

- *Whether any work currently underway needed to be re-oriented; and,*
- *Whether any new projects needed to be initiated in order to cover the issue of traceability.*

60. Therefore, the Committee was invited to consider different scenarios to address traceability in the context of its mandate such as to acknowledge the fact that inspection and certification may be in some situations be the most efficacious means of implementing a requirement for food to be traceable; to attempt to codify the circumstances in which traceability should be applied as a requirement; and, to note that aspects of traceability were specifically referenced in two texts[20] already adopted by the CCFICS and the Codex Alimentarius Commission.

[20]Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995) and Guidelines for the Exchange of Information Between Countries on Rejections of Imported Foods (CAC/GL 25-1997).

61. Many delegations expressed their support for CCFICS to consider the development of the concept of traceability in the context of food import and export inspection and certification systems in parallel to work undertaken in other Codex Committees such as the CCGP. The delegation of the USA presented a Conference Room Document supporting the initiation of work on traceability with respect to food safety. Other delegations expressed the view that in consideration of the on-going discussions on traceability in the context of the Working Principles for Risk Analysis, the CCGP should define the overall Codex framework on traceability prior to any work being initiated by other Codex Committees such as the CCFICS.

62. Several delegations stressed the importance of evaluating the cost-benefit of traceability as a requirement when applied to foods, food ingredients and composite foods throughout the entire food chain. It was proposed that the Committee consider practical issues related to traceability such as consignment records, point of application in the food chain, paper records versus electronic records and product markers and the technical and economic costs and benefits of such issues.

63. Several delegations stressed the need for CCFICS to focus its priorities on the application of traceability to food import and export inspection and certification systems in relation to food safety issues, since it was considered as an appropriate tool to trace-back products and would facilitate recall procedures in case of emergency situations. While some delegations recognised the importance of traceability in relation to other legitimate factors, other delegations believed that discussion on traceability in relation to other legitimate factors by the CCFICS was not appropriate at this stage. Other delegations pointed out that it was not desirable to separate the two aspects of traceability as traceability was a means to achieve both food safety objectives but also to promote fair trade practices in food, consistent within the mandate of the Codex Alimentarius Commission.

64. The importance in establishing a comprehensive traceability system in order to trace-back and withdraw products from the market, which were susceptible in provoking harmful effects to the health of consumers, e.g. BSE, Dioxin, was stressed. However, considering that traceability should be addressed in a coherent and uniform manner at the Codex level it was recommended by some countries that any new work should be delayed pending the development of clear principles by the CCGP.

65. The importance of addressing cost implications, and the possible denial of market access related to the implementation of traceability, including the subsequent economic impact on production systems for developing countries, and especially the least-developed ones, was also noted.

66. However, it was noted that traceability could lead to economic benefits in certain circumstances and that the costs of the absence of traceability should also be taken into account. In particular, the absence of traceability systems in the production chain and food businesses might actually lead to a lack of control in food-borne disease outbreaks and/or the withdrawal of unsafe foods from the market in emergency situations.

Status of the Consideration of Traceability in the Context of Food Inspection and Certification Systems

67. Considering the relevance of this issue for CCFICS and consistent with the mandate provided by the CCEXEC to identify specific areas for the application of traceability to inspection and certification systems in relation to food safety issues, the Committee decided

that a working group led by Switzerland, with the assistance of Argentina, Australia, Bolivia, Brazil, Canada, Chile, France, Germany, India, Ireland, Italy, Japan, Kenya, Korea, Netherlands, Norway, Paraguay, Peru, Philippines, Sweden, Thailand, United Kingdom, United States, the European Commission, Biotechnology Industry Organization (BIO), Confédération des industries agro-alimentaires de l'UE (CIAA), Consumers International (CI), Council for Responsible Nutrition (CRN), Croplife International (GCPF), and International Council of Grocery Manufacturers Associations (ICGMA) and International Federation for Animal Health (IFAH), should draft a discussion paper for circulation, comment and further consideration at its next meeting. The Committee agreed that the discussion paper should specifically address:

- *the adequacy and applicability of traceability in existing or pending texts under elaboration by the CCFICS;*
- *on the basis of the above review, the appropriateness for CCFICS to develop specific guidance on the practical implementation of traceability with respect to food import and export inspection and certification systems, with priorities to be developed in the light of its above discussion;*
- *the outcome of the Chairpersons meeting[22] from the relevant Codex Committees that was scheduled to meet prior to the 17th session of the CCGP on traceability;*
- *a time-frame for any new work that CCFICS could undertake with the understanding that this work should not duplicate the work being undertaken by other Committees.*

[22] *In regard to the Chairperson's Coordination and Advisory Group to facilitate more efficient consideration and finalization of draft standards, the Commission noted that Chairpersons of Codex Committees and Task Forces had been meeting on an informal basis in the margins of some Codex meetings. The Commission agreed that this group should continue to meet, as required, on an informal basis to provide a coordinating role but without the power to take decisions or make recommendations to the Commission (see the Report of the 24th Session of the Codex Alimentarius Commission, ALINORM 01/41, para. 57).*

68. The Committee noted that if possible, the document would be discussed at an informal meeting immediately prior to the next CCFICS session, subject to further discussions between the Codex and Australian Secretariats.

The 11th Session (2003)

ADOPTION OF THE AGENDA (Agenda Item 1)

3. However, the Committee agreed to discuss agenda item 7, Discussion Paper on Traceability in the Context of Food Inspection Systems, immediately after agenda item 3 and to consider agenda item 5, proposed draft Revision to the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations immediately thereafter.

MATTERS REFERRED FROM THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

4. The Committee noted matters arising from the 49th (September 2001) and 50th (June 2002) Sessions of the Executive Committee of the Codex Alimentarius Commission and other Codex Committees related to the Preparation of the Medium-Term Plan 2003-2007 and Discussions Concerning Traceability/Product Tracing in Other Codex Committees and International Organizations. The Committee agreed that the information provided on the activities of other Codex Committees related to Traceability/Product Tracing be considered under agenda item 7.

5. The Committee noted that activities relevant to its work under the Medium – Term Plan Objective 1: Promoting Sound Regulatory Frameworks, had been revised and retained, namely under Activity 22 Traceability and Activity 27 – Judgement of Equivalence. In particular, the 50th Session of the Executive Committee agreed to add the term "product tracing" to the title of Activity 22.4

PROPOPSED DRAFT REVISION TO THE CODEX GUIDELINES FOR THE EXCHANGE OF INFORMATIPN IN FOOD CONTROL EMERGENCY SITUATIONS (Agenda Item 5)

21. The 9th CCFICS reached general agreement that the elaboration of guidelines for food control emergency situations involving international trade should be undertaken in the context of the Codex Guidelines for the Exchange of Information in Food Control Emergency Situations. It was suggested that guidelines concerning food control emergency situations should include the consideration of:

- Final disposition of food products, including the concept of traceability and third country exports;

DISCUSSION PAPER ON TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 7)

46. The 10th Session of the CCFICS agreed that a working group led by Switzerland would prepare a Discussion Paper on Traceability/Product Tracing in the Context of Food Inspection and Certification Systems for further consideration at its next Session.20 The CCFICS noted discussions on Traceability/Product Tracing in other Codex Committees as summarized in document CX/FICS 02/11/2 (agenda item 2).

47. The 49th (Extraordinary) Session of the Executive Committee of the Codex Alimentarius Commission (September 2001) discussed the general issue of traceability/product tracing in the framework of Codex and pointed out that any measures requiring traceability/product tracing should be justified as having a food safety objective as an SPS measure or having a legitimate objective as a TBT measure. The Executive Committee recommended that the Codex Committee on General Principles consider these two aspects of traceability/product tracing and was of the opinion that first consideration should be given to the use of traceability/product tracing as a risk management option in the Working Principles for Risk Analysis. The Executive Committee agreed that it should be for the Committees concerned to undertake work as they deemed appropriate within their respective mandates.21 The Executive Committee also noted the role of the CCFICS in relation to the development of procedures for the application of traceability/product tracing in food import and export inspection and certification systems.

48. The Committee noted that the 50th Session of the Executive Committee of the Codex Alimentarius Commission (June 2002) agreed22 to retain both aspects of traceability/product tracing without mentioning priorities and to indicate that first consideration should be given to the use of traceability/product tracing as a food safety risk management option as already agreed by the 49th Session.

49. In introducing the Discussion Paper, the delegation of Switzerland noted that the Working Group on Traceability23 (Fribourg, Switzerland, 19-20 August 2002) had prepared the document on the basis of specific instructions provided by the 10th CCFICS and written comments submitted. It was noted that the elements identified by the Working Group related to traceability/product tracing were the ability to identify a food (product identification), how it was changed (if appropriate), where it came from and where it was sent (one step backward and one step forward) (product information) and the linkages between product identification and product information, while also noting that the applicability of these elements would depend on the objectives being pursued by the individual texts. In consideration that the Working Group had not had the opportunity to examine all of the CCFICS texts related to traceability/product tracing in detail, the Group also agreed on a specific framework for the continued examination of such texts for their adequacy and applicability within the CCFICS.

50. The Committee thanked the Working Group for their efforts, and generally supported the analysis and approach outlined in the Discussion Paper as a basis for continued discussions on traceability/product tracing within the CCFICS. However, it was felt that the elaboration of specific Guidelines at this stage was premature. The Committee also recognized that the primary responsibility for the development of a definition for traceability/product tracing rested with the Codex Committee on General Principles but that the CCFICS might wish to further expand on the elements required for such a definition.

51. The Committee reached general agreement with the opinion of the Executive Committee that any measures requiring traceability/product tracing should be justified as having a food safety objective as an SPS measure or having a legitimate objective as a TBT measure. However, some delegations were of the opinion that traceability/product tracing should focus

on food safety measures only as a priority while other delegations felt that both food safety and other matters necessary for ensuring fair practices in the food trade, as covered by the mandate of the Codex Alimentarius Commission, should be examined at the same time. It was also stated that guidelines or principles related to traceability/product tracing would more than likely relate to both aspects regardless of efforts to theoretically separate the two concepts.

52. The Committee noted and agreed that:

- *Responsibility for the development of a definition for traceability/product tracing rested with the CCGP;*
- *CCFICS was responsible for traceability/product tracing related to food inspection and certification systems, and;*
- *Existing Codex texts related to food inspection and certification as well as discussions in CCFICS and other Codex Committees and written comments submitted should be taken into account in the determination of the current adequacy and applicability of CCFICS texts related to traceability/product tracing and the need for further work in this area.*

53. In order to carry out the above review and to complete the mandate assigned by the 10th CCFICS, the Committee decided to reconvene the Working Group on Traceability under the Chairmanship of Switzerland and with the participation of Argentina, Australia, Belgium, Brazil, Canada, Chile, France, Germany, India, Italy, Japan, Kenya, Netherlands, New Zealand, Norway, Philippines, Republic of Korea, Sweden, Thailand, United Kingdom, United States, BIO, EC, Greenpeace, ICGMA, IDF and WHO. The Chairman expressed the view that the analysis of existing CCFICS texts should be completed according to the Framework prior to the Working Group meeting so that the Working Group could review the results of this analysis at the meeting. The Working Group should take into account discussions on traceability/product tracing in other relevant Codex committees. The Working Group should prepare a discussion paper with a complete analysis of the issues involved for circulation, additional comment and further consideration at its next Session. It was reiterated that this review should analyze the appropriateness and need for CCFICS to develop specific guidance on the practical implementation of traceability/product tracing and how it is to be progressed. It was also agreed that the Committee's discussions on this issue would be forwarded to the Executive Committee and other Codex Committees for information and potential action.

The 12th Session (Dec 2003)

DISCUSSION PAPER ON TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 4)

62. The 11th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems decided to reconvene the Working Group on Traceability/Product tracing, under the chairmanship of Switzerland, in order to examine the adequacy and applicability of CCFICS texts with regard to traceability/product tracing and the need for further work in this area, to complete the mandate assigned by the 10th CCFICS.

63. The Committee requested the Working Group to prepare a discussion paper with a complete analysis of the issues involved for circulation, additional comments and further consideration at its next Session. It was reiterated that this review should analyze the appropriateness and need for CCFICS to develop specific guidance on the practical implementation of traceability/product tracing and on how the issue was to be progressed. It was also agreed that the Committee's discussions on this issue would be forwarded to the Executive Committee and other Codex Committees for information and potential action.9

64. In introducing the discussion paper, the delegation of Switzerland informed the Committee that the discussion paper had been prepared at the 2nd meeting of the Working Group (Fribourg, Switzerland, 3-5 September 2003). At its meeting the Working Group took note of the discussion held within other Codex Committees and in particular Regional Coordinating Committees. It also noted that the 18th Session of the Codex Committee on General Principles (CCGP) had decided to develop a definition for traceability/product tracing to be considered at its next meeting in May 2004.

65. The Working Group:

- *recognized that traceability/product tracing was not an objective in itself but rather a tool, which may assist countries to demonstrate that imported and/or exported foods meet safety and/or quality requirements and that CCFICS could consider how to use the traceability/product tracing tool within food import and export inspection and certification systems;*
- *undertook a thorough analysis of 8 CCFICS texts based on the framework and on the elements of traceability/product tracing that had been approved by CCFICS at its 11th session;*
- *reached the conclusion that CCFICS texts do not provide a consistent set of principles on traceability/product tracing, although they sometimes reference individual elements of traceability/product tracing. It was concluded that the objectives of most of the examined texts would not be met more adequately if traceability/product tracing elements were included or strengthened;*
- *recognised that it would be helpful that workshops or seminars be organized to address the application, scope and coverage of traceability/product tracing among member countries;*
- *examined the appropriateness and needs for CCFICS to develop specific guidance on traceability/product tracing and decided to develop a broad set of options, which could be considered by the CCFICS as a possible way forward in the examination of traceability/product tracing within CCFICS.*

66. *The Committee expressed its appreciation to the Working Group for the comprehensive work, which provided a good basis for the discussion on this important subject. It recognized that CCFICS was an appropriate forum to continue discussion and develop guidance on traceability/product tracing within its mandate and that there was a clear need to exchange views as to the meaning of traceability/product tracing systems and their practical application.*

67. *The Committee emphasised the need to organise seminars and workshops to provide the opportunity for those countries with practical experience to exchange information with other countries on the types of systems in place, on their scope, application and coverage, to promote a better understanding of this subject. It considered that it was important that these meetings be organised on a regional and global basis with expertise from different regions, before the next CCFICS. The Committee agreed that these seminars were to be conducted in a cost effective manner and facilitate the participation of all Members. In this regard, it was noted that they could be organised in conjunction with the Second Global Forum of Food Safety Regulators (Bangkok, Thailand 10-12 November 2004) and/or with the next meetings of the Codex Regional Coordinating Committees, thus allowing wider participation, especially from developing countries.*

68. *The Committee noted that, subject to availability of funds, FAO and WHO would be ready to assist with these seminars, but indicated that assistance from Members would be required in terms of financial resources and expertise. In this regard, it was noted that countries expertise would be particularly important in the conduct of these seminars. It also observed that the Joint FAO/WHO Secretariat of the Second Global Forum of Food Safety Regulators was seeking papers to be submitted on the following themes: "Strengthening Official Food Control Services", and "Epidemiological Surveillance of Foodborne Diseases and Food Safety Rapid Alert Systems" and both could be related to traceability/product tracing systems.*

69. *The Committee acknowledged that, although there was a broad understanding of the concept of traceability/product tracing, it was still confronted by the lack of a definition and clarity with regard to the scope and coverage of traceability/product tracing within the context of Codex. Some delegations expressed concerns as to the cost of implementing such systems especially for developing countries, while others emphasized the cost that might arise from not having a traceability/product tracing system in place.*

70. *The Committee agreed that existing CCFICS texts did not need to be re-opened with regard to traceability/product tracing.*

71. *Different opinions were expressed on the development of principles and/or guidelines and whether the principles should be a stand-alone document or serve for the further development of guidelines. Most delegations were in favour of CCFICS moving towards the development of principles for the application of traceability/product tracing systems, however they recognized*

the need for a clear understanding of the implications including costs. Other delegations were of the opinion that further work should be deferred pending the conclusion of the work on the definition in the Codex Committee on General Principles. It was noted that an initial discussion on principles had already taken place in the Regional Coordinating Committees that could be used as a starting point to progress work on this matter.

72. Therefore, the Committee agreed to continue its discussion on traceability/product tracing in the context of food inspection and certification systems at its next meeting. It was agreed that the Australian Secretariat would prepare a document containing a preliminary set of "principles on traceability/product tracing", based on the discussion that has occurred over the past two years in the Regional Coordinating Committees, and this document would be circulated for comment through a Circular Letter to all Member countries and international organizations with observer status in Codex.

73. It was proposed that the above document could be used as a tool for information exchange and discussion at the proposed seminars as appropriate.

74. Furthermore, the Committee agreed that the Australian Secretariat would prepare a discussion paper, based on the above document, together with the comments received, the outputs and recommendations from seminars and workshops (as appropriate), discussions in the Codex Committee on General Principles and other relevant Codex Committees and Regional Coordinating Committees, and other relevant documents, for circulation and discussion at its next meeting.

The 13th Session (2004)

DISCUSSION PAPER ON TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

(Agenda Item 4)

81. The Chairperson of the Committee introduced the discussion paper and informed the Committee that the document distilled the progress on the issue of traceability/product tracing in Codex since the last meeting. These included the comments in relation to the Circular Letter (CL 2004/6-FICS), adoption of the definition developed by the Codex Committee on General Principles by the 27th Session of the Commission and the exchange of views that had been expressed during seminars conducted in Mexico, Singapore, the Philippines and Samoa. He informed the Committee that there were other seminars planned before the next Session of the Commission, the first of them to be held in conjunction with the 16th Session of the FAO/WHO Coordinating Committee for Africa (January 2005).

82. The Chairperson indicated that it was clear from his participation in these seminars that there were diverse views on this subject and a number of points to be debated and discussed in full in relation to the application of principles for traceability/product tracing and whether they should be developed for both food safety and fair trade together or separately. He said that this discussion could not take place at this Committee's Session due to time constraints.

83. In order to comply with the request of the 27th Session of the Commission to "present a proposal for new work on principles for the application of traceability/product tracing as a matter of priority" the Chairperson pointed out that the Committee should agree to put forward to the 28th Session of the Commission a proposal for new work broad enough to allow for this discussion.

Scope of the application of traceability/product tracing

84. The Committee noted that there was divergence of views on the scope of the application of traceability/product tracing. In this regard, the Committee recognized the broad application of traceability/product tracing covering food safety and non-food safety matters and the dual mandate of Codex to protect consumers' health and ensure fair practices in food trade.

85. The Delegation of Korea, as Coordinator of CCASIA, informed the Committee of the outcome of the discussion on this matter at the 14th Session of FAO/WHO Coordinating Committee for Asia (September 2004) indicating that the Committee favoured the elaboration of principles for the application of traceability/product tracing, that it should be implemented on a case-by-case basis taking into account the following criteria: the nature and extent of risk has to be determined on the basis of specific risk assessment and only after this assessment should a product be consider for traceability/product tracing; it should be

demonstrated that traceability/product tracing was an effective management option for the identified risk and that there was no other more cost effective alternative to manage that risk; the extent of application of traceability/product tracing in the food chain should be clearly listed out on the basis of the risk assessment; practical applicability and the cost effectiveness; the cost/benefit analysis should be worked out in advance before traceability/product tracing is considered for a particular product; and there should be a clear demonstration of the fact that traceability/product tracing will not be used as a technical barrier to trade9.

86. The Delegation of Argentina, as Coordinator of CCLAC, also informed the Committee of the outcome of the discussion on this matter at the 14th Session of the FAO/WHO Coordinating Committee for Latin America and the Caribbean (December 2004) by quoting the view of the Coordinating Committee namely: "The Committee also agreed that no reference should be made to the aspects of fair trade practices, since traceability/product tracing should be used only as a risk management tool for the purpose of ensuring food safety"10. This view was supported by some other delegations.

87. Another Delegation was of the opinion that traceability/product tracing should apply to processed foods only as in most developing countries farming was carried out by a large number of small scale farmers unevenly distributed across the country and hence, facing difficulties in implementing traceability/product tracing for fresh product, especially food crops and horticulture. Some other delegations shared this view. It was also noted the linkages between matters surrounding traceability/product tracing and equivalence and the importance of working in parallel on these two subjects was highlighted.

88. Other delegations, while recognizing the dual mandate of Codex, were of the opinion that in order to progress work within Codex and in consideration of the great deal of agreement to develop principles for traceability/product tracing applicable to food safety, first priority should be given to the development of traceability/product tracing principles in food import and export inspection and certification systems related to food safety and, in a second step, consideration should be given to the development of principles related to non-food safety matters.

89. The Delegation of the EC indicated that the two main objectives of Codex, protecting consumers' health and ensuring fair practices in food trade could not be dissociated when dealing with traceability/product tracing. In addition, the Delegation indicated that traceability/product tracing was a tool that might be applied within a broader food inspection and certification system for different purposes, food safety but also to protect consumers against deceptive marketing practices and to ensure fair practices in food trade on the basis of accurate product description. Other delegations and Observers also held this view. These delegations felt that the same principles should apply in both cases while some specific provisions could be taken up when elaborating the Principles. It was also noted that there were other international standardization organizations, such as ISO, already working on this matter and that Codex as the internationally recognized food standardization body should take the lead in the development of the traceability/product tracing principles applicable to food safety and fair practices in food trade.

90. It was further noted that traceability/product tracing systems applying to both food safety and fair trade practices were already in place in a number of countries and it was important to share these experiences in addition to work in Codex, other international organizations and taking into account existing legislations.

91. The Committee noted that the current proposal for new work in Annex 1 to CX/FICS 04/13/6 referred to "traceability/product tracing requirements". In this regard, it agreed that the term "requirements" was too restrictive as traceability/product tracing was a tool that food control authorities could use as a risk management option to recall/withdraw foods when a problem in food arose. In view of this, the Committee agreed to delete the reference to "requirements" throughout the text. It was noted that, as a risk management option, the establishment of a traceability/product tracing system should not be imposed by countries on other countries, but that it was a matter for national governments to decide.

Further work on the Principles for the Application of Traceability/Product tracing in the context of Food Import and Export Inspection and Certification Systems

92. The Committee agreed on the need to develop principles for the application of traceability/product tracing in the context of food import and export inspection and certification systems. The Committee also agreed that, at this stage, the project document to be submitted for approval as new work by the 28th Session of the Codex Alimentarius Commission (July 2005) should be kept simple and broad and that further discussion on the extent of the scope of the principles could be taken up in a physical meeting of a Working Group after the approval of the new work by the 28th Session of the Commission. In view of the excellent work carried out by Australia, the Committee agreed that the Working Group would be chaired by Australia. In addition, two Vice-chairpersons from Argentina and Norway were designated in order to keep the inclusiveness of the process by incorporating representatives from developed/developing and importing/exporting countries considering the divergent views that Codex Members held on the matter.

93. In order to facilitate the development of the Principles, the Chairperson, in cooperation with the Vice-chairpersons would prepare a revised set of Principles for the Application of Traceability/Product Tracing in the context of Food Import and Export and Inspection and Certification Systems that would take into account relevant documents and the discussion held at the present Session.

94. The revised set of Principles would then be circulated by means of a Circular Letter. Comments submitted in response to this Circular Letter would be distributed by the Australian Secretariat to the Chairperson and Vice-chairpersons of the Working Group. The revised set of Principles along with the comments received to the Circular Letter would be considered by a physical meeting of the Working Group with a view to elaborating a set of principles that should also take into account the work done or in progress within Codex and other international organizations as well as the outcomes of regional seminars/workshops carried out in regard to traceability/product tracing.

95. The proposed draft Principles, as prepared by the Working Group, would be circulated for comments at Step 3, subject to approval by the Commission as new work, for consideration by the 14th Session of the Committee.

96. The Committee noted that an Invitation Letter from the Chair and its Vice-chairpersons would be issued to attend the meeting of the Working Group. In this regard, it was noted that participation in Working Groups was open to all Codex Members and Observers. The Invitation would be circulated by the Codex Secretariat to Codex Members and Observers through the Codex Electronic Distribution List (Codex-L).

Project Document – CCFICS Proposal for New Work on Principles for the Application of Traceability/Product Tracing in the context of Food Import and Export Inspection and Certification Systems

97. The Committee agreed on a number of amendments to the project document namely:

a) Preparation: The reference to the 13th Session of the Committee in the preparation of the project document;

b) Purpose and Scope of the proposed Standard: the application of traceability/product tracing in relation to official food inspection and certification systems to enable the Working Group to discuss the application of principles in regard to the dual mandate of Codex;

c) Its relevance and timeliness: the reference in the text to the decision of the Codex Alimentarius Commission to request CCFICS to present a proposal for new work on this matter;

d) An Assessment against the Criteria for the Establishment of Work Priorities: the introduction of relevant criteria for the Establishment of New Work (a), (b) and (d);

e) Information on the relation between the proposal and other existing Codex documents: the indication that the new work should take into account the work done or being done within Codex, regional seminars/workshops carried out in regard to traceability/product tracing and should be consistent with the definition of traceability/product tracing adopted at the 27th Session of the Commission.

98. The Committee agreed to forward the amended project document, through the Executive Committee, to the 28th Session of the Commission for approval as new work (see Appendix IV).

The 14th Session (2005)

PROPOSED DRAFT PRINCIPLES FOR THE APPLICATION OF TRACEABILITY/PRODUCT TRACING IN THE CONTEXT OF FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 3c)

50. The Chairperson introduced the document representing the progress on the development of the proposed draft principles since the last session. These included the comments submitted in relation to the Circular Letter (CL 2005/6-FICS), the results of a physical Working Group meeting held in Brussels, Belgium from 12-14 September 2005. The Chairperson thanked the Vice-Chairs from Argentina and Norway for their assistance in the Working Group as well as the 38 delegations that had participated.

51. He said that the meeting had developed a consensus on a number of key themes which had then been applied throughout the drafting of the revised principles.

-Traceability/product tracing is a tool that does not in itself improve food safety and/or fair practice outcomes in the food trade unless it is combined with a relevant measure or requirement;

-Exporting countries should not have to replicate the traceability/product tracing tool of the importing country. They need only meet the objectives of the importing country's food inspection and certification system;

-The concept of traceability/product tracing as a tool is that it should follow food one step forward and one step back;

-Importing countries should be prepared to explain to an exporting country what are the objectives and outcomes of its food inspection and certification system when they incorporate a traceability/ product tracing tool.

General comments

52. Many delegations commended the Working Group for the results reached and said that they were prepared to discuss the document paragraph by paragraph in order be able to advance it in the step procedure.

53. Some delegations were of the opinion that the proposed draft principles should be more closely linked with food safety. The Chairperson advised caution when reopening debate on the extent to which the principles should make reference to both parts of the dual mandate of Codex. He said that the present text had been carefully drafted to reach a consensus in the Working Group.

54. The Delegation of Switzerland, as Coordinator of the FAO/WHO Regional Coordinating Committee for Europe informed the Committee of the conclusions of the CCEURO Seminar on traceability/product tracing (Brussels, 7 September 2005) and indicated that the Seminar agreed to a number of conclusions: traceability/product tracing is a tool which, within the context of a food control and certification system, can be applied to protect the health of consumers by securing food safety and to ensure fair practices in the food trade; traceability/product tracing is an information tool which allows the tracing of food products through the production and distribution chains, in this regard, it can be used to adopt focussed measures should a specific hazard be identified by facilitating the rapid withdrawal of food from the market place and thereby minimising the potential negative impact on the health of consumers, economic losses and the potential negative impact on food trade; a traceability/product tracing tool can reinforce the confidence in the food trade by ensuring the authenticity and accuracy of information provided on the products and their characteristics (e.g. origin, organic farming, animal welfare, religious concerns such as Kosher or Halal); traceability/product tracing principles apply equally to both food safety and fair practices in food trade; the traceability/product tracing tool does not replace food safety measures; traceability/product tracing should cover the entire food chain and cover feed when appropriate; traceability/product tracing systems should avoid any unnecessary trade restrictions and should be designed in terms of outcomes/performance rather than in prescriptive specifications about the system itself.

55. The Delegation of Chile expressed its concern that the Spanish text differed from the English text throughout the document using the term "management tool" (in Spanish

"herramienta de gestión") in the Spanish text rather than "tool" (in Spanish "herramienta"). The Committee amended the Spanish version by adapting it to the English version and noted that the French and Spanish translations should be based on the English text

Specific comments

56. The Committee considered the proposed draft Principles for the Application of Traceability/Product Tracing in the Context of Food Import and Export Inspection and Certification Systems in detail and in addition to some editorial changes, including minor amendments to the French and Spanish translations, agreed to the following changes:

Section 1 - Introduction

57. The Committee changed the name of the Section to "Scope" to better reflect its contents. It deleted paragraph 1 because it did not add any relevant information and moved paragraph 3, as new paragraph 1 under this section as more appropriate. A footnote was added to paragraph 2 to refer to the Codex Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995).

58. The Representative of the OIE indicated that the OIE supported the proposed set of principles. The OIE believed that countries should be provided with guidance in setting up a traceability system that covers the entire food chain without gaps and duplications. Accordingly, the representative suggested that a reference to the standards of other international organisations, in particular OIE and IPPC, be added to paragraph 3. However, the Committee did not agree to this proposal.

Section 2 - Objective

59. The section was deleted as the text had been included in section 1.

Section 3 - Definitions

60. Some delegations expressed concern that the definition of "inspection" needed to be amended to refer also to "supplied products". In this regard, it was noted that these definitions were taken from other texts and that it was not appropriate to consider amendments in this discussion.

Section 4 (renumbered 3) - Principles

Context

61. In paragraph 6 (renumbered 5), the Committee deleted "that in some cases it can be demonstrated" to strengthen the principle that a food inspection and certification system without traceability/product tracing tool might meet the same objective and produce the same outcomes as a food safety inspection and certification system with traceability/product tracing.

62. The Committee clarified the principle in paragraph 7 (renumbered 6) to indicate that, when applicable, it was not compulsory for an exporting country to establish the same traceability/product tracing tool as used by the importing country.

Rationale

63. The Committee agreed to delete "The purpose of" at the beginning of paragraph 8 (renumbered 7) in order to have a consistent application of a traceability/product tracing tool; it also added "and/or efficiency" after "effectiveness" for consistency with the language used in paragraph 9 (renumbered 8) and to emphasise that the application of a traceability/product tracing tool by a competent authority should improve either efficiency or effectiveness or both. The example at the end of the paragraph was put into a new footnote.

64. In paragraph 9 (renumbered 8), the Delegation of the United States noted that, while they supported the concept of traceability/product tracing as a tool, they also believed that, depending on its use, traceability/product tracing could either be a measure or a technical regulation. The Delegation observed that, in their view, the current wording of paragraph 9 excluded the possibility of traceability/product tracing being a measure or technical regulation and proposed to amend the paragraph to allow traceability/product tracing to be considered as a tool, measure or technical regulation according to its use. The Committee discussed the proposal but could not reach consensus, therefore it agreed to retain the existing text. For consistency the example at the end of the paragraph starting with the words "by reinforcing confidence…" was put into a new footnote.

65. In paragraph 10 (renumbered 9), the Committee discussed the usefulness of maintaining the example of the way a traceability/product tracing tool contributes to the protection of consumers against deceptive marketing practices and to the facilitation of trade. In noting that "Principles" documents should be concise and simple, that examples were more appropriate in "Guidelines" documents and that it was useful not to loose these concepts, the Committee agreed to move the example to a footnote. In the footnote, the reference to "country" was amended to read "country of origin" for clarity. For consistency, in paragraph 9 the example on how the traceability/product tracing tool could contribute to the effectiveness and/or efficiency of associated food safety measures was moved to a new footnote.

66. The Committee added a last sentence to paragraph 11 (numbered 10) to include the notion that the scope and the extent of the application of traceability/product tracing tool should also be consistent with the described need.

Design

67. In paragraph 12 (renumbered 11) the word "cover" was replaced with "apply to". In the footnote "should" was replaced with "could" and the reference to the ALINORM deleted, as it was more appropriate to refer only to other adopted texts. There was some discussion as to whether the footnote reference should be placed next to the word "production" in the definition of traceability/product tracing. This was not retained as the definition of traceability/product tracing is contained in the Procedural Manual and should not be altered.

68. Concerning paragraph 13 (renumbered 12) the Observer of Consumers International said that they believed that the minimum requirement for traceability/product tracing should be the recording of the movement of food and feed one step forward and one step back. However, where feasible, more information should be provided on the origin and destination in order to improve the effectiveness of traceability/product tracing and the timeliness of product recalls and withdrawals.

69. Several delegations commented that it had been fundamental in the outcome of previous discussions that if traceability/product tracing is required, each stakeholder in the food chain should only have to record from where they received (one step back) and where they sent the food (one step forward). The Committee left the text unchanged.

Application

70. The delegation of India proposed to add to paragraph 15 (renumbered 14) a sentence referring to the impossibility of applying traceability/ product tracing to primary production. The Chairperson said that the language used in the document had been built around the principle of addressing disparate production systems and therefore it was not necessary to repeat it in the text.

71. As agreed by the Working Group, the Delegation of Argentina proposed a revision of paragraph 15 (renumbered 14), which captured three areas on how the exporting country could be helped:

-By allowing a longer timeframe for compliance in order to maintain opportunities for exports;

-By allowing flexibility regarding the design of the traceability tool;

-By providing technical assistance.

72. After a long discussion the Committee agreed to the inclusion of a new paragraph to address these three areas of assistance. It was reaffirmed that flexibility and longer timeframes for compliance should not compromise the safety of exported food and should not be interpreted as the possibility to derogate from the importing countries' rules

73. The Observer of Consumers International suggested the deletion of paragraph 16, as they felt it was not within the Codex mandate to require that a traceability/product tracing tool "should not be more trade restrictive than necessary". The Committee did not agree to this proposal.

74. The Committee agreed to add a new Principles (paragraph 19) to state that a traceability/product tracing tool should be implemented, when and as appropriate on a case by case basis.

Other Discussion

75. After concluding the detailed review of the proposed draft Principles the Committee considered whether they should be a standalone Codex document or an appendix to an existing Codex document.

76. A number of delegations stated that they would prefer the document to be a food inspection and certification standalone Codex text because this would avoid reopening existing Codex texts which would have to make reference to the Principles. This would also give more prominence to the Principles.

77. Other delegations felt that the Principles were closely related to the Codex Principles for Food Import and Export Inspection and Certification10 and should thus become an appendix to these. Others felt that the document should become an appendix to the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems11.

78. The Chairperson said that there was clearly no consensus on this matter but felt that either way would not impact significantly on the application of the Principles. He suggested moving the Principles forward as a standalone document. The Committee supported this suggestion. The delegations of Argentina, Brazil, Costa Rica, Chile, Cuba, Ecuador, Egypt, Guatemala and Mexico expressed their strong objection to this decision.

79. The Committee did not take any decision as to whether the document would be further developed into guidelines.

Status of the proposed draft Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System

80. The Committee agreed to advance the proposed draft Principles to Steps 5/8, with the omission of Steps 6 and 7, for adoption by the 29th Session of the Commission (see Appendix III).

Appendix III

PROPOSED DRAFT PRINCIPLES FOR TRACEABILITY / PRODUCT TRACING AS A TOOL WITHIN A FOOD INSPECTION AND CERTIFICATION SYSTEM (N04-2005) (at Steps 5/8 of the Elaboration Procedure)

SECTION 1 - SCOPE

1 This document elaborates a set of principles to assist competent authorities in utilising traceability/product tracing as a tool within their food inspection and certification system. This document should be read in conjunction with all relevant Codex texts.

2 Recognising the dual mandate of the Codex Alimentarius, traceability/product tracing is a tool that may be applied, when and as appropriate, within a food inspection and certification system in order to contribute to the protection of consumers against food-borne hazards and deceptive marketing practices and the facilitation of trade on the basis of accurate product description[1].

[1]Codex *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20 – 1995) (para 5).

SECTION 2 - DEFINITIONS

Inspection[2]: is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

Certification[2]**:** is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products**.**

[2] Codex *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20 – 1995).

Equivalence[3]: is the capability of different inspection and certification systems to meet the same objectives.

[3]Codex *Guidelines for the Design, Operation, Assessment and Accreditation of Food*

Import and Export Inspection and Certification Systems. (CAC/GL 26 – 1997).

Traceability/product tracing[4]: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution.

[4] Codex Procedural Manual, 14th Edition.

SECTION 3 - PRINCIPLES

4. These principles cover the context, rationale, design and application of traceability/product tracing as a tool for use by a competent authority within a food inspection and certification system. Context Traceability/product tracing, as defined above, is one of a number of tools that may be utilised by a competent authority within its food inspection and certification system.

5. An importing country should consider that a food inspection and certification system without a traceability/product tracing tool may meet the same objective and produce the same outcomes (e.g. regarding food safety, provide the same level of protection) as a food inspection and certification system with traceability/product tracing[5].

   [5] Codex *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999); Codex *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003)

6. It should not be mandatory for an exporting country to replicate (i.e. establish the same) the traceability/product tracing tool as used by the importing country, when applicable

Rationale

7. The application of a traceability/product tracing tool by a competent authority should improve the effectiveness and/or efficiency of the actions that may be necessary regarding its measures or requirements within its food inspection and certification system.

8. Traceability/product tracing is a tool that when applied in a food safety context does not in itself improve food safety outcomes unless it is combined with appropriate measures and requirements. It can contribute to the effectiveness and/or efficiency of associated food safety measures[6].

   [6] For example, by providing information on suppliers or customers involved in potential food safety issues so enabling targeted product recall/withdrawal.

9. Traceability/product tracing is a tool that when applied in a food inspection and certification system can contribute to the protection of consumers against deceptive marketing practices and facilitation of trade on the basis of accurate product description[7].

   [7] For example, by reinforcing confidence in the authenticity of the product and the accuracy of information provided on the products (e.g. country of origin, organic farming, religious concerns such as kosher or halal).

10. In every case a traceability/product tracing tool should be justified within the context of the food inspection and certification system and the purpose, objectives and specifications of the traceability/product tracing tool clearly described. The scope and extent of application of the tool should also be consistent with the described need.

Design

11. The traceability/product tracing tool may apply to all or specified stages of the food chain (from production[8] to distribution), as appropriate to the objectives of the food inspection and certification system.

    [8] Production could be interpreted in such a broad manner as to cover food producing animals, feed, fertilizers, pesticides, veterinary drugs and any input of plant or animal origin, etc. if relevant for specific applications of traceability/product tracing to food..

12. The traceability/product tracing tool should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system.

13. The objectives, scope and related procedures of a food inspection and certification system

that includes a traceability/product tracing tool should be transparent and made available to competent authorities of the exporting country upon request.

14. The application of traceability/product tracing should take into account the capabilities of developing countries.
15. If in the context of a traceability/product tracing tool an importing country has objectives or outcomes of their food inspection and certification system which cannot be met by an exporting country, the importing country should consider the provision of assistance to the exporting country, and especially in the case of a developing country. Assistance may include longer time frames for implementation, flexibility of design and technical assistance, so that the objectives or outcomes of the food inspection and certification system of the importing country can be met.
16. A food inspection and certification system within which a traceability/product tracing tool is applied should not be more trade restrictive than necessary.
17. The application of the traceability/product tracing tool should be practical, technically feasible and economically viable within a food inspection and certification system.
18. In deciding whether and how to apply the traceability/product tracing tool, in the context of a food inspection and certification system the competent authority should take account of the assessed food safety risks and/or the characteristics of the potential deceptive marketing practices being addressed.
19. Traceability/product tracing tool within the context of a food inspection and certification system should be implemented when and as appropriate on a case by case basis.

CCFICS 15th Session (2006)

OTHER BUSINESS

76. The Committee agreed to the proposal of the Delegation of Norway to prepare a discussion paper on the need for further guidance on traceability/product tracing. In this regard, some delegations were in favour of the development of further guidance, while others considered this premature because more experience was needed with the recently adopted Codex Principles for Traceability/Product Tracing as a Tool within a Food Import and Export Inspection and Certification System (CAC/GL 60-2006).

CCFICS 16th Session (2007)

DISCUSSION PAPER ON THE NEED FOR FURTHER GUIDANCE ON TRACEABILITY/ PRODUCT TRACING (Agenda Item 7)

68. The Delegation of Norway introduced CX/FICS 07/16/7 which provided an overview of the current situation regarding traceability/product tracing, including information on existing guidance to governments and food industry. The document highlighted the importance of using traceability/product tracing to assist in containing food safety problems and in improving the reliability of consumers' information. In Norway's experience, traceability/product tracing had proved to be very efficient in ensuring targeted, accurate and cost-efficient withdrawals of products when needed. The Delegation noted that a number of countries had incorporated traceability into their legislation with different levels of detail in their requirements with the potential to create barriers to trade. They were of the opinion that the development of guidelines to complement the Codex Principles for traceability/product tracing could assist countries in implementing this tool in an efficient and harmonised way. The Delegation further stated that the experience of countries that have developed traceability systems, especially the challenges faced and the solutions found, could be of great benefit in the elaboration of the guidelines.

69. The Committee recognised the importance of traceability/product tracing and most members supported the development of further guidance. However, many delegations felt that starting new work at present would be premature. They considered that countries and industry needed more experience with the implementation of the Codex Principles, adopted in 2006, to identify specific areas where additional guidance was needed and noted the ongoing work by the food industry to develop data systems.

70. Other delegations were of the opinion that guidance was necessary to promote the harmonised use of traceability/product tracing and avoid possible trade problems due to the

proliferation of diverging systems. It was also noted that the scope of new work should be clearly defined and the document should explain in detail how exactly further guidance would assist in the implementation of traceability /product tracing.

71. The Observer from the OIE informed the Committee of the status of the OIE work on animal identification and traceability, as presented in CRD 10, and of the plan to hold in collaboration with Codex an international Conference on animal identification and traceability in 2009.

72. The Committee agreed to continue discussion on this matter at its next session and to establish an electronic Working Group, led by the Delegation of Norway, open to all Members and Observers and working in English only, to prepare a revised discussion paper for consideration at its next session. The revised paper should consider the above discussion and written comments; it should clearly describe the present gaps in the implementation of traceability/products tracing, identify the key elements of the guidelines that would address these gaps and consider the technical and economical feasibility of countries to implement traceability/product tracing. It was agreed that the Working Group would start working as early as possible to allow an ample debate on this matter. The Delegation of Norway said that the active participation of members of the Working Group, contributing their experience, was necessary to successfully complete this task.

Chapter 5

DEVELOPMENT OF DOCUMENT ON PRECAUTION IN THE CODEX COMMITTEE ON GENRAL PRINCIPLES

CONTENTS

1. INITIAL DEBATE

The 13th Session (1998)

WORKING PRINCIPLES FOR RISK ANALYSIS (AT STEP 4 OF THE PROCEDURE)

20, Several Delegations and the Observer from Consumers International requested the inclusion of a reference to the "precautionary principle", stating that the use of this principle was a common factor in many Codex decision-making procedures. Other Delegations, however, stated that the inclusion of such a reference would need to be based on an agreed definition of the "precautionary principle" and understanding of its scope of application.

The 14th Session (1999)

WORKING PRINCIPLES FOR RISK ANALYSIS

Risk Management

27. *The Committee noted that the important issue was how to address uncertainty in scientific evaluation while conducting the risk management process; several delegations and the Observer from the EC pointed out that there was always a measure of uncertainty in the scientific evidence available, and that should not prevent necessary measures to protect public health.*
28. *The Delegation of Sweden proposed to clarify that the precautionary principle could be applied in specific circumstances in the framework of risk management to address uncertainty, as follows: "Lack of full scientific certainty shall not be used as a reason to delay measures intended to prevent adverse effects on human health from hazards present in food. When a preliminary risk assessment indicates a threat of adverse effects on human health from a hazard present in food, it is justifiable to take measures to prevent such effects without awaiting additional scientific data and a full risk assessment. Such measures should be proportionate to the potential health risk and should be kept under review."*
29. *The Delegation of Germany, speaking on behalf of the members of the European Union, supported the inclusion of the precautionary principle in view of its relevance in risk management decisions and the elaboration of guidelines on the use of this principle; this was also essential to build the confidence of consumers in the risk analysis process and reflect that the protection of public health was the primary objective of Codex. This position was supported by other delegations and the Observers of the EC, Consumers International, IBFAN, and IACFO.*
30. *The Delegation of the United States expressed its objection to the inclusion of the precautionary principle as there was no internationally recognized definition and a precautionary approach was already built in risk assessment; this concept should not be used by risk managers to overrule risk assessment. The Delegation recalled that under Article 5.7 of the SPS Agreement, national governments may adopt provisional measures in cases of insufficient scientific evidence but they should seek to obtain additional information for a more objective assessment of risk; at the international level and in the framework of Codex, standards should be based on scientific evidence. This position was supported by other delegations and the observers from CRN, COMISA and GCPF.*
31. *The Delegation of France proposed that if the precautionary principle were not integrated in the Working Principles, the following sentence should be included in the section on Risk Management: " The Codex Alimentarius Commission should not adopt standards or related texts when scientific evidence is insufficient or adverse effects are difficult to assess."*

32. *The Observer from CIAA pointed out that clear guidelines were needed to define the precautionary principle and its application in order to avoid constraints to technological innovation and to ensure that the industry could develop its activities in a transparent and predictable framework. The Observer from EFLA, referring to its written comments, drew the attention of the Committee to the legal implications of the debate and, if the principle were to be introduced as such, stressed the necessity of defining it and clarifying the conditions for its application, with special attention to the question of the burden of proof.*

33. *The Delegation of Canada referred to the definition of the precautionary principle in the area of environment and indicated that for the purposes of Codex, it would be preferable to refer to a precautionary approach, which corresponded to current practice when considering health protection issues and did not represent a new concept. The Delegation of New Zealand stressed the importance of clarifying the principles for risk assessment policy, as this was the essential element in the application of a precautionary approach in the framework of Codex, whereas the precautionary principle was more relevant at the national level.*

34. *Several delegations expressed the view that although there was general agreement on the application of a precautionary approach in order to protect public health, the main difficulty was to define and explain this approach in the framework of Codex risk management. The Committee recognized that for the purposes of health protection in the framework of Codex, a precautionary approach had been consistently taken in health protection matters, but it would be useful to consider further how to integrate this approach in the framework of risk management, possibly through the definition of guidelines. It was agreed that for the moment the text would remain in square brackets and that comments would be sought on a definition of the precautionary principle or a statement of precautionary approach and the conditions under which it would be applied. The Secretariat would then prepare an analysis of all relevant aspects and* proposals for further consideration. The Delegation of the United Kingdom requested that the analysis include guidelines for the application of the precautionary principle or approach.

ROLE OF SCIENCE AND OTHER FACTORS IN RELATION TO RISK ANALYSIS (AGENDA ITEM 7.1)

64. *The Committee recalled that at its last session it had reviewed a paper on the role of science and the extent to which other factors are taken into account in relation to BST. It was agreed at the time that a separate paper should be prepared on the application of other legitimate factors in the framework of risk analysis.*[21]

65. *The Delegation of the United States expressed the view that the scientific basis of risk assessment was essential in the decision process and that the introduction of other factors that are more appropriately considered at the national level was not appropriate in Codex; in particular economic interests should not be considered when the primary focus was health protection. According to the Delegation, environmental aspects were not in the mandate of Codex. The Delegation pointed out that the precautionary principle should not be considered as an other factor as it related to uncertainty, which was already addressed in the framework of risk assessment. This position was supported by several countries and the Observers of ICGMA, COMISA, GCPF and CRN.*

The 15th Session (1999)

3. *Mr. Huwart underlined the interest of the French government in the work of Codex Alimentarius particularly in relation to the new perspectives that applied to world trade. He clearly expressed the opinion that the precautionary principle should be regarded as an appropriate tool of risk management provided that it was not used as an excuse to establish unwarranted and arbitrary trade barriers. He also emphasized that legitimate factors other than strictly scientific data could not be ignored by governments and that the development of world trade could not take place without having regard to the legitimate rights of consumers. Finally, Mr. Huwart welcomed the revision of the Code of Ethics for International Trade in Food and noted that its observance was crucial to ensure the protection of all consumers and the use of fair trade practices. He stressed the necessity of*

ensuring that products that are exported to developing countries in particular should comply with international requirements of food quality and safety.

RISK ANALYSIS: 1) WORKING PRINCIPLES FOR RISK ANALYSIS

8. *The Committee recalled that the last session had discussed the Working Principles for Risk Analysis and had agreed on several amendments to the sections on risk analysis and risk assessment; there had been no consensus on the inclusion of a reference what some Members referred to as the 'Precautionary principle' in the section on risk management.*
9. *The Committee had agreed to return the proposed Draft Working Principles to Step 3 for further comments, including specific proposals on the precautionary principle or approach and asked the Secretariat to prepare a revised draft and an analysis of the questions related to the precautionary principle or approach, in the light of the comments received.*

RISK ANALYSIS – GENERAL ASPECTS

17. *In the section concerning uncertainty and precaution (para. 5), the Committee recognized that precaution was an essential element of risk analysis and agreed to include a statement to this effect at the beginning of the section, as proposed by the Delegation of the United States on the basis of the FAO Conference on International Food Trade beyond 2000 (Melbourne, 1999). It was agreed that this was particularly important when scientific evidence was insufficient and negative effects on health were difficult to evaluate.*

THE APPLICATION OF PRECAUTION: PRECAUTIONARY PRINCIPLE OR APPROACH

43. *The Committee considered an amended text prepared by the Delegations of the United States, the member countries of the European Union, the European Community and several other delegations and describing the use of precaution, with a footnote indicating that this was referred to as the 'Precautionary Principle' in certain member countries (para. 38, now para. 34).*
44. *The Delegation of Australia expressed the view that the content of the proposed footnote could be adequately covered in the report of the meeting together with the alternative views of other countries.*
45. *The Delegation of Malaysia, referring to its written comments, proposed that when precaution was exercised as an interim measure, additional information should be sought and the measures should be reviewed within a reasonable time frame in order to achieve consistency with Article 5.7 of the SPS Agreement. Several delegations supported this proposal and pointed out that the reference to a limited time frame was essential in order to prevent the establishment of unjustified barriers to trade, and was in conformity with the obligations of member countries under the SPS Agreement.*
46. *The two proposals referred to above are presented as alternative texts in paragraph 34 of Appendix III, the proposal from Malaysia appearing first as the other proposal should be read in conjunction with para. 35.*
47. *Some delegations and observers pointed out that the concept of a precautionary principle, which originated in discussions related to the environment, was not generally recognized or defined in relation to food safety, and that precaution was inherent to the risk analysis process, as recognized in the current Working Principles (para. 5 of the revised text). In this perspective, the definition of an additional concept was not necessary.*
48. *Several other delegations, observers and the Representative of WHO stressed that it was essential to address the uncertainties in risk assessment; in some cases, there were inherent difficulties to establish an adequate scientific basis due to the nature of the health hazard; risk assessment might take a long time to complete, or might still contain a wide range of uncertainty after it was carried out. In such cases, risk managers had to take action to protect consumers' health on the basis of precaution. The Delegation of Egypt expressed the view that when there was a doubt concerning scientific evidence it was the duty of risk managers to protect consumers; this was demonstrated clearly by such examples as the use of pesticides which were eventually prohibited, and the case of BSE.*
49. *The Delegation of the United Kingdom, supported by several delegations and observers, expressed the view that the reference to a principle was important and should be retained, at least in a footnote and that a definition of the 'Precautionary Principle' as used for risk assessment in Codex was essential, since this term was used in several countries in order*

to enhance consumer confidence in sanitary measures at the national level. These delegations however noted that in order to facilitate consensus, the reference to 'precaution' in the revised text would be acceptable.

50. *In reply to a question, the Delegation of the United States clarified that the reference to 'robustly' assessing risk corresponded to the terminology used in statistics when data were adequate, but other terms like 'objectively and fully' could be used. The Delegation pointed out that the use of the precautionary principle was not generally recognized or defined and that further discussion on this issue was necessary to clarify how precaution was applied.*

51. *The Delegation of Uruguay pointed out the precautionary approach, as described in the text proposed by several delegations (see para. 46 above), could apply to risk management decisions taken by governments but was not pertinent in the framework of Codex, where a scientific basis was essential to establish international recommendations. Other delegations expressed the view that this was primarily an area for national governments rather than Codex and stressed the need for clarification of this important issue.*

52. *Several delegations stressed that the recommendations on precaution in risk management should be applicable both to governments and in the framework of Codex. The Delegation of Sweden indicated that precaution was reflected in the development of Codex codes of practices when the risk assessment of certain contaminants was not completed, but it was necessary to address public health problems through preventive action*

53. *The Delegation of New Zealand indicated that the text did not adequately address all aspects of uncertainty in risk assessment. The Delegation further noted that while interim measures applied by national governments were provided for under the SPS Agreement, they were very unlikely to be used in elaborating Codex standards when risk assessment was not available.*

54. *The Delegation of Morocco indicated that the responsibility for identifying uncertainty would need to be clarified, since it was not specified in the amended text, although the original text (para. 38) had indicated that risk assessors would identify such uncertainty.*

55. *Some delegations indicated that the criteria proposed in the current text (para. 39, now para. 35) could be used as a starting point for further discussion. The Delegation of the Philippines proposed that the need for a time frame to review provisional measures should be included in this section. Some delegations proposed that the criteria should be discussed first in order to clarify the conditions for the application of precaution, while other delegations stressed the need to describe the nature of the principle or approach before selecting the criteria. The Committee did not discuss the criteria in detail and recognized that both parts of the section would require further consideration at the next session.*

56. *The Representative of WTO, recalling the provisions of SPS Article 5.7, indicated that guidelines on the application of precaution could facilitate common understanding of risk analysis but should not contradict the rights and obligations of member countries under the SPS Agreement.*

57. *The Committee recognized that no consensus existed at this stage on the different proposals put forward on the application of precaution, and discussed how to proceed further. The Chairperson proposed to establish a drafting group, which would work by electronic mail, and prepare revised proposals for consideration by the next session. A Working Group could also be held prior to the next session if necessary in order to facilitate discussion. Some delegations objected to such a discussion in a Working Group since issues of principle should be addressed in the plenary session of the Committee.*

58. *Some delegations proposed that FAO and WHO should convene a workshop to consider matters related to precaution, uncertainty and the interaction between risk management and risk assessment, in order to facilitate a common understanding of these issues. The Representatives of FAO and WHO indicated that they would consider the possibility of holding such a workshop, if this was the wish of member countries and the participation of Members from developing countries should be as large as possible. The Delegation of Chile asked FAO and WHO to consider convening a similar workshop at the level of the Regional Coordinating Committees.*

59. *Some delegations emphasized the responsibility of the Committee to address the issue of*

the application of precaution, as agreed in the FAO Conference on International Food Trade beyond 2000, and stated that this responsibility could not adequately be addressed in another meeting like an expert consultation or a workshop. It was also pointed out that a drafting group would need a clear mandate and an initial text as a basis for discussion.

60. *The Committee agreed that the two proposals referred to as alternative texts (see para 46 and Appendix III, para. 34) would be circulated for comments, as part of the Proposed Draft Working Principles at Step 3, and agreed that a drafting group, coordinated by the French Secretariat, would work by electronic mail in order to prepare a revised text for consideration by the next session. All member countries and international organizations were invited to participate in this electronic drafting group. The Committee noted that the French Secretariat would ensure prompt distribution of material to all members and observers, including replies to the Circular Letter sent at Step 3. The Committee agreed that a Working Group could be held to finalize a revised proposed text on the day preceding the Plenary Session, if required.*

61. *The Committee noted that significant progress had been made on most sections of the Working Principles; however, the application of precaution in risk management still needed additional discussion, and it was preferable to retain the text at Step 3 for further* consideration

2. ELABORATION PROCESS

The 16th Session (2001)

INTRODUCTION

2. *The Session was opened by Mr Jean Glavany, Minister of Agriculture and Fisheries, who highlighted the importance of Codex Alimentarius work to ensure fair practices in international trade. He recalled the importance of the precautionary principle in Europe and the need to establish a clear and transparent framework for its application at the national and international level, and noted that this was a major issue for consideration by the present session. The Minister also pointed out that risk management should take into account other legitimate factors in addition to health protection such as environmental aspects, animal welfare and consumer concerns.*

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS (ITEM 3.A)

12. *The Committee recalled that the elaboration of the Working Principles had been undertaken following the recommendations of the 22nd Session of the Commission concerning the use of risk analysis in Codex. The Committee recalled that its 15th session had returned the Proposed Draft Principles to Step 3 for further comments and consideration by the 16th Session, with the exception of the section on "precaution in risk management" (see paras. 49 to 69, below).*

Scope

22. *The Delegation of the United States expressed the view that the scope of the Principles should be limited to Codex, as this was the original mandate given to the Committee by the Commission. As the current scope referred both to Codex and to governments, this created considerable confusion throughout the text and the interpretation of several sections was not clear, including those addressing precaution. The Delegation indicated that the development of risk analysis principles for application by governments could be considered at a later date but the development of principles for application in Codex was the highest priority. This position was supported by several delegations.*

32. *The Delegation of Australia proposed an amendment to paragraph 5 to provide further clarification on the use of precaution in risk assessment and its importance in the selection of risk management options. The Delegation proposed to delete the second sentence and to add a new sentence as follows: "Precaution should be exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information". The Committee agreed to retain the second sentence and to add the new sentence proposed by Australia. Some delegations expressed their reservation on the use of the term "precaution" and the Committee agreed to place the entire paragraph in square brackets.*

33. *The Delegation of Australia also proposed to add further explanations concerning the relationship between the degree of uncertainty in risk assessment and risk management options, and noted that clarification at this stage might facilitate the debate concerning precaution in risk management (paras. 3435), although this was a separate issue. It was suggested that the additional paragraph should be transferred to the section on precaution in risk management (paras. 34-35) but the Committee agreed to retain it for the time being under General Aspects as paragraph 5b.*

34. *Some delegations expressed their concern with this addition. Other delegations proposed to discuss it further and to consider how it might relate to the discussion on precaution in risk management and in particular the use of precaution in routine and exceptional circumstances. The Committee could not discuss this proposal in detail and agreed that it would require further consideration at the next session. The proposals for the revised text of paras. 5 and 5b are included in Appendix V.*

PRECAUTION IN RISK MANAGEMENT (PARAS. 34-35)

Background

49. At the 15th Session of the Committee it was agreed that a drafting group co-ordinated by the French Secretariat would work by electronic mail in order to propose a revised draft text of these paragraphs. Comments were also requested from Member governments and interested international organizations by means of Circular Letter CL 2000/12-GP. In the light of comments received the French Secretariat prepared a revised text (CX/GP 01/3) which was distributed for further comments. A Working Group was then convened immediately preceding the present Session to discuss this proposal in the light of the comments received. Professor Chevassus-au-Louis, Chairman of the Working Group, presented the report to the Committee (Unnumbered CRD: "Report of the Working Group – 21 April 2001. The Application of Precaution in Risk Management").

Report of the Working Group

50. *"The Working Group had considered the proposed wording of paragraphs 34 and 35 of the Proposed Draft Working Principles for Risk Analysis in document CX/GP 01/3. The main changes introduced to document CX/GP 01/3 were the following:*

51. *The Working Group agreed to delete footnote 1 ("It is recognized that hazard identification is a crucial step in this process") and to replace it by the following phrase "from a preliminary risk assessment" coming after "reasonable evidence". It was recalled that hazard identification is defined in the Procedural Manual. On the other hand, the working group wished to recall that the application of precaution should be exercised following a preliminary risk assessment.*

52. *The Working Group discussed at length the scope for the application of precaution. It wondered whether precaution had to be applied by governments, by Codex or by both. It concluded that the situation described was the same but that precautionary measures could take different forms according to whether they are taken within the Codex framework or by governments. Consequently it suggested a text comprising:*

    -A general paragraph intended for risk managers and describing the situation.

    -Two specific paragraphs, one intended for Codex and the other for governments, which define the action likely to be undertaken.

53. *The Working Group agreed that there was a link between paragraph 34 and elements of paragraph 35, in particular on the issue of proportionality but it did not have time for a full discussion to determine which elements applied to Codex and which applied to governments.*

54. *The Working Group had no time to consider footnote 2 ("Some members refer to this concept as the "precautionary principle"). This discussion would have to take place during the plenary session.*

55. *Finally the Working Group agreed on the appended wording which it proposed to submit to the plenary session of the CCGP (see Appendix V).*

56. *The following reservations were expressed in relation to this wording (in the Working Group):*

-Although recognizing that clarifications had been made, the Delegation of the United States expressed a general reservation on the whole text.

-The Delegation of Brazil stated that the paragraph intended for governments should be put in square brackets.

-Some delegations, including Japan and the European Union wished to discuss further the wording of the last sub-paragraph of paragraph 34 by comparison with the wording initially proposed."

Discussion of the Working Group's "Compromise Text"

57. *Following the presentation of the Working Group report, there was a general debate in the Committee.*

58. *Several delegations including Argentina, Bolivia, Paraguay and Uruguay asked for the deletion of paras. 35-35 as in their view there was a question of the legitimacy of referring to precaution as a principle of international law. The Delegation of Uruguay expressed the view that paragraphs 34 and 35 in the Working Principles should be deleted since the confusion created by these paragraphs as regards terminology and legal aspects could result in measures that would adversely affect the protection of consumers' health and fair trade practices.*

59. *The Committee expressed its appreciation to the Working Group and its Chairman for their efforts to find a solution to the problems raised in relation to paragraphs 34-35. In particular, delegations stated that some progress had been made towards a clearer definition of the means by which Codex on one hand, and Member governments on the other hand, applied precaution in their respective areas of competence. Nevertheless, several delegations stated that without a clarification of the Scope of the Working Principles as a whole, the situation would remain confused. At different points in the discussion, Delegations made reference to differences in the perceived mandate of the Committee as set down by the Commission. One Delegation drew attention to the goals in reference to risk analysis set out by the Commission in 1999 in its Medium-Term Plan 1998-2003. Reference was also made to the initial mandate of the Commission in 1997 to draft "integrated principles for risk management and assessment policy setting, risk communication and documentation for inclusion in the Procedural Manual". However, attention was also drawn to the Commission's statement that "governments should be encouraged to integrate risk analysis in their legislation."*

60. *There was general agreement that governments had the right to take interim measures to protect the health of consumers as set out in Article 5.7 of the SPS Agreement. However, agreement could not be reached about the actions that Codex should take in situations where there was uncertainty and/or lack of scientific information including adverse effects on human health, as some delegations were of the opinion that Codex should not develop international standards, guidelines or recommendations under such conditions. Other delegations stated that Codex did, and should, prepare guidance, as appropriate, under such circumstances.*

61. *Some delegations requested the removal of any explicit reference to "precaution", claiming that all necessary measures to protect consumers' health when scientific evidence was insufficient were covered by the SPS Agreement and that any additional reference could foster the use of precaution for the purpose of trade protection, and that reference to a "precautionary principle" could allow governments to deviate from the disciplines of the SPS Agreement. The Delegation of Argentina, referring to its written comments, stated that it did not recognize any legal status for a so-called "precautionary principle" and therefore requested to delete any reference to such a principle. Other delegations stated that for the purpose of understanding and the fostering of consumer confidence in the risk analysis process, a reference to "precaution" was essential, and stated that this could be a reference to a "precautionary principle" as well as to a "precautionary approach". In the opinion of these delegations the use of either expression would indicate to consumers that a high level of protection was being sought, and that precaution was not being used only in acute situations.*

62. *Several delegations, referring to the International FAO Conference on International Food Trade beyond 2000 (Melbourne 11-15 October 1999), expressed the view that precaution*

was an essential element of risk analysis. There was a difference of opinion as to whether Codex should be encouraged to develop standards, guidelines or recommendations exclusively on this basis, without comprehensive scientific information and evidence.

63. *On the basis of this debate and several explicit proposals for amendment to the Working Group's compromise text, the Chairperson of the Committee tabled a revised text for the consideration of the Committee. The Delegation of Australia also circulated a revised text for consideration.*

Consideration of the Chairperson's Text

64. *The Committee expressed its appreciation to the Chairperson for her efforts in drawing together many of the diverse opinions expressed during the discussion of the Working Group draft.*

65. *The Representative of WHO stated that the issue of food safety had been recognized as one of high significance by the World Health Assembly. He reported that the Director-General of WHO had recently referred to the use of risk analysis as the "third wave" of strategies that were being used to improve the food safety status of countries around the world, the first and second "waves" being the use of Good Manufacturing Practices and the application of HACCP. However, risk analysis gave developing countries the opportunity to make even more significant advances than the developed countries in food safety. The Representative stated that risk analysis had to be considered as a health issue with trade implications and not as a trade issue with health implications, and that the debate on precaution should be viewed in this light.*

66. *Some Delegations stated that explicit reference to the use of precaution in Codex decision-making would reinforce the view that protecting consumers' health was the primary purpose of risk analysis over and above any trade concerns. The Observer from Consumers International expressed concern with the trend, within Codex and at the present meeting, to emphasize trade concerns over and above those of protecting the health of consumers. This view was supported by the Delegations of the United Kingdom and Norway. The Delegation of Argentina referred to the objectives of Codex of protecting consumers' health and ensuring fair practices in food trade.*

67. *Several Delegations stated that there was a need for a single document for use within Codex that described the application of precaution and also guidance for governments on how to apply precaution. These Delegations stated that they could accept most of the Chairperson's text, including the footnote which made explicit reference to "precautionary principle/precautionary approach". In the opinion of most of these Delegations, reference to the application of precaution was essential to maintain consumer confidence in the ability of food control authorities to ensure the safety of the food supply.*

68. *Several other Delegations expressed their preference for a complete deletion of paragraphs 34 and 35 as they should not apply to the work of Codex. Some of these delegations proposed however that, if the Chairperson's text was to be retained, reference to "precaution" should be deleted along with reference to actions to be undertaken by governments. Several delegations were also of the opinion that the footnote that referred explicitly to "precautionary principle/precautionary approach" should be deleted. The Delegation of Bolivia supported deleting the note because the precautionary principle could be used as a justification for trade protectionism. Some delegations also expressed their concern about the proposal to equate "precautionary principle" with "precautionary approach". The Delegation of Uruguay stated that the measures referred to in paras. 34 and 35 should only be applied by governments, in accordance with the WTO Agreements.*

69. *A number of Delegations expressed their preference for the draft text tabled by the Delegation of Australia, stating that the Chairperson's text still retained elements of ambiguity as to the work of Codex and the work of Member governments. These Delegations stated that it was inappropriate to suggest that Codex should develop standards, guidelines or recommendations by recourse to the "precautionary principle" when data were inadequate, even though it was recognized that precaution was an essential element in the Codex normal decision-making process. These Delegations also noted the linkages with the general statement on the application of precaution in risk analysis as contained in the Section on General Aspects (paragraph 5) of the draft*

document (see also paras. 32-34, above).

STATUS OF THE PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS

70. *The Committee noted that it had reviewed the complete text of the Working Principles now for the second time, and that progress had been made on a number of points although it had not been possible to achieve consensus on all of the text, in particular on the paragraphs dealing with Scope (paragraph 1) and precaution (paragraphs 5, 34 and 35). In relation to paragraph 34, the Committee agreed that all of the current alternative proposals, as presented in Appendix V of the present report, would be included in any revised text in square brackets.*

71. *The Committee agreed to request the Commission for a clarification of the intended scope and application of the document; i.e., whether it was a text exclusively for application within the Codex framework, or by Member governments, or both (bearing in mind that some paragraphs then might need to be singled out as being for specific application either by Codex or by Member governments).*

72. *The Committee also agreed to request the advice of the Commission on how Codex should react when scientific data were insufficient or incomplete and evidence of a risk to human health existed, in particular whether it should proceed to elaborate a standard or related text or whether it should refrain from such action.*

73. *In order to assist in the interpretation of the manner in which precaution was being used by Codex, the Committee invited the Chairpersons of relevant Codex Committees as well as governments and interested international organizations, to forward examples to the Secretariat in time to be available for discussion of this matter by the Commission (see para. 60, above).*

74. *On the basis of the Commission's advice, the Committee noted that it should be possible to proceed with the development of a text that would incorporate the decisions made at the present session. It requested the Secretariat to prepare such a revised text for circulation at Step 3 and consideration at the Committee's next session. It also requested the Secretariat to review the editorial presentation of the text, to remove duplication or repetition where possible while ensuring that the consensus decisions of the Committee remained as a they had been agreed.*

75. *The Delegation of Australia stressed the importance of an effective mechanism to ensure progress between the sessions and offered to lead a small working group to redraft the Working Principles for Risk Analysis. Several delegations supported this proposal. The Committee agreed that there was a need for the Host Country to convene an open-ended working group (open to all members and observer organizations) between sessions to review the document and the comments received so as to facilitate the discussion of the text at the Committee's next session. The Delegation of Bolivia expressed the view that this working group should be open to developing countries and be provided with interpretation. The Chairperson confirmed that, as had been the case before the present session, the Working Group would be open to all countries and provided with interpretation into French and Spanish.*

APPENDIX V: PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS: PROPOSALS

CONCERNING PRECAUTION IN RISK ANALYSIS

The Appendix contains the various proposals put forward in relation to paragraphs 5 and 34-35 of the Proposed Draft Working Principles for Risk Analysis (see para. 70 of the Report)

PARAGRAPH 5

[5. Precaution is an essential element of risk analysis. This is particularly important where the scientific evidence is insufficient and negative effects on health difficult to evaluate. Precaution should be exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information.]

Additional Australian Proposal

[5 bis. Many sources of uncertainty exist in the process of risk assessment of food borne

hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. As the degree of scientific uncertainty increases, the assumptions used for the risk assessment and the risk management options selected should become more cautious and conservative.]

PARAGRAPH 34

ORIGINAL TEXT (CX/GP01/3)

"When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food [1], and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for [risk managers/members governments] to apply precaution [2] through interim measures to protect the health of consumers, without awaiting additional scientific data and a full risk assessment.

However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly [within a reasonable time frame/until a more complete risk assessment is performed]."

[1] It is recognized that hazard identification is a crucial step in this process.

[2] Some Members refer to this concept as the "precautionary principle".

WORKING GROUP COMPROMISE TEXT

[34. When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence from a preliminary risk assessment to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for risk managers to apply precaution [1] through actions adapted to circumstances, in order to protect the health of consumers without awaiting additional scientific data and full risk assessment.

34bis. In the case of Codex, such precautionary actions could comprise the development of guidelines, recommendations or, where possible, standards. [In circumstances in which there is insufficient confidence in available information, Codex should not take any action.]

34ter. In addition, in the case of member governments, precaution may be applied through interim measures.

34qua. In both cases, additional information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame.]

[[1] Some Members refer to this concept as the "precautionary principle".]

AUSTRALIAN TEXT

[33bis. In deciding whether to elaborate a standard, guideline or recommendation relating to a particular hazard in food, Codex should consider the adequacy of current scientific knowledge, the level and extent of the risk to human health. Where there is evidence of a risk to human health but scientific knowledge is insufficient to provide a sound basis for a standard (such as maximum limit for a contaminant) Codex may consider other risk management options (such as Codes of Practice to minimise contamination of food) while awaiting further developments in scientific knowledge.

34. When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence from a preliminary risk assessment to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent, it may be appropriate for governments to apply precaution [1] through interim measures, in order to protect the health of consumers without awaiting additional scientific data and a full risk assessment.

However, additional information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame.]

[[1] Some Members refer to this concept as the "precautionary principle".]

PARAGRAPH 35

ORIGINAL TEXT (CX/GP 01/3)

[35. In such situations the following considerations should be taken into account :

a) Examination of the full range of management options should be undertaken with all the stakeholders.

This should include an assessment of the potential advantages and disadvantages of the alternative measures, including, where appropriate, flexibility and cost, effectiveness considerations.

b) There should be a transparent explanation of the need for the measures and the procedures followed to establish them.

c) The decisions/measures taken are proportional to the potential extent of the health risk and based on the available scientific data.

d) The decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information.

e) The measures taken are the least trade restrictive to achieve protection of the health of consumers.

f) The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.

76. g) Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information.]

The 17th Session (2002)

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS (AGENDA ITEM 3A)

THE APPLICATION OF RISK ANALYSIS IN THE APPLICATION OF CODEX STANDARDS (AGENDA ITEM 3B)4

16. The Committee recalled that at its previous session it had considered the Proposed Draft Working Principles for Risk Analysis and had agreed on several amendments to the text; however, it had been unable to arrive at a consensus on the Scope of the document or on the sections dealing with precaution in risk analysis, especially in risk management. The Committee had therefore requested the Commission for guidance on these matters (ALINORM 01/33A, paras 16-75, in particular 70-72). The Commission had confirmed its initial mandate to the Committee to complete the principles for risk analysis within Codex as a high priority, with a view to their adoption in 2003. It had also agreed that the Committee should develop guidance to governments subsequently or in parallel, as appropriate in view of its programme of work. It also made a decision on how Codex should proceed when scientific data were insufficient or incomplete. The Commission had recommended that the host government convene a Working Group to facilitate discussions on the Proposed Draft Principles at the present session of the Committee (ALINORM 01/41, paras. 75-83).

RISK ANALYSIS – GENERAL ASPECTS

28. The Committee discussed proposals to amend the paragraph dealing with precaution (paragraph 12, now 11), in particular to delete the introductory sentence (Argentina) and to provide more detailed clarification on the nature of the risk and its potential public health consequences (USA). Noting however that considerable effort had been made in achieving a consensus on this issue and that the opening sentence was a statement of fact, the Committee agreed to retain the text as drafted.

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS (At Step 5 of the Procedure)

11) Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

The 18th Session (2003)

RISK ANALYSIS

Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius

29. The delegation of India questioned the inclusion of the reference to precaution in paragraph 11 as it might be subject to various interpretations. However, the Committee retained the current text as it reflected a general approach to risk analysis and had been agreed as a result of detailed discussion in earlier sessions.

3. FINAL DOCUMENT

DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THEFRAMEWORK OF THE CODEX ALIMENTARIUS (<u>At Step 8 of the Procedure</u>)

SCOPE

1) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.

2) The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.

3) Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).**RISK ANALYSIS - GENERAL ASPECTS**

4) The risk analysis used in Codex should be:

- applied consistently;
- open, transparent and documented;
- conducted in accordance with both the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Statements of Principle Relating to the Role of Food Safety Risk Assessment; and
- evaluated and reviewed as appropriate in the light of newly generated scientific data.

5) The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission1, each component being integral to the overall risk analysis.

6) The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties[2].

[2]For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations” (see definition of “Risk Communication”)

7) Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.

8) The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

9) There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application10) When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.

11) Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

12) The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis.

Risk Assessment Policy

13) Determination of risk assessment policy should be included as a specific component of risk management.

14) Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

15) The mandate given by risk managers to risk assessors should be as clear as possible.

16) Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

RISK ASSESSMENT4

17) The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined

18) Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.

19) Risk assessment should be conducted in accordance with the Statements of Principle Relating to the Role of Food Safety Risk Assessment and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

20) Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

21) Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

22) Risk assessment should seek and incorporate relevant data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data, analytical and exposure data. Where relevant data are not available from developing countries, the Commission should request that FAO/WHO initiate time-bound studies for this purpose. The conduct of the risk assessment should not be inappropriately delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.

23) Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

24) Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative

and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

25) The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

26) The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

RISK MANAGEMENT

27) While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.

28) Risk management should follow a structured approach including preliminary risk management activities[5], evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles .

[5] For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

29) The Codex Alimentarius Commission and its subsidiary bodies, acting as risk managers in the context of these Working Principles, should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions on the available risk management options, in particular in the setting of standards or maximum levels, bearing in mind the guidance given in paragraph 10.

30) In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

31) The risk management process should be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.

32) The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

33) Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.34) In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary.

35) Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent

with the protection of consumers' health. In taking these elements into consideration, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries.

36) Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

RISK COMMUNICATION

37) Risk communication should :

i) promote awareness and understanding of the specific issues under consideration during the risk analysis ;

ii) promote consistency and transparency in formulating risk management options/recommendations;

iii) provide a sound basis for understanding the risk management decisions proposed;

iv) improve the overall effectiveness and efficiency of the risk analysis ;

v) strengthen the working relationships among participants;

vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;

vii) promote the appropriate involvement of all interested parties; and

viii) exchange information in relation to the concerns of interested parties about the risks associated with food.

38) Risk analysis should include clear, interactive and documented communication, amongst risk assessors (Joint FAO/WHO expert bodies and consultations) and risk managers (Codex Alimentarius Commission and its subsidiary bodies), and reciprocal communication with member countries and all interested parties in all aspects of the process.

39) Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

40) Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para.25).

41) The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties while respecting legitimate concerns to preserve confidentiality (See para. 6).

Note: Original wording was "Precaution is an essential element", which was modified to "Precaution is an inherent element"

1. Precaution is an essential element of risk analysis. This is particularly important where scientific evidence is insufficient and negative effects on health are difficult to evaluate. (15th session)

11) Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard. (17th final session)

Chapter 6

GUIDELINE FOR THE CONDUCT OF SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT DNA PLANTS

CONTENTS

1. ELABORATION PROCESS

2- 50. The Delegation of Japan introduced document CX/FBT 01/5 which had been developed by the Working Group established by the Task Force at its First Session. The Delegation reported that work had begun on the development of the text following the approval of the work by the Executive Committee in June 2000. The Working Group had met in July and October 2000. The working group had given consideration to the preparation of general guidance for all foods derived from biotechnology, but given the experience acquired in Member countries, decided to concentrate on developing guidance for foods derived from genetically modified plants as there seemed to be better prospects for harmonization, at least in the short term. Within this group, it decided to concentrate on recombinant-DNA plants and to exclude plants derived from cell fusion. It noted however, that the guidelines would need to be completed in the future to take into account experience gained in the safety assessment and regulatory approval of the latter.

2-51. The Delegation noted that the Working Group had introduced a new term, “safety assessment” so as to differentiate the process of evaluation from the risk assessment process used for the evaluation of chemicals or microbiological contaminants. The Proposed Draft Guideline was organized around the concept of substantial equivalence, but in the sense that this concept was a starting point for the safety assessment and not an end-point of the assessment. Section 4 of the Guidelines described the step-by-step evaluation process including the consideration of potential toxicity, allergenicity and nutritional consideration. Section 5 took into account several practical considerations.

TITLE

2-54. In view of the restricted scope of the document, the Task Force agreed to amend to Title so as to refer only to recombinant-DNA plants.

3-37. The Task Force discussed the proposals to change the title and agreed to retain the Title as it was. In regard to a proposal to replace the expression “Recombinant-DNA Plants” with “Plants Modified by DNA techniques”, the Task Force noted that such a change in the title could lead to extensive redrafting throughout the text with little net benefit.

SECTION 1 - SCOPE

1: This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. ~~and~~ **It addresses safety and nutritional aspects of foods consisting of, or derived from plants that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits.**

3-38. The Task Force discussed at length the question of whether or not the expression “derived from” recombinant DNA-plant also included the plants themselves or was restricted to derived products. Although it was noted that whole, unprocessed plants were very infrequently consumed the Task Force agreed to provide for such cases. The Task Force also agreed to include a reference to altered traits as well as new traits and to make a reference to the use of “modern biotechnology” for consistency with the Principles. The Task Force also retained the reference to the fact that the Guidelines applied only to foods that been derived from plants with a history of safe use as sources of food; foods derived from other plant sources would need to be assessed by other procedures than those described in the Guidelines. (Paragraph 1)

2. This document does not address animal feed or animals fed the feed. This document also does not address environmental risks. *(new paragraph added at 2nd session)*

2-55. Consistent with its earlier decision, the Task Force agreed that the Guidelines did not apply to animal feeds or to animals fed these feeds nor did they address environmental risks (Paragraph 2).

3. (originally 2**) The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods have been assessed scientifically in a manner that would fully characterise all risks associated with the food. Further, many foods contain substances that would likely be found harmful if subjected to conventional approaches to safety testing. Thus, a more focused approach is required where the safety of a whole food is being considered.**

At 2nd session "that have identifiable hazards and risks" was added in the third line.

4. (originally 3) **This approach is based on the principle that the safety of foods derived from new plant varieties, including recombinant DNA plants, is assessed relative to a similar product having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to a conventional counterpart. This process is commonly referred to as ~~a~~the "safety assessment".**

2-56. The Task Force agreed to use the previously defined term "conventional counterpart" when referring to the product against which a recombinant-DNA plant would be assessed. (see paras. 24 and 25 above) It also agreed that the comparative assessment was not, in itself a safety assessment and therefore deleted a statement that could have been interpreted to this effect (the last sentence in the previous Paragraph 3).

5. (originally 4) **This safety assessment approach falls within the risk assessment framework as discussed in Section 3 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. If a new or altered hazard, nutritional or other food safety concern is identified by the safety assessment, the risk associated with it would first be assessed to determine its relevance to human health. Following the safety assessment and if necessary further risk assessment, the food would be subjected to risk management considerations in accordance with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before it is considered for commercial distribution.**

Minor changes at the 2nd session

6. Risk management measures such as post-market monitoring of consumer health effects may assist the risk assessment process. These are discussed in paragraph 20 of the Draft Principles for the Risk Analysis of Foods derived from Modern Biotechnology.

3-39. The Task Force agreed to insert a new paragraph, taken from the proposed draft Annex on Allergenicity, to link risk management measures outlined in the Principles for Risk Analysis with the safety assessment procedures outlined in this Guideline. (Paragraph 6)

Note: 3-74. The Task Force agreed that the Working Group's recommendation concerning post-market monitoring and its usefulness in informing the safety assessment process had broader implications than the assessment of potential allergens, and agreed to incorporate this paragraph, with consequent amendments, into the main Guideline (see para. 39 above).

7. (originally 5) **The Guideline describes the recommended approach to making safety assessments of foods derived from recombinant DNA plants where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments. While this Guideline is designed for foods derived from recombinant DNA plants, the approach described could, in general, be applied to foods derived from plants that have been altered by other techniques.**

2-57. The Delegation of China proposed to delete the second sentence of Paragraph 5 to maintain the conformity with the amended title of the Guideline. The Task Force decided to maintain the sentence for future consideration. This paragraph becomes paragraph 6.

SECTION 2 - DEFINITIONS

8. (originally 6) **The definitions below apply to this Guideline.**

- "Recombinant DNA Plant" - means a plant in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

- [- "Conventional Counterpart" - means a related plant variety for which there is experience of establishing safety based on common use as food[1].]

[1]It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional comparators.

2-58. The Task Force decided to retain the same definition of Conventional Counterpart as agreed to in the context of Agenda Item 4. The Task Force did not include a definition of "substantial equivalence" as suggested by Mexico in its written comments. Thus, the square bracket was removed.

3-40. The Task Force agreed to retain the definitions for consistency with those of the Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology

SECTION 3 - INTRODUCTION TO <u>FOOD</u> SAFETY ASSESSMENT

2-59. The Task Force agreed to modify the Title of the Section to indicate that the assessment referred to food safety and not to assessment for other purposes. Similar changes were made throughout the document. Thus,

SECTION 3 - INTRODUCTION TO FOOD SAFETY ASSESSMENT

9. (originally 7) **Traditionally, new varieties of food plants have not been systematically subjected to extensive chemical, toxicological, or nutritional evaluation prior to marketing, with the exception of foods for specific groups, such as infants, where the food may constitute a substantial portion of the diet. Thus, new varieties of corn, soya, potatoes and other common food plants are evaluated by breeders for agronomic and phenotypic characteristics, but generally, foods derived from such new plant varieties are not subjected to the rigorous and extensive food safety testing procedures, including studies in animals, that are typical of chemicals such as food additives or pesticide residues that may be present in food.**

10. (originally 8) ~~Animal studies are a major element~~ **<u>The use of animal models for assessing toxicological endpoints is a major element</u> in the risk assessment of many compounds such as pesticides. In most cases, however, the substance to be tested is well characterised, of known purity, of no particular nutritional value, and, human exposure to it is generally low. It is therefore relatively straightforward to feed such compounds to animals at a range of doses some several orders of magnitude greater than the expected human exposure levels, in order to identify any potential adverse health effects of importance to humans. In this way, it is possible, in most cases, to estimate levels of exposure at which adverse effects are not observed and to set safe upper limits by the application of appropriate safety factors.**

2nd Session: Modification of the first line.

11. (originally 9) **Animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds<u>, often</u> characterised by a wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to animals at low multiples of the amounts that might be present in the human diet. In addition, a key factor to consider in conducting animal studies on foods is the nutritional value <u>and balance</u> of the diets used, in order to avoid the induction of adverse effects which are not related directly to the material itself. Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. <u>If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods.</u> Another consideration in deciding the need for animal studies is whether it is appropriate to subject experimental animals to such a study if it is unlikely to give rise to meaningful information.**

3-12. The Task Force had an extended discussion on the necessity of animal studies (feeding trials) on whole foods. The Delegation of Germany proposed that such studies may be necessary to confirm the safety of a foodstuff and this proposal received support from several

delegations. Other delegations were of the opinion that feeding trials would present challenges in application and interpretation with regard to providing the assurance of safety that was needed for consumer protection. The Task Force agreed to specify that such studies could be envisaged when the characterization of the food indicated that data would be insufficient for a thorough safety assessment. (Paragraph 11)

12. (originally 10) **Due to the difficulties of applying traditional toxicological testing and risk assessment procedures to whole foods, a more focused approach is required for the safety assessment of foods derived from food plants, including recombinant DNA plants. This has been addressed by the development of a multidisciplinary approach for assessing safety which takes into account both intended and unintended changes that may occur in the plant or in the foods derived from it, using the concept of substantial equivalence.**

13. (originally 11) **The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart[2]. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.**

> **[2] The concept of *substantial equivalence* has been elaborated in several international fora, such as the joint FAO /WHO expert consultations (2000 and 1996) and OECD (1993).** ~~Related references include: WHO (2000): Safety aspects of genetically modified foods of plant origin, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology; FAO (1996): Biotechnology and food safety, Report of a Joint FAO/WHO Consultation. FAO Food Nutrition Paper 61; and OECD (1993): Safety evaluation of foods derived by modern biotechnology, Concepts and principles.~~

2-60. In the description of the concept of substantial equivalence, the Task Force agreed that reference, in the footnote, should only be made to the most recent statement of the concept, as contained in the 2000 Joint FAO/WHO Expert Consultation (Paragraph 11). Therefore,

Unintended Effects

14. (originally 12) **In achieving the objective of conferring a specific target trait (intended effect) to a plant by the insertion of defined DNA sequences, additional traits could, in some cases, be acquired or existing traits could be lost or modified (unintended effects). The potential occurrence of unintended effects is not restricted to the use of *in vitro* nucleic acid techniques. Rather, it is an inherent and general phenomenon that can also occur in conventional breeding.** ~~Consequently,~~ **Unintended effects may be deleterious, beneficial, or** ~~even~~ **neutral with respect to the health of the plant or the safety of foods derived from the plant.** ~~Nevertheless, careful consideration should be given to reducing the possibility that a recombinant DNA plant has an adverse effect on human health.~~ **Unintended effects in recombinant-DNA plants may also arise through the insertion of DNA sequences and/or they may arise through subsequent conventional breeding of the recombinant-DNA plant. Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA plant would have an unexpected, adverse effect on human health.**

2-61. Some Delegations expressed concern at the reference to unintended effects that arose during the course of conventional plant breeding, and stated that the Guidelines should deal exclusively with recombinant-DNA plants. The Task Force however, was of the opinion that the reference to conventional breeding was appropriate, as it provided additional perspective and insight into the safety assessment process (Paragraph 13).

15. (originally 13) **Unintended effects** ~~may~~ **can result from the random insertion of DNA sequences into the plant genome which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes.**

Unintended effects may also result in the formation of new or changed patterns of metabolites. For example, the expression of enzymes at high levels may give rise to secondary biochemical effects or ~~altered metabolic flux~~ changes in the regulation of metabolic pathways and/or altered levels of metabolites.

Minor changes at 2nd session.

16. (originally 14) **Unintended effects due to genetic modification may be subdivided into two groups: those that are "predictable" and those that are "unexpected". Many unintended effects are largely predictable based on knowledge of the inserted trait and its metabolic connections or of the site of insertion. Due to the expanding information on plant genome and the increased specificity in terms of genetic materials introduced through recombinant DNA techniques compared with other forms of plant breeding, it may become easier to predict unintended effects of a particular modification. Molecular biological and biochemical techniques can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects.**

17. (originally 15) **The safety assessment of foods derived from recombinant-DNA plants involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment for unintended effects takes into account the agronomic/phenotypic characteristics of the plant that are typically observed by breeders in selecting new varieties for commercialization. These observations by breeders provide a first screen for plants that exhibit unintended traits. New varieties that pass this screen are subjected to safety assessment as described in Sections 4 and 5.**

~~taking into account several factors; these may include, but are not limited to:~~

~~A) molecular characterization, including stability of the introduced DNA;~~

~~B) chemical analyses of key nutrients, anti-nutrients, toxicants, vitamins, minerals, and other compounds that are typical of the plant or food;~~

~~C) alterations of metabolites; and~~

~~D) any effects due to food processing.~~

2-62. It was pointed out that the treatment of "predictable" and "unexpected" unintentional effects in Paragraph 15 was unbalanced. The Task Force noted however that the safety assessment framework described in the document was intended to detect both types of unintended effects, even though more information would normally be available for predictable effects. The Task Force also agreed to simplify this paragraph by deleting specific reference to a few selected factors that needed to be taken into consideration, in favour of a more general statement and complete description in the following Section.

Framework of Food Safety Assessment

Note: 2-59. The Task Force agreed to modify the Title of the Section to indicate that the assessment referred to food safety and not to assessment for other purposes. Similar changes were made throughout the document.

18. (originally 16) The **safety assessment of a food derived from a recombinant-DNA plant follows a stepwise process of addressing relevant factors that include:**

A) Description of the ~~new variety~~ recombinant-DNA plant;

B) Description of the host plant and its use as food;

C) Description of the donor organism(s);

D) Description of the genetic modification(s);

E) Characterization of the genetic modification(s); F) Safety assessment:

a) ~~introduced~~ expressed substances (non-nucleic acid substances);

b) compositional analyses of key components;

c) ~~metabolic evaluation;~~ **evaluation of metabolites ;**
d) food processing;
e) nutritional modification; and

G) Other considerations.

Note: 3-43. The Task Force agreed to replace term "new variety" with "recombinant-DNA plant" in the heading and throughout this section in view of the specific use of the term "variety" in plant breeding and genetics. (Paragraph 22) The need to identify unequivocally the recombinant-DNA plant was discussed by the Task Force, but it was noted that this was probably more on issue of risk management than risk assessment.

19. (originally 17) **In certain cases, the characteristics of the product may necessitate development of additional data and information to address issues that are unique to the product under review.**

20. (originally 18**)** **Experiments intended to develop data for safety assessment should be designed and conducted in accordance with sound scientific concepts and principles, as well as, where appropriate, Good Laboratory Practice. Primary data should be made available to regulatory authorities at request. Data should be obtained using** ~~validated~~ **sound scientific methods and analysed using appropriate statistical techniques. The sensitivity of all analytical methods should be documented.**

2-63. It was noted that Good Laboratory Practices were not applicable to all scientific experiments used for the safety assessment of plants, and modified Paragraph 19 accordingly. Consistent with its previous decision, it also deleted reference to the use of validated methods of assessment, but recognised that such methods should be sufficiently sound to withstand scientific peer review.

21. (originally 19) **The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use. The expected endpoint of such an assessment will be a conclusion regarding whether** ~~**or not**~~ **the new food is as safe** ~~and nutritious~~ **as the conventional counterpart** ~~against which it has been compared and for which there exists a history of safe use~~ **taking into account dietary impact of any changes in nutritional content or value. In essence, therefore, the outcome of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to** ~~make informed and proportionate decisions~~ **determine whether any measures are needed and if so to make well-informed and appropriate decisions**.

2-64. The Task Force agreed that safety assessments needed to take into account the best available scientific knowledge (1st sentence).

3-42. In the paragraph dealing with the goal of the safety assessment, the Delegation of the United States proposed to amend the paragraph so as to remove the requirement that the endpoint of the assessment would be a conclusion regarding whether or not the new food would be "as … nutritious as" the conventional counterpart. The objective of the amendment was to allow for new foods that would be more nutritious. The Task Force agreed to delete the reference to "nutritious" in this phrase but added a phrase to require that the dietary impact of any changes in nutritional content or value should be taken into account. (2nd sentence)

SECTION 4 - GENERAL CONSIDERATIONS

Description of the New Variety

22. (originally 20) **A description of the** ~~new plant variety~~ **recombinant-DNA plant being presented for safety assessment should be provided. This description should identify the crop, the transformation event(s) to be reviewed and the type and purpose of the modification. This description should be sufficient to aid in understanding the nature of the food being submitted for safety assessment.**

3-43. The Task Force agreed to replace term "new variety" with "recombinant-DNA plant" in the heading and throughout this section in view of the specific use of the term "variety" in plant breeding and genetics. (Paragraph 22) The need to identify unequivocally the recombinant-DNA plant was discussed by the Task Force, but it was noted that this was probably more on issue of risk management than risk assessment.

Description of the Host Plant and its Use as Food

23. (originally 21) **A comprehensive description of the host plant should be provided. The necessary data and information should include, but need not be restricted to:**

- **A)** ~~taxonomic information, such as species and variety name of the host plant;~~ **common or usual name; scientific name; and, taxonomic classification;**
- **B)** ~~a record of other plant species that have contributed to the host plant's genetic background~~ **history of cultivation and development through breeding, in particular identifying traits that may adversely impact on human health ;**
- **C)** ~~relevant information on the host plant's genotype and phenotype, including any known toxicity or allergenicity;~~ **information on the host plant's genotype and phenotype relevant to its safety, including any known toxicity or allergenicity; and**
- **D) history of safe use for consumption as food.**

2-65. The Task force agreed that information to be provided should be on traits that might affect human health and that the Points B and C of Paragraph 22 as well as Point D of Paragraph 25 should be modified accordingly.

24. (originally 22) **Relevant phenotypic information should be provided not only for the host plant, but also for related species and for plants that have made or may make a significant contribution to the genetic background of the host plant.**

25. (originally 23) **The history of use may include information on how the plant is typically cultivated, transported and stored, whether special processing is required to make the plant safe to eat, and the plant's normal role in the diet (e.g. which part of the plant is used as a food source, whether its consumption is important in particular subgroups of the population, what important macro- or micro-nutrients it contributes to the diet).**

Description of the Donor Organism(s)

26. (originally 24) **Information should be provided on the donor organism(s) and, when appropriate, on other** ~~members of the corresponding~~ **genus** **related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health (e.g. presence of antinutrients). The description of the donor organism(s) should include:**

- **A) its usual or common name;**
- **B) scientific name;**
- **C) taxonomic classification;**
- **D) information about the natural history as concerns food safety;**
- **E) information on** ~~pathogenicity or other potential toxic concerns, particularly the relationship to known pathogens or known producers of toxins, allergens or anti-nutrients within the same family~~ **naturally occurring toxins, anti-nutrients and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and**
- **F) information on the past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g. possible presence as contaminants).**

3-44. The term "members of the corresponding genus" was replaced by "related species" in Paragraph 26. (See WG response below)

WG response to the questions of the Chair concerning clarification of paragraphs 23 and 25 regarding taxonomic classification *(3rd session): The Working Group recommended retaining the term "related species" in paragraph 23 and proposed to change the term "members of the corresponding genus" to "related species" in paragraph 25 for consistency with paragraph 23. However, the reference to "related members of the family" in paragraph 25 was retained. The revised paragraph would read as follows:*

Information should be provided on the donor organism(s) and, when appropriate, on other ~~*members of the corresponding genus*~~ *related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit…*

Description of the Genetic Modification(s)

27. (originally 25) **Sufficient information should be provided on the genetic modification to allow for the identification of all genetic material potentially delivered to the host plant and to provide the necessary information for the analysis of the data supporting the characterization of the DNA inserted in the plant.**

28. (originally 26) **The description of the transformation process should include:**

A) information on the specific method used for the transformation (e.g. *Agrobacterium*-mediated transformation);

B) information, if applicable, on the DNA used to modify the plant (e.g. helper plasmids), including the source (e.g. plant, microbial, viral , synthetic), identity and expected function in the plant; and

C) intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for transformation of the host organism;

29. (originally 27**) Information should be provided on the DNA to be introduced, including:**

A) the characterization of all the genetic components including marker genes, regulatory and other elements affecting the function of the DNA;

B) the size and identity;

C) the location and orientation of the sequence in the final vector/construct; and

D) the function.

Characterization of the Genetic Modification(s)

30. (originally 28) **In order to provide clear understanding of the impact on the composition and safety of foods derived from recombinant-DNA plants, a comprehensive molecular and biochemical characterization of the genetic modification should be carried out.**

31. (originally 29) **Information should be provided on the DNA insertions into the plant genome; this should include:**

A) the characterization and description of the inserted genetic materials;

B) the number of insertion sites;

C) **the organization of the inserted genetic material at each insertion site including copy number and sequence data of the inserted material and <u>of the surrounding region, sufficient to identify any substances expressed as a consequence of the inserted material, or, where more appropriate, other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food</u>** ~~of surrounding region;~~ **and**

D) identification of any open reading frames <u>within the inserted DNA or created by the insertions with contiguous plant genomic DNA</u> including those that could result in fusion proteins.

2nd Session

2-66. The Delegation of Belgium, supported by many Delegations, stated that the sequence data of the inserted material and also of surrounding regions should be always provided as they were considered essential for safety assessment. The Delegation of the United States was of the opinion that only those sequence data related to possible impact on human health should be required. This view was supported by many Delegations, and the Task Force noted that other techniques were available to determine whether insertion sequences had been preserved or rearranged. The Task Force agreed to modify Point D to read "identification of any open reading frames within the inserted DNA or created by the insertions with contiguous plant genomic DNA including those that could result in fusion protein." The Task Force agreed that the number of copies of the inserted gene should be also provided (Paragraph 30).

3rd Session

WG response to the questions of the Chair concerning clarification of paragraph 31*): Regarding characterization of inserted genetic material at each insertion site, the Working Group recommends that the current language in paragraph 30, part C, be amended as follows:*

31. C) the organization of the inserted genetic material at each insertion site including copy number and sequence data of the inserted material and, where appropriate, of surrounding region or other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food; and …

Regarding fusion proteins in paragraph 30, part D, and paragraph 32, part F, the Working Group noted that these two sections have a certain complementarity. Paragraph 30, part D, deals with the potential for fusion proteins to result from the linkage between an insertion and plant genomic DNA; paragraph 32, part F, however, deals with characterization of expressed substances, specifically the identity and expression of any new fusion proteins.

3-45. The Task Force had an extended discussion concerning the amount of information required on the sequence of the region surrounding the insertion site and whether or not sequence data were essential to the characterization of the genetic modification. Several delegations, in particular those of Belgium, France, Norway and Japan stressed the importance of the comprehensive sequence data. Other delegations were of the opinion that other data, such as analysis of the transcript products could in some cases be more revealing as to the nature of the modification. The representative of Greenpeace International called for sequencing of the entire genome of the modified plant. The Task Force agreed that first consideration should be given to the sequence data but that in cases where the transcript data were more useful, information on the sequence data need not be provided. It amended the paragraph accordingly. (Paragraph 31.C)

32. (originally 30) **Information should be provided on any introduced substances in the recombinant DNA plant; this should include:**

A) the gene product (e.g. a protein or an untranslated RNA);

B) the gene product's function;

C) the phenotypic description of the new trait(s);

D) the level and site of expression in the plant of the ~~introduced~~ <u>expressed</u> gene product(s), and the levels of its metabolites in the plant, particularly in the edible portions; and

E) the amount of the target gene product(s) if the function of the ~~introduced~~ <u>expressed</u> sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.

2-67. The Task Force agreed that safety assessment should be conducted on expressed substances rather than introduced substances and changed the wording accordingly throughout the text.

33. (originally 31**) In addition, information should be provided:**

A) to demonstrate whether the arrangement of the genetic material used for ~~transformation~~ insertion has been conserved or whether significant rearrangements have occurred upon integration;

B) to demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for its structure or function;

C) to demonstrate that the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance. It may be necessary to examine the inheritance of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly;

D) to demonstrate that the newly ~~introduced~~ <u>expressed</u> trait(s) are expressed as

expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene;

E) to indicate whether there is any evidence to suggest that ~~a gene~~ one or several genes in the host plant has been affected by the transformation ~~event~~ process; and

F) to confirm the identity and expression pattern of any new fusion proteins.

Minor changes at 2nd session. See 2-67.

Safety Assessment of Introduced Substances (non-nucleic acid substances)

2-68, 1st sentence. The Task Force noted the proposal of the Delegation of Canada for reorganization of this Section; it decided, however, that this should be considered at a later stage. (for paragraphs 34-38 below)

3-46. The structure of this sub-section was amended to reflect the structure of the safety assessment described in Paragraph 18 of the Draft Guideline.

3-47. The Task Force was informed that at its Second Session a consensus had been reached to establish an open-ended Working Group on Allergenicity which had been hosted by the Government of Canada. This Working Group had also been invited to prepare a reorganization of the section on toxicology.

34. In vitro nucleic acid techniques enable the introduction of DNA ~~which~~ <u>that</u> can result in the synthesis of new substances in plants. The <u>new substances</u> can be conventional components of plant foods such as proteins, fats, carbohydrates, vitamins which are novel in the context of that recombinant-DNA plant. <u>New substances might also include new metabolites resulting from the activity of enzymes generated by the expression of the introduced DNA.</u>

Note: 1st and 2nd sentences of the original paragraph 32: "In vitro nucleic acid techniques enable the introduction of DNA which can result in the synthesis of new substances in plants. These can be conventional components of plant foods such as proteins, fats, carbohydrates, vitamins which are novel in context of that recombinant DNA plant. "

WG proposal A: "In vitro nucleic acid techniques enable the introduction of DNA that can result in the synthesis of new substances in plants. **<u>The new substances</u>** can be conventional components of plant foods such as proteins, fats, carbohydrates, vitamins which are novel in the context of that recombinant-DNA plant. **<u>New substances might also include newly generated metabolites which result from the activity of introduced enzymes</u>**." *(Where new text has been added in addition to reorganizing existing text, the new text is highlighted in bold and underlined.)*

3-48. The Task Force agreed to amend the last sentence to "New substances might also include new metabolites resulting from the activity of enzymes generated by the expression of the introduced DNA", for scientific accuracy. (Paragraph 34)

35. The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values. Current dietary exposure and possible effects on population sub-groups should also be considered.

3-49. In Paragraph 35, the Task Force agreed to include reference to the chemical nature of the newly expressed substances to make the paragraph more precise.

Note: 1st and 2nd sentences of original paragraph 34:" The safety assessment of the ~~introduced~~ <u>expressed</u> substance should identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including, as appropriate, variations and mean values. Current dietary exposure and possible effects on population sub-groups should also be considered. "

WG proposal B:" The safety assessment should <u>take into account the function of the newly expressed substance and</u> identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including, as appropriate, variations and mean values. Current dietary

exposure and possible effects on population sub-groups should also be considered.

36. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate anti-nutrients or toxicants.

3-50. In Paragraph 36, the Task Force agreed to delete the first sentence recommended by the Working Group as being redundant and unclear. The Task Force agreed that food processing could also degrade or eliminate anti-nutrients as well as deactivate them, and amended the paragraph accordingly.

Note: Original paragraph 35: "The ~~introduced~~ expressed trait should be shown to be unrelated to any characteristics of donor organisms that could be harmful to human health. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since ~~traditional~~ conventional processing techniques associated with the donor organisms may deactivate anti-nutrients or toxicants."

2-68, 2nd sentence. The Task Force agreed that the words "conventional processing techniques" would describe the nature of the techniques that may deactivate anti-nutrients or toxicants found in the donor organisms (Paragraph 36).

Note: WG proposal 36: "The **introduced** trait should be shown to be unrelated to any characteristics of donor organisms that could be harmful to human health. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional **food** processing techniques associated with the donor organisms may deactivate anti-nutrients or toxicants."

37. For the reasons described in Section 3, conventional toxicology studies may not be considered necessary where the substance or a closely related substance has, taking into account its function and exposure, been consumed safely in food. In other cases, the use of appropriate conventional toxicology or other studies on the new substance may be necessary.

3-51. In Paragraph 37, the Task Force discussed the appropriateness of excluding substances closely related to those that had been safely consumed in food from the requirement of conventional toxicological testing. Some Delegations and representatives of NGOs expressed their concern that term "closely related" was quite vague and it should be deleted, while other delegations and NGOs stated that this term was essential in view of the other requirements of the paragraph. The Task Force agreed to maintain the term. The Task Force agreed, however, that studies other than conventional toxicological studies may be more appropriate in some cases and amended the paragraph accordingly.

Note: 3rd sentence of the original paragraph 32: "Conventional toxicology studies are not considered necessary where the substance or a closely related substance has been consumed safely in food, taking into account its exposure, for the reasons described in Section 3."

Note: WG proposal C: "For the reasons described in Section 3, conventional toxicology studies are not considered necessary where the substance or a closely related substance has, taking into account its function and exposure, been consumed safely in food. In other cases, the use of appropriate conventional toxicology studies on the new substance will be necessary."

38. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients

(e.g. protease inhibitors, lectins) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies3 may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been safely consumed safely in food, and taking into account its biological function in the plant where known.

[3]Guidelines for oral toxicity studies have been developed in international fora, for example the OECD Guidelines for the Testing of Chemicals.

3-52. The Task Force agreed that oral toxicity studies may need to be carried out in cases where the protein present in the food was not similar to proteins that have been safely consumed in food, provided that the biological function of the protein (where known) was taken into account. (Paragraph 38)

*Note: 3rd and 4th sentences of original paragraph 34: "*In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[3] may be carried out in cases where the protein is present in the food, is not similar to proteins that have been safely consumed in food, and has not previously been consumed safely in food. "

WG proposal D: "In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[3] may be carried out in cases where the protein is present in the food is not similar to proteins that have been safely consumed in food, has not previously been consumed safely in food, and taking into account its biological function where known."

39. Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function in the plant of the substance and dietary exposure. The type of studies to be performed may include studies on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/carcinogenicity, reproduction and development toxicity according to the traditional toxicological approach.

3-53. The Task Force debated at length the requirements that would apply to introduced non-protein substances that had not been safely consumed in food. It agreed that these should be assessed on a case-by-case basis in all cases taking into account the other conditions set out in the paragraph. (Paragraph 39)

Note: Originally 36: Additional in vivo or in vitro studies may be needed on a case-by-case basis to assess the toxicity of introduced expressed substances. The types of studies depend on the original source of the introduced expressed substances and their function. Such studies may include assays of metabolism, toxicokinetics, chronic toxicity/carcinogenicity, impact on reproductive function, and teratogenicity.

Minor changes at 2nd session. See 2-67.

WG proposal E: Potential toxicity of introduced non-protein substances that are not similar to substances that have been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function of the substance and dietary exposure. The type of studies to be performed may include assays of metabolism, toxicokinetics, chronic toxicity/carcinogenicity, impact on reproductive function, and teratogenicity.

WG response to the Chair concerning clarification regarding studies on carcinogenicity, reproductive function and teratogenicity: *The Working Group proposed revisions to the section "Assessment of Possible Toxicity" which included revisions addressing this issue.*

40. This may require the isolation of the new substance from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case, the material should be shown to be biochemically, structurally, and functionally equivalent to that produced in the recombinant-DNA plant.

Same as proposed by WG at 3rd session.

Note: Originally 33: In other cases, the use of conventional toxicology studies on the new substance will be necessary. This may require the isolation of the new substance from the recombinant DNA plant, or the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally and biochemically equivalent to that produced in the recombinant DNA plant.

Assessment of possible allergenicity (proteins)[2]

[2] This part will be revised, as necessary, in light of the 2nd Joint FAO/WHO Consultation on Foods Derived from Biotechnology, Allergenicity of genetically modified foods, 22-25 January, 2001.

3-47. The Task Force was informed that at its Second Session a consensus had been reached to establish an open-ended Working Group on Allergenicity which had been hosted by the Government of Canada. The Working Group had also been invited to prepare a reorganization of the section on toxicology.

41. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly-expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or nonallergenicity). As noted in paragraph 20, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in the Annex to this document[4].

[4]The FAO/WHO expert consultation 2001 report, which includes reference to several decision trees, was used in developing the Annex to these guidelines.

3-54. The Task Force noted that this paragraph was intended set out the basic approach to be used in the assessment of potential allergenicity and also to provide a linkage to the Annex. The Task Force agreed that an integrated, stepwise, case-by-case approach should be used, however there was a divergence of opinions as to whether this should be presented as a decision-tree or not. The Delegation of the Netherlands, supported by several other delegations and observers made reference to the decision tree developed by the Joint FAO/WHO 2001 Expert Consultation. These delegations were of the opinion that the use of a decision-tree provided improved transparency in understanding the decisions being made. Other delegations were of the opinion that the use of a decision tree did not provide enough insight into the judgments needed at each step and also noted that the Working Group had recommended a more holistic approach that took into account evidence derived from several types of information and data, based on the concept of a "preponderance of data". In either case, the Task Force agreed that no single criterion was sufficient to determine either the allergenicity or non-allergenicity of a protein.

3-55. The Task Force decided to make a reference to the work of the Joint FAO/WHO Expert Consultation in a footnote to this paragraph, but decided against the elaboration of a decision tree. (Paragraph 41)

Note: Originally 38: When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. ~~The following decision tree strategy can be applied in this assessment (see the attached Chart)~~. A detailed presentation of issues to be considered can be found in annex[4].

[4]To be developed, to reflect the two recent FAO/WHO expert consultation reports.

42. (originally 43) **The newly ~~introduced~~ expressed proteins in foods derived from recombinant-DNA plants should be evaluated for any possible role in the elicitation of gluten-sensitive enteropathy, if the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains.**

Minor changes at 2nd session. See 2-67.

43. (originally 44) **The transfer of genes from commonly allergenic foods and from foods known to elicit gluten-sensitive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.**

3-56. The delegation of Spain requested that paragraphs dealing with gluten-sensitive enteropathy be referred to the Codex Committee on Nutrition and Foods for Special Dietary Uses for their information and this was agreed to by the Task Force (Paragraph 42,43).

Compositional analyses of key components[*]

[*]See for example OECD Consensus Documents on Canola and Soybean for a discussion of key components specific to these crops.

In the 2nd session, the above footnote was deleted.

44. (originally 45) **Analyses of concentrations of key components[5] of the recombinant DNA plant and, especially those typical of the food, should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. In some cases, a further comparison with the recombinant DNA plant grown under its expected agronomic conditions may need to be considered (e.g. application of an herbicide). The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison, in conjunction with an exposure assessment as necessary, is to establish that substances that are nutritionally important or that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.**

[5]Key nutrients or key anti-nutrients are those components in a particular food that may have a substantial impact in the overall diet. They may be major constituents (fats, proteins, carbohydrates as nutrients or enzyme inhibitors as anti-nutrients) or minor compounds (minerals, vitamins). Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased, selenium in wheat) and allergens.

45. (originally 46) **The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimise environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key components.**

Evaluation of Metabolites

2-72. The Task Force agreed that the title should read "Evaluation of metabolites" rather than Metabolic evaluation.

46. (originally 47) **Some recombinant DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. Consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Safety assessment of such plants requires investigation of residue and metabolite levels in the food and assessment of any**

alterations in nutrient profile. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).

Food processing

47. (originally 48) **The potential effects of food processing, including home preparation, on foods derived from recombinant DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant or the bioavailability of an important nutrient after processing. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.**

Nutritional modification

48. (originally 49) **The assessment of possible compositional changes to key nutrients, which should be conducted for all recombinant DNA plants, has already been addressed under 'Compositional analyses of key components'. However, foods derived from recombinant DNA plants that have undergone modification to intentionally alter nutritional quality or functionality should be subjected to additional nutritional assessment to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply.**

49. (originally 50) **Information about the known patterns of use and consumption of a food, and its derivatives should be used to estimate the likely intake of the food derived from the recombinant DNA plant. The expected intake of the food should be used to assess the nutritional implications of the altered nutrient profile both at customary and maximal levels of consumption. Basing the estimate on the highest likely consumption provides assurance that the potential for any undesirable nutritional effects will be detected. Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems. Based on the analysis of nutritional impacts and the dietary needs of specific population subgroups, additional nutritional assessments may be necessary. It is also important to ascertain to what extent the modified nutrient is bioavailable and remains stable with time, processing and storage.**

2-73. The Task Force agreed that attention should be paid also to the particular physiological characteristics and metabolic requirements of population groups with compromised immune systems.

50. (originally 51) **The use of plant breeding, including in vitro nucleic acid techniques, to change nutrient levels in crops can result in broad changes to the nutrient profile in two ways. The intended modification in plant constituents could change the overall nutrient profile of the plant product and this change could affect the nutritional status of individuals consuming the food. Unexpected alterations in nutrients could have the same effect. Although the recombinant DNA plant components may be individually assessed as safe, the impact of the change on the overall nutrient profile should be determined.**

51. (originally 52). **When the modification results in a food product, such as vegetable oil, with a composition that is significantly different from its conventional counterpart, it may be appropriate to use ~~alternative~~ additional conventional foods or food components (i.e. foods or food components whose nutritional composition is closer to that of the food derived from recombinant-DNA plant) as appropriate comparators to assess the nutritional impact of the food.**

3-57. The Task Force amended the paragraph dealing with the modification of the food to provide guidance for identification of appropriate comparators where composition of a food product had been significantly altered or when dealing with individual food components. (Paragraph 51)

Note: Originally 52: "When the modification results in a food product with a composition that is significantly different from its conventional counterpart, it may be appropriate to use alternative conventional foods (i.e. foods whose nutritional composition is closer to that of the food derived from recombinant-DNA plant) as appropriate comparators to assess the nutritional impact of the food. "

WG response to the Chair concerning clarification regarding paragraph 50: *The Working Group proposed revisions to paragraph 50 to address the need to clarify guidance in the identification of appropriate comparators where the composition of a food product is significantly altered. To reflect the modifications in the following text are underlined.*

52. (originally 53) **Because of geographical and cultural variation in food consumption patterns, nutritional changes to a specific food may have a greater impact in some geographical areas or in some cultural population than in others. Some food plants serve as the major source of a particular nutrient in some populations. The nutrient and the populations affected should be identified.**

53. (originally 54) **Some foods may require additional testing. For example, animal feeding studies may be warranted for foods derived from recombinant-DNA plants if changes in the bioavailability of nutrients are expected or if the composition is not comparable to conventional foods. Also, foods designed for health benefits may require specific nutritional, toxicological or other appropriate studies. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, <u>properly designed</u> animal studies could be requested on the whole foods ~~if properly designed~~.**

An editorial Change at 2nd session.

SECTION 5 – OTHER CONSIDERATIONS

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

54. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. The safety assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.

3-58. The Task Force agreed to include a new paragraph proposed by the delegation of Belgium and Canada and dealing with the potential for altered metabolism or accumulation of exogenous substances. (Paragraph 54) It is a modified version of paragraph 37 in the original draft, "The safety assessment should take into account the potential accumulation of any substances, toxic metabolites, contaminants, or pest control agents on plants that might result from genetic modification".

Note: Regarding paragraph 38, the WG agreed that the paragraph should be retained in the text with a recommendation to the Task Force that it should be considered in relation to paragraph 45 (Evaluation of Metabolites) of the guideline text.

Use of Antibiotic Resistance Marker Genes

55. Alternative transformation technologies that do not result in antibiotic resistance marker genes in foods ~~are encouraged~~ <u>should be used</u> in the future development of recombinant-DNA plants, where such technologies are available and demonstrated to be safe.

2-74. The Task Force agreed that use of alternative transformation technologies not resulting in antibiotic resistance marker genes in foods should be more strongly promoted in the text (Paragraph 53).

56. Gene transfer from plants and their food products to gut microorganisms or human cells is considered a rare possibility because of the many complex and unlikely events that would need to occur consecutively. Nevertheless, the possibility of such events cannot be completely discounted[6].

[6]In cases where there are high levels of naturally occurring bacteria which are resistant to the antibiotic, the likelihood of such bacteria transferring this resistance to other bacteria will be orders of magnitude higher than the likelihood of transfer between ingested foods and bacteria.

57. In assessing safety of foods containing antibiotic resistance marker genes, the following factors should be considered:

A) the clinical and veterinary use and importance of the antibiotic in question;

(Certain antibiotics are the only drug available to treat some clinical conditions (e.g. vancomycin for use in treating certain staphylococcal infections). Marker genes encoding resistance to such antibiotics should not be used in recombinant DNA plants.)

B) whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of the orally administered antibiotic; and

(This assessment should provide an estimate of the amount of orally ingested antibiotic that could be degraded by the presence of the enzyme in food, taking into account factors such as dosage of the antibiotic, amount of enzyme likely to remain in food following exposure to digestive conditions, including neutral or alkaline stomach conditions and the need for enzyme cofactors (e.g. ATP) for enzymatic activity and estimated concentration of such factors in food.)

C) safety of the gene product, as would be the case for any other introduced gene product.

58. If evaluation of the data and information suggests that the presence of the antibiotic resistance marker gene or gene product presents risks to human health, the marker gene or gene product should not be present in the food. ~~In general, **antibiotic**~~ **Antibiotic resistance genes used in food production that encode resistance to clinically** ~~important~~ **used antibiotics should not be present in** ~~widely disseminated~~ **foods.**

2-75. The Delegation of Sweden on behalf of the Member States of the European Union present at the session welcomed the inclusion in the Guideline of the restriction of the presence of antibiotic resistant marker genes in foods. It proposed that the restriction should be applied not only to clinically important antibiotics but to all kinds of antibiotics in use in medical and veterinary treatments. This view was supported by many Delegations (Paragraph 56). The Delegation of the United States, supported by other Delegations, stated that the restriction should be limited to clinically important antibiotics. The Delegation of Australia noted that the language' used' in Paragraph 56 was in conformity with the relevant section of the report of the 2000 FAO/WHO Expert Consultation.

2-76. The Task Force agreed that antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in widely disseminated foods.

3-59. The Task Force, after an extended discussion, recognized that the use of wording "in general" could leave a room for an unintended interpretation that there may be cases where antibiotic genes that encode resistance to clinically used antibiotics could be present in foods and therefore decided to delete it. It also agreed that this would apply to all foods and not only to "widely disseminated" foods as had been the case in the previous text. (Paragraph 58)

REVIEW OF SAFETY ASSESSMENTS

Review of Safety Assessments

59. The goal of the safety assessment is a conclusion as to whether the new food is as safe as ~~and no less nutritious than~~ **the conventional counterpart** ~~against which it was compared~~ **taking into account dietary impact of any changes in nutritional content or value. Nevertheless, the safety assessment should be reviewed in the light of new scientific information that calls into question the conclusions of the original safety assessment.**

3-60. The Task Force agreed to modify the reference to nutrition in this paragraph to maintain consistency with the text of Paragraph 20. (Paragraph 59)

2. NOTES

1. "Safety Assessment" is a term that is well defined in codex GM guidelines.

The "safety assessment" is the term defined in Section 3, particularly in paragraph 13.

The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart. (Paragraph 13)

2. How are foods derived from recombinant DNA plants, recombinant DNA microorganisms or recombinant DNA animals defined?

Paragraph 1 of this guideline says "This Guideline <u>supports</u> the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. "

Therefore, the definition in the Principles for the Risk Analysis reproduced below apply to this and other guidelines related to foods derived from modern biotechnology, though the underlined part is not reproduced in the plant, microorganism and animal guidelines

-"Modern Biotechnology" means the application of:

(i). In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(ii). Fusion of cells beyond the taxonomic family,

<u>that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection</u> [4].

"Conventional Counterpart" means a related organism/variety, its components and/or products for which there is experience of establishing safety based on common use as food [5].

[4] This definition is taken from the Cartagena Biosafety Protocol under the Convention on Biological Diversity.

[5] It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

Chapter 7

ANNEX ON THE ASSESSMENT OF POSSIBLE ALLERGENICITY

CONTENTS

1. REPORT FROM AD HOC OPEN-ENDED WORKING GROUP ON ALLERGENICITY (Vancouver, 10-12 September 2001)

The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, at its second session in Chiba, Japan, recognized that the report of the Joint FAO/WHO Expert Consultation on the Allergenicity of Genetically Modified Foods (January 22-25, 2001) introduced a new approach to the assessment of allergenicity. This approach differed significantly from that used as the basis for drafting the allergenicity section of the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants considered at the Second Session. The Task Force agreed to prepare a separate Annex which would contain detailed procedures for the allergenicity assessment. To this end, it decided to establish an Ad Hoc Open-Ended Working Group to draft such an annex which will be considered at Step 3 at the third session of the Task Force to be held in March 2002, for inclusion in the Draft Guideline. The Working Group was also invited to prepare a reorganization of the section on toxicology and to ensure scientific accuracy (see paragraph 70 of ALINORM 01/34A).

The Ad Hoc open-ended Working Group on Allergenicity convened in Vancouver from September 10-12, 2001. This session of the Working Group, hosted by the Government of Canada, was chaired by Mr. Paul Mayers (Health Canada). It was attended by the following delegations: Australia, Belgium, Brazil, Canada, Denmark, France, Germany, Japan, Netherlands, Sweden, Thailand, United Kingdom, United States, Biotechnology Industry Organization (BIO), Consumers International (CI), CropLife International, International Council of Grocery Manufacturers Associations (ICGMA) and International Life Sciences Institute (ILSI).

As requested by the Task Force, the deliberations of the Working Group focused on the development of the draft annex relating to the allergenicity assessment, the reorganization and review of the scientific accuracy of the toxicology section of the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (from ALINORM 01/34A, at step 5 of the elaboration procedure) focusing in particular on questions posed by the chair of the Task Force in this regard.

In order to aid in the proceedings, a discussion draft, for consideration by the Working Group, was developed by a drafting group, which was composed of representatives from Australia, Brazil, Canada, Denmark, Germany, Nigeria, United Kingdom and the United States.

During its deliberations, the Working Group noted the request from the Association of European Coeliac Societies (AOECS) to include gluten sensitive enteropathy in the assessment strategy; however, the Working Group decided to focus specifically on IgE mediated responses. It agreed to recommend to the Task Force that the issue of gluten sensitive enteropathy should be identified as requiring expert discussion before it could be incorporated into the detailed assessment strategy. The Working Group also noted that paragraph 41 of the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants does address gluten sensitive enteropathy, if the introduced genetic material is obtained from wheat, rye, barley, oats or related cereal grains.

2. ELABORATION OF THE TEXT IN THE THIRD SESSION

3-62. The Task Force was informed that at its Second Session it had been agreed to establish an open-ended Working Group on Allergenicity hosted by the Government of Canada to revise the proposed draft Annex on allergenicity14. The Delegation of Canada (Chair of the Working Group) introduced the revised Annex prepared by the Working Group. He noted that the Joint

FAO/WHO Expert Consultation in January 2001 provided a valuable source of expert input for the Working Group to draw upon for the development of the draft annex and encouraged the Working Group to also take into consideration relevant information available since the publication of the consultation as well as such aspects as practicality and validation. The Working Group had discussed the outcome of FAO/WHO Expert Consultation but come to the conclusion that it was not possible scientifically to arrive at clear "Yes/No" decisions at each and every step in the decision process. It had therefore recommended a more holistic approach that took into account a broad range of information that was to be examined in a step-wise and structured manner. This approach differed from the decision tree approach used in the previous draft.*

***Overview of Food Allergies (from Evaluation of Allergenicity of Genetically Modified Foods, FAO/WHO Expert Consultation 22-25 January 2001, pp 3-4):** *The reason why this annex guideline focuses on the allergenicity of protein components.*

Food allergies are caused by a wide variety of foods. The Codex Committee on Food Labelling established, after considerable debate, a list of the most common allergenic foods associated with IgE-mediated reactions on a worldwide basis that includes peanuts, soybeans, milk, eggs, fish, crustacea, wheat, and tree nuts. This list was presented to the Codex Alimentarius Commission and adopted in 1999 at its 23rd Session. These commonly allergenic foods account for over 90% of all moderate to severe allergic reactions to foods, although an extensive literature search has revealed more that 160 foods associated with sporadic allergic reactions (Hefle et al., 1996). Theoretically, any food that contains protein would be capable of eliciting an allergic reaction, although foods vary widely in their likelihood of provoking allergic sensitisation. In addition to the Codex list, allergic reactions to fresh fruits and vegetables, associated with the oral allergy syndrome (OAS), are also rather common (Ortolani et al., 1988). These foods are not included in the Codex list. The symptoms are typically mild and mostly confined to the oropharyngeal region. Some of the most significant allergens from these foods are unstable to heating and digestion. However, OAS in patients allergic to fruits and vegetables may, in some individuals, be followed by a systemic reaction (Ballmer-Weber et al., 2000). The list established by the Codex Committee on Food Labelling also includes gluten-containing cereals (wheat, rye, barley, oats and spelt) that are implicated in the aetiology of gluten-sensitive enteropathy.

In IgE-mediated food allergies, exposure to a specific food and the proteins contained therein

(*continued*)

The manifestations of IgE-mediated food allergies range from mild to severe to life threatening events. Individuals display different thresholds for elicitation of a reaction following ingestion of the offending food. However, the most sensitive food-allergic individuals will experience reactions from exposure to microgram to low milligram quantities or perhaps less of the offending food (limited studies have been conducted on threshold doses so the lowest-observed adverse effect level cannot be deduced precisely for any given allergenic food). Severe reactions can take place after intake of minute amounts of the offending food, and a safe threshold level below which reactions will not occur has not been defined.

Gluten-sensitive enteropathy or celiac disease is a T cell-mediated immunological response triggered by gluten (gliadin) which affects genetically disposed individuals. The active phase of the disease consists of an inflammatory process in the small intestine leading to malabsorption with body wasting, anaemia, diarrhoea, and bone pain along with other symptoms. The disease demands lifelong avoidance of gluten from wheat, rye, barley, and related cereals.

Celiac disease and other enteropathies, although recognized by this Consultation as important medical conditions, were not included in the assessment strategies considered by this Consultation.

Both IgE-mediated food allergies and non-IgE-mediated reactions are treated with specific avoidance diets. Since in both cases, the threshold dose is low and not precisely defined, affected individuals can experience difficulties in the adherence to the avoidance diets.

Almost all food allergens are proteins, although the possibility exists that other food components may act as haptens[2]. While some food allergens have been identified and characterized, many others remain unknown. Many of the known food allergens fall into certain classes of proteins which may aid in the identification of unknown allergens from other sources. Similarly, prolamin proteins from wheat, rye, barley, etc. are involved in the elicitation of glutensensitive enteropathy. While the crops from which staple foods are derived contain thousands of different proteins, relatively few are allergenic. The distribution of these proteins varies in different parts of the plant and can be influenced by environmental factors such as climate and disease stress.

[1] IgE, or immunoglobulin E, is a protein antibody that recognizes an allergen. It circulates in the blood, and becomes fixed on the surfaces of specific cells (basophils and mast cells). When IgE on the cell surface binds to allergen, this triggers the release of chemical mediators that provoke the symptoms associated with allergic reactions.

[2]Haptens are small molecules, which may interact with body proteins or food proteins and cause these proteins to become allergenic.

is likely to induce allergic reactions in some individuals.

[1] **This assessment strategy is not applicable for assessing whether newly expressed proteins are capable of inducing gluten-sensitive or other enteropathies. The issue of enteropathies is already addressed in Assessment of possible allergenicity (proteins), paragraph 42 of the [Draft] Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. In addition, the strategy is not applicable to the evaluation of foods where gene products are down regulated for hypoallergenic purposes.**

2. At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly expressed protein, therefore, it is recommended that an integrated, stepwise, case by case approach, as described below, be used in the assessment of possible allergenicity of newly expressed proteins. This approach takes into account the ~~preponderance of~~ evidence derived from several types of information and data since no single criterion is sufficiently predictive.

3-63. The Task Force agreed to modify Paragraph 2 to take into account the above discussion. In particular it deleted a reference to the "preponderance of evidence".

3. The endpoint of the assessment is a conclusion as to the likelihood of the protein being a food allergen.

3-64. The Task Force agreed to include a new paragraph, taken from paragraph 17 of the Working Group's draft, that gave an explicit indication of the endpoint of the assessment for possible allergenicity. (Paragraph 3)

Section 2 - Assessment Strategy

4. The initial steps in assessing possible allergenicity of any newly expressed proteins are the determination of: the source of the introduced protein; any significant similarity between the amino acid sequence of the protein and that of known allergens; and its structural properties, including but not limited to, its susceptibility to enzymatic degradation, heat stability and/or, acid and enzymatic treatment.

3-65. In Paragraph 4, the Task Force agreed to insert a sentence "and heat stability and/or acid and enzymatic treatment" at the end of this paragraph in order to make this paragraph clearer. The Task Force also agreed to include a text provided by the Delegation of Italy on the attention that should be given to the choice of the expression host.

5. As there is no single test that can predict the likely human IgE response to oral exposure, the first step to characterize newly expressed proteins should be the comparison of the amino acid sequence and certain physicochemical characteristics of the newly expressed protein with those of established allergens in a weight of evidence approach. This will require the isolation of any newly expressed proteins from the recombinant-DNA plant, or the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally and biochemically equivalent to that produced in the recombinant-DNA plant. Particular attention should be given to the choice of the expression host, since posttranslational modifications allowed by different hosts (i.e.: eukaryotic vs. prokaryotic systems) may have an impact on the allergenic potential of the protein.

Underlined sentence was added at 3rd session.

6. It is important to establish whether the source is known to cause allergic reactions. Genes derived from known allergenic sources should be assumed to encode an allergen unless scientific evidence demonstrates otherwise.

Section 3 – Initial Assessment

Section 3.1 - Source of the Protein

7. As part of the data supporting the safety of foods derived from recombinant-DNA plants, information should describe any reports of allergenicity associated with the donor organism. Allergenic sources of genes would be defined as those organisms for which reasonable evidence of IgE mediated oral, respiratory or contact allergy is available. Knowledge of the source of the introduced protein allows the identification of

tools and relevant data to be considered in the allergenicity assessment. These include: the availability of sera for screening purposes; documented type, severity and frequency of allergic reactions; structural characteristics and amino acid sequence; physicochemical and immunological properties (when available) of known allergenic proteins from that source.

66. In Paragraph 7, the Task Force agreed to insert a reference to "physiochemical and immunological properties" at the end of this paragraph to make this paragraph clearer.

Section 3.2 – Amino Acid Sequence Homology

8. The purpose of a sequence homology comparison is to assess the extent to which a newly expressed protein is similar in structure to a known allergen. This information may suggest whether that protein has an allergenic potential. Sequence homology searches comparing the structure of all newly expressed proteins with all known allergens should be done. Searches should be conducted using various algorithms such as FASTA or BLASTP to predict overall structural similarities. Strategies such as stepwise contiguous identical amino acid segment searches may also be performed for identifying sequences that may represent linear epitopes. The size of the contiguous amino acid search should be based on a scientifically justified rationale in order to minimize the potential for false negative or false positive results[2]. Validated search and evaluation procedures should be used in order to produce biologically meaningful results.

[2] **It is recognized that the 2001 FAO/WHO consultation suggested moving from 8 to 6 identical amino acid segments in searches. The smaller the peptide sequence used in the stepwise comparison, the greater the likelihood of identifying false positives, inversely, the larger the peptide sequence used, the greater the likelihood of false negatives, thereby reducing the utility of the comparison.**

9. IgE cross-reactivity between the newly expressed protein and a known allergen should be considered a possibility when there is more than 35% identity in a segment of 80 or more amino acids (FAO/WHO 2001) or other scientifically justified criteria. All the information resulting from the sequence homology comparison between the newly expressed protein and known allergens should be reported to allow a case-by-case scientifically based evaluation.

3-67,1st sentence. In Paragraph 9, the Task Force agreed to modify the paragraph to make an explicit reference the need to report the outcome of the comparison of the sequence homology.

10. Sequence homology searches have certain limitations. In particular, comparisons are limited to the sequences of known allergens in publicly available databases and the scientific literature. There are also limitations in the ability of such comparisons to detect non-contiguous epitopes capable of binding themselves specifically with IgE antibodies.

3-67, 2nd sentence. In paragraphs 10 (also 14), the Task Force accepted the wording provided by Argentina in relation to the epitopes capable of binding with IgE antibodies.

11. A negative sequence homology result indicates that a newly expressed protein is not a known allergen and is unlikely to be cross-reactive to known allergens. A result indicating absence of significant sequence homology should be considered along with the other data outlined under this strategy in assessing the allergenic potential of newly expressed proteins. Further studies should be conducted as appropriate (see also sections 4 and 5). A positive sequence homology result indicates that the newly expressed protein is likely to be allergenic. If the product is to be considered further, it should be assessed using serum from individuals sensitized to the identified allergenic source.

Section 3.3 – Pepsin Resistance

12. Resistance to pepsin digestion has been observed in several food allergens; thus a correlation exists between resistance to digestion by pepsin and allergenic potential[3]. Therefore, the resistance of a protein to degradation in the presence of pepsin under

appropriate conditions indicates that further analysis should be conducted to determine the likelihood of the newly expressed protein being allergenic. The establishment of a consistent and well-validated pepsin degradation protocol may enhance the utility of this method. However, it should be taken into account that a lack of resistance to pepsin does not exclude that the newly expressed protein can be a relevant allergen.

[3] The method outlined in the U.S. Pharmacopoeia (1995) was used in the establishment of the correlation (Astwood et al. 1996).

13. Although the pepsin resistance protocol is strongly recommended, it is recognized that other enzyme susceptibility protocols exist. Alternative protocols may be used where adequate justification is provided[4].

[4]Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (2001): Section "6.4 Pepsin Resistance"

Section 4 – Specific Serum Screening

14. For those proteins that originate from a source known to be allergenic, or have sequence homology with a known allergen, testing in immunological assays ~~is recommended~~ should be performed where sera are available. Sera from individuals with a clinically validated allergy to the source of the protein can be used to test ~~IgE-binding of the protein in in vitro assays~~ the specific binding to IgE class antibodies of the protein in *in vitro* assays. A critical issue for testing will be the availability of human sera from sufficient numbers of individuals[5]. In addition, the quality of the sera and the assay procedure need to be standardized to produce a valid test result. For proteins from sources not known to be allergenic, and which do not exhibit sequence homology to a known allergen, targeted serum screening may be considered where such tests are available as described in paragraph 17.

[5]According to the Joint Report of the FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (22-25 January 2001, Rome, Italy) a minimum of 8 relevant sera is required to achieve a 99% certainty that the new protein is not an allergen in the case of a major allergen. Similarly, a minimum of 24 relevant sera is required to achieve the same level of certainty in the case of a minor allergen. It is recognized that these quantities of sera may not be available for testing purposes.

3-67, 2nd sentence. In paragraphs 10 (also 14), the Task Force accepted the wording provided by Argentina in relation to the epitopes capable of binding with IgE antibodies.

3-68. The Task Force noted that whereas it was desirable to perform immunological assays on proteins from a source known to be allergenic, it recognized that the ability to carry out such assays depended on the availability of appropriate sera, and amended Paragraph 14 accordingly. The Task Force agreed to include consideration of targeted serum screening for protein from sources not known to be allergenic (Paragraph 14).

15. In the case of a newly expressed protein derived from a known allergenic source, a negative result in *in vitro* immunoassays may not be considered sufficient, but should prompt additional testing, such as the possible use of skin test and ex vivo protocols[6]. A positive result in such tests would indicate a potential allergen.

[6]Ex vivo procedure is described as the testing for allergenicity using cells or tissue culture from allergic human subjects (Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods derived from Biotechnology)

3-69. The Task Force noted the unusual reference to ex vivo testing and agreed to make a reference in a footnote to the extended description of these procedures contained in the Joint FAO/WHO 2001 Expert Consultation report. (Paragraph 15).

Note:

A paragraph proposed by WG:" The identification of a newly expressed protein as an allergen through immunological assays suggests that further development for commercialization of the

product be discouraged, unless adequate risk management and risk communication measures could be assured throughout marketing and distribution of the product, since segregation and identity preservation of the new source of this allergen may be difficult or impossible to enforce. “

3-70. The Task Force deleted a paragraph proposed by the Working Group that dealt with the commercialization of products containing identified allergens, considering that this was a matter of risk management and not risk or safety assessment and was therefore better dealt with in the context of the Principles of Risk Analysis.

Section 5 – Other Considerations

3-71. The Task Force agreed to rename this section (“Additional Information” *proposed by WG) and add to it the following Section previously entitled “Areas requiring Further Development”.*

16. The absolute exposure to the newly expressed protein and the effects of relevant food processing will contribute toward an overall conclusion about the potential for human health risk. In this regard, the nature of the food product intended for consumption should be taken into consideration in determining the types of processing which would be applied and its effects on the presence of the protein in the final food product.

17. As scientific knowledge and technology evolves, other methods and tools may be considered in assessing the allergenicity potential of newly expressed proteins as part of the assessment strategy. These methods should be scientifically sound and may include targeted serum screening (i.e. the assessment of binding to IgE in sera of individuals with clinically validated allergic responses to broadly-related categories of foods); the development of international serum banks; use of animal models; and examination of newly expressed proteins for T-cell epitopes and structural motifs associated with allergens.

Note:

Original proposal by WG: “The endpoint of the assessment of the data discussed above is a conclusion as to the likelihood of the protein being a food allergen. The techniques of targeted serum screening (i.e. the assessment of binding to IgE in sera of individuals with clinically-validated allergic responses to broadly-related categories of foods) and the use of animal models, once developed and validated, could enhance the weight of evidence used to derive this conclusion. To allow serum screening, steps should be taken to organize an international serum bank. As scientific knowledge and technology evolves, other methods, such as examination of newly expressed proteins for T-cell epitopes and structural motifs associated with allergens, might also be useful. “

3-72. As noted above (para.64) the Task Force agreed to move the opening sentence of the Working Group’s recommendation to the introduction to the Annex, where it served the useful purpose of providing an overall framework for the assessment process. The remainder of Paragraph 17 was modified to indicate that as new knowledge and techniques continued to be developed they should be considered together with the other techniques described in the Annex.

~~[Section 7 – Post-market Monitoring~~

~~18. Risk management measures such as post-market monitoring of potential consumer health effects, for example allergic responses, are discussed in paragraph [20] of the [draft] Principles for Risk Analysis of Foods derived from Modern Biotechnology.]~~

3-74. The Task Force agreed that the Working Group’s recommendation concerning post-market monitoring and its usefulness in informing the safety assessment process had broader implications than the assessment of potential allergens, and agreed to incorporate this paragraph, with consequent amendments, into the main Guideline (see para. 39 above).

3. DISCUSSIONS BEFORE THE THIRD SESSION

Originally Proposed Paragraphs on Allergenicity

39. When the transferred gene is obtained from a source with a known history of allergenicity,

the assessment should focus initially upon the immunochemical reactivity of the introduced protein with IgE from the serum of individuals with known allergies to the source of the transferred genetic material. In cases where no evidence of immunochemical reactivity is obtained, skin prick tests with extracts containing the introduced protein and double-blind placebo-controlled food challenges (DBPCFC) with the new food should be conducted, if appropriate, on individuals with known allergies to the source of the transferred genetic material, in order to provide confirmation that the introduced protein is not allergenic. This series of tests provides adequate evidence regarding the allergenicity (or lack thereof) of introduced proteins expressed by genes obtained from known allergenic sources.

40. When the transferred gene is obtained from a source with no known history of allergenicity, the decision-tree approach relies upon various criteria used in combination, since no single criterion is sufficiently predictive. The current criteria include the amino acid sequence similarity of the introduced protein to known allergens, the immunochemical reactivity of the introduced protein with IgE from serum of appropriate, allergic individuals when amino acid sequence similarities are found, and the stability of the introduced protein to degradation in appropriate representative gastric and intestinal model systems.

41. The incorporation of two additional criteria to the decision-tree approach might be useful when the source of the genetic material is not known to be allergenic.

the level of the protein in food; and the functional properties of the protein (e.g. storage protein)

42. These criteria taken together offer reasonable evidence as to whether or not the protein is allergenic, is cross-reactive with known allergens, and has a potential to be a food allergen.

2-69. The Task Force observed that the section on allergenicity was an important part of the Guideline document and that the report of the Joint FAO/WHO Expert Consultation on the Evaluation of Allergenicity of Genetically Modified Foods[11] offered considerably useful information. It observed further that the report introduced a new approach for the assessment of allergenicity of genetically modified foods, different significantly from that used as the basis for the drafting of the current wording. The Task Force agreed therefore that the section on allergenicity needed to receive a considerable amount of changes. Some Delegations regretted that there had not been sufficient time to consider the contents of the report in detail.

> *[11]Evaluation of Allergenicity of Genetically Modified Foods: Report of a FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology 22-25 January 2001: FAO Food and Nutrition Paper (in press), FAO, Rome 2001. Also available from the websites of FAO and WHO.*

2-70. In order to proceed, the Task Force agreed to develop a separate annex containing detailed procedures for the allergenicity assessment. It also agreed to establish an open-ended Working Group on Allergenicity to develop such an annex and accepted the offer of the Government of Canada to host the Working Group. The Working Group was also invited to prepare a reorganization of the section on toxicology (see para. 68 above) and to ensure the scientific accuracy.

2-71. Under the understanding that detailed procedures for the allergenicity assessment should be removed from the body of the Guideline, the Task Force agreed to replace the whole section on allergenicity (Paragraphs 38 to 42 of the first version). The paragraphs dealing with gluten-sensitive enteropathy were retained without change. The Task Force agreed further that the transfer of genes from commonly allergenic foods should be "avoided" rather than "discouraged", but retained the restriction that such genes should not code for an allergen or a protein involved in gluten-sensitive enteropathy.

Originally Proposed Decision Tree Approach

40. A decision-tree strategy[5] should be applied in the assessment of the potential allergenicity of the newly-expressed protein(s). The decision-tree approach should rely upon various criteria used in combination (since no single criterion is sufficiently predictive). As noted in Paragraph 19, the data should be obtained using sound scientific methods.

> [5] Decision tree strategies have been developed and modified on the basis of expert consultations in national and international fora, for example, the report of a Joint FAO/WHO Expert Consultation on Foods Derived from

Biotechnology (WHO 2000) and the report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (FAO 2001).

Footnotes to the Chart

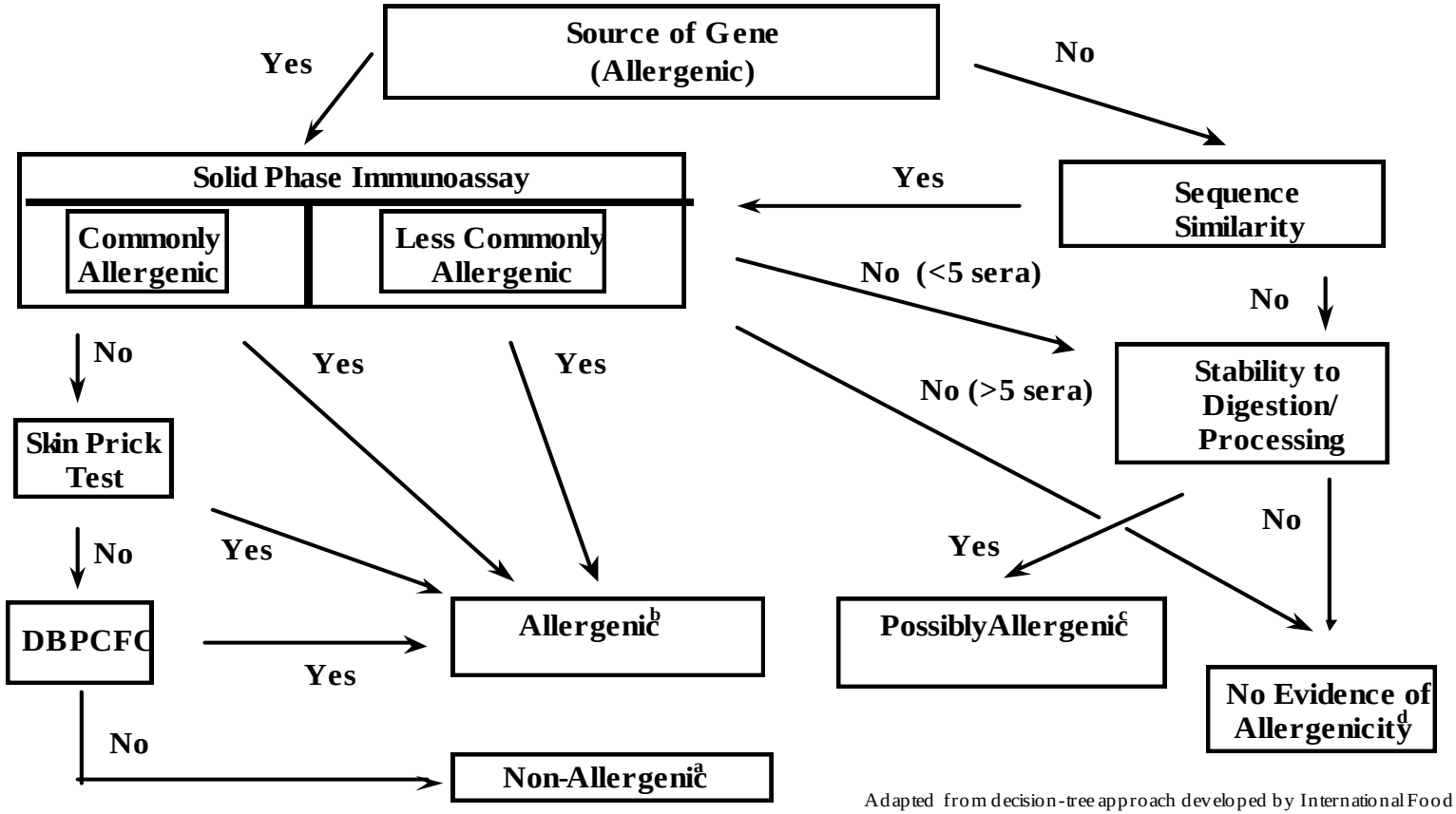
a. The combination of tests involving allergic human subjects or serum from such subjects would provide a high level of confidence that no major allergens were transferred. The only remaining uncertainty would be the likelihood of a minor allergen affecting a small percentage of the population allergenic to the source material.

b. Any positive results obtained in tests involving allergenic human subjects or serum from such subjects would provide a high level of confidence that the introduced protein was a potential allergen. Foods containing such introduced proteins would need to be labelled to protect allergic consumers.

c. An introduced protein either with no sequence similarity to known allergens or derived from a less commonly allergenic source with no evidence of binding to IgE from the serum of a few allergic individuals (<5), but that is stable to digestion and processing should be considered a possible allergen. Further evaluation would be necessary to address this uncertainty. The nature of the tests would be determined on a case-by-case basis.

d. An introduced protein with no sequence similarity to known allergens and that was not stable to digestion and processing would have no evidence of allergenicity. Similarly, an introduced protein expressed by a gene obtained from a less commonly allergenic source and demonstrated to have no binding with IgE from the serum of a small number of allergic individuals (>5 but <14) provides no evidence of allergenicity. Stability testing may be included in these cases. However, the level of confidence based on only two decision criteria is modest. Other criteria might also be considered such as the level of expression of the novel protein.

Assessment of the Allergenic Potential of Foods Derived From Modified Plants



Adapted from decision-tree approach developed by International Food Biotechnology Council and Allergy and Immunology of the International Life Sciences Institute (Metcalfe *et al*., 1996).

Chapter 8

CONSIDERATION OF ANALYTICAL METHODS: FINALIZATION BY CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

CONTENTS

1. WORK DONE IN THE TASK FORCE

First Session (2000)

1-19. The need to consider the methods of analysis, including the detection methods of genetically modified foods was also pointed out by some delegations. Several delegations were of the view that these issues also required the involvement of the Codex Committee on Food Labelling (CCFL) or the Codex Committee on Method of Analysis and Sampling (CCMAS).

1-25. For Methods (Analysis/Sampling) some delegations observed that this was primarily within the terms of reference of the Codex Committee on Methods of Analysis and Sampling (CCMAS) while others were of the opinion that the identification of methods appropriate for the detection of genetic modification should be done primarily by the Task Force. The Task Force agreed finally to include analytical methods within its work area, recognizing the use of such methods for control, monitoring and labelling purposes.

1-36. The second ad hoc Working Group, to be chaired by the Delegation of Germany, would compile a list of appropriate analytical methods for consideration by the Task Force, together with their performance characteristics and the status of their validation. To facilitate this work it was agreed that a Circular Letter would be sent to Members and interested international organizations requesting information and that the information received would be compiled by the Delegation of Germany for review by the Working Group at a one-half day meeting to be held immediately prior to the next Session of the Task Force.

Second Session (2001)

2-85. The Task Force recalled that at its 1st Session it had agreed to establish a list of available analytical methods, including those for the detection or identification of foods or food ingredients derived from biotechnology and had established a Working Group on Analytical Methods under the Chairmanship of Germany to undertake this work.16 The Working Group on Analytical Methods met on Friday, 23 March 2001. The Working Group found that different countries use different methods and that there were no internationally validated methods available at present.

2-86.On the basis of the recommendations of the Working Group on Analytical Methods, the Task Force agreed to document the present status of validation of the methods that had been reported by the member countries. It recommended that a register or depository containing relevant information on methods for the detection or identification of foods or food ingredients derived from biotechnology (as well as the availability of reference materials) be established. The Task Force agreed to prepare a Circular Letter requesting Member countries and interested international organizations:

- *to complement the existing list with documented information on further validated detection methods as well as extraction methods;*
- *to provide information on the criteria of validation as well as performance criteria and specificity of methods;*
- *to comment on the status of publication of validated methods;*
- *to provide opinions on the purpose of a register containing relevant information on methods suitable for the detection of modifications in foods or food ingredients derived from biotechnology and on criteria for their inclusion into a register;*
- *to comment on the appropriate place(s) of a register;*

- *to provide opinions on how the access to reference materials could be guaranteed.*

2-87. The Task Force agreed that there be a collaborative exchange between it and the CCMAS with a view to CCMAS considering appropriate means to validate methods of analysis with respect to biotechnology and ultimately to their endorsement. The Task Force also agreed to inform the CCFL of the progress made in this area.

2-88. In relation to the proposal to establish a register of validated methods, the Secretariat and the Representative of FAO noted that and international information exchange mechanism for food safety and agricultural health was being considered by FAO together with WHO and other partners. This internet-based system was intended to provide official information on national and international food regulations and related measures to all interested parties. Where appropriate, the information could be part of other nationally or internationally maintained data systems.

2-89. The Delegation of France drew attention to the Biosafety Clearinghouse mechanism established under the Cartagena Protocol and expressed the view that care should be taken not to duplicate the work of other UN bodies in this area. The Delegation of Italy drew attention to a register of methods being established by the Joint Research Centre of the European Commission.

3-91. The Task Force recalled that the in the last session it agreed to document the present status of validation of the methods that had been reported by the member countries. The task force also recommended that a register or depository containing relevant information on methods for the detection or identification of foods or food ingredients derived from biotechnology (as well as the availability of reference materials) be established. It further decided to send the list of collected information to the Committee on Methods of Analysis and Sampling (CCMAS) for its consideration.

3-92. Based on this decision, the circular letter was delivered to member countries: to complement the existing list with documented information on further validated detection methods as well as extraction methods; to provide information on the criteria of validation as well as performance criteria and specificity of methods; to comment on the status of publication of validated methods; to provide opinions on the purpose, appropriate place(s) of a register of a register containing relevant information on methods; to provide opinions on how the access to reference materials could be guaranteed.

3-93. The Chairperson of the Working Group on Analytical Methods informed the Task Force that the second session of the Working Group on Analytical Methods had been convened on 1 March 2001 and had considered the list of methods elaborated from the information reported by member countries in response to the circular letter and country comment on the registry. It finally agreed on the list of validated methods of analysis that contain the Annex 1 of CX/FBT 02/9 and methods reported later by Japan and United States.

3-94. The Working Group decided to recommend the Task Force;

- *to forward to the CCMAS for its consideration this agreed list submitted to the Task Force as Appendix 1, 2, 3 of CRD12*[#]
- *to propose to CCMAS to consider further methods of analysis with respect to foods derived biotechnology on the basis of the proposal from member countries*
- *to propose through Codex Alimentarius Commission (CAC) that FAO, WHO and the FAO/IAEA Joint Division for Nuclear Techniques in Food and Agriculture encourage the development and maintenance of information of methods under development or not yet validated in co-operation with national/regional institutions.*

[#]CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY SECOND MEETING OF THE WORKING GROUP ON ANALYTICAL METHODS Appendices 1 – 3

Methods Validated by Interlaboratory Studies (Revised as of May 2, 2002)

From the methods reported by the member countries*, those which have been selected for this list have been validated in interlaboratory studies with at least 5 participating laboratories and which meet CODEX criteria for the selection of methods of analysis[1]. Most of the methods are

based on the polymerase chain reaction (PCR). They are suitable to either screen for or to specifically detect recombinant DNA (rDNA). Several PCR methods can also be used to quantify the amount of rDNA. Two of the reported methods are based on the detection of a heterologous protein.

The list is organised as follows:

- Each method is referred to a food source and/or the target for which it has been designed (first column).

- For PCR based methods the primer sequences and the size of the amplicons are given (columns 2 and 3).

- The reporting countries and notifiers are indicated in column 4.

- Information on the status and the type of method (screening for common heterologous genetic elements, qualitative detection or quantification of rDNA) is given in columns 5 - 8.

- A data sheet is added for each method providing information about performance criteria.

* Appendices 1, 2 and 3 of March 1, 2002 have been compiled. The methods submitted by Japan

(Appendix 2 of March 1, 2002) have been amended considering additional data provided by Japan in April 2002.

[1] Codex Alimentarius Commission Procedural Manual, 12th Edition, p.65 and Codex Alimentarius Checklist of Information, Volume 13-1994, Chapter 1.2 Design, Conduct and Reporting of Results of Collaborative Study Supporting the Endorsement of the Method.

[#]CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY SECOND MEETING OF THE WORKING GROUP ON ANALYTICAL METHODS Appendix 4; Methods Reported by Member Countries (Revised as of March 1, 2002)

Information on all methods reported by member countries have been summarised in the attached list.

Most of the methods are based on the polymerase chain reaction (PCR). They are suitable to either screen for or to specifically detect recombinant DNA (rDNA). Several PCR methods can also be used to quantify the amount of rDNA. Some of the reported methods are based on the detection of a heterologous protein. Some information has also been provided on DNA extraction methods.

The list of methods is organised as follows:

Part I summarises the detection methods as follows:

- Each method is associated with the reporting country (listed in alphabetical order) and the food source and/or the target for which it has been designed (column 1). Those methods which meet CODEX criteria for the selection of methods of analysis[1] are marked with an asterisk.

- For PCR based methods the sizes of the amplicons are given (column 2).

- Information on the validation status and the type of method (screening for common heterologous genetic elements, qualitative detection or quantification of rDNA) is given in columns 3 - 6.

Part II contains the information provided on DNA extraction methods. The methods are referred to the reporting countries. Information on the validation status is given in column 3.

[1] Codex Alimentarius Commission Procedural Manual, 12th Edition, p.65 and Codex Alimentarius Checklist of Information, Volume 13-1994, Chapter 1.2 Design, Conduct and Reporting of Results of Collaborative Study Supporting the Endorsement of the Method.

3-95. The Task Force expressed its gratitude to the delegation of Germany for its work and approved the recommendation by the working Group. In relation to the registry, the Codex Secretariat informed the Task Force that the FAO Biosecurity Portal was under development in cooperation with WHO and other agencies. This will provide an electric information exchange mechanism that will provide a single access point for official national and international

information on food quality and safety, plant and animal life and health. It was envisaged that registries of official information, such as methods of analysis would be available through the Portal.

2. FURTHER DEBATE IN CCMAS

The 27th Session of CCMAS (2006)

84) The Committee recalled that its last session had agreed that an electronic working group led by Germany and the United Kingdom would revise the discussion paper for consideration by the next session.

85) The Delegation of the United Kingdom indicated that the paper had been revised in the light of the comments received; some of the annexes provided the information required for the validation of quantitative and qualitative methods, including the characteristics that could be used to consider existing validated methods and to assist laboratories in the determination of measurement uncertainty, while Annex VI contained a list of validated methods. Annex VII considered GMO proficiency testing and highlighted the difficulties of interpretation due to the lognormal distribution of results from a normal output, and the fact that the error was multiplicative rather than additive in GMO testing based on PCR.

86) The Delegation of Germany drew the attention of the Committee to the provisions in the texts on risk analysis of foods derived from biotechnology developed by the Ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology (TFBT), especially the need to ensure traceability, which required adequate methods of analysis, and recalled that a number of validated methods existed, as appeared in the list considered by an earlier session of the TFBT. The Delegation also noted that ISO and CEN had developed several methods both for quantitative and qualitative determination.

87) The Delegation of the EC stressed the importance of this work as several problems of methodology existed in the identification of foods derived from biotechnology and expressed the view that it was premature to undertake new work at this stage, but that the document should be revised for further consideration by the Committee. The Delegation also drew the attention of the Committee to its specific comments in CRD 18.

88) Some delegations proposed to delete the reference to GMO in the document and to replace it with a reference to foods derived from biotechnology or from "modern biotechnology". The Delegation of Brazil suggested that the terminology should be harmonized with the document already approved by the Ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology.

89) The Delegation of the United States referred to its specific comments in CRD 5 and proposed to consider the revised discussion paper at the next session. The Delegation proposed that the document should be considered for publication by FAO rather than considered in the framework of Codex as this might make this important document available to governments more rapidly. The Secretariat indicated that this proposal would be referred to FAO and WHO but that usually FAO and WHO published the results of expert consultations or related work conducted by the organisations themselves.

90) The Delegation of Cuba expressed the view that priority should be given to the qualitative protein based methods as the use of DNA detection with PCR methods were not available or too costly for developing countries.

91) Some delegations drew the attention of the Committee to their detailed comments on specific sections of the document. The Committee however agreed that the document would not be considered in detail at this stage, as it should be redrafted before the Committee could take a decision as to further work. The Committee expressed its appreciation to the Delegations of Germany and the United Kingdom for their comprehensive work in this complex area and agreed that they would redraft the discussion paper in the light of the written comments, with the assistance of interested delegations, for consideration at the next session.

28th Session (2007)

CRITERIA FOR THE METHODS FOR THE DETECTION AND IDENTIFICATION OF FOODS DERIVED FROM BIOTECHNOLOGY (Agenda item 6)

103) The Committee recalled that its last session had agreed that an electronic working group led by Germany and the United Kingdom would revise the discussion paper for consideration by this session.

104) The Delegation of Germany informed the Committee that a new revised document (CRD 18) had been prepared during the current session with assistance of the delegations of the United States, France, European Community and United Kingdom, taking into account all comments made at previous sessions of the Committee, and proposed that this document be considered by the Committee.

105) It was indicated that an effort had been made to incorporate these comments into the revised document and particularly to address the concerns expressed previously to include protein-based methods in addition to PCR–based methods. The Committee was informed that the document comprised a general section and six annexes providing information that needed to be provided when a method is to be considered for endorsement by the Committee; applicable definitions; validation of PCR-based and protein-based methods and proficiency testing of foods derived from biotechnology. The Delegation proposed that the Committee consider the document further and that it be brought forward as a new work item.

106) The Delegation of the European Community, supported by the Delegation of Norway, stressed the importance of this work in the light of increasing introduction of foods derived from biotechnology and the need for identification of methods using the criteria approach and thus supported its development as a new work item.

107) The Delegation of the United States, supported by several delegations, while acknowledging the importance of the revised document, noted that it had been available only at the session, proposed that the document be circulated to members of the electronic working group and revised as necessary for consideration by the next session.

108) Several delegations also indicated that in addition to the revision of the document which seemed to focus on guidance within Codex, that there was a need for guidance to member countries and proposed that the electronic working group consider the development of such guidance.

109) To the question of the Delegation of Cuba on whether the document should be submitted to the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology for review, it was clarified that the work under discussion originated from that Task Force as well as the Committee on Food Labelling, that the Task Force was mainly responsible for the development of guidance on risk assessments for foods derived from biotechnology and that the work of this Committee was notified to other Codex Committees where necessary through the standard item of matters referred.

110) The Committee held considerable discussion on whether the revision of the document should also be considered by a physical working group either prior to the next session or between sessions as a means of facilitating discussion at the next session. Many delegations preferred the establishment an inter-session physical working group as this would allow sufficient time for the circulation of the revised document for consideration by members, which would not be the case if the group met prior to the session.

111) Following this discussion, it was agreed that the electronic working led by the Delegations of Germany and the United Kingdom would revise the current document and in addition would give consideration to the development of guidelines for governments and prepare a project document as a proposal for new work. It was further agreed to establish a physical working group to be hosted by Germany that would meet inter-session, if necessary, in accordance with the guidelines for physical working groups in the Procedural Manual. The Committee emphasized that the revised document would need to be circulated to members well in advance of the next session to allow for its thorough consideration.

The 29th Session of CCMAS (2008)

CRITERIA FOR THE METHODS FOR THE DETECTION AND IDENTIFICATION OF FOODS

DERIVED FROM BIOTECHNOLOGY (Agenda Item 6)

87) The Committee recalled that its last session had agreed that an electronic working group led by the Delegations of Germany and the United Kingdom would revise the document discussed at that session and in addition would give consideration to the development of guidelines for governments and would prepare a project document as a proposal for new work.

88) The Delegation of Germany, also speaking on behalf of the Delegation of the United Kingdom, as the lead of the electronic working group, introduced the document and informed the committee that the document had been revised taking into consideration comments received, that changes made were not too substantial and that the structure had been maintained. The Delegation also reminded the committee that the ad hoc Task Force on Foods Derived from Biotechnology had encouraged the Committee to proceed with work in this regard. The Delegation, referring to the Principles for the Risk Analysis of Foods Derived from

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Modern Biotechnology (CAC/CL 44-2003), further indicated that for post market monitoring of foodstuffs derived from biotechnology specific risk management tools such as analytical methods were needed and recommended that the Committee consider new work on guidelines as presented in the project document in CRD 21.

89) The Delegation of Argentina, referring to its comments in CRD 4, indicated the need to proceed with caution when developing criteria for methods since reference materials and proficiency testing were necessary for this approach but were not always available.

90) The Delegation of the United States, supported by the Delegation of Australia, referring to its comments in CRD 13, expressed the view that there was no clearly defined need in Codex for methods as no provisions existed and that development of methods were not in line with Codex strategic objectives, in particular as ISO had active work in this area and such work in the Committee could lead to duplication. The Delegation proposed to forward the paper to FAO who could convene an expert consultation to use the paper as a basis for a guidance document for Governments. The Delegation further stated that only once specific provisions requiring detection and identification of foods derived from biotechnology had been established in Codex, development of guidelines should be considered.

91) The Delegation of the EC expressed support for new work as presented in CRD 21 emphasizing that the development of guidelines was essential for future work of Codex, that it would be useful to have methods to assess the foodstuffs entering the market to ensure fair practices in the food trade, and that this was important work particularly for developing countries.

92) In noting the clarification by the Secretariat that since the proposal for new work was guidance for governments, reference to Codex committees in the section on assessment against the criteria for the establishment of work priorities should be deleted, the Committee agreed to revise the project document accordingly.

93) In view of the discussion, the Committee agreed to the proposal for new work and agreed to submit the revised project document, as amended in paragraph 92, to the 31st Session of the Commission for approval as new work, as part of the working document including all proposals for new work. Subject to the decision of the Commission, the Proposed Draft Guidelines as presented in the working document (CX/MAS 08/29/8) would be circulated at Step 3 for comments and consideration by the next session of the Committee. The Delegations of the United States, Australia and New Zealand expressed their opposition to this decision to undertake new work.

The 30th Session of CCMAS (2009)

PROPOSED DRAFT GUIDELINES ON CRITERIA FOR METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS, IN PARTICULAR IN FOODS DERIVED FROM MODERN BIOTECHNOLOGY (Agenda Item 3)3

13. The Committee recalled that the last session had agreed to return the text to Step 2 for

redrafting by an electronic working group co-chaired by Argentina, Germany and the United Kingdom for circulation for comments and consideration by this Session.

14. The Delegation of Argentina introduced the report of the electronic Working Group and explained the process followed in the development of the text and of the success of using an internet platform, specially created to undertake the work of the Committee, which had greatly facilitated participation by large number of countries. This mechanism was available for use by other members and future Codex working groups. The Committee noted the unusually large number of active participants in developing the guidelines. This number clearly indicated the importance and relevance of the document.

15. Although the working group had taken into account the expansion of the scope as agreed by the last session, a final solution regarding the scope-related language could not be reached and in relation to this the working group had also proposed several options for the title. However, consensus had been reached on the majority of the remainder of the text.

16. The Committee expressed its appreciation to Argentina and the working group for the excellent work done.

17. The Committee agreed to first clarify the scope before continuing with further discussion on the proposed guidelines.

General Discussion (Scope)

18. Several delegations expressed their support for the broadening of the scope and thus their support for alternative paragraph 6:

"These guidelines provide information criteria for the validation of food analysis methods involving the detection, identification and quantification of specific DNA sequences and specific proteins of interest that may be present in foods and that will be used by laboratories responsible for food analysis. These methods can provide molecular and immunological approaches for, including among other uses, tests for food authenticity, and biomarkers for foods containing material derived from recombinant- DNA organisms"

and as a consequence alternative title 1:

"Proposed Draft Guidelines on Performance Criteria and Validation of Methods for Detection,

Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods". *The Delegation of Argentina explained that alternative paragraph 6 was clearer and explicitly referred to biomarkers for foods derived from modern biotechnology while the original paragraph was not appropriate since the phrase "in foods derived from modern biotechnology" was used in a way that could be interpreted as being the matrix and not the analyte, which was not the original intention of the work.*

19. The Delegation of Japan expressed the view that the document was comprehensive and informative, but contained too much detail and needed to focus on essential points. With regard to the scope, the Delegation reminded the Committee that the last session had had extensive discussion on the scope and that the discussion should not be re-opened and should rather focus on the proposed text. This view was supported by the Delegation of the Republic of Korea.

20. The Delegation of the European Union emphasized the importance of the work in view of the need for methods to identify genetically modified foods and while recognizing the decision to broaden the scope, expressed support for the original title which in its view would still be appropriate even with an expanded scope. The Delegation also recalled that the initial mandate to carry out this work was focused on methods to identify genetically modified foods, the need for which had on several occasions been underlined by both the Task Force on Foods Derived from Biotechnology and the Committee on Food Labelling. It therefore expressed the view that alternative paragraph 6 could be supported if it were amended to indicate that methods used could also be applied to foods derived from modern biotechnology.

21. To a proposal to use "recombinant DNA organism" rather than "modern biotechnology", it was clarified that the term "modern biotechnology" was widely understood and defined within Codex.

22. Following discussion, the Committee agreed to alternative paragraph 6 amended to indicate

that foods derived from modern biotechnology were covered in the scope.

23. The Committee further agreed that an in-session working group, chaired by Argentina, would revise the body of the text taking into account the agreed scope and the written comments received.

TITLE

24. Several delegations expressed support for the alternative Title I which did not refer to foods derived from biotechnology, noting that there was no need to place specific emphasis on foods derived from modern biotechnology, as stated in the original proposal since this aspect was already covered by the scope and would be misleading to the user as these techniques were also used for authentication of foods and other purposes. Several other delegations expressed support for the original title stating that it reflected the agreed upon scope, was clear to users and in line with the original intent of the work to develop guidelines for methods for foods derived from modern biotechnology. Some delegations pointed out that the Commission had requested the Committee to consider expanding its scope, which it had done and that there was no need to repeat the scope in the title and that it should be kept short, simple and understandable.

25. The Committee considered several proposals to shorten the title by simply referring to "analysis" rather than to "detection, identification and quantification" and to indicate that the methods referred to in the guideline were applicable to not only identification of foods derived from modern biotechnology, but also for food authentication, food speciation and other purposes (e.g. identification of allergens, pathogens, etc) either in a footnote or directly in the title. Some concerns were raised regarding the use of a footnote since users did not necessarily read footnotes and that footnotes did not appear in the titles of texts published on the Codex website and it would thus not be immediately clear to the user that the guidelines also applied to foods derived from modern biotechnology. It was pointed out that users of the described techniques would be familiar with its applications including that for foods derived from modern biotechnology.

26. After extensive discussion, the Committee agreed to the alternate Title I and inserted a footnote to indicate the application of the methods.

Body of the guidelines

27. The Committee considered the revised guidelines (CRD 27) as prepared by the in-session working group noting that the basis for discussion in the working group was CRD 3 which integrated all written comments received.

28. In addition to editorial corrections, improvement of text for purposes of clarity and updating of references, the Committee took the following decisions:

Section 4.1.4 – Unit of Measurement and reporting of results

29. The Committee considered the last section of paragraph 22 which had been square-bracketed due to lack of consensus in the working group. Following the explanation by the Delegation of Argentina that reference to "biological uncertainty" was not appropriate for this section; that its inclusion was misleading noting that "uncertainty" was related to method error distribution and not to other external factors; and that it was not relevant for food purposes, the Committee agreed to its deletion.

Methods acceptance criteria summary table

30. The Committee considered a proposal by the Delegation of Japan to insert a table summarizing the method acceptance criteria referred to in the Annexes of the Guidelines for better readability, as presented in CRD 28.

31. After discussion, the Committee agreed not to proceed with the insertion of the Table as criteria were clearly specified in the Annexes and it was difficult to summarize the information from the Annexes in one table.

32. In recognition of the extensive discussion and agreement reached, the Committee agreed to advance the Guidelines to Step 5/8 for adoption.

Status of the Proposed Draft Guidelines

33. The Committee agreed to forward the Proposed Draft Guidelines to the 33rd Session of the

Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see AppendixIII).

APPENDIX III

PROPOSED DRAFT GUIDELINES ON PERFORMANCE CRITERIA AND VALIDATION OF METHODS FOR DETECTION, IDENTIFICATION AND QUANTIFICATION OF SPECIFIC DNA SEQUENCES AND SPECIFIC PROTEINS IN FOODS* (At Step 5/8 of the Procedure)

* for applications such as food derived from modern biotechnology, food authentication, food speciation and other purposes

SECTION 1 – INTRODUCTION

1. Molecular and immunological analytical methods are currently the recognized tools for determination of DNA and protein analytes in foods. However, in order for the results obtained by such methods from different laboratories to gain wide acceptability and confidence as reliable, there is need for the analytical methods to satisfy certain quality criteria.

2. These guidelines provide appropriate criteria to validate the performance of methods developed to detect specific DNA sequences or specific proteins in foods.

3. Information relating to general considerations for the validation of methods for the analysis of specific DNA sequences and specific protein is given in the first part of these Guidelines. Specific annexes are provided that contain information on validation of quantitative Polymerase Chain Reaction (PCR) methods, validation of qualitative PCR methods and validation of protein-based methods**.**

SECTION 1.1 – PURPOSE AND OBJECTIVES

4. The goal of this document is to support the establishment of molecular and immunological methods for detection, identification and quantification of specific DNA sequences and specific proteins in foods, which produce results with comparable reproducibility when performed at different laboratories

5. The guidelines are aimed at providing guidance on how to establish methods to detect and identify specific DNA sequences and proteins in food by defining appropriate validation criteria, and whether or not a method complies with these criteria based on the performance characteristics of a method. The guidelines specify the relevant criteria and give explanations on how to consider these criteria, i.e.:

-by providing the rationale for the most relevant criteria and

-by showing how to find out whether or not a method fulfils the given criteria requirements.

SECTION 1.2 SCOPE

6. These guidelines provide information on criteria for the validation of food analysis methods involving the detection, identification and quantification of specific DNA sequences and specific proteins of interest that may be present in foods, including those foods containing materials derived from modern biotechnology. These molecular and immunological methods are applicable to a wide range of uses such as tests for biomarkers in foods, including those derived from modern biotechnology and food authentication, and may be used by laboratories responsible for food analysis.

SECTION 2 – METHOD VALIDATION

7. The Codex Alimentarius Commission places an emphasis on the acceptance of methods of analysis which have been validated through a collaborative trial conforming to an internationally accepted protocol according to ISO 5725:1994 or the AOAC/IUPAC Harmonized Protocol. In this area there may be a need to adopt a formal single-laboratory validation as an interim measure in the absence of collaborative trial data. However, methods used for the analysis of DNA sequences and proteins, must be capable of being performed in many laboratories.

Section 2.1 – Criteria Approach

8. These guidelines apply the “criteria approach”.

Section 2.2 – General Method Criteria

9. The general criteria for the selection of methods of analysis have been adopted in the Codex Procedural Manual. Such criteria are applied in this guideline. Additional criteria are described in the appropriate annexes.

Section 2.3 – Validation Process

10. Method validation is a process to establish the performance characteristics and limitations of an analytical method. The results of a validation process describe which analytes can be determined in what kind of matrices in the presence of which interference. The validation exercise results in precision and trueness values of a certain analytical method under the examined conditions.

11. Formal validation of a method is the conclusion of a long process, which includes the following main steps:

• ***Pre-validation of the method***. Pre-validation should be performed on a case-by case as needed. Pre-validation should ensure that a method performs in a manner, which allows a successful conclusion of the validation study, i.e. it should provide evidence about the suitability of the method for its intended purpose. Pre-validation should preferably be carried out by involving 2 - 4 laboratories. Statistical analyses (e.g. of "repeatability" and "reproducibility") should be made according to the validation procedure to be subsequently used.

• ***Validation of the method.*** Validation through a collaborative trial is expensive to undertake and usually follows only after the method has shown acceptable performance both in a single laboratory and a pre-validation study.

SECTION 3 – SPECIFIC CONSIDERATION FOR THE VALIDATION OF METHODS FOR THE DETECTION, IDENTIFICATION AND QUANTIFICATION OF DNA SEQUENCES AND PROTEINS

Section 3.1 – Method Development to Formal Validation

12. Common methodologies for DNA-based analysis are PCR-based methods used to detect a specific (targeted) DNA sequence. Common approaches for protein utilize Enzyme-Linked Immuno-Sorbent Assay (ELISA) and lateral flow devices. For DNA-based analysis, the PCR approach is presently most widely applied, although other DNA-based methods that achieve the same objective may be employed if properly validated. Both DNA and protein-based approaches are considered here.

Section 3.1.1 – Method Acceptance Criteria (Required condition for validation)

13. In order to evaluate a method prior to validation, information concerning both the method and the method testing is required, as detailed in Annex I.

14. The method evaluation should verify that the principle preconditions for using the method for Codex purposes are fulfilled. This section describes the method acceptance criteria, which have to be fulfilled by the method in order to conduct a pre-validation and full collaborative trial.

Section 3.1.2 – Applicability of the Method

15. Applicability of the methods could be determined by confirming whether the methods may be used in the intended foods with the required performance and it should be clearly stated. Especially, in analysis of the DNA sequences and protein, some methods that can be applied to a single raw matrix may not be necessarily applicable to complex matrices and/or processed food, since the DNA and protein may be altered.

16. In principle the method should be applicable to the matrix of concern. In the case of "general purpose" methods to identify and quantify DNA sequences and proteins in a range of food matrices, at least one extraction method applicable to a general food matrix should be available.

Section 3.1.3 – Principle condition

17. DNA-based methods should detect, identify and may quantify the levels of specific DNA sequence(s). Protein-based methods should detect, identify and may quantify the level of a specific protein in the product.

18. Currently, the DNA-based detection method typically consists of PCR methodology and

includes:

• a protocol describing an extraction method which is applicable to a relevant matrix;

• a protocol describing the conditions, including the apparatus used, under which PCR can be used to detect the target DNA sequence;

• a description of the oligonucleotide primer sequences which uniquely amplify the target DNA sequence;

• If applicable, a description of the fluorescent oligonucleotide probe sequence which uniquely identifies the target DNA sequence.

• a description of oligonucleotide primer sequences, which amplify a taxon-specific DNA sequence that should be present in the conventional food matrix irrespective of the presence of the specific analyte, in order to differentiate a negative result from failed extraction/amplification processes, and to quantify the amount of target DNA relative to the taxon-specific DNA.

• if applicable, a description of the fluorescent oligonucleotide probe sequence which uniquely identifies the taxon-specific DNA sequence.

• a description of the method used to detect the DNA

• appropriate control samples and standards.

• descriptions of calculations used to derive the result.

19. Protein-based methods typically consist of a quantitative or qualitative method. These are usually immuno-sorbent analysis systems, and consist of the following:

• a protocol describing an extraction method which is applicable to a relevant matrix;

• a protocol describing the conditions, including the apparatus used, under which immunosorbent analysis can be used to detect the target protein;

• an antibody-coated support,

• an enzyme-conjugated secondary antibody,

• an enzyme substrate for colour development, and washing buffer and sample extraction buffer.

• a description of the method used to detect the protein

• appropriate control samples and standards.

• descriptions of calculations used to derive the result.

20. The method should fulfil the requirements below:

• Protein-based methods should allow for unequivocal detection, identification and/or quantification of a specific antigen or epitope.

• DNA-based screening methods are used to detect a target DNA present in multiple organisms. For instance, screening methods that are used to detect multiple transformation events should allow for detection of a target DNA sequence which is common to a number of transformation events.

• DNA-based specific methods that are used for unequivocal detection, identification and/or quantification of a specific organism which could be mixed with similar organisms should allow for the unequivocal detection, identification and/or quantification of a DNA sequence that is unique or specific to that organism. For instance, target-specific methods that are used for detection of a single transformation event should allow for unequivocal detection, identification and/or quantification of a DNA sequence that is unique or specific to that transformation event. For food authentication, the specific target sequence/s should uniquely define the taxon as required.

• DNA-based taxon-specific methods that are used for detection or relative quantification of target DNA should allow for unequivocal detection, identification and quantification of a DNA sequence that is unique or specific to that taxon

• For target and taxon-specific methods used in relative quantification, identification of the amplified fragment, by e.g. probe hybridization or any appropriate equivalent method, is recommended.

Section 3.1.4 – Unit of Measurement and reporting of results

21. Appropriate units of measurement (e.g. target copy numbers or molar equivalents), performance and data reporting criteria should be specified for each method prior to their use. For qualitative analysis, the results can be provided as present or not detected and for this reason there is no unit of measurement.

22. Measurements may be explicitly expressed as weight/weight or by relative percentage. However, none of the current methods (DNA or protein based) are able to measure them directly.

Section 3.1.5 – Measurement Uncertainty

23. As mentioned in the Codex Guideline on Measurement Uncertainty (CAC/GL 54-2004), laboratories are required to estimate the uncertainty of their quantitative measurements. Sample preparation and analytical methods are two significant sources for error that should be considered when evaluating an analytical measurement. Analysts using methods which have been validated according to these guidelines should have sufficient information to allow them to estimate the uncertainty of their result.

24. For details, refer to the Codex Guideline on Measurement Uncertainty (CAC/GL 54-2004), the section entitled "*The Use of Analytical Results: Sampling Plans, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standard*" from the Codex Procedural Manual.

Section 3.1.6 – Modular Approach to Method Validation

25. The "method" refers to all the experimental procedures needed to estimate the measure and in a particular matrix. For a particular material this may include the processes for DNA or protein extraction and the final quantification in a PCR or Immuno-sorbent assay system, or a determination of the presence or absence of the analyte via a qualitative method. In such a case, the whole chain from extraction up to the analytical step constitutes a method. However, it may be possible to use the same sample preparation (e.g. grinding) method in combination with the same DNA or protein isolation process for several different subsequent analyses to achieve economic efficiencies as long as the validated method processes remain the same.

26. It would be inappropriate to substitute alternative processes, such as a different DNA or protein isolation process, into a validated method without conducting additional studies to show that the substitution does not affect the performance of the method.

Section 3.2 – Collaborative Trial Requirements

Section 3.2.1 – General Information

27. The purpose of a collaborative trial is to validate the data provided by previous testing in a pre-validation or a single laboratory exercise and to determine methodological precision in terms of repeatability and reproducibility.

28. The values of any performance parameters reported from validation studies should be interpreted and compared with care. The exact values and their interpretation may depend – besides the performance of the method - on the extent of the method.

29. If a collaborative trial has been conducted according to the ISO 5725:1994 or the AOAC/IUPAC Harmonized Protocol, then this information can be used to assess the acceptability of the method.

Section 3.2.2 – Minimum Performance Requirements

30. In a collaborative trial, the method performance should comply with the relevant parts of the method acceptance criteria and fulfil the method performance requirements specifically set below for the collaborative trial. In particular, the compliance with the criteria for sensitivity and repeatability/reproducibility standard deviations and trueness should be assessed.

31. In addition to the method acceptance criteria, at least the method performance requirements listed in Annex I should be evaluated from the experimental data of a collaborative trial.

32. The methods and their associated validation data will be revised on a regular basis as the scientific knowledge and experience gained in validation and collaborative trials evolve. These Guidelines are complemented with practical information about the operational steps of the

validation process.

Section 3.2.3 – Collaborative Trial Test Materials

33. In principle, the method should be applicable to and tested on the matrix of concern (i.e. on which any specification has been made).

34. The effects of materials/matrices on the extraction step in a protocol are important to any analysis. When the results of a validation study are reported, it is important that the report includes details of which matrix was analyzed and whether a purified protein or DNA was used as the target for the analysis.

Section 3.2.4 – Specific Information on the Validation of Methods

35. Specific information on the validation of quantitative and qualitative PCR methods is given in Annexes II and III respectively.

36. Specific information on the validation of quantitative and qualitative protein-based methods is given in Annex IV.

SECTION 4 – QUALITY CONTROL REQUIREMENTS

Section 4.1 – Laboratory Quality

37. CAC/GL 27 provides guidance for laboratories involved in the import and export of foods. This guidance is based on compliance with ISO/IEC Standard 17025, proficiency testing and internal quality control as well as the use of methods of analysis validated according to Codex requirements.

Section 4.2 – Reference Material

38. A suitable reference material is generally required for the validation of a method. There are a number of matrices that can be used to develop reference materials or working standards for methods of detection of DNA sequences and proteins. Each has its own advantages and drawbacks for particular purposes. The physical form of the reference material determines its suitability for use with any given method. For ground materials, differences in particle size distribution between reference materials and routine samples may affect extraction efficiency of the target protein or DNA and method reproducibility due to sampling error.

39. Reference material for DNA based methods can be a matrix containing the analyte, DNA extracted from matrix containing the analyte, a plasmid containing the specific DNA, or if certified reference materials are not available, control sample materials, for example from proficiency testing schemes. Use of plasmid or amplicon DNA requires careful consideration of the choice to be incorporated into the plasmid or amplicon to ensure that the plasmid or amplicon DNA will be fit for the required purpose.

40. Reference materials for protein-based methods can be e.g. the protein itself purified from recombinant microbes (such as *E. coli*), a ground plant matrix (typically leaf or grain), or a processed food fraction.

SECTION 5 – TECHNICAL AND METHODOLOGICAL INFORMATION

Technical and methodological aspects of DNA and protein-based methods are listed as references:

- Allmann M, Candrian U, Hoefelein C and Luethy J (1993). Polymerase Chain Reaction (PCR): a possible alternative to immunochemical methods assuring safety and quality of food. *Lebensm. Unters. Forsch* 196:248-251.
- Anklam E, Gadani F, Heinze P, Pijnenburg H and Van den Eede G (2002). Analytical methods for Detection and Determination of Genetically Modified Organisms (GMO's) in Agricultural Crops and Plant-derived Food Products. *European Food Research and Technology* 214:3-26.
- Asensio L (2007). Review: PCR-based methods for fish and fishery products authentication. *Trends in Food Science & Technology* 18(11): 558-566.
- Asensio L, Gonzalez I, Garcia T and Martin R (2008). Determination of food authenticity by enzyme-linked immunosorbent assay (ELISA). *Food Control* 19:1-8.
- Carnegie, PR (1994). Quality control in the food industries with DNA technologies.

Australas. Biotechnol. 4(3):146-9.

- Chapela MJ, Sotelo CG, Pérez-Martín RI, Pardo MA, Pérez-Villareal B, Gilardi P and Riese J (2007). Comparison of DNA extraction methods from muscle of canned tuna for species identification. *Food Control.* 18(10):1211-1215
- Codex Alimentarius Commission Procedural Manual. The Use of Analytical Results: Sampling Plans, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards. CAC/GL 54-2004. Codex Guidelines on Measurement Uncertainty.
- Colgan S, O'Brien LO, Maher M, Shilton N, McDonnell K and Ward S (2001). Development of a DNAbased assay for species identification in meat and bone meal. *Food Research International* 34(5):409-414.
- Dahinden I, von Büren M and Lüthy J (2001). A Quantitative competitive PCR system to detect contamination of wheat, barley or rye in gluten-free food for coeliac patients. *European Food Research and Technology* 212(2):228-233.
- Dieffenbach CW and Dveksler GS (1993). Setting up a PCR laboratory. *PCR Methods Appl.* 3(2):S2-7.
- ISO 5725:1996 Accuracy (Trueness and Precision) of Measurement Methods and Results. Geneva: International Organization for Standardization.
- ISO 21569:2005 Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Qualitative nucleic acid based methods. Geneva: International Organization for Standardization.
- ISO 21570:2005. Foodstuffs - Methods for the detection of genetically modified organisms and derived products - Quantitative nucleic acid based methods. Geneva: International Organization for Standardization.
- ISO/DIS 24276:2006. Foodstuffs - Nucleic acid based methods of analysis for the detection of genetically modified organisms and derived products - General requirements and definitions. Geneva: International Organization for Standardization.
- ISO/IEC Standard 17025:2005. General requirements for the competence of testing and calibration laboratories. Geneva: International Organization for Standardization.
- Grothaus GD, Bandla M, Currier T, Giroux R, Jenkins R, Lipp M, Shan G, Stave J., and V. Pantella (2007). Immunoassay as an Analytical Tool in Agricultural Biotechnology. *Journal of AOAC International.* 85: 3, pp 780-786.
- Holst-Jensen A. and Berdal KG (2004). The modular analytical procedure and validation approach and the units of measurement for genetically modified materials in foods and feeds. *Journal of AOAC International* 87(4):927-36.
- Horwitz E. ISO/AOAC/IUPAC Harmonized Protocol for the Design, Conduct and Interpretation of Method- Performance Studies (1995). *Pure and Applied Chemistry* 67:331-343.
- Kwok S and Higuchi R (1989). Avoiding false positives with PCR. *Nature* 339(6221):237-238.
- Lipp M, Shillito R, Giroux R, Spiegelhalter F, Charlton S, Pinero D and Song P (2005) Polymerase Chain Reaction Technology as an analytical tool in Agricultural Biotechnology. *Journal of AOAC International* 88 (1):36-155.
- Meyer R, Candrian U (1996). PCR-based DNA Analysis for the Identification and Characterization of Food Components. *Lebensmittel-Wissenschaft und-Technologie*. 29(1-2):1-9.
- Mifflin TE (2007) Setting Up a PCR Laboratory. *Cold Spring Harbor Protocols* 14 (doi:10.1101/pdb.top14)
- Miraglia M, Berdal KG, Brera C, Corbisier P, Holst-Jensen A, Kok EJ, Marvin HJP, Schimmel H, Rentsch J, van Rie JPPF and Zagon J (2004). Detection and traceability of genetically modified organisms in the food production chain. *Food and Chemical Toxicology* 42:1157-1180.

- Newton CR, Herbitter A and Gubler U (1995). PCR: Essential Data. Hoboken (NJ): J. Wiley & Sons.
- Olexova L, Dovičovičová L, Švec M, Siekel P, Kuchta T. (2006). Detection of gluten-containing cereals in flours and “gluten-free” bakery products by polymerase chain reaction. *Food Control* 17(3):234-237 .
- Poms, RE; Klein CL, Anklam E (2004). Methods for allergen analysis in food: a review. *Food Addit. Contam*. 21(1):1-31.
- Trapmann S, Burns M, Broll H, Macarthur R, Wood RKS, Žel Jana (2009). Guidance document on measurement uncertainty for GMO testing laboratories. *EUR - Scientific and technical research series*.
- Luxembourg: Office for official publications of the European communities.
- Turci M, Sardaro MLS, Visioli G, Maestri E, Marmiroli, M and Marmiroli N (2010). Evaluation of DNA extraction procedures for traceability of various tomato products. *Food Control*. 21(2):143-149.
- Williams R. (2005). Gene tests served up to tell fine foods from fakes. *Nature* 434:262.
- Woolfe M and Primrose S (2004). Food forensics: using DNA technology to combat misdescription and fraud. *Trends in Biotechnology* 22(5):222-6.

ANNEX I: REQUIRED INFORMATION WHEN METHODS ARE TO BE CONSIDERED FOR USE

1. A complete and detailed description of all the components of the method should be provided. The use of multiple plates for PCR and protein methods, as an example, should be explicitly addressed. The description should also include information on the scope of the method, and the unit of measurement should be clearly indicated, as well as the following:

Purpose and relevance of the method

2. The purpose of the method should be indicated in the method. The method should be fit for purpose for the intended use.

Scientific basis

3. An overview of the scientific principles on which the method is based (e.g., the molecular biology underlying the use of a real-time PCR method) should be provided.

Specification of the prediction model/mathematical model needed for the method

4. The DNA and protein-based techniques used to detect and quantify DNA sequences and proteins are based on different principles. In PCR the targeted DNA is amplified in an exponential manner. Moreover, the quantification by real-time PCR is often based on two independent PCR assays: one for the target DNA and one for the taxon specific DNA sequence. In contrast to PCR, immuno-sorbent assays involve binding one or more layers of antibodies to each initial target molecule, and amplification of the signal is proportional to the number of reporter molecules and, if applicable, the enzymatic reaction time.

5. If the derivation of the results relies upon a mathematical relationship this should be outlined and recorded (e.g., ΔΔCt method or a regression line or calibration curve obtained by other means). Instructions for the correct application of the model should be provided. These may include, depending on the method, a recommended number and range of levels to be analyzed, minimum number of replicates and/or dilutions to be included for routine analyses or the means and confidence intervals to evaluate the goodness-of-fit.

SPECIFIC INFORMATION REQUIRED FOR DNA-BASED METHODS

6. For DNA-based procedures, the following additional information should be supplied in particular:

Primer pairs

7. General methods have to provide the defined primer pairs and the sequence they target. Recommendations as to the efficiency/use of primer set have to be clearly stated, including if the primers are suitable for screening and/or quantification.

• ***Amplicon length***

8. Food processing will generally lead to a degradation of target DNA. The length of the amplified product may influence the PCR performance. Therefore the selection of shorter amplicon sizes (within reason) will increase the possibility to get a positive signal in the analysis of highly processed foodstuffs. In general the length of the amplified fragment for the taxon-specific DNA sequence and the target sequence should be in a similar size range.

• ***whether the method is instrument or chemistry specific***

9. At the moment a number of different types of real-time instruments and chemistries are available. These instruments and chemistries may have different performance such as stability of reagents, heating and cooling characteristics, which affects ramp rates and affects the time necessary for a whole PCR run.

10. Beside the differences in the heating and cooling system there are differences in the technique and software used to induce and subsequently to record the fluorescence. The detection and quantification of the fluorescence could also vary according to the recording instruments and software used. Qualitative methods generally tend to be less instrument-specific than quantitative methods.

11. The methods are generally instrument and chemistries dependent and cannot be transferred to other equipment and chemistries without evaluation and/or modification.

• ***whether single- or multi-plex PCR amplifications are undertaken***

12. Using more than one primer set in a single reaction is called multi-plex PCR.

13. The information provided should demonstrate the robustness of the method for inter-laboratory transferability. This means that the method should have been tested by at least one other laboratory besides the laboratory which has developed the method. This is an important pre-condition for the success of the validation of the method.

SPECIFIC INFORMATION REQUIRED FOR PROTEIN-BASED METHODS

14. The following additional information should be supplied for protein-based procedures:

Assay applicability

15. Food processing will generally lead to degradation or denaturation of the target protein, which may result in a substantial change in immunoreactivity. Immunoassays should be evaluated for applicability to the target in processed products. Empirical results from testing the method for applicability for target in processed foods should be provided.

Hook Effect

16. In an antibody-based lateral flow device and plate format assay, a hook (saturation) effect could lead to a false negative result. A thorough demonstration that the working concentration range comfortably covers the practical need of target analytical samples is necessary. Therefore, empirical results from testing for a hook effect in target matrices should be provided.

Confirmatory method

17. For immunoassays**,** antibodies may cross-react with other proteins present in the matrix; thus, it is necessary to demonstrate the selectivity of assays. Another method may be used as a confirmatory method. Empirical results from testing both methods with aliquots of the same analytical samples of known concentration may be provided.

INFORMATION ABOUT THE METHOD PERFORMANCE

Selectivity testing

18. The method has to be clear on the use of appropriate negative controls, such as animal and plant-derived material, different strains or target DNA sequence which should be used with this purpose, if those have been defined.

19. Empirical results from testing the method with DNA from non-target species/varieties and DNA from the reference species/variety material should be provided. This testing should include closely related materials and cases where the limits of the sensitivity are truly tested. In addition it might be appropriate, particularly or taxon-specific DNA sequence, to test other sources of similar foods to reduce the potential for obtaining a false positive.

20. Similarly, for protein methods, empirical results from testing the method with proteins from non-target and closely relevant species/varieties/traits, and purified target protein and/or reference positive control materials should be provided.

Stability testing

21. Empirical results from testing the methods (to detect both reference and target DNA sequences, or proteins) with different species, subspecies, varieties, cultivars, animal lines, or microbial strains as appropriate, may be provided in order to demonstrate, for instance, the stability of the copy number and sequence conservation of the taxon-specific gene DNA, or the stability of expression of the protein.

22. For protein methods, empirical results from testing the methods with target material and its derived/processed products, as appropriate, should be provided to demonstrate the stability of the immunoreactive form of the protein.

Sensitivity testing

23. Empirical results from testing the method at different concentrations in order to test the sensitivity of the method should be provided. Limits of detection (LOD) may be defined using samples comprising of single ingredients only. For food products made up of multiple ingredients, the actual sensitivity will be reduced, as total extracted DNA will be derived from more than one ingredient so that the starting amount of the actual measure and will be decreased.

24. LOD should be determined for each method and matrix, if necessary.

Robustness testing

25. Empirical results from testing the method against small but deliberate variations in method parameters should be provided.

Extraction efficiency

26. Empirical results from testing the method for its extraction efficiency in each matrix should be provided to demonstrate the extraction is sufficient and reproducible. For quantitative detection, the method of calibration for incomplete extraction may need to be provided.

PRACTICAL APPLICATION OF THE METHOD

Applicability

27. Indication of the matrix (e.g., processed food, raw materials, etc.), the type of samples and the range to which the method can be applied should be given. Relevant limitations of the method should also be addressed (e.g. interference by other analytes or inapplicability to certain situations). Limitations may also include, as far as possible, possible restrictions due to the costs, equipment or specific and non-specific risks implied for either the operator and/or the environment.

Operational characteristics and practicability of the method

28. The required equipment for the application of the method should be clearly stated, with regards to the analysis *per se* and the sample preparation. Information on costs, practical difficulties, and on any other factor that could be of importance for the operators should be also provided.

Experimental design

29. The experimental design, including the details about the number of runs, samples, replicates, dilutions etc. should be stated.

Operator skills requirements

30. A description of the practical skills necessary to properly apply the proposed method should be provided.

ANALYTICAL CONTROLS

31. The proper use of controls when applying the method should be indicated, when available. Controls should be clearly specified and their interpretation recorded. These may include positive and negative controls, their detailed contents, the extent into which they should be used and the interpretation of the obtained values.

32. The following should be stated:

• Types of analytical controls used:

i. Positive and negative controls

ii. Internal control used if applicable (competitive or non competitive).

iii. Other types of controls like matrix control (to confirm sample was added to PCR) or extraction processing.

• Control samples.

• Reference materials used.

METHOD PERFORMANCE

33. Data on the criteria referred to in Section 2.2, “General Method Criteria” should be provided, as well as a general assessment that the method is fit for its intended purpose.

ANNEX II: VALIDATION OF A QUANTITATIVE PCR METHOD

INTRODUCTION

1. DNA-based analysis is commonly performed using PCR. This technique amplifies a specific segment of DNA to the extent that its quantity can be measured instrumentally (e.g. using fluorometric means). Food processing operations (e.g. due to heat, enzymes and mechanical shearing), can result in degradation or reduction in the total amount of DNA. Methods should preferably be designed to amplify relatively short target- or taxon-specific DNA sequences.

2. Quantitative determinations are often expressed in terms of percent of a target-specific DNA sequence relative to a taxon-specific DNA sequence. In such a relative quantitative test, this measurement actually involves two PCR-based determinations – that of the target-specific DNA sequence and that of the endogenous, or taxon-specific sequence. Each of these determinations has its own uncertainties, and the two are likely to have different measurement characteristics. In most applications, the target DNA sequence will be present at low concentrations, and the taxon-specific DNA sequence will be present at concentrations 10 to 1000 times higher. It is thus important that both measurements are properly validated. In cases where the measurement is expressed directly as a percentage, these factors should be considered when validating the method. The results can be reported in other measure units such as copy numbers.

3. The consequence is that the analysis of DNA, especially in processed foods, aims at detecting a very small amount of target-specific DNA, often in the nanogram/gram range or lower. The result of a quantitative PCR analysis is often expressed in % as the relative amount of target DNA relative to the total amount of DNA of the comparator taxon/species DNA in a specific food matrix. The food matrix may also contain significant amounts of DNA from many other species/taxons.

4. Validation of methods consists of two phases. The first is an in-house validation of all of the parameters above except reproducibility. The second is a collaborative trial, the main outcome of which is a measure of the repeatability and reproducibility together with detailed information on the transferability of methods between laboratories. It is strongly recommended that a small-scale collaborative trial be performed to test the general robustness of a particular method before the expense of organizing a large-scale trial is incurred. In case any improvement of the method or the method description is needed, only limited expenses are incurred through the pre-trial, while a failure of a full interlaboratory method validation due to ambiguous method description is a very costly failure. Additionally, it may be pointed out that the implementation of an already validated method in a laboratory needs to include necessary experiments to confirm that the implemented method performs as well under local conditions as it did in the interlaboratory method validation. It is important to note that a method should be validated using the conditions under which it will be performed.

VALIDATION

5. A quantitative PCR assay should be validated for the intended use or application. The ISO 5725:1996 or AOAC/IUPAC Harmonized Protocol were developed for chemical analytical

methods. These define the procedures necessary to validate a method. It is important to emphasize that all the principles and rules of the harmonized protocol are applicable to quantitative PCR methods.

6. A number of the parameters involved in validation of the performance of a quantitative PCR assay will be discussed in detail. These are scope, LOD and LOQ, trueness, precision, sensitivity and robustness. Other important factors are acceptance criteria and interpretation of results, and the issue of the units in which results are expressed.

7. There is a general scientific discussion about the interpretation of the percentage values. It is recognized that so far there is no reliable weight to copy number relationship because of uncertainty in the correlation of weight of ingredient to number of molecules of DNA. Both the weight to weight ratio and copy number to copy number ratio calculations are acceptable provided this is clearly stated when reporting results.

8. All parameters listed below, including selectivity and sensitivity, have to be assessed individually for each of the assays involved, including both reference and target specific PCR assays**.** These are given alphabetically, not necessarily in order of importance.

Applicability

9. The analytes, matrices and concentrations for which a method of analysis may be used should be stated.

10. It is required from an extraction method, independent of matrix to which it is to be applied, that it yields DNA of sufficient quantity, structural integrity and purity to allow a proper evaluation of the performance of the subsequent method steps (e.g. adequate amplification of DNA during the PCR step) to be undertaken.

11. In real-time PCR analysis, Ct-values can be used to estimate the efficiency of PCR. The efficiency can be tested, for example, by setting up a dilution series of the template DNA and determining the Ct-value (The threshold number of cycles at which the measured fluorescence signal crosses a user-defined threshold value) for each dilution. In the ideal situation, when amplification efficiency is 100%, a two-fold reduction in quantity of template DNA added to the PCR will result in an increase in the Ct value of one. Therefore, if DNA is diluted 10X, the theoretical difference in Ct values between the diluted and undiluted DNA should be approx 3.32. Theoretical numbers may not be achieved in real situations. Significant deviations from this relationship may indicate that the extracted DNA contains PCR inhibitors, that the DNA solution is not homogenous or the DNA quantity so low that stochastic variation in the amount of DNA in the reactions yield unreliable quantitative estimates. This is also the case for end-point PCR reactions carried out using fluorescent probes.

Dynamic Range - Range Of Quantification

12. The scope of the methods defines the concentration range over which the analyte will be reliably determined. The relative amount of taxon-specific DNA to total DNA in the DNA extract will vary depending on whether the DNA was extracted from a single ingredient or a complex food matrix. This desired concentration range defines the standard curves and a sufficient number of standards should be used, when applicable e.g. with calibration curves, to adequately define the relationship between concentration and response. The relationship between response and concentration should be demonstrated to be continuous, reproducible and should be linear after suitable transformation.

13. The range of a quantitative target-specific method can be designed to be from near zero to 100 percent relative to the taxon-specific DNA (w/w). However, it is common to validate a method for a range of concentrations that is relevant to the scope of the application. If a method is validated for a given range of values, the range may not be extended without further validation. For certain applications (e.g. food or grain analysis) the use of genomic DNA for the preparation of the standard curve (see discussion on the use of plasmid DNA below) may be considered. While it is easy to establish a nominal 100% standard it is difficult to reliably produce standard solutions below 0.1%. Additionally, the number of target sites (DNA sequence to be amplified) becomes so small that stochastic errors will begin to dominate and less reliable analysis is possible.

14. The DNA used as calibrator should be traced back (in its metrological meaning) to a

reference of highest metrological order, e.g. a certified reference material. The range will be established by confirming that the PCR procedure provides an acceptable degree of linearity and trueness when applied to samples containing amounts of analyte within or at the extremes of the specified range of the procedure.

15. The unique characteristics of quantitative PCR impose particular restrictions on the low end of the dynamic range of a quantitative PCR. This is due to the difficulty in determining LOD and LOQ values due to the non-normal distribution of values in this range.

Limit of Detection (LOD) and Limit of Quantification (LOQ)

16. If the validation of the quantitative PCR assay shows that the assay can measure DNA at (for example) 0.1% with acceptable trueness and precision, then it is often not necessary to determine the LOD and LOQ, as the method is only being applied above the range where these are relevant. However, if the method is being used at concentrations close to the LOD and LOQ (typically 0.01-0.05%), then the assessment of the LOD and LOQ will become part of the validation procedure.

17. In quantitative PCR, the distribution of measurement values for blanks is not Gaussian and typically follows a Poisson distribution. If the LOD is required, it should be experimentally determined. For quantitative methods the LOD is the amount of analyte at which the analytical method detects the presence of the analyte at least 95% of the time (<5% false negative results)

18. For a quantitative method, it is important to know whether the LOQ for a particular matrix is close to the values to be measured. The LOQ needs to be experimentally determined, since the distribution measurement for quantitative PCR is not normally distributed.

19. In practice, two procedures have been employed to determine the LOQ. The first approach is to assay a number of conventional samples that have been supplemented (spiked) with known amounts of analyte. The LOQ is then the level at which the variability of the result meets certain preset criteria (such as +/- 2 SD from the lowest calibration data point, etc.). DNA extraction, however, may be difficult from some matrices, e.g. starches or ketchup, and lower extraction efficiencies may have to be accepted. When extraction efficiencies are low, this should be stated in the validation data and in the analytical report. A more complete approach is to test the method using a number of samples that contain known amounts of analyte. This is more complicated as it requires access to significant quantities of reference materials that contain a known range of concentrations of the DNA sequences of interest.

Practicability

20. The practicability of the method should be assessed by considering parameters such as: the quantity of samples that can be processed within a given time, estimated fixed costs to implement the method and the approximate cost per sample, practical difficulties on daily use or under particular conditions, as well as other factors that could be of importance for the operators.

Repeatability standard deviation (RSDr)

21. The relative repeatability standard deviation for the PCR step should be ≤25% over the whole dynamic range of the method.

Reproducibility standard deviation (RSDR)

22. The relative reproducibility standard deviation for the PCR step should be below 35% over the majority of the dynamic range, except at the limit of quantification, where the RSDR could be higher. **Robustness**

23. Robustness is a measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage. Examples of such variations include: reaction volumes (e.g., 29 vs. 30µl), annealing temperature (e.g., +/-1^{o}C) and/or other relevant variations. The experiments need to be performed at least in triplicate. The response of an assay with respect to these small changes should not deviate more than ±35% in reproducibility experiments from the response obtained under the original conditions.

24. The adequacy of the robustness testing needs to be demonstrated on a method-by-method

basis. For instance, for a real-time PCR method, the following factors and their origin / source should ideally be taken into account: different thermal cycler models, DNA polymerase, uracyl-n-glycosylase, magnesium chloride concentration, primer forward and reverse concentration, probe concentration, temperature profile, time profile, dNTP (including dUTP, if applicable) concentrations.

Sensitivity

25. For a quantitative PCR method, a linear relationship of the Ct as a function of the logarithm of the template concentration should be obtained across the range of the method. The correlation coefficient, y intercept and slope of the regression line should be reported. The % of residual for each of the calibrators should preferably be ≤30%.

26. Besides reporting the curve parameters, it is suggested to define which range of slope values is acceptable in order to conduct the quantification as it is also important to calculate the reaction efficiency. (Eg. -2.9 to -3.3 for DNA detection or the corresponding optimal values which indicate amplification efficiency close to 100%).

27. In cases where the ΔCt-method is employed by a laboratory instead of a calibration based quantitative method, it will be the responsibility of the analyst to ensure that the overall amount of DNA is well within the range for which the assay was validated.

Selectivity

28. The selectivity of the method should be demonstrated by providing experimental evidence. This demonstration should include analysis of samples containing a mixture of target DNA and non-target DNA where the limits of the detection (if appropriate to the dynamic range) are truly tested. As the method should be selective for the target DNA, it should only give a positive result with a food matrix containing the target DNA.

29. Primers and probes should have been checked against pertinent sequence databases for possible homologies with other sequences potentially present in the expected matrices, according to the intended use. After such an assessment, selectivity should then be demonstrated experimentally.

30. For assays selective for the target DNA. Experimental evidence of selectivity for the target DNA should include:

• Assays of at least ten samples from different lots or batches of foods or ingredients lacking target DNA sequences, although the samples should contain taxon-specific DNA. All of these assays should have a negative result. For example, if the target DNA corresponds to a specific recombinant-DNA plant transformation event, samples could be derived from other (non-target) transformation events, as well as non-recombinant-DNA plants belonging to the same plant species.

• An appropriate number of DNA samples from each source should be tested.

• Two replicates should be analyzed for each DNA sample, which shall give results within a Ct-value of 0.5.

31. Test results should clearly indicate that no significant instrument reading or chemistry effects are observed.

32. For assays on taxon-specific DNA sequences. Experimental evidence of taxon selectivity should include:

• Assays of at least ten samples from different lots or batches of foods or ingredients derived from organisms belonging to the taxon of interest, but classified in different sub-taxon categories. All of these assays should have a positive result. For instance, if the taxon specificity supposedly corresponds to a plant species such as maize, the samples could correspond to maize varieties with different genetic origins.

• Assays of at least ten samples from different lots or batches of similar foods or ingredients derived from organisms not belonging to the taxon of interest, which may be present in the relevant food matrixes. All of these assays should have a negative result. For instance (and continuing with the earlier example) if the first ten assays were applied to different maize flours, in the second group of assays it could be appropriate to assay wheat/soy/rice flour.

• An appropriate number of DNA samples from each source should be tested.

• Two replicates should be analyzed for each DNA sample, which shall give results within a Ct-value of 0.5.

33. Test results shall clearly indicate that no significant instrument reading or chemistry effects are observed.

Trueness

34. As for any method, the trueness of a method should be determined by comparing results obtained from analysis of a reference material with the known or assigned value for that reference material. The impact of sample matrix effects, particularly when the sample matrix differs from that of the reference material, should be considered.

35. A trueness value of ± 25%, in regards to the PCR step, should be acceptable over the whole dynamic range.

REFERENCES FOR ANNEX II

- AOAC (2002). International Methods Committee: Guidelines for Validation of Qualitative and Quantitative Food Microbiological Official Methods of Analysis.
- Cankar K, Štebih D, Dreo T, Žel J, Gruden K (2006). Critical points of DNA quantification by real-time PCR-effects of DNA extraction method and sample matrix on quantification of genetically modified organisms. *BMC Biotechnol.* 6(37).
- Chapela MJ, Sotelo CG, Pérez-Martín RI, Pardo MA, Pérez-Villareal B, Gilardi P and Riese J (2007). Comparison of DNA extraction methods from muscle of canned tuna for species identification. *Food Control*. 18(10):1211-1215.
- Horwitz E. ISO/AOAC/IUPAC Harmonized Protocol for the Design, Conduct and Interpretation of Method-Performance Studies (1995). *Pure and Applied Chemistry* 67:331-343.
- Huebner P, Waiblinger HU, Pietsch K and Brodmann P (2001). Validation of PCR methods for quantitation of genetically modified plants in food. *Journal of AOAC International* 84(6):1855-1864.
- Kay S and Van den Eede G (2001). The limits of GMO detection. *Nature Biotechnology* 19(5):504.
- Turci M, Sardaro MLS, Visioli G, Maestri E, Marmiroli, M and Marmiroli N (2010). Evaluation of DNA extraction procedures for traceability of various tomato products. *Food Control*. 21(2):143-149.

ANNEX III: VALIDATION OF A QUALITATIVE PCR METHOD

Introduction

1. A qualitative PCR should be validated as much as possible in the same way as it is intended to be used for routine analyses – that means the sensitivity of the method should be shown to be such that it can reliably detect a positive sample, and does not give rise to a significant number of false positives.

2. By their very nature, qualitative test results refer to the identification above/below a detection limit. Like the limit of detection for quantitative methods, the limit of detection for a qualitative method can be defined as the concentration at which a positive sample yields a positive result at least 95% of the time. This results in a rate of false negative results of 5% or less. This is also expressed as a ratio or percentage.

False Positive Rate

3. This is the probability that a known negative test sample has been classified as positive by the method. For convenience this rate can be expressed as percentage:

% false positive results = 100 x number of misclassified known negative samples total number of known negative samples

False Negative Rate

4. This is the probability that a known positive test sample has been classified as negative by the method. For convenience this rate can be expressed as percentage:

% false negative results = 100 x (number of misclassified known positive samples /total number of known positive samples)

Note: since there are different definitions in use for the false positive and false negative rates, the validation report should clarify which one has been used.

5. In order to demonstrate the false negative rate for qualitative assay, a series of samples with a constant, known concentration of positive material in a pool of negative material have to be analysed and the results evaluated. It is important to note that the concept of confidence intervals and statistical uncertainty needs to be applied to the risk of false positive and/or false negative results as well. The desired level of confidence determines the size and number of pools that need to be tested.

Robustness

6. As with any validated method, reasonable efforts should be made to demonstrate the robustness of the assay. This involves careful optimisation and investigation of the impact of small modifications made to the method due to technical reasons, as described in the annex for quantitative PCR.

ANNEX IV: VALIDATION OF A PROTEIN-BASED METHOD

QUANTITATIVE TESTING

1. The following description of the procedure is only one of several possibilities to carry out an immunological detection assay for proteins of interest.

2. For example, in typical ELISA for proteins, the amount of the reporter substance from an enzymatic reaction is measured. The standard curve is generated by plotting the optical density (OD) on the y-axis against the concentration of the standards on the x-axis, obtaining a dose response curve using quadratic equation or other required curve fit model from the method. To obtain an accurate quantitative value, the OD for the sample solutions must pertain to the linear portion of the calibration curve. If the OD is too high, the sample solution must be diluted until the OD falls within the quantification range of the assay. The concentration of the protein analyte in the original sample is calculated by correcting for any dilution factor that was introduced in preparing the sample for application to the micro plate. The initial weight of the sample and the volume of extraction liquid, as well as any subsequent dilutions are used to calculate the dilution factor.

3. Various assay controls can be employed to demonstrate the performance of the assay. A blank sample such as an empty well or buffered solution can be run in parallel to determine any background response which shall be subtracted from sample and calibration responses if desired. A negative control sample (i.e. matrix extract solution known to contain no analyte) shall be used to demonstrate any non-specific response or matrix interference effects occurring in the assay. A positive control or matrix extract spiked with a known amount of the analyte can be run to demonstrate the accuracy of the test. Standards and samples can be run in an appropriate number of replicates to appreciate the precision of the test. Blanks, negative controls, positive controls, reference materials, and replicates can be run on each microplate to control for plate-plate variation.

REFERENCE MATERIALS

4. When applicable, the reference material consists of the same matrix as the target analytical sample to be tested. It typically includes negative control and positive reference materials. For example, if the matrix to be tested is soybean flour the standardized positive reference material would be soybean flour containing a known proportion of protein of interest. Alternatively, a pure sample or extract of the protein of interest may be used, providing the use of such protein reference materials has been validated against the matrix in question. In some cases the reference matrix, may be unavailable. Access to reference materials is important during the development, validation, and use of immunoassays for analysis of proteins in food matrix. The best available reference material should be used in order to comply with regulations and testing requirements.

5. Where food or food ingredients with and without the analyte are available, it is fairly

straightforward to prepare a control sample with a known proportion of the target material. In other cases, generating control samples for certain matrices and analytes can be difficult. Stability and uniformity are important considerations. For example, if the matrix to be tested consists of a mixture of materials, the operator will need to combine materials in such a way as to achieve a homogeneous control sample with a known amount of the protein. The stability of these materials would need to be evaluated under storage and test conditions.

VALIDATION OF A QUANTITATIVE PROTEIN-BASED METHOD

6. The principles of method validation defined in the harmonized ISO/IUPAC/AOAC standard apply to protein methods.

7. Quantitative method validation parameters include accuracy/trueness, selectivity, extraction efficiency, sensitivity, range of quantification, precision, robustness, applicability and practicability.

8. Accuracy is demonstrated by measuring the recovery of analyte from spiked samples and is reported as the mean recovery at several levels across the quantitative range.

9. The recovery of proteins of interest should be determined by comparing results obtained from analysis of a reference material with the known or assigned value for that reference material. The impact of sample matrix effects, particularly when the sample matrix differs from that of the reference material, should be considered. The recovery should be between 70 and 120%.

10. Extraction efficiency is a measure of how efficient a given extraction method is at separating the protein analyte from the matrix. It is expressed as percent analyte recovered from the sample. It can be difficult to truly demonstrate efficiency of the extraction procedure. There may not be an alternate detection method against which to compare the immunoassay results. One approach to addressing extraction efficiency is to demonstrate the recovery of the target protein analyte from each type of food fraction by exhaustive extraction, i.e. repeatedly extracting the sample until no more of the protein is detected.

11. The intra-assay precision describes how much variation occurs within an assay. It can be evaluated by determining the variation between replicates (% Coefficient of Variation) assayed at various concentrations on the standard curve and on the pooled variation (RSDr) derived from absorbance values in standards from independent assays performed on different days. Inter-assay precision describes how much variation occurs between separate assays and can be measured by analysis of quality control samples on every microplate.

The quality control samples required would consist of two pools of extracts, one extract from target analyte containing samples and one from the control samples. If the protein is stable in extract, it can be stored frozen and a portion would be thawed and assayed on every microplate. Inter-assay precision can be evaluated over time and expressed as % Coefficient of Variation.

12. The relative repeatability standard deviation (RSDr) should be ≤25% over the whole dynamic range of the method.

13. The relative reproducibility standard deviation (RSDR) should be below 35% at the target concentration and over the majority of the dynamic range, excepting at the limit of quantification, where it could be greater.

14. Dilution agreement or linearity is used to evaluate that the assay is capable of giving equivalent results regardless of where in the quantitative range of the standard curve the sample OD interpolates. To conduct these experiments, samples that are positive for the target protein are ideally diluted such that at least three of the dilutions result in values that span the quantitative range of the curve. The Coefficient of Variation of the adjusted results from several dilutions of a single sample extract should ideally be ≤ 20%.

Limit of Detection (LOD) and Limit of Quantification (LOQ)

15. It is worth noting that if the LOD or LOQ is established to be much lower than the range in which the method is intended to be used, a precise determination is not necessary. This would be the case, for example, when the LOD is in the range of 1 ng/kg, while the range of the method validation extends only for concentrations ranging in µg/kg.

16. It is common practice when estimating the LOD to assume that it is the signal strength of a blank increased by three times the standard deviation of the blank. This method gives at best an

estimate, and relies on normal Gaussian distribution of the blank measurements around zero. This can generally be assumed for methods such as ELISA, but the LOD is best determined experimentally. Alternatively the LOD is commonly defined as a concentration equal to the lowest standard used in the assay, should a positive value be consistently obtained with that standard.

17. For a quantitative method, it is important to know whether the LOQ for a particular matrix is close to the values to be measured.

Cross-reactivity

18. The cross-reactivity is the degree to which analogs or other molecules can bind to the detection antibodies and therefore should be characterized and described in the method. The absence of cross-reactivity should be assessed using experimental results from testing the method with proteins or molecules from non-target and closely related taxa, purified target protein or reference positive control materials. The potential for interferences from reagents and labware can be evaluated by assaying extracts from analyte-free material.

Matrix effects

19. If the response of the method is affected by a substance in the final extract other than the specific protein analyte, the non-specific response is referred to as a matrix effect. One way to manage matrix effects is to demonstrate that the analytical method gives similar results with or without sample matrix present in the extract. In this approach, freedom from matrix effects would have to be demonstrated in all matrices for which the assay is to be used. Another approach (although less desirable) to managing matrix effects would be to prepare the standard solutions in extracts from analyte-free matrix. This would ensure that any matrix effects are consistent between the standards and the samples.

Robustness

20. Robustness is a measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage. Examples of such variations include: reaction volumes, incubation temperature (e.g. +/- 1°C for oven incubations and +/- 4°C for incubations at “room temperature”) and/or other relevant variations. The experiments need to be performed at least in triplicate and the recovery needs to be calculated. The response of an assay with respect to these small changes should not deviate more than ±30% from the response obtained under the original conditions.

QUALITATIVE TESTING

21. Lateral flow devices are useful tools for on-site or field testing, although other immuno-sorbent assays such as traditional ELISA methods can also be used for qualitative testing. In order to ensure reliable results, assays should be validated and a description of the performance characteristics should include sensitivity, selectivity, applicability, limit of detection, robustness, matrix effects, and, if applicable, hook-effect.

VALIDATION OF A QUALITATIVE PROTEIN-BASED METHOD

22. The same principles apply to qualitative protein-based testing as to qualitative PCR testing. These approaches, including calculation of false positive and false negative rates, can therefore be applied to protein-based methods. In general, due to the reliable nature of protein-based lateral flow strip methods, they are not performed in duplicate on each sample. However, in ELISA testing (due to its quantitative nature), duplicate wells are typically used.

Applicability

23. The analytes, matrices and concentrations for which a method of analysis may be used should be stated.

24. Protein extraction can be a key factor in the performance of a protein method, and the buffers used can also affect the performance of the detection step. Thus careful optimization is required to ensure that protein detection methods are reliable. The criteria for determination of the LOD should be established for the method. For confirming the LOD of qualitative assays, fortification levels near to the LOD may be used, as long as one of the levels used meets the criteria of being above but close to the LOD. While such procedures can give an indication of

the performance of the method, incurred samples with well known characteristics (if available) are the best matrix on which to establish the applicability of a method.

Practicability

25. The practicability of the method should be assessed by considering parameters such as: the quantity of samples that can be processed within a given time, estimated fixed costs to implement the method and the approximate cost per sample, practical difficulties on daily use or under particular conditions, as well as other factors that could be of importance for the operators.

REFERENCES FOR ANNEX IV

- Grothaus GD, Bandla M, Currier T, Giroux R, Jenkins GR, Lipp M, Shan G, Stave JW and Pantella V. (2006). Immunoassay as an Analytical Tool in Agricultural Biotechnology. *AOAC International* 89:913-928
- Guidelines for the Validation and Use of Immunoassays for Determination of Introduced Proteins in Biotechnology Enhanced Crops and Derived Food Ingredients. Lipton et al., *Food and Agricultural Immunology*, 2000, 12, 153-164.
- Horwitz E. ISO/AOAC/IUPAC Harmonized Protocol for the Design, Conduct and Interpretation of Method-Performance Studies (1995). *Pure and Applied Chemistry* 67:331-343.
- ISO 21572:2004. Foodstuffs-Methods for the detection of genetically modified organisms and derived products-protein based methods. Geneva: International Organization for Standardization.
- Mihaliak CA and Berberich SA (1995). Guidelines to the Validation and Use of Immunochemical Methods for Generating Data in Support of Pesticide Registration, in: Nelson JO, Karu AE and Wong RB (eds.) Immunoanalysis of Agrochemicals: Emerging Technologies. *ACS Symposium Series 586*:288-300.
- Stave JW (1999). Detection of the new or modified proteins in novel foods derived from GMO: future needs. *Food Control* 10:367-374.
- Rogan GJ, Dudin YA, Lee TC, Magin KM, Astwood JD, Bhakta NS, Leach JN, Sanders PR and Fuchs RL (1999). Immunodiagnostic methods for detection of 5-enolpyruvylshikimate-3-phosphate synthase in Roundup Ready(R) soybeans. *Food Control* 10(6):407-414.
- USDA (2004). U.S. Department of Agriculture/Grain Inspection, Packers and Stockyards Administration Directive 9181.2. [On line] http://archive.gipsa.usda.gov/reference-library/directives/9181-2.

Chapter 9

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF RECOMBINANT-DNA MICROORGANISMS

CONTENTS

1. GENRAL DISCUSSION

The 2nd Session (2001)

2-91. Referring to the priorities identified at its 1st Session17, the Task Force agreed, subject to the approval by the 24th Session of the Codex Alimnetarius Commission, to initiate a new work on the elaboration of a guideline for conduct of food safety assessment of modified microorganisms in food. It further agreed to establish an open-ended Working Group to advance the preparation of the draft proposed guideline, being aware of the fact that the new work should be proceeded in an expeditious manner in order to be completed before the 25th Session of the Codex Alimentarius Commission in 2003 when the Task Force would cease to exist. The Government of the United States offered to host the Working Group, which was accepted by the Task Force with appreciation.

2-92. The Representatives of FAO and WHO offered to convene a joint FAO/WHO expert consultation to address the safety assessment of genetically modified microorganisms in food to facilitate the work of the Task Force by providing scientific back grounds in this area. Both representatives stressed that the organization, in particular the selection of experts participating in the consultation would be conducted in a transparent manner. The Representatives of FAO and WHO also offered to consider the convening of a Joint Expert Consultation on the food safety evaluation of genetically modified fish to provide the scientific framework for any future work in this area. The Task Force expressed its appreciation for these initiatives.

The 3rd Session (2003)

3-75. The Task Force recalled that at its second Session, it had agreed to initiate a new work on the elaboration of the guideline for the conduct of food safety assessment of modified microorganisms and had established an open-ended Working Group chaired by the United States of America in order to prepare a proposed draft guideline. Following the approval of this new work by the Codex Alimentarius Commission at its 24th Session, the Working Group met in Oakland, California in November 2001.

3-76. In introducing the document, the delegation of the United States noted that the Working Group had based on the guideline on the Proposed Draft Guideline for the Conduct of Food Safety Assessment of the Foods derived from Recombinant-DNA Plants. The Task Force expressed its gratitude to the Government of the United States for hosting the meeting and to the Working Group for its accomplishment. ***See Annex 1.***

3-77. The Task Force noted that there were safety assessment procedures that should be applied to both the recombinant-DNA plant and recombinant-DNA microorganisms. The Task Force therefore agreed to use the text of the guideline document for recombinant-DNA plant wherever possible with a view to maintaining consistency between two documents. On the other hand, the Task Force also noted that there were issues specific to microorganisms such viability and colonization of the microorganisms in the digestive tract, transfer of plasmids and other genetic material, etc. that would have to be dealt with in the present text.

3-78. Due to time constraints, the Task Force made a number of editorial changes and

corrections for clarity and also approved proposals from delegations to provide guidance for the continued elaboration of the document. It decided to include as many proposals for amendment as seemed appropriate, but placed them in square brackets for the time being so that member countries and observer organizations could reflect on them and provide comment in advance of the next session of the Task Force. The following discussion represents the main decisions reached by the Task Force. ***See Annex 2.***

The 4th Session (2004)

4-3. In welcoming the delegates, the Representative of FAO, Mr. Ezzeddine Boutrif stated that biotechnology provides powerful tools for the sustainable development of agriculture, fisheries and forestry. When appropriately integrated with other technologies for the production of food, agricultural products and services, biotechnology can be of significant assistance in meeting the needs of an expanding and increasingly urbanised world population. However, for certain applications of biotechnology, in particular the production of genetically modified organisms, expected benefits must be analysed against its potential risks, both to human and animal health and to the environment. He emphasized the need for a strong scientific backing to all decisions concerning GM products. Mr. Boutrif, announced FAO's plan to conduct later in 2003, jointly with WHO, an expert consultation on safety assessment of foods derived from genetically modified animals, particularly fish. Mr. Boutrif thanked members of the Task Force for their hard work, and the Japanese Government for its excellent support. He expressed the wish that the spirit of consensus building that guided the work of the Task Force in previous sessions, would continue during the present session and invited the delegates to give thought to what needs to be done further to complement the international regulatory framework governing the production and distribution of foods derived from biotechnology.

4-4. The representative of WHO, Dr Jørgen Schlundt, Director, Food Safety Department gave a welcome address on behalf of the Director-General of the WHO. He mentioned that WHO has launched a project namely "Biotech Mega Study" which attempts a review of the area related to a broader evaluation of foods derived from modern biotechnology as well as cost benefit and socio-economic consideration, and this report would be finalized in the near future. He introduced that WHO has established a booklet entitled "20 Questions on Genetically Modified Foods" which gives information about GM foods using easy to understand language. Both representatives urged the Task Force to make maximum efforts to advance the finalization of the current draft text on its Agenda to respond to the pressing demand for the text.

4-6. The Task Force noted that the 50th Session of the Codex Executive Committee had adopted "Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms" at Step 5.

2. REPORT OF THE WORKING GROUP

Presented at the 3rd Session (2003)

Annex 1

PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF RECOMBINANT-DNA MICROORGANISMS IN FOODS AT STEP 4

BACKGROUND

1. The Codex Ad-Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (Task Force) agreed at its Second Session, subject to the approval by the Codex Alimentarius Commission, to initiate new work on the elaboration of a guideline for the conduct of food safety assessment of modified microorganisms in food (ALINORM 01/34A, para.91). The Task Force further agreed to establish an Open-Ended Working Group (Working Group) to advance the preparation of the draft proposed guideline with the understanding that the work on the guideline would need to be completed by the 25th Session of the Codex Alimentarius Commission in 2003 when the Task Force would cease to exist. The Government of the United States offered to host the Working Group; this offer was accepted by the Task Force.

2. The Codex Alimentarius, at its 24th Session in 2001, approved new work for the development of a *Guideline for the Conduct of Food Safety Assessment of Recombinant-DNA Microorganisms in Food* (Proposed Draft Guideline).

REPORT OF THE WORKING GROUP

3. A meeting of the Working Group, hosted by the United States, was held from 6-9 November 2001, in Oakland, California, to develop recommendations to the Task Force on a Proposed Draft Guideline. The United States prepared a Discussion Draft to facilitate the work of the open-ended Working Group.

4. The Working Group, in their revision of the Discussion Draft of the Proposed Draft Guideline agreed to change the title of the document to Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms. The Working Group agreed that the original title would encompasses work that would be too broad in scope given the limited remaining time of the Task Force and that the revised title more appropriately reflected the narrower scope of the document.

5. The Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms as prepared by the Drafting Group is contained in Annex 1. A set of Chairman's notes from the meeting of the Working Group, summarising key points of the meeting's discussion, appears in Annex 2.

CHAIRMAN'S NOTES Codex Ad-Hoc Intergovernmental Task Force on Foods Derived from Biotechnology: Open-Ended Working Group on the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (November 6-9, 2001, Oakland, California, U.S.A.)

The following notes summarize the key points of discussion of the Open-Ended Working Group's (termed Working Group) consideration of the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (referred to as the "Guideline" document). Paragraph references, when used, refer to the paragraph numbering of the draft document submitted for the Task Force's consideration (see Annex 1).

In addition to comments brought forward by members attending the Working Group, the Working Group considered all written comments submitted by countries that could not attend the meeting.

GENERAL NOTES

The Working Group agreed that this document on food safety assessment of foods produced using recombinant-DNA microorganisms should, both with respect to format and technical content, be as similar as possible to the Task Force's document on the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (referred to as the "Plant" document) unless a difference between plants and microorganisms warrant a change.

The Working Group carefully considered the findings of the Joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Microorganisms, carried out from 24-28 September, 2001, in Geneva, Switzerland. The Working Group also had at hand the report of the Task Force's Ad-Hoc Open-Ended Working Group on Allergenicity, hosted by the Government of Canada in Vancouver, Canada, from 10-12 September, 2001.

The Chairman of the Working Group notes that, while significant discussion occurred with respect to all sections of the document, and many changes were made from the initial Discussion Draft, no bracketed language occurs in the document presented to the Task Force for its consideration.

NOTES ON SPECIFIC SECTIONS OF THE DOCUMENT

TITLE

The Committee noted that the proposed title of the document (Discussion Draft: Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced by Recombinant-DNA Microorganisms) is different from that adopted as new work by the 24th Session of the Codex Alimentarius Commission (Proposed Draft Guideline for the Conduct of

Food Safety Assessment of Recombinant-DNA Microorganisms). The Working Group agreed that the title proposed by the Commission would encompasses work that would be too broad in scope given the limited remaining time of the Task Force and agreed to recommend to the Task Force the new title for the Guideline document.

SECTION 1 – SCOPE

History of Safe Use: While some delegations expressed interest in having the document consider both microorganisms with and without a history of safe use, most delegations indicated that the document should restrict its consideration to microorganisms with a history of safe use, recognizing that significant additional guidance would be needed if the scope were to be expanded to encompasses microorganisms without a history of safe use. Consensus was reached by the Working Group that the document should be restricted to microorganisms with a history of safe use. For microorganisms without a history of safe use, the Working Group agreed to state that their safety had to be determined but that it was beyond the scope of this guidance document to provide details on their safety assessment. Taking into consideration this discussion, the Working Group agreed that the term "new strain" could lead to confusion and agreed to replace it with the term "recombinant-DNA microorganism".

Inclusion of Food Additives and Processing Aids: The Working Group noted the limited amount of time available to the Task Force to complete its work on this Guideline document. The Working Group recognized that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) carries out safety assessments of food additives. Additionally, the Working Group noted that JECFA has elaborated guidelines for General Specifications and Considerations for Enzyme Preparations used in food processing and that these guidelines have been used to evaluate enzyme preparations derived from genetically modified microorganisms. While different views were presented as to whether food additives and processing aids should be included within the scope of the Guideline, the Working Group agreed for the reasons noted here that food additives and processing aids should be excluded from the scope of the Guideline. The Working Group noted that the general concepts described in this draft guideline are applicable to microorganisms used to produce food additives and processing aids. However, the Task Force may wish to review whether there is a need to develop guidelines for risk assessment for food additives obtained using modern biotechnology that are not already being addressed currently by JECFA or by Codex.

The Chairman of the Working Group suggests that the Task Force reaffirm the limited scope of this Guideline document.

SECTION 2 – DEFINITIONS

Regarding the definitions for "Recombinant-DNA Microorganism" and "Modern Biotechnology": The Working Group noted several points regarding the application of the definition of modern biotechnology to the use of microorganisms in producing foods. Recognizing that fusion of cells was not a currently applicable technique with microorganisms (although it could potentially occur in fungi and certain other microorganisms), the Working Group considered and agreed to a proposal to move the term "in-vitro nucleic acid techniques" into the definition of recombinant-DNA microorganisms and to delete the term "modern biotechnology" from the definition for recombinant-DNA microorganisms. The Working Group discussed the appropriateness of the term "breeding" when applied to microorganisms. The Working Group recognized that "strain-development" is the preferred word choice with respect to microorganisms rather than "breeding". Finally the Working Group noted that modern biotechnology is defined currently in the Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, and agreed to delete the definition for modern biotechnology from the Guideline document.

SECTION 3 – INTRODUCTION TO FOOD SAFETY ASSESSMENT

Approaches to Safety Assessment: To enhance clarity, the Working Group agreed to separate into two paragraphs, paragraphs 9 and 10 concerning the discussion of concepts dealing with the safety assessment of historically used microorganisms and the discussion of the safety assessment of the use recombinant-DNA microorganisms, originally contained in a single paragraph in the Discussion Draft.

Persistence/Residence: In discussing the retention of microorganisms in the intestinal environment, (see paragraphs 13, 47), it appeared that more clarity was needed in regards to persistence versus residence, the precise meaning of “significant periods of time”, and the impact of transitory passage through the intestinal tract. However, since this is an issue that impacts both plants and microorganisms, the Working Group felt that this was an issue that might be more effectively considered by the Task Force.

Unintended Effects: Several changes for clarity were made to the section dealing with unintended effects (paragraphs 15-19). A final sentence was added to paragraph 16 noting that “In addition, genetic instability and its consequences need to be considered”. Additionally, the impact of unintended effects on the formation of new or changed patterns of metabolites was placed into a separate paragraph (paragraph 17).

Modification vs. Event: Paragraph 20, point E refers to “Characterization of genetic modification(s). The Working Group discussed whether the term “events” should be used in addition to “modification”. Some delegations noted that it was important to provide specific information on the event transformation(s) that occurred. Other delegations noted that while this was often the case, there may be situations where providing information on each transformation event may not be required and that the document should provide flexibility in this regard, therefore the term modification was preferred. The Working Group reached consensus to use the term “modification”.

Availability of Reference Material: Paragraph 22 contains the sentence “Primary data should be made available to regulatory authorities upon request.” The Working Group considered a recommendation to include reference material in the data that should be made available to regulatory authorities. There was a difference of views on this recommendation with some Delegations supporting the inclusion and some Delegations indicating that it was not necessary to include this provision in the guidance. The Working Group ultimately agreed to omit the provision for reference material.

Placement of sentence regarding safety assessment of whole population: Attention is called to the sentence in paragraph 23 stating that “Safety assessments should address the health aspects for the whole population, including immuno-compromised individuals”. The Working Group recognized this statement to be a very important one and discussed the best placement for this sentence. Originally this statement was contained in the section on “Introduction to Food Safety Assessment and was moved to the current location as a more appropriate placement for the sentence. The Task Force may wish to consider whether this sentence is properly placed or whether an alternate location for the sentence is more appropriate.

SECTION 4 – GENERAL CONSIDERATIONS

Culture Collections: The Working Group considered a proposal to insert the following sentence at the end of Paragraph 24, “All recombinant -DNA microorganisms should be deposited into an international culture collection with appropriate identification using modern molecular methods.” The Working Group had a difference of views regarding the appropriateness of depositing recombinant-DNA microorganisms into an international culture collection. While some delegations supported the approach, others noted the impracticality of the proposal, citing proprietary, cost and maintenance considerations. The Working Group agreed to not include the sentence.

Genetic Stability: The Working Group considered the issue of genetic stability to be of significant importance and added the following sentence to Paragraph 26, “Information on the genetic stability of the recipient microorganism should be considered when available including the presence of mobile DNA elements, i.e., insertion techniques, transposons, plasmids, and prophages.

General Statement on Chromosomal Integration: Paragraph 29, in the Discussion Draft, contained a sentence reading “In general, chromosomal integration of genes reduces the likelihood of gene transfer of genetic material introduced by recombinant-DNA technology. The Working Group agreed to delete this sentence as there are many exceptions to the statement and the statement does not provide helpful guidance.

Extraneous DNA: The Working Group considered a sentence proposed to be added to the end

of paragraph 29 reading "Extraneous-DNA should be minimized in the recombinant-DNA microorganism". The Working Group had an extensive discussion on the need for a statement on extraneous DNA. To provide appropriate guidance in this regard, the Working Group added the following sentence to the end of paragraph 32: "To facilitate the safety assessment, the DNA to be inserted should be limited to the sequences necessary to perform the intended functions."

Information on DNA Modifications: In paragraph 33, the Working Group added a bullet point to read "the number of insertion sites" and deleted as unnecessary a bullet point reading "the purity of the DNA. Additionally, in Item C, the Working Group replaced "cellular site" with "insertion site" to provide more general wording applicable to microorganisms.

Regulatory Sequences: The Working Group considered a proposal to add the words "or regulatory sequences" after "open reading frames" in Item D of paragraph 33. The Working Group discussed the need for this additional guidance, noted that Items A and C of this paragraph was sufficient, and decided not to add the proposed wording.

Closely Related Substances: In paragraph 36, some Delegations suggested deleting the phrase "or a closely related substance" when referring to the applicability of conventional toxicological studies to substances that have a history of safe use. The Working Group agreed to retain closely related substances, noting that the need for toxicological studies must be determined on a case-by-case basis. Additionally, the Working Group deleted the sentence "Verification of similarity of the substance to the

original substance should be presented" from paragraph 36 since it was not clear as to what was meant by the term "verification".

New/Altered Metabolites: An additional paragraph (paragraph 42) was added to the text relating to the impact of new or altered levels of metabolites on the microbial populations of mixed cultures, including the potential for increasing the risk for growth of harmful microorganisms or accumulation of harmful substances.

Antibiotic Resistance: While retaining the guidance appearing in the Discussion Draft, the Working Group substantially modified and strengthened this section of the document. Portions of the original text were rearranged and revised. Two introductory sentences were added to the start of paragraph 49 relating to the lack of assessment of traditional strains of microorganisms for antibiotic resistance and intrinsic resistance to specific antibiotics of many microorganisms used in food production. A new paragraph (paragraph 52) relating to minimizing the possibility of gene transfer was added. The Working Group agreed that, where antibiotic resistance genes are used, they should not be present in the recombinant-DNA microorganism.

3. ELABORATION OF THE TEXT

PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS PRODUCED USING RECOMBINANT-DNA MICROORGANISMS ~~IN FOOD~~

3-79. The Task Force approved the proposal by the Working Group to change the title of the document as "Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms" because the object of the assessment should be the food rather than the modified organism per se.

SECTION 1 – SCOPE

1. This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and addresses safety and nutritional aspects of foods produced through the actions of recombinant-DNA microorganisms.[1] The recombinant-DNA microorganisms that are used to produce these foods are typically derived using the techniques of modern biotechnology from strains that have a history of safe, purposeful use in food production. However, in instances where the recipient strains do not have a history of safe use their safety will have to be established.[2] Such food and food ingredients may contain viable or non-viable recombinant-DNA microorganisms or may be produced by fermentation using recombinant-DNA microorganisms from which the recombinant-DNA microorganisms may have been removed.

[1] **The microorganisms included in these applications are bacteria, yeasts, and filamentous fungi. (Such uses include, but are not limited to, production of yogurt, cheese, fermented sausages, natto, kimchi, bread, beer, and wine.)**

[2] **The criterion for establishing the safety of microorganisms used in the production of foods where there is no history of safe use is beyond the scope of the current document.**

2. Recognizing that the following issues may have to be addressed by other bodies, this document does not address:

- **safety of microorganisms used in agriculture (for plant protection, biofertilizers, in animal feed or food derived from animals fed the feed etc.);**
- **risks related to environmental releases of recombinant-DNA microorganisms used in food production;**
- **safety of substances produced by microorganisms that are used as additives or processing aids, including enzymes for use in food production;**[3]
- **specific purported health benefits or probiotic effects that may be attributed to the use of microorganisms in food; or**
- **issues relating to the safety of food production workers handling recombinant-DNA microorganisms.**

[3] **The** ~~Working Group noted that the~~ **Joint FAO/WHO Committee on Food Additives (JECFA) is revising guidelines for General Specifications and Considerations for Enzyme Preparations used in food processing. These guidelines have been used to evaluate enzyme preparations derived from genetically modified microorganisms.**

3-80. In regard to the Scope of the document, the Task Force had extensive discussions on the exclusions listed in paragraph 2 and whether or not the "indirect exposure" of recombinant-DNA microorganisms either through the use in agricultural production or release to the environment should be included in the scope. The delegation of Consumers International pointed out that the report of the joint FAO/WHO Expert Consultation held in September 2001 that discussed the safety assessment of the foods produced with the aid of genetically modified microorganisms dealt with this issue. It noted that the proposed draft Guideline was limited in its scope, and the use of recombinant microorganisms outside the scope of the Guideline would require a different kind of safety assessment than the one described in the Guideline. For example, the Task Force noted that the enzymes used as food additives and produced using genetically modified microorganisms were out of the scope of this guideline but were covered by the activities of the Joint FAO/WHO Committee on Food Additives (JECFA) and Codex Committee on Food Additives and Contaminants (CCFAC). The Task Force stressed that the chapeau of the paragraph 2 clearly stated that issues not addressed in the present Guidelines would have to be addressed by other appropriate bodies.

4-13. The Task Force had extensive discussions on several proposals to expand the Scope. First, the Task Force considered the proposal to include"microalgae" in footnote 1 of paragraph 1. However, the Task Force did not agree with this inclusion as the opinions diverged among delegations and observers as to the history of safe use of "microalgae" as food. It was also noted that they were not included in the definition used for the purpose of the FAO/WHO Expert Consultation.

4-14. In Paragraph 2, the Task Force also discussed proposals to include in the scope "indirect exposure" of recombinant-DNA microorganisms or their products either through the use in agricultural production or release into the environment as well as food additives and processing aids produced from recombinant-DNA microorganisms or their products. After an exchange of opinions, the Task Force concluded it would not change the scope as the entire text of the draft guideline had already been developed to conduct safety assessment of foods produced using recombinant DNA microorganisms where recipient strains had a history of safe use and

therefore inclusion of those items would require different elements of safety assessment. It was also pointed out that the scope should not be changed from that adopted by the FAO/WHO Expert Consultation on Safety Assessment of Foods Derived from Genetically Modified Microorganisms as the present guideline was based on the scientific considerations by this consultation. However, the Task Force recognized the importance of these issues and the necessity to address them as future work in appropriate international bodies including the Codex Alimentarius Commission and its subsidiary bodies.

3. A variety of microorganisms used in food production have a long history of safe use that predates scientific assessment. Few microorganisms have been assessed scientifically in a manner that would fully characterize all potential risks associated with the food they are used to produce, including, in some instances, the consumption of viable microorganisms. ~~Microorganisms are amenable to modification using recombinant-DNA technology and new strains can be rapidly developed due to their rapid growth rates.~~ **Furthermore, the Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or specific chemical or microbial contaminants that have identifiable hazards and risks; they were not originally intended to apply to intentional uses of microorganisms in food processing or in the foods transformed by microbial fermentations. The safety assessments that have been conducted have focused primarily on the absence of properties associated with pathogenicity in these organisms and the absence of reports of adverse events attributed to ingestion of these organisms, rather than evaluating the results of prescribed studies. Further, many foods contain substances that would be considered harmful if subjected to conventional approaches to safety testing. Thus**, ~~an alternative~~ **a more focused approach is required where the safety of a whole food is being considered.** .

4-15. The Task Force deleted the third sentence in paragraph 3 "Microorganisms are amenable to modification using recombinant-DNA technology and new strains can be rapidly developed due to their rapid growth rates." as it was not necessary.

4. Information considered in developing this approach includes:

A) uses of living microorganisms in food production;

B) consideration of the types of genetic modifications likely to have been made in these organisms;

C) the types of methodologies available for performing a safety assessment; and

D) issues specific to the use of the recombinant-DNA microorganism ~~microorganisms used~~ **in food production, including their genetic stability, potential for gene transfer, colonization of the gastrointestinal tract and persistence[4] therein and, interactions that the recombinant-DNA microorganism may have with** ~~the recombinant-DNA microorganism,~~ **the gastrointestinal flora** ~~and~~ **or the mammalian host, and** ~~impacts~~ **any impact of the recombinant-DNA microorganism on the immune system.**

[4] Persistence connotes survival of microorganisms in the gastrointestinal tract longer than two intestinal transit times (International Life Science Institute, The safety assessment of viable genetically modified microorganisms used as food, 1999, Brussels; the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology- Safety assessment of foods derived from genetically modified microorganisms, 24-28 September, 2001, Geneva, Switzerland).

4-16. The Task Force revised sub-paragraph D of paragraph 4 on the issues specific to microorganisms to improve its clarity. (See 4-59.)

5. This approach is based on the principle that the safety of foods produced using recombinant-DNA microorganisms is assessed relative to conventional counterparts that

have a history of safe use, not only for the food produced using a recombinant-DNA microorganism, but also for the microorganism itself. This approach takes both intended and unintended effects into account. Rather than trying to identify every hazard associated with a particular food or the microorganism, the intention is to identify new or altered hazards relative to the conventional counterpart.

4-17. For paragraph 5 and several following paragraphs, the Observer from the 49th Parallel Biotechnology Consortium expressed its concern over the approach adopted throughout the text, which according to the Observer, would conduct safety assessment mainly from the information on the introduced genes.

6. This safety assessment approach falls within the risk assessment framework as discussed in Section 3 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. If a new or altered hazard, nutritional or other food safety concern is identified by the safety assessment, the risk associated with it would first be assessed to determine its relevance to human health. Following the safety assessment and, if necessary, further risk assessment, the food or component of food, such as a microorganism used in production, would be subjected to risk management considerations in accordance with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before it is considered for commercial distribution.

7. Risk management measures such as post-market monitoring of consumer health effects may assist the risk assessment process. These are discussed in paragraph 20 of the Draft Principles for the Risk Analysis of Foods derived from Modern Biotechnology.

4-18. The Task Force agreed to include paragraph 20 from the Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology on the "Post Market Monitoring" after paragraph 6 as a new paragraph to ensure consistency between the two guidelines.

8. ~~7.~~ **The Guideline describes approaches recommended for making safety assessments of foods produced using recombinant-DNA microorganisms, using comparison to a conventional counterpart.** ~~In some instances, the~~ **The safety assessment will focus on the safety of the recombinant-DNA microorganisms used in food production,** ~~**or**~~ **and, where appropriate, on metabolites produced by the action of recombinant-DNA microorganisms on food. The Guideline identifies the data and information that are generally applicable to making such assessments. When conducting a comparison of a recombinant-DNA microorganism or a food produced using recombinant-DNA microorganism with their respective conventional counterparts, any identified differences should be taken into account, whether they are the result of intended or unintended effects. Due consideration should be given to the interactions of the recombinant-DNA microorganism with the food matrix or the microflora and to the safety of any newly-expressed protein(s) and secondary metabolic products. While this Guideline is designed for foods produced using recombinant-DNA microorganisms or their components, the approach described could, in general, be applied to foods produced using microorganisms that have been altered by other techniques.** [~~On the condition that the microorganism is considered to be safe when compared with the conventional counterpart taking into account its interactions with the food matrix or the microflora, that any newly expressed protein(s) encoded by the modified DNA is considered to be safe, and that any secondary metabolic products present as a consequence of the genetic modifications are deemed to be safe, it is unlikely that the food produced by the microorganism would be harmful to human health.~~]

3-81. A number of delegations and observer organizations questioned the intent of paragraph 7, especially the reference to the endpoint of the assessment as being that a food would be "unlikely" to be harmful to human health. Many delegations and observer organizations that spoke were of the opinion that this was an insufficient expression of the level of consumer

protection required. Some observer organizations were of the opinion that the risk assessment as described in paragraph 7 was not sufficient guarantee to consumer protection.

4-19. In paragraph 7 (paragraph 8 in the new text), the Task Force agreed to delete the term [or] and the square brackets in the second sentence, that should read "the safety assessment will focus on the safety of the recombinant-DNA microorganism used in food production, and, where appropriate, on metabolites…".

4-20. The Task Force had an extensive discussion on the last part of the paragraph, that had been retained in square brackets at the last session. Some delegations and observers pointed out that the sentence reflected an inappropriate application of the concept of substantial equivalence as an end point and that it was not sufficient to ensure the safety of foods produced from recombinant-DNA microorganisms. They pointed out that even if the microorganism, the newly expressed protein and the secondary metabolite were safe, the food should not necessarily be considered as safe, especially due to the complex interaction of the microorganism with the food. Some delegations also pointed out that the sentence was not clear and repeated some provisions that were already included in other sections.

4-21. Other delegations proposed to retain the sentence as it addressed the main elements of the safety assessment that were further developed further in the document, and was consistent with its main recommendations in this respect. The Task Force discussed proposals for clarification put forward by the Delegations of Canada and Japan. The Representative of WHO pointed out that all aspects relevant to safety should be taken into account and proposed to rearrange the sentence accordingly in order to facilitate a compromise.

4-22. Following further discussion and a meeting of an informal drafting group, the Task Force considered a compromise text5. The Task Force agreed that the differences identified in the recombinant-DNA microorganism or the food produced using the microorganism should be taken into account, whether they were the result of intended or unintended effects. The Task Force also agreed that due consideration should be given to the interaction of the microorganism with the food matrix or the microflora and to the safety of any newly expressed protein(s) and secondary metabolic products. The Task Force agreed to delete the last sentence of the proposed text that referred to the result of the comparison with the conventional counterpart as it was addressed in another section (paragraph 24 (paragraph 26 in the new text)).

4-23. The revised text was inserted after the third sentence of the paragraph rather than at the end in order to improve the logical sequence of the text.

SECTION 2 – DEFINITIONS

9. ~~8.~~ **The definitions below apply to this Guideline:**

"Recombinant-DNA Microorganism" **- means bacteria, yeasts or filamentous fungi in which the genetic material has been changed through in vitro nucleic acid techniques[4] including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.**

~~[4] These include but are not limited to: recombinant-DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as microinjection, macroinjection, chemoporation, electroporation, microencapsulation, and liposome fusion.~~

"Conventional Counterpart"[5] **means:**

- **a microorganism/strain**[5] ~~used for food production or processing related to the recombinant-DNA strain, preferably the parent or recipient strain,~~ **with a known history of safe use in producing <u>and/or processing</u> the food <u>and related to the recombinant-DNA strain</u>** ~~to be produced by the recombinant-DNA microorganism~~**. The microorganism may be viable in the food or may be removed in processing or rendered non-viable during processing; or**
- **food produced using the traditional food production microorganisms for which there is experience of establishing safety based on common use in food**

production.

[5]It is recognized that for the foreseeable future, microorganisms derived from modern biotechnology will not be used as conventional counterparts.

3-82. The Task Force agreed to amend the definition of Conventional Counterpart by deleting reference to a preference for the "parent or recipient strain" as the basis for comparison, as this was thought to be too vague for a definition. It noted that the substantive requirement later in the document indicated that the ideal comparator was the near isogenic parent strain and agreed that this provided the guidance needed in this regard. It also agreed to define the conventional counterpart of the foods produced using by recombinant-DNA microorganisms should not be derived from modern biotechnology by shifting the footnote to the entire title of Conventional Counterpart in paragraph 8.

4-24. In paragraph 8 "Definition" (paragraph 9 in the new text), the Task Force agreed to reword the definition of "Conventional Counterpart" for clarification purposes and to delete Footnote 4 as it was not necessary to list specific techniques.

SECTION 3 - INTRODUCTION TO FOOD SAFETY ASSESSMENT

10. ~~9.~~ **Most foods produced as a result of the purposeful growth of microorganisms have their origins in antiquity, and have been deemed safe long before the emergence of scientific methods for assessing safety. Microorganisms possess properties, such has fast growth rates, that enable genetic modifications, whether employing conventional techniques or modern biotechnology, to be implemented in short time frames. Microorganisms used in food production derived using conventional genetic techniques have not customarily been systematically subjected to extensive chemical, toxicological, epidemiological, or medical evaluations prior to marketing. Instead microbiologists, mycologists, and food technologists have evaluated new strains of bacteria, yeasts and filamentous fungi for phenotypic characteristics that are useful in relation to food production.**

11.~~10.~~ **Safety assessments of recombinant-DNA microorganisms should document the use of related microorganisms in foods, the absence of properties known to be characteristic of pathogens in the recombinant-DNA microorganisms or the recipient strains used for constructing the recombinant-DNA microorganisms, and known adverse events involving the recipient or related organisms. In addition, when a recombinant DNA microorganism directly affects or remains in the food,** ~~the effects and safety~~ **any effect on safety of the food should be examined.**

4-25. The Task Force decided to modify paragraph 10 (paragraph 11 in the new text) by replacing the wording "the effect and safety" with "any effect on the safety" in order to clearly identify the effects concerned.

12. ~~11.~~ **The use of animal models for assessing toxicological** ~~endpoints~~ **effects is a major element in the risk assessment of many compounds, such as pesticides. In most cases, however, the substance to be tested is well characterized, of known purity, of no particular nutritional value, and human exposure to it is generally low. It is therefore relatively straightforward to feed such compounds to animals at a range of doses some several orders of magnitude greater than the expected human exposure levels, in order to identify any potential adverse health effects of importance to humans. In this way, it is possible, in most cases, to estimate levels of exposure at which adverse effects are not observed and to set safe** ~~upper limits~~ **intake levels by the application of appropriate safety factors.**

13. ~~12.~~ **Animal studies cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, and often characterized by a**

wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to animals at low multiples of the amounts that might be present in the human diet. In addition, a key factor to consider in conducting animal studies on foods is the nutritional value and balance of the diets used, in order to avoid the induction of adverse effects that are not related directly to the material itself. Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. <u>If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole food.</u> Another consideration in deciding the need for animal studies is whether it is appropriate to subject experimental animals to such a study if it is unlikely to give rise to meaningful information.

4-26. In paragraph 12 (paragraph 13 in the new text), the Task Force agreed to insert a sentence regarding the need for animal studies when available data are insufficient on the characteristics of foods produced by using genetically modified microorganisms, in order to maintain consistency with the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. Although the same sentences are found in paragraphs 13 and 57 (paragraphs 14 and 59 in the new text), the Task Force agreed that it was necessary to include this text in paragraph 12 (paragraph 13 in the new text) as the issue addressed was different.

14. ~~13.~~ **Animal studies typically employed in toxicological evaluations also cannot be readily applied to testing potential risks associated with ingestion of microorganisms used for food production. Microorganisms are living entities, containing complex structures composed of many biochemicals, and therefore are not comparable to pure compounds. In some processed foods, they can survive processing and ingestion and can compete and, in some cases, be retained in the intestinal environment for significant periods of time.** ~~When deemed appropriate, animal studies in a validated model may be used~~ **<u>Appropriate animal studies should be used</u> to evaluate the safety of recombinant-DNA microorganisms where the donor, or the gene or gene product do not have a history of safe use in food<u>, taking into account available information regarding the donor and the characterization of the modified genetic material and the gene product</u>. Further, appropriately designed studies in animals may be used to assess the nutritional value of the food or the bioavailability of the newly expressed substance in the food.**

4-27. In paragraph 13 (paragraph 14 in the new text), the Delegation of the United States proposed to amend the text to reflect that animal studies were not necessary in all cases when the donor organism was not a food source organism. Some delegations and observers, however, expressed the view that the current text should be retained to ensure adequate consumer protection. After an exchange of views, the Task Force agreed that appropriate animal studies should be used as indicated in the current text with the addition of the following clarification at the end of the sentence "taking into account available information regarding the donor and characterization of the modified genetic material and the gene product".

15. ~~14~~. **Due to the difficulties of applying traditional toxicological testing and risk assessment procedures to whole foods** ~~produced using microorganisms~~, **an** ~~alternative~~ **<u>more focused</u> approach is required for the safety assessment of foods produced using** ~~microorganisms, including~~ **recombinant-DNA microorganisms. This has been addressed by the development of a multidisciplinary approach for assessing safety, that takes into account the intended effect, the nature of the modification, and detectable unintended changes that may occur in the microorganism or in its action on the food, using the concept of *substantial equivalence*[6].** [While the focus of a safety assessment will be on the recombinant-DNA microorganism, additional information on its interaction with the food matrix should be taken into consideration when applying the concept of substantial equivalence, which is a key step in the safety assessment process. However, the concept of substantial equivalence is not a safety assessment in itself; rather it represents the starting point that is

used to structure the safety assessment of a recombinant-DNA microorganism relative to its conventional counterpart. This concept is used to identify similarities and differences between a recombinant-DNA microorganism used in food processing and its conventional counterpart. Generally, the comparison should be between the recombinant-DNA microorganism and its recipient strain used in its development. An evaluation of the differences between the recombinant-DNA microorganism and its conventional counterpart will generally be sufficient to address safety concerns. However, there will be instances when the food or specific gene product(s) encoded by the modified DNA and produced by the recombinant DNA microorganism should be compared with the appropriate conventional counterpart. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the recombinant-DNA microorganism can be considered relative to its conventional counterpart.]

[6] **The concept of *substantial equivalence* as described in FAO /WHO Expert Consultation on Foods Derived from Biotechnology-Safety aspects of genetically modified plants, 29 May – 2 June, 2000, Geneva, Switzerland, and Section 4.3 of the Joint FAO/Who Expert Consultation of Foods Derived from Biotechnology,- Safety assessment of foods derived from genetically modified microorganisms, 24-28 September, 2001, Geneva, Switzerland.**

Note: The sentences in square brackets are removed from paragraph 15 to become paragraph 16.

3-83. The representative of Greenpeace expressed serious concern at the treatment of the concept of substantial equivalence as contained in paragraph 14. In its opinion, the paragraph should clearly express the idea that the determination of substantial equivalence was not a safety assessment in itself, but rather was a starting point used to structure the safety assessment. The representative of Consumers International also requested to modify this paragraph so that comparison to its conventional counterpart in safety assessment should be conducted not only between microorganisms themselves but also between the foods produced from modified and unmodified microorganisms. Delegations pointed out that these concerns were addressed in paragraph 14.

*4-28. Regarding paragraph 14 (paragraph 15 in the new text), the first sentence was amended for clarification purposes and to ensure consistency with paragraph 3 concerning the approach to safety assessment, as proposed by the Representative of FAO. The Task Force also agreed that a new paragraph should start with the third sentence, as proposed by the Delegation of Japan, in order to make the text more easily readable (**See the new paragraph 16**).*

16. While the focus of a safety assessment will be on the recombinant-DNA microorganism, additional information on its interaction with the food matrix should be taken into consideration when applying the concept of substantial equivalence, which is a key step in the safety assessment process. However, the concept of substantial equivalence is not a safety assessment in itself. Rather ~~rather~~ **it represents the starting point that is used to structure the safety assessment of ~~[~~both~~]~~ ~~–~~a recombinant-DNA microorganism relative to its conventional counterpart** ~~[as well as the food produced with the aid of the RDM relative to its conventional counterpart]~~ **and the food produced using recombinant-DNA microorganism relative to its conventional counterpart. This concept is used to identify for evaluation similarities and differences between a recombinant-DNA microorganism used in food processing** ~~and~~ **as well as the food produced using the recombinant-DNA microorganisms and their** ~~its~~ **respective conventional** ~~counterpart~~ **counterparts as defined in paragraph 9.** ~~Generally, the comparison should be between the recombinant-DNA microorganism and its recipient strain used in its development. [An evaluation of the differences between the recombinant-DNA microorganism and its conventional counterpart could be a starting point to address safety concerns.] However, there will be instances when the food or specific gene product(s) encoded by the modified DNA and produced by the recombinant DNA microorganism should be compared with the appropriate conventional counterpart. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences~~

~~so that the safety of the recombinant-DNA microorganism can be considered relative to its conventional counterpart.~~ **It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods produced using recombinant-DNA microorganisms. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the recombinant-DNA microorganism and the food produced using recombinant-DNA microorganism can be considered relative to** ~~its conventional counterpart.~~ **their respective conventional counterparts.**

4-29. The Task Force agreed with the proposal of the Delegation of the United States to clarify the fourth sentence concerning substantial equivalence as a starting point for safety assessment.

4-30. The Task Force discussed whether the seventh sentence ([An evaluation of the differences between the recombinant-DNA microorganism and its conventional counterpart could be a starting point to address safety concerns.]*) should be deleted. It was noted that only the identification of the differences was mentioned elsewhere in the text, but not their evaluation and that this notion should be retained. After an exchange of views, it was agreed to indicate in the fifth sentence* (This concept is used to identify for evaluation similarities and differences between a recombinant-DNA microorganism used in food processing as well as the food produced using the recombinant-DNA microorganisms and their respective conventional counterparts as defined in paragraph 9.) *that the concept of substantial equivalence was used to identify similarities and differences "for evaluation", in order to make it clear that these were two distinct processes. The seventh sentence was therefore deleted in order to simplify the text.*

4-31. As a consequence of the rewording of the paragraph, the sixth and eighth sentences were also deleted in order to avoid duplication. The Task Force agreed to add a new sentence to clarify the use of substantial equivalence that corresponded to a similar recommendation in paragraph 13 of the Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, as proposed by the Delegation of Belgium.

4-32. The Task Force agreed that the comparison to the conventional counterpart should apply not only to the recombinant-DNA microorganism but also to the food produced using the microorganism. The text was therefore amended accordingly in this paragraph and throughout the document where relevant.

UNINTENDED EFFECTS

17. ~~15.~~ **In achieving the objective of conferring a specific target trait (intended effect) to a microorganism by the addition, substitution, removal, or rearrangement of defined DNA sequences, including those used for the purpose of DNA transfer or maintenance in the recipient organism, additional traits could, in some cases, be acquired or existing traits could be lost or modified.** ~~Such unanticipated changes are referred to as unintended effects.~~ **The potential for occurrence of unintended effects is not restricted to the use of in vitro nucleic acid techniques. Rather, it is an inherent and general phenomenon that can also occur in the development of strains using traditional genetic techniques and procedures, or from exposure of microorganisms to intentional or unintended selective pressures. Unintended effects may be deleterious, beneficial, or neutral with respect to competition with other microorganisms, ecological fitness of the microorganism, the microorganism's effects on humans after ingestion, or the safety of foods produced using the microorganism. Unintended effects in recombinant-DNA microorganisms may also arise through intentional modification of DNA sequences or they may arise through recombination or other natural events in the recombinant-DNA microorganism. [~~[~~Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA microorganism would have an unexpected, adverse effect on human health.~~]~~**

4-33. In paragraph 15 (paragraph 17 in the new text), the Task Force agreed to delete the second sentence. The Task Force discussed differences between "unintended effect" and "unexpected effect", and agreed that these two terms have different meanings and retained

these two words as currently used. After some discussion, the Task Force agreed to retain the last sentence deleting square brackets, in order to ensure consistency with the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.

18. ~~16.~~ **Unintended effects can result from the insertion of DNA sequences new to a microorganism into the microbial genome; they may be compared with those observed following the activity of naturally occurring transposable genetic elements. Insertion of DNA may lead to changes in expression of genes in the genome of the recipient. The insertion of DNA from heterologous sources into a gene may also result in the synthesis of a chimeric protein, also referred to as a fusion protein. In addition genetic instability and its consequences need to be considered.**

19. ~~17.~~ **Unintended effects may also result in the formation of new or changed patterns of metabolites. For example, the expression of enzymes at high levels or the addition of an enzyme new to the organism may give rise to secondary biochemical effects, changes in the regulation of metabolic pathways, or altered levels of metabolites.**

20. ~~18.~~ **Unintended effects due to genetic modification may be subdivided into two groups: those that could be predicted and those that are "unexpected." Many unintended effects are largely predictable based on knowledge of the added trait, its metabolic consequences or of the site of insertion. Due to the expanding knowledge of microbial genomes and physiology, and the increased specificity in function of genetic materials introduced through recombinant-DNA techniques compared with other forms of genetic manipulation, it may become easier to predict unintended effects of a particular modification. Molecular biological and biochemical techniques can also be used to analyse changes that occur at the level of transcription and translation that could lead to unintended effects.**

21. ~~19.~~ **The safety assessment of foods produced using recombinant-DNA microorganisms involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information is necessary to assess unintended effects, because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health. These data and information, when considered in total, <u>should</u> provide assurance that the food is unlikely to have an adverse effect on human health. The assessment ~~for~~ <u>of</u> unintended effects takes into account the biochemical, and physiological characteristics of the microorganism that are typically selected for improving strains for commercial food or beverage uses. These determinations provide a first screen for microorganisms that exhibit unintended traits. Recombinant-DNA microorganisms that pass this screen are subjected to safety assessment as described in Section 4.**

FRAMEWORK OF FOOD SAFETY ASSESSMENT

22. ~~20.~~ **The safety assessment of a food produced using a recombinant-DNA microorganism is based on determining the safety of using the microorganism, which follows a stepwise process of addressing relevant factors that include:**

A) Description of the recombinant-DNA microorganism;
B) Description of the recipient microorganism and its' use in food production;
C) Description of the donor organism(s);
D) Description of the genetic modification(s) including vector and construct;
E) Characterization of the genetic modification(s);
F) Safety assessment:

a. expressed substances<u>:</u> assessment of potential toxicity and other traits

related to pathogenicity; ~~including toxins or other traits related to pathogenicity (e.g., adhesins, invasins);~~

b. compositional analyses of key components;

c. evaluation of metabolites;

d. effects of food processing;

e. assessment of immunological effects;

f. assessment of viability and residence of microorganisms in the human ~~gut~~ gastrointestinal tract;

g. antibiotic resistance and gene transfer; and,

h. nutritional modification.

4-34. In paragraph 20 (paragraph 22 in the new text), the Task Force reviewed the titles of sections a) to f) describing the factors that should be considered under section F) Safety Assessment in conjunction with the text of the respective sections, and agreed that points a) and f) should read as follows:

a) expressed substances: assessment of potential toxicity and other traits related to pathogenicity (see also paragraph 52)

f) assessment of viability and residence of microorganisms in the human gastro-intestinal tract

23. ~~21.~~ **In certain cases, the characteristics of the microorganisms and/or the foods produced/processed using these microorganisms may necessitate** ~~development~~ **generation of additional data and information to address issues that are unique to the** ~~product~~ **the microorganisms and/or food products under review.**

24. ~~22.~~ **Experiments intended to develop data for safety assessments should be designed and conducted in accordance with sound scientific concepts and principles, as well as, where appropriate, Good Laboratory Practice. Primary data should be made available to regulatory authorities upon request. Data should be obtained using sound scientific methods and analysed using appropriate statistical techniques**~~, when applicable~~. **The sensitivity of all analytical methods should be documented.**

4-35. In paragraph 22 (paragraph 24 in the new text), the Delegation of Brazil proposed to delete the last sentence as all analytical data had to be documented. However the Task Force agreed to retain the current sentence referring only to the sensitivity of the analytical method in consistency with the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.

25. ~~23.~~ **The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food will not cause harm when prepared or consumed according to its intended use, nor should the organism itself cause harm when viable organisms remain in the food. Safety assessments should address the health aspects for the whole population, including immunocompromised individuals, infants, and the elderly. The expected endpoint of such an assessment will be a conclusion regarding whether** ~~or not~~ **the new food and/or microorganisms are** ~~is~~ **as safe and nutritious as the conventional counterparts taking into account dietary impact of any changes in nutritional content or value** ~~against which it has been compared and for which there exists a history of safe use~~. **Where the microorganism is likely to be viable upon ingestion,** ~~the~~ **its safety** ~~of the microorganism~~ **should be compared to a conventional counterpart taking into account residence of the recombinant-DNA microorganism in the** ~~GI~~ **gastrointestinal tract and where appropriate, interactions between it and the gastrointestinal flora of mammals (especially humans) and impacts of the recombinant-DNA microorganism on the immune system.. In essence, the outcome of the safety assessment process is to define the product under consideration in such a**

way as to enable risk managers to determine whether any measures are needed to protect the health of consumers and if so to make well-informed and appropriate decisions in this regard.

4-36. In paragraph 23 (paragraph 25 in the new text), the Task Force agreed that, in the case of viable microorganisms, the interaction with the gastrointestinal flora and the impact on the immune system should be considered where appropriate, and amended the sentence accordingly. In the last sentence it was agreed that the measures taken by risk managers were needed "to protect the health of consumers" and some editorial amendments were also made to the paragraph.

SECTION 4- GENERAL CONSIDERATIONS

DESCRIPTION OF THE RECOMBINANT-DNA MICROORGANISM

26. ~~24.~~ A description of the bacterial, yeast, or fungal strain and the food being presented for safety assessment should be provided. This description should be sufficient to aid in understanding the ~~intended differences in~~ the nature of the organism or food produced using the organism being submitted for safety assessment ~~[All recombinant-DNA microorganisms should be deposited into an international culture collection with appropriate identification using modern molecular methods.]~~ **Recombinant-DNA microorganisms used in food production or contained in food, should be conserved as stock cultures with appropriate identification using molecular methods, and preferably, in established culture collections. This may facilitate the review of the original safety assessment. Such stock cultures should be made available to regulatory authorities upon request.**

3-84. Several delegations supported the proposal of Italy to provide that "all recombinant-DNA microorganisms should be deposited in an international culture collection with appropriate identification using modern molecular methods". It was noted that this had been discussed by the Working Group, but had not been included as it was not a requirement for safety assessment. The Task Force agreed to include the text in square brackets for further consideration. (Paragraph 24)

4-37. The Task Force discussed extensively the last sentence of paragraph 24 (paragraph 26 in the new text) concerning the culture collections of recombinant DNA-microorganisms. Some delegations and observers proposed that all such microorganisms be deposited in an international culture collection, in order to ensure access to the original reference material. Some delegations and observers also proposed that the cultures should be made available to requesting parties. Other delegations expressed the view that it might adversely affect intellectual property rights, but that the cultures should be made available to regulatory authorities on request. The Representative of WHO indicated that in the scientific community these microorganisms were deposited in international collections and noted the importance of their availability for the purpose of public health protection.

4-38. Following an informal Working Group, the Task Force agreed on a compromise text6 recommending that Recombinant DNA-Microorganisms should be conserved as stock cultures with appropriate identification using molecular methods, preferably in established culture collections, that they should be made available to regulatory authorities upon request, and noting that this may facilitate the review of the original safety assessment.

DESCRIPTION OF THE RECIPIENT MICROORGANISM AND ITS' USE IN FOOD PRODUCTION

27. ~~25.~~ A comprehensive description of the recipient microorganism or microorganism subjected to the modification should be provided. Recipient microorganisms should have a history of safe use in food production or safe consumption in foods. Organisms that produce toxins, antibiotics or other substances that should not be present in food, or that bear genetic elements that could lead to genetic instability, antibiotic resistance or that are likely to contain genes conferring functions associated with pathogenicity (i.e., also known as pathogenicity islands or virulence factors) should not be considered for use as recipients. The necessary data and information should include, but need not be

restricted to:

A)Identity: scientific name, common name or other name(s) used to reference the microorganism, strain designation, information about the strain and its source, or accession numbers or other information from a recognized culture repository from which the organism or its antecedents may be obtained, if applicable, information supporting its taxonomical assignment;

B) history of use and cultivation, known information about strain development (including isolation of mutations or antecedent strains used in strain construction); in particular, identifying traits that may adversely impact human health;

C) information on the recipient microorganism's genotype and phenotype relevant to its safety, including any known toxins, antibiotics, antibiotic resistance factors or other factors related to pathogenicity, or immunological impact, and information about the genetic stability of the microorganism; ~~and~~

D) history of safe use in food production; and

E) information on the relevant production parameters used to culture the recipient microorganism.

4-39. In paragraph 25 (paragraph 27 in the new text), the Task Force agreed to amend the introductory paragraph and section C) to reflect the need to consider antibiotics and antibiotic resistance factors. A reference to "safe consumption in food" was also added to the "history of safe use in food production" (section D), as proposed by the Delegation of Japan.

4-40. The Delegation of Australia proposed to add a new section (E) addressing culture parameters as these could affect the production of secondary metabolites and was therefore relevant for safety assessment. After an exchange of views, the Task Force agreed to add a simplified text referring to "relevant production parameters used to culture the recipient microorganism".

28. ~~26.~~ Relevant phenotypic and genotypic information should be provided not only for the recipient microorganism, but also for related species and for any extrachromosomal genetic elements that contribute to the functions of the recipient strain, particularly if the related species are used in foods or involved in pathogenic effects in humans or other animals. Information on the genetic stability of the recipient microorganism should be considered ~~when available~~ including, as appropriate, the presence of mobile DNA elements, i.e. insertion sequences, transposons, plasmids, and prophages.

4-41. In paragraph 26 (paragraph 28 in the new text), the Task Force agreed to clarify that information on genetic stability should be considered including "as appropriate" the presence of mobile DNA elements.

29. ~~27.~~ The history of use may include information on how the recipient microorganism is typically grown, transported and stored, Quality Assurance measures typically employed, including those to verify strain identity and ~~characteristics relevant to production,~~ production specifications for microorganisms and foods, and whether these organisms remain viable in the processed food or are removed or rendered non-viable as a consequence of processing.

DESCRIPTION OF THE DONOR ORGANISM

30. ~~28.~~ Information should be provided on the donor organism(s) and any intermediate organisms, when applicable, and, when relevant, related organisms. It is particularly important to determine if the donor or intermediate organism(s) or other closely related species naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor or intermediate organism(s) should include:

A) identity: scientific name, common name or other name(s) used to reference the ~~micro~~organism, strain designation, information about the strain and its

source, or accession numbers or other information from a recognized culture repository from which the organism or its antecedents may be obtained, if applicable, and information supporting its taxonomic assignment;

B) information about the organism or related organisms that concerns food safety;

C) information on the ~~micro~~organisms' genotype and phenotype relevant to its safety including any known toxins, antibiotics, antibiotic resistance factors or other factors related to pathogenicity, or immunological impact; and

D) information on the past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants)~~; and~~

~~E) information on opportunistic pathogenicity.~~

4-42. In paragraph 28 (paragraph 30 in the new text), the Task Force agreed to delete the last section E) on opportunistic pathogenicity, as it was already covered in section C) and made some editorial amendments to ensure consistency with the rest of the document.

DESCRIPTION OF THE GENETIC MODIFICATION (S) INCLUDING VECTOR AND CONSTRUCT

31. ~~29.~~ **Sufficient information should be provided on the genetic modification(s) to allow for the identification of all genetic material potentially delivered to or modified in the recipient microorganism and to provide the necessary information for the analysis of the data supporting the characterization of the DNA added to, inserted into, modified in, or deleted from the microbial genome.**

4-43, 1st sentence. In paragraph 29 (paragraph 31 in the new text), it was agreed that reference should be made to the identification of "all" genetic material for clarification purposes.

32. ~~30~~. **The description of the strain construction process should include:**

A) information on the specific method(s) used for genetic modification[6];

B) information~~, if applicable,~~ on the DNA used to modify the microorganism, including the source (e.g., plant, microbial, viral, synthetic), identity and expected function in the recombinant-DNA microorganism, and copy number for plasmids; and

C) intermediate recipient organisms including the organisms (e.g., other bacteria or fungi) used to produce or process DNA prior to introduction into the final recipient organism.

[6]~~General mechanisms of genetic exchange have been specified in footnote 4. Mobile promoter elements or virus-mediated exchange events and processes may not yet be available but are equally as valid as the general categories listed.~~

4-44. The Task Force agreed to delete Footnote 6 (Working Group on paragraph 24) as it was not necessary to list specific techniques and this would be consistent with its earlier decision to delete Footnote 4 in the Definitions.

4-43, 2nd sentence. In paragraph 30 B) (paragraph 32 B) in the new text), the Delegation of Iran proposed that the description of the strain construction process include the complete sequence of the transgene(s), plasmid or carrier DNA used during genetic modification of the microorganism. However, the Task Force agreed that this question should be addressed in the section on the characterization of the genetic modification in paragraph 33 (paragraph 35 in the new text).

33. ~~31~~. **Information should be provided on the DNA added, inserted, deleted, or modified, including:**

A) the characterization of all genetic components including marker genes, vector genes, regulatory and other elements affecting the function of the DNA;

B) the size and identity;

C) the location and orientation of the sequence in the final vector/construct; and

D) the function.

CHARACTERIZATION OF THE GENETIC MODIFICATION (S)

34. ~~32.~~ **In order to provide clear understanding of the impact of the genetic modification on the composition and safety of foods produced using recombinant-DNA microorganisms, a comprehensive molecular and biochemical characterization of the genetic modification should be carried out. To facilitate the safety assessment, the DNA to be inserted should be preferably limited to the sequences necessary to perform the intended functions.**

4-45. In paragraph 32 (paragraph 34 in the new text), the Delegation of Iran pointed out that as it was not always feasible to insert only the sequences necessary for the intended functions and the Task Force agreed that the DNA inserted should "preferably" be limited to those sequences.

35. ~~33.~~ **Information should be provided on the DNA modifications in the recombinant DNA microorganism; this should include:**

A) the characterization and description of the added, inserted, deleted, or otherwise modified genetic materials, including plasmids or other carrier DNA used to transfer desired genetic sequences. This should include an analysis of the potential for mobilization of any plasmids or other genetic elements used, the locations of the added, inserted, deleted, or otherwise modified genetic materials (site on a chromosomal or extrachromosomal location); if located on a multicopy plasmid, the copy number of the plasmid;

B) the number of insertion sites;

C) the organization of the modified genetic material at each insertion site including copy number ~~, if applicable. Sequence data of the inserted material and of the surrounding region should be provided in electronic format to facilitate of analysis using sequence databases;~~ **and sequence data of the inserted, modified, or deleted material, plasmids or carrier DNA used to transfer the desired genetic sequences, and the surrounding sequences. This will enable the identification of any substances expressed as a consequence of the inserted, modified or deleted material;**

D) identification of any open reading frames within inserted DNA, or created by the modifications to contiguous DNA in the chromosome or in a plasmid, including those that could result in fusion proteins~~, and expression of fusion proteins~~**; and**

E) particular reference to any sequences known to encode potentially harmful functions.

4-46. The Task Force had an extensive discussion on the information to be provided on the DNA modification, as presented in paragraph 33 (paragraph 35 in the new text) and agreed to retain the current text of point A) but to concentrate on the revision of point C).

4-47. The Delegation of Iran expressed the view that the complete sequence of inserted material should be described and that the copy number should be required as a general requirement, not "if applicable". The Delegation of Australia proposed to follow more closely the approach taken in the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and to delete the requirement concerning the sequence information in electronic format in order to allow more flexibility. The Delegation of the United States pointed out that the sequence did not always provide the information necessary for safety assessment and that other data had to be taken into account. Several delegations proposed that data should be provided on the material "inserted, modified or deleted", in order to address all types of genetic modifications. Following an informal working group7 and further discussion, the Task Force agreed on a compromise text that referred to the sequence data of inserted, modified or deleted material, plasmides or carrier DNA, and the surrounding

sequences; and recognized that this would enable the identification of any substances expressed in the process.

4-48. In point D), the Task Force agreed to delete the reference to "the expression of fusion protein" and to retain only "fusion protein" as proposed by some delegations to ensure consistency with the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. The Task Force agreed that point E) should cover any sequences known to encode "or to influence the expression" of potentially harmful functions.

36. ~~34.~~ **Information should be provided on any expressed substances in the recombinant-DNA microorganism; this should include**~~, when applicable~~:

A) the gene product(s) (e.g., a protein or an untranslated RNA) or other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food;

B) the gene product's function;

C) the phenotypic description of the new trait(s);

D) the level and site of expression (intracellular, periplasmic - for Gram-negative bacteria, organellar - in eukaryotic microorganisms, secreted) in the microorganism of the expressed gene product(s), and, when applicable, the levels of its metabolites in the organism;

E) the amount of the inserted gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the level of a specific endogenous mRNA or protein; and

F) the absence of a gene product, or alterations in metabolites related to gene products, if applicable to the intended function(s) of the genetic modification(s).

37. ~~35.~~ **In addition, information should be provided:**

A) to demonstrate whether the arrangement of the modified genetic material has been conserved[87] or whether significant rearrangements have occurred after introduction to the cell and propagation of the recombinant strain to the extent needed for its use(s) in food production <u>including those that may occur during its storage according to current techniques</u>;

B) to demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for its structure or function;

C) to demonstrate that the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable for the extent of propagation needed for its use(s) in food production and is consistent with laws of inheritance. It may be necessary to examine the inheritance of the inserted or modified DNA or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly[~~8bis~~ 8];

D) to demonstrate that the newly expressed trait(s) is expressed as expected and targeted to the appropriate cellular location or is secreted in a manner and at levels that is consistent with the associated regulatory sequences driving the expression of the corresponding gene;

E) to indicate whether there is any evidence to suggest that one or ~~several~~ <u>more</u> genes in the recipient microorganism has been affected by the modifications or the genetic exchange process; and

F) to confirm the identity and expression pattern of any new fusion proteins.

[~~8~~ 7] **Microbial genomes are more fluid than those of higher eukaryotes; that is, the organisms grow faster, adapt of changing environments,**

and are more prone to change. Chromosomal rearrangements are common. The general genetic plasticity of microorganisms may affect recombinant DNA in microorganisms and must be considered in evaluating the stability of recombinant DNA microorganisms.

~~[~~ ~~[8bis~~ **[8] Modified strains should be maintained** ~~by successive subculture or new culture to be used in an uninterrupted way during the successive productions in order to verify~~ **in a manner to enable verification of the genetic stability** **the genetic stability.]**

3-85. The Task Force also took note of the proposal of Argentina relating to the stability of the microorganism in successive generations, and included the text in square brackets in a footnote (8bis) to paragraph 35 C.

4-49. Some editorial amendments were made to paragraphs 34, 35 (paragraphs 36 and 37 in the new text) and footnote 8 for clarification purpose. A reference to the changes that may occur during storage was introduced in point A) of paragraph 35 (paragraph 37 in the new text), as proposed by the Delegation of Argentina.

SAFETY ASSESSMENT

38. ~~[36. In vitro nucleic acid techniques enable the introduction of new DNA to cells or enable precise changes to DNA in cells, which can result in the synthesis of new substances in or by microorganisms, alterations to the substances produced by microorganisms, or the regulation of these substances. Methods for implementing precise genetic changes are readily available for application to microorganisms and DNA is easily integrated into microbial genomes. These can be normal cellular components such as proteins, fats, carbohydrates, or other compounds such as vitamins or metabolites that are not normally present or produced by the recipient organism. Conventional toxicology studies are not considered necessary where the substance or a closely related substance has been consumed safely in food or used in food processing, taking into account its function and exposure. Effects of the recombinant-DNA microorganisms on the food matrix should be considered.]~~

The safety assessment of the modified microorganism should be performed on a case by case basis depending on the nature and extent of the introduced changes. Conventional toxicology studies may not be considered necessary where the substance or a closely related substance has, taking into account its function and exposure, been consumed safely in food. In other cases, the use of appropriate conventional toxicology or other studies on the new substance may be necessary. Effects of the recombinant-DNA microorganism on the food matrix should be considered as well. If the characterisation of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal or *in vitro* studies with the recombinant-DNA microorganism and/or the food produced using it could be considered necessary.

3-36. The Task Force noted several comments in relation to the content of paragraph 36, in particular to the precision (or lack of precision) of the changes brought about by genetic modification. Although part of the text was modified to make it consistent with the wording of the Guideline on recombinant-DNA plants, the Task Force agreed to place the entire paragraph in square brackets for further consideration.

4-50. The Task Force agreed to delete the three first sentences of paragraph 36 (paragraph 38 in the new text) as they were not directly relevant to recommendations on safety assessment. A new sentence concerning the need for a case by case safety assessment was introduced, as proposed by the Delegation of Germany.

4-51. The Task Force discussed the type of studies that were required where the substance or a closely related substance had been consumed safely in food. Some delegations and several observers expressed their concerns with the term "closely related" as this reflected the concept of substantial equivalence and they reiterated their earlier position that it would not provide adequate consumer protection. Several delegations pointed out that the notion of identity would be too restrictive and that "closely related substances" were mentioned in the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. The

Task Force agreed to insert the wording used in paragraph 37 (paragraph 39 in the new text) of the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants as it adequately addressed this issue. An additional sentence was included at the end of the paragraph concerning the need for properly designed animal or in vitro studies when available data were insufficient for a thorough safety assessment.

Expressed Substances Including Potential Toxins or Other Traits Related to Pathogenicity

4-52. The Delegation of Germany proposed to delete the reference to toxin and other traits related to pathogenicity in the title and to retain only "expressed substances" as this was the most important aspect. Other delegations noted that, as the text of the section did refer to toxins and pathogenicity, there was no contradiction with the title. After some discussion, the Task Force agreed with the proposal of the Delegation of Australia to refer to "assessment of potential toxicity" in the title rather than to "toxins".

39. ~~37~~. **When a substance is new to foods or food processing, the use of conventional toxicology studies or other applicable studies on the new substance will be necessary. This may require the isolation of the new substance from the recombinant-DNA microorganism, the food product if the substance is secreted, or if necessary, ~~[or~~ the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally, and biochemically equivalent to that produced in the recombinant-DNA microorganism.~~]~~ Information on the anticipated exposure of ~~the substance by~~ consumers to the substance, the potential intake and dietary impact of the substance should be provided.**

4-53. In paragraph 37 (paragraph 39 in the new text), some delegations and observers proposed to delete the sentence in square brackets on the synthesis or production of the substance from an alternative source and indicated that this could be justified in the case of plants, but not for microbes. Several delegations however pointed out that the use of an alternative source was necessary to obtain sufficient material. The Task Force therefore agreed to retain the current text without square brackets and to add that the use of an alternative source may be required "if necessary".

40. ~~38.~~ **The safety assessment of the expressed substance should take into account its function and concentration in the food. The number of viable microorganisms remaining in the food should be also determined, compared to a conventional counterpart. All quantitative measurements should** ~~include variation and mean values~~ **be analysed using appropriate using appropriate statistical techniques. Current dietary exposure and possible effects on population sub-groups should also be considered.**

- **In the case of proteins, the assessment of potential toxicity should take into account the structure and function of the protein and should focus on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g., protease inhibitors, siderophores) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[9] may be carried out in cases where the protein is present in the food, but is not closely similar to proteins that have been safely consumed in food, and has not previously been consumed safely in food, and taking into account its biological function where known.**
- **Potential toxicity of non-protein substances that** ~~result from the genetic modification that are not similar to substances that have been safely consumed~~ **have not been safely consumed in food should be assessed in a case-by-case basis depending on the identity, concentration, and biological function of the substance and dietary exposure. The type of studies to be performed may include evaluations of**

metabolism, toxicokinetics, chronic toxicity/carcinogenicity, impact on reproductive function, and teratogenicity.

[9] Guidelines for oral toxicity studies have been developed in international fora, for example the OECD Guidelines for the Testing of Chemicals.

4-54. In paragraph 38 (paragraph 40 in the new text), the Task Force agreed that all quantitative measurements should be analyzed using appropriate statistical techniques, as proposed by the Delegation of Sweden. In the first sub-paragraph, it was agreed that the assessment of potential toxicity should "take into account the structure and function of the protein". The Task Force agreed that oral toxicity studies may be carried out when the protein was not "closely similar" to proteins that have been safely consumed in food, as a compromise between the current text and a proposal to refer to an "identical" protein.

41. ~~39~~. **The newly expressed or altered properties should be shown to be unrelated to any characteristics of donor organisms that could be harmful to human health. Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to recombinant-DNA microorganisms that do not normally express those toxic or anti-nutritious characteristics.**

- **Additional in vivo or in vitro studies may be needed on a case-by-case basis to assess the toxicity of expressed substances, taking into account the potential accumulation of any substances, toxic metabolites or antibiotics that might result from the genetic modification.**

Compositional Analyses of Key Components

42. ~~40.~~ **Analyses of concentrations of key components[10] of foods produced by recombinant-DNA microorganisms should be compared with an equivalent analysis of a conventional counterpart produced under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. Ideally, the comparator(s) used in this assessment should be food produced using the near isogenic parent strain. The purpose of this comparison, in conjunction with an exposure assessment as necessary, is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.**

[10] Key nutrients or key anti-nutrients are those components in a particular food that may have a substantial impact in the overall diet. They may be major nutritional constituents (fats, proteins, carbohydrates), enzyme inhibitors as anti-nutrients, or minor compounds (minerals, vitamins). Key toxicants are those toxicologically significant compounds known to be produced by the microorganism, such as those compounds whose toxic potency and level may be significant to health. Microorganisms traditionally used in food processing are not usually known to produce such compounds under production conditions.

Evaluation of Metabolites

43. ~~41~~. **Some recombinant-DNA microorganisms may be modified in a manner that could result in new or altered levels of various metabolites in foods produced using these organisms. Where altered** ~~residue or~~ **metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g., procedures for assessing the human safety of chemicals in foods).**

4-55. In paragraph 41 (paragraph 43 in the new text), the Task Force agreed to delete the reference to "residue" as this could create confusion due to other uses of that term, and to consider only "altered metabolites".

44. ~~42.~~ **New or altered levels of metabolites produced by a recombinant-DNA microorganism may change the population of microorganisms in mixed culture, potentially increasing the risk for growth of harmful organisms or accumulation of harmful substances. Possible effects of genetic modification of a microorganism on other microorganisms should be assessed when a mixed culture of microorganisms is used for food processing, such as for production of natural cheese, miso, soy sauce, etc.**

Effects of Food Processing

45. ~~43.~~ **The potential effects of food processing, including home preparation, on foods produced using recombinant-DNA microorganisms should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant or the bioavailability of an important nutrient after processing. Information should therefore be provided describing the processing conditions used in the production of a food. For example, in the case of yoghurt, information should be provided on the growth of the organism and culture conditions.**

Assessment of immunological effects

46. ~~44.~~ **When the protein(s) resulting from an inserted gene is present in the food, it should be assessed for its potential to cause allergy. The likelihood that individuals may already be sensitive to the protein and whether a protein new to the food supply will induce allergic reactions should be considered. A detailed presentation of issues to be considered is presented in** ~~[an annex for the proposed draft guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants[11]][in~~ **the Annex to this guideline**~~]~~.

~~[11] Codex *Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants* (under development at Step 7) including the *Proposed Draft Annex on the Assessment of Possible Allergenicity of the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (under development at Step 4).~~

4-56. With regard to the annex on allergenicity, the Task Force decided to adopt the second option in paragraph 44 (paragraph 46 in the new text) to append the annex specific for microorganisms to this guideline. The Task Force agreed on the draft prepared by Japan as annex of CRD 7.

47. ~~45. The transfer of genes from species that are commonly allergenic when ingested as food should be avoided, unless the proteins associated with allergy from those species have been identified and do not include the protein encoded by the transferred gene.~~ **Genes derived from known allergenic sources should be assumed to encode an allergen and be avoided unless scientific evidence demonstrates otherwise. The transfer of genes from organisms known to elicit gluten-sensitive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.**

4-57. The Task Force agreed to revise paragraph 45 (paragraph 47 in the new text) in view of consistency with the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants as paragraph 43 of the guideline refers to "gluten-sensitive enteropathy" and to improve its clarity. For this purpose, the Task Force inserted the second sentence of paragraph 6 in the Annex on Allergenicity of the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants as the first sentence in paragraph 45 (paragraph 47 in the new text) with a slight modification to express clearly the avoidance of genes derived from known allergens. Furthermore, the Task Force incorporated paragraph 43 of the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from

Recombinant-DNA Plants with a slight modification to deal with the case of "gluten-sensitive enteropathy".

48. ~~46.~~ **Recombinant-DNA microorganisms that remain viable in foods may interact with the immune system in the intestinal tract. Closer examination of these interactions will depend on the types of differences between the recombinant-DNA microorganism and its conventional counterpart.**

4-58. In paragraph 46 (paragraph 48 in the new text), regarding the interaction of recombinant-DNA microorganisms that may remain viable in foods with immune system in gastrointestinal tract, the delegation of Italy proposed to add that "Efforts should be made to establish animal models or in vitro models to study above interactions.". The Task Force agreed that this was a useful recommendation for the purpose of research but that it should not be included in the current guideline as its purpose was to provide recommendations to safety assessment.

Assessment of Viability and Residence of Microorganisms in the Human Gut

49. ~~47.~~ **In some foods produced using recombinant-DNA microorganisms, ingestion of these microorganisms and their residence[~~12~~11] may have an impact on the human intestinal tract. The need for further testing of such microorganisms should be based on the presence of their conventional counterpart in foods, and the nature of the intended and unintended effects of genetic modifications. If processing of the final food product eliminates viable microorganisms (by heat treatment in baking bread, for example), or if accumulations of endproducts toxic to the microorganism (such as alcohol or acids) eliminate viability, then viability and residence of microorganisms in the alimentary system need no examination.**

> [11]**Permanent life-long colonization by ingested microorganisms is rare. Some orally administered microorganisms have been recovered in faeces or in the colonic mucosa weeks after feeding ceased.** ~~Residence connotes survival of microorganisms in the GI tract longer than two intestinal transit times (International Life Science Institute, The safety assessment of viable genetically modified microorganisms used as food, 1999, Brussels;~~ **Whether the genetically modified microorganism is established in the gastrointestinal tract or not, the possibility remains that it might influence the microflora or the mammalian host (WHO/FAO Joint Expert Consultation on Foods Derived from Biotechnology -*Safety assessment of foods derived from genetically modified microorganisms,* 24-28 September, 2001, Geneva, Switzerland).**

4-59. In paragraph 47 (paragraph 49 in the new text), the Task Force agreed with the revision of footnote 12 (footnote 11 in the new text) by adding a sentence from the FAO/WHO Expert Consultation on possible Influence of microorganisms on microflora. The Task Force also amended the 3rd sentence of footnote 12 (footnote 11 in the new text) to change the subject from "Residence" to "Persistence", and moved the sentence to a new footnote to paragraph 4 D) in order to provide an explanation of the term "persistence" as proposed by the delegation of Denmark.

50. ~~48.~~ **For applications in which recombinant-DNA microorganisms used in production remain viable in the final food product, (for example, organisms in some dairy products), [it may be desirable to demonstrate the viability (or residence time) of the microorganism** ~~in the digestive tract in animal model systems or to establish the residence times for the microorganisms in the alimentary tract and how dose affects other microorganisms in the alimentary system] /[it is desirable to demonstrate the viability and colonization of the microorganism in the digestive tract as well as how dose affect other microorganisms in the alimentary system]/[the viability (or residence time) of the microorganism~~ **alone and within the respective food matrix in the digestive tract and the impact on the intestinal microflora** ~~should be examined~~ **in appropriate systems.**~~]~~. ~~[~~**The nature of the intended and unintended effects of genetic modification and the degree of differences from the conventional**

counterpart will determine the ~~need~~ extent for such testing. ~~]~~

3-86. The Task Force agreed to include alternative texts concerning the viability of the microorganism in the human gut and its ability for colonization, for consideration at the next session.

4-60. The Task Force considered paragraph 48 (paragraph 50 in the new text) where several options were proposed as to how the safety assessment would deal with the case in which recombinant-DNA microorganisms remain viable in the final food. The Task Force agreed that it "may be desirable" to demonstrate the viability of the microorganism alone and the viability of microorganism in the food matrix in the digestive tract and the impact on the intestinal microflora by "appropriate system". It was noted that this option allowed flexibility and practicability under the present situation where methods for evaluation had not been fully established. It was also agreed that the nature of intended and unintended effects should be taken into account for determining the extent of such testing.

Antibiotic Resistance and Gene Transfer

51. ~~49.~~ In general, traditional strains of microorganisms developed for food processing uses have not been assessed for antibiotic resistance. Many microorganisms used in food production possess intrinsic resistance to specific antibiotics. Such properties need not exclude such strains from consideration as recipients in constructing recombinant-DNA microorganisms. However, strains ~~with transmissible antibiotic resistance~~ in which antibiotic resistance is encoded by transmissible genetic elements should ~~be avoided~~ should not be used ~~[when such a resistance is present in genetic elements] as candidate recipients for constructing recombinant-DNA strains. The absence of plasmids, transposons, and integrons containing such resistance genes should be [verified].~~ where such strains or these genetic elements are present in the final food. Any indication of the presence of plasmids, transposons, and integrons containing such resistance genes should be specifically addressed.

4-61. The Task Force had an extensive discussion on the case where strains had transmissible anti-biotic resistance when it considered the first bracketed sentence in paragraph 49 (paragraph 51 in the new text). During the discussion, the Representative of WHO stressed the importance of a global approach in the prevention of antibiotic resistance and encouraged the Task Force to provide clear recommendations in this area. The Task Force considered whether such a strain should be avoided as a candidate for recipient for construction of recombinant-DNA microorganisms or whether such strain should be prohibited from food production. An alternative proposal was made to specify that such strains should not remain in the final foods. As a result of discussion, the Task Force agreed not to use the strains for food production in which anti-biotic resistance is encoded by transmissible antibiotic genes where such strain and gene element were present in the foods.

52. ~~50.~~ Alternative technologies, demonstrated to be safe, that do not rely on antibiotic resistance marker genes in viable microorganisms present in foods should be used for selection purposes in recombinant-DNA microorganisms. In general, use of antibiotic resistance markers for constructing intermediate strains should pose no significant hazards that would exclude the use of the ultimate strains in food production, provided that the antibiotic resistance marker genes have been removed from the final construct.

53. ~~51~~. Transfer of plasmids and genes between the resident intestinal microflora and ingested recombinant-DNA microorganisms may occur. The possibility and consequences of gene transfer from recombinant-DNA microorganisms and food products produced by recombinant-DNA microorganisms to gut microorganisms or human cells should also be considered. Transferred DNA would be unlikely to be maintained in the absence of selective pressure. Nevertheless, the possibility of such events cannot be completely discounted.

54. ~~52.~~ **In order to minimize the possibility of gene transfer, the following steps should be considered:**

- chromosomal integration of the inserted genetic material may be preferable to localization on a plasmid;

~~- genes that could provide a selective advantage [,under the condition in which the recombinant microorganisms is used in the food production and stays viable in the human GI tract after its consumption,]~~ **where the recombinant-DNA microorganism will remain viable in the gastrointestinal tract, genes should be avoided in** ~~constructing the introduced genetic material~~ **the genetic construct that could provide a selective advantage to recipient organisms to which the genetic material is unintentionally transferred; and,**

- sequences that mediate integration into other genomes should be avoided in constructing the introduced genetic material.

4-62. In paragraph 52 (paragraph 54 in the new text), the Task Force agreed to replace the bracketed sentence in the second bullet with the sentence "where the recombinant-DNA microorganism will remain viable in the gastrointestinal tract, genes should be avoided in the genetic construct that could provide a selective advantage to recipient organisms to which the genetic material is unintentionally transferred." which was proposed by the Delegation of United States to improve clarity.

Nutritional Modification

55. ~~53.~~ **The assessment of possible compositional changes to key nutrients, which should be conducted for all foods produced using recombinant-DNA microorganisms, has already been addressed under 'Compositional analyses of key components.' If such nutritional modifications have been implemented, the food should be subjected to additional testing to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply.**

56. ~~54.~~ **Information about the known patterns of use and consumption of a food and its derivatives should be used to estimate the likely intake of the food produced using the recombinant-DNA microorganism. The expected intake of the food should be used to assess the nutritional implications of the altered nutrient profile both at customary and maximal levels of consumption. Basing the estimate on the highest likely consumption provides assurance that the potential for any undesirable nutritional effects will be detected. Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems. Based on the analysis of nutritional impacts and the dietary needs of specific population subgroups, additional nutritional assessments may be necessary. It is also important to ascertain to what extent the modified nutrient is bioavailable and remains stable with time, processing, and storage.**

57. ~~55.~~ **The use of modern biotechnology to change nutrient levels in foods produced using microorganisms could result in broad changes to the nutrient profile. The intended modification in the microorganism could alter the overall nutrient profile of the product, which, in turn, could affect the nutritional status of individuals consuming the food. The impact of changes that could affect the overall nutrient profile should be determined.**

58. ~~56.~~ **When the modification results in a food product with a composition that is significantly different from its conventional counterpart, it may be appropriate to use additional conventional foods or food components (i.e., foods whose nutritional composition is closer to that of the food produced using the recombinant-DNA microorganism) as appropriate comparators to assess the nutritional impact of the food.**

59. ~~57.~~ Some foods may require additional testing. For example, animal-feeding studies may be warranted for foods produced using recombinant-DNA microorganisms if changes in the bioavailability of nutrients are expected or if the composition is not comparable to conventional foods. Also, foods designed for health benefits, may require an assessment beyond the scope of these guidelines such as specific nutritional, toxicological or other appropriate studies. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods.

REVIEW OF SAFETY ASSESSMENTS

60. ~~58.~~ The goal of the safety assessment is a conclusion as to whether the food produced using a recombinant-DNA microorganism is as safe as ~~and no less nutritious than~~ the conventional counterpart ~~against which it was compared~~ taking into account dietary impact of any changes in nutritional content or value. Nevertheless, the safety assessment should be reviewed in the light of new scientific information that calls into question the conclusions of the original safety assessment.

Chapter 10

ESTABLISHMENT OF THE SECOND ROUND OF TASK FORCE ON FOOFD DERIVED FROM MODERN BIOTECHNOLOGY

CONTENTS

1. GENERAL DISCUSSION

The 5th Session (2005)

5-3. In welcoming the delegates on behalf of FAO, Mr. Ezzeddine Boutrif, Chief, Food Quality and Standards Service, highlighted the role that biotechnology can play in meeting the needs of an expanding and increasingly urbanized world population. However, for certain applications of biotechnology, expected benefits must be weighed against potential risks, both to human and animal health and to the environment, using a solid scientific framework. The Representative suggested that in defining its work programme, the Task Force should give consideration to those issues that would bring the maximum benefit to consumers' health and enhance food security and nutrition wellbeing of low-income communities, taking due account of work undertaken by other national authorities and relevant organizations. The Representative suggested that in the future an international expert body could be set up to assist in reviewing safety assessments undertaken by different parties with a view to assessing their conformity with Codex guidelines. The Representative also emphasized the need to assist developing countries to build their capacity in the safety assessment of foods derived from biotechnology. The Representative reiterated FAO's readiness to support, jointly with WHO, the work of the Task Force by providing the necessary scientific advice.

5-4. On behalf of the World Health Organization (WHO), Dr Jørgen Schlundt, Director, Department of Food Safety, Zoonoses and Food borne Diseases, expressed appreciation to the Government of Japan for the continued hosting of the Task Force and attributed the success of the first four-year period of the Task Force to the efficient management of the process from the Japanese Government and a collaborative spirit between participating Member States. The Representative recalled that a resolution of the 53rd World Health Assembly requested WHO to support Member States in providing the scientific basis for health-related decisions regarding genetically modified foods. More recently, the 109th Executive Board of WHO in January 2002 endorsed the Food Safety Strategy which states that WHO will promote a holistic approach to the production and safe use of foods derived from new methods of production, including genetic engineering. The WHO Representative also referred to a new International Food Safety Authorities Network (INFOSAN) which WHO had initiated recently in collaboration with FAO. Finally the Representative re-affirmed WHO's commitment to provide scientific advice necessary for further work of the Task Force.

5-5. The Task Force agreed to the proposal of Kenya to discuss on the issue of foods derived from animals exposed to protection against disease through gene therapy or recombinant-DNA vaccines under Item 5 (Other Business) if time was available.

MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND THE OTHER CODEX COMMITTEES

5-8. The Task Force noted the information presented in document CX/FBT 05/5/2 concerning the matters referred to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology by the Codex Alimentarius Commission and the other Codex Committees, in particular, the decision by the 27th Session of the Commission to re-establish the Task

Force and the recent activities undertaken by the Codex Committees on Methods of Analysis and Sampling and on Food Labelling.

REVIEW OF THE WORK BY INTERNATIONAL ORGANIZATIONS ON THE EVALUATION OF THE SAFETY AND NUTRITION ASPECTS OF FOODS DERIVED FROM BIOTECHNOLOGY

5-10. The Representative of the Convention on Biological Diversity (CBD) informed the Task Force that the third session of the Conference of the Parties serving as the meeting of the Parties to Cartagena Protocol on Biosafety (COP-MOP) would be held in March 2006. A Technical Expert Group on Risk Assessment established by the COP-MOP, to be held in November 2005, would discuss the existing approaches to risk assessment, identifying gaps and capacity building needs, and forward recommendations to COP-MOP 3. A document would be also prepared on the needs and modalities of standards with respect to the paragraph 3 of the Article 18 of the Protocol, including identification, handling, packaging and transport practices for Living Modified Organisms.

5-11. The Representative of the Organisation for Economic Cooperation and Development (OECD) informed the Task Force of the recent activities by the OECD Task Force on Novel Foods and Feeds, especially elaboration of a series of Consensus Documents on food and feed safety which provided information on the major nutrients, toxicants, anti-toxicants and allergens of specific crops. In this respect, new work had started to elaborate consensus documents on the crops of particular interests for developing countries such as papaya and cassava. Attention was also drawn to the fact that additional work was being undertaken by the OECD Task Force in areas such as molecular characterization of transgenic plants and considerations for the safety of animal feeds derived from genetically modified plants, the latter not being covered by the Codex Task Force.

5-12. The Representative of FAO referred to the work of the Inter-Departmental Working Group on Biotechnology in Food and Agriculture which coordinates the work of the different units related to biotechnology and in particular to FAO's 2004 publication "The State of Food and Agriculture" which included a paper entitled "Agricultural Biotechnology: meeting the needs of the poor?". The Representative also informed the Task Force of the work of the FAO working Group on Biosafety and of its plan to conduct an Expert Consultation on Biosafety and of a Workshop of Safety Assessment on Food Derived from Biotechnology, later this year. He indicated that work was in progress on the development of training materials on the safety assessment of GM foods, in cooperation with WHO, OECD and the Canadian authorities. This material would be based on Codex adopted guidelines, and include practical and concrete examples of how such assessment was carried out.

5-13. The WHO Representative drew the attention of the Task Force to a recent WHO report "Modern Food Biotechnology, Human Health and Development: an evidence-based study, as the outcome of a three-year study". The report suggests that the development of GM Foods can contribute to enhancing human health and economic development, only if properly assessed before marketing, through broad, coherent, evidence-based evaluation. This assessment should include human health and environmental assessment, but also assessments of potential benefits and social and ethical concerns. The report also stated that GM foods available on the market have passed food safety risk assessment and are not likely to present risks for human health. Finally the report referred to Codex principles and guidelines as the appropriate international basis for food safety risk assessment.

5-14. The Task Force also noted the information provided by the International Centre for Genetic Engineering and Biotechnology (ICGEB) and the World Organisation for Animal Health (OIE). Especially, attention was drawn to the report on the state of application of genetic engineering for livestock and the recently adopted resolution by the OIE International Committee.

5-15. In order to facilitate discussion under this Agenda item and to provide members and observers with an opportunity to freely express opinions, the Task Force agreed to have a general exchange of views on the whole range of possible areas for new work before examining each of the subjects one-by-one. The Task Force noted that there was a diversity of views among delegations and observers, including the priorities they assigned to different

areas of work. The Task Force also noted the particular situations of developing countries in relation to the prevalence of malnutrition and nutrient deficiency diseases as well as their needs for capacity building on the safety assessment of food derived from biotechnology. The Task Force then proceeded with further discussion, item-by-item, as follows.

Recombinant-DNA Animals (*See the separate chapter on this matter*)

Recombinant-DNA plants modified for nutritional or health benefits (*See the separate chapter on this matter*)

Low level (Adventitious) presence of unauthorized recombinant-DNA plant materials (*See the separate chapter on this matter*)

Comparative composition analysis (*See below*)

Plants with stacked genes (*See below*)

Plants producing pharmaceutical or bioactive substances (*See below*)

Post market surveillance (*See below*)

Comparative composition analysis

5-39. Several delegations proposed to give high priority to the proposed work on comparative composition analysis of recombinant-DNA plants including staple crops of particular importance for developing countries.

5-40. Other delegations pointed out that some international organizations had already undertaken relevant work in this area. Particular reference was made to the development of Consensus Documents by OECD which aimed at assisting in the conduct of comparative compositional analysis by national authorities.

5-41. The Representatives of FAO and WHO informed the Task Force of their current activities related to capacity building of countries in the safety assessment of foods derived from biotechnology, in particular, a document under development which would provide useful guidance for conducting safety assessments of recombinant-DNA plants and strengthening national infrastructure and expertise in developing countries.

5-42. The Task Force noted that there was a need to further clarify the scope for new additional work on top of the existing guidance in the Plant Guideline (CAC/GL-45-2003) and agreed that it was premature to consider new work on this subject.

5-43. The Delegation of India, referring to its written comment, proposed that the Task Force should start, in the future, new work on comprehensive analysis of nutrients, anti-nutrients as well as methods of toxicity studies because quantitative and qualitative analytical methods would be necessary tools to conduct safety assessment of recombinant-DNA plants.

5-44. The Task Force agreed to invite India to submit a discussion paper on this subject for further consideration by the next session of the Task Force. In this respect, the Task Force noted that the work undertaken by the Codex Committee on Methods of Analysis and Sampling and other relevant international organizations should be fully taken into account when assessing the need for future work, if any.

DISCUSSION PAPER ON COMPARATIVE FOOD COMPOSITION ANALYSIS OF STAPLE FOODS

6-60. The Delegation of India, referring to working document CX/FBT 06/6/6, explained the background, objectives and expected benefits of the proposal. The Delegation observed that there were the limitations in existing knowledge on compositional analysis of genetically engineered staple crops, namely macro- and micro-nutrients, inherent plant toxins, anti-nutrients, plant metabolites and allergens. The Delegation was of the view that the absence of globally acceptable analytical methods for food consumption analysis constituted an obstacle to conducting these analyses.

6-61. The Representative of OECD informed the Task Force that the OECD had already produced a number of consensus documents containing compositional and other relevant information for the staple crops listed in the annex of document CX/FBT 06/6/3, including

wheat, maize and rice, and that the OECD Task Force had started discussion on how to update these documents to make them more complete. The Representative welcomed increasing participation of non OECD members in the work of the OECD Task Force on consensus documents.

6-62. The Representative of FAO stated that under the coordination of the International Network of Food Data Systems (INFOODS), FAO had produced a number of food composition tables using data from different parts of the world and that these were available to all members of FAO. The Representative suggested that Codex should not duplicate the existing or ongoing work of other international organizations. The Task Force also noted that a number of methods of analysis for nutrients were already included in the Codex Alimentarius and other international publications.

6-63. After some discussion, the Task Force decided not to initiate new work in this area.

Plants with stacked genes

5-45. The Task Force discussed whether or not new work should be initiated on the issue of plants with stacked genes. The Delegation of Japan proposed the definition of the plants with staked genes as the first generation of plants obtained through conventional crossing of two parent recombinant-DNA plants whose safety had been already evaluated. The delegation further suggested development of an Annex to the Plant Guideline (CAC/GL 45-2003) in order to provide guidance to governments as to when and how the safety assessment for this type of plants should be conducted in accordance with the Plant Guideline.

5-46. The Task Force noted that the term "stacked genes" was understood in different ways and recognized the necessity to have a clear, common understanding of "plants with stacked genes" before deciding on the need for new work. Some delegations pointed out that the definition presented by Japan was not sufficient and suggested further elaboration.

5-47. Several delegations stressed the importance of initiating new work in this area in view of the increasing development of recombinant-DNA plants by crossing between recombinant-DNA plants and the diversification of national legislations applied to these products. Other delegations pointed out that this issue needed to be addressed on a case by case basis, which made it difficult to develop general guidance. Attention was also drawn to the fact that many plant varieties had been produced through conventional crossing without adverse health effects and that traditional plant breeding had a long history of safe use.

5-48. After a lengthy discussion, the Delegation of Japan, supported by the Delegation of the United States, expressed the view that although the existing plant guideline did not specifically address plant varieties with two or more recombinant-DNA traits obtained through conventional crossing, many of which had already been developed and commercialised, the guideline provided sufficient guidance for the conduct of safety assessment and that a safety assessment might be needed on a case by case basis for this type of hybrid where each parental recombinant-DNA plant had individually been assessed, and the extent of safety assessment might vary depending on the potential interactions between inserted sequences in the hybrids.

5-49. The Delegation of European Community, supported by Norway, expressed the view that whilst a pre-market safety assessment was always necessary, in accordance with paragraph 11 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, the extent of the safety assessment might vary on a case by case basis depending on the potential interactions between inserted sequences in the case of plants with stacked genes.

5-50. After an exchange of views on this subject, the Task Force acknowledged that there was a diversity of opinions among members and therefore decided not to take a decision to initiate new work. The Delegation of Iran, while not objecting to this decision, emphasized that in addition to the safety assessment of parental recombinant-DNA plants, a case by case safety assessment of plants with stacked genes was required at various levels, taking into account the potential interaction between inserted sequences in the hybrids, and stressed that the development of an annex to the Plant Guideline was necessary.

Plants producing pharmaceutical or bioactive substances

5-58. Several delegations and observers pointed out that the issues related to plants

producing pharmaceutical or bioactive substances were beyond the mandate of Codex. Some delegations suggested that the term of "bioactive substance" should be clearly defined for judging whether or not plants producing such substances could be considered as foods and be addressed by the Task Force.

5-59. The Delegation of Norway expressed its opinion that issues on contamination of food supply with plants producing pharmaceutical substances could be addressed by the Task Force with a view to assuring food safety and protecting consumers' health, if there was a slightest possibility for the plants to reach to food chain.

5-60. The Task Force noted that there was no consensus on this matter and agreed not to start new work on this subject.

Post market surveillance

5-61. The Delegation of Mexico, referring to its written comment, proposed to start new work on post market surveillance with the aim of obtaining scientific information which could support and complement risk assessment of foods derived from biotechnology.

5-62. Due to the late availability of the written proposal, the Task Force agreed that Mexico submit a discussion paper to the next session of the Task Force with respect to the sanitary surveillance after placing on the market of foods derived from biotechnology.

DISCUSSION PAPER ON SANITARY SURVEILLANCE AFTER PLACING ON THE MARKET OF FOODS DERIVED FROM BIOTECHNOLOGY

6-64. The Delegation of Mexico, referring to working document CX/FBT 06/6/7, explained that the objective of the proposed new work project was to collect scientific information which could support and complement risk assessment of food derived from biotechnology when there was a scientifically founded doubt. However, recognizing that the work on the "proposed draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits" had already started, the Delegation considered that it was not appropriate to start new work until being able to analyse the result of the already initiated work.

6-65. The Task Force, noting that the matter could be covered, at least partly, by another ongoing work of the Task Force (see Agenda Item 5 of the present report), decided not to initiate new work.

OTHER BUSINESS

Foods derived from animals exposed to protection against disease through gene therapy or recombinant-DNA vaccines

5-5. The Task Force agreed to the proposal of Kenya to discuss on the issue of foods derived from animals exposed to protection against disease through gene therapy or recombinant-DNA vaccines under Other Business if time was available.

5-63. The Delegation of Kenya, referring to its written comments, proposed that the Task Force should consider, as possible future work, safety assessment of foods derived from animals exposed to protection against disease through gene therapy or recombinant-DNA vaccines.

5-64. The Task Force noted that the World Organisation for Animal Health (OIE) and other international organizations had ongoing work on the application of these techniques in food animals and that duplication of work with these organizations should be avoided. The Task Force further noted that its terms of reference did not include issues relating to animals that were not modified as such but were fed with genetically modified feeds or treated with recombinant-DNA vaccines.

5-65. The Task Force however recognized that there might be a potential food safety issue associated with foods derived from animals treated with recombinant-DNA vaccines or gene therapy and that there was a merit in following up the issue in the light of the work being undertaken by other organizations, namely OIE.

5-65. The Task Force therefore invited Kenya to submit a discussion paper to the next session of the Task Force to further elaborate the matter.

DISCUSSION PAPER ON SAFETY ASSESSMENT OF FOODS DERIVED FROM ANIMALS EXPOSED TO PROTECTION AGAINST DISEASES THROUGH GENE THERAPY OR RECOMBINANT-DNA VACCINES

6-66. The Task Force recalled that the Fifth Session of the Task Force had considered the proposal by Kenya on future work for the safety assessment of foods derived from animals exposed to protection against diseases through gene therapy or recombinant-DNA vaccines and had decided to invite Kenya to submit a discussion paper to the present session in order to further consider the matter, noting that OIE had ongoing work on the application of these techniques13.

6-67. The Delegation of Kenya introduced document CX/FBT 06/6/8 to the Task Force and stressed that possible risks to human health by the application of these techniques should be carefully examined although the possibility of such occurrences might be very low. The Delegation further pointed out that the activities of OIE were centred on animal health and may not address the food safety aspects and that this should therefore be addressed by Codex.

6-68. The Task Force expressed its appreciation to the contribution of Kenya in developing the discussion paper.

6-69. The Task Force noted that the subgroup of vaccine established under the OIE ad hoc Group on Biotechnology was working in this area and that the mandate of OIE included food safety aspects as they relate to animal health. The Task Force further recalled its earlier decision to include the "non-heritable applications" in the questions addressed to the FAO/WHO expert consultation to be held in early 2007, which could partly cover the issues in question.

6-70. While some delegations recognized that there was certain information gap to be filled in this area, several delegations believed that the proposed work would be more appropriately done by OIE and did not support the work by the Task Force. Some delegations believed that there was no clear justification for dealing with recombinant-DNA vaccines differently from the conventional ones and that the approval system for pharmaceuticals usually had regard to the food safety dimension.

6-71. After some discussion, the Task Force decided not to initiate the new work for the present and agreed to monitor the progress of the ongoing work by OIE with respect to food safety aspects. In this regard, the Task Force decided to request the Codex Secretariat to liaise with OIE so that a report of OIE's activities in this area would be submitted to the next session of the Task Force, while informing OIE of the expectation of the Task Force on the ongoing work of the ad hoc Group. The Task Force further agreed that this matter also be referred to the Committee on Residues of Veterinary Drugs in Foods for information and advice as appropriate.

Safety assessment of composite foods containing ingredients derived from recombinant-DNA organisms

5-67. The Task Force also agreed that Pakistan submit a discussion paper to the next session of the Task Force with regard to the safety assessment of composite foods containing ingredients derived from recombinant-DNA organisms so that the Task Force could evaluate the need for new work.

Future Work

5-68. The Task Force noted that the following items would be considered at its next session:

-Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (led by Australia and Japan);

-Proposed Draft Annex (scoping document) to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or

Health Benefits (led by Canada);

-Discussion paper on Comparative Food Composition Analysis of Staple Foods (prepared by India);

-Discussion paper on Sanitary Surveillance after Placing on the Market of Foods Derived from Biotechnology (prepared by Mexico); and

-Discussion paper on Safety Assessment of Foods Derived from Animals Exposed to Protection against Disease through Gene Therapy or Recombinant-DNA Vaccines (prepared by Kenya).

SUMMARY OF WRITTEN COMMENTS **(compiled by H.Y.)**

I. Plant biotechnology

Argentina

(1) **Plants with stacked genes**,

(2) Plants expressing **enhanced levels of nutritional or functional compounds** already synthesized by the plant

(3) Plants expressing significant levels of nutritional or functional compounds which were not previously produced by the plant and whose synthesis is made possible through the introduction, complete or partial, of relevant genes of biosynthetic pathways.

Australia

1. Plant expressing bioactive substances or nutritionally enhanced plants
   - Many of the issues raised under this title could equally apply to novel foods in general, not just those derived from modern biotechnology, and may apply to food derived from TG animals.
   - "**Nutritionally enhanced** plants" would be valuable particularly in relation to assessing the impact of the nutritional modification on the whole diet, and the role and usefulness of animal feeding and human studies in assessing nutritional impact and bioavailability.
   - Plant expressing **bioactive substances** (ex. phytosterols, omega-3 fatty acids) needs additional scientific advice in the form of **Expert Consultation**)

2. "Plants with stacked genes" is of low priority, and "low level presence of unauthorized genetically engineered foods in authorized food" is the matter of **CCFICS.** Biopharming is outside the scope of codex

Brazil

1. The first priority is "stacked genes" and then,
2. Low level presence of **new GM foods not yet evaluated in different parts of the world** (in place of unauthorized genetically engineered foods, as TF is technical one, not legislative one) in authorized foods".
3. Plant expressing bioactive substances or nutritionally enhanced plants could be covered by the plant guideline. Nutritionally enhanced plants are produced by **other technologies like conventional breeding**, not by modern biotechnology only.

Canada

1. Novel foods derived from second generation plants and associated novel traits.
   - Title should be "**Nutritionally-enhanced plants, including plants expressing food-related bioactive substances".**
   - Altered oil composition profile, antioxidant lycopene, etc. but not pharmaceuticals or other non-food use.
   - Additional safety and nutritional considerations, bioavailability, physical function and effectiveness of the food.
2. Plants with stacked genes and low level presence of unauthorized genetically engineered food can be undertaken but are of lower priority
3. Avoid duplication of OECD Task Force on the Safety of Novel Foods and Feeds, CCFL, and CCMAS.

EC

1. Genetically modified plants expressing pharmaceutical or other non-food substances ("bioactive" substances)
   -Identify type of substances allowed in crops used for food.
   - Cultivation methodology for confinement
   - Safety assessment with regard to food safety
   (*Project document*)
2. Stacked genes
   - Safety issues associated with the conventional crossing of recombinant DNA plants
   - Examination of the existing safety assessment to determine which issues in the plant guideline are appropriate to establish the food safety of plants with stacked genes
   (*Project document*)

Iran

1. Expert consultation to clarify issue of compositional analysis and the role and limitation of Substantial Equivalence.
2. The top priority is "Foods derived from **GM plants**", then "Presence of low level of unauthorized GM foods", and "Comparative food composition analysis".
3. Development of guidelines annexed to the plant GL for "Safety assessment of plants expressing bioactive substances and nutritionally-enhanced foods", "Plants with stacked genes", and Plants expressing pharmaceutical or other non-food substances".

Japan

1. Stacked genes.
   - Plants obtained through conventional breeding of recombinant-DNA plants with other recombinant-DNA plants, both developed for food.
2. Nutritionally-enhanced plants.
   - Plants that express nutritional substances endogenous to the host plants at altered levels, or nutritionall substances coded by genes derived from other species.
   - Exposure assessment should be addressed in other committees.

USA

Plants expressing bioactive substances or nutritionally-enhanced plants are covered by the present plant guideline. Safety issues related to specific traits should be assessed on case-by case basis (difficult to develop general guidelines). "Stacked genes" are also covered by the present plant guideline. Biopharming or non-food use are out of codex scope

Venezuela

1. Biopharmaceutical agriculture" and "producer plants of pharmacological or other non-nutritive substances" are different.
2. "Flow of genes" and biosecurity (effect on environmental) should be considered.

CI (Consumers International)

1. No to bioactive plants, biopharming, as they are not foods and not within codex scope.
2. Nutritionally-enhanced plants are covered by the present plant guideline.

II. Animal

Argentina

"Foods derived from animals" should **not deal with cloned animal,** as they are not transgenic. The development of such animals is still in infancy; **more scientific information** is required. Delete "including fish" because animal includes fish.

Australia

The first priority is "transgenic animals".

- Pressing need for international guidance, as its commercial development is said to be imminent.
- Number of issues is to be solved before any work could commence.
- **The development of generic guidance, applicable to all classes of animals with special consideration of fish** to be given a high priority within the work.
- **Use the plant guideline as a starting point;** toxicity and allergenicity assessment would be directly transferable, while compositional analysis needs more significant modification.
- **Use of animal health as parameter;** a healthy animal is likely to produce safe food products. Experience in cloned animals can be useful.
- **Questions:** molecular characterization of TG animals/ Any issues related to transgene copy number and homozygosity/ method of transformation that may pose greater risks/ information on the key constituents/ appropriate developmental stages and tissues for compositional analysis.

The second priority is "cloned animals"

- Scope should be limited to **somatic cell nuclear transfer** (SCNT)
- Cloned animals from SCNT could be interpreted as foods derived from modern biotechnology *(??)*
- **Expert consultation is needed**. OIE should be present in the consultation.

Brazil

Work on GM animals should be initiated after the work on GM plants is advanced. Cloning is not part of the scope of the modern biotechnology.

Canada

Novel foods derived from animal origin

- **Additional expert advice** may be sought as appropriate.
- Follow the approach used for the plant guideline to allow identification of **commonalities applicable** to the safety assessment of foods derived from different recombinant animals as well as the identification of the **peculiarities** of such foods
- Develop GL for cloned animals complementing the GL for recombinant animals.

EC

1. Food safety assessment of genetically modified animals (including fish) and derived products

- Develop guidelines from the experience of plant guideline
- Due consideration should be given to environmental and ethical aspects (*proposal document*)

2. Cloned animals

- Animals produced by **somatic cell nuclear transfer** and their offspring are about to be produced commercially
- Identify safety issues
- Methodology to assess and manage the issues.
- FAO/WHO expert consultation needed.

(*Project document*)

Iran

Transgenic animals and cloned animals are low priority.

Japan

Transgenic fish.

- Focus only on safety of fish as food.
- Animals in general are too broad as a category, and transgenic mammals (and birds?) as food are in early stage of development.

(Project documents)

New Zealand

The first priority is **Foods derived from recombinant DNA animals**.

- Develop guidelines along the lines of the plant and microbe guidelines.
- Determine if there are areas that need updating the FAO/WHO report on the GM animals or further **scientific advice** on this topic.

USA

1. Transgenic animals
   - **Limited national experience** on which to base a guideline.
   - If undertaken, a **step-wise approach** should be taken with clear decision points on proceeding further with work on the subject. First, **identify elements** relevant to GM-animal foods, additional relevant concepts, and any topics that need further scientific input (from FAO/WHO consultation). Then, develop guidelines, describing **elements common** to the safety assessment of foods derived from GM animals. **Particular cases**, ex. particular species modified for particular end-uses, could be addressed.

2. Cloned animals are not appropriate.

49P

"Transgenic animals": OLF is an important element for the debate.

CI

Transgenic animals

- Important as it raises a range of ethical, religious, animal welfare and other issues that fall under the rubric of OLF. Religious issues, mixing of genetic elements, human protein expressed in TG animals (cannibalism), animal welfare, etc. FAO/WHO consultation recognized ethical issues and talked about ways to incorporate ethical issues into the risk assessment.
- Environmental issues, especially, of TG fish and shellfish.
- No to cloned animals, as it is not derived from modern biotechnology.

(*Project document*)

No to "Low level presence in food of unauthorized GM food", as it is primarily a legal issue. Until unauthorized GM foods completes a full food safety assessment as laid out in the plant document, it should not be permitted on the market and that should be zero tolerance for this food in authorized foods.

III. Comparative Food Analysis

Argentina

Comparative food composition analysis comes next to "animals", though the concept of "**comparative**" needs clarification.

Australia

Comparative food composition analysis

- To study design, sample sizes, number of field trial sites, choice of appropriate comparator.
- **Conceptual approach** to interpreting information from these studies (*Consultation needed?*).

Brazil

Compositional analysis already covered by the plant GL paras 44-45

EC

Food safety issues specific to staple food crops for developing countries; support US proposal

Mexico

Comparative **compositional** analysis of foods to focus on the application of new technologies.

USA

"Food safety issue specific to staple food crops for **developing countries** (food composition).

- Identify key components, ex. important nutrients, anti-nutrients, and toxins
- Data on the range of concentration of each component reported
- Other information specific to staple crops, ex. cassava, plantain, sweet potato, that are important to developing countries
- Provide information to countries on food composition analysis

IV. Low level presence

Argentina

It does **not oppose "low level** presence of unauthorized genetically engineered foods in authorized foods. The distinction between unauthorized and authorized foods is country-dependent, as well as the reliability of the regulatory system by which it is authorized. Dispute concerning the authorization may fall within different non-codex international agreements.

EC

Low level presence of unauthorized genetically modified material in food

- Argument based on science would help alleviate or prevent potential trade disputes caused by low levels of GMOs through adventitious contamination of non-GM products during production, transport or storage, and promote fair practices in food trade.
- The present plant guideline may not be appropriate to establish food safety of the adventitious presence of low level of recombinant-DNA plants.
- Examine the present plant guideline to determine which issues in the guideline are appropriate to establish the food safety of low level of recombinant-DNA plant.

(*Project document*)

USA

Low-level presence in food of plant material derived from recombinant-DNA plants

- Increasing number of new varieties in research and development phase are tested in the fields; older varieties coming off the market continued to be present in the food supply.
- Identify issues associated with low level presence of recombinant-DNA plant material in food (*not specific to unauthorized one?*)

(*Project document*)

Venezuela

Low level presence in food of unauthorized GM food: It is not clear whether it refers to concentration in the raw material or in the final product.

49P

No to "Low level presence in food of unauthorized GM food": Unauthorized is unauthorized. Cartagena protocol Article 18 should be reminded of.

BIO

1. Guidelines/Principles for the assessment of the inadvertent, intermittent low-level presence of proteins in food/food ingredients for
   - **Approved/authorized** within a country/countries **that follow codex risk assessment principles** for products of plant biotechnology
   - **Unapproved/unauthorized traits** – traits, which may be present but have not yet to be approved in a country/countries that follow codex risk assessment principles for products of plant biotechnology

CI

No to "Low level presence in food of unauthorized GM food", as it is primarily a legal issue. Until unauthorized GM foods completes a full food safety assessment as laid out in the plant document, it should not be permitted on the market and that should be zero tolerance for this food in authorized foods.

V. Other Subjects

Mexico

Surveillance after GM foods have been put on the market.

49P

"Ethical, environmental and socio-economic ramifications of foods derived from modern biotechnology"

2. GENERAL INFORMATION GIVEN IN SIXTH AND SEVENTH SESSIONS

The 6th Session (2006)

REVIEW OF THE WORK BY INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS RELATED TO FOODS DERIVED FROM BIOTECHNOLOGY

6-9. The Codex Secretariat drew the attention of the Task Force to the written contribution from the Secretariat for the Convention on Biological Diversity (CBD). The Task Force noted that the Third meeting of the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol (COP-MOP 3) had agreed on the detailed requirements for documentation accompanying shipments of living modified organisms intended for direct use as food or feed, or for further processing. The Task Force also noted that COP-MOP3 requested the Executive Secretary of CBD to continue pursuing, reinforcing, and intensifying cooperative arrangements with several international organizations including Codex.

6-10. The Representative of FAO highlighted a number of activities carried out by FAO or jointly with WHO, which included the development of several tools, such as an FAO/WHO guidance document aimed at assisting countries to implement Codex food safety assessment guidelines, technical assistances to countries, as well as the development of networks for information exchange among public and private entities in charge of biosafety at the regional level. The Representative also informed that the Organization was, in cooperation with WHO, prepared to hold an expert consultation in order to provide scientific advice on specific issues which would be identified by the Task Force at the present session.

6-11. The Representative of WHO stated that it had been carrying out a number of activities in the field of biotechnology and human health, among which only those related with biotechnology in food production were explained in its written contribution contained in CX/FBT 05/5/3. The Representative further mentioned that all detailed information on the activities of the Organization in this field at the national and regional levels was available at the WHO website.

6-12. The Representative of the Organisation of the Economic Cooperation and Development (OECD), referring to the written submission, highlighted some of the activities undertaken by the OECD Task Force for the Safety of Novel Foods and Feeds. Recently, non-OECD member countries were actively participating in the work of the Task Force, including development of consensus documents of particular importance to developing countries, such as on papaya and cassava. Furthermore, work was started on the updating of consensus documents which had already been published, in the light of new scientific information; the Working Group on Harmonization of Regulatory Oversight in Biotechnology revised the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants; and a new version of OECD's database of products of modern biotechnology approved for commercial application was launched.

6-13. The Representative of the World Organization for Animal Health (OIE) informed the Task Force that the OIE ad hoc Group on Biotechnology had started to work on reproductive animal biotechnologies, on vaccines and on nanotechnology. The ad hoc Group also revised the draft chapter on principles of veterinary vaccine production in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. Recently, the terms of reference of the Group had been revised to include development of guidelines on the animal health risks arising from somatic cell nuclear transfer (SCNT) cloning of production animals and guidelines for new vaccine technologies, monitoring of developments on nanotechnology and advising the OIE on suitable procedures for the identification and tracing of animals and animal products resulting from biotechnology interventions. While current emphasis of work was placed on the development of guidelines on SCNT cloning in livestock, the Group was addressing vaccine-related issues as well.

6-14. The Delegation of European Community thanked the international organizations for their activities complementing the work of the Codex Task Force, and encouraged these organizations, especially OECD, to strengthen programmes related to information

gathering and sharing.

The 7th Session (2007)

MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)

7-5. The Task Force noted the information presented in document CX/FBT 07/7/2 concerning the matters of interest to the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology arising from the 30th Session of the Codex Alimentarius Commission and the recent sessions of the Committees on Methods of Analysis and Sampling and on Food Labelling.

7-6. The Task Force was informed that the Committee on Residues of Veterinary Drugs in Foods, at its 17th Session, had not provided any advice on the issue of animals treated with recombinant-DNA vaccines in reply to the referral by the Task Force, considering that the issue was beyond the mandate of the Committee4.

7-7. The Task Force also noted the new work undertaken by the Committee on Nutrition and Foods for Special Dietary Uses to elaborate a proposed draft principle of nutritional risk analysis, addressing nutritional risk assessment and related key concepts. These concepts might be relevant to the discussion of Agenda Item 5.

7-8. The Task Force noted that that the work underway in the Committee on Methods of Analysis and Sampling on the detection and identification of foods derived from biotechnology was complementary to the work of the Task Force and agreed to encourage this committee to proceed with its work with urgency.

REVIEW OF THE WORK BY INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS RELATED TO FOODS DERIVED FROM BIOTECHNOLOGY (Agenda Item 3)

7-9. The Task Force noted with appreciation the information presented in document CX/FBT 07/7/3 submitted by several international intergovernmental organizations concerning their work related to foods derived from biotechnology.

7-10. The Representative of the Organisation for Economic Cooperation and Development (OECD) underlined a few recent developments in the OECD Task Force for the Safety of Novel Foods and Feeds. First, the Representative noted and welcomed increasingly active participation of non-member countries, especially in the development of some OECD Consensus Documents. Second, the Representative informed the Task Force that the OECD Task Force had initiated the update of the Consensus Documents on low erucic acid rapeseed and on soybean. Furthermore, the Representative drew the attention of the Task Force to the work on unique identifiers by the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, which had recently revised the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants to cover gene-stacked events and had been considering a guidance for unique identifiers for transgenic microorganisms, starting from bacteria.

7-11. The Representative of the World Organisation for Animal Health (OIE) informed the Task Force of most recent work by the ad hoc Group on Biotechnology. The ad hoc Group had met a third time in June 2007 and developed two Guidelines, which were forwarded to the Biological Standards Commission of the OIE, meeting in September 2007. The Guidelines for Somatic Cell Nuclear Transfer in Production Livestock and Horses, which primarily dealt with identification of animal health risks and their management, as well as risks and prevention measures related with the technology, recommended four steps in risk analysis processes: management of the animal health risks associated with embryo production; management of the animal health risks related to the recipients (surrogate dams); management of the animal health risks of animal clones themselves; and management of the animal health risk of the next generation. The Task Force was informed that the Guidelines for DNA Vaccines, which covered vaccines delivering genes encoding relevant immunogen response in the form of bacterial plasmid DNA molecules, were intended to provide guidance to manufactures

seeking to develop these vaccines. The Representative indicated that the work of the ad hoc Group on Biotechnology was coordinated, as necessary, with the work of the ad hoc Groups on Traceability and Animal Identification and on Animal Welfare, as well as the OIE Animal Production Food Safety Working Group.

7-12. The Representative of FAO, on behalf of both FAO and WHO, expressed the commitment of FAO and WHO to continue to support Codex work in biotechnology, particularly that done by the Task Force. The Representative further explained that FAO's work in the area of biotechnology was coordinated by an internal working group composed of representatives from several departments of the Organization, which had been active in releasing science-based information about biotechnology in the form of newsletters. The Representative also referred to the FAO Glossary of Biotechnology for Food and Agriculture, published in four languages on CD-ROM, and to the training-of-trainers workshop on safety assessment of foods derived from biotechnology held in Ottawa, which had been a pilot test of a training package FAO was preparing for finalization.

7-13. The Representative of FAO, on behalf of both FAO and WHO, introduced document CX/FBT 07/7/3Add.1 (summary of the Report of the FAO/WHO Expert Consultation on the Safety of Foods Derived from Recombinant-DNA Animals), which was closely linked to Agenda Item 4 and accordingly considered therein in more detail.

7-14. In response to the request for clarification made by several delegations about the possible further involvement of the OIE in the food safety aspects of foods derived from biotechnology, in particular on the issue of animals treated with recombinant-DNA vaccines, the Representative of the OIE clarified that the organization's main area of concern was animal health, which might have a bearing on food safety, while not excluding the possibility of addressing food safety aspects of recombinant-DNA vaccines in the future if the organization was so requested. In this respect, the Representative of FAO, while generally welcoming the cooperation between FAO and OIE, especially in the provision of scientific advice and technical assistance, noted that the responsibilities of other normative issues on food safety should lie primarily within the Codex Alimentarius Commission and the Task Force.

7-15. While recalling that the Task Force at its last session had taken a decision not to start new work on the food safety assessment of animals treated with recombinant-DNA vaccines, several delegations requested that to avoid a policy vacuum in the area of food safety assessment of recombinant-DNA vaccines, follow-up actions be taken by FAO, WHO and OIE as appropriate, with particular reference to some of the recommendations of the 2007 FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA Animals, which, among others, called for a joint FAO/WHO/OIE expert group to consider the animal health and food safety issues raised by recombinant-DNA vaccines.

7-16. After some discussion, the Task Force welcomed the recommendations from the 2007 FAO/WHO Expert Consultation reproduced in document CX/FBT 07/7/3 Add.1, especially those addressed to FAO, WHO and OIE, with the understanding that these agencies would further discuss priorities and concrete modalities for conducting joint activities.

7-17. The Task Force expressed appreciation to FAO and WHO for organizing the expert consultation on a prompt manner and encouraged FAO and WHO to continue efforts to follow up on the above recommendations.

Chapter 11
GUIDELINES FOR RISK ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS

CONTENTS

1. PREPARATORY DISCUSSION

Fifth Session (2005)

5-16. The Task Force considered the proposal, put forward by several members and observers, to develop a guideline for food safety assessment of foods derived from recombinant-DNA animals including fish. Many delegations supported this work as new work to be undertaken as high priority in view of the possible commercialization of recombinant-DNA animals, especially fish, in a foreseeable future and the availability of the scientific advice already provided by the Joint FAO/WHO Expert Consultation on Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish (Rome, November 2003). Other delegations ranked this work as low priority due to higher priority given by these delegations to the proposed new work related to recombinant-DNA plants and due to insufficient experience at the national level in this area.

5-17. Some delegations proposed new work for the food safety assessment of animals produced using somatic cell nuclear transfer (SCNT) cloning techniques, either as a separate work item or as part of the new work on recombinant-DNA animals, recognizing that animal cloning was often used complementary to the production of recombinant-DNA animals. Other delegations considered that this work was out of the scope of the Task Force. The Task Force agreed that no new work would be commenced, at this stage, to address the food safety of cloned animals as such, while noting that the issue could be considered, if appropriate and to the extent necessary, during the process of developing a draft guideline for the food safety assessment of recombinant-DNA animals. The Delegation of European Community further stated that the decision not to start new work on cloned animals might lead to diversification of national legislations.

5-18. Several delegations and observers proposed that the issues relating to ethics, environmental effects, animal welfare be included in the scope of the draft Guideline for recombinant-DNA animals. These delegations and observers stated that these issues constituted "other legitimate factors" as they may have impact on human health and on food trade and that a holistic approach should be taken to appropriately address the concerns of consumers, especially in the context of recombinant-DNA animals. An observer pointed out that the objectives of the Task Force referred to "having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair practices in the food trade". Several delegations, while recognizing that these were important issues, expressed the view that ethical and other issues should not be addressed by Codex, which had no expertise to handle them, but by other appropriate international organizations such as OIE, which had started work on animal welfare, and UNESCO, working on ethics in food and biotechnology. The Task Force noted that the existing work by the Council for International Organization of Medical Sciences (CIOMS) could also be relevant. It was also pointed out that the future guideline should provide safety assessment guidance under the risk analysis framework set out by the Principle for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003, hereafter referred as "Principle") and that paragraph 7 of the Principles excluded ethical and other factors from the scope.*

***OIE RESOLUTION No. XXVIII,** PARIS, May 2005

Applications of Genetic Engineering for Livestock and Biotechnology Products

CONSIDERING THAT

The development of animal health applications for biotechnology is accelerating at a rapid pace and has the potential for significant advances in animal and veterinary public health.

A survey of the OIE 167 Member Countries conducted in 2005 identified a number of potentially beneficial applications of biotechnology and noted the absence of uniform guidance or international standards for assessment.

Responses received from this survey of OIE Member Countries indicated broad consensus that comprehensive regulatory controls are required and that ethical issues and societal concerns will need to be addressed in order to ensure responsible introduction and social acceptance of these technologies.

The maximising of benefits and minimising of negative consequences are best achieved through transparency and an international engagement to ensure that science-based standards are developed to direct the application of emerging technologies and to protect animal and public health.

THE COMMITTEE RESOLVES THAT

OIE continue to provide scientific advice and support to enable countries to develop harmonized technical standards for regulation of biotechnology-derived animal health products, and genetically modified production animals through:

• The constitution of an Ad hoc Group on Biotechnology to support the work of OIE Specialist Commissions and related Working Groups.

• Maintaining and expanding collaboration with other international organizations including, but not limited to, the FAO, WHO, VICH, and IETS.

• Facilitating international collaboration among regulatory agencies.

• The standardisation of the techniques of assessment of bioengineered animals or products and training Member Countries to conduct risk analysis through the recognition of international collaborating centre(s).

These objectives will be reached by the OIE taking into account the following priorities:

1. Development and adoption of standards and guidelines for research on the use of live attenuated vaccines in animal health.

2. Development of recommendations and guidelines for use of DNA vaccines.

3. Development of guidelines and recommendations for the animal health risks linked with somatic cell nuclear transfer cloning.

4. Develop objective criteria for assessing the health of embryos and production animals derived from cloning, and associated safety of cloned production animals and their products.

5. Develop policy guidelines for exclusion of unapproved animals and products from the livestock population, and segregation from the feed and food supply.

6. Develop identification, testing, and certification guidelines for international trade in production animals and their products for which biotechnology procedures have been employed.

7. Development of guidelines relevant to the application of Nanoscience/Nanotechnology as it relates to animal health

5-19. After an extensive exchange of views, the Task Force agreed to start new work on the food safety assessment of foods derived from recombinant-DNA animals, with the understanding that the initial work would be focused on developing a guideline for recombinant-DNA animals in general, which could be complemented by an annex dealing with issues specific to the food safety assessment of recombinant-DNA fish, if appropriate.

5-20. In finalizing a Project Document, the Task Force had a lengthy debate on whether or not "ethical or other considerations" should explicitly be included in the purposes and scope of the new work in the Project Document. As a compromise solution, the Task Force decided that the project document referred to the Statement of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account[5].

[5] Codex Alimentarius, Procedural Manual

5-21. The Delegation of European Community regretted that no explicit reference to ethical, environmental and animal welfare considerations were included in the project document. This position was supported by several delegations and observers. The Delegation of Iran reserved its position as to the decision by the Task Force. The Delegation of Egypt and the Delegation of Iran stressed that religion should be mentioned as part of ethical considerations. The Delegation of Canada stated that each country could take into account other legitimate factors before making final risk management decisions but the work of the Task Force should be based solely on scientific considerations as relate to food safety assessment. The latter position was supported by the Delegations of Argentina and Brazil.

5-22. The Representative of FAO, speaking on behalf of both FAO and WHO, stated that given the importance of ethical and other considerations in regard to the international trade of foods derived from recombinant-DNA animals, a workshop could be convened to address these issues, back-to-back with a future session of the Task Force. The Representative of WHO stressed the importance of identifying all problems relevant to the concern of consumers, as part of effective risk communication.

5-23. The Task Force decided to forward the Project Document, as agreed, to the 58th Session of the Executive Committee for critical review and to the 29th Session of the Codex Alimentarius Commission for approval as new work (Appendix II).

5-24. The Delegation of Brazil reserved its position by pointing out that the proposed new work on recombinant-DNA animals did not meet the criterion "Diversification of national legislation and apparent resultant or potential impediments to international trade" in the Criteria for the Establishment of Work Priorities in the Procedural Manual.

5-25. With respect to the advancement of work prior to the next session, the Task Force agreed to establish a physical working group which would prepare a Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, co-chaired by Australia and Japan. The working group would meet sometime between February and April 2006 in Japan, using English as working language, with other languages possibly being added if possible. The following members and observers expressed their interest in participating in this working group: Argentina, Brazil, Canada, European Community, France, Germany, Italy, Iran, Kenya, the Netherlands, New Zealand, Norway, Switzerland, Thailand, Turkey, the United States of America, 49th Parallel, BIO, CI, IACFO, ICGMA, FAO and WHO. The proposed draft document would then be circulated for comments at Step 3, prior to consideration by the 6th Session of the Task Force at Step 4.

5-26. In deciding on the establishment of the working group, the Task Force noted that drafting work would start before the formal approval of new work could be given by the Commission at Step 1, earliest in July 2006. The Task Force therefore agreed to draw the attention of the Executive Committee to the need for a degree of flexibility in the efforts not to delay the standards development by the Codex subsidiary bodies, especially ad hoc Task Forces operating within limited timeframes.

5-27. While noting that the drafting of the guideline could start, without delay, on the basis of the report of the FAO/WHO Expert Consultation Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, the Task Force agreed on the following initial list of questions for which scientific advice might be sought from an FAO/WHO expert consultation at a later stage. The Task Force agreed that whether or not further scientific advice was needed would be considered during the elaboration of the draft guideline.

- In relation to the potential risks to human health from the consumption of foods derived from recombinant-DNA animals, what critical information is necessary to assess the safety of

viral and other vectors used to generate recombinant-DNA animals?

- *Recognizing that animal health assessment will be an important element of overall food safety assessment of foods derived from recombinant-DNA animals, what animal health parameters are important to consider and how should the appropriate comparators be selected for different classes of animals and why?*

- *Recognizing that targeted compositional analysis is an important element in the overall food safety assessment of food derived from recombinant-DNA plants, how can this approach be practically applied to the safety assessment of food derived from recombinant-DNA animals and how should the appropriate comparators be selected?*

PROJECT DOCUMENT - APPENDIX II

1. Purposes and scope of the proposed work To develop a guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals, taking into account the Statement of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors are Taken into Account.[1] The guideline would take as a model the Codex Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants (CAC/GL 45-2003), taking into account the differences between plants and animals.

[1] Codex Alimentarius, Procedural Manual

2. Relevance and timeliness

This work would be in line with the recommendations of the First Session of the Task Force on Foods Derived from Biotechnology of March 2000 (ALINORM 01/34, para 28) which identified the development of guidelines on safety of foods produced from recombinant-DNA animals as a third priority. The development of this third guideline is timely because recombinant-DNA animals are in development in many countries and could be placed on the market in the near future. The availability of Codex guidelines would help individual countries to develop their own safety standards and regulatory framework.

3. The main aspects to be covered

The guidelines will form a framework for assessing the safety of food from recombinant-DNA animals, using the plant guideline (CAC/GL 45-2003) as a model.

4. Assessment against the criteria applicable to general subjects as contained in the Criteria for the establishment of work priorities.

General Criterion *Consumer protection from the point of view of health, food safety, ensuring fair trade practices in the food trade and taking into account the identified needs of developing countries*: this new work will contribute to enhancement of consumer protection by providing guidance as to how to perform safety assessment of food derived from recombinant-DNA animals.

Criteria applicable to general subjects

a. Diversification of national legislations and apparent resultant or potential impediments to international trade: This new work will provide scientific guidance which countries will be able to use to develop their own safety assessment methodology, safety standards and regulatory framework, and which, when applied internationally, may assist in providing a harmonized approach.

b. Scope of work and establishment of priorities between the various sections of work: See section 1, above.

c. Work already undertaken by other organizations in this field and/or suggested by the relevant international intergovernmental body(ies): This new work does not duplicate work undertaken by other international organizations and builds on work undertaken by the FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish (2003).

5. Relevance to Codex Strategic Objectives

The new work contributes to protecting the health of consumers and ensuring fair practices in the trade of foods derived from modern biotechnology by satisfying the following 'Strategic Objectives and Priorities' (CAC Strategic framework 2003-07):

Objective 1: Promoting sound regulatory frameworks

Objective 2: Promoting widest and consistent application of scientific principles and risk analysis

Objective 4: Enhance capacity to respond effectively and expeditiously to new issues, concerns and developments in the food sector Objective 6: Promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents

The proposed document will not duplicate existing Codex documents and, in particular, will be consistent with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius2 and the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003). It will complement the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA-Plants (CAC/GL 45-2003), and the Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant DNA Microorganisms (CAC/GL 46-2003).

7. Identification of any requirement for and availability of expert scientific advice

FAO and WHO held an Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, including Fish, in Rome, Italy on 17-21 November 2003, whose outcome should be used, as applicable, in the preparation of this new document. The need for further scientific advice will be considered during the elaboration process of the texts.

8. Identification of any need for technical input to the standard from external bodies that this can be planned for

Coordination with the OIE may be required, as appropriate.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

It is expected that the document can be completed within the four-year life span of the Task Force.

The 6th Session (2006)

6-15. The Task Force recalled that at its Fifth Session it had agreed to establish a physical working group, co-chaired by Australia and Japan, to elaborate a proposed draft guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals (hereinafter referred to as "the proposed draft guideline") and that the proposed draft guideline contained in CL 2006/27-FBT was circulated for comments at Step 3, prior to consideration at Step 4 at its current session.

6-16. The Delegation of Australia, speaking on behalf of the co-chairs of the working group and referring to the report of the working group, highlighted some major points as follows: i) it was agreed to use the existing plant guideline as a template in elaborating the proposed draft guideline; ii) it was also agreed to follow an approach whereby deviations from the language in the plant guideline be made only when scientifically justified on the basis of biological differences between plants and animals; and iii) the working group recognized that the Fifth Session of the Task Force had agreed that the initial work would focus on developing a guideline for recombinant-DNA animals in general.

6-17. The Task Force congratulated the working group for its achievement and agreed to consider the proposed draft guideline contained in Annex 1 to the report of the working group, paragraph by paragraph. In doing so, the Task Force paid particular attention to those parts kept in square brackets for which the working group could not reach conclusion or consensus.

REPORT OF THE WORKING GROUP (ANNEX 1)

Report of the Working Group on the Safety Assessment of Foods Derived from Recombinant-DNA Animals (Tokyo, 13 – 15 February 2006; Brussels, 30 May – 1 June 2006)

INTRODUCTION AND BACKGROUND

The Fifth Session of the Codex Ad Hoc Task Force on Foods Derived from Biotechnology agreed to establish a physical working group to prepare a Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (the draft guideline) with the working group to be co-chaired by Australia and Japan. In initiating development of this guideline, the Task Force also agreed:

- That the initial work would be focussed on developing a guideline for recombinant-DNA animals in general, which could be complemented by an annex dealing with issues specific to the food safety assessment of recombinant fish, if appropriate;

- That the Guideline would take as a model the Codex Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants (CAC/GL 45-2003; the plant guideline);

- To address the food safety of cloned animals, if appropriate and to the extent necessary, during the process of developing a draft Guideline on Safety Assessment of Foods Derived from Recombinant-DNA Animals;

- To an initial list of questions for which scientific advice might be sought from an FAO/WHO expert consultation at a later stage. Whether or not further scientific advice was needed would be considered during the elaboration of the draft guideline.

The Task Force also noted that in establishing the working group, drafting work on the guideline would start before formal approval for new work could be given by the Commission at Step 1, which would occur at the earliest in July 2006.

The Working Group on the Safety Assessment of Foods Derived from Recombinant-DNA Animals held two meetings. The first meeting, hosted by the Government of Japan, was held in Tokyo, Japan 13-15 February 2006 and the second, hosted by the European Community, was held in Brussels 30 May – 1 June 2006. The meetings were chaired by Dr Marion Healy (Food Standards Australia New Zealand, Australia) and Dr Tamami Umeda (Ministry of Health, Labour and Welfare, Japan).

The meetings of the Working Group were attended by the following delegations: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Costa Rica, Denmark, Finland, France, Germany, India, Italy, Ireland, Japan, Republic of Korea, Malaysia, Mali, Netherlands, New Zealand, Norway, Poland, Thailand, United Kingdom, United States of America, European Community, Biotechnology Industry Organization, and Consumers International (see Annex 3 for a full list of participants). The Chair of the Task Force on Foods Derived from Biotechnology, Dr Hiroshi Yoshikura, also attended both meetings. Written comments were received from Kenya, Japan and Thailand.

The deliberations of the Working Group focused on the following:

- The development of a draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, and

- Questions to be submitted to an expert consultation to obtain further scientific advice to assist in developing the draft guideline.

DEVELOPMENT OF THE PROPOSED DRAFT GUIDELINE

In order to facilitate the work of the Working Group, the co-Chairs prepared a draft guideline document to be considered by the Working Group. The draft guideline document was modelled on the Codex Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants (CAC/GL 45- 2003). The co-Chairs' draft guideline was circulated to members of the Commission and international organisations with observer status with the Codex prior to the working group meetings. The Working Group

focussed its comments on the co-Chair's draft. The completed document, as revised by the Working Group, appears at Annex 1 to this report.

During its deliberations on the proposed draft guideline, the Working Group identified a number of issues raised by participants to be noted in the report to the Task Force:

- The draft guideline identifies a number of issues (e.g., animal welfare, ethical, moral and socioeconomic aspects, environmental risks, etc) that the guideline is not intended to address (paragraph 2). The Working Group extensively discussed both the issues to be included in this list and the chapeau statement for the paragraph. Several proposals are included in the current draft of the guideline for further consideration by the Task Force.

- The draft guideline identifies that DNA sequence data should be provided to support the safety assessment. However, some participants have ongoing concerns about the draft text that describes the DNA sequence information required at various stages in the assessment process.

- The health status of the animal was recognised as one of the essential steps in ensuring the safety of food derived from recombinant animals. The Working Group recognised the one of the elements to be included in the evaluation of the animal's health status was physiological measures, including clinical and analytical parameters, such as haematological and immunological parameters.

- The Working Group further discussed the use of antibiotic resistance marker genes. Some participants[4] asked that their concerns be noted about the use of antibiotic resistance marker genes and the text in paragraphs 64-67 that was derived from the plant guideline.

[4] European Community, Italy, Consumers International

QUESTIONS FOR AN EXPERT CONSULTATION

The Working Group also discussed the possibility and timing of an expert consultation as well as possible questions. The Working Group considered the initial list of questions that appeared in the Report of the Task Force as well as additional questions that had been proposed by the co-Chairs and other members of the Working Group.

In considering the initial list of questions, the Working Group noted that they had been drafted prior to commencement of work on the proposed draft guideline. Now that a first draft of the proposed guideline had been completed, the Working Group was of the view that these questions had been addressed through the drafting process and therefore did not require further consideration by an expert group. The Working Group therefore did not consider this initial set of questions further.

Following extensive discussion, the Working Group reached agreement on a number of questions addressing the following themes: marker and reporter genes; and non-heritable applications. The questions drafted by the Working Group addressing these themes appear in Annex 2 to this report.

During discussion of possible questions for an expert consultation, some participants commented on developments in the assessment of possible allergenicity that have occurred since 2001, when the

FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology had been held. It was suggested by some participants that updating the allergenicity annex could form the basis of a proposal for new work, if agreed by the Task Force.

2. ELARORATION OF THE TEXT

PROPOSED DRAFT GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS

6-18. The Task Force agreed to ensure terminological consistency throughout the proposed draft guideline; a phrase "used as food" was replaced with "used as food or for food production"

in several paragraphs, in addition to other editorial changes. Other discussion held and amendments agreed upon on specific paragraphs are as follows.

SECTION 1 — SCOPE

1. **This Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. It addresses safety and nutritional aspects of foods consisting of, or derived from, animals that have a history of safe use as sources of food, and that have been modified by modern biotechnology to exhibit new or altered expression of traits.**

~~*Option 1*~~

~~2. [Recognizing that the following issues are being, or may have to be, addressed by other bodies or instruments, this document does not address:~~

~~- animal welfare;~~

~~- the safety of food derived from recombinant-DNA animals intended to be used [exclusively] for other purposes than food (e.g. pharmaceutical, xenotransplantation, or industrial uses);~~

~~- environmental risks related to the environmental release of recombinant-DNA animals used in food production;~~

~~- the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.]~~

~~OR *Option 2*~~

~~2. [The following issues/[legitimate factors] play important roles and should be given due consideration in decision making concerning recombinant-DNA animals. As such, these issues are being, or may have to be, addressed by other bodies or instruments. Hence, this document will not address:~~

~~- animal welfare;~~

~~- ethical, moral and socio-economical aspects;~~

~~- the safety of food derived from recombinant-DNA animals intended to be used [exclusively] for other purposes than food (e.g. pharmaceutical, xenotransplantation, or industrial uses);~~

~~- environmental risks related to the environmental release of recombinant-DNA animals used in food production;~~

~~- the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.]~~

~~OR *Option 3*~~

~~3. [This document does not address animal feed or animals fed with the feed. This document also does not address environmental risks.]~~

~~OR *Option 4*~~

~~2. [This Guideline addresses only food safety and nutritional issues. It therefore does not address:~~

~~- animal welfare;~~

~~- ethical, moral and socio-economical aspects;~~

~~- the safety of food derived from recombinant-DNA animals intended to be used [exclusively] for other purposes than food (e.g. pharmaceutical, xenotransplantation, or industrial uses);~~

~~- environmental risks related to the environmental release of recombinant-DNA animals used in food production;~~

~~- the safety of recombinant-DNA animals used as feed, or the safety of animals fed with~~

~~feed derived from recombinant-DNA animals, plants and microorganisms.]~~

~~OR *Option 5*~~

2. ~~[~~**The development, raising and use of animals for human purposes, and in particular, for use for food, raise a variety of issues beyond food safety. Without prejudice to their legitimacy or importance, or to whether or how the use of recombinant-DNA methods in developing animals for food use might affect those additional issues, this Guideline addresses only food safety and nutritional issues. It therefore does not address:**

- **animal welfare;**
- **ethical, moral and socio-economical aspects;**
- ~~the safety of food derived from recombinant-DNA animals intended to be used [exclusively] for other purposes than food (e.g. pharmaceutical, xenotransplantation, or industrial uses);~~
- **environmental risks related to the environmental release of recombinant-DNA animals used in food production;**
- **the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.**~~]~~

6-19. The Task Force had intensive discussion on this paragraph of the proposed draft guideline, which contained five different options in square brackets. There were diverse views among members on which option would be the most appropriate and on the reasoning behind.

6-20. Several delegations and observers supported Option 2 as, in their view, it clearly articulated the legitimate factors to be taken into account by Codex members in the decision making process. These delegations and observers also proposed to maintain the third bullet under the paragraph and to delete the word "exclusively", in order to stress that the proposed draft guideline should not address the animals developed for pharmaceutical or other non-food uses and that these animals should not enter the food chain. The Representative of European Community highlighted that there was no intension in the EU to develop guidelines for the assessment of recombinant-DNA animals for pharmaceutical uses in relation to foods.

6-21. Some other delegations were of the opinion that there was no rationale to discriminate between plant and animals in this paragraph, therefore proposed to adopt Option 3 to ensure consistency with the plant guideline.

6-22. Several other delegations supported Options 4 because its chapeau part did not contain statements on the importance, legitimacy or need for other bodies or instruments to address non food safety-related factors associated, or potentially associated, with recombinant-DNA animals. Some of these delegations proposed to maintain all the bullet points. The other delegations proposed deletion of the third bullet point because there might be legitimate circumstances in which a country might wish to apply a food safety assessment to recombinant-DNA animals intended for non-food purposes. There was a divergence of views as to whether to maintain the term "exclusively" if the third bullet was retained.

6-23. After a lengthy discussion, the Task Force agreed, as a compromise, to the text in Option 5 by deleting the word "additional" from the chapeau part and deleting the third bullet point.

6-24. The Task Force noted that, with the solution reached, the document would remain silent as to whether the guideline could be applied to the safety assessment of food derived from recombinant-DNA animals intended to non-food use and that it was entirely up to member countries to decide on the most appropriate approach.

3. **The Codex principles of risk analysis, particularly those for risk assessment, are primarily intended to apply to discrete chemical entities such as food additives and pesticide residues, or a specific chemical or microbial contaminant that have identifiable hazards and risks; they are not intended to apply to whole foods as such. Indeed, few foods, whatever their origin, have been assessed scientifically in a manner that would fully characterize all risk associated with the food. Further, many foods contain**

substances that would likely be found harmful if subjected to conventional approaches to safety testing. Thus, a more focused approach is required where the safety of a whole food is being considered.

4. **This approach is based on the principle that the safety of foods derived from new animal lines, including recombinant-DNA animals, is assessed relative to the conventional counterpart having a history or safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to the conventional counterpart.**

5. **This safety assessment approach falls within the risk assessment framework as discussed in Section 3 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. If a new or altered hazard, nutritional or other food safety concern is identified by the safety assessment, the risk associated with it would first be assessed to determine its relevance to human health. Following the safety assessment and, if necessary, further risk assessment, the food would be subjected to risk management considerations in accordance with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology before it is considered for commercial distribution.**

6. **Risk management measures such as post-market monitoring of consumer health effects may assist the risk assessment process. These are discussed in paragraph 20 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology.**

7. **The Guideline describes the recommended approach for the food safety assessment of foods derived from recombinant-DNA animals where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments.[1] In assessing the safety of food from recombinant-DNA animals, the approach should take into account all of the following:**

A) the nature of the recombinant-DNA construct and its expression product(s), if any;

B) the health status of the recombinant-DNA animal; and

C) the composition of foods produced from recombinant-DNA animals, including key nutrients.

While this Guideline is designed for foods derived from recombinant-DNA animals, the approach described could, in general, be applied to foods derived from animals that have been altered by other techniques.

[1]The approach to the safety assessment of foods derived from recombinant-DNA animals was first discussed at the 1991 Joint FAO/WHO Consultation on Strategies for Assessing the Safety of Foods Produced by Biotechnology. Further elaboration of the recommended approach was undertaken at the 2003 Joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, Including Fish.

8. **A diverse range of animals are used as food <u>or for food production</u> (e.g. mammals, birds, finfish and shellfish) and may be modified using in vitro nucleic acid techniques. Because of the combined impacts of their genetic diversity, husbandry, and conditions under which they are raised or harvested, assessment of food safety must be considered on a case-by-case basis, with due regard to the framework presented in this Guideline.**

SECTION 2 — DEFINITIONS

9. **The definitions below apply to this Guideline:**

***"Recombinant-DNA Animal"* — an animal in which the genetic material has been changed through in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.**

***"Conventional Counterpart"* — an animal breed with a known history of safe use as food from which the recombinant-DNA animal line was derived, as well as the breeding partners used in generating the animals ultimately used as food, and/or food derived from such animals[2].**

[2]It is recognized that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.

SECTION 3 — INTRODUCTION TO FOOD SAFETY ASSESSMENT

10. **Traditionally, food products derived from animals developed through conventional breeding or obtained from wild species have not been systematically subjected to extensive chemical, toxicological, or nutritional evaluation prior to marketing. Thus, although new breeds of animals are often evaluated by breeders for phenotypic characteristics, they are not subjected to the rigorous and extensive food safety testing procedures, including validated toxicity studies in test animals, that are typical of chemicals such as food additives or contaminants that may be present in food. Instead, food derived from an animal of known and acceptable health status has generally been considered suitable for human consumption.**

11. **The use of animal models for assessing toxicological endpoints is a major element in the risk assessment of many compounds, such as pesticides. In most cases, however, the substance to be tested is well characterized, of known purity, of no particular nutritional value, and human exposure to it is generally low. It is therefore relatively straightforward to feed such compounds to test animals at a range of doses some several orders of magnitude greater than the expected human exposure levels, in order to identify any potential adverse health effects of importance to humans. In this way, it is possible in most cases, to estimate levels of exposure at which adverse effects are not observed and to set safe intake levels by the application of appropriate safety factors.**

12. **Studies using test animals cannot readily be applied to testing the risks associated with whole foods, which are complex mixtures of compounds, and often characterized by a wide variation in composition and nutritional value. Due to their bulk and effect on satiety, they can usually only be fed to test animals at low multiples of the amounts that might be present in the human diet. In addition, a key factor to consider in conducting animal studies on foods is the nutritional value and balance of the diets used, in order to avoid the induction of adverse effects that are not related directly to the material itself. Detecting any potential adverse effects and relating these conclusively to an individual characteristic of the food can therefore be extremely difficult. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed studies using test animals could be requested on the whole food. Another consideration in deciding the need for studies with test animals is whether it is appropriate to subject test animals to such a study if it is unlikely to give rise to meaningful information.**

13. **Due to the difficulties of applying traditional toxicological testing and risk assessment procedures to whole foods, and based on the experience of assessing the safety of whole foods, a more focused approach is required for the safety assessment of food derived from animals, including recombinant-DNA animals. This has been addressed by the development of a multidisciplinary approach for assessing safety, which takes into account both intended and unintended changes that may occur in the animal or in the food products derived from it, using the concept of substantial**

equivalence.

14. **The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point, which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food relative to its conventional counterpart[3,4] . It aids in the identification of potential food safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA animals. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart.**

[3]The concept of substantial equivalence as described in the report of the 2000 joint FAO/WHO expert consultations (Document WHO/SDE/PHE/FOS/00.6, WHO, Geneva, 2000).

[4]The concept of substantial equivalence was further considered in the context of comparative safety assessment at the FAO/WHO expert consultation on the Safety Assessment of Foods Derived from Genetically Modified Animals, Including Fish, 2003.

UNINTENDED EFFECTS

15. **In achieving the objective of conferring a specific trait (intended effect) to an animal by the insertion of defined DNA sequences, additional traits could, in some cases, be acquired or existing traits could be lost or modified (unintended effects). The potential occurrence of unintended effects is not restricted to the use of in vitro nucleic acid techniques. Rather, it is an inherent and general phenomenon that can also occur in conventional breeding as well in association with the use of assisted reproductive technologies currently in use. Unintended effects may be deleterious, beneficial, or neutral with respect to the health of the animal or the safety of the foods derived from the animal. Unintended effects in recombinant-DNA animal may also arise through the insertion of DNA sequences and/or they may arise through subsequent conventional breeding of the recombinant-DNA animal. Safety assessment should include data and information to reduce the possibility that a food derived from a recombinant-DNA animal would have an unexpected, adverse effect on human health.**

16. **Unintended effects can result from the random insertion of DNA sequences into the animal genome, which may cause disruption or silencing of existing genes, activation of silent genes, or modifications in the expression of existing genes. [Unintended effects may also result in the formation of new or changed patterns of metabolites.** ~~For example, the expression of enzymes at high levels may give rise to secondary biochemical effects or changes in the regulation of metabolic pathways and/or altered levels of metabolites.]~~

6-25. The Task Force considered whether the two sentences in square brackets should be retained as proposed by several delegations, while noting that the working group was of the view that consideration of secondary metabolites was not always required in the context of recombinant-DNA animals.

6-26. After some discussion, the Task Force agreed to retain the first sentence, and delete the second sentence, which was felt as overly descriptive, as proposed by the Representative of OIE.

17. **Unintended effects due to in vitro nucleic acid techniques may be subdivided into two groups: those that are "predictable" and those that are "unexpected". Many unintended effects are largely predictable based on knowledge of the inserted trait and its metabolic**

connections or of the site of insertion. As ~~With time, as~~ knowledge of animal genomes grows, and familiarity with in vitro nucleic acid techniques increases, it may become easier to predict unintended effects of a particular modification. For example, homologous recombination, where appropriate, allows precise gene placement and so may reduce the occurrence of unintended effects associated with random integration. For example, homologous recombination, where appropriate, allows precise gene placement and so may reduce the occurrence of unintended effects associated with random integration. Molecular biological and biochemical techniques can also be used to analyse changes that occur at the level of transcription and translation that could lead to unintended effects. These should all be considered on a case-by-case basis.

18. **The safety assessment of food derived from recombinant-DNA animals involves methods to identify and detect such unintended effects and procedures to evaluate their biological relevance and potential impact on food safety. A variety of data and information are necessary to assess unintended effects, because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health. These data and information, when considered in total, provide assurance that the food is unlikely to have an adverse effect on human health. The assessment of unintended effects takes into account the phenotypic characteristics of the animal that are typically monitored by breeders during animal production stock development and improvement. These assessments provide a first screen for recombinant-DNA animals exhibiting unintended traits. Recombinant-DNA animals that pass this screen are subjected to safety assessment as described in Sections 4 and 5.**

FRAMEWORK OF FOOD SAFETY ASSESSMENT

19. The safety assessment follows a stepwise process of addressing relevant factors that include:

A) General description of the recombinant-DNA animal;

B) Description of the recipient animal prior to the modification[5] and its use as food or for food production;

C) Description of the donor organism or other source(s) of the introduced recombinant-DNA;

D) Description of the genetic modification(s) including the construct(s) used to introduce the recombinant-DNA;

E) Description of the initial recombinant-DNA animal[6,7] and the methods used to produce the recombinant-DNA animal ultimately used as food or for food production;

F) Characterization of the genetic modification(s) in the recombinant-DNA animal ultimately used for food production;

G) Safety assessment:

- **a. Health status of the recombinant-DNA animal;**
- **b. Expressed substances (non-nucleic acid substances);**
- **c. Compositional analyses of key components;**
- **d. Food storage and processing; and**
- **e. Intended nutritional modification;**

H) Other considerations.

[5] Not to be confused with a surrogate dam.

[6] First animal produced as a result of introducing the recombinant-DNA construct.

[7] Sometimes referred to as the founder animal.

20. **In certain cases, the characteristics of the food may necessitate additional data and information to address issues that are unique to the product under review.**

21. **Experiments intended to develop data for safety assessment should be designed and conducted in accordance with sound scientific concepts and principles, as well as, where appropriate, Good Laboratory Practice. Primary data should be made available to regulatory authorities at request. Data should be obtained using sound scientific methods and analysed using appropriate statistical techniques. Analytical methods should be documented.[8]**

[8] Reference is made to General Criteria for the Selection of Methods of Analysis in the Codex Alimentarius Procedural Manual (Appendix).

22. **The goal of each safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food does not cause harm when prepared, used and/or eaten according to its intended use. Safety assessments should address the health aspects for the whole population, including immunocompromised individuals, infants, the elderly and individuals with food hypersensitivities. The expected endpoint of such an assessment will be a conclusion regarding whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. In essence, therefore, the outcome of the safety assessment process is to define the product under consideration in such a way as to enable risk managers to determine whether any measures are needed to protect the health of consumers and if so to make well-informed and appropriate decisions in this regard.**

SECTION 4 — GENERAL CONSIDERATIONS

GENERAL DESCRIPTION OF THE RECOMBINANT-DNA ANIMAL

23. **A description of the recombinant-DNA animal being presented for safety assessment should be provided. This description should identify the introduced recombinant-DNA, the method by which the recombinant-DNA is introduced to the recipient animal and the recombinant-DNA animal ultimately used for food or for food production, as well as the purpose of the modification. The potential risk of introducing pathogenic elements (e.g. e.g. elements responsible for transmissible spongiform encephalopathies and other infectious disease ~~TSE, infectious disease~~) originating from biological materials used as sources or during the production should be considered. The description should be sufficient to aid in understanding the nature and types of food being submitted for safety assessment.**

DESCRIPTION OF THE RECIPIENT ANIMAL PRIOR TO THE MODIFICATION AND ITS USE AS FOOD

24. **A comprehensive description of the recipient animal prior to the modification should be provided. The necessary data and information should include, but need not be restricted to:**

A) common or usual name; scientific name; and taxonomic classification;

B) history of development through breeding, in particular identifying traits that may adversely impact on human health;

C) information on the animal's genotype and phenotype relevant to its safety, including any known toxicity or allergenicity, symbiosis with toxin-producing organisms, potential for colonization by human pathogens;

D) information on the effect of feed, exercise and growth environment on food products; and

E) history of safe use ~~for food consumption~~ as food or for food production. .

25. **Relevant phenotypic information should be provided not only for the recipient animal prior to the modification, but also for related lines and for animals that have made or may make a significant contribution to the genetic background of the recipient animal prior to the modification, if applicable.**

26. **The history of use may include information on how the animals breed and grow, how its food products are obtained (e.g. harvest, slaughter, milking), and the conditions under which those food products are made available to the consumer (e.g. storage, transport, processing). The extent to which the food products provide important nutritional components to particular subgroups of the population, and what important macro- or micronutrients it contributes to the diet should also be considered.**

DESCRIPTION OF THE DONOR ORGANISM OR OTHER SOURCE(S) OF THE INTRODUCED RECOMBINANT-DNA

27. **Information should be provided:**

A) Whether ~~if~~ the recombinant-DNA was synthesized and it is not from a known natural source;

B) If derived from another organism:

i. that organism's usual or common name;

ii. scientific name;

iii. taxonomic classification;

iv. information about the natural history as concerns food safety;

v. information on naturally occurring toxins, and allergens;

vi. for microorganisms, additional information on pathogenicity (to humans or the animal) and the relationship to known human or animal pathogens;

vii. for donors of animal or viral origin, information on the source material (e.g. cell culture) that has been used, and its origins; and

viii. information on the past and present use, if any, in the food supply and exposure route(s) other than the intended food use (e.g. possible presence of contaminants).

It is particularly important to determine whether the recombinant-DNA sequences impart pathogenicity or toxin production, or have other traits that affect human health (e.g. allergenicity).

6-27. The Task Force agreed to change the word "if" to "whether" under sub paragraph A) for clarity in English version.

DESCRIPTION OF THE GENETIC MODIFICATION(S) INCLUDING THE CONSTRUCT(S) USED TO INTRODUCE THE RECOMBINANT-DNA

28. **Sufficient information should be provided on the genetic modification to allow for the identification of all genetic material potentially delivered to the recipient animal and to provide the necessary information for the analysis of the data supporting the characterization of the DNA inserted into the recombinant-DNA animal ultimately used <u>as food or</u> for food production**.

29. **The description of the process of introducing and incorporating (if appropriate) the recombinant-DNA into the recipient animal should include:**

A) information on the specific methodology used for the transformation;

B) information, if applicable, on the DNA used to modify the animal (e.g. genes coding for proteins used for packaging vectors), including the source, identity and expected function in the animal;

-if viral vectors or known zoonotic organisms have been used, information on their natural hosts, target organs, transmission mode, pathogenicity, and potential for recombination with endogenous or exogenous pathogens; and

C) intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for producing the initial recombinant DNA animal.

30. **Information should be provided on the DNA to be introduced, including:**

A) the primary DNA sequence if the recombinant-DNA was synthesized and it is not from a known natural source

B) the characterization of all the genetic components including marker genes, regulatory and other elements affecting the expression and function of the DNA;

C) the size and identity;

D) the location and orientation of the sequence in the final vector/construct; and

E) the function.

DESCRIPTION OF THE METHODS USED TO PRODUCE INITIAL RECOMBINANT-DNA ANIMAL AND ~~THE METHODS USED TO PRODUCE IT~~ THE PROCESSES TO PRODUCE THE RECOMBINANT DNA ANIMAL ULTIMATELY USED AS FOOD OR FOR FOOD PRODUCTION

6-28. The Task Force agreed to amend the title over paragraphs 31-35 to bring it in line with the provisions of these paragraphs.

31. **Information should be provided on the various techniques and processes that are used to introduce the recombinant-DNA to obtain the initial recombinant-DNA animal. Examples of possible techniques may include transformation of gametes, microinjection of early embryos, nuclear transfer of transgenic cells.**

32. **A description of the methods used to demonstrate heritability should be provided, including descriptions of how heritability is attained (e.g., breeding mosaic animals to obtain true germ-cell transmissible insertions).**

33. **Although initial recombinant-DNA animals are generally not intended to be used for food or for food production, knowledge of the method to generate these animals may be useful in hazard identification.**

34. **Information should also be provided on how the initial recombinant-DNA animal leads to the production of the animal ultimately used as food or for food production. This information should, if applicable, include information on the breeding partners, or surrogate dams including genotype and phenotype, husbandry, and conditions under which they are raised or harvested.**

35. **The history of use of food products from the animals used to generate the animals ultimately used for food production from the initial recombinant-DNA animal (e.g., breeding partners, surrogate dams) may include information on how the animals breed and grows, its food products are obtained (e.g., harvest, slaughter, milking), and the conditions under which those food products are made available to consumers (e.g., storage, transport, processing).**

CHARACTERIZATION OF THE GENETIC MODIFICATION(S) IN THE RECOMBINANT-DNA

ANIMAL ULTIMATELY USED AS FOOD OR FOR FOOD PRODUCTION

36. **In order to provide clear understanding of the impact on the composition and safety of foods derived from recombinant-DNA animals, a comprehensive molecular and biochemical characterization of the genetic modification should be carried out.**

37. **Information should be provided on the DNA insertions into the animal genome; this should include:**

A) the characterization and description of the inserted genetic materials. This should include an analysis of the potential for mobilization or recombination of any construct material used;

B) the number of insertion sites;

C) ~~[~~the organization of the inserted genetic material at each insertion site including copy number and sequence data of the inserted ~~[, modified or deleted]~~ material and of the surrounding region, sufficient to identify any substances expressed as a consequence of the inserted material, or, where scientifically more appropriate~~/[and, if applicable]~~, other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food; and~~]~~

D) identification of any open reading frames within the inserted DNA or created by insertion with contiguous animal genomic DNA, including those that could result in fusion proteins.

Paragraph 37 C)

6-29. Several delegations and one observer were of the view that full molecular characterization of inserted materials and other relevant information at each insertion site including surrounding regions should be provided, and, if applicable, other information such as analysis of transcripts with a view to appropriately conducting safety assessment of recombinant-DNA animals in accordance with paragraph 36 of the proposed draft guideline. These delegations were in favour of retaining the text added in square brackets.

6-30. Several other delegations proposed the deletion of the texts in square brackets on the ground that the provisions should remain as the same as in the plant guideline except where scientifically justified on the basis of biological differences between plants and animals.

6-31. After some discussion, the Task Force agreed to delete all the text in square brackets and amend the phrase, in conjunction with the second set of square brackets, to read "or where scientifically more appropriate".

38. **Information should be provided on any newly expressed substances in the recombinant-DNA animal; this should include:**

A) the gene product(s) (e.g. a protein or an untranslated RNA) or other information such as analysis of transcripts or expression products to identify any new substances that may be present in the food;

B) the gene product(s)' function;

C) the phenotypic description of the new trait(s);

D) the level and site of expression in the animal of the expressed gene product(s), and the levels of its metabolites in the food ~~(e.g. milk, eggs)~~; and

E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.

6-32.The Task Force agreed to insert a word "newly" in the chapeau sentence for clarity and delete the reference to milk and eggs as examples in point D of this paragraph and in paragraph 45, as such explanation was unnecessary in the guideline applied to animals in general.

39. **In addition, information should be provided to:**

A) demonstrate whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangement have occurred upon integration;

B) demonstrate whether deliberate modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affected sites critical for its structure or function;

C) demonstrate whether the intended effect of the modification has been achieved and that all expressed traits are stable and are expressed as expected. It may be necessary to examine the inheritance of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly;

D) demonstrate whether the newly expressed trait(s) are expressed as expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene. ~~[It may be necessary to examine the expression of the new traits under more than one typical husbandry condition];~~

E) indicate whether there is any evidence to suggest that one or several genes in the recombinant-DNA animal has been affected by the transformation process; and

F) confirm the identity and expression pattern of any new fusion proteins.

6-33. The Task Force noted that the working Group did not have time to discuss the square-bracketed text. Several delegations suggested to retain the square bracketed sentence, however, the Task Force agreed to the deletion of the text, in view of the scope of the guideline applicable to all animals. The Task Force however noted the view of the delegations supporting the retention of the text that the examining of new traits under more than one typical husbandry condition might be relevant to recombinant-DNA fish in particular.

SAFETY ASSESSMENT OF THE RECOMBINANT-DNA ANIMAL ULTIMATELY USED AS FOOD FOR FOOD PRODUCTION

Health Status of the Recombinant-DNA Animal

40. **In contrast to the situation with plants, animals that have a history of safe use as sources of food generally do not contain genes encoding for toxic substances. Because of this, the health of a conventional animal has traditionally been used as a useful indicator of the safety of derived foods. The practice of only allowing animals with known and acceptable health status to enter the human food supply has been and continues to be an essential step to ensuring safe food.**

41. **An evaluation of the health of the animal is one of the essential steps in ensuring safety of food derived from recombinant-DNA animals. In undertaking this evaluation, it is important to compare the health status of the recombinant-DNA animal to the health status of the appropriate conventional counterpart, taking into account developmental stage.**

42. **The evaluation should include the following:**

A) General health and performance indicators, including behaviour, growth and development, general anatomy, and reproductive function, if appropriate;

B) Physiological measures including clinical and analytical parameters;

C) Other species-specific considerations, where appropriate.

6-34. In reply to a proposal to insert a reference to susceptibility to disease, the Task Force agreed that the concept was already covered by Bullets A and B and therefore there was no need to amend the text.

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity or bioactivity

43. **In vitro nucleic acid techniques enable the introduction of DNA that can result in the synthesis of new substances in recombinant-DNA animals. The new substances can be conventional components of animal derived foods, such as proteins, fats, carbohydrates, vitamins, which are novel in the context of that recombinant-DNA animal. New substances might also include new metabolites resulting from the activity of enzymes generated by the expression of introduced DNA.**

44. **It is recognized that the evaluation of the health status of the recombinant-DNA animals may give information about possible toxicity and bioactivity of the expressed substances. However, it is still generally expected that the safety assessment will include evaluation of these substances.**

45. **The safety assessment should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible tissues and other derived food products ~~(e.g. milk, eggs)~~ of the recombinant-DNA animal, including variations and mean values. Current dietary exposure and possible effects on population sub-groups should also be considered.**

46. **Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in donor organisms, if applicable, are not transferred to recombinant-DNA animals that do not normally express those toxic or anti-nutritious characteristics. This assurance is particularly important in cases where food derived from the recombinant-DNA animal is processed differently from the donor organism, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate anti-nutrients or toxicants.**

47. **For the reasons described in Section 3, conventional toxicology studies may not be considered necessary where the substance or a closely related substance has, taking into account its function and exposure, been consumed safely in food. In other cases, the use of appropriate conventional toxicology or other studies on the new substances may be necessary.**

48. **In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[9] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, taking into account its biological function in the animal where known.**

[9] Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

49. **Potential toxicity of non-protein substances that have not been safely consumed in food should be assessed on a case-by-case basis depending on the identity and biological function in the animal of the substance and dietary exposure. The type of studies to be performed may include studies on metabolism, toxicokinetics, sub-chronic toxicity, chronic toxicity/carcinogenicity, reproduction and development toxicity according to the traditional toxicological approach.**

50. **In the case of newly expressed bioactive substances, recombinant-DNA animals should be evaluated for potential effects of those substances as part of the overall animal health evaluation. It is possible that such substances may be active in humans. Consideration should therefore be given to potential dietary exposure to the substance,**

whether the substance is likely to be bioactive following consumption and, if so, its potential to exert effects in humans.

51. **Assessment of potential toxicity may require the isolation of the new substance from the recombinant-DNA animal, or the synthesis or production of the substance from an alternative source, in which case, the material should be shown to be biochemically, structurally, and functionally equivalent to that produced in the recombinant-DNA animal.**

Assessment of possible allergenicity (proteins)

52. **When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or non-allergenicity). As noted in paragraph 21, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in the Annex to this document[10].**

[10] The FAO/WHO expert consultation 2001 report, which includes reference to several decision trees, was used in developing the Annex to these guidelines.

53. **The transfer of genes from commonly allergenic foods should be avoided unless it is documented that the transferred gene does not code for an allergen.**

Compositional Analysis of Key Components

54. **Analyses of concentrations of key components[11] of the recombinant-DNA animal and, especially those typical of the food, should be compared with an equivalent analysis of a conventional counterpart grown and bred under the same husbandry conditions. Depending on the species (and the nature of the modification) it may be necessary to make comparisons between products from recombinant-DNA animals and appropriate conventional counterparts raised under more than one set of typical husbandry conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. However, it should be acknowledged that, particularly in the case of certain animal species, the available number of samples may be limited and there is likely to be large variation between animals, even those bred and raised under the same husbandry conditions. The comparator(s) used in this assessment should ideally be matched in housing and husbandry conditions, breed, age, sex, parity, lactation, or laying cycle (where appropriate). In practice, this may not be feasible at all times, in which case conventional counterparts as close as possible should be chosen. The purpose of this comparison, in conjunction with an exposure assessment as necessary, is to establish that substances that are nutritionally important or that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.**

[11] Key nutrients are those components in a particular food that may have a substantial impact in the overall diet. They may be major constituents (fats, proteins, carbohydrates as nutrients or enzyme inhibitors as anti-nutrients) or minor compounds (minerals, vitamins). Key toxicants are those toxicologically significant compounds known to be inherently present in the organism, such as those compounds whose toxic potency and level may be significant to health and allergens. In animals, the presence of toxicants would be rare, whereas the presence of allergens would be common in some species.

Food Storage and Processing

55. **The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA animals should also be considered. For example, alterations could occur in the heat stability of a toxicant or the bioavailability of an important nutrient after processing. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the animal.**

56. **If the modification is intended to change storage or shelf-life, the impact of the modification on food safety and/or nutritional quality should be evaluated.**

Intended Nutritional Modification

57. **The assessment of possible compositional changes to key nutrients, which should be conducted for all recombinant-DNA animals, has already been addressed under 'Compositional analyses of key components'. However, foods derived from recombinant-DNA animals that have undergone modification to intentionally alter nutritional quality or functionality should be subjected to additional nutritional assessment to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply.**

58. **Information about the known patterns of use and consumption of a food, and its derivatives should be used to estimate the likely intake of the food derived from the recombinant-DNA animal. The expected intake of the food should be used to assess the nutritional implications of the altered nutrient profile both at customary and maximal levels of consumption. Basing the estimate on the highest likely consumption provides assurance that the potential for any undesirable nutritional effects will be detected. Attention should be paid to the particular physiological characteristics and metabolic requirements of specific population groups such as infants, children, pregnant and lactating women, the elderly and those with chronic diseases or compromised immune systems. Based on the analysis of nutritional impacts and the dietary needs of specific population subgroups, additional nutritional assessments may be necessary. It is also important to ascertain to what extent the modified nutrient is bioavailable and remains stable with time, processing and storage.**

59. **The use of animal breeding, including in vitro nucleic acid techniques, to change nutrient levels in animal derived foods can result in broad changes to the nutrient profile in two ways. The intended modification in animal constituents could change the overall nutrient profile of the animal product and this change could affect the nutritional status of individuals consuming the food. Unexpected alterations in nutrients could have the same effect. Although the recombinant-DNA animal components may be individually assessed as safe, the impact of the change on the overall nutrient profile should be determined.**

60. **When the modification results in a food product with a composition that is significantly different from its conventional counterpart, it may be appropriate to use additional conventional foods or food components (i.e. foods or food components whose nutritional composition is closer to that of the food derived from the recombinant-DNA animal) as appropriate comparators to assess the nutritional impact of the food.**

61. **Because of geographical and cultural variation in food consumption patterns, nutritional changes to a specific food may have a greater impact in some geographical areas or in some cultural population than in others. Some animal derived foods serve as**

the major source of a particular nutrient in some populations. The nutrient and the populations affected should be identified.

62. Some foods may require additional testing. For example, animal feeding studies may be warranted for foods derived from recombinant-DNA animals if changes in the bioavailability of nutrients are expected or if the composition is not comparable to conventional foods. Also, foods designed for health benefits may require specific nutritional, toxicological or other appropriate studies. If the characterization of the food indicates that the available data are insufficient for a thorough safety assessment, properly designed animal studies could be requested on the whole foods.

SECTION 5 — OTHER CONSIDERATIONS

POTENTIAL ALTERED ACCUMULATION OR DISTRIBUTION OF SUBSTANCES OR MICROORGANISMS SIGNIFICANT TO HUMAN HEALTH

63. **Some recombinant-DNA animals may exhibit traits that may result in the potential for altered accumulation or distribution of xenobiotics (e.g., veterinary drug residues, metals), which may affect food safety. Similarly, the potential for altered colonization by and shedding of human pathogens or new symbiosis with toxin-producing organisms in the recombinant-DNA animal could have an effect on food safety. The safety assessment should take the potential for these alterations into account, and where ~~. Where~~ such alterations are identified, consideration should be given to the potential impacts on human health using conventional procedures for establishing safety.**

6-35. For clarity, the Task Force agreed to modify the final sentence of this paragraph to state that the safety assessment should take the potential for these alterations into account. Insertion of a reference to shedding of pathogens was made to the second sentence.

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

64. **Alternative transformation technologies that do not result in antibiotic resistance marker genes in foods should be used in the future development of recombinant-DNA animals, where such technologies are available and demonstrated to be safe.**

65. **Gene transfer from animals and their food products to gut microorganisms or human cells is considered a rare possibility because of the many complex and unlikely events that would need to occur consecutively. Nevertheless, the possibility of such events cannot be completely discounted[12].**

[12] In cases where there are high levels of naturally occurring bacteria which are resistant to the antibiotic, the likelihood of such bacteria transferring this resistance to other bacteria will be orders of magnitude higher than the likelihood of transfer between ingested foods and bacteria.

66. **In assessing safety of foods containing antibiotic resistance marker genes, the following factors should be considered:**

A) the clinical and veterinary use and importance of the antibiotic in question;

(Certain antibiotics are the only drug available to treat some clinical conditions (e.g. vancomycin for use in treating certain staphylococcal infections). Marker genes encoding resistance to such antibiotics should not be used in recombinant-DNA animals.

B) whether the presence in food of the enzyme or protein encoded by the antibiotic resistance marker gene would compromise the therapeutic efficacy of orally administered antibiotic; and

(This assessment should provide an estimate of the amount of orally ingested antibiotic that could be degraded by the presence of the enzyme in food, taking into account factors such as dosage of the antibiotic, amount of enzyme likely to

remain in food following exposure to digestive conditions, including neutral or alkaline stomach conditions and the need for enzyme cofactors (e.g. ATP) for enzyme activity and estimated concentration of such factors in food.)

C) safety of the gene product, as would be the case for any other expressed gene product.

67. If evaluation of the data and information suggests that the presence of the antibiotic resistance marker gene or gene product presents risks to human health, the marker gene or gene product should not be present in food. Antibiotic resistance genes used in food production that encode resistance to clinically used antibiotics should not be present in foods.

Paragraphs 64-67

6-36. The Delegation of the European Community expressed the view that the use of antibiotic-resistance marker genes should be excluded in the recombinant-DNA animals with a view to addressing safety concerns in relation to the integration of transgenes derived from inserted antibiotic-resistance marker genes into the animal genome and proposed to revisit these paragraphs for further discussion after the outcome of an expert consultation to be convened in early 2007 become available.

6-37. The Delegation of Canada expressed the view that, at the working group discussions, agreement to the two sets of questions being proposed for the expert consultation was based on the understanding that due to the nature of these questions, the outcome of the consultation should not affect the content of the proposed draft guideline. Other delegations were of the view that the current text did not require revision at this moment because no scientific justification existed to apply criteria different from those in the plant guideline.

6-38. The Task Force agreed that it would consider the need to further work on these paragraphs at its next session, prior to which the report of the expert consultation should be circulated.

REVIEW OF SAFETY ASSESSMENTS

68. **The goal of the safety assessment is a conclusion as to whether the new food is as safe as the conventional counterpart taking into account dietary impact of any changes in nutritional content or value. Nevertheless, the safety assessment should be reviewed in the light of new scientific information that calls into question the conclusions of the original safety assessment.**

ANNEX: ASSESSMENT OF POSSIBLE ALLERGENICITY

6-39. The Task Force agreed to the annex attached to the proposed draft guideline "Assessment of Possible Allergenicity", noting that the text in the annex was identical to that attached to the plant guideline, with the exception of the deletion of references to gluten sensitivity, which was considered as not relevant to the safety assessment of recombinant-DNA animals.

SECTION 1 — INTRODUCTION

1. **All newly expressed proteins[13] in recombinant-DNA animals that could be present in the final food should be assessed for their potential to cause allergic reactions. This should include consideration of whether a newly expressed protein is one to which certain individuals may already be sensitive as well as whether a protein new to the food supply is likely to induce allergic reactions in some individuals.**

[13]This assessment strategy is not applicable to the evaluation of foods where gene products are down regulated for hypoallergenic purposes.

2. **At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly expressed protein, therefore, it is recommended that an integrated, stepwise, case by case approach, as described below, be used in the assessment of possible allergenicity of newly expressed proteins. This approach takes into account the evidence derived from several types of information and data since no**

single criterion is sufficiently predictive.

3. **The endpoint of the assessment is a conclusion as to the likelihood of the protein being a food allergen.**

SECTION 2 — ASSESSMENT STRATEGY

4. **The initial steps in assessing possible allergenicity of any newly expressed proteins are the determination of: the source of the introduced protein; any significant similarity between the amino acid sequence of the protein and that of known allergens; and its structural properties, including but not limited to, its susceptibility to enzymatic degradation, heat stability and/or, acid and enzymatic treatment.**

5. **As there is no single test that can predict the likely human IgE response to oral exposure, the first step to characterize newly expressed proteins should be the comparison of the amino acid sequence and certain physicochemical characteristics of the newly expressed protein with those of established allergens in a weight of evidence approach. This will require the isolation of any newly expressed proteins from the recombinant-DNA animal, or the synthesis or production of the substance from an alternative source, in which case the material should be shown to be structurally, functionally and biochemically equivalent to that produced in the recombinant-DNA animal. Particular attention should be given to the choice of the expression host, since post-translational modifications allowed by different hosts (i.e. eukaryotic vs. prokaryotic systems) may have an impact on the allergenic potential of the protein.**

6. **It is important to establish whether the source is known to cause allergic reactions. Genes derived from known allergenic sources should be assumed to encode an allergen unless scientific evidence demonstrates otherwise.**

SECTION 3 — INITIAL ASSESSMENTSECTION 3.1 – SOURCE OF THE PROTEIN 7. **As part of the data supporting the safety of foods derived from recombinant-DNA animals, information should describe any reports of allergenicity associated with the donor organism. Allergenic sources of genes would be defined as those organisms for which reasonable evidence of IgE mediated oral, respiratory or contact allergy is available. Knowledge of the source of the introduced protein allows the identification of tools and relevant data to be considered in the allergenicity assessment. These include: the availability of sera for screening purposes; documented type, severity and frequency of allergic reactions; structural characteristics and amino acid sequence; physicochemical and immunological properties (when available) of known allergenic proteins from that source.**

SECTION 3.2 – AMINO ACID SEQUENCE HOMOLOGY

8. The purpose of a sequence homology comparison is to assess the extent to which a newly expressed protein is similar in structure to a known allergen. This information may suggest whether that protein has an allergenic potential. Sequence homology searches comparing the structure of all newly expressed proteins with all known allergens should be done. Searches should be conducted using various algorithms such as FASTA or BLASTP to predict overall structural similarities. Strategies such as stepwise contiguous identical amino acid segment searches may also be performed for identifying sequences that may represent linear epitopes. The size of the contiguous amino acid search should be based on a scientifically justified rationale in order to minimize the potential for false negative or false positive results.[14] Validated search and evaluation procedures should be used in order to produce biologically meaningful results.

> **[14]It is recognized that the 2001 FAO/WHO consultation suggested moving from 8 to 6 identical amino acid segments in searches. The smaller the peptide sequence used in the stepwise comparison, the greater the likelihood of identifying false positives, inversely, the larger the peptide sequence used, the greater the likelihood of false negatives, thereby reducing the utility of the comparison.**

9. **IgE cross-reactivity between the newly expressed protein and a known allergen should be considered a possibility when there is more than 35% identity in a segment of 80 or more amino acids (FAO/WHO 2001) or other scientifically justified criteria. All the**

information resulting from the sequence homology comparison between the newly expressed protein and known allergens should be reported to allow a case-by-case scientifically based evaluation.

10. **Sequence homology searches have certain limitations. In particular, comparisons are limited to the sequences of known allergens in publicly available databases and the scientific literature. There are also limitations in the ability of such comparisons to detect noncontiguous epitopes capable of binding themselves specifically with IgE antibodies.**

11. **A negative sequence homology result indicates that a newly expressed protein is not a known allergen and is unlikely to be cross-reactive to known allergens. A result indicating absence of significant sequence homology should be considered along with the other data outlined under this strategy in assessing the allergenic potential of newly expressed proteins. Further studies should be conducted as appropriate (see also sections 4 and 5). A positive sequence homology result indicates that the newly expressed protein is likely to be allergenic. If the product is to be considered further, it should be assessed using serum from individuals sensitised to the identified allergenic source.**

SECTION 3.3 – PEPSIN RESISTANCE

12. **Resistance to pepsin digestion has been observed in several food allergens; thus a correlation exists between resistance to digestion by pepsin and allergenic potential.[15] Therefore, the resistance of protein to degradation in the presence of pepsin under appropriate conditions indicates that further analysis should be conducted to determine the likelihood of the newly expressed protein being allergenic. The establishment of a consistent and well-validated pepsin degradation protocol may enhance utility of this method. However, it should be taken into account that a lack of resistance to pepsin does not exclude that the newly expressed protein can be a relevant allergen.**

13. **Although the pepsin resistance protocol is strongly recommended, it is recognized that other enzyme susceptibility protocols exist. Alternative protocols may be used where adequate justification is provided[16].**

> **[15]The method outlined in the U.S. Pharmacopoeia (1995) was used in the establishment of the correlation (Astwood et al. 1996).[16]Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (2001): Section "6.4 Pepsin Resistance".**

SECTION 4 — SPECIFIC SERUM SCREENING

14 **For those proteins that originate from a source known to be allergenic, or have sequence homology with a known allergen, testing in immunological assays should be performed where sera are available. Sera from individuals with a clinically validated allergy to the source of the protein can be used to test the specific binding to IgE class antibodies of the protein in *in vitro* assays. A critical issue for testing will be the availability of human sera from sufficient number of individuals.17 In addition, the quality of the sera and the assay procedure need to be standardized to produce a valid test result. For proteins from sources not known to be allergenic, and which do not exhibit sequence homology to a known allergen, targeted serum screening may be considered where such tests are available as described in paragraph[17].**

> **[17]According to the Joint Report of the FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (22-25 January 2001, Rome, Italy) a minimum of 8 relevant sera is required to achieve a 99% certainty that the new protein is not an allergen in the case of a major allergen. Similarly, a minimum of 24 relevant sera is required to achieve the same level of certainty in the case of a minor allergen. It is recognized that these quantities of sera may not be available for testing purposes.**

15. **In the case of a newly expressed protein derived from a known allergenic source, a negative result in *in vitro* immunoassays may not be considered sufficient but should prompt additional testing, such as the possible use of skin test and ex vivo protocols.[18] A positive result in such tests would indicate a potential allergen.**

[18]***Ex vivo*** **procedure is described as the testing for allergenicity using cells or tissue culture from allergic human subjects (Report of Joint FAO/WHO Expert Consultation on Allergenicity of Foods derived from Biotechnology).**

SECTION 5 — OTHER CONSIDERATIONS

16. **The absolute exposure to the newly expressed protein and the effects of relevant food processing will contribute toward an overall conclusion about the potential for human health risk. In this regard, the nature of the food product intended for consumption should be taken into consideration in determining the types of processing which would be applied and its effects on the presence of the protein in the final food product.**

17. **As scientific knowledge and technology evolves, other methods and tools may be considered in assessing the allergenicity potential of newly expressed proteins as part of the assessment strategy. These methods should be scientifically sound and may include targeted serum screening (i.e. the assessment of binding to IgE in sera of individuals with clinically validated allergic responses to broadly-related categories of foods); the development of international serum banks; use of animal models; and examination of newly expressed proteins for T-cell epitopes and structural motifs associated with allergens.**

Scientific Advice from FAO and WHO

6-40. The Delegation of Australia, on behalf of the co-chairs of the working group, referring to the report of the working group, noted that the three questions (See paragraph 5-27) raised at the Fifth Session of the Task Force had adequately been addressed during the course of elaboration of the proposed draft guideline and did not require further consideration by an expert consultation. This view was confirmed by the Task Force.

6-41. The Task Force was invited to consider two sets of questions listed in Annex 2 of the report of the working group on: i) marker and reporter genes; and ii) non-heritable applications, with a view to forwarding them to FAO and WHO for scientific advice.

6-42. Some delegations and one observer, referring to CRD 2 prepared by Argentina, in collaboration with Brazil and Norway, expressed the view that some new scientific information had become available since the Codex guidance on the assessment of allergenicity was adopted and that it was necessary to review the relevant information and to assess the need for revision of the annex on allergenicity attached to the proposed draft guideline as well as the two adopted guidelines on recombinant-DNA plants and on recombinant-DNA microorganisms. These delegations requested that scientific advice be sought on the advances made in the assessment of allergenicity in terms of bioinformatics methods, in vivo and ex vivo methods and on how to take into account the effect of food processing. They also requested expert advice as to whether consideration should be given to expressed substances which might act as adjuvants.

6-43. Some other delegations, noting the importance of allergenicity assessment for assuring the safety of foods derived from recombinant-DNA organisms, were of the view that it was not clear whether the evidence and information that became available since the last FAO/WHO expert consultation in 2001 was such that the recommendations of the previous expert consultations should be revisited right now. Several delegations pointed out that it might be difficult for FAO and WHO to address at once a large number of questions covering distinct areas and requiring different expertise.

6-44. The Representative of FAO, speaking on behalf of FAO and WHO, recognized practical difficulties in addressing those diverse and complex questions together at a single expert consultation and requested the Task Force to prioritize the questions so that an expert consultation to be convened in early 2007 could address the most urgent ones and provide scientific advice required for further development of the proposed draft animal guideline within the agreed timeframe of the Task Force. The Representative also indicated that it might be possible to convene another expert consultation at an appropriate time during the next biennium

(2008-2009) to address other questions including issues related to allergenicity.

6-45. After some discussion, the Task Force agreed to forward only those questions regarding marker and reporter gene and non-heritable applications to FAO and WHO for scientific advice. The list of questions is attached to the present report as Appendix II.

6-46. The Task Force noted that the background information on non-heritable applications as contained in CRD 2 (Comments of Argentina) would be provided as a working document to the forthcoming expert consultation.

6-47. The Task Force agreed that all the questions on the list should be addressed by the expert consultation in the context of the food safety assessment of recombinant-DNA animals used as food or for food production, while some delegation noted that there would be no impediment for the expert consultation to consider, where appropriate, horizontal aspects of the questions related to non-heritable construct as the technology could also be potentially applied to plants.

6-48. The Task Force noted, with satisfaction, that all square brackets had been removed from the proposed draft guideline and all the sections were finalized from a technical point of view and were ready, in principle, for adoption by the Commission, with the exception of paragraphs 64-67. The Task Force expressed their appreciation of the excellent work of the working group co-chaired by Australia and Japan in developing this document.

6-49. There was extensive discussion about the advancing of the document to reflect the achievement of the Task Force. Several delegations supported advancing the document to Step 5/8 with recommendation of omitting Steps 6 and 7, while other delegations were in favour of taking a more cautious approach.

QUESTIONS FOR AN EXPERT CONSULTATION

Marker and Reporter Genes

What developments have occurred in the development and use of reporter and selectable marker genes?

Are there non-antibiotic resistance marker or reporter genes that have been demonstrated to be safe to humans in food products, and if so, what are they?

When removal of specific DNA sequences is desired, are reliable and safe techniques available to do this on a routine basis?

Non-heritable applications

The term ‘non-heritable applications’ covers the direct introduction of nucleic acids into non-germ line tissue of animals that will enter the food supply.

Are there relevant differences from a food safety perspective between animals with heritable and non-heritable traits, and if so, what are they?

Are there specific food safety questions (e.g. with regard to types of vectors) that should be considered relative to the assessment of safety of food from animals containing heritable versus non-heritable traits?

Status of the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals

6-50. The Task Force agreed to return the section on “Use of Antibiotic Resistance Marker Genes” (paragraphs 64-67) to Step 3 for comments and hold the remaining sections of the proposed draft guideline at Step 4. The Proposed Draft Guideline, as amended by the current session, is attached to the present report as Appendix III.

6-51. The Task Force noted that at its next Session, discussion should focus on: i) the section of the Use of Antibiotic Resistance Marker Genes (paragraphs 64-67); and ii) any other amendments necessary to accommodate non heritable applications, if possible and appropriate, fully taking into account the outcome of the forthcoming expert consultation.

Seventh Session (2007)

Scientific advice from FAO and WHO

7-18. The Task Force recalled that its Sixth Session had agreed to forward questions regarding i) marker and reporter genes, and ii) non-heritable applications, to FAO and WHO for scientific

advice.7 The Task Force noted that the reply to these questions from a joint FAO/WHO expert consultation on safety assessment of foods derived from recombinant DNA animals, held on 26 February – 2 March 2007, were reproduced in document CX/FBT 07/7/3-Add.1.

Proposed draft guideline

7-19. The Task Force recalled that at its Sixth Session it had agreed to return the section on "Use of Antibiotic Resistance Marker Genes" (paragraphs 64 - 67) to Step 3 for comments and retain the remaining sections of the proposed guideline at Step 4, pending certain questions to be answered by a joint FAO/WHO expert consultation.

7-20. The Task Force, at the current session, agreed to focus its discussion on: i) the section of the "Use of Antibiotic Resistance Marker Genes" taking into account comments submitted to the current session and ii) whether any other amendments were necessary in conjunction with non-heritable applications, fully taking into account the outcome of the FAO/WHO expert consultation.

7-21. The discussion held and decision made are summarized below:

(i) Marker and reporter genes

7-22. Many delegations expressed the view that the current text in this section should remain unchanged since the report of the above expert consultation had not brought any new scientific evidence that would justify the need for additional or different provisions in the section on antibiotic resistance marker gene (paragraph 64-67), compared to the corresponding section in the Codex Plant Guideline (CAC/GL 45-2003).

7-23. The Delegation of Kenya, supported by some other delegations, proposed to require insertion of introns within the marker genes so as to make them non-functional in gut microflora that may take up the gene. However, the Task Force, noting that gene transfer from animal tissues to human gut microorganisms or human cells was considered a remote possibility and that the proposed technology, involving rather complex procedures and implications regarding other risks, might not be generally applicable and would require further research to determine its relevance, agreed that this proposed amendment was not necessary.

7-24. The Task Force noted the view expressed by an observer, supported by some delegations, that the current provisions on marker genes in the proposed draft guideline discouraged the use of marker genes encoding resistance to the drugs of clinical and veterinary importance. The observer drew the attention of the Task Force to a conclusion of the expert consultation responding to the question on reliable and safe techniques available to remove specific DNA sequences. As the recommendation encouraged continuing validation and development of gene excision systems that would allow the controlled removal of specific DNA sequences in recombinant-DNA animals, the section on marker and reporter genes in the draft guideline could be revisited in the future, when sufficient data and information on the gene excision technique became available.

7-25. After some discussion, the Task Force agreed to maintain the section on marker and reporter genes unchanged.

(ii) Non-heritable constructs

7-26. The Task Force considered the remaining paragraphs of the draft proposed guideline, to determine whether any other amendments were necessary in conjunction with non-heritable applications.

7-27. The Delegation of the European Community pointed out that the FAO/WHO expert consultation addressed the issues on non-heritable constructs in detail and provided a series of conclusions and recommendations regarding, among others, potential hazards in relation to non-heritable constructs. The Delegation stated that the proposed draft guideline, being developed without specific consideration of non-heritable applications, mainly due to lack of sufficient time to do so, should recognize this fact in its text. The Delegation thus proposed to introduce two amendments, in order to indicate that the issue of non-heritable construct was not addressed by the guideline. Specifically, the Delegation proposed to change the term "trait" to "heritable trait" in paragraph 1 and add a new footnote to paragraph 7 to state that non-heritable constructs would require specific safety considerations that were outlined by the report of the 2007 FAO and WHO expert consultation.

7-28.One delegation pointed out that the expert consultation had concluded that the difference between recombinant-DNA constructs regarding the nature of the hazards and risks were a function of whether the construct had been integrated into the genome or maintained episomally and did not depend on its heritability. For this delegation, there was no scientific basis for supporting the proposal from the Delegation of the European Community.

7-29. Some delegations were of the view that, according to the expert consultation's recommendations, there might arise a need to develop an additional guideline on non-heritable constructs in the future, possibly in the form of an annex and that it was desirable to keep such possibility open in the current document. At the same time, it was also recognized that in most cases, the proposed draft guideline could provide useful guidance for assessing the food safety of non-heritable constructs, and, therefore, that while the proposed draft guideline was primarily intended for heritable constructs, the text could remain silent on non-heritable applications.

7-30. The Task Force noted a view that the Codex Plant Guideline remained silent as to non-heritable constructs, whereas there were some cases where non-heritable constructs might be introduced in plants.

7-31. A question was raised as to whether all the animals treated with recombinant-DNA vaccines should be considered as containing non-heritable recombinant-DNA constructs. One delegation stated that certain non-heritable constructs including recombinant-DNA vaccines were intended to remain episomal for some time, according to the report of the expert consultation, and that not all animals treated with recombinant-DNA vaccines should be considered as recombinant DNA animals. The delegation also argued that the application of non-heritable constructs, as such, was not a recombinant-DNA technology, and was therefore out of the scope of the proposed draft guideline.

7-32. After some discussion, the Task Force agreed to include a footnote to paragraph 1, so as to clarify that the draft proposed guideline had been developed primarily for animals bearing heritable recombinant-DNA constructs. The Task Force also agreed to add a footnote to the last sentence of paragraph 7, indicating possible need for additional specific consideration for the food safety assessment of non-heritable constructs.

Status of the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals

7-33. The Task Force agreed to forward the proposed draft guideline, as amended above and with some editorial changes, for adoption at Steps 5/8 by the 31st Session of the Commission, with the recommendation to omit Steps 6 and 7. The proposed draft guideline is presented in Appendix II to this report.

7-34. The Task Force also agreed that, upon the final adoption of the proposed draft guideline, a consequential change be made in the existing text in the footnote 6 to paragraph 13 of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAL/GL 44-2003), to add a reference to the title of the proposed draft guideline.

7-35.The Task Force recognized the intensive work done by delegations during the plenary of the Task Force as well as at the meetings of the physical working groups in the course of elaborating the proposed draft guideline. The recommendation above to omit Steps 6 and 7 was the reflection of all the efforts and contribution of Codex members and observers.

7-107. The Observer from the OIE informed the Task Force that as a follow-up to the FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from Recombinant-DNA animals (26 February – 2 March 2007), the OIE would convene an expert meeting, jointly with FAO and WHO, probably in 2008, to consider the issues related to the animals with non-heritable recombinant-DNA constructs including recombinant-DNA vaccines.

Chapter 12
RECOMBINANT-DNA PLANTS MODIFIED FOR NUTRITIONAL OR HEALTH BENEFITS

CONTENTS

1. PREPARATORY DISCUSSION

The 5th Session (2005)

5-28. Several delegations stated that the current trend on development of nutritionally enhanced crops might have significant impact on the health of consumers, especially in developing countries, and suggested that the Task Force start new work to provide further guidance regarding the safety assessment of these new crops. Attention was drawn to the need to improve capacities of developing countries for conducting safety assessment of these plants and to the potential of these plants to solve problems on malnutrition and nutrient deficiency diseases. These delegations stated that paragraphs 48-53 of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003, hereafter referred as "Plant Guideline") related to nutritional aspects as part of the food safety assessment did not provide detailed guidance and that the Task Force should produce a comprehensive text as an annex to the existing Plant Guideline.

5-29. Several other delegations, while recognizing special needs of developing countries, pointed out that safety assessment of nutritionally enhanced plants was sufficiently addressed by the current Plant Guideline and that there was no need to start new work. It was also pointed out that nutritionally enhanced plants had also been developed using conventional breeding and that there was no justification to apply additional safety assessment to recombinant-DNA plants only.

5-30. Some delegations expressed concerns that nutritionally enhanced staple crops might lead to excessive intake of enhanced nutrients in certain populations and that risk management measures might become necessary for the protection of consumers' health. An observer expressed its view that food and nutrient intake study might be necessary in order to monitor health effects where nutritionally enhanced plants were used because the availability and perceived benefits of such plants could change food consumption patterns of the population.

5-31. The Delegation of the European Community, supported by some other delegations and observers, stated that considerations on post marketing monitoring systems should be an essential element of the work on this item because consumptions of nutritionally enhanced plants may cause significant changes in dietary intake patterns, in accordance with paragraph 20 of the Principle for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003).

5-32. After some discussion, the Task Force decided to initiate new work in the form of an annex to the Plant Guideline (CAC/GL 45-2003) and proceeded with further scoping of the work on the basis of the draft project documents (CRD 16 and CRD 16 Revised) prepared by Canada.

5-33. The Task Force agreed that the project title and section 3 of the project document should refer to "plants modified for nutritional or health benefits" rather than to "nutritionally enhanced plants", to include those plants in which certain compositional elements were intentionally reduced. The final title of the project document was "Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits".

5-34. The Task Force also agreed that the new work should ensure consistency and links with the existing Codex texts dealing with nutrition and health labelling and claims, and avoid duplication of work with the Codex Committee on Nutrition and Foods for Special Dietary Uses.

5-35. The Representatives of FAO and WHO suggested that the new work on this item should

make full use of the report of the Joint FAO/WHO Nutrient Risk Assessment Workshop (Geneva, 2-6 May 2005) and other relevant texts, where appropriate, noting that if scientific advice was required FAO and WHO would consider convening a small-scale expert group meeting to consider specified topics, including exposure assessment, in relation to nutritionally enhanced plants.

5-36. The Task Force agreed to forward the project document, amended as above, to the 58th Session of the Executive Committee for critical review and to the 29th Session of the Commission for approval as new work (Appendix III).

5-37. The Task Force further agreed to establish an electronic working group led by Canada to formulate a proposed draft document (scoping document) to be presented to the next session of the Task Force. The following members and observers expressed their interests in participating in the working group: Argentina, Australia, Austria, Belgium, Brazil, China, Costa Rica, Cuba, Denmark, European Community, Egypt,

Finland, France, Germany, Indonesia, Italy, Iran, Kenya, Japan, Madagascar, Mexico, Mongolia, the Netherlands, Nepal, New Zealand, Norway, Pakistan, the Philippines, Republic of Korea, South Africa, Switzerland, Spain, Sweden, Thailand, Turkey, Uganda, the United Kingdom, the United States of America, BIO,CI, Croplife International, ETA, ICGMA and Europabio.

5-38. It was also agreed that a Circular Letter be sent to request further comments on this work, on the basis of which the electronic working group should initiate its work. The working language of the working group would be English in principle, while members and observers would be allowed to contribute to the work in French and Spanish, if necessary.

PROJECT DOCUMENT (*APPENDIX III)*

Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

1. Purposes and scope of the proposed work To provide further guidance, in the form of an annex to the Guidelines for the Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants (CAC/GL 44-2003), with respect to any additional safety and nutritional considerations related to the assessment of foods derived from nutritionally-enhanced recombinant DNA plants. The scope of this work would not cover plants expressing pharmaceuticals or other non-food related substances as the primary purpose of these plants is not food use but rather for use as factories to produce industrial or pharmaceutical compounds.

2. Relevance and timeliness

There is currently extensive research and development in the area of “second generation” recombinant-DNA plants, including those intentionally modified to enhance the nutritional attributes of foods derived from these plants. It is expected that these products will be ready for commercialization in the very near future.

The Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) describes the recommended approach to carry out safety assessment of food derived from recombinant-DNA plants. It also provides general guidance with respect to intentional nutritional modification (paragraphs 48-53). In particular, it is stated that “foods derived from recombinant-DNA plants that have undergone modification to intentionally alter nutritional quality or functionality should be subjected to additional nutritional assessment [beyond that conducted when modifications are for other purposes] to assess the consequences of the changes and whether the nutrient intakes are likely to be altered by the introduction of such foods into the food supply.”

There would be significant value for the Task Force to undertake work aimed to provide further guidance relating to additional safety and nutritional considerations that the assessment of these nutritionally-enhanced foods may require.

3. The main aspects to be covered

Additional safety and nutritional considerations for the assessment of foods derived from

recombinant-DNA plants modified for nutritional or health benefits include such aspects as bioavailability and physiological function of the intended modification. Particular focus will be given to staple crops of interest to populations in developing countries

4. Assessment against the criteria applicable to general subject as contained in the Criteria for the establishment of work priorities. This proposal is consistent with:

General Criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

Criteria applicable to general subjects:

(a) Diversification of national legislations and apparent resultant or potential impediment to international trade: This new work will provide scientific guidance which countries will be able to use to develop their own safety assessment approach, and when applied internationally, may assist in providing a harmonized approach.

(c) Work already undertaking by other international organizations in this field and/or suggested by relevant international intergovernmental body(ies): There is no other international organization that has undertaken international standard setting activities for foods derived from nutritionally enhanced recombinant-DNA plants.

5. Relevance to Codex Strategic Objectives

The proposal meets the following objectives:

Objective 1: Promoting sound regulatory frameworks

Objective 2: Promoting widest and consistent application of scientific principles and risk analysis

Objective 4: Enhancing capacity to respond effectively and expeditiously to new issues, concerns, and developments in the food sector

Objective 6: Promoting maximum application of Codex standards

6. Information on the relation between the proposal and other existing Codex documents.

This proposed approach to complementing the existing plant guidelines for nutritionally enhanced products is consistent with that taken by the Task Force to provide detailed guidance on the assessment of potential allergenicity of newly expressed protein(s).

The proposal supports but not duplicates the Codex Principles for the Risk Analysis of Foods derived from Modern Biotechnology (CAC/GL 44-2003) and the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003).

There may be a need to ensure consistency and links, as appropriate, between the draft annex and the existing Codex texts dealing with health and nutrition labelling and claims.

7. Identification of any requirement for and availability of expert scientific advice.

There may be a need to consult other relevant Codex Committees (e.g., Codex Committee on Nutrition and Foods For Special Dietary Uses).
The following document may be taken into account:
Joint WHO/FAO Nutrient Risk Assessment Workshop: A model for establishing upper levels of intake for nutrients and related substances, 2-5 May 2005, Geneva, Switzerland.
The need for further scientific advice may be considered during the elaboration process of the draft annex.

8. Identification of any need for technical input to the standard from external bodies that this can be planned for.

The following documents may be taken into account:

- Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds (Ottawa, Canada, 2001)
- Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through

Biotechnology – Prepared by the Task Force of the ILSI International Food Biotechnology Committee as published in IFT's Comprehensive Reviews in Food Science and Food Safety (2004).

The need for further scientific advice may be considered during the elaboration process of the draft annex.

9. The proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years.

It is expected that the document can be completed within the 4 year life-span of the Task Force.

The 6th Session (2006)

6-52. The Task Force recalled that the Fifth Session of the Task Force had decided to initiate new work on the development of an annex to the Plant Guideline, which would provide further guidance on the food safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits, and to establish an electronic working group led by Canada to formulate a scoping document to be presented at the present session. The Task Force further recalled that the new work was subsequently approved by the Commission.

6-53. The Delegation of Canada introduced the report of the electronic working group contained in CX/FBT 06/6/5 and briefly explained the process by which the scoping document contained in the Appendices to the document was prepared. Many delegations expressed their appreciation to the work by the electronic working group and to Canada's contribution to this process, recognized the prospective value of the proposed draft Annex and agreed to further proceed with the work, preferably through the establishment of a physical working group. The Task Force noted that there was general agreement on pursuing the work on the basis of the proposed structure for the Annex and invited delegations to provide further comments on the scoping document.

6-54. Several delegations stated that the special reference to developing countries in the context of stability of the level of expression of a particular trait was inappropriate, as the most important factor was the agroecological conditions of the place in question and not the development status of the country concerned.

6-55. The Delegation of Argentina, supported by other delegations of the countries in Latin America and the Caribbean Region, proposed that the Annex should address not only staple crops but all crops and should not introduce differences in food safety assessment guidance for developing versus developed countries.

6-56. The Delegation of the European Community, referring to its written comments contained in CX/FBT 06/6/5-Add.1, highlighted the importance of (1) comparative animal feeding study and (2) selection of the most appropriate comparator. In this regard, the ongoing work by the European Food Safety Authority would be of interest to the Task Force. The Delegation of Germany suggested that in certain cases post-market monitoring may also be useful.

6-57. The Delegation of Mexico, referring to the provisions of paragraph 20 of the Principles for the Risk Analysis of the Foods Derived from Modern Biotechnology (CAC/GL 44-2003), pointed out that any risk assessment might leave scientifically-founded doubts as to nutrient intake estimate and identification of health risks and benefits, which could not necessarily be verified prior to the entry into market of the products, and that further study, including post-market monitoring, might be required where such approach was scientifically justified.

6-58. The Delegation of New Zealand pointed out that the Annex was being developed as part of the safety assessment guideline and that the outcome of this new work should support the existing guideline.

Status of the proposed draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

6-59. The Committee agreed to return the proposed draft Annex to Step 2 for further drafting by a physical working group led by Canada, co-chaired by Argentina and New Zealand, and open to all the members and observers9. The working group would prepare the proposed draft Annex to the Plant Guideline on the basis of the report of the previous electronic working group and the comments at Step 3 contained in documents CX/FBT 06/6/5 and CX/FBT 06/6/5-Add.1, as well as comments provided during the present Session. The working group, which would probably meet in Ottawa in early April 2007, would work primarily in English, however, subject to the availability of resources, translation of the working documents into French and Spanish would be considered. The proposed draft Annex, prepared by the working group, would be circulated for comments at Step 3, well in advance of the next Session of the Task Force, and be considered by the next session of the Task Force at Step 4.

The 7th Session (2007)

7-36.The Task Force recalled that at its Sixth Session, it had agreed to return the proposed draft annex to Step 2 for redrafting by a physical working group led by Canada, co-chaired by Argentina and New Zealand. The revised proposed draft annex, prepared by the Physical Working Group had been circulated for comments at Step 3, prior to consideration at Step 4.

7-37. The Delegation of Canada, speaking as Chairperson of the Physical Working Group, introduced the report of the Physical Working Group and highlighted that the Working Group had agreed to exclude, from the scope of the proposed draft annex, risk management measures and assessment of benefits. The Delegation indicated that some texts were kept in square brackets as the Working Group had not considered them in detail due to time constraints.

7-38. The Task Force agreed to consider the proposed draft annex, as contained in the above Circular Letter CL 2007/18-FBT, paragraph by paragraph. The discussion held and decisions made are summarized below. Paragraph numbers indicated in parentheses below correspond to those in the final text, in Appendix III to this report.

REPORT OF THE WORKING GROUP ON THE PROPOSED DRAFT ANNEX TO THE CODEX GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT –DNA PLANTS: FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS MODIFIED FOR NUTRITIONAL OR HEALTH BENEFITS

BACKGROUND

1. At the Sixth Session (2006), the Codex ad hoc Intergovernmental Task Force on Food Derived from Biotechnology (Task Force) was invited to discuss the Proposed Draft Annex (Scoping Document) to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived From Recombinant-DNA Plants Modified for Nutritional or Health Benefits1 and comments on this document, at Step 3, were received by the Task Force by October 1st, 20062.

2. At the Sixth Session (2006), the Task Force agreed to return the proposed draft Annex to Step 2 for further drafting by a physical working group to be chaired by Canada and co-chaired by New Zealand and Argentina. The Task Force agreed that the Working Group would prepare the proposed draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on the basis of the outputs of the previous electronic Working Group and the comments received at Step 3 contained in CX/FBT 06/6/5 and CX/FBT 06/6/5-Add.1, as well as comments provided during the Sixth Session of the Task Force.

3. The Working Group met in Ottawa, Ontario, Canada. on May 7-9, 2007. Attachment 3 lists the Working Group participants. The Working Group developed a proposed draft Annex to the Codex Plant Guideline, which is presented in Attachment 1.

4. The key points brought forward in the discussion of the Working Group include the following.

Scope and Structure of the Annex

5. The Working Group agreed with the overall approach taken by the co-chairs in drafting the proposed draft annex using the structure of a risk assessment, as described in the Working

Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[3]. However, it was stressed that the proposed draft was intended to support existing safety assessment guidance rather than extending to guidance on risk assessment.

[3] Codex Alimentarius Commission Procedural Manual, 16th edition.

6. The Working Group agreed that the scope of the document would be limited to the food safety assessment of foods derived from plants modified for nutritional or health benefits and that risk management measures were outside this scope. Extensive discussion was held on whether specific examples of risk management measures should be included in the text, but the Working Group agreed that this was not required.

7. The Working Group agreed that the assessment of the benefits of foods derived from plants modified for nutritional or health benefit was outside the scope of the document. However, the delegation of the European Community and the delegations of its three Member States attending the meeting, in line with the common position already expressed by the European Community and delegates, were of the view that the positive work started by the Working Group on Food Safety Assessment of Foods derived from recombinant-DNA Plants modified for Nutritional or Health benefit needs to be completed by further Codex work on the specific characterization of the benefits related to the food derived from recombinant-DNA Plants modified for nutritional or health benefit. In particular the delegations referred to above were of the view that risks and benefits should be expressed in a way they can be weighed up.

8. The Working Group agreed that taking into account the agreed scope the annex, it should not repeat or revise the safety assessment approach taken in the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and instead agreed it should focus specifically on those areas which are specific to the assessment foods derived from plants modified for nutritional or health benefit.

9. The Working Group discussed whether there would be a need to revisit the formatting and the structure of the draft annex attached to this report. Some delegations suggested that, for the sake of clarity, it would be advantageous to revisit the sequential order of the paragraphs in section three during Seventh Session of the Task Force meeting to be held in September 2007.

Assessment of Food Safety Considerations

10. Some discussion occurred in the Working Group around the need to include examples at certain points in the text. In particular the Working Group discussed whether examples of the term “undesirable substances” would be need in paragraph 1b of Attachment 1. One delegation indicated a preference to include the examples of “toxins, allergens and anti-nutritional factors”. The group could not agree on the addition of these examples to the text and due to time limitations the group agreed that these examples would be left out of the draft Annex.

11. The Working Group had some very useful discussions on the need to include definitions for the text, which terms would require definition and the correct definition of those terms. After several lengthy discussions on the subject the Working Group agreed that the only definition that would be included in the Annex was that for “nutrient”. The group agreed that definitions for “related substances”, “bioavailability”, “undesirable substances” and “upper levels” were not to be included in the text, either because an established definition existed in other codex publications or because the Working Group felt that other Codex Committees were better qualified to define those terms.

12. Text was proposed by the European Community specifically proposing a general principle to be taken into account during the exposure assessment, regarding that these foods should not be nutritionally disadvantageous to the consumer compared with the foods intended to be replaced. Argentina and other delegations expressed that this text was likely outside the scope of the document since it encompasses the consideration of benefits and besides it refers to decisions to be taken during risk management, and for these reasons it should not be included in the draft Annex. Mexico also noted that the text was presented on the third day of the meeting and due to time constraints it could not fully considered by the delegates or even discussed. Therefore, it was agreed that this text would be placed in the draft annex in square brackets (in paragraph 14 of Attachment 1) to be further discussed at the Task Force meeting.

13. Additional text, regarding the proper design of feeding studies, was also proposed by the

European Community. Again this text was introduced on the final day of the meeting and so could not be fully discussed by the delegates. It was agreed to the insertion of the text in square brackets (in paragraph 12 of Attachment 1) so that it could be fully discussed at the Task Force meeting

14. The Working Group noted that the term "multiple chemical forms" was ambiguous, so it was placed in square brackets (in paragraph 9 of Attachment 1) so that it could be clarified. New Zealand, as one of the cochairs, offered to provide examples to illustrate what was meant by the term. These examples are included in Attachment 2.

15. The Task Force is invited to consider the proposed draft Annex to the Codex Plant Guideline on Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional of Health Benefits with a view towards its further progression in the Codex Step Procedure.

2. ELABORATION OF THE TEXT

Attachment 1

PROPOSED DRAFT ANNEX: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

Section 1 – Introduction

1. General guidance for the safety assessment of foods derived from recombinant-DNA plants is provided in the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline). This annex provides additional considerations that are specific to foods modified for nutritional or health benefits. The document does not extend beyond a safety assessment and therefore, it does not cover assessment of the benefits themselves or any corresponding health claims, or risk-management measures[1].

[1]Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003, paragraph 19)

2. The following factors determine whether a recombinant-DNA plant is a recombinant-DNA Plant Modified for Nutritional or Health Benefits, and as such within the scope of this Annex:

(a) the recombinant-DNA plant exhibits a particular trait in portion(s) of the plant intended for food use, and;

(b) The trait is a result of~~ either i)~~ i) introduction of a new nutrient(s) or related substance(s), or ii) alteration of either the quantity or bioavailability of a nutrient(s) or related substance(s), ii) removal or reduction of undesirable substance(s) (e.g. allergens or toxicants), or~~iii)~~ iv) alteration of the interaction(s) of nutritional or health relevance of these substances.

7-39. The Task Force agreed to add the words "introduction of a new nutrient(s) or related substance(s)" in point b of paragraph 2, as new item i), so as to indicate appropriately the scope of the proposed draft annex, which should cover nutrients or related substances newly introduced through recombinant-DNA techniques.

7-40. The Task Force did not agree to a proposal made by the Delegation of Thailand to add a reference to "related to nutritional benefits" after the words "undesirable substance". Instead, the Task Force agreed to add, in point b, a reference to allergens and toxicants, as examples of undesirable substances.

7-41. It was agreed to add a reference to "health relevance" to item iii), re-numbered as iv), for consistency with the scope of the annex.

Section 2 - Definition:

3. The definition below applies to this Annex:

***Nutrient*[2] - means any substance normally consumed as a constituent of food:**

(a) which provides energy; or

(b) which is needed for growth and development and maintenance of healthy life; or

(c) a deficit of which will cause characteristic biochemical or physiological changes to occur.

[2]General Principles for the addition of essential Nutrients to Foods - CAC/GL 09-1987 (amended 1989, 1991)

7-42. The Task Force agreed to assign a paragraph number "3" to the first sentence under Section 2 and renumbered the following paragraphs accordingly.

7-43. The Delegation of the European Community expressed the view that it was important to define certain terms used in the Annex, including those relevant to nutritional risk assessment. This proposal was supported by some other delegations and an observer. The Delegation suggested that definitions of these terms could be developed by the Task Force, using, as a basis, some definitions found in the report of the Joint FAO/WHO Technical Workshop on Nutrient Risk Management, held in 2005.

7-44. Other delegations were of the opinion that the work to develop definitions related to nutritional safety assessment should be entrusted to the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). It was pointed out that new work had already been started by the CCNFSDU to elaborate risk analysis principles including definitions of "bioavailability", "related substances" and "upper level". Therefore, future potential inconsistency of definitions should be avoided between the Task Force and the CCNFSDU, the latter having a primary role on nutrition matters within the Codex system.

7-45. After some discussion, the Task Force agreed not to develop additional definitions, with a view to avoiding duplication with ongoing work undertaken by the CCNFSDU. Instead, the Task Force agreed to insert a text, as new paragraph 4 (see below), indicating that the proposed draft annex draws, where appropriate, on the definitions of key nutritional concepts to be found or to be developed in relevant Codex texts, especially those elaborated by the CCNFSDU.

4. This Annex draws, where appropriate, on the definitions of key nutritional concepts to be found or to be developed in relevant Codex texts, especially those elaborated by the Codex Committee on Nutrition and Foods for Special Dietary Uses.

Section 3 – Food Safety Assessment

5. The Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987 (amended 1989, 1991) (Codex Essential Nutrient Principles) are generally applicable to the assessment of food derived from a plant which is modified by increasing the amount of a nutrient(s) or related substance(s) available for absorption and metabolism. The Food Safety Framework outlined within the Codex Plant Guideline[3] applies to the overall safety assessment of a food derived from a recombinant-DNA plant modified for nutritional or health benefits. This annex presents additional considerations regarding the food safety assessment of those foods.

[3]Paragraphs 18-21 (Safety Framework) and 48-53 (Nutrition Modification)

6. ~~4.~~ Foods derived from recombinant-DNA plants modified for nutritional or health benefits may benefit certain populations/sub populations, while other populations/sub populations may be at risk from the same food[4].

[4]Further guidance for susceptible and high-risk population groups is provided in paragraph 49 of CAC/GL 45-2003 - Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants.

7-46. The Task Force did not agree to a proposal to refer to the case where "populations/sub-populations may be unaffected", to maintain the intent of the text.

7. ~~5.~~ Rather than trying to identify every hazard associated with a particular food, the intention of a safety assessment of food derived from recombinant-DNA plants is the identification of new or altered hazards relative to the conventional counterpart[5]. Since recombinant-DNA plants modified for nutritional or health benefits result in food products with a composition that may be significantly different from their conventional counterparts, the choice of an appropriate comparator[6] is of great importance for the safety assessment addressed in this Annex ~~annex (Codex Plant Guideline paragraph 4 and 51).~~ Those alterations identified in a plant modified to obtain nutritional or health benefits are the subject of this safety assessment.

[5] Codex Plant Guideline, paragraph 4 [6] Codex Plant Guideline, paragraph 51

7-47. To improve clarity, it was agreed to separate the reference to "Codex Plant Guideline paragraphs 4 and 51" to footnotes 5 and 6 respectively.

8.~~6.~~ Upper levels of intake for many nutrients have been set out by some national, regional and international bodies[8] may be considered, as appropriate.

[8] Where such guidance is not provided by Codex, information provided by the FAO/WHO may be preferably considered.

7-48. With regard to the study on upper levels of nutrient intake, the Delegation of the United States of America, referring to its written comment, pointed out that there were yet limitations in available dose-response and clinical data in identifying risks associated with nutrient substances at high levels of intake , and therefore proposed to add a new text so as to emphasize the need to consider the basis for deriving these upper levels in assessing the public health implication of exceeding intake levels of nutrients. The Task Force concurred with this proposal.

9.~~7.~~ The safety assessment of related substances should follow a case-by-case approach taking into account upper levels as well as other values~~, e.g. Acceptable Daily Intake (ADI),~~ where appropriate.

1 The safety assessment of related substances should follow a case-by-case approach taking into account upper levels as well as other values, where appropriate.

7-49. The Task Force agreed to delete the reference to "Acceptable Daily Intake (ADI)", recognizing that in Codex standards setting work as well as in risk assessments by JECFA, the concept of ADI was usually used for the assessment of chemicals such as food additives and residues of veterinary drugs, and would not necessarily apply to the safety assessment of nutrition.

10.~~8.~~ Although it is preferable to use a scientifically-determined upper level of intake of a specific nutrient or related substance, when no such value has been determined, consideration may be given to an established history of safe use for nutrients or related substances that are consumed in the diet if the ~~resulting~~ expected or foreseeable exposure would be consistent with those historical safe levels.

7-50. The Task Force agreed to replace the word "resulting" with "expected or foreseeable", for the sake of clarity.

11. **~~9.~~ With conventional fortification of food, typically~~ the [chemical form] of~~ a nutrient or a related substance is ~~characterised and~~ added at controlled concentrations and its chemical form is characterized. ~~Concentration levels~~ Levels of plant nutrients or related substances may vary in both conventionally bred and recombinant-DNA plants due to growing conditions. In addition, more than one ~~[multiple~~ chemical form~~s/analogues]~~ of the nutrient might be expressed in the food as a result of the modification and these ~~that~~ may not be characterized from a nutrition perspective**

~~might be expressed in the food as a result of the modification~~. **Where appropriate, information may be needed on the** ~~[multiple~~ **different chemical forms** ~~/ analogues]~~ **of the nutrient(s) or related substance(s) expressed in the portion of the plant intended for food use~~,~~ their respective levels** ~~and their combined bioavailability in the food.~~

7-51. The Task Force had discussion on the terms in square brackets (regarding chemical forms/analogues of nutrients and related substance). The Task Force agreed not to use the terms "multiple" and "analogues" as these were considered ambiguous. The Task Force made some editorial changes for the sake of clarity, and agreed to delete the reference to "combined bioavailability", noting that the concept was captured in the sentence newly added to paragraph 10 (new paragraph 12) (see para 55).

7-52. The Task Force noted that the list of examples of different chemical forms of nutrients presented in Attachment 2 of CL 2007/18-FBT had been prepared only for facilitating discussion and that it was not intended to be incorporated into the proposed draft annex.

12. ~~10.~~ **Bioavailability of the nutrient(s), related substance(s), or undesirable substance(s) in the food that were the subject of the modification in the recombinant-DNA plant should be established, where appropriate. If more than one chemical form of the nutrient(s) or related substance(s) is present, their combined bioavailability should be established, where appropriate.**

53. The Delegation of Thailand questioned whether consideration of bioavailability of undesirable substances was necessary, pointing out that the text read differently between 2(b) and paragraph 10.

54. To this question, it was clarified that requirement in paragraph 10 was describing certain exceptional cases where levels of undesirable substances warranted a study on bioavailability. Therefore, the Task Force agreed to retain the reference to undesirable substances.

55. In relation to an amendment made to paragraph 9, the Task Force agreed to add a new sentence at the end of paragraph 10 to state that "if more than one chemical form of the nutrients or related substances is present, their combined bioavailability should be established, where appropriate".

13. ~~11.~~ **Bioavailability will vary for different nutrients, and methods of testing for bioavailability** ~~regimes~~ **should be relevant to the nutrient, and the food containing the nutrient, as well as the health, nutritional status and dietary practices of the specific populations consuming the food. *In vitro,* and *in vivo* methods to determine bioavailability** ~~– methods~~ **exist, the latter conducted in animals and in humans. *In vitro* methods can provide information to assess extent of release of a substance from plant tissues during the digestive process. *In vivo* studies in animals are of limited value in assessing nutritional value or nutrient bioavailability for humans and would require careful design in order to be relevant. *In vivo* studies, in particular, human studies may provide more relevant information about whether and to what extent the nutrient or related substance is bioavailable.**

~~12. [In the case animal studies are performed to assess the nutritional value and the bioavailability of the newly expressed substance(s), the animal species (strain/sex) should be sensitive enough to the nutrient(s), or substance(s) in question. The control diets need to be formulated in such a way that the key measured endpoints are responsive to a difference in the quantity and/or bioavailability of the enhanced nutrient(s), substance(s), or decreased undesirable substance(s). In the case of a new, or increased level of a nutrient(s) or related substance(s), the choices for control diets may be made on a case-by-case basis and the appropriate comparator(s) with and without external fortification may be necessary.]~~

7-56. The Task Force had extensive discussion on paragraph 12 in square brackets.

7-57. The Delegation of European Community recalled that the text was prepared to provide details on animal studies if such studies were to be performed to assess the nutritional value

and the bioavailability of the newly expressed substances. Two observers supported the proposed text pointing out that it provided useful guidance on animal study design.

7-58. Several delegations expressed the view that paragraph 54 of the Codex Plant Guideline already provided sufficient guidance on animal studies and that detailed description of the design for animal studies was not necessary in this annex and proposed the deletion of the paragraph.

7-59. Some delegations suggested amending the proposed text to provide more general guidance on animal studies. It was also stated that the text should not over-emphasise the importance of animal studies vis-à-vis human studies.

7-60. After some discussion, recognizing that the elements of paragraph 12 could better be placed in paragraph 11, the Task Force agreed to delete paragraph 12 and to add a new sentence, as the second last sentence of paragraph 11, stating that "in vivo studies in animals are of limited value in assessing nutritional value or nutrient bioavailability for humans and would require careful design in order to be relevant."

7-61. The Task Force also agreed to make some editorial amendments to other sentence in paragraph 11 in relation to testing methods.

14. ~~13~~. **Guidance on dietary exposure assessment of foods derived from recombinant-DNA plants with nutritional modifications is provided in paragraph 49 of the Codex Plant Guideline. In the context of this Annex, dietary exposure assessment is the estimation of the concentration of the nutrient(s) or related substance(s) in a food, the** ~~usual~~ **the expected or foreseeable consumption of that food, and any known factors that** ~~impact~~ **influence bioavailability. Exposure to a nutrient(s) or related substance(s) should be evaluated in the context of the total diet and the assessment should be carried out based on the customary dietary consumption, by the relevant population(s), of the corresponding food that is likely to be displaced. When evaluating the exposure, it is appropriate to consider information on whether the consumption of the modified food could lead to adverse nutritional effects as compared to consumption of the food that it is intended to replace. Most, if not all, aspects of exposure assessment are not unique to recombinant-DNA plants modified for nutritional or health benefits[8].**

[8] **Additional applicable guidance on dietary exposure assessment of nutrients and related substances is provided in the Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Management, 2-6 May 2005.**

~~14. [When evaluating the exposure, it is appropriate to take into account that the consumption of the modified food should not be nutritionally disadvantageous to the consumer compared with the food that it intends to replace. Possible exceptions to this consideration related to differences in regional consumption patterns could be assessed on a case-by-case basis.]~~

Paragraph 13 (new paragraph 14) and paragraph 14

7-62.The Task Force considered, in detail, paragraph 14 in square brackets, regarding the evaluation of exposure to recombinant-DNA plants with nutritional modification.

7-63. The Delegation of the European Community expressed the view that the safety assessment should take into account the assessment of the nutritional or health benefits of foods derived from recombinant-DNA plants modified for such purposes. The evaluation of potential benefit of a product in a given population should be made by the respective competent national authorities when such products were placed on the market. This position was supported by two observers.

7-64. Some delegations pointed out that the assessment of nutritional advantage/disadvantage as stated in the text belonged to risk management measures, and therefore, proposed to delete the paragraph. These delegations stated that the concept of being nutritionally disadvantageous was ill defined and should be replaced by the concept of "nutritional risk" if the paragraph was to be retained. One observer also pointed out that elements of paragraph 14 were already covered by paragraph 13.

7-65. During the long discussion and exchange of views, several different alternative texts were proposed by delegations, some of which were reproduced in CRD 12.

7-66. After further discussion, the Task Force agreed to delete paragraph 14 and insert a new sentence as the second last sentence in paragraph 13, which read: "When evaluating the exposure, it is appropriate to consider information on whether consumption of the modified food could lead to adverse nutritional effects as compared to consumption of the food that it is intended to replace."

7-67. The Task Force also agreed to amendments to other sentences of paragraph 13, to replace "impact" by "influence" and "usual" with "expected or foreseeable", for clarity.

15. The first step of an exposure assessment is determining the level(s) of the substance(s) in question in the portion of the plant intended for food use. Guidance on determining changes in levels of these substances is provided in the Plant Guideline.[9]

[9] CAC/GL 45-2003. Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants, paragraphs 44 and 45.

16. Consumption patterns will vary from country to country depending on the importance of the food in the diet(s) of a given population(s). Therefore, it is recommended that consumption estimates are based on national or regional food consumption data when available, using existing guidance ~~[10]~~ on estimation of exposure in a given population(s) [10]. When national or regional data is unavailable, ~~FAO diet~~ food availability data may provide a useful resource[11]. ~~Data on staple food products may also be supplemented by information from FAO Food Balance Sheets.~~

[10] A Model for Establishing Upper Levels of Intake for Nutrients and Related Substances. Report of a Joint FAO/WHO Technical Workshop on Nutrient Risk Assessment. WHO Headquarters, Geneva, Switzerland, 2-6 May 2005

[11] Data on staple food products may also be supplemented by information from FAO Food Balance Sheets.

7-68. The Delegation of the United States of America, referring to its written comment, proposed to delete the last two sentences which contained the reference to the FAO diet data and the FAO Food Balance Sheet. The Delegation pointed out that the report of the FAO/WHO Nutrient Risk Assessment Workshop stated on page 167 that national or regional food-use data such as food balance sheet, regional diet, and sales data provided very limited information for quantitative exposure estimation.

7-69. Some delegations opposed the deletion of these sentences and suggested to retain them as they were or as a footnote, observing that data from the FAO database were sometimes the only information available in developing countries which often lacked data on food consumption.

7-70. he Representative of FAO clarified that the Food Balance Sheet did not represent actual consumption data, but indicated the amount of foods available per capita.

7-71. The Task Force agreed to move the last sentence to a footnote to allow for some flexibility and make some amendments to clarify the remaining sentences.

7-72. The Delegation of Sudan proposed to add a reference to the "importance of tradition(s) and custom(s) of a given population", since those two factors also influenced food consumption patterns. The Representative of FAO clarified that, from a technical point of view, the proposed two factors influenced food consumption patterns through their impact on diets, which was already recognized in the text. The Task Force decided to keep the text as it was.

17. To assess the safety of a food derived from a recombinant-DNA plant modified for a nutritional or health benefit, the estimated intake of the nutrient or related substance in the population(s) is compared with the nutritional or toxicological reference values, such as upper levels of intake, ADIs for that nutrient or related substance, where these values exist. This may involve assessments of different consumption scenarios against the relevant nutritional reference value, taking into account possible changes in bioavailability, or extend to probabilistic methods that characterise the distribution of

exposures within the relevant population(s).

[Attachment 2

Examples of different chemical forms of nutrients[11]

[11] Table adapted from Gibson RS (2007) The role of diet- and host-related factors in nutrient bioavailability and thus in nutrient-based dietary requirement estimates. Food and Nutrition Bulletin vol. 28, no. 1 (supplement), 77-100.

Nutrient / Forms

Iron / Porphyrin-bound iron in hemoglobin and myoglobin from meat, poultry, and fish is more readily absorbed than nonheme iron found in foods of plant and animal origin.

Selenium / Main food sources of selenium are the organic forms, selenocysteine and selenomethionine, which tend to be better absorbed than selenite, the inorganic form

Zinc / Organic zinc complexes (e.g., from oysters) are more readily absorbed than inorganic zinc salts

Folate / Polyglutamates (mainly 5-methyl tetrahydrofolate [5MeTHF] in fresh food) are less well absorbed than synthetic monoglutamate form (i.e., folic acid)

Vitamin B6 / Free pyridoxine, pyridoxamine (plus phosphorylated forms) in plants and pyridoxal (plus phosphorylated forms in animal foods) are better absorbed than pyridoxine β-D-glucoside in heat-processed milk products

Niacin / Niacin in mature maize, present as nicotinic acid esterified to polysaccharides, which is unavailable for absorption]

Attachment 2 was not included in the Annex.

The Task Force noted that the list of examples of different chemical forms of nutrients presented in Attachment 2 of CL 2007/18-FBT had been prepared only for facilitating discussion and that it was not intended to be incorporated into the proposed draft annex.

Status of the Proposed Draft Annex: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

7-73. The Task Force, recognizing that the substantial progress had been made to the text at the plenary and the working group of the Task Force and that all outstanding issues had been resolved, agreed to forward the proposed draft annex, as amended above and with some editorial changes, for adoption at Steps 5/8 by the 31st Session of the Commission, with the recommendation to omit Steps 6 and 7. The proposed draft annex is presented in Appendix III to this report.

7-74. Recognizing that the proposed draft annex contained references to certain concepts related to nutrition, the Task Force agreed to invite the 29th Session of the CCNFSDU to review the document and provide comments if necessary. In this regard, the Task Force noted the priority this work should be given by the CCNFSDU, given the time constraints of the Task Force. The Task Force also noted the view of the European Community that the CCNFSDU might wish to review the annex in light of the WHO Global Strategy on Diet, Physical Activity and Health.

7-75. In view of the relatively short time left prior to the 29th Session of the CCNFSDU (12-16 November 2007), the Task Force agreed to urge the Task Force's delegates to liaise closely with their counterpart delegates to the CCNFSDU, with a view to facilitating review of the proposed draft annex by the CCNFSDU.

7-76. The Task Force also agreed that, upon the final adoption of the proposed draft guideline, a consequential change be made in paragraph 48 of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA-Plants (CAL/GL 45-2003); the new sentence to be added at the end of paragraph 48 of the Guideline would read: "A detailed presentation of issues to be considered can be found in Annex 2 to this document". The current Annex on Assessment of Possible Allergenicity would become Annex 1 to the Guideline. Paragraph 41 of the Guideline and its footnote 4 would be amended accordingly.

Chapter 13

LOW LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD RESULTING FRON ASYNCHRONOUS AUTHORIZATIONS

CONTENTS

1. DISCUSSION IN THE FIFTH SESSION

The 5th Session (2005)

Low Level (Adventitious) Presence of Unauthorized Recombinant-DNA Plant Materials

5-51. The Task Force noted that some delegations had proposed this work item as high priority. Several delegations and one observer expressed the view that this was a very important issue for the Task Force to consider and supported initiation of new work in this area.

5-52. The Delegation of the United States stated that development of a new guidance document, as an Annex to the Plant Guideline, would assist member countries in conducting safety assessments of low level adventitious presence of recombinant-DNA plant materials originating from new varieties in the development or field testing stage or from older varieties coming off the market. The delegation believed that many countries would increasingly be faced with these situations where the safety of food needed to be determined.

5-53. The Delegation of the European Community stated that a low level (adventitious) presence of unauthorized recombinant-DNA plants was often attributable to differences in the approval status of recombinant-DNA plants among countries. An annex to the Plant Guideline could be developed to provide guidance on how to deal with the adventitious presence of unapproved recombinant-DNA plants developed for food use, resulting from asymmetrical approvals.

5-54. Accordingly, the Delegation of the European Community emphasized the need for establishing an international data sharing system through which member governments could obtain data regarding safety assessments of recombinant-DNA plants conducted in other countries. Such a data sharing system could be developed building on the existing OECD database on the approved events in member countries. In response to this proposal, the Representative of OECD clarified that the current data system operated in close cooperation with the CBD had a specific purpose and that an eventual enlargement of the scope of the database to cover other purposes needed to be carefully examined, in consultation with other organizations such as CBD, FAO and WHO, taking into account feasibility and cost implications.

5-55. Some delegations pointed out that the term such as "low level" or "unauthorized" as well as the scope of this work required further clarification before new work would be started. Several delegations stated that this issue belonged to risk management and would not fit in the context of the Plant Guideline where the scope was confined to safety assessment based on scientific considerations. Several observers expressed their opposition to the proposal for new work since no recombinant-DNA plants should be allowed on the market without approval by the national authority.

5-56. After an exchange of views, the Task Force realized there still remained among delegations different views in the scope of the proposed work and therefore decided not to start new work at the current session.

5-57. The Delegation of the United States indicated that the delegation would wish to further study this issue to decide whether to revisit the subject at a future session of the Task Force. The Delegation of the European Community expressed its willingness to continue discussion on this item and requested that information on existing databases on recombinant-DNA plants and possible development of a more comprehensive database of recombinant-DNA events be provided by relevant international organizations at the next session of the Task Force.

The 6th Session (2006)

6-72. The Delegation of the United States, referring to document CX/FBT 06/6/1 Add.1, provided a brief account of the proposal, whose objective would be to provide guidance on the food safety assessment of foods derived from recombinant-DNA plants in which those plants have already been authorized in one or more countries for commercialization for food use based on an assessment according to the Codex Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants (CAC/GL 452003), but are unintentionally present in low levels in food in countries in which the recombinant-DNA plants are not authorized.

6-73. Many delegations strongly recommended that new work be started by the Task Force in this area. The Delegation of the European Community explained that it already had a comprehensive legal framework governing the assessment of recombinant-DNA material in plants, whereby the presence of unauthorized adventitious material at whatever level is illegal. It could only agree to work commencing subject to the condition outlined in CRD 13. Moreover it considered that the focus of any such work should be on strengthening data and information sharing mechanisms. The Delegation of Mexico did not support the content of the proposal from the United States because importing countries' concerns with regard to the contamination with recombinant-DNA plants that were unauthorized by any regulatory authority were not adequately addressed. However recognizing the importance of the subject, the delegation supported the beginning of work provided that the countries' concerns from regulatory point of view would be reflected and these national concerns were shared by other delegation. Some delegations and observers objected to the use of the term "asynchronous" since the term implied that the recombinant-DNA plant in question would later be authorized by both exporting and importing countries. Instead, it was proposed to refer to "asymmetric authorizations". Some observers stated that there was no need for new work by Codex since the framework of the Convention on Biological Diversity and its Biosafety Clearing-House already provided useful instruments for information sharing on modified food plants, and the occurrence of adventitious presence of unauthorized recombinant-DNA plant material in food was primarily a legal and not a scientific issue.

PROPOSAL FOR FUTURE WORK PREPAREDY BY UNITES STATES: Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-level Presence of Recombinant-DNA Plant Material

1. Purpose and scope of the proposed work

The goal of the project will be to develop recommendations to the Task Force on performing a safety assessment in situations of low level ~~situations~~ in which the recombinant-DNA plant has already been found to be safe and authorized for commercialization for food by one or more countries through an assessment performed according to the Plant Guideline, but the importing country has not determined its food safety and on the requisite data and information sharing systems to facilitate this process.

With this in mind, the objectives of the project will be to:

Identify and incorporate into a draft annex the relevant sections of the Plant Guideline essential to the safety assessment in low level situations, and

Identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety ~~a risk assessment~~ in the importing country.

The project would not:

Address risk management measures; national authorities will determine when a recombinant DNA ~~rDNA~~ plant material is present at a level low enough for this Annex to be appropriate.

Preclude national authorities from conducting a full risk assessment; countries can decide when and how to use the Annex within the context of their regulatory systems.

Eliminate the responsibility of industries, exporters and, when applicable, national competent authorities~~, industries and exporters to continue~~ to meet countries' relevant import requirements, including in relation to unapproved recombinant-DNA material.

2. Relevance and timeliness

An increasing number of recombinant-~~r~~DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant-~~r~~DNA plant materials that have passed a food safety assessment in one or more countries may on occasion be present in food in countries in which the food safety of the relevant recombinant-~~r~~DNA plants has not been determined. This Annex is intended to aid countries that want to determine the food safety of a~~n~~ recombinant-~~r~~DNA plant under such circumstances or in advance preparation for such potential circumstances.

3. The main aspects to be covered

Identify and incorporate into a draft annex the relevant sections of the Plant Guideline essential to the safety assessment in situations of low level presence ~~situations~~, and

Identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety ~~risk assessment~~ in the importing country.

4. Assessment against the *Criteria for the establishment of work priorities*

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries: The project would provide additional guidance for countries to use in assessing the food safety of the low level presence of unauthorized recombinant-~~r~~DNA foods, thus evaluating the underlying safety of the food and appropriate protection of consumers. The project could particularly assist countries that have limited experience with food safety risk assessments.

Diversification of national legislations and apparent resultant or potential impediments to international trade: The project would provide internationally recognized scientific guidance and information and data exchange mechanisms that countries may use to establish individual standards or guidance. Such internationally agreed guidance can help ensure consistent approaches for the food safety assessment for such foods.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by the Task Force on a high priority basis.

Work already undertaken by other organizations in this field: The project does not duplicate work undertaken by other international organizations, and is an extension of work developed in the first Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology.

5. Relevance to Codex Strategic Objectives

This proposal is consistent with the following strategic goals presented in the Codex Draft Strategic Plan 2008-2013:

• Promoting Sound Regulatory Frameworks; and

• Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis;

6. Information on the relation between the proposal and other existing Codex documents

The work product would be an Annex that complements and extends the Codex *Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any requirement for and availability of expert scientific advice

None identified.

8. Identification of any need for technical input to the standard from external bodies that this can be planned for

None identified.

9. The proposed timeline for completion of the new work, including start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years

It is expected that the work can and should be completed within the remaining timeframe for the Task Force.

If the proposal ~~proposed new work~~ is approved as new work ~~recommended by the 6th Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (November, 2006) and adopted as new work~~ by the 30th Session of the Codex Alimentarius Commission (July, 2007), a proposed draft Annex would be circulated ~~presented to the Task Force at its next Session (2007)~~ for comments ~~consideration~~ at Step 3 and be considered by the Task Force at its next Session (2007) at Step 4.

Note: *See Annex 13-4 for the original version of the proposal by United States, which was modified by the in-session Working Group and further amended in the Plenary as above (See below).*

6-74. Several delegations were of the opinion that the establishment of mechanisms for data sharing and information exchange would be a key to ensuring the food safety in situations of the low-level presence of unauthorized recombinant-DNA plants. The Delegation of New Zealand expressed the view that the Biosafety Clearing-House did not serve this purpose as it had been designed to deal exclusively with living modified organisms. The Delegation of the European Community pointed out that there was less than satisfactory progress in constructing databases and relevant mechanisms to make information available for this purpose and there was the need to share, among regulatory authorities, relevant information including detection methods, molecular characterizations and testing protocols. Other delegations also pointed out that the need for information on detection methods and reference materials.

6-75. The Representative of FAO indicated that FAO was prepared to consult with other international bodies such as CBD and OECD, as well as industry consortiums with a view to designing and establishing a data-sharing mechanism while giving due considerations to the protection of confidential information. Several observers representing developers of recombinant-DNA plants expressed their willingness and commitment to contributing to information sharing mechanisms by providing relevant food safety data and information that has been previously reviewed by the country or countries that have satisfactorily completed their food safety assessment. In this context, reference was also made to the ILSI database.

6-76. To reach consensus on the scope and other content of the project document for new work, the Task Force agreed to establish an in-session physical working group[15]. The working group submitted a revised project document contained in CRD 17, on the basis of which the Task Force pursued its deliberation.

[15]Chaired by the United States of America. The following members and observers participated in the in-session physical working group: Argentina, Australia, Austria, Belgium, Canada, Brazil, Chile, China, Costa Rica, Denmark, European Community, Finland, France, Germany, Iran, Japan, Kenya, Thailand, Mexico, New Zealand, Nigeria, Norway, Paraguay, Philippines, Republic of Korea, South Africa, Sweden, Switzerland, the United States of America, 49P, BIO, CI, CropLife International, ETA, EUROPABIO, ICA and IICA.

6-77After some discussion, during which some editorial and other amendments were made, the Task Force agreed on a project document for future work: Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-level Presence of Recombinant-DNA Plant Material and agreed to forward the project document (attached to this report as Appendix IV) to the Executive Committee for critical review and for approval by the next Session of the Commission in July 2007.

6-78. In order to proceed with the elaboration of the proposed draft Annex without delay and to complete the work within the timeframe of the Task Force, the Task Force agreed to establish a physical working group on low-level presence of recombinant-DNA plant material, chaired by the United States and co-chaired by Germany and Thailand[16]. Its terms of reference were

agreed as follows:

To develop recommendations to the Task Force on performing a safety assessment in situations of low-level presence in which the recombinant-DNA plant has already been found to be safe and authorized for commercialization for food by one or more countries through an assessment performed according to the Codex Plant Guideline, but the importing country has not determined its food safety, and on the requisite data and information sharing systems to facilitate this process[17].

The working group will:

-Identify and incorporate into a draft annex the relevant sections of the Plant Guideline essential to the safety assessment in situations of low-level presence; and

-Identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety in the importing country. The draft annex would not:

-Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate.

-Preclude national authorities from conducting a full risk assessment; countries can decide when and how to use the Annex within the context of their regulatory systems.

-Eliminate the responsibility of industries, exporters, and when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unapproved recombinant- DNA material.

[16]The following members and observers expressed their interest in taking part in the working group: Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Costa Rica, Denmark, European Community, Finland, France, Greece, Germany, India, Iran, Ireland, Italy, Japan, Kenya, Mexico, Mali, Norway, Paraguay, Philippines, South Africa, Sweden, Switzerland, Thailand, the United States of America, ETA, CropLife International, CI, BIO, 49P, EUROPABIO, IICA

[17]The guidance would not be intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

6-79. The Task Force agreed that the physical working group would first meet either in the end of February or March 2007 in the United States, using English, French and Spanish as working languages. Germany expressed its willingness to host a second meeting of the working group, if required.

6-80. The Task Force agreed that the proposed draft annex to be elaborated by the working group at Step 2 would be circulated for comments at Step 3, prior to consideration by the Seventh Session of the Task Force at Step 4.

WORKING GROUP REPORT

The 7th Session (2007)

7-77. The Task Force recalled that at its Sixth Session it had agreed on new work on an annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on low-level presence of recombinant-DNA plant material, which was subsequently approved by the 30th Session of the Commission. A physical working group on low-level presence of recombinant-DNA plant material had been established, chaired by the United States and co-chaired by Germany and Thailand.[10]

7-78. The Delegation of the United States of America, speaking as the Chairperson of the Physical Working Group, summarized the discussions and recommendations contained in Circular Letter CL 2007/17FBT Rev. The Task Force appreciated the work of the Physical Working Group, which had agreed on the proposed draft Annex in its entirety, while leaving two options for the structure of the annex, and noted that the Physical Working Group had agreed that Co-chairs and representatives of the biotechnology industry would meet with international

organizations, such as FAO, in order to discuss arrangements for a future database for data and information sharing for the purpose of the annex.

7-79. The Representative of FAO informed the Task Force that a consultative meeting, which had met at the FAO Headquarters in May 2007 in response to the request by the Physical Working Group, had noted that the OECD BioTrack Product Database had covered most of the information items required for the purpose of the annex and, while expressing its preference for a database hosted by FAO, had recommended that FAO and OECD find a workable cooperation arrangement. The Representative further indicated that FAO and OECD had subsequently reached an agreement to develop a database system housed in FAO, which would draw data from, and export data to, the OECD Database.

7-80. The Representative of FAO outlined the proposed functionality of the database and procedures for its establishment as follows:

-The database, covering all the information items identified in Section 3 of the proposed draft annex, would be accommodated in the International Portal on Food Safety, Animal and Plant Health (IPFSAPH), a portal site managed by FAO in cooperation with Codex, CBD, IPPC, OIE, WHO and WTO, which provides links to SPS-related regulatory information with powerful search function;

-Initial data entry to the database would be accomplished by the incorporation of relevant data from the OECD Database and manual entry of information items which are not covered by the OECD Database, followed by confirmation by Codex members of the accuracy of the data entered, upon which the database would be made publicly accessible;

*-The database would be kept up to date through new entries upon notification to FAO by Codex members and automated bidirectional data sharing between the FAO and OECD databases.**

***SUBJECT: Request for review of information and data set on the Food safety assessments of recombinant-DNA plants on a test server of the International Portal on Food Safety, Animal and Plant Health (IPFSAPH).**

Background

The Seventh Session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology (TFFBT) (Chiba, Japan, 24-28 September, 2007) considered the Proposed Draft Annex: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food. Section 3 of the Proposed Draft Annex provides guidance on data and information sharing on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline.

In order to make such the data and information available, FAO has started development of a data set and data entry mechanism designed to facilitate the publication of food safety assessments and related information, as outlined in the Proposed Draft Annex.

Through the International Portal on Food Safety, Animal and Plant Health (IPFSAPH - www.ipfsaph.org), FAO agreed to develop and maintain a publicly accessible central data set containing relevant information to food safety assessments of recombinant-DNA plants[3].

[3]Where a competent authority of a government undertakes safety assessment of recombinant-DNA plant products which are supposed to be consumed for food and feed purpose, information on food safety assessment of recombinant DNA plants may contain that for feed safety assessments.

In view of the possible adoption of the above Annex by the 31st Session of the Codex Alimentarius Commission in July 2008, the FAO/IPFSAPH Secretariat, in conjunction with OECD, recently finalised a non-public test version of this data set. This letter provides details on how Members of FAO, as well as other interested parties, can access and review the non-public test version of the data set in advance of related discussions at the 31st Session of the Commission.

In addition, this letter reminds Members of FAO, Codex member countries and other interested parties of the previous letter of 22nd October 2007 encouraging nomination of their contact point(s) regarding food safety assessments of recombinant-DNA plants and

submit their email address(es) to IPFSAPH-Safety-Assessment@fao.org, in order to facilitate the alerting of new information both to and from FAO/IPFSAPH on this topic.

Request for review of data set via IPFSAPH test server environment

Prior to the 31st Session of the Codex Alimentarius Commission, Members of FAO, Codex member countries and other interested parties are kindly requested to review the initial data set of recombinant-DNA plant material food safety assessments under IPFSAPH. The data set, currently containing 204 individual records[4], can be accessed via: IPFSAPH test server at http://tinyurl.com/6jevke.

[4]The IPFSAPH food safety assessment data set currently comprises food (and/or feed) safety assessments harvested and collated from the OECD BioTrack Product Database; EC Register of GM Food and Feed; CBD Biosafety Clearing House; FSANZ GM Current Applications and Approvals; and the Japanese Biosafety Clearing House.

Please note that the test server is far slower than the production version will be, and depending on the speed of your Internet connection, may take some time to load. Members are requested to reserve any comments and questions they may have for discussions during the 31st Session of the CAC in July 2008.

Procedures for the future provision of information and data on food safety assessments of recombinant-DNA plants to the IPFSAPH

Members of FAO, Codex member countries and other interested parties will be able to provide information concerning new and/or revised food safety assessments to IPFSAPH via one of the following three methods:

1. If safety assessments are already notified by national competent authorities to one of the following five online sources, they will be automatically included in the IPFSAPH data set, which is regularly updated, and no further action is required:

OECD BioTrack Product Database

EC Register of GM Food and Feed

CBD Biosafety Clearing House

Food Standards Australia and New Zealand - GM Current Applications and Approvals

Japanese Biosafety Clearing House (J-BCH)

2. Alternatively, national competent authorities can make a request to the IPFSAPH Secretariat (Email: IPFSAPH-Safety-Assessment@fao.org) for detailed information on how to login IPFSAPH and insert by themselves a food safety assessment record into the relevant IPFSAPH Data Entry Form.

3. If the above two methods are not feasible, national competent authorities can email IPFSAPH-Safety-Assessment@fao.org directly with details of new/revised safety assessments, containing the following information:

OECD Unique Identifier (UID);

Scope of authorisation, date of approval, and short description (if available);

A URL link to the location of the food safety assessment (FTP or HTTP), or provision of the food safety assessment as a file attachment (PDF or DOC format);

Contact details of the competent authority(ies) responsible for the food safety assessment;

URL links to information on the same product in other databases maintained by relevant international organizations, if appropriate;

Details on where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained, as appropriate.

If required, further information and clarification on the above can be obtained directly from the International Portal on Food Safety, Animal and Plant Health via IPFSAPH-Helpdesk@fao.org.

Please note that a special presentation on this topic will be made during the 31st Session of the CAC in Room 1, 1st Floor of the International Conference Centre, Geneva on 4th

July 2008 at 10:30, open to all delegates and observers.

7-81. The Task Force commended the work done by FAO in coordination with OECD, which had met the expectation of the Task Force and its Physical Working Group within a short period of time. In response to requests for clarification by some delegations with regard to the sustainability of the arrangement for the database, the Representative of FAO explained that the activities on the IPFSAPH, which was managed within the Regular Budget of FAO, had been accorded high priority by the Organization due to its link with the SPS Agreement and that it would continue to be the case for the foreseeable future. Automated data entry and data sharing with the OECD Database would keep the maintenance cost to a reasonable level.

7-82. One delegation stressed the need for capacity building activities in the area of food safety assessment and detection of recombinant-DNA plant materials, so that developing countries could cope with the situation of low-level presence in accordance with the Proposed Draft Annex. The Representative of FAO stated that FAO/WHO had implemented a number of capacity building activities, including the strengthening of the regulatory framework for safety assessment of foods derived from biotechnology and enhancement of capacities for the detection of recombinant-DNA material as well as the conduct of safety assessments. While more activities could be envisaged in the future, subject to the availability of extra-budgetary funds.

7-83. Prior to in-depth consideration of the proposed draft annex, the Delegation of the European Community reiterated its position expressed at the Sixth Session of the Task Force that it had comprehensive regulatory framework for addressing adventitious presence and could agreed with this new work on condition that the annex provided for an effective system for data and information sharing. Subsequently, the Task Force considered the proposed draft annex paragraph by paragraph and considered and agreed on amendments as follows, as well as some other editorial changes.

General Issues

7-84. The Task Force was reminded that the term "food safety assessment" was a result of long and difficult consultations during the first term of the Task Force and had become a core concept on which the Task Force based its work. The Task Force noted that introducing a new term "assessment of food safety considerations" as proposed by the Physical Working Group might lead to possible confusions and agreed to revert to the term "food safety assessment", originally used throughout the Codex Plant Guideline, and use it consistently in the annex, as it was clear that this term applied in situations of low-level presence in the context of this annex.

7-85. With regard to the choice between the longer and shorter versions of the proposed draft annex, the Task Force agreed to base its discussion on the shorter one (Attachment 2 of the CL 2007/17-FBT Rev.) because it allowed clear indication of the difference between the provisions of the Codex Plant Guideline and those applicable to the food safety assessment in situations of low-level presence of recombinant-DNA plant material, and because an annex to a Codex document usually did not repeat what was included in the main document.

REPORT OF THE WORKING GROUP ON THE PROPOSED DRAFT ANNEX TO THE CODEX *GUIDELINE FOR THE CONDUCT OF FOOD**SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT –DNA PLANTS*: ASSESSMENT OF FOOD SAFETY CONSIDERATIONS ARISING FROM LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

BACKGROUND

1. The Fifth Session (2005) of the Codex ad hoc Intergovernmental Task Force on Food Derived from Biotechnology (Task Force) considered a proposal by the United States to undertake new work on the low-level presence of unauthorized recombinant-DNA plant material1. Although, the Task Force did not accept the proposal for new work at that time, it indicated that the United States may wish to further study the issue to decide whether to revisit the subject at a future session of the Task Force. The Delegation of the European Community expressed its willingness to continue discussion on the item with a particular focus on information on existing databases on recombinant-DNA plants and possible

development of a more comprehensive database of recombinant-DNA events.

2. At the Sixth Session (2006) of the Task Force, the United States again proposed work on the subject but with a different focus2. The United States proposed that the Task Force develop guidance on carrying out an assessment of food safety considerations in situations of low-level presence in which the r-DNA plant has already been found to be safe and authorized for commercialization for food by one or more countries through an assessment performed according to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Plant Guideline), but the importing country has not determined its food safety. It was further proposed that the guidance be developed as an Annex to the Codex Plant Guideline.

3. After extensive discussion, including an in-session Working Group to help develop a Terms of Reference for the project and a draft project proposal, the Task Force agreed to undertake this new work. The Task Force developed a project proposal[3] with two objectives:

To identify and incorporate into a draft annex of the Plant Guideline, the relevant sections of the Plant Guideline essential to the safety assessment in situations of low-level presence; and,

To identify information-sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply, and the data necessary to conduct an assessment of food safety in the importing country.

4. The Task Force also agreed on what the project would not do. This project would not:

Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate.

Preclude national authorities from conducting a full risk assessment; countries can decide when and how to use the Annex within the context of their regulatory systems.

Eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unapproved recombinant-DNA material.

5. The Task Force agreed to establish a physical Working Group[4] to undertake development of the Annex and accepted the willingness of the United States to Chair the Working Group and the willingness of Germany and Thailand to Co-Chair the Working Group.

[4]The following members and observers expressed their interest in taking part in the Working Group: Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Costa Rica, Czech Republic, Denmark, European Community, Finland, France, Greece, Germany, India, Iran, Ireland, Italy, Japan, Kenya, Mexico, Mali, Norway, Paraguay, Philippines, South Africa, Sweden, Switzerland, Thailand, the United States of America, ETA, CropLife International, CI, BIO, 49P, EUROPABIO, IICA.

6. The Task Force agreed that the proposed draft annex to be elaborated by the Working Group at Step 2 would be circulated for comments at Step 3, prior to consideration by the Seventh Session of the Task Force at Step 4.

MEETING OF THE WORKING GROUP

7. The Working Group met in Washington, D.C., U.S.A., on March 13-15, 2007. Attachment 3 lists the Working Group participants. The Working Group developed a proposed draft Annex to the Codex Plant Guideline, which is presented in two versions in Attachments 1 and 2. The proposed draft Annex of Attachment 1 contains all relevant paragraphs from the Codex Plant Guideline, with modification as warranted. It also includes two additional paragraphs (paragraphs 7 and 8), which list the paragraphs of the Codex Plant Guideline that have been modified and explain how and why they have been modified. The proposed draft Annex of Attachment 2 lists the numbers of all the relevant paragraphs from the Codex Plant Guideline, but contains text only of those paragraphs that have been altered.

8. The key points brought forward in the discussion of the Working Group included the following.

Assessment of Food Safety Considerations

9. The Working Group agreed that low level presence could pose different exposure issues depending on whether the low level presence was of a commodity product like grains, beans and oils seeds, or an unprocessed whole food ordinarily eaten in undiluted form, such as many fruits and vegetables.

10. The Working Group agreed that all components of the Codex Plant Guideline that related to safety of any new proteins produced in the plant as a result of the genetic modification would be relevant to both situations of low level presence and should be included in the Annex.

11. The Working Group agreed that, with some modification relating to nutritional composition, the following Codex Plant Guideline sections should be included in the Annex:

description of the recombinant-DNA plant;

description of host plant and its use as food;

description of the donor organism(s);

description of the genetic modification(s);

characterization of the genetic modification(s);

assessment of possible toxicity of expressed (non-nucleic acid) substances; and

assessment of possible allergenicity of newly expressed proteins.

12. The Working Group agreed, in accordance with the terms of reference agreed by the Task Force, that it would be up to importing countries to decide when recombinant-DNA plant material unauthorized in the importing country was at a level low enough to be subject to the Annex, but that as a general matter, it would have to be at least low enough that the importing country could be confident that the material would not have nutritional significance for its population. Therefore, it was agreed that components of the Codex Plant Guideline relating to nutritional modification (paragraphs 48 – 53 of the Codex Plant Guideline) or changes in levels of nutrients or antinutrients would not be relevant to the Annex.

13. Similarly, it was agreed that changes in levels of endogenous toxicants would likely be relevant to low level presence of recombinant-DNA plant material primarily in the case of unprocessed whole foods that ordinarily are eaten in undiluted form, such as many fruits and vegetables. Paragraphs 44 – 47 and 54 were modified accordingly.

14. The Working Group recognized that using the term “food safety assessment” in the Annex could cause confusion with a food safety assessment for unrestricted food use conducted according to the Codex Plant Guideline. The Working Group therefore agreed to use the phrase “assessment of food safety considerations” instead of “food safety assessment” or “safety assessment” when referring to the assessment carried out according to the Annex, noting that the use of the new phrase did not indicate any deviation from the comparative approach outlined in the Codex Plant Guideline.

Data and Information Sharing

15. The Working Group agreed on a set of information that would be made available in an agreed format via a publicly-accessible website. The agreed set of information would facilitate rapid access by importing Codex Member countries to additional information from the authorizing Codex Member country and the product applicant relevant to the assessment in accordance with the Annex. Further, it would increase transparency while enabling the website to be set up relatively quickly and maintained relatively easily because it would contain a limited set of data and information.

16. The Working Group agreed that upon request the authorizing Codex Member shall

make available to other Codex Members additional complementary information on the outcome of its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework, and as appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline.

17. The Working Group agreed that the product applicant shall make all reasonable efforts to provide further information and clarification as necessary to allow the assessment according to the Annex to proceed, as well as a validated protocol and non-viable reference materials.

18. Norway stated for the record that it preferred that the website also contain validated detection methods and all the information necessary to conduct an assessment of food safety considerations arising from low level presence of recombinant DNA plant material in food.

19. The Working Group agreed that it would be best if an international organization, such as FAO, could host and maintain the website, but that the website should not duplicate existing websites. The website AGBIOS Biotech crop database, which is maintained by a private party in Canada, was mentioned as a useful existing website that should also be considered. It was noted that the electronic Biosafety Clearing-House (BCH) maintained by the Secretariat of the Convention on Biological Diversity (CBD) as part of the Cartagena Protocol on Biosafety might also contain relevant information on national decisions on recombinant-DNA plants and could be applied to avoid duplication of work.

20. It was agreed that the Co-Chairs and representatives of the biotechnology industry would meet with international organizations, such as FAO, to discuss how the website might be maintained and whether FAO or another group (e.g., AGBIOS, CBD Secretariat) might set it up and maintain it. The results of that meeting are to be reported to the Task Force in Chiba in September, 2007. The representatives also agreed to provide more detail on industry's commitment to supply to countries the information and data described in the Annex.

Structure of the Annex

21. The Working Group discussed whether the Annex should reproduce the relevant paragraphs from the Codex Plant Guideline or only refer to them and only reproduce those that had been modified from the Codex Plant Guideline.

22. The advantage of reproducing all the relevant paragraphs was that the document could stand alone and would be easier to use. The advantage of reproducing only the modified paragraphs was that it would result in a shorter document more typical of an annex and would highlight the differences from the Codex Plant Guideline.

23. There were a variety of views by delegations, none strongly held, but more favoured the shorter approach than the stand-alone approach. It was decided that the Co-Chairs would circulate the shorter version (Attachment 2) to the participants of the Working Group via electronic means for review before finalizing the report of the working group meeting, although the possibility was raised that the 24. Co-Chairs might circulate both the shorter version and the longer version (Attachment 1) to allow better comparison.

24. The Co-Chairs electronically circulated both versions of the Annex to the Working Group participants. Few delegations expressed a preference in response, although of those that did, more preferred the longer version. The Co-Chairs therefore decided that both versions should be provided to the Task Force, so that it could decide which to progress.

RECOMMENDATION

25. The working group recommends that:

-the Task Force, at its Seventh Session, should consider the proposed draft Annex to the Codex Plant Guideline on Assessment of Food Safety Considerations Arising from Low Level Presence of Recombinant-DNA Plant Material in Food with a view towards its further progression in the Codex Step Procedure.

-as part of that consideration, the Task Force should decide which of the two versions of the Annex to pursue.

2. ELABORATION OF THE TEXT

PROPOSED DRAFT ANNEX TO THE CODEX *GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS* (CAC/GL 45-2003): ASSESSMENT OF FOOD SAFETY CONSIDERATIONS ARISING FROM LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

SECTION 1 – PREAMBLE

1. An increasing number of recombinant–DNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Plant Guideline) in one or more countries may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined.

2. This Annex describes the recommended approach to ~~making assessments of~~ **the food safety** ~~considerations~~ **assessment in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances[1].**

[1] This guidance is not intended for a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

Note: See the last sentence of 7-88.

3. This annex also describes data and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

4. This Annex can be applied in two different dietary exposure situations:

That involving commodities, such as grains, beans or oil seeds, in which exposure to food from a variety not authorized in the importing country would likely be to dilute low level amounts at any one time. This would likely be the more common situation of low-level presence of recombinant-DNA plant material. Because any food serving of grains, beans or oil seeds would almost necessarily come from multiple plants, and because of how these types of commodities generally are sourced from multiple farms, are commingled in grain elevators, are further commingled in export shipments, at import and when used in processed foods, any inadvertently commingled material derived from recombinant-DNA plant varieties would be present only at a low level in any individual serving of food.

That involving foods that are commonly consumed whole and undiluted, such as some fruits and vegetables like potatoes, tomatoes, and papaya, in which exposure would be rare but could be to an undiluted form of the unauthorized recombinant-DNA plant material. While the likelihood of consuming material from such an unauthorized variety would be low and the likelihood of repeated consumption would be much lower, any such consumption might be of an entire unauthorized fruit or vegetable.

5. In both cases, the dietary exposure will be significantly lower than would be considered in a food safety assessment of the recombinant-DNA plant according to the Codex Plant Guideline. As a result, only certain elements of the Codex Plant Guideline will be relevant and therefore are included in this Annex.

6. This Annex does not:

Address risk management measures; national authorities will determine when a recombinant-DNA plant material is present at a level low enough for this Annex to be appropriate;

preclude national authorities from conducting a safety assessment according to the

Codex Plant Guideline[6]; countries can decide when and how to use the Annex within the context of their regulatory systems; or

eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material.

[6] The Terms of Reference states that the annex would not preclude national authorities from conducting a "full risk assessment." However, the Working Group noted that in the context of an annex to the Codex Plant Guideline, it would be better to state that the annex would not preclude national authorities from conducting a "safety assessment according to the Codex Plant Guidelin**e."**

Note: Footnote 6 was deleted. See below.

7-86. The Task Force noted that the footnote to the second bullet point of paragraph 6 had been only for the purpose of reporting discussion by the Physical Working Group and agreed on its deletion.

~~**SECTION 2 – SECTIONS OF THE CODEX PLANT GUIDELINE APPLICABLE TO THE LOWLEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD**~~

~~7. The following sections of the Codex Plant Guideline apply to the assessment of the food safety considerations arising from low-level presence of recombinant-DNA plant material in food. Paragraphs that apply are specifically indicated. If paragraphs are not listed, they can be omitted from consideration.~~

SECTION 2- GENERAL AND OTHER CONSIDERATIONS

7. For the food safety assessment in situations of low-level presence of recombinant DNA plant materials in food, sections 4 and 5 of the Codex Plant Guideline apply as amended as follows. The applicable paragraphs are specifically indicated. Those paragraphs of the Codex Plant Guidelines that are not listed can be omitted from consideration.

7-87. The Task Force noted that the applicability of the sections of the Codex Plant Guideline other than Sections 4 and 5 was not clear from the proposed wording in paragraph 7, which simply stated that the paragraphs listed under this section applied to food safety assessment in situations of low-level presence, and amended the first sentence as follows: "For the food safety assessment in situations of low-level presence of recombinant-DNA plant materials in food, Sections 4 and 5 of the Codex Plant Guideline apply as amended as follows."

7-88. The Task Force noted that paragraphs contained in Section 2 after paragraph 7 should be renumbered in a continuous sequence. The Task Force also noted that paragraphs 22 and 41 of the Codex Plant Guideline did not need to be reproduced in the annex because these paragraphs had become identical to the corresponding paragraphs in the Codex Plant Guideline after the decision of the Task Force not to introduce the new term "assessment of food safety considerations" (see para. 84 above).

~~**GENERAL CONSIDERATIONS**~~

DESCRIPTION OF THE RECOMBINANT-DNA PLANT

~~Paragraph 22 applies as written:~~

~~22. A description of the recombinant-DNA plant being presented for assessment of food safety considerations should be provided. This description should identify the crop, the transformation event(s) to be reviewed and the type and purpose of the modification. This description should be sufficient to aid in understanding the nature of the food being submitted for assessment of food safety considerations.~~

8. Paragraph 22 of the Codex Plant Guideline applies.

DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD

9. Paragraphs 23, 24 and 25 of the Codex Plant Guideline apply.

DESCRIPTION OF THE DONOR ORGANISM(S)

~~Paragraph 26 applies as written:~~

10. ~~26.~~ Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor organism(s) should include:

A. its usual or common name;

B. scientific name;

C. taxonomic classification;

D. information about the natural history as concerns food safety;

E. information on naturally occurring toxins and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and,

F. information on past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants).[2]

[2] The text of this paragraph was adapted from paragraph 26 of the Codex Plant Guideline.

DESCRIPTION OF THE GENETIC MODIFICATION(S)

11. Paragraphs 27, 28 and 29 of the Codex Plant Guideline apply.

CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

~~Paragraphs 30, 31, 32 and 33 apply, except that 32 (D) applies as written:~~

~~32 (D): the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the edible portions of the plant; and~~

12. Paragraphs 30 and 31 of the Codex Plant Guideline apply.

13. Information should be provided on any expressed substances in the recombinant-DNA plant; this should include:

A) the gene product(s) (e.g. a protein or an untranslated RNA);

B) the gene product(s)' function;

C) the phenotypic description of the new trait(s);

D) the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the edible portions of the plant; and

E) where possible, the amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein.[3]

[3] The text of this paragraph was adapted from paragraph 32 of the Codex Plant Guideline.

14. Paragraph 33 of the Codex Plant Guideline applies.

Note: paragraph 32 in the Working Group proposal was deleted.

~~ASSESSMENT OF FOOD SAFETY CONSIDERATIONS~~ SAFETY ASSESSMENT

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity

~~Paragraphs 35 and 36 apply as written:~~

15. ~~35.~~ The safety assessment ~~of food safety considerations~~ should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values[4].

[4] The text of this paragraph was adapted from paragraph 35 of the Codex Plant Guideline.

16. ~~36.~~ Information should be provided to ensure that genes coding for known toxins present in the donor organisms are not transferred to recombinant-DNA plants that do

not normally express those toxic characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate toxicants.[5]

[5] Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

17. Paragraph 37 of the Codex Plant Guideline applies.

~~Paragraph 38 applies as written:~~

18, ~~38.~~ In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[6] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known[7].

[6] The text of this paragraph was adapted from paragraph 36 of the Codex Plant Guideline.

[7] The text of this paragraph was adapted from paragraph 38 of the Codex Plant Guideline.

19. Paragraphs 39 and 40 of the Codex Plant Guideline apply.

Assessment of possible allergenicity (proteins)

~~Paragraph 41 applies as written:~~

~~41. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly-expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or non-allergenicity). As noted in paragraph 20, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in the annex to the Codex Plant Guideline entitled Assessment of Possible Allergenicity.[16]~~

~~[16] The FAO/WHO expert consultation 2001 report, which includes reference to several decision trees, was used in developing the allergenicity Annex.~~

20. Paragraphs 41, 42 and 43 of the Codex Plant Guideline apply.

Analyses of Key Toxicants and Allergens

~~Paragraphs 44 and 45 apply as written:~~

21. ~~44.~~ Analyses of key toxicants[8] and allergens are important in certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted, such as potatoes, tomatoes, and papaya). Analyses of concentrations of key toxicants and allergens of the recombinant-DNA plant typical of the food should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.[9]

[15] Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

[8] Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be

significant to health (e.g. solanine in potatoes if the level is increased).

[9] The text of this paragraph was adapted from paragraph 44 of the Codex Plant Guideline.

22. ~~45~~. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of key toxicants and allergens over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimize environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key toxicants and allergens.[10]

[10] The text of this paragraph was adapted from paragraph 45 of the Codex Plant Guideline.

Evaluation of Metabolites

~~Paragraph 46 applies as written:~~

23.~~46.~~ Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. ~~Assessment of food safety considerations arising from~~ Food safety assessment in situations of low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods)[11].

[11] The text of this paragraph was adapted from paragraph 46 of the Codex Plant Guideline.

Food Processing

~~Paragraph 47 applies as written:~~

24. ~~47.~~ The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.[12]

[12] The text of this paragraph was adapted from paragraph 47 of the Codex Plant Guideline.

~~OTHER CONSIDERATIONS~~

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

~~Paragraph 54 applies as written:~~

25.~~54~~. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), the risk assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.[13]

[13] The text of this paragraph was adapted from paragraph 54 of the Codex Plant Guideline.

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

26. Paragraphs 55, 56, 57 and 58 of the Codex Plant Guideline apply.

SECTION 3 – GUIDANCE ON DATA AND INFORMATION SHARING

Note: The paragraph numbers in the following paragraphs refers to those contained in the Attachment 2 of the CL 2007/17FBT Rev. Paragraphs 8 to 13 correspond to paragraphs 27 to 32 of the Appendix IV to this report.

7-89. The Task Force noted that the modal verb "shall" was used in several places in Section 3 and, with the understanding that all Codex standards and related texts were voluntary in nature, agreed to replace it with "should" throughout the text.

27. ~~8.~~ **In order for Codex Members to use this Annex, it is essential that they have access to requisite data and information.**

28. ~~9.~~ **Codex Members shall make available to a publicly accessible central database** ~~(~~**to be maintained by**~~...)~~ **FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline This information shall be presented in accordance with the following format:**

a. name of product applicant

b. summary of application

c. country of authorization

d. date of authorization

e. scope of authorization

f. unique identifier

g. links to the information on the same product in other databases maintained by relevant international organizations, as appropriate;

h. ~~**g.** summary of safety assessment by competent authority(s), and~~ **summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline;**

i. where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained[14]; and

j. ~~**h.**~~ **contact details of the competent authority(s) responsible for the safety assessment and the product applicant.**

[14]This information may be provided by the product applicant or in some cases by Codex members.

7-90. The Task Force agreed to amend the chapeau of paragraph 9 to clarify that the database should be "publicly accessible".

29. ~~10.~~ **This process shall facilitate rapid access by importing Codex Member countries to additional information relevant to the assessment of food safety considerations arising from low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.**

30. ~~11.~~ **The authorizing Codex Member** ~~shall~~ **should make available complementary information to other Codex Members on** ~~the outcome of~~ **its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.**

7-91. The Task Force agreed to the proposal one delegation to delete the words "the outcome of" from paragraph 11.

31. ~~12.~~ **The product applicant** ~~shall~~ **should** ~~make all reasonable efforts to provide further information and clarification as necessary to allow the assessment according to this Annex to proceed~~ **provide further information and clarification as necessary to allow the assessment according to this Annex to proceed,, as well as a validated protocol for an event-specific or trait-specific detection method** ~~as specified by the Codex Member, and nonviable reference materials.~~ **suitable for low level situations and appropriate reference materials (nonviable, or in certain circumstances, viable). This is without prejudice to**

legitimate concerns to safeguard the confidentiality of commercial and industrial information.

7-92. The Task Force had intensive discussion on the proposals by the Delegation of the European Community (CRD 13) on the nature and format of information to be submitted to the proposed database as provided in paragraph 9, as well as related provisions in paragraph 12.

32. ~~13~~. As appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline by the authorizing country should be made available

Links to information in other databases

7-93. The Delegation of the European Community proposed to include in the database a reference to a notification(s) to the Biosafety Clearing House (BCH) of the Cartagena Protocol and/or OECD BioTrack Product Database.

7-94. While some observers supported the proposal, stating that such reference would allow users easy access to the information contained in these two databases, many delegations were against its inclusion because in their view these databases, not being focused on food safety specifically, did not provide useful information for the purpose of this annex. Other delegations were of the view that there should be no reference to the Cartagena Protocol or to the OECD, to which not all the Codex members were party or member. It was also pointed out that the Cartagena Protocol addressed living modified organisms only, while Codex had to address food.

7-95. The Delegation of Argentina indicated that, considering that some members had concerns on the reference to the BCH and the OECD, a more general reference on information sources could be acceptable, such as "links to the information on the same product in other international databases." One delegation found the proposal too general and preferred to limit the scope to those databases relevant to food safety. Another delegation, noting that such links to other relevant databases might not always exist, proposed to add "as appropriate" at the end of the sentence. With these modifications, many delegations supported the proposal by the Delegation of Argentina.

7-96. The Delegation of the European Community proposed, as an alternative or additional to the revised reference above, to add a footnote to "f. unique identifier", which read "Unique identifier allows access to complementary information on recombinant-DNA plants notified to the Biosafety Clearing House of the Cartagena Protocol and/or the OECD BioTrack Product Database". However, other delegations did not agree to this proposed footnote, even as a factual statement, for the reasons mentioned above.

7-97. After some further discussion, the Task Force agreed not to add a footnote to item f but to add the following item, without reference to "food safety relevance", after item f "unique identifier": "Links to the information on the same product in other databases maintained by relevant international organizations, as appropriate". It was understood that in certain cases, the BCH and the OECD BioTrack Product Database could provide important information to regulating authorities.

Summary of the safety assessment

7-98. The Delegation of the European Community proposed that the summary of the safety assessment should be structured following the headings of the Codex Plant Guideline and be focused on the areas of specific relevance and interest of the risk assessor. The Delegation clarified that this provision would not only ensure that the safety assessment be conducted in accordance with the Codex Plant Guideline but also would allow rapid access to relevant information, which is critical to the food safety assessment in situations of low-level presence.

7-99. While some delegations expressed support to the proposal by the Delegation of the European Community because they believed that a uniform and standardized presentation of the summary of the food safety assessment would facilitate the review of the food safety assessment, particularly for developing countries, several other delegations were not supportive

of the proposal because it would require rearrangement of the existing summaries of food safety assessments when the format for such summaries under their national legislation was different from the structure of the Codex Plant Guideline even though the safety assessment itself was in line with the Codex Plant Guideline. Some delegations also pointed out that it would be practically impossible to determine, in advance, the "areas of specific relevance and interest to the risk assessor" at the time of submission of the information to the database.

7-100. After some discussion, the Task Force agreed that the summary of the safety assessment "should be consistent with the framework of food safety assessment of the Codex Plant Guideline".

Detection method and reference material

7-101. The Delegation of the European Community proposed to include "either a validated protocol for an event-specific detection method suitable for low-level situations and appropriate (either viable or nonviable) reference material, or information on where these can be secured", as another information item in the database. The Delegation stressed that access to such information was key to the management of situations of low-level presence, in which competent authorities should urgently assess the actual presence of recombinant-DNA plant materials in the commodity in question.

7-102. The Delegation of the United States of America, while recognizing the need for and usefulness of such information, proposed that the database contain information only where it could be obtained. The Delegation, supported by an observer, also expressed some concern on the inclusion of "viable" reference material, the provision of which was in most cases impossible due to intellectual property rights.

7-103. The Task Force, with the understanding that the submission of the viable reference material was optional and would usually not be needed, agreed to include the following information item in the database: "where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situations may be obtained", with a footnote indicating that this information might be provided by the product applicant or in some cases by Codex members. The Task Force also agreed to amend the reference to viable/non-viable material in paragraph 12 to make it consistent with the decision taken on paragraph 9.

7-104. The Task Force noted that while paragraph 12 included provisions similar to those under paragraph 9, the requirements in this paragraph was intended for product applicants, not Codex members, and agreed to retain paragraph 12 (new paragraph 31). The Task force agreed with the proposal by the Delegation of the European Community to clarify that the provision of this paragraph was without prejudice to legitimate concerns to safeguard the confidentiality of commercial and industrial information.

7-105. In reply to a proposal to delete the reference to trait-specific detection method, several delegations noted that a trait-specific detection method could be sufficient in cases, for example, where the trait in question was not authorized in the importing country.

Status of the Proposed Draft Annex: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food

7-106. In view of the progress made and consensus reached, the Task Force agreed to forward the proposed draft annex as amended above for adoption at Steps 5/8 by the 31st Session of the Commission, with the recommendation to omit Steps 6 and 7. The proposed draft annex is presented in Appendix IV to this report. The Task Force also agreed to request FAO to provide update on the database for data and information sharing at the 31st Session of the Commission.

Chapter 14
HISTORY OF THE DEBATE ON "GM LABELLING"

CONTENTS

PART I

I. SHORT SUMMARY AND SOME QUESTIONS

1. Introductory Phase

The 19th Session of Codex Alimentarius Commission (CAC) in 1991 requested CCFL to" provide guidance on the possibilities to inform the consumer that a food had been produced through modern biotechnology". In the 22nd Session of CCFL in 1993, the United States volunteered to prepare a discussion paper, which was submitted to the 23rd Session of CCFL in 1995.

*In 1991, Executive Committee (CCEXEC) "**recommended** that the horizontal committees identified - the Codex Committees on Nutrition and Foods for Special Dietary Uses, on Food Labelling, on Food Additives and Contaminants and on Food Hygiene - should discuss issues related to biotechnology". CAC discussed the matter with the input from CCEXEC. It **noted** that while consumers would benefit from "modern" food biotechnology, some consumers felt that this technology would pose certain problems. For example, individual consumers might, on ethical or other grounds, not wish to buy foods derived from "modern" biotechnology". The Commission **requested** the Codex Committee on Food Labelling to provide guidance on how the fact that a food was derived from "modern" biotechnologies could be made known to the consumers".*

It is interpreted that the terms of reference/mandate of CCFL was to provide guidance on how the fact that a food was derived from "modern" biotechnologies could be made known to the consumers", and the underlined part concerning the consumer concern was simply observations made by CAC, i.e., no part of the mandate.

Record of Discussion

CCEXEC 1991: IMPLICATIONS OF BIOTECHNOLOGY ON INTERNATIONAL FOOD STANDARDS AND CODES OF PRACTICE (Agenda Item 5)

32. In introducing document ALINORM 91/11, the Committee was reminded that the issue of biotechnology was first discussed in 1989 during the 18th Session of the Commission. At that time, the Commission had been informed of an initiative of WHO to convene, jointly with FAO, a Consultation on the Assessment of Biotechnology in Food Production and Processing as Related to Food Safety. This Consultation had taken place in Geneva in November 1990 and the Report of it would be available, as a formal WHO publication, at the end of 1991. The Consultation had recognised biotechnology as a continuum, embracing traditional breeding techniques and modern techniques based on recombinant DNA - technologies. "Modern" biotechnologies had the potential of revolutionizing the food supply, both in quantity and quality. While the Consultation was of the opinion that foods derived from "modern" biotechnologies were inherently not less safe than those derived from traditional biotechnologies, the issue of safety had to be considered. In addition, nutritional concerns may have to be addressed.

33. Based on scientific and technical advice by Joint FAO/WHO expert committees and consultations, the Codex Committees on Nutrition and Foods for Special Dietary Uses, on Food Labelling, on Food Additives and Contaminants and on Food Hygiene were expected to be the main committees with responsibilities for matters on biotechnologies. In addition, several commodity committees (e.g. Vegetable Protein, Cereals, Pulses and Legumes, Fish and Fishery Products, Fats and Oils) might need to play a role in reaching international consensus on particular novel foods.

34. In appreciating the work of the Joint FAO/WHO Consultation, the Committee felt that it and the Commission needed to monitor the developments in the field of food biotechnology which ought to be encouraged. It recommended that the horizontal committees identified above should discuss issues related to biotechnology. Concerning the data bases on the nutrient and toxicant content of food; the molecular analysis of organisms used in food production, and the molecular, nutritional and toxicant content of genetically modified organisms identified for the use in food production, the establishment of which had been recommended by the Consultation, the Committee felt that Codex should play a role in the prioritization process.

CAC 1991: IMPLICATIONS OF BIOTECHNOLOGY ON INTERNATIONAL FOOD STANDARDS AND CODES OF PRCTICE

88. In considering document ALINORM 91/11, the Commission recalled that the issue of biotechnology was first discussed in 1989 during its 18th Session. At that time, the Commission had been informed of an initiative of WHO to convene, jointly with FAO, a Consultation on the Assessment of Biotechnology in Food Production and Processing as Related to Food Safety. This Consultation had taken place in Geneva in November 1990 and the Report of it would be available, as a formal WHO publication, at the end of 1991. The Consultation had recognized biotechnology as a continuum, embracing traditional breeding techniques and modern techniques based on recombinant DNA - technologies. “Modern” biotechnologies had the potential of revolutionizing the food supply, both in quantity and quality. While the Consultation was of the opinion that foods derived from “modern” biotechnologies were inherently not less safe than those derived from traditional biotechnologies, the issue of safety had to be considered. In addition, nutritional concerns may have to be addressed.

89. Based on scientific and technical advice by Joint FAO/WHO expert committees and consultations, the Codex Committees on Nutrition and Foods for Special Dietary Uses, on Food Labelling, on Food Additives and Contaminants and on Food Hygiene were expected to be the main committees with responsibilities for matters on biotechnologies. In addition, several commodity committees (e.g. Vegetable Protein, Cereals, Pulses and Legumes, Fish and Fishery Products, Fats and Oils) might need to play a role in reaching international consensus on particular novel foods.

90. The Commission endorsed the conclusions and recommendations of the Joint FAO/WHO Consultation. It noted that while consumers would benefit from “modern” food biotechnology, some consumers felt that this technology would pose certain problems. For example, individual consumers might, on ethical or other grounds, not wish to buy foods derived from “modern” biotechnology. The Commission requested the Codex Committee on Food Labelling to provide guidance on how the fact that a food was derived from “modern” biotechnologies could be made known to the consumers.

91. The need to provide consumers with sound, scientifically based information which explained the application of biotechnology in food production and processing and clarified the safety issues was stressed. In this context, the Commission was informed that WHO was exploring possibilities to prepare a book on food biotechnology for the non-technical reader which would be based on the report of the Joint FAO/WHO Consultation.

92. The Commission endorsed the views expressed by its Executive Committee and agreed that the Commission should monitor developments in the field of food biotechnology and that the General Subject Committees identified above should discuss issues related to biotechnology within the context of their Terms of Reference (see ALINORM 91/4, para. 34). The Commission requested WHO to make copies of the Consultation report available to all

Codex Contact Points. A progress report is to be presented to the 20th Session of the Commission.

1993 (22nd CCFL)

9. The Committee was informed of the request of the 19th Session of the Codex Alimentarius Commission that CCFL should provide guidance on the possibilities to inform the consumer that a food had been produced through "modern" biotechnologies. 10. The Committee welcomed the offer of the Delegation of the United States to prepare a discussion paper concerning this subject for circulation and government comments well before the next Session.

1995 (23rd CCFL)

114. The Committee expressed its appreciation to the Delegation of the United States for this comprehensive document and the presentation of current issues associated with biotechnology. It was also noted that, due to time constraints, the document had not been circulated with ample time for comments. Moreover, several delegations indicated that their scientific and legal authorities were considering this complex issue at the moment and that they would need additional time to examine in detail the questions the Committee was mandated to address.

2. Amendments agreed on sections related to allergenicity in General Standard for Labelling of Prepackaged Foods

CCFL agreed rather quickly (in total 4 sessions, 1997-2000) on allergenicity (See record of discussion in Ref. 1). The statement in the agreed document is as follows;

> Section 4.2.2: The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Ref. 1: Record of Discussion

1997 (25th CCFL): The Committee recalled that its last session had agreed that, subject to the advice of the Executive Committee, the Secretariat should initiate the preparation of guidelines to address the labelling issues associated with foods obtained through biotechnology. The Executive Committee had recommended that the Statements of Principle concerning the Role of Science[9] should be closely adhered to and that the recommendations of the Joint FAO/WHO Expert Consultation on Food Safety and Biotechnology should be taken into account (52). The Secretariat indicated that the recommendations had been presented in the form of an amendment to the General Labelling Standard, following the approach taken for similar issues, and presented the conclusions of the Expert Consultation of particular relevance where labelling was concerned. The Committee noted that the elaboration of the recommendations had already been approved by the CCEXEC and that comments at Step 3 had not yet been requested in view of time constraints (53). The Committee agreed that the Proposed Draft Recommendations, as included in Appendix VI, should be circulated for government comments at Step 3, redrafted by the Secretariat, taking into account all comments received, for further consideration and thorough discussion in the plenary meeting at the next session (60).

16. The Consultation considered the specific issues related to allergenicity in the case of biotechnology and made recommendations for the assessment of potential allergens, including a number of criteria to be applied in identifying potential allergenicity. It proposed that foods which would pose a health risk should not be released. It recommended that foods that fail to elicit positive results in *in vitro* or *in vivo* tests should be treated like any other foods in regard to allergenicity. The recommendations made by the CCFL concerning the labelling of potential allergens would therefore apply to foods obtained through biotechnology as to conventional foods.

17. As regards the possibility of transfer of allergenic properties to foods which normally are not allergenic, the Consultation made the following recommendations:

• The transfer from commonly allergenic foods should be discouraged unless it can be documented that the gene transferred does not code for an allergen.

• Foods which contain an allergen transferred from the organism which provided the DNA should not be considered for market approval unless they can be clearly identified in the marketplace and this identity would not be lost during distribution or processing. Labelling approaches may not be practical in these situations, and particular problems for consumers who cannot read, or who may not be provided with labels. Foods which are not presented on the market in a pre-packaged form and generally not labelled should be taken into account.

25. Recommendations relating to allergens should be considered in conjunction with the specific discussion on this subject, and the amendment of the General Standard, under Agenda Item 6 (Proposed Draft Recommendations for the Labelling of Foods that can cause Hypersensitivity).

27. The following amendments to the **General Standard for the Labelling of Prepackaged Foods** are therefore proposed as a basis for discussion and for consideration by the Committee:

Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods) (At Step 3 of the Procedure)

Recommendations concerning allergens

Two possible approaches are proposed:

[In view of the recommendations of the Consultation, it is not proposed at this stage to establish labelling requirements for material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population (especially allergens) as the preferred approach would be to discourage the marketing of such products.**]**

OR

[Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.3[5], shall be declared.

1998 (26th CCFL): The Committee, recognizing the need to concentrate its efforts on the areas where consensus could be achieved, as proposed by the Chairperson, had an exchange of views on the definition of foods obtained through biotechnology. The Committee noted the proposals 1) to replace "new" with "modern" biotechnology, and 2) to avoid using the term " biotechnology" as it might create confusion for the consumer. Taking into account the amendments to the definition proposed by Canada and the EC, the Committee agreed on a revised definition which clarified the scope of the text. The Committee also agreed to require the labelling of allergens transferred through genetic modification, as proposed in the current text (section 4.2.2.) (48). The Committee agreed to forward the amended Definition in square brackets and Section 4.2.2. (allergens) to Step 5 (see Appendix VII) and to return all other sections of the Proposed Draft to Step 3 for further comments and consideration by the next session (see Appendix VIII) (49).

Appendix VII

Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

2000 (28th CCFL): The Committee noted that no comments had been received at Step 6 on Section 4.2.2 concerning the declaration of allergens transferred from any of the products listed in Section 4.2.1.4, and agreed that it should be advanced to Step 8 for inclusion in the General Standard as a new section (36).

Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared*.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Section 4.2.1.4

The following foods and ingredients are known to cause hypersensitivity and shall always be declared as such:

Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;

Crustacea and products of these;

Eggs and egg products;

Fish and fish products; Peanuts, soybeans and products of these;

Milk and milk products (lactose included); Tree nuts and nut products; and

Sulphite in concentrations of 10 mg/kg or more.

Ref. 2: The paragraphs related to genetically modified organisms appearing in the Guidelines for Organically Produced Food.

Section 1. SCOPE

1.5 All materials and/or the products produced from genetically engineered/modified organisms (GEO/GMO) are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

Section 2. DESCRIPTION AND DEFINITIONS

Genetically engineered/modified organisms. The following provisional definition is provided for genetically/modified organisms. Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Techniques of genetic engineering/modification include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.

B. LIVESTOCK AND LIVESTOCK PRODUCTS

Nutrition

15. Notwithstanding the above, where an operator can demonstrate to the satisfaction of the official or officially recognized inspection/certification body that feedstuffs satisfying the requirement outlined in paragraph 13 above are not available, as a result of, for example, unforeseen severe natural or manmade events or extreme climatic weather conditions, the inspection/certification body may allow a restricted percentage of feedstuffs not produced according to these guidelines to be fed for a limited time, providing it does not contain genetically engineered/modified organisms or products thereof. The competent authority shall set both the maximum percentage of non-organic feed allowed and any conditions relating to this derogation.

18. If substances are used as feedstuffs, nutritional elements, feed additives or processing aids in the preparation of feedstuffs, the competent authority shall establish a positive list/s of substances in compliance with the following criteria:

General criteria

a) substances are permitted according to national legislation on animal feeding;

b) substances are necessary/essential to maintain animal health, animal welfare and vitality; and

c) such substances:

− contribute to an appropriate diet fulfilling the physiological and behavioural needs of the species concerned; and

− do not contain genetically engineered/modified organisms and products thereof; and

− are primarily of plant, mineral or animal origin.

Specific criteria for feedstuffs and nutritional elements

19. Silage additives and processing aids may not be derived from genetically engineered/modified organisms or products thereof, and may be comprised of only:

– sea salt;
– coarse rock salt;
– yeasts;
– enzymes;
– whey;
– sugar; or sugar products such as molasses;
– honey;
– lactic, acetic, formic and propionic bacteria, or their natural acid product when the weather conditions do not allow for adequate fermentation, and with approval of the competent authority.

Species specific requirements

Beekeeping and bee products

64. The certification body or authority must identify zones where hives, that meet these requirements, should not be placed due to potential sources of contamination with prohibited substances, genetically modified organisms or environmental contaminants.

TABLE 3: Ingredients of non-agricultural origin referred to in section 3 of these guidelines

3.4 Preparations of micro-organisms and enzymes

Any preparation of micro-organisms and enzymes normally used in food processing, with the exception of micro-organisms genetically engineered/modified or enzymes derived from genetic engineering.

TABLE 4: PROCESSING AIDS WHICH MAY BE USED FOR THE PREPARATION OF PRODUCTS OF AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

Preparations of micro-organisms and enzymes

Any preparations of micro-organisms and enzymes normally used as processing aids in food processing, with the exception of genetically engineered/modified organisms and enzymes derived from genetically engineered/modified organisms.

3. Organically Produced Food

CCFL agreed quickly on exclusion of genetically modified organisms or products thereof from the production of organically produced food without much debate. The agreed text relating to this particular issue is reproduced in Ref. 2.

4. ***Fourteen years' debate without change in original positions of delegates (Ref. 3)***

It is remarkable that members supporting labeling and those opposing have not changed their positions in the past 14 years.

Voices for labeling

1996: "the opinions of many delegations and observers which called for the mandatory and comprehensive labelling of all foods prepared with the aid of biotechnology on the basis of the consumer's right to know the origin and nature of the foods which they purchased and the right to make informed choices

2007: "mandatory labelling was necessary in order to provide clear information to consumers and to allow them to make an informed choice. These delegations and some observers stressed the fundamental right of consumers to know the nature of the food they were consuming"

2009: "expressed the need for mandatory labelling to allow consumer choice, noting that GM/GE foods were a sensitive issue for consumers in their respective countries"

Voices against labeling

1996: "labelling should address the specific concerns of safety (including potential allergenicity), nutrition and food composition, all of which could be subject to scientific study and evaluation, and that labelling should be considered on a case-by-case basis"

2007: "mandatory method of production labelling of foods derived from biotechnology was not justified on the grounds of food safety or fair trade practices, and that the consumer's right to know was not one of the objectives of Codex"

2009: "work on this issue should be discontinued noting that the matter had been discussed for almost two decades without consensus, that there was very little prospect of consensus in the future"

Concern on the safety of foods derived from biotechnology is continuously expressed by the members requesting mandatory labelling, even five years after agreement on Guidelines on Foods Derived from Modern Biotechnology, which clearly mandated the pre-market risk assessment, e.g.,

2007: Some delegations expressed the view that labelling was also related to food safety in view of the potential risks to consumer's health.

Some delegations informed the Committee that serious concerns were expressed in their countries regarding the safety aspects of GM/GE foods

Lasting claim from the party that supports mandatory labeling is "right to know of consumers";

1996: The Committee noted the opinions of many delegations and observers which called for the mandatory and comprehensive labelling of all foods prepared with the aid of biotechnology on the basis of the consumer's right to know the origin and nature of the foods which they purchased and the right to make informed choices based on a variety of considerations and personal values

2007: "request for mandatory GM/GE labelling is not a food safety issue, but an issue related to consumer information"

2009: expressed the need for mandatory labelling to allow consumer choice, noting that GM/GE foods were a sensitive issue for consumers in their respective countries

Codex Evaluation's View: Report of the EVALUATION OF THE CODEX ALIMENTARIUS AND OTHER FAO AND WHO FOOD STANDARDS WORK (15 Nov. 2002). See also box 1.

Ref. 3: Extracts from the reports of the 24th and the 35th sessions

Opinions "for" labelling

1996 (24th CCFL): The Committee noted the opinions of many delegations and observers which called for the mandatory and comprehensive labelling of all foods prepared with the aid of biotechnology on the basis of the consumer's right to know the origin and nature of the foods which they purchased and the right to make informed choices based on a variety of considerations and personal values (42).

2007 (35th CCFL): Several delegations recalled that foods derived from biotechnology have to undergo a pre-market safety assessment in order to protect consumers' health and therefore the request for mandatory GM/GE labelling is not a food safety issue, but an issue related to consumer information. Some delegations expressed the view that labelling was also related to food safety in view of the potential risks to consumer's health. The Observer from 49P noted that a great proportion of GE foods being sold have not been subjected to any governmental safety assessments, and therefore labelling helped consumers make their own decisions about health and safety (108). Some delegations informed the Committee that serious concerns were expressed in their countries regarding the safety aspects of GM/GE foods, and also concerning the social and economic consequences of their use in agriculture, especially for small farmers (104). Several delegations indicated that, in their countries, consumers had no objections in principle to the use of GM/GE foods, but that mandatory labelling was necessary in order to provide clear information to consumers and to allow them to make an informed choice. These delegations and some observers stressed the fundamental right of consumers to know the nature of the food they were consuming (109).

2009 (37th CCFL): Many other delegations and several observers expressed the view that some progress had been made over time and emphasized that especially many developing countries looked to Codex for guidance on approaches for the labelling of GM/GE foods and that the proposed draft recommendations could prove useful in this respect. One Observer recalled that Codex had a dual mandate to not only protect the health of consumers but also to ensure fair practices in the food trade and thus a failure to label GM/GE foods could in itself be considered misleading. Several delegations and observers expressed the need for mandatory labelling to allow consumer choice, noting that GM/GE foods were a sensitive issue for consumers in their respective countries and therefore stressed the importance of continuing this work. In addition many delegations and several observers expressed their view that one of the main conclusions of the work already carried out by several working groups was that several approaches for labelling of GM/GE foods were possible. One delegation indicated that their population preferred foods derived from GM/GE techniques because they were cheaper but while this was the case the consumers would still prefer the choice of being informed if the foods were derived from GM/GE techniques and therefore could not see the rationale for the discontinuation of this work (95).

Opinions "against" labelling

1996 (24th CCFL): Many other delegations and observers stressed that labelling should address the specific concerns of safety (including potential allergenicity), nutrition and food composition, all of which could be subject to scientific study and evaluation, and that labelling should be considered on a case-by-case basis taking these considerations into account. In such cases, the provision of consumer information other than that required for the purposes of safety, nutrition and food composition could be considered by means other than labeling (43).

2007 (35th CCFL): Several other delegations expressed the view that mandatory method of production labelling of foods derived from biotechnology was not justified on the grounds of food safety or fair trade practices, and that the consumer's right to know was not one of the objectives of Codex, and referred to the view expressed by the Executive Committee in 1996 to the effect that "the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labeling" (ALINORM 97/3, para. 29). These delegations pointed out that governments had the possibility of requesting mandatory labelling in their national legislation if it fulfilled a legitimate objective but that it should not be imposed to all countries at the international level. In this respect, it was recalled that one of the Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principles was that "some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world wide" (111).

2009 (37th CCFL): Some delegations and some observers, were of the opinion that work on this issue should be discontinued noting that the matter had been discussed for almost two decades without consensus, that there was very little prospect of consensus in the future and considerable financial and human resources had been dedicated to this work over the years which could be better used to address more pressing health issues such as the implementation of the Global Strategy on Diet, Physical Activity and Health currently under discussion in the Committee. One delegation recalled that the first priority of Codex was protection of consumer health and food safety as asserted by the 25th Session of the Commission[13]. One delegation mentioned that Codex texts already gave sufficient guidance for the labelling of GM/GE foods and that identifying the method of production claims such as those related to GE should be a market driven decision of the private sector. One delegation noted that it was not clear that there is agreement within the committee on the nature of the work to be undertaken (93).

Box 1 Labelling of Foods Derived from Biotechnology (GM Labelling)

The Codex Committee on Food Labelling (CCFL) first considered labelling of foods derived from biotechnology - in 1993. In 1997, the secretariat prepared guidelines, on the basis of advice from CCEXEC, and the statement on the role of science and other factors and the findings of an FAO/WHO expert consultation. The guidelines were presented as amendment to the General Labelling Standard for comments and major divergences of opinion continued. In 1998, CCFL forwarded the definitions and the provisions on allergens to CAC for adoption at Step 5 and returned the labelling requirements to Step 3. In 1999, the CAC adopted the *Proposed Draft Amendment Concerning the Labelling of Foods Obtained Through Biotechnology* (partial text) at Step 5. At the CCFL in 1999, there was debate on the requirement of labelling for foods containing *or* obtained from genetically-modified organisms (GMO). The United States stated that there was no scientific basis for systematic labelling and suggested, supported by industry IGOs, that it may be misleading to consumers. The European Union, supported by consumers advocated mandatory labelling. CCFL agreed to return the labelling provisions to Step 3 for redrafting.

At the CCFL, in 2000, "modern biotechnology" was replaced with "genetic modification/genetic engineering" throughout definitions. There was further debate over "modified" versus "engineered" (both versions were retained) and the definition of "no longer equivalent/differs significantly", which was left in square brackets. CCFL advanced the draft amendment on allergens to Step 8 for adoption at the CAC in 2001 and it was adopted. CCFL returned the definitions to Step 6. The working group presented revised labelling provisions with *either* labelling when products obtained through biotechnology differ significantly from the corresponding food *or* the declaration of the method of production for foods containing or produced from GMOs. The US, and other delegations, highlighted the implications of enforcement, methodology, economic cost and consumer perception; and that developing countries would face technical difficulties. Due to the diversity of opinions, CCFL decided to return the labelling provisions to Step 3.

At the CCFL in 2001, the central issue for definitions was the need for consistency throughout Codex [The Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (TFFBT) had taken its definition of "modern biotechnology" from the Cartagena Protocol, in accordance with its terms of reference to use established international definitions.] with the inclusion of "modern biotechnology" (Argentina, Brazil) versus use of terminology such as "genetic modification/genetic engineering" that consumers would understand (Norway, Ireland, India, Nigeria, Consumers International). Based on a compromise text, proposed by the working group, the definitions were retained and "modern biotechnology" was added. The CCFL agreed to forward the definitions to Step 8 for adoption by the CAC in 2001. However, due to the lack of consensus on the appropriate terminology for the definitions, CAC agreed to return the text to Step 6 demonstrating that the proposal to the CAC had been premature. The working group revised the labelling provisions in the form of guidelines. Argentina expressed reservation due to the implications in international trade and WTO. Some delegations indicated that Codex should give general recommendations that could be applied in all countries as a basis for international harmonization. CCFL was not able to proceed further due to time constraints and returned the text to Step 3. At the CCFL in 2002, CCFL could not reach consensus on the definitions and they returned again to Step 3.

Polarization has increased as governments incorporate labelling provisions in their national legislation. There are accusations of inflexibility, criticism of the chair and general frustration at the lack of progress. This outcome suggests that CCFL could have benefited from more focused direction from the Codex Commission. Furthermore, CCFL did not have the benefit of an expert consultation on risk management or communication. As the working group became larger, there was less efficiency and less progress. Furthermore, while the Task Force on Foods Derived from Biotechnology benefited from the Cartagena Protocol definition, it was a source of divergence for CCFL. The issue of "other factors" complicated the picture further and Principles for Risk Communication had not yet been elaborated. Due to political aspects of risk management and communication, and the current impasse, CCFL may not be able to resolve this dispute.

4bis. Final Agreement

The 39th session of CCFL (2010) concluded the long debate by agreeing on the text reproduced in page 369. It agreed to "recall and assemble in a single document some important elements of Codex texts, which are relevant to labeling of foods derived from modern biotechnology", while recognizing there are "different approaches regarding labeling of foods derived from modern biotechnology" and that "foods derived from modern biotechnology are not necessarily different from other foods simply due to their method of production". It recommended that "Any approach implemented ny Codex members should be consistent with already adopted Codex provisions".

5. Several questions

1) Mandate given by Codex Alimentarius Commission

The sentence appearing in the 1991 Commission's report, "The Commission requested the Codex Committee on Food Labelling to provide guidance on how the fact that a food was derived from "modern" biotechnologies could be made known to the consumers", was continued to be referenced, e.g.,

2003: In this context, the delegation of Norway recalled that the mandate given to the Committee by the Codex Alimentarius Commission in 1991 "to provide guidance on how the fact that a food derived from "modern biotechnologies" could be made known to the consumers" still holds (Paragraph 90 ALINORM 91/41) (72).

2004: During the discussion, the Delegation of Switzerland, supported by the Observer from Greenpeace, recalled the mandate that had been given to the Committee by the Commission in 1991 "to provide guidance on how the fact that a food was derived from "modern" biotechnologies would be made known to the consumers" (ALINORM 91/40, para. 90) (83).

It is interesting to note that the request from Codex Commission was not "to provide guidance on labeling of a food derived from "modern biotechnologies", *but* "to provide guidance on how the fact that a food was derived from "modern" biotechnologies would be made known". *The Commission's request appears to allow wider options (not just labeling) for making consumers know the fact that a food was derived from "modern" biotechnologies.*

2) Executive Committee recommended CCFL to adhere to the Statements of Principle Concerning the Role of Science in the debate on GM labeling (paragraph 52, 25th CCFL, 1997).

The statements are;

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

The statement 1 requests sound scientific analysis.

According to the statement 2, Codex considers other legitimate factors relevant for the health of consumers and fair trade.

According to statement 3, while other legitimate factors being considered, role of labeling is in furthering the health of consumers and fair trade.

The statement 4 relates to allowance of abstention from the codex standards by member countries when they hold differing views about considerations that are other than the necessary level of protection of public health.

<Questions>

- *As regards statement 3, how can labeling further the objectives of protection of health and fair trade in the situation where foods derived from modern biotechnology are marketed after prior risk assessment?*
- *As regards statement 4, what are "considerations that are other than the necessary level of protection of public health"?*
- *How should CCFL use these four statements in the debate of GM labeling?*
- *"Right to know" has been frequently claimed by those requesting the mandatory labeling. The view expressed by the Executive Committee in 1996 was that "the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labeling" (ALINORM 97/3, para. 29).*
- *Is the "right to know" an issue unique to the foods derived from modern biotechnology? Consumers may want to know many things, such as producer's name, place and method of cultivation, animal husbandry, harvest, trade route, etc, even for conventional foods. The request may become endless. If "right-to-know" is used as a criterion of labeling, certain criteria of "right to know" may be necessary. How should "right to know" be handled in Codex in general?*

3) Divergence of different regulatory options taken by member countries regarding the GM labeling.

In the 29th session in 2001;

> 67. Some delegations questioned the development of Guidelines which would provide different options according to the regulatory approach taken in member countries since this was not the usual approach in Codex and it was not clear how this would apply in case of trade disputes. These delegations indicated that Codex should rather give general recommendations that could be applied in all countries as a basis for international harmonization.

In the 32nd session in 2004, Cameroon indicated;

> 83. …. many countries had established national regulations.

Such statements were confirmed by countries' responses appearing in Appendix II of Report of the CCFL Working Group on Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering in Oslo (CX/FL 07/35/8).

As the delegates themselves are regulating labeling according to the law of their own countries, it will be very difficult for them to accept publicly a scheme that does not fit their own law. The delegates may have no other choice than imposing their own labeling system to others. In such a situation, is it possible for codex to agree on any common guidelines (particularly if the delegates pursue a very descriptive guidance)?

4) General Standard for the Labelling of Prepackaged Foods gives guidance on labeling of foods in general. Are there any sections that are not suitable or not applicable to foods derived from modern biotechnology in the present form?

If all or nearly all of the provisions in the Standard apply to foods derived from modern biotechnology, is it necessary to replicate them in a separate document specially dedicated to the foods derived from modern biotechnology?

5) CCFL working group proposed the 35th session of CCFL the following options to

advance the work in CCFL.

1. Discontinue work on this agenda item
2. Distil common principles and themes which we could agree to take forward
3. Develop general horizontal overarching principles which would be consistent with all the GM approaches presented by members.
4. Refer back to the CAC
5. Share the experience we have gathered in the Oslo workshop
6. Continue working on the draft guidelines taking into consideration the outcome of the working group based on information shared by the working group members
7. Discontinue work related to consumer information which should be based on national legislation
8. Continue work related to consumer information.
9. Focus on guidelines for labelling of GM foods where there is a significant difference from its conventional counterpart where only the significant difference is labelled.

The option 5 was useful in realizing different regulatory options already taken by member countries. The question is how CCFL takes this information into account.

The option 1, discontinuing the work, could be a choice, because the regulatory systems are already different among countries and there could be no room for changing the countries' own rules in near future. The question is, however, how or in which way to discontinue the work without dissatisfying the party which wants labeling guidance.

How about option 2 or 3? What options other than the above nine are there?

6) ***How can the agreements already obtained in codex be used for debate on GM labelling?*** *For example, how can the consumers be informed that under the codex guidance pre-market safety assessment is prerequisite for placing the products on the market?*

7) Are GM food like products of the conventional counterparts or not?

In CCFL session in 2004, "it was pointed out that method of production labeling could be inconsistent with some provisions of the Agreement on Technical Barriers to Trade" (paragraph 84)

It is not clear which article in TBT Agreement is mentioned by this statement. However, it may be Article 2, 2.1**,** Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country.

Whether foods derived from modern biotechnology and their conventional counterparts are like products or not could be debatable. However, they appear so from the paragraphs taken from a TBT dispute settlement document, because GM and non-GM products are no doubt in competition and commercially interchangeable (See box 1 below).

Box 1 ***T.7.4.1 US — Cotton Yarn*, paras. 96-98**

According to the ordinary meaning of the term "competitive", two products are in a competitive relationship if they are commercially interchangeable, or if they offer alternative ways of satisfying the same consumer demand in the marketplace. "Competitive" is a characteristic attached to a product and denotes the *capacity* of a product to compete both in a current or a future situation. The word "competitive" must be distinguished from the words "competing" or "being in actual competition". It has a wider connotation than "actually competing" and includes also the notion of a potential to compete. It is not necessary that two products be competing, or that they be in actual competition with each other, in the marketplace at a given moment in order for those

products to be regarded as competitive. Indeed, products which are competitive may not be actually competing with each other in the marketplace at a given moment for a variety of reasons, such as regulatory restrictions or producers' decisions. Thus, a static view is incorrect, for it leads to the same products being regarded as competitive at one moment in time, and not so the next, depending upon whether or not they are in the marketplace.
It is significant that the word "competitive" is qualified by the word "directly", which emphasizes the degree of proximity that must obtain in the competitive relationship between the products under comparison. As noted earlier, a safeguard action under the *ATC* is permitted in order to protect the domestic industry against competition from an imported product. To ensure that such protection is reasonable, it is expressly provided that the domestic industry must be producing "like" and/or "directly competitive products". …
When … the product produced by the domestic industry is not a "like product" as compared with the imported product, the question arises how close should be the competitive relationship between the imported product and the "unlike" domestic product. It is common knowledge that unlike or dissimilar products compete or can compete in the marketplace to varying degrees, ranging from direct or close competition to remote or indirect competition. The more unlike or dissimilar two products are, the more remote or indirect their competitive relationship will be in the marketplace. The term "competitive" has, therefore, purposely been qualified and limited by the word "directly" to signify the degree of proximity that must obtain in the competitive relationship when the products in question are unlike. Under this definition of "directly", a safeguard action will not extend to protecting a domestic industry that produces unlike products which have only a remote or tenuous competitive relationship with the imported product.
T.7.5 Article 6.2 — "like products"
T.7.5.1 US — Cotton Yarn, para. 97
… Like products are, necessarily, in the highest degree of competitive relationship in the marketplace. In permitting a safeguard action, the first consideration is, therefore, whether the domestic industry is producing a like product as compared with the imported product in question. If this is so, there can be no doubt as to the reasonableness of the safeguard action against the imported product.

8) Other legitimate factors

The paragraph 16 of Principles for the Risk Analysis for Foods Derived from Modern Biotechnology recommends to take into account "other legitimate factors.

1) According to STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT (Ref. 5),

2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

The statements recognize important role of labeling in furthering the health promotion of consumers and fair practices in food trade. ***How does labeling further these objectives if the products are already passed the safety assessment before being placed on the market?***

2) Among eight criteria in "Criteria for the Consideration of the Other Factors

Referred to in the Second Statement of Principle", the following five criteria may potentially have relation to the labeling, i.e.,

- consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;
- only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex
- the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
- the integration of other legitimate factors in risk management should not create unjustified barriers to trade[53]; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

How should these criteria be considered in the labeling that are considered as risk management option?

Ref. 5 **STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT**

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle[51]

- when health and safety matters are concerned, the *Statements of Principle Concerning the Role of Science* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* should be followed;
- other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;
- consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;[52]
- only those other factors which can be accepted on a worldwide basis, or on a regional basis in the

case of regional standards and related texts, should be taken into account in the framework of Codex;

- the consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;
- the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
- the integration of other legitimate factors in risk management should not create unjustified barriers to trade[53]; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

[50] Decision of the 21st Session of the Commission, 1995. [51] Decision of the 24th Session of the Commission, 2001. [52] Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level. [53] According to the WTO principles, and taking into account the particular provisions of the SPS and TBT Agreements.

6. Labelling appearing in the codex text produced by Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology

1) Allergen

Paragraphs related to allergenicity in General Standard for the Labelling of Prepackaged Foods and in Guideline for Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants are as follows;

General Standard for the Labelling of Prepackaged Foods (CCFL)

Section 4.2.2: The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Task Force of Biotechnology)

43. The transfer of genes from commonly allergenic foods and from foods known to elicit gluten-sensitive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.

The Section 4.2.2 of the CCFL guidelines was agreed in 2000 and paragraph 43 of the Task Force was agreed in 2003. These two paragraphs are almost concordant but not entirely so.

Section 4.2.2 of the Prepackaged Guideline does not exclude the possibility of marketing of food or food ingredients that acquired allergen through biotechnology. It recommends declaration of their presence if they are present. Meanwhile, paragraph 43 of the Task Force's guideline recommends avoidance of marketing of such products.

Among the products listed in Section 4.2.1.4, lactose and sulphite do not fit into the description in Section 4.2.2 as they are chemicals that contain no genes to be transferred.

2) Labelling

There is one paragraph directly referring to labeling. It is paragraph 19 of Principles for the Risk Analysis of Foods Derived from Modern Biotechnology,

19. Risk management measures may include, as appropriate, labelling conditions for

marketing approvals and post-market monitoring.

This paragraph recognizes that labelling is used as risk management.

3) ***Risk Management related to paragraph 19 of Principles for the Risk Analysis of Foods Derived from Modern Biotechnology***

How is "risk management" considered in the same document then? Paragraph 16 may be most relevant.

16. Risk management measures for foods derived from biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, where relevant, taking into account other legitimate factors* in accordance with the general decisions of the Codex Alimentarius Commission (CAC) as well as the Codex Working Principles for Risk Analysis.

It is assumed that risk management measures (including labeling) be based on the outcome of the risk assessment (Ref. 6). The measures should take into account other legitimate factors (See Ref. 5) and Codex Working Principles of Risk Analysis (7).

Ref.6: Principles for the Risk Analysis of Foods Derived from Modern Biotechnology

16. Risk management measures for foods derived from modern biotechnology should be proportional to the risk, based on the outcome of the risk assessment and, where relevant, taking into account other legitimate factors in accordance with the general decisions of the Codex Alimentarius Commission (CAC) as well as the Codex Working Principles for Risk Analysis.
17. It should be recognized that different risk management measures may be capable of achieving the same level of protection with regard to the management of risks associated with safety and nutritional impacts on human health, and therefore would be equivalent.
18. Risk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties.
19. Risk management measures may include, as appropriate, food labelling[8], conditions for marketing approvals and post-market monitoring.

[8]Reference is made to the CCFL in relation to the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients obtained through certain techniques of genetic modification/genetic engineering(proposed Draft Amendment to the General Standard for the Labelling of Prepacked Foods) at Step 3 of the procedures.

25. A consistent approach should be adopted to characterise and manage safety and nutritional risks associated with foods derived from modern biotechnology. Unjustified differences in the level of risks presented to consumers between these foods and similar conventional foods should be avoided.

Ref. 7: WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS

SCOPE

1. These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
2. The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.
3. Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

RISK ANALYSIS -GENERAL ASPECTS

4. The risk analysis used in Codex should be:
   - applied consistently;
   - open, transparent and documented;
   - conducted in accordance with both the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*[24]; and,

[24] See Appendix: General Decisions of the Commission

   - evaluated and reviewed as appropriate in the light of newly generated scientific data.
5. The risk analysis should follow a structured approach comprising the three distinct but closely linked

components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission[25], each component being integral to the overall risk analysis.

25 See Definitions of Risk Analysis Terms Related to Food Safety.

6. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties[26].

26 For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations" (see definition of "Risk Communication")

7. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.
8. The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.
9. There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.
10. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.
11. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.
12. The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis.

RISK ASSESSMENT POLICY

13. Determination of risk assessment policy should be included as a specific component of risk management.
14. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.
15. The mandate given by risk managers to risk assessors should be as clear as possible.
16. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

RISK ASSESSMENT[2]

27 Reference is made to the Statements *of Principle Relating to the Role of Food Safety Risk Assessment:* See Appendix: *General Decisions of the Commission.*

17. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined
18. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.
19. Risk assessment should be conducted in accordance with the Statements of Principle Relating to the Role of Food Safety Risk Assessment and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.
20. Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.
21. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.
22. Risk assessment should seek and incorporate relevant data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data, analytical and

exposure data. Where relevant data are not available from developing countries, the Commission should request that FAO/WHO initiate time-bound studies for this purpose. The conduct of the risk assessment should not be inappropriately delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.

23. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.
24. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.
25. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.
26. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

RISK MANAGEMENT

27. While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.
28. Risk management should follow a structured approach including preliminary risk management activities 28 , evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles[29].

[28] For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

[29]See Appendix: General Decisions of the Commission.

28. The Codex Alimentarius Commission and its subsidiary bodies, acting as risk managers in the context of these Working Principles, should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions on the available risk management options, in particular in the setting of standards or maximum levels, bearing in mind the guidance given in paragraph 10.
29. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.
30. The risk management process should be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.
31. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.
32. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.
33. In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary.
34. Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health. In taking these elements into consideration, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries.
35. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

RISK COMMUNICATION

37. Risk communication should:
    (i) promote awareness and understanding of the specific issues under consideration during the risk analysis;
    (ii) promote consistency and transparency in formulating risk management options/recommendations;
    (iii) provide a sound basis for understanding the risk management decisions proposed;
    (iv) improve the overall effectiveness and efficiency of the risk analysis;
    (v) strengthen the working relationships among participants;
    (vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
    (vii) promote the appropriate involvement of all interested parties; and
    (viii) exchange information in relation to the concerns of interested parties about the risks associated with food.
38. Risk analysis should include clear, interactive and documented communication, amongst risk assessors (Joint FAO/WHO expert bodies and consultations) and risk managers (Codex Alimentarius Commission and its subsidiary bodies), and reciprocal communication with member countries and all interested parties in all aspects of the process.
39. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.
40. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 25).
41. The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties while respecting legitimate concerns to preserve confidentiality (see para. 6).

4) Paragraph 16 of Principles for the Risk Analysis of Foods Derived from Modern Biotechnology recommends consideration of WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS (Ref.7)

The relevant paragraphs could be paragraphs 27 and 28 of the codex working principles. They are;

27. While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.

28. Risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles.

Issues related to "differences in the level of consumer health protection to address similar risks in different situations" (paragraph 27 of the Working Principles for Risk Analysis) were discussed in The Task Force on Foods Derived from Biotechnology discussed in its third session. It appears in the following paragraph of the report;

31. "The Task Force exchanged opinions on a proposal of how to clearly express the necessity of maintaining consistency in the level of consumer protection against risks associated with foods, regardless whether the food is derived from biotechnology or a conventional counterpart. The Task Force reached a consensus to replace the second sentence with new formulation to state that

> unjustifiable differences in the level of risks between foods derived from modern biotechnology and similar foods should be avoided. In the same sentence, the Task Force also accepted a proposal to include “conventional” after “similar”.

The corresponding paragraph agreed finally by Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology reads;

> 25. A consistent approach should be adopted to characterise and manage safety and nutritional risks associated with foods derived from modern biotechnology. Unjustified differences in the level of risks presented to consumers between these foods and similar conventional foods should be avoided.

How should WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS be considered for labeling as a risk management measure?

Note: To the above issues, consideration of “like products” may be necessary. See 5. Several questions, 7) “Are GM foods like products of the conventional counterpart or not?” of this chapter.

PART II: COMPILATION OF RECORDS OF DISCUSSION

1993 (22)

Implications of Biotechnology on International Food Standards and Codes of Practice

9. As indicated in Conference Room Document 1 (CX/FL 93/2-Add. 1), the Committee was informed of the request of the 19th Session of the Codex Alimentarius Commission that CCFL should provide guidance on the possibilities to inform the consumer that a food had been produced through "modern" biotechnologies (paras. 88-92, ALINORM 91/40). The Committee also noted discussions held at the 25th Session of the Codex Committee on Food Additives and Contaminants concerning this subject, and especially that the competence of CCFL with respect to the labelling of food additives produced through biotechnology had been reasserted (paras. 81-93, ALINORM 93/12A).

From 19th Session of Codex Alimentarius Commission

IMPLICATIONS OF BIOTECHNOLOGY ON INTERNATIONAL FOOD STANDARDS AND CODES OF PRACTICE (Agenda Item 11)

88. In considering document ALINORM 91/11, the Commission recalled that the issue of biotechnology was first discussed in 1989 during its 18th Session. At that time, the Commission had been informed of an initiative of WHO to convene, jointly with FAO, a Consultation on the Assessment of Biotechnology in Food Production and Processing as Related to Food Safety. This Consultation had taken place in Geneva in November 1990 and the Report of it would be available, as a formal WHO publication, at the end of 1991. The Consultation had recognized biotechnology as a continuum, embracing traditional breeding techniques and modern techniques based on recombinant DNA - technologies. “Modern” biotechnologies had the potential of revolutionizing the food supply, both in quantity and quality. While the Consultation was of the opinion that foods derived from “modern” biotechnologies were inherently not less safe than those derived from traditional biotechnologies, the issue of safety had to be considered. In addition, nutritional concerns may have to be addressed.

89. Based on scientific and technical advice by Joint FAO/WHO expert committees and consultations, the Codex Committees on Nutrition and Foods for Special Dietary Uses, on Food Labelling, on Food Additives and Contaminants and on Food Hygiene were expected to be the main committees with responsibilities for matters on biotechnologies. In addition, several commodity committees (e.g. Vegetable Protein, Cereals, Pulses and Legumes, Fish and Fishery Products, Fats and Oils) might need to play a role in reaching international consensus on particular novel foods.

90. The Commission endorsed the conclusions and recommendations of the Joint FAO/WHO Consultation. It noted that while consumers would benefit from “modern” food biotechnology, some consumers felt that this technology would pose certain problems. For example, individual consumers might, on ethical or other grounds, not wish to buy foods derived from “modern” biotechnology. The Commission requested the Codex Committee on Food Labelling to provide guidance on how the fact that a food was derived from “modern” biotechnologies could be made known to the consumers.

91. The need to provide consumers with sound, scientifically based information which explained the application of biotechnology in food production and processing and clarified the safety issues was stressed. In this context, the Commission was informed that WHO was exploring possibilities to prepare a book on food biotechnology for the non-technical reader which would be based on the report of the Joint FAO/WHO Consultation.

92. The Commission endorsed the views expressed by its Executive Committee and agreed that the Commission should monitor developments in the field of food biotechnology and that the General Subject Committees identified above should discuss issues related to biotechnology within the context of their Terms of

Reference (see ALINORM 91/4, para. 34). The Commission requested WHO to make copies of the Consultation report available to all Codex Contact Points. A progress report is to be presented to the 20th Session of the Commission.

10. In view of the complexity and importance of the issue of biotechnology as related to food labelling, the Committee welcomed the offer of the Delegation of the United States to prepare a discussion paper concerning this subject for circulation and government comments well before the next Session. It was also agreed that general comments and information on national policies concerning this issue would be requested by Circular Letter for consideration by the Delegation of the United States.

11. The Committee was further informed of the conclusions of the Committees on Food Hygiene, on Food Additives and Contaminants, on General Principles, on Food Import and Export Inspection and Certification Systems, on Nutrition and Foods for Special Dietary Uses, and on Methods of Analysis and Sampling. The Committee noted that the Table of Proposed Conditions for Claims for Nutrient Contents, agreed upon by CCNFSDU as part of the proposed Draft Guidelines on Nutrition and Health Claims for Food Product Labelling, would be considered under Agenda Item 6.

1995 (23)

9. The Committee was informed of the proposal of the 41st Session of the Executive Committee for a reorganization of the work of the Committee on Nutrition and Foods for Special Dietary Uses, especially in order to provide a structure to address new issues such as biotechnology. Some delegations expressed their concern with the reference to labelling as related to biotechnology and the Secretariat indicated that the general responsibility of the reorganized CCNFSDU for a framework project on biotechnology did not detract from the specific competence of CCFL in this area, as the present session was considering the implications of biotechnology for labelling at the request of the Commission. While recognizing the need for close cooperation with the CCNFSDU and other Committees when necessary, the Committee expressed its firm view that it should take the lead on all matters related to food labelling.

IMPLICATIONS OF BIOTECHNOLOGY FOR FOOD LABELLING (Agenda Item 9)

113. The Delegation of the United States introduced document CX/FL 94/8 on the Implications of Biotechnology, which had been prepared at the request of the 22nd Session of the Committee and following the recommendations of the Commission. This document was intended as a discussion paper, as the establishment of a national policy in this matter was currently under review and an extensive debate was taking place on this question in the United States. A number of major issues had been identified as areas where further elaboration and comments should be sought, including the relation of genetical engineering to conventional breeding techniques, scientific safety evaluation of substances obtained through recombinant DNA techniques, the use of marker genes, allergenicity and ethical considerations. The document presented recent developments as to technology, recalled how this issue had been previously discussed within Codex, and concentrated on the labelling issues raised, including enforcement, for the specific consideration of the Committee, and the current status of labelling. The Committee also had before it the comments of ASSILEC in CX/FL 94/8-Add. l and IOCU in CRD 1.

114. The Committee expressed its appreciation to the Delegation of the United States for this comprehensive document and the presentation of current issues associated with biotechnology. It was also noted that, due to time constraints, the document had not been circulated with ample time for comments. Moreover, several delegations indicated that their scientific and legal authorities were considering this complex issue at the moment and that they would need additional time to examine in detail the questions the Committee was mandated to address.

115. Some delegations expressed the view that it was too early to decide on particular rules for products obtained through biotechnology, and that labelling should be required only when the food or ingredient was significantly different from its traditional equivalent, or if safety concerns were involved. Other countries stressed the necessity for full information, as new technologies could benefit the consumers as well as the industry, and transparency in such instances could only help build confidence between the industry and the consumer. As biotechnology covered a broad spectrum of processes and disciplines, the Delegations of Indonesia and Romania

suggested that the term "genetically engineered foods" should be used throughout the discussion instead of "biotechnology", in order to avoid confusion.

116. The Observer from the EC informed the Committee that a Proposed Directive was currently being discussed in the Community and emphasized the importance of studying carefully each specific case. The Observer from IFGMA supported in general the United States discussion paper as an accurate statement of the scientific situation. The Observer noted that that the comments submitted by IFGMA contained the following guiding principles: (1) foods derived from the use of genetic modification should be determined safe for consumers and meet the same high standards as foods made by other techniques, (2) labelling should be determined on a case-by-case basis, and (3) no general labelling requirement for all foods derived from the use of genetic modification techniques should be made. Also, all decisions should be based on science. The Observer also stated that IFGMA supported the views expressed by the Delegations of Japan and the United Kingdom that biotechnology labelling should be considered on a case-by-case basis. The Observer from CIAA expressed general agreement with the comments made by IFGMA and the Delegations of Japan and the United Kingdom, and was of the opinion that labelling should be required on a case-by-case basis and only when a real modification in the composition of the food had taken place. CIAA considered that consumer education with respect to new technologies was of crucial importance in order to ensure their acceptance.

117. The Observer from IOCU noted that, as indicated in their written comments in CRD 1, a great diversity of views existed on this question and full consideration of the issues would require time. Consumer organizations were in favour of mandatory labelling for foods obtained through biotechnology, as this would enable them to make an informed choice. The Observer also stressed the need for countries to seek the views of consumers while they were in the process of developing national policies in this area. The Observer from AOECS held a similar view and pointed out that clear identification of products should be a general rule of food labelling.

118. The Observer from IFOAM pointed out that a distinction should be made between the different technologies used, and expressed the view that consumer education in general was not the only aspect to be considered, but that environmental aspects and especially biodiversity were also involved. The Observer supported those countries which proposed that the consumer should be fully informed and was of the view that such countries should be allowed to pursue this policy and that labelling of products obtained through genetical engineering should be required. This view was shared by many NGOs, which were studying this subject and an open dialogue should be encouraged in the framework of Codex on the issues raised, as this had been the case, during the discussion on the Guidelines for Organic Products.

119. The Committee agreed that additional comments on the paper and recommendations on how the Committee should proceed would be requested through Circular Letter, with a view to further consideration of this matter by the next session.[11]

1996 (24)

40. The 23rd Session of the Committee (1994) had considered a discussion paper prepared by the authorities of the United States on the implications of biotechnology for food labelling. The Committee had agreed that additional comments should be sought on the paper including recommendations on how the Committee should proceed in this area. The Commission, at its 21st Session (1995), had approved a Project Plan for Biotechnology developed by the Executive Committee, which called for the establishment of guidelines for labelling of foods derived from biotechnology.

41. The Committee noted that subsequent to the 21st Session of the Commission, FAO and WHO had agreed to convene a Second Joint FAO/WHO Expert Consultation on the Food Safety Aspects of Biotechnology, to be held in Rome, 30 September to 4 October 1996. The Consultation would not discuss labelling issues *per se*, but would be invited to consider such labelling matters as may be necessary on the grounds of food safety or nutritional value.

42. Extensive comments had been received in response to CL 1995/29-FL. The Committee noted the opinions of many delegations and observers which called for the mandatory and

comprehensive labelling of all foods prepared with the aid of biotechnology on the basis of the consumer's right to know the origin and nature of the foods which they purchased and the right to make informed choices based on a variety of considerations and personal values.

43. Many other delegations and observers stressed that labelling should address the specific concerns of safety (including potential allergenicity), nutrition and food composition, all of which could be subject to scientific study and evaluation, and that labelling should be considered on a case-by-case basis taking these considerations into account. In such cases, the provision of consumer information other than that required for the purposes of safety, nutrition and food composition could be considered by means other than labelling.

44. The Committee was informed that the European Community was unable to take a definitive position on the issue; a draft regulation concerning novel foods and novel food ingredients (which included foods derived from biotechnology) being the subject of discussions between the relevant European Union and EC institutions. Several delegations stated that the situation in their countries was also still under review and that taking a position on the matter would be premature. One delegation drew attention to current discussions on the trans-boundary movement of genetically-modified organisms in the context of the Convention on Biological Diversity. The Observer from IFOAM suggested that a difference in labelling should be made between genetic engineering and classical or modern biotechnology.

45. The Committee agreed to seek the advice of the Executive Committee on how the guidelines foreseen in the Project Plan should be formulated, especially in view of the four statements of principle on the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account. It agreed that, based on the advice of the Executive Committee, the Secretariat should initiate the preparation of proposed draft guidelines as provided for at Step 2 of the Uniform Procedure for the Elaboration of Codex Standards and Related Texts[15]. It suggested that the Secretariat should also take into account the findings of the Joint FAO/WHO Expert Consultation mentioned above.

1997 (25)

RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY (Agenda Item 8)

52. The Committee recalled that its last session had agreed that, subject to the advice of the Executive Committee, the Secretariat should initiate the preparation of guidelines to address the labelling issues associated with foods obtained through biotechnology. The Executive Committee had recommended that the Statements of Principle concerning the Role of Science[9] should be closely adhered to and that the recommendations of the Joint FAO/WHO Expert Consultation on Food Safety and Biotechnology should be taken into account.

53. The Secretariat indicated that the recommendations had been presented in the form of an amendment to the General Labelling Standard, following the approach taken for similar issues, and presented the conclusions of the Expert Consultation of particular relevance where labelling was concerned. The Committee noted that the elaboration of the recommendations had already been approved by the CCEXEC and that comments at Step 3 had not yet been requested in view of time constraints.

54. Several delegations indicated that their national policy supported comprehensive labelling of genetically modified foods and expressed the view that the food safety approach reflected in the paper did not address concerns of consumers in such areas as ethics and environmental protection. It was pointed out that the Expert Consultation was essentially focused on food safety rather that food labelling and that the document under consideration should be redrafted in order to encompass all relevant issues. Other delegations expressed their appreciation of the document which was consistent with traditional food labelling approaches and provided a basis for further development of the recommendations.

55. The Delegation of Norway expressed the view that the issues associated with modern biotechnology went beyond information about products characteristics, that the right of consumers to make their choice should be respected even if this meant broadening the basis for labelling requirements, and that reliable labelling was the only means to ensure consumer confidence in this area.

56. Some delegations suggested that a distinction be established according to the presence of genetically modified organisms in the food, and that the definitions, including that for "organism", should be clarified in this respect. Other delegations suggested that the term "modern biotechnology" or “genetically modified” be used to differentiate the technology in question from other traditional techniques.

57. The Observer from the EC informed the Committee that the recently adopted EC Regulation No.258/97 concerning novel foods and novel foods ingredients, included provisions for foods containing or consisting of genetically modified organisms as well as foods derived from them.

58. The Observer from Consumers International stressed the need for comprehensive labelling in order to allow consumers to make an informed choice and the necessity to proceed rapidly in this area in view of the importance of the subject for consumers. The Observer from IFOAM pointed out that this issue was also very important for the organically produced food industry and supported comprehensive labelling of all genetically modified foods.

59. In view of the considerable implications of this question both for consumers and industry, many delegations indicated that they needed more time to review the document in detail, in order to establish their national position accordingly. The Committee agreed that as a first step, comprehensive governments comments would be required in order to identify the issues to be addressed and provide specific orientations for the work of the Committee.

Status of the Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods)

60. The Committee agreed that the Proposed Draft Recommendations, as included in Appendix VI, should be circulated for government comments at Step 3, redrafted by the Secretariat, taking into account all comments received, for further consideration and thorough discussion in the plenary meeting at the next session.

APPENDIX VI

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD OBTAINED THROUGH BIOTECHNOLOGY (PROPOSED DRADT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS) (At Step 3 of the Procedure)

Background

1. Following earlier consideration of issues related to biotechnology, the 21st Session of the Commission agreed that work on the safety, labelling and nutrition aspects of biotechnology, being undertaken by relevant Committees, should be coordinated by the Executive Committee of the Codex Alimentarius Commission in the framework of a project plan. Support was also expressed for holding a second Joint FAO/WHO Consultation on safety of food produced by biotechnology (ALINORM 95/37, para.10).

2. The 23rd Session of the Codex Committee on Food Labelling (CCFL) considered a discussion paper prepared by the United States on labelling aspects of biotechnology and identified a number of issues: the relation of genetic engineering to conventional breeding techniques; scientific safety evaluation of substances produced through recombinant DNA techniques; the use of marker genes; allergenicity and ethical considerations (ALINORM 95/22, paras. 113-119). Further comments were requested on issues associated with biotechnology and considered by the Committee’s 24th Session. It was agreed that, based on the advice of the Executive Committee, the Secretariat should initiate the preparation of such guidelines, taking into account the findings of the Expert Consultation (ALINORM 97/22, para. 45).

3. The 42nd session of the Executive Committee stressed that the four Statements of Principle concerning the Role of Science adopted by the Commission should be closely adhered to. It noted the opinion that, while consumers may claim the right to know whether foods had been produced by biotechnology, this right was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling. It highlighted the elements to be taken into

account when considering the labelling of foods in relation to production processes. Foremost among these was the protection of consumers' health from any risks introduced by the production process, followed by nutritional implications resulting from changes to the composition of the food, any significant technological changes in the properties of the food itself, and the prevention of deceptive trade practices. To a considerable extent such matters would have to be decided on a case-by-case basis. The Executive Committee noted that the possibility of voluntary labelling always existed.

4. The Executive Committee agreed that a paper containing proposed draft guidelines or other appropriate advice should be prepared on this basis for consideration by the CCFL and recommended that the conclusions of the Joint FAO/WHO Expert Consultation on Food Safety and Biotechnology should be taken into account in the preparation of the paper (ALINORM 97/3, para. 29-30).

Scope of the recommendations

5. Although the CCFL is responsible only for labelling aspects of biotechnology, these should not be considered separately but in the wider context of ensuring food safety and preventing deceptive practices. It is also necessary to determine the issues related to biotechnology which can be addressed in the framework of Codex, as part of the Project Plan, and those which are outside its mandate.

6. A number of issues raised by the use of biotechnology cannot be addressed in the framework of Codex as they are not related to the food itself, but to the process or other factors which have no bearing on the safety and quality of the product as consumed. In particular, environmental aspects of the release of genetically engineered products may be legitimate consumer concerns but they should be addressed by competent organizations dealing with the protection of the environment at the national and international level. Concerns which are not related to the properties of the food are sometimes put forward as justifying systematic labelling of all foods produced through biotechnology, whether or not they differ from conventional foods. Such questions as the production of pharmaceuticals through genetically modified organisms or the use of marker genes were also taken into account by the Expert Consultation, as indicated below. It is therefore necessary to focus on the questions which are within the mandate of the CCFL, essentially labelling issues related to the characteristics of the food itself.

7. As regards the form in which recommendations should be made, the CCFL's mandate is limited to questions specifically related to labelling. It does not include establishing comprehensive recommendations concerning the production processes related to biotechnology, especially as this essentially involves considerations of food safety for which other Committees or Expert Groups are competent, and the Expert Consultation has already made specific recommendations in this area. Guidelines have been prepared or are under development by CCFL in areas where food safety considerations are not essential, such as organic agriculture or the use of the term "halal". Such matters strengthen the role of labelling as a means to ensure fair practices in food trade. In such cases, the Committee took the responsibility to formulate requirements concerning the production process itself, as no other Codex Committee was competent in such matters, and as it was necessary in order to clarify labelling issues. However, in the case of biotechnology, as the Committee is not responsible for food safety aspects, which are addressed elsewhere, it should focus only on the aspects related to labelling.

8. The recommendations put forward by the CCFL would therefore most adequately take the form of an amendment to the General Standard for the Labelling of Prepackaged Foods. This approach was taken concerning irradiation and is currently followed as regards foods which can cause hypersensitivity. This would also make it clear that labelling requirements related to biotechnology are set in the overall context of the General Standard, and the general objectives of providing clear information to the consumer and preventing misleading description or presentation of pre-packaged food.

9. Section 4.1.2 of the General Standard requires the identification of production processes when it is necessary to identify the nature or type of the food (dried,

concentrated, etc.). This relates to the treatment undergone by the food itself, but Codex provisions do not go into the production processes of raw materials at the level of agriculture or the mode of selection of plant or animal species. Only in the case of organic agriculture did the CCFL consider means of production because a specific claim was made concerning the type of agriculture and had to be defined. However, unless such no claim is made, labelling requirements apply only to the nature of the food and not to the agricultural practices or selection processes. An indication relating to the selection and/or production process, as in the case of biotechnology, would go beyond the current area covered by labelling provisions, and this raises an issue of principle concerning the competence of the CCFL and Codex in this area.

10. Such a requirement should be clearly justified in the light of food safety concerns and the prevention of deceptive practices, as all foods put on the market should be clearly identified regarding their characteristics or composition. Any food obtained though biotechnology differing substantively from the corresponding food should be clearly identified as to its specific characteristics, and any new food (with no existing equivalent) should be described. This is a general requirement which should also apply to any new food put on the market, irrespective of the production process. If the character of a food has been modified in any substantive way from the conventional food which is currently used by consumers, they should be informed of the nature of the changes.

11. The rationale for requiring additional information beyond what is usually covered by Codex is not the nature of the process, but the fact that the essential characteristics of the food have been modified. In order to be consistent with general Codex labelling policy, information on the process should apply only in relation to information on the product itself.

Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety[1]

[1]FAO Food and Nutrition Paper No. 61 (1996)

12. As a number of consumer concerns in relation to biotechnology are linked to the safety of what may appear a new type of food, an overview of the conclusions and recommendations of the Consultation would be useful to set the debate on labelling in its general context and facilitate the distinction between food safety issues and specific labelling issues.

General food safety issues

13. The Expert Consultation (30 September - 4 October 1996) addressed the evaluation of the safety, for the purposes of consumption, of all food and food components produced using techniques involving biotechnology, whether plant, animal or microbial in origin. It emphasized the first recommendation of the 1990 Consultation[2],that comprehensive and well-enforced food regulations are important in protecting consumer health, and that all national governments should ensure that such regulations keep pace with developing technology. This general recommendation should be supported by concerned Codex Committees dealing with different aspects of biotechnology.

[2]WHO, 1991, Strategies for assessing the safety of foods produced by biotechnology, Report of a Joint FAO/WHO Consultation.

14. The Consultation recommended that safety assessment based on the concept of substantial equivalence, as described in the report, be applied in establishing the safety of foods and food components derived from genetically modified organisms. It made a number of recommendations on how to determine substantial equivalence and agreed on the following general conclusions:

• When substantial equivalence is established for an organism or food product, it is regarded to be as safe as its conventional counterpart and no further safety consideration is needed.

• When substantial equivalence apart from certain defined differences is established, further safety assessment should focus on those defined differences

• When substantial equivalence cannot be established, it does not necessarily mean

that the product is unsafe.

15. The Consultation advised designing any testing program on a case-by-case basis taking into account the reference characteristics of the food or food component. Human nutritional studies may be needed, especially when the new food is intended to replace a significant part of the diet.

Allergenicity

16. The Consultation considered the specific issues related to allergenicity in the case of biotechnology and made recommendations for the assessment of potential allergens, including a number of criteria to be applied in identifying potential allergenicity. It proposed that foods which would pose a health risk should not be released. It recommended that foods that fail to elicit positive results in *in vitro* or *in vivo* tests should be treated like any other foods in regard to allergenicity. The recommendations made by the CCFL concerning the labelling of potential allergens would therefore apply to foods obtained through biotechnology as to conventional foods.

17. As regards the possibility of transfer of allergenic properties to foods which normally are not allergenic, the Consultation made the following recommendations:

• The transfer from commonly allergenic foods should be discouraged unless it can be documented that the gene transferred does not code for an allergen.

• Foods which contain an allergen transferred from the organism which provided the DNA should not be considered for market approval unless they can be clearly identified in the marketplace and this identity would not be lost during distribution or processing. Labelling approaches may not be practical in these situations, and particular problems for consumers who cannot read, or who may not be provided with labels. Foods which are not presented on the market in a pre-packaged form and generally not labelled should be taken into account.

Other aspects

18. The Consultation also considered aspects which are not directly related to food safety but to public health issues. These are mentioned briefly as being of interest to the Committee in view of consumer concerns in those areas and to place labelling issues in a general perspective. It should also be clear that such issues are not within the mandate of Codex and cannot be addressed by the CCFL or any other committee, especially as they were not even within the competence of the Consultation on food safety.

19. As regards food organisms expressing pharmaceuticals or chemicals, the Consultation recognised that, generally, genetically-modified organisms (GMOs) would not be used as food without prior removal of the pharmaceutical or industrial chemical. When the GMO or its products were used as food, the concept of substantial equivalence could be applied for safety assessment.

20. In addition to food safety concerns, the Consultation recognised that genetic modification to produce pharmaceuticals may raise ethical and control issues that were outside its remit because the issues were unrelated to food safety and recommended that these be brought to the attention of FAO and WHO.

21. The Consultation considered gene transfer from GMOs and as likelihood of transfer from a genetically modified plant to a micro-organism in the gastro-intestinal tract is remote but cannot be entirely ruled out, the Consultation recommended that FAO/WHO convene an expert consultation to address whether there are conditions or circumstances in which antibiotic-resistance marker gene(s) should not be used in genetically modified plants intended for commercial use and, if so, to define those conditions/circumstances.

Proposed amendments to the General Standard for the Labelling of Prepackaged Foods

22. Any confusion between safety and labelling issues should be avoided and in particular, it should be clear that labelling is not intended to replace safety evaluation. It

is sometimes proposed to label all foods produced through biotechnology as some of them might not be safe. However, the essential principle of any food legislation is to ensure that foods should not be available if they are not safe for consumption, whether conventional or produced through biotechnology. Labelling should provide the consumer with information on precautions for use if necessary, but the inherent safety of the product is a pre-requisite in any case.

23. Under the circumstances, the risk posed by transferred allergens can be addressed as a food safety issue or as a labelling issue. The Committee is invited to consider the opportunity of encouraging national authorities to prevent the approval of such foods in view of the fact that labelling in itself cannot entirely solve the problems for some sections of the population. However, the CCFL is currently considering recommendations for the labelling of foods that can cause hypersensitivity and amendments to the General Standard, and may consider the alternative option of specific requirements in such cases. Section 4.2.2 could therefore be modified to require labelling of foods obtained through biotechnology which contain the gene of a known potential allergen not present in the corresponding food.

24. In view of the above information, it appears that recommendations concerning the labelling of foods produced through biotechnology should focus on the areas which are within the mandate of Codex and of the CCFL, and that is relating to the food itself, its safety, characteristics, nutritional composition or intended use, in order to provide clear information to the consumer for any new product obtained through biotechnology presenting specific characteristics not found in conventional foods. Reference to a particular food manufacturing or production process is not usual in Codex and could be relevant in the perspective of Codex objectives only if it is clearly linked to the food itself. Similarly, the General Standard for the Labelling of Prepackaged Foods (Section 4.2.2.2) addresses the question of labelling of foods which may pose specific religious or ethical concerns by requiring the declaration of specific food ingredients. It is proposed that the food components derived by biotechnology from these same sources also be declared.

25. Recommendations relating to allergens should be considered in conjunction with the specific discussion on this subject, and the amendment of the General Standard, under Agenda Item 6.

Definition

26. The 1990 Consultation defined biotechnology as “the integration of natural sciences and engineering sciences in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services” This was a general definition and reflected the scope of the first consultation. The 1996 Consultation referred to this definition and agreed to focus on the safety assessment of “foods and food components which have been produced by techniques that change the heritable traits of an organism, such as recombinant DNA (rDNA) technology”. Following earlier discussions held at the CCFL, it appears that where labelling and consumer information are concerned, the major issues are related to genetically modified organisms, while biotechnology may cover a wide range of processes. It was also suggested that a distinction should be made between genetic engineering and other types of biotechnology. In order to avoid any confusion, it is therefore proposed to give a more detailed definition for the purposes of labelling recommendations, on the basis of the current EC definition[3].

[3] Council Directive 90/220/EEC of 23 April 1990

27. The following amendments to the **General Standard for the Labelling of Prepackaged Foods** are therefore proposed as a basis for discussion and for consideration by the Committee:

Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods) (At Step 3 of the Procedure)

Section 2. Definition of Terms

Add at the end of the Section:

Products obtained through biotechnology

For the purpose of the General Standard, "products obtained through biotechnology" are foods composed of or containing genetically modified organisms, defined as organisms whose genetic material has been altered in a way which does not occur naturally through multiplication and/or natural recombination.

Genetic modification techniques include:

• recombinant DNA techniques which use vector systems

• techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism including micro-injection, macro-injection and micro-encapsulation

• cell fusion or hybridization techniques in which living cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods which do not occur naturally

Section 5. Additional Mandatory Requirements

Foods obtained through biotechnology

When a food or food ingredient obtained through biotechnology, as defined in Section 2, is no longer substantially equivalent to the corresponding existing food or food ingredient as regards

• composition

• nutritional value

• intended use

the characteristics which make it different from the reference food should be clearly identified in the labelling. In particular, the following requirements apply:

• if the nutrient content is significantly modified, [relevant/comprehensive] nutrient declaration should be provided in conformity with the Guidelines for Nutrition Labelling.

• if the mode of preparation is significantly different from that for the equivalent food, clear instructions for use should be provided.

When a food produced by biotechnology is not substantially equivalent to any existing food in the food supply and no conventional comparator exists, the labelling shall indicate clearly the nature of the product, its nutritional composition, its intended use, [the method by which it was obtained] and any other essential characteristics necessary to provide a clear description of the product.

Substantial equivalence is established by a demonstration that the characteristics assessed for the genetically modified organism, or the specific food derived therefrom, are equivalent to the same characteristics of the conventional comparator (conventional foods or food components already available in the food supply), within the natural variation for such characteristics, based upon appropriate analysis of data[4].

[4] Report of the Expert Consultation, FAO Food and Nutrition Paper 61, p. 23

In addition, the presence in a food obtained through biotechnology of material from the sources referred to in Section 4.2.2.2 which is not present in an existing equivalent foodstuff shall always be declared.

Recommendations concerning allergens

Two possible approaches are proposed:

[In view of the recommendations of the Consultation, it is not proposed at this stage to establish labelling requirements for material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population (especially allergens) as the preferred approach would be to discourage the marketing of such products.**]**

OR

[Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.3[5], shall be declared.**]**

[5]PROPOSED DRAFT AMENDMENTS TO CODEX GENERAL STANDARD FOR THE LABELLING OF PRE-PACKAGED FOODS1 (at Step 5 of the Procedure)

[1] Proposed additions underlined. Section 4.2.1.3, repeated here for ease of reference, is currently under consideration (see also Appendix VI).

Section 4.2.1.3

Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than [5%] of the food, the ingredients, other than food additives which serve a technological function in the finished product and ingredients known to cause allergic or intolerance reactions, need not be declared.

Section 4.2.1.4

The following foods and ingredients are known to cause hypersensitivity and shall always be declared as such:

Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;

Crustacea and products of these;

Eggs and egg products;

Fish and fish products; Peanuts, soybeans and products of these;

Milk and milk products (lactose included); Tree nuts and nut products; and

Sulphite in concentrations of 10 mg/kg or more.

Section 4.2.2.1

Except for those ingredients listed in section 4.2.1.4, and unless a general class name would be more informative, the following class names may be used ..... (remainder of section as is)

Section 4.2.3.2

A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids listed in section 4.2.14.

1998 (26)

41. The Committee recalled that the Proposed Draft Recommendations considered by the last session had been circulated for comments at Step 3 and redrafted in the light of the comments received. In particular, the text included an alternative proposal referring to general labelling of foods containing GMOs and labelling of foods produced from GMOs but not containing them when they were significantly different from conventional foods.

42. The Delegation of Brazil stressed the importance of adhering to the four principles on the role of science in Codex and recalled that the safety of foods was a prerequisite to their marketing in any case; this principle had been followed very strictly in the case of genetically modified products, as the selection process was controlled more effectively than with other techniques. This position was supported by several delegations and observers, who pointed out that the principles for the labelling of such foods should be the following, as proposed in the working paper ALINORM 97/22A, Appendix VI. “When a food produced by biotechnology is not substantially equivalent to any existing food in the food supply and no conventional comparator

exists, the labelling shall indicate clearly the nature of the product, its nutritional composition, its intended use and any other essential characteristic necessary to provide a clear description of the product". However, there was no justification in terms of food safety for specific labelling of foods that were substantially equivalent to conventional foods, as there was no evidence of any specific health hazards.

43. It was pointed out that the identification of significant modifications in composition were already required for novel foods which were not obtained though biotechnology but were different from conventional foods, and the Committee noted that this was consistent with existing labelling provisions that provide clear information to the consumer.

44. The Observer from the EC informed the Committee that EC legislation required labelling of all foods containing GMOs and of foods produced from GMOs but not containing them when no longer equivalent to existing foods or ingredients. This was intended to ensure transparency and address consumer concerns for clear information on these products in order to make informed choices. The Observer also indicated that specific rules provide that foods which do not contain protein or DNA resulting from genetic modification are considered to be equivalent to existing foods or ingredients and shall not be subject to specific labelling requirements. Several delegations supported this position as based on scientific evaluation and expressed the view that the concept of substantial equivalence was not relevant to labelling issues; consequently they supported the alternative proposal on the labelling of foods containing or produced from GMOs in the revised text (see para. 41).

45. The Delegations of Norway and India expressed the view that the issues associated with modern biotechnology went beyond information about product characteristics, that the right of consumers to make their choice should be respected even if this meant broadening the basis for labelling requirements, and that reliable labelling was the only means to ensure consumer confidence in this area.

46. The Observer from Consumers International, supported by several delegations and observers, emphasized the extreme importance of this issue for consumers and the necessity for comprehensive labelling of genetically engineered products in order to allow consumers to make an informed choice. The Observer noted that mandatory comprehensive labelling was needed to allow consumers their fundamental right to information to choose according to their own ethical, cultural, and other personal preferences, and to provide vital health information for consumers sensitive to uncommon or unknown allergens. Substantial equivalence was strongly opposed as a basis for labelling since it involved value judgments that excluded consumer input. Consumers International opposed the terms "biotechnology" and "modern biotechnology" and favored "genetically engineered/modified" instead.

47. The Observer from IFOAM pointed out that organic producers needed to ensure that when they used substances coming from the conventional market, these did not include GMOs and related products; identification of products derived from genetic engineering was essential and consequently IFOAM supported comprehensive mandatory labelling requirements.

48. The Committee, recognizing the need to concentrate its efforts on the areas where consensus could be achieved, as proposed by the Chairperson, had an exchange of views on the definition of foods obtained through biotechnology. The Committee noted the proposals 1) to replace "new" with "modern" biotechnology, and 2) to avoid using the term " biotechnology" as it might create confusion for the consumer. Taking into account the amendments to the definition proposed by Canada and the EC, the Committee agreed on a revised definition which clarified the scope of the text. The Committee also agreed to require the labelling of allergens transferred through genetic modification, as proposed in the current text (section 4.2.2.).

Status of the Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology

49. The Committee agreed to forward the amended Definition in square brackets and Section 4.2.2. (allergens) to Step 5 (see Appendix VII) and to return all other sections of the Proposed Draft to Step 3 for further comments and consideration by the next session (see Appendix VIII).

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD OBTAINED THROUGH BIOTECHNOLOGY (PROPOSED DRAFT AMENDMENT TO THE GENERAL

STANDARD FOR THE LABELLING OF PREPACKAGED FOODS) (At Step 5 of the Procedure)

[Section 2 Definition of Terms]

Products obtained through biotechnology

For the purpose of the General Standard:

"Products obtained through [new/modern] biotechnology" are foods composed of or containing genetically modified organisms, [or foods produced from, but not containing genetically modified organisms.]

["Organism" is any biological entity capable of replication or of transferring genetic material].

["Genetically modified /genetically engineered organism" is an organism in which the genetic material has been changed in a way that does not occur naturally by multiplication and/or natural recombination.]

Examples of these modifications include but are not limited to:

- recombinant DNA techniques which uses vector systems
- techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism including micro-injection and micro-encapsulation
- cell fusion [including protoplast fusion] or hybridization techniques with new combinations of heritable genetic material formed through the fusion of two or more cells by means of methods which do not occur naturally

Examples of techniques which are not considered to result in genetic modification include but are not limited to:

[on condition that they do not involve the use of recombinant DNA molecules or GMOs]:

- in vitro fertilization
- conjugation, transduction, transformation or any other natural process,
- [polyploidy induction] [on condition that they do not involve the use of GMOs as recipient or parental organism]:
- Mutagenesis
- [cell fusion [including protoplast fusion] of plant cells where the resulting organisms can also be produced by traditional breeding methods]

Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.41 shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

1999 (27)

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY (Agenda Item 6)[5]

40. The Committee recalled that the 26th Session had forwarded to the Commission for adoption at Step 5 the Definitions related to biotechnology (section 2) and the provisions on allergens (section 4.2.2), and had returned to Step 3 for further comments the labelling requirements (section 5)[6].

[6] ALINORM 99/22, Appendices VII and VIII

41. The Delegation of the United States pointed out that there was no scientific basis to require systematic labelling of foods containing or obtained from genetically modified organisms and that only those foods which differed significantly from their conventional counterpart as regards composition, use or nutritional quality should be specifically labelled. The Delegation also stressed the difficulties of implementing systematic labelling requirements, indicated that distinctions based on the mode of production might imply that foods produced from GMOS were not safe, and expressed concern about the possibility of misleading negative labelling by

competitors. This position was supported by the Observers from IFCGA, ASSINSEL and CRN who stressed that labelling of all foods produced from GMOs would be contrary to the general principles of labelling in Codex, would provide misleading information to consumers and would not be enforceable in practice.

42. The Delegation of Argentina stressed the importance of the role of science and risk analysis as a basis for decisions in Codex, and pointed out that there was no scientific basis for requesting information on the mode of production in the specific case of biotechnology, especially as this would not offer any additional guarantee concerning the safety of the food.

43. The Delegation of Germany, speaking on behalf of the member states of the European Union, indicated its clear preference for the alternative proposal based on the principle of mandatory labelling, noting however that this proposal required some amendments. The Observer from the EC indicated that, in order to allow consumers to make an informed choice, EC legislation required systematic labelling of all foods or ingredients consisting of or containing GMOs and labelling of foods and ingredients produced from GMOs but not containing them, when they were not any longer equivalent to existing foods or ingredients. The Observer stated that the notion of equivalence was currently evaluated according to the presence in foods or ingredients of DNA or protein resulting from genetic modification, and that these provisions allowed to take into account specific health problems (allergy) and ethical considerations. This position was supported by several delegations, which recalled that there was a strong demand for information on the mode of production from consumers in Europe.

44. The Delegation of Norway supported mandatory labelling of all products containing or issued from GMOs as ethical concerns of consumers related to the mode of production should be addressed, and comprehensive labelling was essential to ensure consumer confidence in food labelling in general. The Delegation supported the alternative proposal as amended by CI, but indicated that the proposal from the EC was acceptable as a second best alternative. The Delegation of Denmark expressed concern about the fact that the mode of production should be taken into account and therefore all foods containing or derived from biotechnology should be labelled.

45. Several delegations informed the Committee that consultations were ongoing in their countries on the development of a legislation addressing the labelling of genetically modified products, taking into account the views of the consumers and the industry, and the practical aspects of legislation enforcement. In reply to a question, the Secretariat informed the Committee that the Executive Committee had included in the Mid-Term Plan 1998-2002 the consideration of a general standard for foods derived from biotechnology and that the Commission would decide how to proceed with the elaboration of this standard.

46. The Observer from Consumers International, supported by the Observers from IACFO, RAFI, IFOAM recommended comprehensive and mandatory labelling of foods containing or produced directly from genetically modified organisms, in order to address health concerns, especially related to allergens, and to allow consumers to make an informed choice. This labelling should extend to foods produced from genetically modified ingredients processed to the extent that they were no longer detectable. In addition, the Observers from IFOAM, RAFI and IACFO stressed the importance of the identification of genetically modified products for organic farmers since GMOs or products thereof were not allowed in organic production systems. The Observer from IFOAM expressed concern that the terms "biotechnology" or "modern biotechnology" were misleading for consumers and indicated that "genetically engineered/modified" was more appropriate.

47. The Committee had an exchange of views on the opportunity of applying the recommendations to novel foods which were not produced through biotechnology; some delegations stressed that changes in composition, nutritional value or other characteristics of all foods should be made known to the consumers irrespective of the mode of production, while other delegations and observers supported limiting the scope of the text to foods derived from GMOs. The Committee did not come to a conclusion on this matter.

48. Several delegations pointed out that the concept of substantial equivalence was used in the context of safety assessment but was not appropriate when considering labelling issues and the Committee agreed that the word "substantial" would be deleted and consideration would be

given to the term "equivalence" with a conventional food in this perspective. The Committee agreed with the proposal of the Delegation of Canada to consider further how the concept of equivalence could be clarified for the purpose of labelling, which could be achieved by a working group.

Status of the Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology

49. The Committee agreed to return the Proposed Draft Recommendations to Step 3 for redrafting by a Working Group7 coordinated by the Delegation of Canada, which would prepare a revised version for circulation and consideration by the next session.

2000 (28)

OPENING OF THE SESSION

2. The Session was opened by Ms. Diane Gorman, Assistant Deputy Minister, Health Protection Branch, Health Canada, who recalled the considerable achievement of the Committee since its creation, with the completion of several essential texts which had been developed to ensure consumer information. Ms. Gorman stressed the importance of risk analysis principles for public health protection issues and the need to involve all interested parties in the review of national policies. This was reflected in the current review of nutrition labelling policy in Canada, which had been conducted on a wide consultative basis and would soon be completed. Ms. Gorman pointed out that the Committee was scheduled to consider very complex issues, especially as regards biotechnology, and that its conclusions would contribute to facilitate the current debate on biotechnology, and she wished delegates all success in this important work.

3. Mr Thomas Billy, Chairman of the Codex Alimentarius Commission, highlighted the areas of priority in order to ensure the success of Codex work the scientific basis of decisions; support from the parent organizations; the increased participation of developing countries, and the involvement of non-Governmental Organizations. He stressed the importance of transparency as well as efficiency in the decision process in order to address the critical issues that the Committee had to consider, especially as regards biotechnology.

DRAFT GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS (LIVESTOCK PRODUCTION)

24. While the use of vaccines was approved under certain circumstances within the Guidelines, it was recognized that many vaccines are derived from genetic modification/engineering. It was noted that this issue was beyond the expertise of the Working Group and would need to be addressed by the organic industry in the short term. The Committee noted that the method used to obtain the vaccine is not currently a factor to determine the suitability of the vaccine in the Guidelines.

ROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY (PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS) (Agenda item 5)

Sections 2: Definition of Terms and Section 4: Mandatory Labelling of Prepackaged Food

30. The Committee recalled that the 23rd Session of the Commission had adopted the proposed draft amendment to Section 2 and 4 at Step 5 and that the draft amendment had been circulated for government comments at Step 6. It also noted that the Working Group, coordinated by the delegation of Canada, proposed revisions to the Section 2 in connection with its deliberation on Section 5. The text prepared by the Working Group was presented to the Committee as CX/FL 00/6.

31. After an exchange of opinions, the Committee decided not to use the term “modern biotechnology” as the term covers a broad range of techniques, not only genetic modification and genetic engineering that were the primary focus of the discussion in the Committee. It agreed to replace the words “food and food ingredients obtained through modern biotechnology” with the words “food and food ingredients obtained through certain techniques of genetic modification/ genetic engineering” throughout Section 2 and in the Title. The Committee further agreed to remove the square brackets enclosing the words “obtained through gene technology”.

32. The Committee agreed to remove the brackets around the two references to cell fusion, as

the text had been further clarified in view of the government comments submitted and the final text of the Cartagena Protocol on Biosafety.

33. Concerning the use of the words “genetically modified / engineered organism”, many delegations and observer organizations supported the use of the word “modified” as they believed that consumers were more familiar with “modified” than “engineered”, while other delegations preferred the word “engineered” since it was currently used in their countries. The Committee decided to leave both words in the Section taking into account the different situations in different countries and to remove the square brackets.

34. Regarding the definition of “no longer equivalent /differs significantly“, many delegations noted that this paragraph was closely related to the provisions set forth in Section 5 and therefore it was premature to decide on the necessity and the exact wording of the definition before the Committee had discussed Section 5. Some delegations and observers proposed to delete this paragraph since they supported comprehensive labelling of all foods obtained through gene technology irrespective of the differences with corresponding foods or ingredients. Other delegations and observer organizations supported the inclusion of the paragraph because specific labelling would be required for foods and ingredients that were significantly different. The Committee agreed to leave the proposed text of the paragraph as it was in square brackets.

35. Several delegations pointed out that the need for individual definitions in Section 2 depended on the provisions of Section 5, and that discussion on both Sections should be closely interrelated and should proceed in parallel in the Step Procedure.

36. The Committee noted that no comments had been received at Step 6 on Section 4.2.2 concerning the declaration of allergens transferred from any of the products listed in Section 4.2.1.4, and agreed that it should be advanced to Step 8 for inclusion in the General Standard as a new section.

Status of the Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering (Draft Amendment to the General Standard for the Labelling of Prepackaged Foods - Sections 2 and 4)

37. The Committee agreed to advance the draft amendment to Section 4.2.2 to Step 8 for adoption at the 24th Session of the Commission (Appendix III) .

38. The Committee agreed that the draft amendment to Section 2, as amended at the present session, should be returned to Step 6 for government comments (Appendix V).

Section 5: Additional Mandatory Labelling

39. The Committee noted that the Working Group established at the last session under the chairmanship of Canada had presented a revised proposed draft amendment to Section 5, which contained two options for consideration (CX/FL 00/6). The first option requires labelling when products obtained through biotechnology differ significantly from the corresponding food as regards composition, nutritional value, or intended use. The second option requires the declaration of the method of production for foods and ingredients composed of or containing genetically modified / engineered organisms, or food or food ingredients produced from but not containing GMO/GEOs if they contain protein or DNA resulting from gene technology or differ significantly from the corresponding food. The Committee expressed its appreciation to the Chair of the Working Group, Mr. G. Reasbeck, and the members of the Working Group for their constructive work in clarifying complex issues to facilitate discussion at the current session.

40. Several delegations and observer organizations supported Option 1 in document CX/FL 00/6 with the view that the information on the change of composition, nutritional value, or intended use was the most important element for consumer information, rather than the method of production.

41. Many other delegations and observer organizations supported Option 2 in the document, which required the declaration of the method of production under certain conditions because this approach would provide better information to the consumers and allow the possibility to make an informed choice.

42. Several delegations expressed the view that the requirement for mandatory labelling was essential throughout the food chain. The Observer from IFOAM pointed out that laboratory

analysis should only be carried out in addition to product flow analysis and process oriented labelling, such as already existed for organically produced foods.

43. The Delegation of the United States, supported by some delegations and observers, stressed the need to address all the implications of labelling of foods derived from biotechnology as regards enforcement, methodology, economic cost, and consumer perception, and proposed that the Committee, with assistance of the Working Group, should consider these aspects carefully before taking a decision on mandatory labelling provisions. It was also pointed out that developing countries would face technical difficulties in implementing provisions for the labelling of foods derived from biotechnology.

44. As regards the threshold levels indicated in Option 2, several delegations pointed out that analytical methods should be considered by the Codex Committee on Method of Analysis and Sampling (CCMAS). It was noted that the *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology had decided to discuss this issue at its next Session in March 2001. The Committee recognized the importance of close collaboration among Codex bodies and decided to ask the CCMAS to study the analytical methods for the detection or identification of food and food ingredients derived from biotechnology. The Chairman of the CCMAS, Dr. Biacs (Hungary) informed the Committee that CCMAS would be ready to discuss the matter at its next Session in February 2001, taking into account the work already being done by various organizations in this area. A Circular Letter would invite governments and international organizations to submit relevant material to that Committee. It was also noted that the Task Force on Foods Derived from Biotechnology would consider a discussion paper prepared by France on the issue of traceability.

45. The Delegations of Norway and India, supported by other delegations and observer organizations (CI, RAFI, IACFO), expressed the view that of all food and food ingredients produced by means of genetic engineering should be labelled, that labelling should be mandatory, and that the Committee should continue its consideration of this proposal. Labelling should be required whether or not the product had different properties or characteristics compared to conventional foods and/or contained protein or DNA resulting from gene technology. The Delegations stressed that only this approach would ensure consumer confidence in new products and new technologies. The Delegation of India informed the Committee that India was currently in the process of enacting new legislation based on this approach.

46. The Delegation of Japan proposed that the ideas described in Option 2 could be developed as a separate guideline, like in the case of the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*, rather than as an amendment to the mandatory labelling section of the General Standard for the Labelling of Prepackaged Foods. The Delegation indicated that the provisions in Option 2 included a broad spectrum of aspects, such as threshold levels and the mode of declaration as well as examples for labelling, and that the proposed approach would allow for flexibility in the application of these concepts in national legislation by Member countries This proposal was supported by several delegations.

47. The Committee noted that many Member countries were currently reviewing their national legislation on the labelling of foods obtained through biotechnology to ensure better information for consumers and that it was important for the Committee to continue its progress on this matter to achieve international harmonization.

48. The Committee, recognizing the diversity of opinions among Member countries, decided to return the proposed draft amendment to Step 3. It was also agreed that the Working Group, coordinated by Canada, would continue its deliberations and combine Options 1 and 2, in the light of the proposal from Japan on the development of guidelines, and consider the proposal from Norway and India for comprehensive labelling. The Working Group would also consider all key issues related to labelling discussed by the Plenary Session including, as appropriate, the questions raised by the United States and others.

Status of the Proposed Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods - Section 5)

49. The Committee agreed to return the text to Step 3 for redrafting by the Working Group, which would prepare a revised version for circulation and consideration by the next session.

Appendix III

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING)

(At Step 8 of the Procedure)

Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

APPENDIX V

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING) (At Step 6 of the Procedure)

Section 2. Definition of Terms

For the purpose of the General Standard:

"Food and food ingredients obtained through certain technologies of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through gene technology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through gene technology.

"Organism" means any biological entity capable of replication or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through gene technology in a way that does not occur naturally by multiplication and/or natural recombination.

Examples of these techniques used in gene technology include but are not limited to:

- recombinant DNA techniques that use vector systems
- techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism[4]

  [4] [Examples of these techniques include, but are not limited to, micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion.]
- Cell fusion (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family.

Unless the donor/recipient organism is derived from any of the above techniques, examples of excluded techniques include but are not limited to the following:

- *in vitro* fertilization
- conjugation, transduction, transformation, or any other natural process, polyploidy induction
- mutagenesis
- Cell fusion (including protoplast fusion) or hybridization techniques where the donor cells/protoplasts fall within the same taxonomic family

[**"no longer equivalent"/ "differs significantly"** means a food or food ingredient obtained through certain technologies of genetic modification/genetic engineering where a scientific assessment demonstrates, through an appropriate analysis of data, that the characteristics assessed are different in comparison to those of the corresponding existing food or food ingredient, having regard to accepted limits of natural variation for that food or food ingredient"]

2001 (29)

***Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology**

10. In addition to the matters mentioned in the document, the Committee noted that the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (Chiba, Japan, March 2001) had advanced to Step 5 the Proposed Draft Principles for the Risk Analysis of Foods Derived from Biotechnology and the Proposed Draft Guidelines for the Conduct of Food Safety Risk Assessment of Foods Derived from Recombinant-DNA Plants. It had agreed to use the term "modern biotechnology" as defined by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity to ensure consistency, and asked the CCFL to give consideration to using the same definition in its work, although some delegations and observers were of the opinion that for food labelling purposes it may be appropriate to use terms and definitions that were easier for consumers to understand. The Task Force had also considered available analytical methods, and agreed that there should be a collaborative exchange with the CCMAS with a view to CCMAS considering the validation of methods of analysis and ultimately their endorsement, and had agreed to inform the CCFL of its progress in this area.

11. The Delegation of France referred to the discussion on traceability in the Task Force and pointed out that the work of the CCFL in several areas, especially organically produced foods and genetically modified foods, reflected the importance of traceability throughout the food chain. The Committee noted that the Committee on Food Import and Export Inspection and Certification Systems had asked the Commission to consider traceability from a general perspective in order to provide guidance to relevant Committees and to ensure a harmonized approach throughout Codex, on the basis of a paper prepared by the Secretariat.

12. The Committee had an exchange of views to decide whether it should take specific action concerning traceability. Many delegations and some observers expressed the view that this was an essential aspect of the work of the Committee, and proposed that the Committee should inform the Commission of its wish to participate actively in future work on traceability.

13. The Delegation of Argentina recalled that the last session of the Committee on General Principles had discussed traceability and "looked forward to receiving the advice of the Commission on this matter and drew attention to its role of ensuring a consistency of approach of such matters throughout the Codex system. It looked forward to contributing positively to the future development of this topic" (ALINORM 01/33A, para. 15).

14. Several delegations, including the United States, stressed that it was premature to undertake any work in the Committee before the Commission had given clear direction to Codex Committees on how to proceed in this area, especially as this appeared to be a controversial subject. The Committee agreed that it should be kept informed of further discussions on traceability in the Commission and Codex Committees.

DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS): DEFINITIONS (Agenda item 5a)

49. The Committee recalled that the Draft Amendment (Definitions) had been adopted at Step 5 by the 23rd Session of the Commission and considered by the last session of the CCFL, which had made a number of amendments and returned the text to Step 6 for further comments.

"Modern biotechnology"

50. The Delegation of Argentina, supported by the Delegation of Brazil, proposed to replace the current definition with the definition of "modern biotechnology" in order to be consistent with the decision of the Ad Hoc Intergovernmental Task Force, which had agreed to use the definition of the Cartagena Protocol. These delegations also pointed out that the Definitions should be at the same Step as the rest of the text to facilitate discussion. The Chairperson recalled that the Draft

Definitions had been adopted by the Commission at Step 5 in 1999 and that this decision could not be changed by the Committee.

51. The Delegation of Norway, while recognizing the need for consistency in Codex, stressed the need to consider definitions for the purposes of food labelling and in relation to the indications that would actually be used in the label. The Delegation indicated that the result of a search on the internet demonstrated clearly that the references to “Genetic modification/genetic engineering” (combined) outnumbered more than 30 times the references to “modern biotechnology” as related to foods, and that these terms were more widely used. The Delegation of India proposed to replace the current text with a reference to “genetically modified foods and food ingredients and products derived therefrom” as it was more easily understood by consumers.

52. The Committee had an extensive discussion on the need to retain the definition of “genetic modification/genetic engineering” or to replace it with a definition of “modern biotechnology”. Several delegations stressed the need for consistency throughout Codex and with the Cartagena Protocol and supported the reference to “modern biotechnology”. Several other delegations and observers stressed the need to retain a definition for labelling purposes that would correspond to the terms commonly used and understood by consumers worldwide, and to the regulations established by several countries. The Delegation of the United States also noted that it would be difficult to find a term that would be acceptable globally. Several delegations also pointed out that the Cartagena Protocol referred to living modified organisms, and that the terminology currently used in the text would therefore be consistent with the Protocol.

53. The Delegation of Ireland expressed the view that the replacement of “genetically modified/engineered” by the term “modern biotechnology” would confuse consumers and recommended retention of the current terminology. The Observer form Consumers International stated that following consultations with its members worldwide, the terms “genetically modified/engineered” were acceptable, but “modern biotechnology” was not an acceptable term. The Delegations of India and Nigeria supported the views expressed by Ireland and CI.

54. The Observer from IFOAM, supported by the Observer from RAFI, expressed the view that consistency should be achieved with the existing definition of genetically engineered/ modified organisms in the Guidelines for the Production Processing Marketing and Labelling of Organically Produced Foods and expressed concern with the adoption of a new definition which could affect current provisions for organically produced foods. The Secretariat indicated that since the Guidelines were an adopted text, its provisions were not affected by the development of another Codex text with a different scope; the definition in the Guidelines had been adopted for the specific purpose of defining the “organic” claim while the text under discussion concerned general labelling requirements.

55. The Delegation of Argentina requested that the terms “derived from certain techniques..” should replace “obtained from certain techniques..” for a more precise Scope definition. The Committee decided to refer to “obtained through/derived from” in the Spanish version of the text.

56. The Committee also discussed the reference to “no longer equivalent/differs significantly”. The Delegation of Malaysia proposed to retain the current text without square brackets as both terms were acceptable and to refer to “techniques” instead of “technologies” to ensure consistency throughout the text. Several delegations proposed to retain only “no longer equivalent”. The Delegation of India proposed to use the term “not equivalent” as it provided clear information for the consumer. Other delegations indicated that the notion of equivalence was not clearly defined and open to various interpretations, and supported the term “differs significantly’ as this was more precise from a scientific perspective.

57. Following the proposal of the Delegation of the Netherlands, the Committee agreed to delete this definition as it did not appear necessary, and agreed that it would address the use of these terms further while considering labelling requirements, including the Scope, sections 3.1 and 6.1 (Label declarations).

58. The Committee considered a compromise text for the Definitions proposed by the Delegation of Canada, and further amended after discussion in a small drafting group (Canada, Malaysia, Mexico, Senegal, Sweden, United States, Consumers International, International Council of Grocery Manufacturers Associations), as follows: the definitions in the current text

were retained and clarified and the definition of “modern biotechnology” was added, in order to take into account the different approaches taken by member countries as regards the definitions under consideration in the CCFL.

59. The Delegation of India, supported by the Observer from IBFAN, expressed the view that modern biotechnology was not defined clearly and should not be included, and that the text agreed at the last session should be retained unchanged. The Observer from IFOAM, supported by the Delegation of India, proposed that “modern biotechnology” be mentioned only in a footnote for clarification purposes and that it should not be used in the labelling. The Observer from IBFAN supported this view and stated that the use of “modern biotechnology” could be construed as promotional.

60. The Delegation of Nigeria expressed its objection to the revised text as the use of “modern biotechnology” should be restricted to use at the national level in those countries where it was allowed, but should not be used at the international level, and the process of genetic modification should always be declared in the label, especially in view of adverse effects that might originate from intermediate products. The Committee noted that a number of examples of label declarations were contained in section 6 of the Proposed Draft Guidelines.

61. Many delegations and observers supported the revised text as a compromise, in order to achieve significant progress on the important issues under consideration, with the understanding that the labelling requirements would be discussed in the text under consideration in Agenda 5b, and the Committee agreed that the Draft Definitions should be forwarded to Step 8 for final adoption.

62. The Delegations of Austria, Germany and Switzerland indicated that they could generally support the compromise text, but they needed more time in order to reach a final decision, and they might be able to do so before the Commission met.

63. The Delegations of Argentina, Brazil, Costa Rica and the United States expressed their reservation on the revised Definitions as member countries needed more time to consider the text; without prejudging of its content, they proposed that it should be returned for further comments and consideration at the next session. The Delegation of the United States noted that continued separation of the Definitions from the Guidelines could complicate the work of the Committee.

Status of the Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification

64. The Committee agreed to forward the Draft Amendment to Step 8 for adoption by the 24th Session of the Codex Alimentarius Commission (see Appendix IV).

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS)

63(extr). The Committee recalled that its last session had returned the Proposed Draft Recommendations for redrafting by a Working Group coordinated by Canada in order to combine the different labelling options proposed in the comments and during the discussion.

64(extr) The Chair of the Working Group (Mr Gerry Reasbeck, Canada) informed the Committee that a smaller Drafting Group had met twice to facilitate the revision of the text and expressed his thanks to India and Brazil for hosting these meetings between the sessions. As a result of extensive discussion, the Working Group had revised the text in the form of Guidelines which allowed different labelling options, including comprehensive labelling, and provided guidance on labelling requirements in each case. The Guidelines presented in CX/FL 01/7 also included an explanation of the changes made in Annex 2 and a discussion paper on a number of issues which had been raised at the last session of the CCFL (Attachment A).

65(extr) The Committee expressed its appreciation to Mr Reasbeck and to the Working Group for their considerable efforts and constructive approach to address these complex issues, in order to facilitate the work of the Committee.

General comments

66. The Delegation of Argentina expressed a general reservation on the entire document in principle due to its likely implications in international trade, recalling the basic objectives of Codex and the Statements of Principle on the Role of Science and the Extent to which Other Factors are Taken into Account. The Delegation emphasized that labelling of food according to the process of production had been object of negative decisions in the framework of WTO. It recalled that the Committee on General Principles at its last session, had agreed that reference to « other factors » beyond science should be based on recommendations from other multilateral fora. It requested, accordingly, that no further work should be undertaken on this document. The Delegation of the United States also referred to rights and obligations previously agreed in the WTO. The Secretariat recalled that the CCGP had discussed the role of science and other factors in relation to risk analysis and proposed several Criteria for the Consideration of Other Factors in relation to the Statements of Principle but there had been no agreement on the reference to the « recommendations of relevant multilateral intergovernmental organizations » and the relevant text (in square brackets) was forwarded to the Commission for consideration (ALINORM 01/33A, paras. 92-98). The Secretariat also recalled that the development of labelling provisions for different types of foods, including those produced through biotechnology was in conformity with the terms of reference of the CCFL and the mandate of Codex.

67. Some delegations questioned the development of Guidelines which would provide different options according to the regulatory approach taken in member countries since this was not the usual approach in Codex and it was not clear how this would apply in case of trade disputes. These delegations indicated that Codex should rather give general recommendations that could be applied in all countries as a basis for international harmonization.

Purpose

68. The Committee agreed that the purpose was “to provide guidelines to ensure” that labelling provided the required information and amended the text accordingly.

69. The Committee noted proposals to replace “obtained through” with “ derived from” certain techniques and to replace “certain techniques” with “techniques” in the purpose and the Title. After an exchange of views, the Committee however agreed to retain the wording used in the Definitions which had been finalized earlier (see para 64 above).

70. Some delegations proposed to refer to “verifiable” information, as there was no guarantee against misleading labelling and claims if the information could not be verified. Other delegations objected to this inclusion as it would restrict the information provided to consumers.

71. Several delegations proposed to delete the reference to “facilitating consumer choice” as it was not necessary and it was clear that information was provided “to consumers”. Other delegations stressed that the overall objective of food labelling was to facilitate consumer choice and it was retained in the Purpose.

72. The Delegation of Argentina, supported by several delegations proposed that the information should be “relevant for consumer health protection and the promotion of fair practices in foods trade”, as indicated in the second Statement of Principles on the Role of Science and the Extent to which Other Factors are Taken into Account . Some delegations indicated that such a reference was not relevant, as the purpose of labelling was to ensure consumer information irrespective of health concerns. As a compromise, the Committee agreed that reference should also be made to the third Statement of Principle concerning labelling, as proposed by the Observer from Consumers International.

73. The Committee agreed that the revised text of the first paragraph including the above amendments should be placed in square brackets for further consideration (see Appendix V). The Delegation of India proposed that the second paragraph should be deleted. The Committee did not discuss specifically the second paragraph and it was not amended.

Scope

74. The Delegation of Argentina proposed to include a statement to the effect that Codex standards should not affect other obligations of member countries at the international level, as recommended by the Committee on General Principles (see also para. 66).

75. The Delegation of India proposed to refer to “genetically modified foods and food ingredients and products derived therefrom” which are “not equivalent” as it was more easily understood by

consumers, and to retain only “and” between the different cases described in section 1.1 to reflect that the Guidelines applied in all cases.

76. The Committee agreed to replace “corresponding existing food and ingredients” with “conventional counterpart”11 to be consistent with the term used in the Task Force on Foods Derived from Biotechnology and the FAO/WHO Expert Consultation on Safety Aspects of Genetically Modified Foods of Plant Origin.

77. The Delegation of Italy proposed that labelling should not be limited to foods intended for the final consumer but should apply throughout the food chain. The Committee noted that further discussion would be required on this question, since the purpose of the Guidelines currently referred to providing information to consumers.

78. The Committee agreed with the proposal of the Delegation of Norway to separate section 1.1 into three sub-sections (1.1.1, 1.1.2, and 1.1.3) to make it clear that the three options presented were open for further consideration and “and/or” was retained between these options. The Delegations of Canada and the United States proposed to retain the current section 1.1.2 in square brackets until a decision was made on labelling to indicate the method of production. The Delegation of Australia pointed out that there was no agreement on methodology or criteria for determining compliance/enforcement of the Proposed Draft Guidelines. The Committee did not consider this section further at this stage.

Status of the Proposed Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification

79. The Committee was not able to proceed further with the consideration of the Guidelines due to time constraints and agreed that the current text, as amended at the current session should be returned to Step 3 for further comments (see Appendix V). It was also agreed that the existing Working Group, extended to all interested member countries and international organizations and coordinated by Canada would work by electronic mail to consider the comments received in order to prepare a revised text for consideration by the next session.

APPENDIX IV

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING) DEFINITIONS (At Step 8 of the Procedure)

Section 2. Definition of Terms

For the purpose of the General Standard:

“Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering” means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

“Organism” means any biological entity capable of replication, reproduction or of transferring genetic material.

“Genetically modified / engineered organism” means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

“Modern biotechnology” means the application of:

a. In vitro nucleic acid techniques[1], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[2] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[1] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary

materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, microencapsulation and liposome fusion

[2] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

(1) **PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING)** (At Step 3 of Procedure)

(2) PURPOSE OF THE GUIDELINES

[To provide guidelines to ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provides factual, verifiable, understandable and non-misleading information relevant to protect consumer's health and to ensure fair practices in food trade. Food labelling plays an important role in furthering both of these objectives and to facilitate consumer choice.]

These guidelines set out a number of approaches and related information that could be used for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

(3) 1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.1 These guidelines apply to the labelling of such food and food ingredients:

1.1.1 when they are [no longer equivalent to / differ significantly] from the corresponding conventional counterparts, as regards its: composition, nutritional value or intended use; and/or

1.1.2 when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or

1.1.3 when they are produced from, but do not contain, genetically modified / engineered organisms, protein or DNA resulting from gene technology.

(4) 2.0 DEFINITION OF TERMS (At Step 8 of the Procedure)

For the purpose of these guidelines:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

c. In vitro nucleic acid techniques[3], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

d. Fusion of cells[4] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

[3]These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary

materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[4]Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

(6) **3.0 LABELLING PROVISIONS** (At Step 3 of the Procedure)

In adopting a specific approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering the following provisions could be used:

(7) 3.1 When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2 are [no longer equivalent to / differ significantly] from the corresponding existing food and food ingredients, as regards:

-composition; and/or

-nutritional value; and/or

-intended use;

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 6.l on label declarations.

(8) 3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification/genetic engineering of an allergen transferred from any of the products listed in Section 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 11985 (Rev.1-1991, Amended 1999) shall be declared[5]

[5]This provision is at Step 8 for consideration by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

(9) 3.3 [The presence of substances that are absent [or present in altered proportions having regard to accepted limits of natural variation] in corresponding existing foods that may have implications for the health of certain sections of the population [should] [shall] be labelled].

(10) 3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2):

(a) When they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or

(b) When they are produced from, but do not contain, genetically modified /engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value, intended use [and/or other parameters].

(11) 3.5 [Notwithstanding Section 4.2.2.2 of the General Standard[6]], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of ethical objections [should] [may] be labelled. [Where such labelling is used, member countries should establish criteria on how labelling decisions, based on ethical considerations, will be decided and implemented in a manner that is fair, transparent and consistent.]

[6]Section 4.2.2.2 requires that pork fat, lard and beef fat shall always be declared by their specific names

(12) **[4.0 THRESHOLD LEVELS**

4.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, are labelled to declare the method of production, consideration may be given to:

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/genetic engineering, below which labelling would not apply[7]] and/or

[Establishment of a de minimis threshold level for adventitious or accidental inclusion in food and food ingredients, of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, below which labelling would not apply]]

[7] Consideration of a threshold must address existing provisions of the Codex General Standard for the Labelling of Prepackaged Foods, e.g. Section 4.2.1.3 (Compound Ingredients)

(13) **[5.0 EXEMPTIONS**

5.1 Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.]

(14) **6.0 LABEL DECLARATIONS**

In accordance with the General Principles section of the Codex General Standard for the Labelling of Prepackaged Foods and the Codex General Guidelines on Claims, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.

Where food and food ingredients obtained through certain techniques of genetic modification/engineering are labeled to indicate final product characteristics, the following requirements should apply:

(a) if the composition or nutritional value of food and food ingredients is [no longer equivalent to/differs significantly] from the corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Section 4.1 and 4.2.2 of the General Standard. In addition, nutrient declaration should be provided in conformity with the Codex Guidelines on Nutrition Labelling.

(b) if the mode of storage, preparation or cooking is [no longer equivalent to/differs significantly] from the corresponding existing food and food ingredients, clear instructions for use should be provided.

(16) 6.2 In addition to the provisions in Subsection 6.1, where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

a) [“Produced from genetically modified (naming the source)”] e.g. “produced from genetically modified soya”

(b) If the ingredient is already listed as produced from the source, [“genetically engineered(naming the food)”], e.g. “genetically engineered maize flour”

(c) [“Grown from seeds obtained through [modern] plant biotechnology”]

(d) If the ingredient is designated by the name of a category, [“contains (name of the ingredient) produced from genetically modified (source)”], e.g. starch (“contains starch produced from genetically modified maize”)

(e) [“Genetically engineered (naming the characteristic) (naming the food)”] e.g. “genetically

engineered high oleic soybean oil” (f) [“Product of plant / animal biotechnology”]

(g) [“Naming the food/food ingredient (genetically modified)”] e.g. “soybean (genetically modified)”

(h) [“Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)”) e.g. “soybean (genetically modified soybean not segregated)”

(i) [“Product of gene technology”]

2002 (30)

DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH

CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS): DEFINITIONS (Agenda Item 5a)

27. The Committee recalled that the 24th Session of the Codex Alimentarius Commission had returned the Draft Amendment (Definitions) to Step 6 due to lack of consensus on the appropriate terminology for the Definitions. It also noted that the 3rd Session of the Codex Ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology had agreed to advance the *Draft Principles for Risk Analysis of Foods Derived From Modern Biotechnology*, and the *Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant–DNA Plant* to Step 8 for adoption by the 25th Session of the Commission. The definition of "modern biotechnology" was used in the *Draft Principles* and was consistent with the definition adopted in the Convention on Biological Diversity. The Secretariat recalled that the definitions were currently under consideration as a Draft Amendment to the General Standard for the Labelling of Prepackaged Foods but were also included in the Guidelines. The Chairperson, referring to the progress made in the Task Force on Foods Derived from Biotechnology, urged the Committee to make as much progress as possible during this Session in view of the importance of this subject.

28. The Delegation of the United States, supported by the Delegations of Ireland and Brazil, expressed its concern over the present process of discussion whereby the Definition of terms was separated from the Guidelines and at a different Step in the Procedure, and proposed to discuss the definitions in conjunction with the main text of the Guidelines.

29. Many delegations and observer organizations supported "genetically modified/engineered" because this terminology is more familiar to consumers, stressing the importance to use familiar terminology for the purpose of labelling. In this context the Delegation of Ireland expressed its serious concern that a majority of consumers would not understand the significance of the term "Modern Biotechnology" on a food label. The Delegation of India pointed out that the word "modern" in itself was rather vague.

30. On the other hand, many other delegations and observers supported "Modern Biotechnology" in order to maintain consistency with other Codex texts and with other internationally agreed texts such as the Cartagena Protocol. Some of these delegations stressed that "Modern Biotechnology" was more understandable to the consumers in their countries. The Delegation of Brazil further proposed to use "Modern Biotechnology" in the title for the purpose of consistency throughout Codex. The Delegation of Japan expressed the opinion that it would accept the use of the term "modern biotechnology" but it did not intend to exclude the term "genetically modified/engineered" from the Definitions section.

31. After a first round of exchange of opinions, the Delegation of Spain, speaking on behalf of the member states of the European Union, expressed its willingness to compromise by accepting "Modern Biotechnology" on the condition that the terminology used in the definition did not affect the terminology used in the actual labelling. The Delegation proposed to add a new footnote for this purpose. The Observer from Greenpeace, supported by some observers proposed to indicate in the footnote that "modern biotechnology" should not be used for labelling purposes. However, some delegations pointed out that the decision to use specific terminology in the labels was the responsibility of member countries at the national level. Several delegations expressed their willingness to accept the footnote proposed by the Delegation of Spain as a compromise.

32. The Delegation of the United States proposed a modification to the footnote suggested by Spain to reflect wording found in paragraph 153 of the report of the 24th Session of the Codex Alimentarius Commission. They also proposed to retain only "Modern Biotechnology" by deleting the other definitions and the existing footnotes 1 and 2. The Delegation also suggested that the wording necessary for labeling should be considered at a later stage. The Delegation of Spain, supported by India, opposed this proposal and requested the retention of all the definitions and present footnotes. The Delegation of Canada referred to the compromise reached at the last session on the definition of "modern biotechnology" and proposed to retain its associated footnotes.

Status of the Draft Recommendations for the Labelling of Foods Obtained through

Certain Techniques of Genetic Modification/Genetic Engineering (Draft Amendment to the General Standard for the Labelling of Prepackaged Foods): Definitions

33. The Committee could not reach a consensus and decided to return the current text of the Draft Definitions, with the addition of the footnote proposed by the Delegation of Spain, to Step 6 for further comments and discussion in the next Session (see Appendix III).

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING): LABELLING PROVISIONS (Agenda Item 5b)

34. The Committee recalled that the last session had not completed the discussion on the Proposed Draft Guidelines due to lack of time and had returned them to Step 3 for further comments. The Delegation of Canada presented the working document that had been prepared with the inclusion of all comments submitted by member countries and observers in each section, in order to facilitate the discussion. The Committee discussed the document section by section as follows.

Title

35. Some delegations proposed to amend the title to refer to “modern biotechnology” in order to ensure consistency with the terminology used by the CTFBT. Other delegations and observers supported the current title referring to “certain techniques of genetic modification/genetic engineering” as it should reflect the contents of the text, and the purpose of the guidelines was not to address risk analysis but food labelling. It was also proposed to replace “certain techniques” with “techniques”.

36. As no consensus could be reached, the Committee agreed to proceed with the consideration of the guidelines and to reconsider the terminology used in the title and definitions and in all relevant parts of the text when the entire text had been discussed.

Purpose of the Guidelines

37. The Delegation of Mexico proposed that the information mentioned in the first sentence should be qualified as “necessary” rather than “relevant”. Other delegations objected to this amendment and after an exchange of views, the Committee agreed to delete “relevant” as it did not improve the clarity of the text. The Delegation of India suggested to include the second paragraph of the *Purpose of the Guidelines* in the *Scope*.

38. Some delegations proposed to delete the last sentence concerning the role of food labelling as it was redundant. The Delegation of the United States stated that the sentence went beyond the Statements of Principle that had been agreed in Codex. Other delegations pointed out that this text was identical to the third *Statement of Principle* and reflected an essential aspect of Codex work, and that the notion of “consumer choice” was also mentioned in general labelling texts. The Delegation of Australia pointed out that the sentence was not identical to the third *Statement of Principle*. After some debate, the Committee agreed that food labelling “plays an important role in providing information to consumers and thereby facilitating consumer choice”. The square brackets were deleted around the first paragraph and the second paragraph was left unchanged.

Section 1. Scope

39. The Delegation of the United States, supported by other delegations including Australia and Brazil, proposed to focus on the sections on which consensus could be reached, and especially on the labelling of foods that differed from their conventional counterparts. Other delegations expressed the view that these provisions should be discussed with the labelling requirements based on the method of production and that the text should be discussed as a whole. The Delegation of Mexico proposed to refer to a case by case evaluation but the Committee agreed that this was relevant in relation to risk analysis and not in the case of labelling.

40. The Committee had an extensive discussion on section 1.1.1 and the use of the terms “no longer equivalent/ differ significantly” and agreed on a compromise text proposed by the Delegation of Canada and other delegations in order to clarify the nature of the comparison, the reference to natural variations, and the type of products covered by this comparison. The

Committee also agreed that further discussion of this text would be necessary in conjunction with other relevant sections.

41. The Delegation of the United States expressed its objections to the inclusion of labeling requirements for foods that were not different from their conventional counterpart as it would be misleading for consumers and imply that the product was unsafe, and the practical implications related to the enforcement of such labelling had not been addressed. This position was supported by the Delegations of Argentina and Brazil. The Delegation of Australia noted that the issue of general labelling was unlikely to gain international consensus and, in accordance with the agreed text in the Procedural Manual for consideration of other factors referred to in the second *Statement of Principle*, was best left to individual member countries.

42. Other delegations supported the labelling of foods that contained DNA and protein, as indicated in section 1.1.2, however they objected to the labelling of foods that were produced from GMOs but did not contain DNA and/or modified protein as this, in their view, was not enforceable in practice. The Observer from the EC stressed the importance of adequate labelling to ensure consumer confidence and supported the current text.

43. The Delegation of Norway, supported by India and some observers, supported comprehensive labelling in all cases for foods derived from biotechnology irrespective of the differences with other foods in order to ensure consumer information and allow consumer choice.

44. The Observer from IBFAN supported comprehensive labelling as it may have health implications in the case of infant formula containing GM soybean that may not have been tested, and this information was critical to allow an informed choice.

45. The Committee noted the proposal of the Delegation of Canada, supported by other delegations, to reorganize the section to distinguish between the types of information related to the characteristics of the product and to the method of production, but it was not discussed in detail and paragraphs 1.1.2 and 1.1.3 were left unchanged. As these two sections were not discussed in detail, the Delegations of Australia and the United States expressed the opinion they should have been placed in square brackets.

46. The Delegation of Brazil proposed to include a definition of “gene technology” as this term was used in the text. The Committee agreed to include the definition of “gene technology” as a footnote but it was placed in square brackets as it was not possible to discuss it in detail.

Section 3. Labelling Provisions

47. The Delegation of the Netherlands, supported by other delegations, proposed to use the term “shall” rather than “should” in section 3.3 to reflect that the declaration of the substances mentioned was mandatory, as this would be consistent with the adopted section on the declaration of allergens (section 3.2).

48. The Delegation of Canada, supported by other delegations, proposed to reword section 3.3 for clarification purposes, referring to “substances which may result in physiological or metabolic disorders for certain sections of the populations” that “should be labelled”. The Committee did not come to a conclusion on these proposals and agreed to retain the text proposed by Canada and “should/shall” in square brackets. The Delegation of the United States expressed its reservation as it was their view that the text was too broad and could be misleading to consumers.

49. In section 3.4b), several delegations proposed to clarify or to delete the reference to “other parameters” as it was not well defined. After an exchange of views the Committee agreed to delete this term.

50. The Delegations of Argentina, Canada and South Africa expressed the view that labelling of foods that did not significantly differ from their conventional counterparts could be on a voluntary basis only. The Delegation of Argentina also pointed out that the labelling according to the method of production should not be a condition for access to markets.

51. Several delegations, including Brazil, expressed their reservations on section 3.4 b) concerning the labelling of foods that were produced from GMOs but did not contain DNA and protein, as these provisions would mislead consumers and could not be enforced in practice.

52. The Delegation of the United States reiterated its objections to labelling based on the method of production and expressed the view that even in the case of voluntary labelling the declaration of the process could be misleading and would not benefit consumers.

53. Several other delegations and observers supported the current text as it covered all types of products concerned, and the section was retained with the understanding that it would be discussed further at the next session.

54. The Committee had an exchange of views on the provisions concerning ethical objections in section 3.5. Some delegations proposed to delete any reference to ethical or cultural objections in the text as this should not be considered at the international level and should be left to individual countries. Several delegations supported additional wording concerning religious and cultural concerns, while other delegations proposed to refer to “dietary restrictions”. The Committee considered a compromise text proposed by several countries and referring to “dietary restrictions, based on religious and cultural practices” but could not come to a conclusion and left the amended text in square brackets for further consideration.

Section 4. Threshold Levels

55. Some delegations and observers expressed their general objection to threshold levels as labeling should be mandatory in all cases and therefore proposed to delete the section. Other delegations supported the establishment of threshold levels only to take into account adventitious presence of GM foods and food ingredients, and proposed to retain only the second part of the section. Some delegations proposed to retain the entire section without square brackets as they agreed with both types of threshold levels. The Committee did not reach a consensus and agreed to retain the entire section in square brackets for further consideration.

Section 5. Exemptions

56. Some delegations and observers proposed to delete the reference to exemptions, and pointed out that they were not acceptable especially in the case of highly processed ingredients. Other delegations proposed to retain the section for further consideration. The Committee did not come to a conclusion and retained the section in square brackets.

Section 6. Label Declarations

57. In section 6.1 a), The Delegation of Swaziland proposed to refer to “genetic characteristics” of the foods in addition to the composition or nutritional value. The Committee however noted that this was not clearly defined and the current wording was retained.

58. In section 6.2 the Delegation of New Zealand proposed new text to the effect that labelling should be meaningful for the intended consumer. The Committee agreed to a revised text proposed by the Delegation of Brazil in cooperation with other countries in order to clarify the introductory paragraph, with one change to the text. Following a short discussion, the Committee agreed to put "intended" (consumer) in square brackets for further consideration.

59. The Committee discussed the need for examples and the examples that should be retained. The Delegation of Spain, referring to the written comments of the EC proposed to delete some examples that would be misleading for consumers. The Delegation of India proposed to delete all examples referring to "modern biotechnology" as it would mislead consumers. The Observer from Consumers International noted that having consulted with its members worldwide, they were opposed to the terms "modern biotechnology", "biotechnology" and "gene technology" in the examples of label declarations, since these terms were not understood by consumers who widely understood the terms "genetic engineering and/or genetic modification". Other delegations pointed out that the examples listed were only indicative and that the decision on the terminology used in the label was taken by member countries at the national level. All current examples were retained in square brackets.

60. The Observer from IFOAM expressed its concern that the term “ biotechnology”, especially if abbreviated as “bio” would confuse consumers in those countries where a similar term was used to describe organically produced foods. This would cause serious difficulties for organic producers especially as the organic production system did not allow the use of GMOs and products thereof. The Observer therefore proposed to include additional provisions to address this problem in section 6.2.

Section 7. Implementation

61. Several delegations expressed the view that this section should be retained for further discussion of issues related to verification, product tracing, analytical methods and other measures required for control purposes and to ensure consumer confidence. The section was retained in square brackets for further discussion at the next session.

Status of the Proposed Draft Guidelines for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions

62. The Committee, recognizing that no consensus had been reached on several important issues, agreed to return the Proposed Draft Guidelines, as amended at the present session, to Step 3 for further comments and consideration at the next session (see Appendix IV).

APPENDIX III

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING) DEFINITIONS (At Step 6 of the Procedure)

SECTION 2. DEFINITION OF TERMS[2]

For the purpose of the General Standard:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques3, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells4 beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[2]The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[3] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[4] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

APPENDIX IV

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (At Step 3 of Procedure)

PURPOSE OF THE GUIDELINES

To provide guidelines to ensure that the labelling of food and food ingredients obtained through

certain techniques of genetic modification/genetic engineering provides factual, verifiable, understandable and nonmisleading information to protect consumer's health and to ensure fair practices in food trade. Food labeling plays an important role in providing information to consumers and thereby facilitating consumer choice.

These guidelines set out a number of approaches and related information that could be used for the labeling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.1 These guidelines apply to the labelling of such food and food ingredients:

1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation[5]; and /or

1.1.2 when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology[6]; and/or

1.1.3 when they are produced from, but do not contain, genetically modified / engineered organisms, protein or DNA resulting from gene technology.

[5] This would include products such as oils with altered fatty acid levels, but would not include products such as those with agronomic modifications which contain recombinant DNA and/or protein but no further overall change to composition, nutritional value or intended use.

[6] [Gene Technology: Means a collection of techniques which are used to alter the heritable genetic material of living cell or organisms in a way that does not occur naturally by multiplication and/or recombination]

2.0 DEFINITION OF TERMS[7] (At Step 6 of the Procedure)

[7] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

For the purpose of these Guidelines:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

c. In vitro nucleic acid techniques8, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

d. Fusion of cells[9] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

[8] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[9] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

3.0 LABELLING PROVISIONS

In adopting a specific approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering the following provisions could be used:

3.1 When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2 are [no longer equivalent to / differ significantly] from the corresponding existing food and food ingredients, as regards:

-composition; and/or

-nutritional value; and/or

-intended use;

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 6.l on label declarations.

3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification/genetic engineering of an allergen transferred from any of the products listed in Section 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991) shall be declared[10]

[10] This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

3.3 [The presence of substances which may result in physiological or metabolic disorders for certain sections of the population and that are absent in corresponding existing foods[should][shall] be labelled].

3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2):

(a) When they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or

(b) When they are produced from, but do not contain, genetically modified /engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value and, intended use.

3.5 [Notwithstanding Section 4.2.2.2 of the General Standard6, the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent.]

[4.0 THRESHOLD LEVELS

4.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, are labelled to declare the method of production, consideration may be given to:

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/genetic engineering, below which labelling would not apply[11]] and/or

[11] Consideration of a threshold must address existing provisions of the Codex General Standard for the Labelling of Prepackaged Foods, e.g. Section 4.2.1.3 (Compound Ingredients)

[Establishment of a de minimis threshold level for adventitious or accidental inclusion in food and food ingredients, of food and food ingredients obtained through certain techniques of

genetic modification/genetic engineering, below which labelling would not apply]]

[5.0 EXEMPTIONS

5.1 Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.]

6.0 LABEL DECLARATIONS

In accordance with the General Principles section of the Codex General Standard for the Labelling of Prepackaged Foods and the Codex General Guidelines on Claims, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.

6.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to indicate final product characteristics, the following requirements should apply:

(a) if the composition or nutritional value of food and food ingredients is [no longer equivalent to/ differs significantly] from the corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Sections 4.1 and 4.2.2 of the General Standard. In addition, nutrient declaration should be provided in conformity with the Codex Guidelines on Nutrition Labelling.

(b) if the mode of storage, preparation or cooking is [no longer equivalent to / differs significantly] from the corresponding existing food and food ingredients, clear instructions for use should be provided.

6.2 In accordance with Section 6.0 and in addition to the provisions in Subsection 6.1, food labels should be meaningful to the [intended] consumer. Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

(a) [“Produced from genetically modified (naming the source)”] e.g. “produced from genetically modified soya”

(b) If the ingredient is already listed as produced from the source, [“genetically engineered (naming the food)”], e.g. “genetically engineered maize flour”

(c) [“Grown from seeds obtained through [modern] plant biotechnology”]

(d) If the ingredient is designated by the name of a category, [“contains (name of the ingredient) produced from genetically modified (source)”], e.g. starch (“contains starch produced from genetically modified maize”)

(e) [“Genetically engineered (naming the characteristic) (naming the food)”] e.g. “genetically engineered high oleic soybean oil”

(f) [“Product of plant / animal biotechnology”]

(g) [“Naming the food/food ingredient (genetically modified)”] e.g. “soybean (genetically modified)”

(h) [“Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)”] e.g. “soybean (genetically modified soybean not segregated)”

(i) [''Product of gene technology'']

6.2 (extr) Where the presence of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering is declared on the label, the following would apply:

(a) In the case of single-ingredient foods, or where there is no list of ingredients, the information should appear clearly on the label of the food; or

(b) In the case of a food ingredient(s) in a multi-ingredient food, the information should be shown in the list of ingredients or in parentheses immediately following the

ingredient(s). Alternately, the ingredient(s) may be identified by an asterisk and the required wording should appear in a statement immediately following the list of ingredients.

[**7.0 IMPLEMENTATION**

Consistent with the approach(es) adopted under Section 3, additional consideration should be given to procedures and methodologies for the identification of food and food ingredients produced using certain techniques of genetic modification/genetic engineering and verification of label declarations. These include, but are not limited to: development of validated detection methods; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure.]

2003 (31)

DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS): DEFINITIONS (Agenda Item 7a)

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 7b)

69. The Committee recalled that the 30th Session of the Committee had extensive discussions on this agenda item, however, the Committee had returned the Draft Definitions to Step 6 and the Proposed Draft Guidelines to Step 3 for further comments and discussion in this session due to lack of consensus.

70. The Chair, recalling the history of the discussions on this agenda by the Committee for a long time, proposed to establish a Group of “Friends of the Chair” as an intersessional mechanism to break through the difficulty the Committee had been facing, in order to develop options to manage the issue for consideration by all Committee members at the next session. The Chair expressed the view that the Group would better function with a smaller number of participants than the full Committee. The Chair also referred to the importance of the transparency and participation in a balanced geographical representation, and between developed and developing countries.

71. The Committee supported this proposal and many delegations expressed their willingness to participate in this Group. These delegations and observers pointed out that transparency in the process, appropriate composition as regards participants, clear mandate for this Group and attention to the interests of developing countries were very important elements to take into account and also essential factors for a successful conclusion of this Group. Some delegations requested to distribute to all members of the Committee the summary of the discussion of the Group in order to ensure transparency. Regarding the inclusiveness, the Committee recognized that differing views were voiced such as that participation should be open to all members or that the Group should be limited to a smaller number of participants.

72. In this context, the delegation of Norway recalled that the mandate given to the Committee by the Codex Alimentarius Commission in 1991 “to provide guidance on how the fact that a food derived from “modern biotechnologies” could be made known to the consumers” still holds (Paragraph 90 ALINORM 91/41) and expressed its expectation that the Committee and the Group under discussion would pay attention to this aspect in their future work. The Delegation also made a comment on CX/FL 03/8-Add.1 presented by Canada in relation to the Extraordinary Session of the Commission held in February 2003 on the priority for Codex that was mentioned in the Recommendations from the Codex Evaluation. The Delegation indicated that although the Commission emphasized the priority of the development of standards having an impact on consumer health and safety, this did not imply that Codex should not take fair practices into account when establishing standards.

73. The Committee agreed to establish a Working Group composed of the following member countries based on their interest to participate; Argentina, Australia, Barbados, Bolivia, Brazil,

Canada, China, Egypt, France, India, Indonesia, Japan, Kenya, Korea, Mexico, Netherlands, New Zealand, Norway, Sweden, Switzerland, South Africa, United States, European Community. The Committee also agreed that the mandate of this Group would be to develop options for management of this agenda item and that the summary of the discussions by the Group as well as the proposals submitted to this Group would be circulated to all Codex members. The Chair invited interested countries to submit proposals to the Canadian Secretariat and indicated that the Group could meet between the sessions as required, the exact arrangement to be determined by the host country.

Status of the Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering (Draft Amendment to the General Standard for the Labelling of Prepackaged Foods): Definitions and the Proposed Draft Guidelines for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions

74. The Committee, bearing in mind the above decision, agreed to retain the Draft Definitions and the Proposed Draft Guidelines at Step 7 and 4 respectively for further discussions in the next session of the Committee.

2004 (32)

DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS): DEFINITIONS (Agenda Item 6a)6

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 6b)7

79. The Committee recalled that the 31st Session of the Committee had decided to establish a Working Group with a mandate to develop options for the management of this agenda item. The Working Group, which was held in Calgary, Canada from 28th to 30th October 2003, recommended that the Committee should continue to consider this item and retain it on the agenda. The Working Group also expressed considerable interest in maintaining a single document with a mandatory component and other provisions which would be considered optional, although no consensus could be reached on this issue. Noting concerns related to possible interpretations by a WTO dispute panel associated with the “optional” elements in Codex texts, the Working Group suggested that the Committee may consider it useful to bring this matter to the attention of the Commission and request the Commission to seek an opinion from the FAO, WHO and WTO. The Committee expressed its appreciation to the Government of Canada for hosting a very useful meeting.

80. The Delegation of the United States expressed the view that there was a consensus on the need for mandatory labelling in cases where significant changes in the product composition, characteristic, nutritional value or end use existed. The Delegation did not agree that a single document was the best way to move forward. The Delegation opposed the idea of labelling based solely on method of production. The Delegation expressed the view that no unsafe food should be allowed on the market. Further, labelling two identical products based only on method of production would be misleading as many consumers would perceive this as a safety warning. In this sense, the Delegation pointed out that such labelling would be an unfair practice in food trade and thus violate the fundamental principles of Codex.

81. The Delegation of the European Community supported a single document with mandatory and optional elements since the proposal to split the document was rejected twice, noting also that the Working Group in Calgary had agreed to maintain a single text, drawing on the existing format of the General Standard. The Delegation stressed that the purpose of labelling of foods is to provide consumers with useful information and not only to draw attention to health and safety information. The Delegation highlighted a number of provisions in the General Standard for the Labelling of Prepackaged Foods which were not related to health and safety such as common name, country of origin labelling and net weight. The Delegation also reminded the Committee

of the situation as regards nutrition labelling which is optional in some countries and mandatory in others. In view of this, the Delegation supported to continue work on a single document with both mandatory and optional components. The Delegation did not support the proposal of the Working Group to seek opinions of FAO, WHO, WTO on this matter. It also suggested that progress could be made with respect to the definition.

82. The Delegation of Canada, referring to its discussion paper in CRD 11, pointed out that the 25th (Extraordinary) Session of the Commission had confirmed that protection of consumer health was the first priority in the work of Codex. The Delegation stated that the 43rd Session of the Executive Committee had expressed the view that the Four *Statements of Principles* should be closely adhered to in considering the guidelines for labelling of foods derived from biotechnology and that the consumers claimed right to know could not be used by Codex as the primary basis for decision-making on appropriate labelling. The Delegation also pointed out that method of production labelling did not comply with the principle that only those other factors which can be accepted on a worldwide basis should be taken into account in the framework of Codex, as stipulated in the *Criteria for the Consideration of the Other factors referred to in the Second Statement of Principles*. Although there was considerable interest in maintaining a single document, the Working Group in Calgary had not reached a consensus on this. Therefore, the Delegation proposed to split the text and to advance the health and safety-related labelling since there appears to be consensus on this part of the guidelines. In addition, the Delegation proposed to develop principles to provide a framework for consideration of method of production labelling, in order to make progress in the discussion[8].

[8]These principles are included in CRD 11.

Note: See Ref 5 for ***"STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT*** (Decision of the 21st Session of the Commission, 1995)" in page 274-275

83. The Committee had a lengthy discussion on this issue. The Committee noted the written comments of Malaysia, that was not represented at the session. Many delegations, including Brazil, India, Norway and Switzerland, and observers supported the opinion of the European Community and stated that labelling of foods derived from biotechnology was not intended for health and safety as genetically modified products are evaluated for their safety before being placed on the market. These delegations, including Cameroon, stated that there was strong demand from consumers to label genetically modified foods based on method of production and many countries had already established national regulations. During the discussion, the Delegation of Switzerland, supported by the Observer from Greenpeace, recalled the mandate that had been given to the Committee by the Commission in 1991 "to provide guidance on how the fact that a food was derived from "modern" biotechnologies would be made known to the consumers" (ALINORM 91/40, para. 90). Some Delegations further stated that the credibility of the Committee would be lost if the Committee failed to respond to the enormous demand from consumers in this respect. These Delegations also pointed out that the Committee had already established method of production labelling such as organic and halal labelling. It was pointed out that the lack of method of production labelling on genetically modified foods was itself an unfair trade practice.

84. Other delegations and observers supported the view expressed by the Delegations of the United States and Canada. Some Delegations stressed the importance of taking into account the possible impact of the method of production labelling on food prices in developing countries and also the practicality of this labelling system as regards enforcement by the national authorities. It was pointed out that method of production labelling could be inconsistent with some provisions of the Agreement on Technical Barriers to Trade.

> *Note: It is not clear which article in TBT Agreement is mentioned by this statement. However, it may be Article 2,* 2.1**,** Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country.
>
> *Whether foods derived from modern biotechnology and their conventional counterparts are*

like products or not could be debatable. However, they appear so from the paragraphs taken from a TBT dispute settlement document, because GM and non-GM products are no doubt in competition and commercially interchangeable. See Box 1 (T.7.4.1 US — Cotton Yarn, paras. 96-98) in page 273.

85. Some Delegations also highlighted the problems faced by developing countries, especially exporting countries, due to trade barriers resulting from differences in national regulations and lack of international harmonization regarding labelling of foods derived from biotechnology. It was also pointed out that several countries had difficulties in the development of their national regulations for the same reasons.

86. Concern was also expressed on the legal consequences that optional texts intended for governments in view of the relationship of Codex with the WTO.

87. The Delegation of the European Community expressed its concern that lack of international harmonization for the labelling of foods derived from modern biotechnology might harm the uptake of biotechnology, in particular in developing countries

88. The Observer from ICGMA, supported by other observers, expressed the view that labelling based on the method of production would discriminate against safe products and would provide limited and misleading information to consumers.

89. The Delegation of New Zealand proposed to continue consideration of a single document with provisions that might be advanced at different steps through the Codex Elaboration Procedure. In this regard, the Chair requested interested delegations to develop a draft project plan for a proposed Ad hoc Working Group.

90. The Delegation of Canada reporting on behalf of the small group of interested delegations9 indicated that the group had proposed the following Terms of reference for the proposed Ad hoc Working Group:

1) Lay out the most expeditious route forward on matters related to the draft guidelines, including time lines

2) Examine suggested and other appropriate options (e.g. principles approach, optional labelling) with a view to unravelling relevant questions, prioritizing work, and developing the most appropriate course forward, including the development of updated text, as appropriate.

A work schedule had also been proposed to allow the preparation of a revised document for consideration by the next session of the Committee (CRD 27). The Committee expressed its appreciation to the Delegations of New Zealand and Canada for their efforts to facilitate consensus on this complex issue.

91. The Delegation of the European Community expressed its objections to the establishment of the proposed Ad hoc Working Group which might result in reopening the discussion on management issues that had already taken place in the working group held in October 2003, and as it was preferable at this stage to discuss the text of the Proposed Draft Guidelines in the presence of Codex Members and Observers, focusing on the sections in square brackets. The Delegation of the United States supported the establishment of a working group with the proposed Terms of Reference as it would facilitate further progress in the discussion.

92. After some discussion, the Committee recognized that there was no consensus to convene a working group between sessions and agreed to return the Proposed Draft Guidelines to Step 3, as presented in ALINORM 03/22, Appendix IV, with the addition of Appendix V of CX/FL 04/6. The Committee agreed that there would be no working group prior to the session but that the next session would devote one entire day to review the text section by section, taking into account all comments received. The Committee also noted that all sections were open for comments and discussions at its next session.

Status of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering : Labelling Provisions

93. The Committee agreed to return the Proposed Draft Guidelines, as amended at the present session, to Step 3 for comments and consideration at the next session (see Appendix VI).

Status of the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering : Definitions.

94) The Committee did not discuss the Definitions. They will be considered by the next session of the Committee at Step 7 (see Appendix V).

APPENDIX V

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING) DEFINITIONS (At Step 7 of the Procedure)

SECTION 2. DEFINITION OF TERMS[5]

For the purpose of the General Standard:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques[6], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[7] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[5] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[6] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[7] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

APPENDIX VI

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (At Step 3 of the Procedure)

PURPOSE OF THE GUIDELINES

To provide guidelines to ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provides factual, verifiable, understandable and non-misleading information to protect consumer's health and to ensure fair practices in food trade. Food labelling plays an important role in providing information to consumers and thereby facilitating consumer choice.

These guidelines set out a number of approaches and related information that could be used for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.1 These guidelines apply to the labelling of such food and food ingredients:

1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation[8]; and /or

1.1.2 when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology[9]; and/or

1.1.3 when they are produced from, but do not contain, genetically modified / engineered organisms, protein or DNA resulting from gene technology.

[8] This would include products such as oils with altered fatty acid levels, but would not include products such as those with agronomic modifications which contain recombinant DNA and/or protein but no further overall change to composition, nutritional value or intended use.

[9] [Gene Technology: Means a collection of techniques which are used to alter the heritable genetic material of living cell or organisms in a way that does not occur naturally by multiplication and/or recombination]

2.0 DEFINITION OF TERMS[10] (At Step 7 of the Procedure)

For the purpose of these Guidelines:

“Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering” means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

“Organism” means any biological entity capable of replication, reproduction or of transferring genetic material.

“Genetically modified / engineered organism” means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

“Modern biotechnology” means the application of:

a. In vitro nucleic acid techniques[11], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[12] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

[10] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[11] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[12] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

3.0 LABELLING PROVISIONS

In adopting a specific approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering the following provisions could be used:

3.1 When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2 are [no longer equivalent to / differ significantly] from the corresponding existing food and food ingredients, as regards:

-composition; and/or

-nutritional value; and/or

-intended use;

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 6.l on label declarations.

3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification/genetic engineering of an allergen transferred from any of the products listed in Section 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991) shall be declared[13]

[13] This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

3.3 [The presence of substances which may result in physiological or metabolic disorders for certain sections of the population and that are absent in corresponding existing foods[should][shall] be labelled].

3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2):

(a) When they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or

(b) When they are produced from, but do not contain, genetically modified /engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value and, intended use.

3.5 [Notwithstanding Section 4.2.2.2 of the General Standard[6], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent.]

[4.0 THRESHOLD LEVELS

4.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, are labelled to declare the method of production, consideration may be given to:

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/genetic engineering, below which labelling would not apply[14]] and/or

[Establishment of a de minimis threshold level for adventitious or accidental inclusion in food and food ingredients, of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, below which labelling would not apply]]

[14]Consideration of a threshold must address existing provisions of the *Codex General Standard for the Labelling of Prepackaged Foods*, e.g. Section 4.2.1.3 (Compound Ingredients)

[5.0 EXEMPTIONS

5.1 Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.]

6.0 LABEL DECLARATIONS

In accordance with the General Principles section of the Codex General Standard for the Labelling of Prepackaged Foods and the Codex General Guidelines on Claims, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.

6.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to indicate final product characteristics, the following requirements should apply:

(a) if the composition or nutritional value of food and food ingredients is [no longer equivalent to/ differs significantly] from the corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Sections 4.1 and 4.2.2 of the General Standard. In addition, nutrient declaration should be provided in conformity with the Codex Guidelines on Nutrition Labelling.

(b) if the mode of storage, preparation or cooking is [no longer equivalent to / differs significantly] from the corresponding existing food and food ingredients, clear instructions for use should be provided.

6.2 In accordance with Section 6.0 and in addition to the provisions in Subsection 6.1, food labels should be meaningful to the [intended] consumer. Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

(a) [“Produced from genetically modified (naming the source)”] e.g. “produced from genetically modified soya”

(b) If the ingredient is already listed as produced from the source, [“genetically engineered (naming the food)”], e.g. “genetically engineered maize flour”

(c) [“Grown from seeds obtained through [modern] plant biotechnology”]

(d) If the ingredient is designated by the name of a category, [“contains (name of the ingredient) produced from genetically modified (source)”], e.g. starch (“contains starch produced from genetically modified maize”)

(e) [“Genetically engineered (naming the characteristic) (naming the food)”] e.g. “genetically engineered high oleic soybean oil”

(f) [“Product of plant / animal biotechnology”]

(g) [“Naming the food/food ingredient (genetically modified)”] e.g. “soybean (genetically modified)”

(h) [“Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)”] e.g. “soybean (genetically modified soybean not segregated)”

(i) ["Product of gene technology"]

6.3 Where the presence of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering is declared on the label, the following would apply:

(a) In the case of single-ingredient foods, or where there is no list of ingredients, the information should appear clearly on the label of the food; or

(b) In the case of a food ingredient(s) in a multi-ingredient food, the information should be shown in the list of ingredients or in parentheses immediately following the ingredient(s). Alternately, the ingredient(s) may be identified by an asterisk and the required wording should appear in a statement immediately following the list of ingredients.

[7.0 IMPLEMENTATION

Consistent with the approach(es) adopted under Section 3, additional consideration should be given to procedures and methodologies for the identification of food and food ingredients produced using certain techniques of genetic modification/genetic engineering and verification of label declarations. These include, but are not limited to: development of validated detection methods; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure.]

ANNEX

[Optional Labelling: Without prejudice to the acceptance of the approach to method of production labelling as a "legitimate concern"* of governments in establishing their national legislation, the following is provided as optional considerations to member countries:]

[*Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account]

2005 (33)

CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS): DEFINITIONS (Agenda Item 5a)

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 5b)

46. The Committee recalled that the 32nd Session of the Committee had decided to return the Proposed Draft Guidelines to Step 3 for comments and consideration at the next session. The Committee exchanged general views on the proposed draft guidelines and considered Item 5b) before Item 5a).

47. Many delegations and observers supported retaining the current structure of the Proposed Draft Guidelines which had both provisions for health and safety-related labelling and for method of production labelling. These delegations and observers stressed that the purpose of food labelling is to provide consumers not only with health and safety information but also various useful information, as required. They also noted

that when products had been subject to safety evaluation prior to authorization on the market, this did not preclude their declaration on the label, as in the case of food additives. In view of this, the Proposed Draft Guidelines needed to include method of production labelling since there was a strong demand from consumers to label genetically modified foods based on method of production, in order to allow informed choices. It was also pointed out that many provisions in the General Standard for the Labelling of Prepackaged Foods were not related to health and safety and the Committee had already established method of production labelling such as organic and halal labelling.

48. Some delegations and observers recalled that the mandate given to the Committee by the Commission in 1991 was "to provide guidance on how the fact that a food was derived from "modern" biotechnologies could be made known to the consumers" (ALINORM 91/40, para. 90) and narrowing the scope would be against the Commission decision.

49. The Delegation of the European Community, supported by other delegations, proposed to restructure the guidelines into two parts; one for mandatory labelling provisions relevant to changes in nutrient content, product composition, end use and the other for optional labelling provisions linked to labelling of method of production, following the proposal by Canada (CRD 2). Several delegations also expressed the view that progress had been made as a result of earlier discussions in the Committee and stressed the need to continue work to achieve consensus.

50. Some delegations pointed out that clear labelling on the method of production would facilitate consumer acceptance of biotechnology and would ensure fair practices in international trade.

51. Several other delegations and some observers expressed their opposition to the inclusion of method of production labelling in the Proposed Draft Guidelines for the following reasons: such labelling did not address food safety issues and was not based on scientific evidence; it would not provide useful information to consumers but rather increase confusion; and it would create barriers to trade. These delegations proposed to focus on the provisions that reflected consensus on the need for mandatory labelling in cases where significant changes in the product composition, nutritional value or intended use existed. In this context, the Committee was reminded of the recommendation of the 55th CCEXEC to redefine or narrow the scope of the work when consensus was deemed difficult to achieve (see para. 10). Some delegations also indicated that in case of a possible dispute in the World Trade Organization, the Dispute Settlement Body would not establish any distinction between mandatory and voluntary provisions contained in a Codex standard. In this respect, the Delegation of Argentina pointed out that when mentioning mandatory and voluntary provisions in a

Codex standard, reference is not made to the Codex standard per se, but to the modalities of its implementation at the national level in the countries that decide to adopt it. Consequently, the objective sought by including voluntary labelling provisions in these Guidelines would not be met.

52. Some of these delegations stated that the 43rd Session of the Executive Committee (1996) had expressed the view that the Four *Statements of Principle* should be closely adhered to in considering the guidelines for labelling of foods derived from biotechnology and that the consumers' claimed right to know was ill defined and could not be used by Codex as the primary basis for decision-making on appropriate labelling.

53. Several delegations and some observers stressed that the information on labelling should be accurate, verifiable and should not mislead consumers. In this respect, it was pointed out that labelling two identical products based only on method of production would convey misleading message that these products were different and many consumers would perceive this as a safety warning although safety evaluation had been conducted before these products were placed in the market. Some delegations also raised a question on the practicality of implementing method of production labelling, especially in developing countries.

54. With respect to the cost implications of method of production labelling, the Committee noted that different views were expressed. Some delegations indicated that mandatory method of production labeling would not result in an increase in the prices of the products. However, some other delegations pointed out that the method of production labelling might entail additional cost necessary to comply with the labelling

requirements which would finally result in the increase in food prices, without providing additional benefits to consumers.

55. After a general exchange of views, the Committee considered how to proceed. Several delegations expressed their preference for considering the text section by section in detail. However, the Committee noted the difficulty to achieve agreement on the text in the present situation as major differences existed in the basic stance taken by members.

56. Several delegations supported the proposal made in the comments of Canada to consider two levels of labelling, including mandatory provisions in relation to changes in nutrition content, composition, end use, or concerns with allergens; and optional provisions linked to voluntary labelling of the method of production by the industry. The Delegation of the EC stated that the EC and its member states were prepared to assist

Canada in "reconstructing" the Proposed Draft Guidelines provided that they remained at Step 3 until the Committee had decided to replace it with the "reconstructed" Proposed Draft Guidelines to be provided by Canada.

57. After some further discussion, the Committee decided that the text should be reconstructed, taking into account the discussion held at the present session and the comments received including those of countries not present in the session (Bolivia, Costa Rica, Peru and

Zimbabwe) and considered at the next session. The Committee also confirmed that the revised text would include the same contents as the current Proposed Draft Guidelines, including provisions for both health and safety-related labelling and method of production labelling.

58. For this purpose, the Committee decided to establish an electronic working group led by Canada with the assistance of Argentina, Australia, Austria, European Community, Brazil, Germany, Ghana, Guatemala, India, Indonesia, Japan, Kenya, Malaysia, Norway, Papua New Guinea, Paraguay, Sweden, Switzerland, Thailand, United States, Bio and Consumers International. The Committee also noted that the working group would be open to all members and observers.

59. The Delegation of Mexico expressed its reservation on this decision as it objected to the Committee's decision to continue work on method of production labelling provisions, considering the implications that this would have in international trade. In addition, the Delegation pointed out that the decision had not been taken by consensus as several delegations had expressed contrary views and as all the recommendations of the 55th Session of the CCEXEC had not been considered. The Delegation highlighted the necessity to analyze the impact of this decision in trade and in particular in the relation of the Codex Alimentarius with WTO. The Delegation of Argentina supported the views of Mexico, and expressed its reservation on the possibility for a Codex standard to include a mandatory and a voluntary part, since this would not make any significant distinction in the context of the World Trade Organization. The Delegation of the United States supported the reservations expressed by the delegations of Mexico and Argentina.

60. The Delegation of Malaysia expressed its reservation on the decision not to consider the current text section by section at the present session as it was noted that many delegations wanted to proceed with the discussion of the current text.

Status of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering : Labelling Provisions

61. The Committee agreed to return the Proposed Draft Guidelines for redrafting by the above mentioned working group, comments at Step 3 and consideration at its next session.

Definitions

62. The Committee noted that the Draft Definitions at Step 7 had been retained as a draft amendment to the General Standard for the Labelling of Prepackaged Foods because the recommendations had been developed initially as an amendment to the General Standard. The recommendations had subsequently been redrafted as independent Proposed Draft Guidelines, that also included a section on definitions.

63. The Committee noted that in order to delete the Draft Definitions as Draft Amendment to the General Standard from the Agenda, discontinuation of work should be proposed to the Commission. Several delegations supported discontinuation of work and consideration of the text of the definitions only as part of the Proposed Draft Guidelines at Step 3. Other delegations and observers proposed to retain the Draft Definitions as a separate text at Step 7 and not to discontinue work at this stage, with the understanding that this question would be considered further at the next session.

APPENDIX III

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING) DEFINITIONS (At Step 6 of the Procedure)

SECTION 2. DEFINITION OF TERMS[2]

For the purpose of the General Standard:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food

ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques3, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells4 beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[2]The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[3] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[4] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

2006 (34)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING (Agenda Item 5)

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING): DEFINITIONS (AT STEP 7) (Agenda Item 5a)

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 5b)

82. The Committee recalled that its last session had agreed to return the Proposed Draft Guidelines for redrafting by an electronic Working Group led by Canada. The mandate of the Working Group was to reconstruct the Guidelines, including mandatory provisions for health and safety related labelling and optional method of production labelling provisions in the light of the comments made at the 33rd Session and received prior to the session.

83. The Delegation of Canada informed the Committee that it had redrafted the Guidelines as agreed at the last session, and circulated it twice for comments within the Working Group; however it had not been possible to reach consensus on a revised version of the Guidelines. The revised draft was provided in the report for information and consideration by the Committee.

84. Many delegations expressed their appreciation to Canada for its considerable work on the preparation of the document and for its continuous efforts to facilitate consensus on this issue in previous sessions.

85. Several delegations, while recognizing the efforts made by Canada to redraft the Guidelines, did not support the approach taken in the revision, especially the separation of the document into mandatory and voluntary provisions, or according to safety and other aspects, and stressed that the mandate of Codex was not to provide guidelines for the industry, but recommendations for governments.

86. The Chairperson recalled that although considerable efforts had been made since the Committee had undertaken work on this item, under consideration in the Step Procedure since 1997, including extensive consideration of all the issues involved in the Committee or in working groups, there was no consensus on further development of the Guidelines or on their content. The Chairperson invited the Committee to consider whether work should be discontinued or suspended at this stage, with the understanding that work could be resumed as required in the light of new developments.

87. Several delegations indicated that they applied general mandatory labelling of foods derived from genetic modification at the national level and supported the same approach in the Proposed Draft Guidelines in order to ensure adequate consumer information. The Chairperson however recalled that the Committee was not discussing the content of the Guidelines at this stage but invited delegations to consider how the Committee should proceed further with its work.

88. Many delegations and some observers supported further discussion of this issue in view of its importance for consumers and as many governments had established regulations in this area, and recalled that the role of Codex was to provide guidance to governments, pointing out that the Committee and the Codex Alimentarius Commission would not comply with their mandate if they failed to develop relevant guidelines. These delegations therefore supported the establishment of a physical Working Group to discuss further all relevant issues, and noted that the considerable work carried out in previous sessions should be taken into account in the process. Several delegations proposed in particular to take into account the Proposed Draft Guidelines discussed in the Committee in 2004 (ALINORM 04/27/22 Appendix VI) and the work undertaken by Canada for the present session.

89. Several other delegations and some observers supported discontinuation or suspension of work as this issue had been discussed for many years and it was clear that there was no consensus and no prospect of further progress in the near future, and the resources of the Committee should be better used to address other issues. Some of these delegations highlighted the recommendations of the 55th Session of the Executive Committee concerning the options that should be considered when no consensus existed, and proposed either to discontinue work or to narrow the scope of Guidelines and focus on the areas that were not controversial. These delegations supported further work on labelling provisions addressing health, food safety and nutrition aspects of genetically modified/genetically engineered foods and noted that consensus could be achieved on the approach to such labelling. Some delegations expressed concern with the impact on trade of labelling provisions in this area.

90. Some delegations pointed out that foods derived from biotechnology were assessed in their countries for safety prior to approval for marketing and that labelling requirements did not relate to concerns for their safety but to the information of the consumer as to the nature of the product, and that the Committee needed to address the issue in this perspective. Some delegations and observers recalled that the Committee had a specific mandate from the Commission in this respect.

91. Some delegations stressed the importance of Codex recommendations in order to provide guidance to developing counties, as it would facilitate the establishment of national policy or requirements concerning labelling of GM/GE foods and therefore supported further work in this area.

92. The Chairperson noted that there was considerable support to continue work and to establish a physical Working Group for this purpose and proposed that it should consider all relevant issues in order to identify the main problems, and take into account the experience of the countries that had established relevant regulations, including communication aspects. The Committee agreed to hold a physical Working Group in Norway. After some discussion, the Committee agreed that the Working Group would be held in January 2007 in Norway, would be co-chaired by Norway, Argentina and Ghana, and would work in English, French and Spanish.

93. Some delegations expressed their concern with the role and mandate of such a Working Group in relation to the work under consideration in the Committee and stressed that it should not go beyond the mandate of the Codex. Some delegations stressed the need to take into

account the work that had already been carried out in previous years, especially the Proposed Draft Guidelines.

94. Some delegations expressed the view that it was particularly important to take into account the general recommendations set forth in the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. Other delegations pointed out that this proposal was too restrictive and that all relevant Codex texts should be taken into account, especially as regards labelling, and that the focus of the discussion should remain on labelling issues, in conformity with the mandate of the Committee.

95. After some further discussion, the Committee considered the proposed terms of reference prepared by a group of countries[11] and agreed on the following objectives and terms of reference for the Working Group.

[11] United States, Canada, Thailand, India, EC and the co-chairs of the proposed working group, Norway, Argentina and Ghana

96. The objective of the Working Group is to assist the Codex Committee on Food Labelling with guidance relating to the further development of the Draft Proposed Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification-Genetic Engineering.

Within the mandate of Codex, the Working Group shall address the following areas:

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods.
5. The output CCFL may require to respond to items 1-4 above.

97. The Committee agreed that in undertaking this work, the Working Group should take into account information presented in:

- Existing proposed draft texts on the labelling of foods and food ingredients obtained from certain techniques of genetic modification/genetic engineering prepared by the Codex Committee on Food Labelling, and associated comments and committee reports.
- Relevant Codex texts such as, but not limited to, the Codex Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, particularly those sections relating to risk management and risk communication.
- The WHO document 20 Questions on Genetically Modified (GM) Foods.

98. The Committee agreed that the Working Group would be held in January, 2007, and its report would be presented at the 35th Session of the CCFL. The Circular Letter requesting information on items 1 to 4 above should be issued to provide sufficient time for responses to be received in advance of the January, 2007 Working Group meeting.

99. The Committee noted that many delegations and observers expressed their interest in

participation in the Working Group[12] and recalled that physical working groups were open to all members and observers. For practical reasons, it was recommended that delegations should not exceed two participants

Status of the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering): Definitions

100. The Committee agreed to retain the Draft Amendment at Step 7.

Status of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions

101. The Committee agreed to retain the Proposed Draft Guidelines at Step 4 pending consideration of the report of the Working Group established at the present session.

2007 (35)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING (Agenda Item 5)

DRAFT AMENDMENT TO THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS* (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING): DEFINITIONS (AT STEP 7) (Agenda Item 5a)

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 5b)[10]

[10] CX/FL 07/35/8 (report of the Working Group)

98. The Committee recalled that its last session had agreed to establish a physical working group co-chaired by Argentina, Ghana and Norway to be held in Norway between the sessions, and that the Draft Amendment and Proposed Draft Guidelines had been held respectively at Steps 7 and 4 pending consideration of the report of the working group.

99. The Delegation of Norway indicated that the Working Group had identified seven approaches to the labelling of GM/GE foods and considered the rationale for the members' approach to each individual approach. Some delegations had expressed the view that consideration should be given to the reasons why countries chose not to adopt a certain approach, and to the cost and benefit aspects of each approach. The Working Group had identified nine possible options for further action by the Committee but had not considered them in detail as this was for the plenary session to decide.

100. The Delegation of Ghana informed the committee that co-chairing the working group had been a very useful experience, and had allowed to raise awareness of Codex issues in Ghana.

101. The Delegation of Argentina expressed its appreciation to its co-chairs and to the working group and its satisfaction for the convening of the meeting and the mandate that was sufficiently broad to encompass the reasons for the different views regarding the labelling of foods derived from GM/GE, and noted that the discussion had been very useful in order to understand the rationale for the positions taken by governments on the labelling of GM/GE foods. The Delegation however pointed out that several questions had not been discussed, in particular the positive and negative aspects of each possible approach; technical and economic viability; and the costs of implementation, especially for developing countries.

102. Many delegations expressed their appreciation to Norway, Argentina and Ghana respectively for hosting and co-chairing the working group, as it had provided a very useful opportunity to discuss the fundamental approaches to the labelling of GM/GE foods as well as the practical experience of governments at the national level. Several delegations stated that although the working group had been a very useful forum, it had also served to further highlight the lack of consensus on approaches to GM/GE labelling.

103. The Committee had a general discussion on the outcome of the working group and considered how to proceed further with the consideration of this issue.

CX/FL 07/35/8
Report of the CCFL Working Group on Labelling of Foods and Food Ingredients obtained through certain techniques of Genetic Modification/Genetic Engineering
Oslo 6-7 February 2007

1. The Working Group on Labelling of Foods and Food Ingredients obtained through certain techniques of Genetic Modification/Genetic Engineering established by the 34th Session (May 2006) of the Codex Committee of Food Labelling convened in Oslo, Norway on 6-7 February 2007. The meeting was co-chaired by Professor Josephine Nketsia-Tabiri (Ghana), Mr Federico Alais (Argentina) and Mr Kjetil Andreas Tveitan (Norway), and was attended by 60 delegates representing 25 member governments, 1 member organization (EC), WHO and 6 observer organizations. The list of participants is attached as Appendix I.

2. The Working Group was mandated to assist the Codex Committee on Food Labelling with guidance relating to the further development of the *Draft Proposed Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification-Genetic Engineering.* Within the mandate of Codex, the Working Group should address the following areas:

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification /genetic engineering with particular reference to how Members label these foods.
5. The output CCFL may require to respond to items 1-4 above. The Committee agreed that in undertaking this work, the Working Group should take into account information presented in:

- Existing proposed draft texts on the labelling of foods and food ingredients obtained from certain techniques of genetic modification/genetic engineering prepared by the Codex Committee on Food Labelling, and associated comments and committee reports.
- Relevant Codex texts such as, but not limited to, the Codex *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account* and the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius,* particularly those sections relating to risk management and risk communication.
- The WHO document *20 Questions on Genetically Modified (GM) Foods.*

3. The co-Chairs reviewed the mandate of the Working Group, informed the group of comments received from 14 member governments and 1 Member Organization (the EC) following the circular letter and invited open discussion. The group was invited to identify the main problems and share relevant experiences.

Identify the current standards, regulations, acts/decrees, etc.

4. Based on comments submitted and discussions, the working group identified the following approaches in member states to GM labelling [2]:

1. Mandatory GM[3] labelling as such of all foods derived from or containing ingredients derived from organisms produced using gene technology (food consisting of, containing

or produced from GMOs)
2. Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food.
3. Mandatory GM labelling as such of GM food where it is significantly different from its conventional counterpart and where GM labelling is required in addition to the significant change
4. Mandatory labelling of GM foods where it is significantly different from it conventional counterpart and where only the significant difference is labelled, but not the method of production
5. Voluntary labelling (Voluntary labelling guidelines for foods that are or are not products of genetic engineering).
6. No special labelling requirement for bioengineered foods as a class of foods
7. Labelling Requirements Under Development

[2]Countries may use more than one approach in labelling GM food
3"Genetically modified/engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by dultiplication and/or natural recombination.

5. The working group noted that a country's labelling requirements might be covered by several of the above listed categories and that the discussion did not cover exemptions or exclusions from these regulations. The categories may not fully reflect the situation in different countries and do not reflect the full complexity.
6. Some delegations objected to the inclusion of "labelling requirements under development" given that the working group should only address current regulations, while other delegations believed it should be kept as it reflected their current situation. It was further underlined that the lack of guidance given by Codex was an important reason explaining why some countries, especially developing countries, still had their labelling requirements under development.

Consideration of the rationale for Members' approach

7. The co-Chairs invited members to explain the rationale behind their regulations in the different approaches. For the purpose of ordering the discussion countries were asked to only explain the rationale behind their own approach and not comment upon the approach of other countries. The intention was to identify the various rationales and not seek consensus on this item. Rationales were given during the plenary meeting and handed in during the afternoon.
8. It was noted that when a country chooses a certain labelling regime, it also considers and rejects other possibilities (pros and cons). As there was insufficient time for a country to present its entire rationale the discussion was limited to why a country chose a certain approach and not why another approach was not considered suitable. Further there was no exchange of views regarding technical feasibility, economic costs of implementing labeling regimes, or proportionality of the adopted measures or their impact on the consumers' right and demand to make an informed choice. These subjects could not be explored within the time frame of the WG.

Approach 1

9. Mandatory GM labelling as such of all foods derived from or containing ingredients derived from organisms produced using gene technology (food consisting of, containing or produced from GMOs).

The following views were presented:

I. The main rationale behind this is based on the CAC mandate from 1991 ALINORM 91/40 paragraph 90,[4] and the consumers' right to make an informed choice. The aim is to meet the demands expressed in consumer surveys, and it is the only approach which allows consumers to choose according to the method of production i.e. between GM and non GM foods.

[4] 88. In considering document ALINORM 91/11, the Commission recalled that the issue of biotechnology was first discussed in 1989 during its 18th Session. At that time, the Commission had been informed of an initiative of WHO to convene, jointly with FAO, a Consultation on the Assessment of Biotechnology in Food Production and Processing as Related to Food Safety. This Consultation had taken place in Geneva in November 1990 and the Report of it would be available, as a formal WHO publication,

at the end of 1991. The Consultation had recognized biotechnology as a continuum, embracing traditional breeding techniques and modern techniques based on recombinant DNA - technologies. "Modern" biotechnologies had the potential of revolutionizing the food supply, both in quantity and quality. While the Consultation was of the opinion that foods derived from
"modern" biotechnologies were inherently not less safe than those derived from traditional biotechnologies, the issue of safety had to be considered. In addition, nutritional concerns may have to be addressed.
89. Based on scientific and technical advice by Joint FAO/WHO expert committees and consultations, the Codex Committees on Nutrition and Foods for Special Dietary Uses, on Food Labelling, on Food Additives and Contaminants and on Food Hygiene were expected to be the main committees with responsibilities for matters on biotechnologies. In addition, several commodity committees (e.g. Vegetable Protein, Cereals, Pulses and Legumes, Fish and Fishery Products, Fats and Oils) might need to play a role in reaching international consensus on particular novel foods.
90. The Commission endorsed the conclusions and recommendations of the Joint FAO/WHO Consultation. It noted that while consumers would benefit from "modern" food biotechnology, some consumers felt that this technology would pose certain problems. For example, individual consumers might, on ethical or other grounds, not wish to buy foods derived from "modern" biotechnology. The Commission requested the Codex Committee on Food Labelling to provide guidance on how the fact that a food was derived from "modern" biotechnologies could be made known to the consumers.
91. The need to provide consumers with sound, scientifically based information which explained the application of biotechnology in food production and processing and clarified the safety issues was stressed. In this context, the Commission was informed that WHO was exploring possibilities to prepare a book on food biotechnology for the non-technical reader which would be based on the report of the Joint FAO/WHO Consultation.
92. The Commission endorsed the views expressed by its Executive Committee and agreed that the Commission should monitor developments in the field of food biotechnology and that the General Subject Committees identified above should discuss issues related to biotechnology within the context of their Terms of Reference (see ALINORM 91/4, para. 34). The Commission requested WHO to make copies of the Consultation report available to all Codex Contact Points. A progress report is to be presented to the 20th Session of the Commission.

II. This approach secures transparency and facilitates the consumer's right to informed choice. It is enforceable in combination with a traceability system and also in compliance with Codex Standards for labelling.
III. It was stated that the safety assessment is an integral part of the mandatory GM labelling requirements. These requirements are proportionate as they take into account the demands of consumers and the economic concerns of industry and they apply to both locally produced and imported foods.
IV. Mandatory GM labelling also highlights the intrinsic qualities of GM foods in comparison with their conventional counterparts (e.g. fewer pesticides).

Approach 2

10. Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food.

The following views were presented:

I. The main rationale behind this is to allow consumers to purchase food based on its actual content, rather than the process by which it was made. It was stated that it prevents consumer deception by only requiring labelling when GM material is present in the final food and thus allows consumers to make an informed choice. The category provides adequate consumer information commensurate with national demands for information.
II. It is enforceable because it avoids requiring labelling of food that does not contain novel DNA or protein which cannot be verified by analytical methods, since there is no current testing available for distinguishing between GM foods and non-GM foods when there is no novel protein or DNA present in the final food.
III. It does not impose additional costs on industry and enforcement agencies due to tracking origin of ingredients which could not be justified on the basis of a cost benefit analysis.
IV. The mandatory GM labelling requirements are related to full implementation of a safety assessment and are not based on safety.

Approach 3

11. Mandatory GM labelling as such of GM food where it is significantly different from its

conventional counterpart and where GM labelling is required in addition to the significant change. The following views were presented:

I. The main rationale is to state that a food has been genetically engineered or genetically modified and the label specifies the difference (composition, nutritional change, use) and it is mandatory to indicate that it is a GMO product.
II. Novel foods, including those produced through biotechnology or genetic engineering, are subjected to comprehensive health and safety requirements.

Approach 4

12. Mandatory labelling of GM foods where it is significantly different from its conventional counterpart and where only the significant difference is labelled, but not the method of production.

The following views were presented:

I. The main rationale is food safety linked to labelling of the significant difference and not method of production. It does not require the words GM or GE on the label. It was argued that consumers should be informed about any significant change in the food and not the method of production. The important element of information is the substantial difference a food may have as compared to its conventional counterpart.
II. Novel foods and GM products are subjected to comprehensive health and safety requirements. If the assessment demonstrates that a GM product is found to have undergone a change in composition, nutrition, toxicity or allergenicity consumers need to be informed, and mandatory labelling informs about these changes. This approach informs consumers about material facts related to the use of the product without misleading the consumer when there are no differences between similar foods based on the method of production. It allows use of labelling as a measure to communicate possible risk to consumers, as a result of a scientifically based risk assessment of the food and is the only approach that has a scientific basis.
III. This approach provides consumers with information to manage their diet and ensures transparency to garner consumer trust.
IV. This approach is consistent with existing Codex standards for mandatory labelling and is enforceable.
V. It retains proportionality between the measure and the risk, and is technically and economically viable for developing countries.

Approach 5

13. Voluntary labelling (voluntary labelling guidelines for foods that are or are not products of genetic engineering).

The following views were presented:

I. Voluntary labelling allows the industry to use labelling as a measure to communicate different aspects; for instance if there is a market advantage to provide such labelling. In this regard, food producers and manufacturers may voluntary label their products, provided the label is truthful, not misleading, and in compliance with all domestic regulatory requirements.
II. Voluntary labelling provides guidance that will assist consumers in making an informed choice, while allowing the agri-food industry the flexibility to make appropriate business decisions in response to market demands. It responds to specific niches or groups to be able to differentiate between their products and addresses the potential market demand for GM labelling information. It allows positive and negative labelling on the basis that the claim is factual and not misleading.
III. This labelling can coexist with mandatory labelling (e.g. mandatory positive labeling and voluntary negative labelling). It allows the possibility of using both positive and negative labelling.
IV. This approach allows the development of regulations that provide a net benefit to consumers. Consumer research indicates that mandatory labelling is not required and that voluntary

labelling is sufficient for the method of production.

V. The benefits of this approach outweigh the cost, and the regulatory burden authorities introduce is the required minimum to meet regulatory needs.

Approach 6

14. No special labelling requirement for bioengineered foods as a class of foods.

The following views were presented:

I. Codex General Labelling Standards are applicable to all food classes including bioengineered foods.

II. There is no information showing that bioengineered foods differ in any meaningful or uniform way, or as a class present any different or greater safety concern than foods developed by traditional plant breeding. Therefore standards/ regulations are based on the GMOs' identified characteristics and risks, rather than the process by which the GMOs originated. In other words, the system addresses GMOs in terms of the proposed use, considering only those aspects in the procedures for obtaining them that might mean a risk to the environment, agricultural production or public health.

III. This approach informs consumers about material facts related to the use of the product without misleading the consumer when there are no differences between similar foods based on method of production. It ensures transparency to garner consumer trust.

IV. This approach incorporates criteria that are enforceable. It retains proportionality between the measure and the risk, and is technically and economically viable for developing countries.

Approach 7

15. Labelling requirements under development.

The following views were presented:

I. This category covers members which currently have labelling requirements under development which are yet not established, but may be before parliament or because of administrative procedures, are being worked on.

II. Countries are awaiting a decision by Codex on the development of a GM standard. Their national legislation can be aligned with international standards as these countries are not able to develop regulations alone, and thus they are awaiting a steer from Codex. Countries are afraid they might be sanctioned because they have not complied with recommendations made.[5]

III. Reference was made to report 0629/22 paragraph 91[6].

[5] There is no internal agreement on the thrust of the national legislation or approach. *It was therefore noted that this is not a reason for deferring taking a decision at a national level for countries that want to take a decision to avert any possible risk, e.g. not providing info to consumers on GMs*

[6] "Some delegations stressed the importance of CODEX recommendations in order to provide guidance to developing countries as it would facilitate the establishment of national policy or requirements concerning labelling of GM/GE foods and therefore supported further work in this area"

16. Consumer interests were used as the rationale in several of the approaches and the WG noted that Consumers in each member country may not share the same concerns. Countries have different concerns and so do the different consumers around the world.

17. An observer organization pointed out that a consumer world congress expressed the request for mandatory labelling of all foods derived from or consisting of GMOs.

Identify Members' practical experiences

18. The co-Chairs invited the group to look at practical experiences and suggested that countries share their experience without repeating what had already been submitted (attached appendix II).

19. Delegations informed the working group of their varying practical experiences, and the following elements were presented:

I. Countries have approval systems and the primary aim of these systems is to make sure that GM food on the market is safe through a risk assessment. Details were given about a consultative process between authorities and the companies wanting to introduce a product derived from biotechnology.

II. The need to provide consumers with comprehensive information.

III. The labelling system has to be economically viable following a cost benefit analysis.
IV. Several countries are monitoring the GM field; reports are available on the Internet (see attached comments to the CL). Members conduct open consultations involving consumers and all stakeholders on different aspects concerning labelling.
V. Countries that are monitoring labelling requirements argued that enforceable legislation meets a high level of compliance. Any action of non-compliance would be in response to complaints to a food inspection agency regarding false and misleading advertising.
VI. Traceability can be used as a tool for monitoring labelling and traceability can be used to monitor the documentation which accompanies food.
VII. The appropriate role of governments should be considered before intervening in labelling. Governments might choose leaving voluntary GM labelling to the industry, however the label must not be false or misleading.
VIII. Some countries informed about having few products on the marketplace.

Identify communication strategies

20. The Co-Chairs invited the Working Group to discuss communication strategies with particular focus on results of information campaigns etc. without repeating details from their written submissions (see appendix II).

21. Members explained their communication strategies which showed a wide range of strategies and measures in the different member countries.

Countries explained that their strategies and measures included:

I. objective information to consumers and stakeholders on techniques of genetic modification, their implication on health (e.g allerginicity, nutrition,) and the legal requirements regarding their production, marketing and labelling;
II. public consultations, surveys and activities in the process of developing guidelines and regulations and publications of official reports on basis of feedback;
III. information and guidance on regulations in terms of lectures, work-shops, multistakeholder meetings, conferences and laymen's conferences;
IV. communication materials in terms of fact sheets, booklets, news releases, web sites and web-based information to help the general public gain a better understanding of genetic modification, its use in food production and labelling requirements;
V. consumer research (public opinion research) as important instruments to review consumer behaviour and as an opportunity to consider whether the authorities are providing consumers with information which is useful to them. It was also pointed out that the authorities have a responsibility to understand how consumers use the information and to ensure they are making correct judgments;
VI. education sessions for industry and stakeholders
VII. industry user guides (which outline labelling requirements and provide information on how industry can determine whether they have a labelling obligation and how they ensure ongoing compliance);
VIII. Labelling is considered as a part of the communication strategy

22. Different views were expressed as to whether GM labelling was misleading or informing the consumer. It was argued that labelling two identical products based only on method of production would be misleading as many consumers would perceive this as a safety or health warning, even though the food had undergone a safety assessment and been found to be safe. It was also stated that the primary responsibility of the authorities in adopting standards is to protect consumers given that there is no different safety risk in GM food compared to conventional products. Adopting general labelling standards for products derived from GMO may be interpreted as a disproportionate measure. It was also claimed that consumers' negative perception needs to be changed with more education rather than with measures contributing to this perception.

23. On the other hand, it was argued that foods derived from biotechnology have been assessed for safety prior to approval for marketing and thus labelling only informs the consumer of the method of production in order to allow informed choices. It was also stated that the authorities should not decide what information the consumers want.

24. It was argued that "communication strategy" is a complex issue; particularly in some developing countries were you might find a high level of illiteracy and communication has to be adapted for various conditions and regions. One delegation stated that the authorities have to make decisions based on what is in the market place and what information should be provided to the consumer when the public's capacity to understand such complex issues is restricted. Others argued that in this discussion, illiteracy cannot be the basis on which to base guidelines since illiteracy is also associated with a lack

of specific knowledge.

The output to CCFL – possible ways forward

25. The co-chairs invited the working group to focus on the output for CCFL and to outline some possible ways forward to deliver to CCFL. The following possibilities were listed by various participants at the working group:

1. Discontinue work on this agenda item
2. Distil common principles and themes which we could agree to take forward
3. Develop general horizontal overarching principles which would be consistent with all the GM approaches presented by members.
4. Refer back to the CAC
5. Share the experience we have gathered in the last two days with CCFL
6. Continue working on the draft guidelines taking into consideration the outcome of the working group based on information shared by the working group members
7. Discontinue work related to consumer information which should be based on national legislation
8. Continue work related to consumer information.
9. Focus on guidelines for labelling of GM foods where there is a significant difference from its conventional counterpart where only the significant difference is labelled.

26. *Discontinue work on this agenda item.* It was stated that this seemed to be one way forward considering CCEXEC 55th session[7]. Work on this item has been going on for the past 15 years without any result and thus continuing this work is wasting the scarce resources of Codex. It is not possible to apply universal labelling standards as consumers are different and they have different concerns. It was further noted that the question of cost-benefit analysis regarding labelling had not been touched on. Another comment presented was that suspension rather than discontinuation of work might be a preferable option leaving then time for science to provide new facts which could facilitate the establishment of a consensus on a certain approach.

[7] 41. The Executive Committee agreed to give a general recommendation to Codex Committees to make all efforts to achieve progress on controversial issues, and, if progress was slow or consensus was unlikely to be reached, to consider the following options: redefining or narrowing the scope of the text, concentrating on the areas where consensus could be reached; suspending consideration of the issue for a period of time; or discontinuing the work.

27. *Distil common principles and themes which we could agree to take forwar*d. It was requested that the CCFL explore a way to capture information given in this Working Group, make it more widely available and look at common principles which unite rather than divide us.

28. *Develop general horizontal overarching principles which would be consistent with all the GM approaches presented by members. S*ome horizontal principles were presented by a delegation as examples of principles which could be further explored by CCFL and these principles could address issues related to: food safety, e.g. change in composition of nutritional properties, allergenicity etc., different consumer needs and various levels of approaches regarding labelling, the consumer's basic rights to information; appropriate control measures to prevent false and misleading labelling and the limitations of developing countries. The principles were not considered by the Working Group.

29. *Refer back to the CAC.* It was noted that CCFL would not comply with its mandate from 1991 to provide guidance to governments if they failed to develop relevant guidelines. However reference was made to ALINORM 97/3 1997[8] claiming that the consumer's right to know was "ill defined".

[8] 29. In the matter of the proposal to initiate the preparation of proposed draft guidelines for the labelling of foods prepared with the aid of biotechnology, the Executive Committee stressed that the Four Statements of Principle should be closely adhered to. It noted the opinion claiming that while consumers may claim the right to know whether or not foods had been prepared by such means, it also noted that the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling. The Executive Committee stated that there were certain elements which clearly had to be taken into account when considering the labelling of foods in relation to production processes. Foremost among these was the protection of consumers' health from any risks introduced by the production process, followed by consideration of any nutritional implications which resulted from changes to the composition of the food, by any significant technological changes in the properties of the food itself, and the prevention of deceptive trade practices. To a considerable extent such matters would have to be decided on a case-by-case basis. The Executive Committee noted that there was always the possibility of voluntary labelling.

30. *Share experience we have gathered in the last two days with CCFL.* The experiences gathered on communication strategies during the WG could provide guidance to developing countries.

31. *Continue working on the draft guidelines taking into consideration the outcome of the working group based on information shared by the working group members.* The guidance which the WG can

offer CCFL can emerge from the information shared, and can ensure that the draft guideline is continued. Some developing countries indicated this was important for them while other delegations noted that existing Codex labelling texts provided sufficient guidance."

32. *Discontinue work related to consumer information which should be based on national legislation.* Codex's main objective is to protect health thus the consumers' right to know information should be left to national legislation.

33. *Continue work related to consumer information*. Much of the work in CCFL is about consumer issues, thus CCFL has to continue work on consumer information. The mandate of Codex is to protect the health of consumers and ensure fair practices in the food trade; however, it is important to continue working with questions relating to information for consumers.

34. Focus on guidelines for labelling of GM foods where there is a significant difference from its conventional counterpart where only the significant difference is labelled but not the method of production. One possible way forward could be to identify guidelines for labeling significant differences where there is a change as regards nutrition, use and .composition.

35. There was an extensive discussion on how the working group should move its discussions forward to the CCFL and what should be included in the report. Many regretted that there was not sufficient time to:

- discuss pros and cons with regard to the labelling regimes (see paragraph 4 and paragraph 8),
- discuss and go further into the rationale for members' approach (see paragraph 7),
- discuss further practical experiences with specific reference to cost benefit (paragraph 17 III),
- exchange more views on communication strategies and their effectiveness.

104. Some delegations informed the Committee that serious concerns were expressed in their countries regarding the safety aspects of GM/GE foods, and also concerning the social and economic consequences of their use in agriculture, especially for small farmers.

105. The Representative of WHO informed the Committee of the extensive work carried out by FAO and WHO as regards safety assessment of foods derived from biotechnology especially through the Joint FAO/WHO expert consultations on foods derived from recombinant-DNA (r-DNA) plants and microorganisms, and genetically modified animals. The Representative also drew attention to the report of the FAO/WHO Expert Consultation on Evaluation of Allergenicity of Genetically Modified Foods (2001) which was particularly relevant to the Committee.

106. The Chair of the *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology, Professor Yoshikura (Japan) informed the Committee that the Task Force had elaborated several texts subsequently adopted by the Commission (2003) to address risk analysis of foods derived from biotechnology, safety assessment of foods derived from recombinant-DNA plants, recombinant-DNA microorganisms, including assessment of possible allergenicity, and that these texts had been developed on the basis of the scientific advice provided by FAO and WHO. Professor Yoshikura also informed the Committee of the current work being undertaken by the Task Force related to low level presence of r-DNA plant material, foods derived from r-DNA animals, and r-DNA plants modified for nutritional or health benefits. He also noted that there was a possible discrepancy between the provisions of paragraph 4.2.2 of the *General Standard for the Labelling of Prepackaged Foods* and paragraph 43 of the *Guidelines for the Conduct of Food Safety Risk Assessment of Foods Derived from r-DNA Plants*.

107. The Secretariat recalled that, in conformity with the Codex mandate, several aspects of foods derived from biotechnology were considered in the relevant committees and the above mentioned Task Force, including food safety, methods of analysis and sampling and labelling. The issues related to agricultural policy and economy were the competence of FAO and were addressed in the programmes developed by FAO to provide guidance to member countries concerning the various aspects of biotechnology in agriculture, including capacity building to allow countries to establish their national framework for policy or regulations.

108. Several delegations recalled that foods derived from biotechnology have to undergo a pre-market safety assessment in order to protect consumers' health and therefore the request

for mandatory GM/GE labelling is not a food safety issue, but an issue related to consumer information. Some delegations expressed the view that labelling was also related to food safety in view of the potential risks to consumer's health. The Observer from 49P noted that a great proportion of GE foods being sold have not been subjected to any governmental safety assessments, and therefore labelling helped consumers make their own decisions about health and safety

109. Several delegations indicated that, in their countries, consumers had no objections in principle to the use of GM/GE foods, but that mandatory labelling was necessary in order to provide clear information to consumers and to allow them to make an informed choice. These delegations and some observers stressed the fundamental right of consumers to know the nature of the food they were consuming.

110. Taking into account the above arguments, many delegations supported further work on GM/GE food labelling in the Committee, in view of the importance of the subject for consumers and in order to provide guidance to governments. Many delegations pointed out that it was especially important as many developing countries relied on Codex recommendations to develop their national policy or regulations in this area. Some delegations recalled that the Committee had received a specific mandate from the Commission in this respect in 1991. It was underlined by several delegations that the consumer right to know and to make informed choices was an essential element of GM labelling. Several delegations further pointed out that the work on GM labelling was consistent with the mandate of Codex. The Delegation of Barbados, supported by the Delegation of Ireland, stated that Codex should not abdicate its responsibility to provide appropriate guidance on GM/GE labelling. The Observers from NHF and 49P expressed their views, based on the comments of the delegations of Norway and France, that since one of the Codex mandates is to ensure fair trade practices, developing guidelines on GM/GE food labelling would be appropriate.

111. Several other delegations expressed the view that mandatory method of production labelling of foods derived from biotechnology was not justified on the grounds of food safety or fair trade practices, and that the consumer's right to know was not one of the objectives of Codex, and referred to the view expressed by the Executive Committee in 1996 to the effect that "the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labeling" (ALINORM 97/3, para. 29). These delegations pointed out that governments had the possibility of requesting mandatory labelling in their national legislation if it fulfilled a legitimate objective but that it should not be imposed to all countries at the international level. In this respect, it was recalled that one of the Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principles was that "some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world wide"

112. Some delegations expressed the view that they supported mandatory labelling of GM foods only to address a food safety or public health issue such as allergenicity, or when a substantial change existed in composition or nutritional value.

113. Several countries expressed the view that this question had been discussed since 1997 in the Step Procedure without any progress, and that in view of the fundamental differences in the approaches taken to such labelling, it was not likely that progress would be made in the near future. These delegations therefore supported discontinuation of work, taking into account the general guidance provided by the Executive Committee in the framework of the Critical Review. Some of these delegations pointed out that consideration of this issue had taken up substantial resources of Codex although it was not related to health and safety and that it would be preferable to concentrate on issues such as the implementation of the Global Strategy in the CCFL. The Delegation of Canada recommended that the Committee refer this item to the Executive Committee for consideration under its Critical Review Process.

114. Several delegations expressed the view that the working group had been very useful but that is had not been able to complete its mandate and that further discussion would be necessary to clarify all the issues raised in the Oslo working group and at the current session, and therefore proposed to hold a new physical working group between the sessions, possibly with more time to allow for comprehensive discussion.

115. Several delegations, referring to one of the options proposed in the Working Group report, suggested considering the development of overarching principles which would be consistent with all approaches to GM food labelling presented by members.

116. The Delegation of the United States expressed that it had been giving consideration to the concerns from developing countries and indicated that there was no need for the development of new guidelines as current labelling texts contained a number of provisions that could be used by governments for the purpose of addressing the labelling of GM/GE foods. The United States therefore proposed to prepare a background paper that would identify such provisions, especially in the General Standard for the Labelling of Prepackaged foods and the General Guidelines on Claims.

117. After some further discussion, the Committee agreed to establish a physical working group between the sessions and agreed that its terms of reference would be the following:

1. The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:
    a. The rationale for adopting or not adopting a particular approach
    b. The communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
2. The undertaking of an analysis of current Codex texts, particularly Codex labelling texts, to evaluate whether or not these texts supply sufficient guidance on the labelling of foods derived from genetic modification/genetic engineering.
3. The consideration of appropriate ways forward, taking into account the result of the analysis undertaken in 2 and the suggestion of the possible ways forward identified by the Oslo WG, (e.g. guidelines, principles or discontinuation of work).
4. The development of an outcome, appropriate to the findings of 2 and 3, taking into account the discussions of the 35th session of the CCFL, the needs identified by developing countries, including those expressed at the 35th session of the CCFL, and the mandate of Codex.

The Working Group will take into account:

a) The outcome of the Oslo Working Group including the report of the Working Group.
b) The report of the 35th session of the CCFL, including the written comments.
c) An informative background paper to be prepared by the United States, Canada and Nigeria on how current Codex texts relate to the labelling of Food and Food Ingredients obtained through certain techniques of genetic modification/genetic engineering.
d) Previous guidance on the labelling of foods derived from genetic modification/genetic engineering by the Codex Executive Committee and the Commission[11].
e) Existing guidance provided in the Codex Procedural Manual relating to the Consideration of Other Factors referred to in the second Statement of Principle.
f) Any other relevant Codex, WHO or FAO texts.

[11] ALINORM 91/40, para. 90; ALINORM 97/3, para. 29

118. The Committee agreed that the Working Group would take place in Ghana in early 2008, would be three days in length and complete its work in sufficient time for the report of the Working Group to be considered by the Codex members in advance of the next Session of the Committee; and that the languages of the meeting would be English, French and Spanish. For practical reasons, it was recommended that delegations should not exceed two participants.

119. It was further agreed that a Circular letter would be issued requesting comments on items 1, 2 and 3 of the terms of the reference. The background paper to be prepared by the US, Canada and Nigeria would be attached to the CL for information.

120. The Committee briefly discussed the status of the Draft Definitions and Proposed Draft

Guidelines. Some delegations proposed to advance the Definitions to Step 8 as they were consistent with the definitions developed by the Task Force on Foods Derived from Biotechnology and included in the Cartagena Protocol. Other delegations pointed out that the definitions had not been discussed for several sessions, that there had been no consensus earlier to finalise them, and that they were also included in the Proposed Draft Guidelines, and should not be finalised separately. The Committee recognised that there was no consensus to advance the definitions to Step 8.

Status of the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods* (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering): Definitions

121. The Committee agreed to retain the Draft Amendment at Step 7.

Status of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions

122. The Committee agreed to retain the Proposed Draft Guidelines at Step 4 pending consideration of the report of the Working Group established at the present session.

123. The Committee agreed that the time frame for the completion of this work was four years.

2008 (36)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING:

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING): DEFINITIONS (AT STEP 7) (Agenda Item 5a) & **DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING): LABELLING PROVISIONS** (Agenda Item 5b)

75. The Committee recalled that its last session had agreed to establish a physical working group cochaired by Argentina, Ghana and Norway to be held in Ghana between the sessions and that the Draft Amendment on the Definitions and the Proposed Draft Labelling Provisions had been held respectively at Steps 7 and 4 pending consideration of the report of the working group.

76. The Delegation of Ghana introduced the report of the working group and expressed its thanks to its co-Chairs, Argentina and Norway, and to all participants for their active contribution to the discussion. The Delegation indicated that the working group had considered the rationale for different approaches to GM/GE labelling adopted by national governments, the communications strategies used in communicating information to the public on GM/GE foods; and an analysis of current Codex texts which may provide guidance on the labelling of GM/GE foods, as presented in a background paper considered by the working group (CL 2007/38-FL). Several key concepts derived from this paper were identified, modified and brought together in a draft document (Appendix III of CX/FL 09/36/8). The working group had discussed the possible title and proposed alternative texts for chapeau statements but had not reached consensus on the text. The Delegation of Argentina, as co-Chair, explained the process that the working group had followed to consider this subject, after identifying three main proposals in the course of its discussions.

77. The Committee expressed its appreciation to Ghana for its kind hospitality in hosting the working group and to the three Co-chairs, Ghana, Argentina and Norway for their chairmanship that had allowed the working group to make substantial progress on complex issues. The Committee considered how to proceed further in the light of the report of the working group.

REPORT OF THE WORKING GROUP ON THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING

1) In accordance with the decision of the 35th Session of the Codex Committee on Food Labelling[1], a physical Working Group (WG) on the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering (GM/GE) convened in Accra, Ghana, January 28 – 30, 2008. The WG was co-chaired by Professor Josephine Nketsia-Tabiri (Ghana), Dr. Andrea Nilda Calzetta Resio (Argentina) and Mr. Kjetil Andreas Tveitan (Norway) and was attended by 84 delegates representing 25 Member countries, 1 member organization (EC), the WHO and 5 Observer Organizations. A complete list of participants is attached as Appendix I to this report.

[1] ALINORM 07/30/22, Report of the 35th Session of the Codex Committee on Food Labelling, para. 117.

2) The meeting was opened by Professor Samuel Sefa-Dedeh, Vice-Chair of Ghana's National Codex Committee. The WG co-chairs reminded participants of the Terms of Reference of the WG, contained in CL 2007/38-FL and the written comments that were submitted in response to the Circular Letter (Appendix II). In particular, they drew the attention of WG participants to the written comments from Costa Rica, Mexico and Thailand who were not present at the meeting.

Adoption of the agenda:

3) WG participants were invited to adopt the provisional agenda. Although a proposed amendment was discussed, the WG agreed to adopt the provisional agenda as originally presented while limiting the time allocated to discussion of the rationale which had previously taken place at the Oslo WG meeting (Oslo, Norway, February 6-7, 2007).

Consideration of the rationale for different approaches to GM/GE labelling adopted by national governments:

4) Following an exchange of views on the rationale for the adoption of different approaches to the labelling of foods and food ingredients obtained through certain techniques of GM/GE, it was recognized that a variety of approaches have been adopted by countries, depending on their respective regulatory framework, consumers' preferences, and other factors. These approaches ranged from no labelling, to voluntary labelling, to mandatory labelling when there are significant changes to composition or use, to mandatory labelling of all foods and food ingredients obtained through certain techniques of GM/GE, and/or a combination of approaches. It was noted that what is applicable in one country may not be appropriate in another. Some delegations clarified that their labeling regimes had been developed following extensive consultations and taking into account various factors such as health and safety considerations, legislative authorities, consumers' preferences and outcomes of cost/benefit analyses.

5) There was agreement that labelling regimes are not a substitute for pre-market safety assessments. Several countries further noted that GM/GE foods undergo rigorous safety assessments before being allowed on the market.

The communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering:

6) Members exchanged information on their respective communication strategies and tools, noting that communication needed to be a two-way process. These tools included internet/web-based information, public media, information brochures and flyers, education in schools and universities, parliamentary committees, public consultations and workshops, public opinion research, and radio programs including call-in programs. The information provided included aspects relevant to labelling and to other biotechnology-related information. Sources of communication included governments and non-governmental organizations. The delegation of Norway expressed the view that the label is the tool upon which consumers rely to make informed choices.

Presentation of the analysis of current Codex texts, particularly Codex labelling texts, to evaluate whether or not these texts supply sufficient guidance on the labelling of foods obtained through certain techniques of GM/GE:

7) The United States, Canada, and Nigeria presented an overview of their analysis of current Codex texts[3] (background paper) that may provide guidance on the labelling of food and food ingredients obtained through certain techniques of GM/GE. In their presentation, these countries noted that existing Codex texts have several provisions that address labelling of foods, including GM/GE foods. Four key issues related to GM/GE foods that have been raised during CCFL discussions were highlighted: 1) provide consumers with necessary health and safety-related information about the food (such as the presence of allergens); provide consumers with information related to the significant differences in composition, characteristics, nutritional properties, or intended use of the food; 3) protect consumers from false and misleading labelling information; and 4) ensure truthful and non-misleading information related to consumer preferences. [3] Annex I of CL 2007/38-FL, Appendix II of this report.

8) Following the presentation, a number of delegations expressed their views on the analysis and whether existing Codex texts provide sufficient guidance with respect to the labelling of GM/GE foods. Many delegations indicated that the background paper was very useful. There was general recognition that existing Codex texts provide adequate guidance in those situations where the genetic modification results in significant compositional and/or nutritional changes or in the introduction of an allergen. However, there was a divergence of views as to whether those texts provide sufficient guidance for the establishment of a labelling regime for foods and food ingredients obtained through certain techniques of GM/GE, particularly in response to consumer preferences.

9) A number of delegations considered the background paper as a good starting point for further discussion and consideration of gaps in existing Codex texts. The delegation of Norway expressed the view that consumers' right to know had not been clearly addressed in the paper. Other delegations were of the view that the background paper represented areas where there is consensus and the gaps referred to by other delegations reflect gaps in existing Codex texts and not gaps in the background paper. They also expressed concerns about discussing gaps which might lead into areas that had been extensively discussed in previous years and where no consensus had been achieved and would not likely be achieved.

Discussion of Proposed Ways Forward

10) Several proposals were put forth, many of which revolved around how to use the information in the background paper. Proposals included: extracting key concepts from the background paper and from comments submitted in response to CL 2007/38-FL, using the background paper to develop guidelines, recommending to CCFL that the 2008 CCFL report include a summation of existing Codex texts that are applicable to GM/GE labelling, use the background paper to develop a compendium of applicable Codex texts, making the background paper an official Codex document and filling in the gaps, and recommending that FAO and WHO develop guidance manuals on how to establish labelling regimes, including for GM/GE labelling.

11) The delegation of Ghana, supported by several delegations, expressed the view that a compilation of Codex texts providing guidance on the establishment of a labelling regime applicable to GM/GE foods would be desirable. The delegation further added that detailed guidance on how to label GM/GE foods, such as wording to use, where text goes on the label, etc., would be helpful.

12) Other delegations noted, however, that it would be difficult to move forward with more specific text in view of the differences in regulatory approaches/frameworks and varying consumer preferences amongst countries. One delegation noted that a section of the General Standard for the Labelling of Prepackaged Foods (GSLPF) provides guidance on presentation of mandatory label information.

13) The co-chairs summarized the discussion, identifying three main proposals that seemed to have emerged from the deliberations:

- Extract key concepts from the background paper and from the comments received in response to CL 2007/38-FL;
- Use the background paper as a starting point and develop guidance/principles on how to label foods and food ingredients obtained through certain techniques of GM/GE techniques;
- Recommend that the 2008 CCFL report include a summation of Codex labeling texts

applicable to GM/GE labelling.

14) The co-chairs suggested that WG participants reflect on these proposals and develop specific wording for further consideration by the WG. Subsequently, a number of key concepts derived from the background paper were identified and brought together in a draft document, with further clarifications relevant to the labelling of unpackaged/non-retail foods.

15) It was indicated that a title, a chapeau statement and a purpose for the document should be identified. Texts for chapeau statement(s) were proposed and discussed, resulting in the two Chapeau statements reflected in Appendix III*. A number of delegations supported Chapeau 1, expressing the view that it contained a number of important concepts such as recognition of consumer preferences and that these may vary from country to country. Other delegations expressed support for a simple, overarching statement of purpose as contained in Chapeau 2, noting that safety and consumer preferences are already covered within the subsequent text and, thus, need not appear in the Chapeau statement. The WG could not reach consensus on which of the Chapeau statements should be included in the text as the preamble.

** See Appendix VII of Report of this CCFL Session (2008) for Appendix III of this WG report*

16) The delegations of Canada and the United States did not support the inclusion of paragraph 1 of chapeau 1 since it contained concepts on which consensus had not be achieved in previous years and would not likely be achieved in the future.

17) Following the discussion of the chapeau statements, proposed modifications were made to the texts extracted from the background paper. These modifications are reflected in Appendix III, as underlined text. It was noted that due to time limitations, there was insufficient opportunity to consider the body of the document in detail. Therefore, these various modifications, as recorded in Appendix III, have not been fully discussed or agreed to.

18) The delegation of Kenya stated that, based on current science, allergens could also be created through techniques of GE/GM, and proposed to include wording to that effect either in the text or as footnote to paragraph no. 5 of Appendix III, since the proposed text was taken from the Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) and refers only to the transfer of genes from commonly allergenic foods.

(Note: paragraph numbers 19-20 are missing in this WG report)

21) Noting that one of the proposed modifications to the extracted text included the deletion of the reference to the *Statements of Principle Concerning the Role of Science in the Codex-Decision Making Process and the Extent to Which Other Factors are Taken into Account*, an observer organization expressed the view that this reference should be reinstated in the text as it was in the Procedural Manual. The Secretariat clarified that texts in the Procedural Manual, including *the Statements of Principle Concerning the Role of Science in the Codex-Decision Making Process and the Extent to Which Other Factors are Taken into Account*, are intended as guidance to Codex Committees and were not intended for application by governments.

22) The WG further noted that Codex could recommend that FAO/WHO develop guidance or manuals on how to establish a labelling regime which would include guidance on the labelling of GM/GE foods.

23) With respect to the text developed by the WG, the EC stated its preference that it becomes an official Codex document. The EC also clarified that all their interventions were made on behalf of all Member States present at the meeting.

24) In response to enquiries about the outcome of the meeting and the status of the text contained in Appendix III, the Secretariat clarified that the outcome of the meeting would be forwarded to the CCFL for its consideration, and Appendix III had no status in the Codex step procedure. It would be the decision of the 36th Session of the CCFL as to whether the text would be further discussed and/or subsequently introduced into the step procedure.

25) The WG briefly discussed the status of the *Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering*, currently at Step 4, and decided not to forward any recommendations to the CCFL in that respect.

Conclusion

26) Appendix III is forwarded to the Codex Committee on Food Labelling for consideration by its 36th Session.

27) The co-chairs and other participants expressed appreciation for the efforts of the WG.

28) The WG meeting concluded with the recognition by the co-chairs and WG participants of Ghana's

contribution in hosting the meeting and its excellent hospitality.

78. Some delegations referred to their experience at the national level in the development of regulations on GM/GE labelling and noted that the background paper had been useful for this purpose or that they would use it in the future. The Committee expressed its appreciation to the delegations of the United States, Canada and Nigeria for this useful and excellent document.

79. The Delegation of the United States pointed out that the background paper was intended to address the need of member countries, especially developing countries, for guidance on the labelling of GM/GE foods and addressed four key issues: providing consumers with necessary health and safety-related information; providing consumers with information related to the significant differences in composition, characteristics, nutritional properties, or intended use of the food; protecting consumers from false and misleading labelling information; and ensuring truthful and non-misleading information to meet consumer demand. The Delegation further noted that in the working group held in Norway it was evident that countries had taken different approaches due to the different legal, regulatory and social frameworks. Such differences were an indication that such work should not be continued in Codex. The Delegation indicated that it was possible to respond to the 1991 request of the Commission and therefore proposed that this document be forwarded to the Commission, as it could be used by governments as guidance regarding labelling of GM/GE foods and that the Committee should discontinue work on the development of a Codex text, as this item had been considered for many sessions and there was no prospect of reaching consensus. The Delegation stated that Appendix III was not an adequate basis for discussion as it was a simplification of the background document and included some areas where the Committee had failed to reach consensus. Several delegations and Observers supported this position.

80. Some delegations pointed out that mandatory labelling would substantially increase the costs of food production for the manufacturers and negatively affect the availability of foods, which would especially affect developing countries and low income consumers, especially in view of the increase in the price of food commodities at the international level.

81. Many other delegations and some observers supported further work on GM/GE food labelling, especially further consideration of Appendix III. These delegations underlined that although the two recent working groups came to the conclusion that no consensus was possible on a recommended approach to label GM/GE foods, they considered it was possible to agree on a list of principles or concepts to be taken into consideration by the countries willing to develop and implement rules on labelling of GM/GE foods. Such a document would address the requests expressed at the 34th and 35th sessions of the Committee by many delegations requesting Codex guidance on the labelling of GM/GE foods.

82. Some delegations and observers expressed the view that the consideration of this document was a first stage and that mandatory labelling of GM/GE foods should be required in order to ensure the right of consumers to be informed. The Observer from IFOAM supported further work and stressed the importance of mandatory labelling to allow consumer choice, and stated that as GM/GE crops are not allowed in the organic system, labelling of GM/GE foods is essential for the purposes of traceability and inspection in order to ensure the integrity of the organic system.

83. Some delegations and the Observer from NHF expressed the view that labelling of GM foods was necessary in order to address health concerns of consumers. Other delegations pointed out that all foods derived from biotechnology were subject to pre-market safety assessment, that unsafe foods should not be present on the market and therefore there was no justification to require mandatory labelling of such foods from the point of view of health protection.

84. The Chair drew the attention of the Committee to the requirements for safety assessment of foods derived from biotechnology prior to marketing in the countries where GM/GE foods were produced and to the work of Codex in this area.

85. The Chair of the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology,

Professor Yoshikura (Japan) informed the Committee that the Task Force had finalised three documents addressing food safety assessment of foods derived from Recombinant-DNA animals, Recombinant-DNA plants modified for nutritional or health benefits, and food safety assessment in situations of low level presence of Recombinant-DNA plant material in food. It had also been agreed that FAO would host a database for data and information sharing for the purpose of the Annex. The Chair of the Task Force also recalled that according to the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003, para. 19) "Risk management measures may include, as appropriate, food labelling conditions for marketing approvals and post-marketing monitoring".

86. The Delegation of Argentina expressed the view that safety and consumer health protection were priority aspects in the work of Codex; however in the discussion of the agenda items it perceived a contradiction in the fact that various member countries who supported labelling of GM/GE foods, which was not based on safety or health protection, were opposed to mandatory nutrition labelling, which was part of the WHO Global Strategy to reduce non communicable diseases, due to economic reasons, lack of understanding by consumers and excess of information on the labels.

87. As a compromise, some delegations proposed to limit further work to the consideration of Table 1 of Appendix III which provided only the list of relevant Codex texts without additional text, as it would provide useful guidance to governments and could be acceptable to all delegations. Some delegations, while not objecting to the consideration of Appendix III, indicated that it should be limited to those provisions on which consensus existed and that they would not support any modification beyond these areas of consensus.

88. The Committee recognized that there was large support for proceeding with work on the basis of Appendix III of CX/FL 08/36/8 and agreed that it would replace the text of the Proposed Draft Guidelines held at Step 4 in earlier sessions (ALINORM 04/27/22, Appendix VI). In view of the nature of the text, it was agreed that the title would refer to "Recommendations" instead of "Guidelines". It was further agreed that Appendix III should be considered in conjunction with the background document in CL 2007/38-FL.

89. The Delegation of the United States did not agree to the proposal for proceeding with work on Appendix III and noted that the areas of disagreement highlighted in Ghana and reiterated during the current session of CCFL were the same issues that had prevented the Committee from reaching consensus for the previous decade.

Definitions

90. The Committee considered how to proceed with the Draft Definitions currently at Step 7 in view of the above discussion.

91. The Delegations of the European Community and Switzerland, supported by other delegations, pointed out that the definitions had been held at Step 7 in earlier sessions pending the finalisation of the Proposed Draft Guidelines, and should be retained as they were essential to define the products under consideration. It was underlined that the fact that the definitions had reached Step 7 reflected a high level of consensus on these. Some other delegations proposed to delete the definitions as similar definitions already existed in the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003). The Committee did not consider the definitions in more detail.

Status of the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering): Definitions

92. The Committee agreed to retain the Draft Amendment at Step 7 (see Appendix VI).

Status of the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering

93. The Committee agreed to circulate the Proposed Draft Recommendations at Step 3 for comments and consideration at the next session (see Appendix VII).

APPENDIX VI

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING) DEFINITIONS (At Step 7 of the Procedure)

SECTION 2. DEFINITION OF TERMS[8]

For the purpose of the General Standard:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques[9], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[10] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[8] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[9] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[10] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

APPENDIX VII

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (At Step 3 of the Procedure)

[[Chapeau *1*

"Food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other. Labelling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption. For additional assurance on safe and appropriate use of food, food labelling can be employed to provide consumers with essential information. It is recognized that consumers' expressed needs may vary in different regions of the world. These differences might lead to various levels of approaches regarding labelling of foods obtained by GM/GE modifications.

The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques."

Chapeau 2

"The purpose of this document is to recall and assemble in a single document some important

elements from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques."]

1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:

- The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985)
- The Codex General Guidelines on Claims (CAC/GL 1-1979)
- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
- Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms
- Working Principles for Risk Analysis for Food Safety for Application by Governments

2 Codex labelling and other texts apply to foods sold in unpackaged/non-retail containers including those foods obtained through GM-GE techniques and sold in such manner. Labelling means "any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal."

3. Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption. Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose[11].

[11] Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003).

4. The Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) states that the "transfer of genes from commonly allergenic foods . . . should be avoided unless it is documented that the transferred gene does not code for an allergen . . .".

5. The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed (section 4.2.2, GSLPF).

6. When the physical, chemical, or functional characteristics of a food are significantly altered through any means (production or processing), the labelling of such food be appropriately modified from its traditional labelling to ensure that the food is described or presented in a manner that is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect. The traditional name of such food may need to be changed or qualified with additional words or phrases to describe the true nature of the food and to avoid misleading or confusing the consumer.

7. In cases where GM/GE modifications result in a claim related to the nutritional properties of the food, the claim language should be consistent with the Guidelines for Use of Nutrition and Health Claims.

8. The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods.

9. Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences.

10. Any representations made on the label or in the labelling of GM/GE foods should be

consistent with the GSLPF (Codex Stan 1-1985) and the General Guidelines on Claims (CAC/GL 1-1979).

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods

Mandatory Labelling Provisions

General Standard for the Labelling of Prepackaged Foods	
3.1	Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
3.2	Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.
4.1.1	The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.
4.1.2	There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.
4.2.2	The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Voluntary Labelling Provisions

General Standard for the Labelling of Prepackaged Foods	
7.1	Optional labelling – Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3 – General Principles.
General Guidelines on Claims	
1.2	The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
1.3	The person marketing the food should be able to justify the claims made.
2	Definition – For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.
3.3	Prohibited claims – Claims which cannot be substantiated.
3.5	Prohibited claims – Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.
4.1	Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives.
5.1(iii)	Conditional claims – Terms such as “natural,” “pure,” “fresh,” “home made,” “organically grown,” and “biologically grown” when they are used, should be in accordance with the national practices in the country where the food is sold. The

	use of these terms should be consistent with the prohibitions set out in Section 3.
5.1(v)	Conditional claims – Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.
5.1 (vi)	Conditional claims – Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance: (b) is one which consumers would normally expect to find in the food; (d) is one whose presence or addition is permitted in the food.
Guidelines for Use of Nutrition and Health Claims	

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LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING

DRAFT AMENDMENT TO THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS:* DEFINITIONS (at Step 7) (Agenda Item 6a)

88. Several delegations proposed discontinuation of the work on the definitions noting that they were linked to a paper that was no longer under discussion.

89. Several other delegations clarified that the definitions were an amendment for inclusion in the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) because 4.2.2 of the General Standard made reference to food or food ingredients obtained through biotechnology without defining this term. They proposed the definition be advanced to Step 8 for adoption.

90. The Delegation of Japan proposed two amendments. One is the first definition to read "food and food ingredients obtained through biotechnology" means food and food ingredients…." to be consistent with the GSLPF. To modify the third definition by stopping the sentence after the words modern biotechnology. The Committee however did not give consideration to this proposal, but agreed that it could be considered at the next session and to retain the draft amendment at Step 7.

Status of the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*: Definitions

91. The Committee agreed to retain the Draft Amendment at Step 7 (Appendix VI).

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (at Step 4) (Agenda Item 6b)

92. The Committee recalled the decision of its last session to replace the text of the Proposed Draft Guidelines (ALINORM 04/27/22, Appendix VI) with Appendix III of CX/FL 08/37/8, *Proposed draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering* and to circulate it at Step 3 for comments and consideration by this session of the Committee. It further recalled that the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*: Definitions had been held at Step 7 pending further discussion on the proposed draft recommendations.

General remarks

93. Some delegations and some observers, were of the opinion that work on this issue should be discontinued noting that the matter had been discussed for almost two decades without consensus, that there was very little prospect of consensus in the future and considerable financial and human resources had been dedicated to this work over the years which could be better used to address more pressing health issues such as the implementation of the Global Strategy on Diet, Physical Activity and Health currently under discussion in the Committee. One

delegation recalled that the first priority of Codex was protection of consumer health and food safety as asserted by the 25th Session of the Commission[13]. One delegation mentioned that Codex texts already gave sufficient guidance for the labelling of GM/GE foods and that identifying the method of production claims such as those related to GE should be a market driven decision of the private sector. One delegation noted that it was not clear that there is agreement within the committee on the nature of the work to be undertaken.

[13] ALINORM 03/25/5, para. 15

94. One delegation mentioned that governments were sovereign to adopt labelling provisions that they deem necessary to provide information to the consumer within the framework of their respective legislation and that therefore there was no reason for Codex to be involved in establishing specific provisions on this subject matter.]

95. Many other delegations and several observers expressed the view that some progress had been made over time and emphasized that especially many developing countries looked to Codex for guidance on approaches for the labelling of GM/GE foods and that the proposed draft recommendations could prove useful in this respect. One Observer recalled that Codex had a dual mandate to not only protect the health of consumers but also to ensure fair practices in the food trade and thus a failure to label GM/GE foods could in itself be considered misleading. Several delegations and observers expressed the need for mandatory labelling to allow consumer choice, noting that GM/GE foods were a sensitive issue for consumers in their respective countries and therefore stressed the importance of continuing this work. In addition many delegations and several observers expressed their view that one of the main conclusions of the work already carried out by several working groups was that several approaches for labelling of GM/GE foods were possible. One delegation indicated that their population preferred foods derived from GM/GE techniques because they were cheaper but while this was the case the consumers would still prefer the choice of being informed if the foods were derived from GM/GE techniques and therefore could not see the rationale for the discontinuation of this work.

96. In view of the large support to continue work, the Committee proceeded to discuss the proposed draft recommendations.

Chapeau 1 and 2

97. The Committee considered the two options for the chapeau as presented in ALINORM 08/31/22, Appendix VII as “chapeau 1” and “chapeau 2”. As in the written comments there was no consensus on either of the chapeaux in the plenary discussion. Different delegations proposed amendments to one or the other chapeau, which received varying degrees of support but no consensus could be reached on any of the versions proposed.

98. In view of the lack of consensus, the Committee considered a proposal by the Chairperson to delete the chapeau and to start the document with paragraph 1.

99. There was no agreement to the text as it stood without the chapeau and several proposals were made to amend the first part of paragraph 1 to include that:

(1) any information or pictorial device may be displayed on labels of foods obtained from GM/GE techniques provided that these are not in conflict with Codex standards and guidelines (text adapted from the optional labelling provisions in CODEX STAN 107-1981); and

(2) to indicate that foods derived from GM/GE were not in any way different or less safe due to their method of production provided that they had undergone safety assessments consistent with relevant Codex guidelines.

10. However, no agreement could be reached on the text with these amendments.

101. In view of the lack of consensus, the Committee considered a proposal by the Chairperson to hold the work in abeyance for a minimum of three sessions until more experience had been gained on labelling of GM/GE foods by member states and to allow for bilateral and multilateral exchanges and further discussion on this matter on an informal basis.

102. Many delegations and several observers did not support this proposal, reiterating their view

that progress had been made, and that only a few members were not in agreement with the work done to date, and that the document could serve as a useful basis for further discussion and would provide useful guidance to developing countries in particular. Several delegations and observers underlined that suspension of the work on such an important labelling issue recognised by the majority of the consumers of the world would undermine the credibility of the Committee and require attention in other fora such as the regional coordinating committees.

103. Other delegations, while acknowledging the needs of developing countries but noting that not all developing countries supported continuation of work on this issue, supported the view that a pause could possibly allow common ground to develop among members to progress on the work in the future and that in the meantime the Committee could concentrate its efforts on the work to facilitate the implementation of the Global Strategy on Diet, Physical Activity and Health.

104. Noting the lack of support for the proposal, the Committee therefore agreed to retain the two original chapeau proposals, in addition to several of the proposals to amend them and the proposal for paragraph 1 as amended for comments at Step 3 and further consideration by the next session of the Committee.

Status of the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering

105. The Committee agreed to circulate the Proposed Draft Recommendations at Step 3 for comments and consideration at the next session (Appendix VII).

APPENDIX VI

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS - DEFINITIONS (At Step 7 of the Procedure)

SECTION 2. DEFINITION OF TERMS[1]

For the purpose of the General Standard:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques[2], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[3] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[1] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[2] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[3] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome

natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

APPENDIX VII

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (At Step 3 of the Procedure)

[Chapeau 1:

"Food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other. Labelling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption. For additional assurance on safe and appropriate use of food, food labelling can be employed to provide consumers with essential information. It is recognized that consumers' expressed needs may vary in different regions of the world. These differences might lead to various levels of approaches regarding labelling of foods obtained by GM/GE modifications.

The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods obtained by GM/GE techniques."] ***/*** **or**

[Chapeau 2:

"The purpose of this document is to recall and assemble in a single document some important elements from Codex texts which are relevant for ~~the labelling of~~ foods obtained by GM/GE techniques."] /or

[Chapeau 2 as amended by the USA:

"The purpose of this document is to recall and assemble in a single document some important elements from Codex LABELLING AND OTHER texts which are relevant for ~~the labelling of~~ foods obtained by GM/GE techniques AS THEY ARE FOR ALL FOODS. THIS DOCUMENT IS NOT INTENDED TO SUGGEST OR IMPLY THAT GM/GE FOODS ARE IN ANY WAY DIFFERENT FROM OTHER FOODS SIMPLY DUE TO THEIR METHOD OF PRODUCTION."] /or

[Chapeau 2 as amended by Brazil:

"The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques. It also recognizes that each country can adopt different approaches regarding labelling of foods obtained by GM/GE techniques and that food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other."] / or

[Amendment to the first sentence of paragraph 1 as developed during the 37th Session of the CCFL as alternative to chapeau 1 and 2:

"1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE techniques.

Any information or pictorial device may be displayed on labels of foods obtained from GM/GE techniques provided that these are not in conflict with Codex standards and guidelines.

This document is not intended to suggest or imply that food obtained from GM/GE techniques are in any way different or less safe from other foods simply due to their method of production provided that they have undergone safety assessment according to the guidance of the Codex Alimentarius Commission."]

[Text as annexed to report of the 36th Session of the CCFL:

"1. The following Codex standards and related texts contain provisions applicable to the labeling of food products and may be applied to foods obtained by GM/GE:]

- The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985)
- The Codex General Guidelines on Claims (CAC/GL 1-1979)

- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
- Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms
- Working Principles for Risk Analysis for Food Safety for Application by Governments

2 Codex labelling and other texts apply to foods sold in unpackaged/non-retail containers including those foods obtained through GM-GE techniques and sold in such manner. Labelling means "any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal."

3. Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption. Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose[1].

[1] Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003).

4. The Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) states that the "transfer of genes from commonly allergenic foods . . . should be avoided unless it is documented that the transferred gene does not code for an allergen . . .".

5. The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed (section 4.2.2, GSLPF).

6. When the physical, chemical, or functional characteristics of a food are significantly altered through any means (production or processing), the labelling of such food be appropriately modified from its traditional labelling to ensure that the food is described or presented in a manner that is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect. The traditional name of such food may need to be changed or qualified with additional words or phrases to describe the true nature of the food and to avoid misleading or confusing the consumer.

7.In cases where GM/GE modifications result in a claim related to the nutritional properties of the food, the claim language should be consistent with the Guidelines for Use of Nutrition and Health Claims.

8. The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods.

9. Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences.

10. Any representations made on the label or in the labelling of GM/GE foods should be consistent with the GSLPF (Codex Stan 1-1985) and the General Guidelines on Claims (CAC/GL 1-1979).

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods

Section

Mandatory Labelling Provisions

General Standard for the Labelling of Prepackaged Foods

3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

3.2 Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

4.1.1 The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.

4.1.2 There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Section Voluntary Labelling Provisions

General Standard for the Labelling of Prepackaged Foods

7.1 Optional labelling – Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3

– General Principles.

General Guidelines on Claims

1.2 The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

1.3 The person marketing the food should be able to justify the claims made.

2 Definition – For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

3.3 Prohibited claims – Claims which cannot be substantiated.

3.5 Prohibited claims – Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.

4.1 Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives. 5.1(iii) Conditional claims – Terms such as “natural,” “pure,” “fresh,” “home made,” “organically grown,” and “biologically grown” when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.

5.1(v) Conditional claims – Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.

5.1 (vi) Conditional claims – Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:

(b) is one which consumers would normally expect to find in the food;

(d) is one whose presence or addition is permitted in the food.

Guidelines for Use of Nutrition and Health Claims “]

2010 (38)

Critical review by CCEXEC 62/63

8. The Committee noted that the Executive Committee had discussed progress of the work on Definitions and Proposed Draft Guidelines for the Labelling of Foods Obtained through Certain Techniques of GM/GE and had noted the deadline the CCFL had set for itself and fully expected that it would complete its work by the 2011 deadline; if it did not, the Executive Committee would recommend corrective action. During the remaining two years, the Executive Committee suggested that the CCFL try all possible means to reach consensus, such as using a facilitator.
9. The delegation of the European Union said that it was important to finalise this work so that it would not be stopped by the EXECUTIVE COMMITTEE if the deadline was not met. The delegation stressed the importance of this work for consumers and that it would be a failure for the Committee and Codex in general if no consensus could be found.
10. The delegation of the United States said that the Committee had spent a significant amount of time on this issue but that fundamental differences of opinion remained. They recalled that an extensive discussion paper had been prepared by the United States, Canada and Nigeria (CL 2007/38-FL), which could possibly be considered a way forward.

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING

Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods:* Definitions

134. The Committee discussed whether to advance the proposed definitions held at Step 7 (ALINORM 09/32/22, Appendix VI) to the Commission for adoption at Step 8. Some delegations supported the advancement of these definitions, while the Delegation of Japan, supported by several other delegations proposed to advance the text with amendments so as to define “food and food ingredients obtained through biotechnology” for consistency with the terms used in Section 4.2.2 of the General Standard for Labelling of Prepackaged Foods (GSLPF) and to amend the definition for GM/GE in line with the definition in the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) (CRD 11).
135. Other delegations proposed discontinuation of the work on definitions since they were linked to a paper that was no longer under discussion, noting that definitions in relation to biotechnology already existed in Codex.
136. Some delegations, while supporting consistency in the use of terms, noted that the intent of section 4.2.2 was to address the presence of allergens, which is a food safety issue. Those delegations felt that should there be need for a definition, then it should be within a food safety context.
137. It was also proposed to introduce a chapeau stating that the definition was for the purpose of section 4.2.2. An alternative proposal was to address this issue through a footnote in 4.2.2 where biotechnology is mentioned to reference the Principles on Risk Analysis since these Principles already defined certain terms of relevance and there currently are inconsistencies between the documents in these definitions. There was however no agreement on either of the proposals as some delegations were opposed to limiting the definition to section 4.2.2. Some delegations were also of the opinion that reference to the Principles on Risk Analysis would call undue attention to the safety of foods derived from biotechnology noting that it was generally accepted that such foods are safe after being assessed using the relevant Codex guidance.
138. Noting the lack of consensus on advancing the definitions, but the general support for the amendments proposed by Japan*, the Committee agreed to return the revised definitions to Step 6 for comments and consideration by the next session.

* Japan would like to reiterate the same position expressed during the previous Session of the CCFL, as follows:

**Comments by Japan*

In Section 4.2.2 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) (hereinafter referred to as “GSLPF”), it is stated that “The presence in any food

or food ingredients obtained through **biotechnology**…" and there is no reference to "genetic modification/genetic engineering". In order to ensure consistent use of the term between this Draft and the GSLPF, we propose to revise the current draft definition as follows:

"**Food and food ingredients obtained through ~~certain techniques of genetic modification / genetic engineering~~ biotechnology**" means food and food ingredients composed of or containing genetically modified/ engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified/ engineered organisms obtained through modern biotechnology.

In Section 2 of the Scope and Definitions of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003), it is stated that "***"Modern Biotechnology"*** means ...". With regard to the definition for "Genetically modified/engineered organisms", we propose the following amendments:

"Genetically modified/ engineered organism" means an organism in which the genetic material has been changed through modern biotechnology~~ in a way that does not occur naturally by multiplication and / or natural recombination~~.

Status of the draft amendment to the General Standard for the Labelling of Prepackaged Foods: definitions

139. The Committee agreed to return the draft amended definitions to Step 6 for comments and consideration by the next session (Appendix IX).

Proposed draft Recommendations for the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering *General remarks*

140. Many delegations and several observers expressed the hope that progress could be made on this matter and that this was important for the Committee and Codex in general as many countries expected guidance from Codex in this area. They mentioned that Codex had already shown itself to be capable of finding a consensus on issues related to foods derived from modern biotechnology, first in the relevant task force that had established risk analysis principles and guidance and more recently in the Committee on Methods of Analysis and Sampling that had established criteria for analytical methods. It was mentioned that while this was not a food safety issue, Codex had the mandate to ensure fair practices in the food trade and a failure to provide guidance on the labelling of GM/GE foods could in itself be considered misleading to the consumer. One delegation mentioned that Codex had already developed labelling guidance according to production or processing methods such as irradiation, halal foods or organic products.

141. Other delegations continued to be of the opinion that work on this issue should be discontinued noting that the matter had been discussed for almost two decades without consensus and that there was very little prospect of consensus. It was also mentioned that the guidance currently in the proposed draft text was not considered sufficient by those delegations supporting this work and that it was not realistic to consider that the Committee could develop adequate guidance in the timeframe permitted. Recognizing the inability to find consensus on this matter should not be seen as a failure of Codex and CCFL but as a strength to acknowledge that sufficient international basis for consensus did not exist. It was mentioned that the time of the Committee could be better used to address more pressing health issues such as the implementation of the Global Strategy on Diet, Physical Activity and Health.

142. As there was no consensus to discontinue the work the Committee considered the proposed draft Recommendations for the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

143. ***Chapeau text***

144. Many delegations and some observers supported the chapeau text entitled "chapeau 2 as amended by Brazil" or declared that while they preferred a different text they could accept it as a compromise. Some other delegations stated that they preferred the chapeau text entitled "chapeau 2 as amended by the USA".

145. Differences of opinion were mainly on two sentences. The sentence "It also recognizes that

each country can adopt different approaches regarding labelling of foods obtained by GM/GE techniques and that food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other", as contained in the Brazil text was considered by some as too permissive by allowing various approaches and by others as not necessary as Codex texts are voluntary. Other delegations noted that similar statements are found in some Codex texts.

146. The sentence "This document is not intended to suggest or imply that GM/GE foods are in any way different from other foods simply due to their method of production.", as contained in the USA proposal was not supported by many delegations which were of the view that there was a difference between foods obtained by GM/GE methods and other foods as Codex had created a task force that developed a number of guidelines for the risk assessment of such foods.

147. The Chair clarified that according to the Codex Guidelines for the safety assessment of foods derived from modern biotechnology those foods that have been approved as a result of the use of Codex safety assessment guidance are recognised to be as safe as their conventional counterparts.

148. Several proposals were made to amend the proposals among others to align the language with that used in other Codex text i.e. to refer to "foods derived from modern biotechnology" instead of "foods obtained by GM/GE techniques".

149. The Chairperson summed up the changes proposed to the Brazil proposal as follows for consideration by the Committee: "The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. It also recognizes that each country can adopt different approaches regarding labelling of foods derived from modern biotechnology. This text is not intended to suggest or imply that GM/GE foods are necessarily different from other foods simply due to their method of production."

150. The delegation of Argentina was of the opinion that the right of a country to adopt different approaches insofar as labelling is concerned is done under the auspices of the WTO but is not the responsibility of Codex and proposed that the recognition of availability of different approaches could be included in a footnote: "The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods derived from modern biotechnology/obtained by GM/GE techniques[*]. This text is not intended to suggest or imply that GM/GE foods are necessarily different from other foods simply due to their method of production.

[*] There are different approaches regarding labelling of foods derived from modern biotechnology which are applied by national authorities."

151. Some other delegations supported Argentina and noted that referring to different national approaches brings into question the purpose of working on an international standard.

152. Many other delegations were of the view that several approaches for the labelling GM foods were possible as long as Codex basic principles were respected in line with the conclusions of the working group held in Oslo.

153. Several delegations indicated that even though they were not in favour of the last sentence in the chairs proposal they could accept it if the second sentence remained intact as in the Brazil proposal i.e. including the part of the sentence "and that food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other" as this gave the important context to the chapeau.

154. Some observers opposed the inclusion of the last sentence in the chairs proposal while another observer supported it.

155. During the lunch hour, many delegations assembled in a session facilitated by the chair to concentrate on the objectives they wanted to achieve with the text instead of focussing on specific wording and the Chairman developed an alternative proposal as follows: "Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are available, the purpose of this document is only to recall and assemble in a

single document some important elements of guidance from existing Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production."

156. The Chair proposed that this text be circulated for comments at Step 3 together with the remainder of the draft recommendations with a view to collect comments and finalise the text at the next session.

157. It was proposed that not only this text but also the original chair's proposal (see para 149) and the Argentinean proposal (see para 150) should be circulated. It was also mentioned that the phrase starting "and that food labelling is the primary means..." should be reintroduced in the chapeau.

158. The delegation of Austria said that they would prefer to refer to "foods obtained by GM/GE techniques" instead of "foods derived from modern biotechnology".

159. After some discussion, the Committee agreed that the original chair's proposal for a chapeau (see para 149) and the proposal for a chapeau developed by the facilitated lunchtime session should be circulated together with the rest of the document at Step 3 for comments. The Committee also accepted the offer from the delegation of the European Union to host a facilitated work session in Brussels in the three working languages that would be chaired by Ghana and facilitated by the chair of the CCFL with the goal of exploring the objectives of different delegations and reconcile them in one text if possible.

160. Delegations were invited to provide in their comments a very clear rationale with respect to their objectives in relation to their proposals for changing text and that this would also be the approach in the facilitated work session because going back to the objectives would allow new options to be explored which could bridge the gap between different positions. The Chair indicated that all options would be considered in the facilitated session.

Status of the proposed draft Recommendations for the labelling of foods and food ingredients obtained through certain techniques of Genetic Modification / Genetic Engineering

161. The Committee agreed to circulate the Proposed Draft Recommendations at Step 3 for comments and consideration at the next session (Appendix X).

APPENDIX IX

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS – DEFINITIONS (At Step 6 of the Procedure)

SECTION 2. DEFINITION OF TERMS[1]

For the purpose of the General Standard:

"Food and food ingredients obtained through biotechnology" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques2, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells3 beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[1] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[2] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[3] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

APPENDIX X

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (At Step 3 of the Procedure)

*[**Chapeau version 1**: The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. It also recognizes that each country can adopt different approaches regarding labelling of foods derived from modern biotechnology. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.]*

*[**Chapeau version 2**: Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are available, the purpose of this document is only to recall and assemble in a single document some important elements of guidance from existing Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.]*

[Text as annexed to report of the 36th Session of the CCFL:

1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:]

   • The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985)

   • The Codex General Guidelines on Claims (CAC/GL 1-1979)

   • The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)

   • Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);

   • Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)

   • Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms

   • Working Principles for Risk Analysis for Food Safety for Application by Governments

2 Codex labelling and other texts apply to foods sold in unpackaged/non-retail containers including those foods obtained through GM-GE techniques and sold in such manner. Labelling means “any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.”

3. Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption. Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose4.

4. The Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) states that the “transfer of genes from commonly allergenic foods . . . should be avoided unless it is documented that the transferred gene does not code for an allergen . . .”.

5. The presence in any food or food ingredients obtained through biotechnology of an allergen

transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed (section 4.2.2, GSLPF).

[4] Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003).

6. When the physical, chemical, or functional characteristics of a food are significantly altered through any means (production or processing), the labelling of such food be appropriately modified from its traditional labelling to ensure that the food is described or presented in a manner that is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect. The traditional name of such food may need to be changed or qualified with additional words or phrases to describe the true nature of the food and to avoid misleading or confusing the consumer.
7. In cases where GM/GE modifications result in a claim related to the nutritional properties of the food, the claim language should be consistent with the Guidelines for Use of Nutrition and Health Claims.
8. The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods.
9. Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences.
10. Any representations made on the label or in the labelling of GM/GE foods should be consistent with the GSLPF (Codex Stan 1-1985) and the General Guidelines on Claims (CAC/GL 1-1979).

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods

Section

Mandatory Labelling Provisions

General Standard for the Labelling of Prepackaged Foods

3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

3.2 Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

4.1.1 The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.

4.1.2 There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Section Voluntary Labelling Provisions

General Standard for the Labelling of Prepackaged Foods

7.1 Optional labelling – Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3 – General Principles.

General Guidelines on Claims

1.2 The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

1.3 The person marketing the food should be able to justify the claims made.

2 Definition – For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

3.3 Prohibited claims – Claims which cannot be substantiated.

3.5 Prohibited claims – Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.

4.1 Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives.

5.1(iii) Conditional claims – Terms such as “natural,” “pure,” “fresh,” “home made,” “organically grown,” and “biologically grown” when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.

5.1(v) Conditional claims – Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.

5.1 (vi) Conditional claims – Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:

(b) is one which consumers would normally expect to find in the food;

(d) is one whose presence or addition is permitted in the food.

Guidelines for Use of Nutrition and Health Claims

“**]**

2010 (39)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING (Agenda Item 6)

Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Definitions (at Step 7)(Agenda Item 6a)

120 Several delegations proposed that, rather than including definitions in the General standard, a cross reference could be made in 4.2.2 to the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) as the word “biotechnology” was used in section 4.2.2 but was not defined. In order to make section 4.2.2 consistent with the terminology used CAC/GL 44-2003, it was proposed to add the word “modern” in front of “biotechnology”.

121 Other delegations however were of the opinion that the scope of the word “biotechnology” as it relates to allergens was wider than that of “modern biotechnology” thus the proposed change would be a substantial change to the scope of that section, to which they could not agree. They proposed to discontinue work on separate definitions for inclusion in the General standard. As a new text had been agreed under 6b, they proposed to make a reference to the

Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) in a footnote to the title of this new text.

122 The Committee agreed to this proposal.

123 One observer noted that the difference in terms was just historical as the word “modern” had been introduced at a later stage but there was no difference in meaning.

Status of the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Definitions (at Step 7)

124 The Committee agreed to propose to the Commission discontinue work on this issue.

Proposed draft Recommendations for the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering (Agenda Item 6b)

125 The Committee recalled that the item had been on its agenda for a number of years and that to make progress and to reconcile different opinions it had agreed at its last session to hold a facilitated work session, chaired by Ghana, facilitated by the Chairperson of the Committee and hosted by the European Union.

126 The Delegation of Ghana introduced the report of the facilitated work session of the Committee*, which was held in Brussels in November 2010 with the goal of exploring the objectives of different delegations with regard to various versions of texts being considered under the CCFL agenda item dealing with the labelling of foods derived through modern biotechnology and to reconcile them in one text if possible.

*See **FACILITATED WORK SESSION 15/16 NOVEMBER 2010, BRUSSELS, BELGIUM CHAIRPERSONS REPORT in the box.**

127 The Committee agreed to discuss the topic on the basis of the outcome of the facilitated session (CX/FL 11/39/13, Appendix 3: Guidance text options).

128 The Committee noted that Appendix 3 presented three options for consideration. All options contained the same proposals for the initial sections (title, purpose and consideration) and varied in the presentation of the final section concerning the listing of the various Codex texts. The Committee agreed to discuss the proposals section by section.

General remarks

129 Many delegations congratulated the facilitated session on its work.

130 Some delegations stated that it was necessary for the Committee to make progress on the issue also keeping in mind the statements made by the Executive Committee and the deadline that the Committee had set itself. Other delegations expressed concern about continuing work on this agenda item.

131 Some delegations stated that Codex guidance on this issue should be short and concise concentrating on a list of applicable Codex texts to which all members could agree.

132 Some delegations were not in favour in principle of Codex guidance in this area but could accept a very concise document that could find consensus in the Committee.

133 One delegation recalled that during the long work of Codex on this issue many accomplishments had been achieved such as the criteria on allergens in section 4.2.2 of the General Standard for the Labelling of Prepackaged Foods and the background paper prepared by Nigeria, Canada and the United States for the working group in Ghana and that the Committee had not been able to achieve consensus on other items.

Title

134 All delegations and observers that intervened preferred the second option given in the Appendix for the title of the document.

135 In the discussion, the text proposed was simplified to read ”Proposed Draft Compilation of Codex texts relevant to labelling of foods derived from modern biotechnology”.

136 Some delegations suggested to add “as for all foods” at the end of the title. Other delegations and observers did not think this was appropriate as some of the texts referred to in the document applied to foods derived from modern biotechnology only.

137 One delegation stated that the Codex texts on food labelling, referred to in the text were applicable to all foods and this should be clarified in the title possibly through a footnote.

138 The Committee agreed to leave the title as amended as a “working title” and come back to the question raised when discussing the placement of the text.

Section 1 – Purpose

139 The Committee agreed with the proposal of the facilitated session that the purpose should read as follows: “The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology.”

Section 2 – Considerations

140 There were several proposals for possible amendments to the first sentence of this section. One delegation proposed that the first part of the sentence could be included in a footnote. Others proposed to delete the first part of the sentence, as the purpose of the document was to give guidance to countries that needed it and not to acknowledge what other countries were doing. Other delegations and observers proposed to delete the second part of the sentence, as it was confusing in relation to the first part.

141 After some discussion the Committee agreed to clarify that the first part was not an acknowledgement or endorsement but a statement of a fact. The text of the first sentence was split into two sentences and the first sentence amended to read as follows: “Different approaches regarding labelling of foods derived from modern biotechnology are used.”

142 The Committee also agreed to harmonise the wording of “framework” and “approach” to read “approach” and to inverse the order of the second and the third sentence as it considered it more logical if the statement of fact on different approaches used appeared in conjunction with the obligation that any approach should be consistent with already adopted Codex provisions, whereas the new last sentence was a clarification.

Section 3 – Compilation of relevant Codex texts

143 Many delegations and observers supported the first option proposed by the facilitated session i.e. to include in the listing only references to Codex texts and not to include the actual texts referred to either partly or completely as suggested in second and third option. The main reason was to facilitate the maintenance of the text as otherwise it would have to be changed each time one of the referred texts was changed.

144 The Committee noted however the concerns of a number of delegations and observers that the text could be difficult to use because of the many references contained and access might be difficult especially in countries with slow Internet connections.

145 The Committee agreed that to facilitate the widest possible use of the text, the Codex secretariat will include hyperlinks in the listing of Codex texts and explore the possibility to print compilations of the text (including all texts referred to) in accordance with the needs of members and the funds available

146 After some discussion, the Committee agreed to delete the introductory text to the listing as all relevant text had already been included in the sections on purpose and considerations.

147 Many delegations and observers supported including the General Guidelines for Use of the Term “Halal” (CAC/GL 24-1997), as foods derived from modern biotechnology could have an impact on halal foods. Other delegations were of the opinion that this text did not mention foods derived from modern biotechnology and questioned why it would be included.

148 The Committee noted that also some of the other texts referenced did not make mention of foods derived from modern biotechnology but were relevant to labelling of claims. It was clarified that including the text on halal here did not mean to say that foods derived from modern biotechnology were or were not “halal” as this determination was to be made by the relevant religious authorities.

149 It was noted that Section 5.1(v) of the General Guidelines on Claims (CAC/GL 1-1979) was also relevant and was included in the relevant list of sections.

150 Recalling that, when discussing the title of the document, one delegation had noted that it should be clarified that some of the texts referenced applied to all foods, the Committee agreed

to reorder the texts as follows: first those texts applying to all foods, followed by the Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007), followed by the other relevant texts on Risk Analysis and Food Safety Assessments related to foods derived from modern biotechnology.

151 One delegation proposed that the Committee could report to the Commission that the Committee had achieved its task providing relevant guidance to governments in the text discussed at this session and the background document from the Ghana workshop.

152 Some delegations proposed that the text should become an annex to the General Guidelines on Claims (CAC/GL 1-1979) as it dealt predominantly with representations about foods.

153 Many other delegations and observers were not of the opinion that the text predominantly dealt with claims and supported that the text was important guidance to countries and should be a standalone Codex text.

154 The Committee noted that when work had begun on the issue it was intended to become part of the General Standard for the Labelling of Prepackaged Foods (Codex Stan 1-1985) and that at a later stage the focus had changed, and the text had been discussed as stand-alone recommendations or guidance document, whereas it had not been previously discussed to make it an annex to the General Guidelines on Claims.

Status of the Proposed draft Recommendations for the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering

155 Many delegations were of the opinion that as no further open questions remained in the document it should be advanced to the Commission for adoption at steps 5/8.

156 Some delegations preferred to advance the document only to Step 5 to allow for more consideration as to the placement of the text but stated that they could agree with advancing it to steps 5/8 if it was annexed to the General Guidelines on Claims.

157 As all major issues related to the document had been solved, the Committee agreed to advance the text as contained in Appendix III to the Commission for adoption at steps 5/8 as a standalone document.

158 The delegation of Argentina expressed its reservation to this decision.

Note to paragraph 148: Response of religious groups to foods derived from modern biotechnology is found among others in the following documents;

- Report of the Committee on the Ethics of Genetic Modification and Food Use, Ministry of Agriculture Fisheries and Food, London, UK, 1993
- Acceptable Genes? Conrad G. Brunk & Harold Coward (eds), State University of New York Press, Albany, 2009.

APPENDIX III

PROPOSED DRAFT COMPILATION OF CODEX TEXTS RELEVANT TO LABELLING OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY (At Step 5/8 of the Procedure)

1. Purpose

The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology.

2. Considerations

Different approaches regarding labelling of foods derived from modern biotechnology are used. Any approach implemented by Codex members should be consistent with already adopted Codex provisions. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.

3. Compilation of relevant Codex texts

3.1 General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985); and

particularly, Sections 3.1, 3.2, 4.1.1, 4.1.2, 4.2.2, 7.1

3.2 General Guidelines on Claims (CAC/GL 1-1979); and particularly, Sections 1.2, 1.3, Section 2 – Definition of Claim, 3.3, 3.5, 4.1, 5.1(iii), 5.1(iv), 5.1 (v), 5.1(vi)

3.3 Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997); Introduction and particularly, Sections 1.1, 1.2, 1.3, 1.4 and 1.5

3.4 Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999); and particularly Section 1.5

3.5 General Guidelines for Use of the Term "Halal" (CAC/GL 24-1997)

3.6 Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)

3.7 Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003); and particularly, Paragraph 19.

3.8 Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)

3.9 Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms (CAC/GL 46-2003)

3.10 Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals (CAC/GL 68-2008)

FACILITATED WORK SESSION 15/16 NOVEMBER 2010, BRUSSELS, BELGIUM CHAIRPERSONS REPORT

As agreed by the 38th Session of the Codex Committee on Food Labelling, a facilitated working session of the Codex Committee on Food Labelling was held in Brussels to further consider the matter of the labelling of foods derived through modern biotechnology. The meeting was chaired by Professor Josephine Nketsia-Tabiri from Ghana and facilitated by the Chair of the CCFL, Mr. Paul Mayers. Attached is the Chair's report of that facilitated meeting.

1. A facilitated session of the Codex Committee on Food Labelling (CCFL) was held in Brussels, Belgium 15/16 November 2010 hosted by the European Union. This facilitated session, which had been agreed to by the 38th Session (May 2010) of the CCFL, was chaired by Ghana and facilitated by the chair of the CCFL with the goal of exploring the objectives of different delegations with regard to various versions of texts being considered under the CCFL agenda item dealing with the labelling of foods derived through modern biotechnology and to reconcile them in one text if possible. The session was attended by 71 participants representing 31 member governments and 10 international non-governmental organizations. A list of participants is attached as Appendix 1 to this report.

2. Prior to the facilitated session, a CL was circulated (CL2010/19-FL) inviting members and observers to provide in their comments a very clear rationale with respect to their objectives in relation to their proposals for changing text and that this would also be the approach in the facilitated work session because going back to the objectives would allow new options to be explored which could bridge the gap between different positions. Comments received in response to the CL will be circulated separately to all members and observer organizations as document CX/FL 11/39/13.

3. The facilitator began the session by reminding participants of the original charge to the CCFL from the 19th Session of the CAC to "provide guidance on how the fact that a food was derived from modern biotechnology could be made known to the consumer". He further noted that the purpose of the discussions was not to defend a particular view or to criticize other views but rather to focus on objectives and the rationale behind positions. He also explained that the facilitation process would draw on "systems thinking" which is an approach that has had some success in seeking to improve/address "wicked problems". "Wicked problems" are characterized by ambiguity, uncertainty, several different perspectives on the issues and disagreement on goals and values. The approach involves a structured dialogue during which participants were expected to actively listen and be open to new ideas as all opinions were relevant. The chairperson would handle requests for the floor leaving the facilitator free to focus on exploring the rationale underlying interventions.

4. To start the process, each delegation was asked to complete the following two framing statements:

Q.1 To be acceptable, a compromise text will need to reflect consideration….

Q.2 In order to reduce the potential that a compromise text will be rejected, it should avoid…

5. Consideration of the various responses to the framing questions revealed several themes, the most prevalent being that it was important to include consideration that different approaches were used to label GM/GE foods but that texts had to be consistent with existing Codex texts.

6. Several delegations preferenced their responses by questioning whether the mandate given to the CCFL in 1991 was still relevant in the context of the current Codex environment. Some participants were of the view that the text should include reference to:

- Purpose of the text
- Clarity that the text could achieve

- Method of production
- Applicability to all foods (not just GM)
- Recognition of substantial equivalence
- Consideration of the mandate of Codex

7. It was further noted by a number of other participants that the text should avoid:

- Being too prescriptive resulting in one approach being favoured over others
- Introducing new principles in Codex
- Referring or ratifying national standards/interests at the international level.
- Reference to method of production
- Ambiguous/complex language that could lead to confusion, misinterpretation, etc. (e.g. terms not agreed in Codex)
- Use of consumer preference as the primary basis for setting international standards
- Misleading the consumer on the nature of the products they buy.

8. These thematic issues were discussed extensively by the participants after which the facilitator divided them into four groups. He charged each of these groups to (a) develop a statement regarding the objective of a labelling text and (b) what would be the key indicators of success that such a text would reflect. A compilation of the outcomes of the group discussions is attached as Appendix 2. After the various groups reported back, the facilitator offered the following as a general compilation of an objective statement recognizing that it is neither a consensus objective nor does it seek to avoid inherent conflicts in some elements. Key factors of success were summarized, stressing that it was not intended to be considered a consensus text but merely a text that reflected the various views offered during the discussion:

> "Articulate guidance based upon existing Codex texts which can inform member countries national frameworks for the labelling of foods derived through modern biotechnology (FDMB):
>
> - Providing principles relevant to FDMB within the Codex framework for labelling all foods.
> - Supporting informed choice by consumers
> - Enabling different approaches to the national framework supporting the above"

9. On the basis of the significant dialogue and exploration of objectives and considerations influencing the positions of the various delegations, the facilitated session considered the current text as contained in Appendix X to Alinorm 10/33/22, (Report of the 38th Session of the CCFL). To facilitate the discussion of the options regarding texts, participants were asked to consider adjustments that would focus on bridging various positions on the basis of four bridging principles:

- Avoid winners and losers
- Minimize value judgement elements
- Simple construction
- Neutrality

10. Before considering the chapeau statements, the participants considered the ten paragraphs contained in the text following the chapeau statements. It was suggested that the document should only reference the relevant Codex texts identified in paragraph 1 of the Appendix as well as the more specific sections of these texts which were identified in table 1. It was also suggested that the list of relevant Codex texts in paragraph 1 should be expanded to include the Codex Guidelines for the Production, Packaging and Labelling of Organic Foods and the Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals.

11. A number of participants expressed concern that merely reproducing sections of the relevant texts might result in text being used out of context as these texts had been developed with a particular objective in mind. Others felt that principles reflected by only referencing Codex texts did not provide sufficient guidance for their needs. After some discussion, the participants recognized there were three possible approaches with regards to the above guidance and would provide these options for consideration by the 39th Session of the CCFL:

(a) The guidance could make reference to the relevant texts in paragraph 1 of the Appendix with the addition of the Codex Guidelines for the Production, Packaging and Labelling of Organic Foods and the Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals and include reference to particularly pertinent sections.

(b) The guidance could make reference to the relevant texts found in paragraph 1 (with the addition of the Codex Guidelines for the Production, Packaging and Labelling of Organic Foods and the Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals) and include reproductions of the relevant specific sections in table 1.

(c) All relevant texts could be reproduced in the guidance document.

12. During the discussions of the chapeau statements, it was noted that the statements appeared to be a mix of identification of the purpose of the document as well as some principles. This contributed to confusion and ambiguity. Several delegations expressed the view that the chapeau statements were intended to be an introduction to the text that followed and hence needed to reflect the purpose of the document which might also include key considerations. It was also felt that the title of the document added to the confusion.

13. The facilitator led the group in an exercise to develop a common statement of purpose for the text and the articulation of key considerations. The objectives and success factors previously discussed, again served to underpin the exercise. Through this process, the session was able to assemble "Purpose" and "Considerations" text

which it agreed should be considered by the 39th Session of CCFL and is reflected in each option under consideration.
14. It was not, however, possible to agree on a revised title to the text and instead three options were retained for further consideration.
15. Recognizing that full consensus was not achieved, it was viewed as a useful basis for consideration by the Committee. The participants therefore agreed to forward to the 39th Session of the CCFL for consideration the three possible options as outlined in Appendix 3 to this report.

Appendix 2: Compilation of Breakout Group Presentations

ENGLISH GROUP 1:

Provide direction/statement on how/that existing Codex texts can be used by countries to develop their national framework for foods derived from modern biotechnology.

Key Indicators:

Compilation of Codex texts
Members have adequate guidance
Mechanistic indicators – [FAO]?

ENGLISH GROUP 2:

1. To provide guidance to countries that want information on whether, and if so how, to label foods derived from modern biotechnology (FDMB).
2. To provide guidance consistent with existing Codex texts.
3. To assemble together texts of Codex that are useful in providing guidance for labelling of FDMB
4. Guidance on how FDMB could be known by consumers.

Key Indicators:

1. Consistency with Codex texts
2. Consensus on approach
3. Utilization of the guidance document developed by CCFL
4. Facilitate promotion of fair practices in the food trade
5. Allows traceability of FDMB
6. Allows informed choice by consumers

GROUPE FRANCOPHONE:

Donner des lignes directives aux membres du Codex pour l'étiquetages des denrées alimentaires dérivées des biotechnologies sur la base des textes existants du Codex.

Indicateurs de succès :

• Prise en compte des textes existants
• Les principes établis ne doivent pas favoriser une approche par rapport à une autre
• Applicable/acceptable à l'échelle globale
• Respecte des 2 objectifs du Codex :
Protection de la santé du consommateur
Promotion de pratiques loyales dans le commerce internationale

GRUPO ESPAΨOL

The document should provide orientation regarding Codex guidelines, standards and principles related to foods derived from modern biotechnology, including those related to food labelling.

Document then could include a list of relevant Codex texts.

Indicators of success

(1) The document grouped after this objective fulfills the CAC mandate to CCFL.
(2) These documents have been approved by member states;
(3) These documents have a long standing enforcement period which leaves no doubt regarding ambiguity.
(4) As these texts are applicable to all foods, they are already including foods derived from modern biotechnology.
(5) This idea encompasses all the approaches related to labelling of foods derived from modern biotechnology.

Appendix 3: GUIDANCE TEXT OPTIONS
OPTION 1: (Reference to relevant texts)
Title:
[Proposed Draft Guidance regarding the Labelling of foods derived from Modern Biotechnology], or
[Proposed Draft Compilation of [references] Codex Labelling and other texts relevant to labelling foods derived from modern biotechnology], or
[Proposed Draft Guidance Drawn from Codex Texts relevant to the labelling of foods derived from modern biotechnology].
Purpose:

The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology.

Considerations:
Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are used, this document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production. Any framework implemented by Codex members should fully respect the already adopted Codex provisions
1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:]

- The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985); and particularly, Sections 3.1, 3.2, 4.1.1, 4.1.2, 4.2.2, 7.1
- The Codex General Guidelines on Claims (CAC/GL 1-1979); and particularly, Sections 1.2, 1.3, Section 2 – Definition of Claim, 3.3, 3.5, 4.1, 5.1(iii), 5.1(iv), 5.1(vi)
- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997); Introduction and particularly, Sections 1.1, 1.2, 1.3, 1.4 and 1.5
- Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003); and particularly, Paragraph 19.
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms (CAC/GL 46-2003)
- Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 44-2003)
- Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals (CAC/GL 68-2008)
- The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999); and particularly Section 1.5

OPTION 2: (Reproduction of relevant texts current found in Table 1 of Appendix X of ALINORM 10/33/22)
Title:
[Proposed Draft Guidance regarding the Labelling of foods derived from Modern Biotechnology], or
[Proposed Draft Compilation of [references] Codex Labelling and other texts relevant to labelling foods derived from modern biotechnology], or
[Proposed Draft Guidance Drawn from Codex Texts relevant to the labelling of foods derived from modern biotechnology].
Purpose:
The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology.
Considerations:
Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are used, this document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production. Any framework implemented by Codex members should fully respect the already adopted Codex provisions

1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:]
   - The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985);

- The Codex General Guidelines on Claims (CAC/GL 1-1979)
- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997
- Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003)
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms;
- Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 44-2003)
- Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals (CAC/GL 68-2008)
- The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999)

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods
• *Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985)*
Section 3.1: Prepackaged foods shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any

respect.

Section 3.2: Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

Section 4.1.1: The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.

Section 4.1.2: There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.

Section 4.2.2: The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Section 7.1: Optional labelling – Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3 – General Principles.

• *Codex General Guidelines on Claims (CAC/GL 1-1979)*

Sections 1.2: The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

Section 1.3: The person marketing the food should be able to justify the claims made.

Section 2 – Definition of Claim - For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

Section 3.3: Prohibited claims – Claims which cannot be substantiated.

Section 3.5: Prohibited claims – Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.

Section 4.1: Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives.

Section 5.1(iii): Conditional claims – Terms such as “natural,” “pure,” “fresh,” “home made,” “organically grown,” and “biologically grown” when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.

Section 5.1(iv): Conditional claims – Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.

Section 5.1(vi): Conditional claims – Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:

(b) is one which consumers would normally expect to find in the food;

(d) is one whose presence or addition is permitted in the food

• *Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)*

Introduction - Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed. Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers’ eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex General Guidelines on Claims are prohibited

Section 1.1: These guidelines relate to the use of nutrition and health claims in food labelling and, where required by the authorities having jurisdiction, in advertising.

Section 1.2: These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.

Section 1.3: These guidelines are intended to supplement the Codex General Guidelines on Claims and do not supersede any prohibitions contained therein.

Section 1.4: Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

• *Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);*

Paragraph 19: Risk management measures may include, as appropriate, food labelling conditions for marketing approvals and post-market monitoring.

• *Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)*
• *Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms (CAC/GL 46-2003)*
• *Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)*
• *Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals (CAC/GL 68-2008)*
Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999);

Section 1.5: All materials and/or the products produced from genetically engineered/modified organisms (GEO/GMO) are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

OPTION 3: (Reproduction of all relevant texts)
Title:
[Proposed Draft Guidance regarding the Labelling of foods derived from Modern Biotechnology], or
[Proposed Draft Compilation of [references] Codex Labelling and other texts relevant to labelling foods derived from modern biotechnology], or
[Proposed Draft Guidance Drawn from Codex Texts relevant to the labelling of foods derived from modern biotechnology].
Purpose:
The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology.
Considerations:
Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are used, this document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production. Any framework implemented by Codex members should fully respect the already adopted Codex provisions

1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:]

• The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985);
• The Codex General Guidelines on Claims (CAC/GL 1-1979);
• The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997);
• Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
• Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
• Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms
• Working Principles for Risk Analysis for Food Safety for Application by Governments
• Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals (CAC/GL 68-2008)
• The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999);

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods
All the relevant texts from the above referenced documents would be reproduced here. In order to conserve paper, these texts are not reproduced in this report but this is an option being forwarded to the Committee for its consideration.

APPENDIX: EVALUATION OF THE CODEX ALIMENTARIUS AND OTHER FAO AND WHO FOOD STANDARDS WORK (15 November 2002)

Note: The following paragraphs related to foods derived from biotechnology are extracts from the above document.

66. Developing country governments consider science-based standards important, but continue to value commodity standards and would like to see the list of standards extended to products particularly relevant to them (although this was often found in country visits to apply to such concerns as pesticide MRLs handled in horizontal committees). Consumer groups in particular value the information content of labels.

67. Asked in the questionnaire to rate future priorities for Codex work, 81% of government respondents and 87% of observers accorded very high priority to strengthening the science base for health risk analysis in standard establishment in Codex's future work. There continues to be support among low- and middle-income countries for extending the coverage of commodity standards, but little enthusiasm from developed countries. Product descriptors are seen as low priority. Likewise, there was limited enthusiasm for future work on non-health related aspects of food labelling such as fair trade, animal welfare, religious and cultural labelling. There is relatively more support from governments for work on organic labelling, point of origin and quantitative ingredient declaration (QUID), though among high-income regions, Europe is more favourably disposed than is North America. Observer groups with the exception of consumers are opposed to all forms of non-health-related labelling. In assessing priorities for future work, governments and observers gave the highest proportion of 'very high priority' scores (about 80% in each case) to pesticides, veterinary drugs, additives and contaminants—all health-related, science-based issues.

Box 1: Labelling of Foods Derived from Biotechnology (GM Labelling)

The Codex Committee on Food Labelling (CCFL) first considered labelling of foods derived from biotechnology - in 1993. In 1997, the secretariat prepared guidelines, on the basis of advice from CCEXEC, and the statement on the role of science and other factors and the findings of an FAO/WHO expert consultation. The guidelines were presented as amendment to the General Labelling Standard for comments and major divergences of opinion continued. In 1998, CCFL forwarded the definitions and the provisions on allergens to CAC for adoption at Step 5 and returned the labelling requirements to Step 3. In 1999, the CAC adopted the Proposed Draft Amendment Concerning the Labelling of Foods Obtained Through Biotechnology (partial text) at Step 5. At the CCFL in 1999, there was debate on the requirement of labelling for foods containing or obtained from genetically-modified organisms (GMO). The United States stated that there was no scientific basis for systematic labelling and suggested, supported by industry IGOs, that it may be misleading to consumers. The European Union, supported by consumers advocated mandatory labelling. CCFL agreed to return the labelling provisions to Step 3 for redrafting.

At the CCFL, in 2000, "modern biotechnology" was replaced with "genetic modification/genetic engineering" throughout definitions. There was further debate over "modified" versus "engineered" (both versions were retained) and the definition of "no longer equivalent/differs significantly", which was left in square brackets. CCFL advanced the draft amendment on allergens to Step 8 for adoption at the CAC in 2001 and it was adopted. CCFL returned the definitions to Step 6. The working group presented revised labelling provisions with either labelling when products obtained through biotechnology differ significantly from the corresponding food or the declaration of the method of production for foods containing or produced from GMOs. The US, and other delegations, highlighted the implications of enforcement, methodology, economic cost and consumer perception; and that developing countries would face technical difficulties. Due to the diversity of opinions, CCFL decided to return the labelling provisions to Step 3.

At the CCFL in 2001, the central issue for definitions was the need for consistency throughout Codex [The Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology

(TFFBT) had taken its definition of "modern biotechnology" from the Cartagena Protocol, in accordance with its terms of reference to use established international definitions.] with the inclusion of "modern biotechnology" (Argentina, Brazil) versus use of terminology such as "genetic modification/genetic engineering" that consumers would understand (Norway, Ireland, India, Nigeria, Consumers International). Based on a compromise text, proposed by the working group, the definitions were retained and "modern biotechnology" was added. The CCFL agreed to forward the definitions to Step 8 for adoption by the CAC in 2001. However, due to the lack of consensus on the appropriate terminology for the definitions, CAC agreed to return the text to Step 6 demonstrating that the proposal to the CAC had been premature. The working group revised the labelling provisions in the form of guidelines. Argentina expressed reservation due to the implications in international trade and WTO. Some delegations indicated that Codex should give general recommendations that could be applied in all countries as a basis for international harmonization. CCFL was not able to proceed further due to time constraints and returned the text to Step 3. At the CCFL in 2002, CCFL could not reach consensus on the definitions and they returned again to Step 3.

Polarization has increased as governments incorporate labelling provisions in their national legislation. There are accusations of inflexibility, criticism of the chair and general frustration at the lack of progress. This outcome suggests that CCFL could have benefited from more focused direction from the Codex Commission. Furthermore, CCFL did not have the benefit of an expert consultation on risk management or communication. As the working group became larger, there was less efficiency and less progress. Furthermore, while the Task Force on Foods Derived from Biotechnology benefited from the Cartagena Protocol definition, it was a source of divergence for CCFL. The issue of "other factors" complicated the picture further and Principles for Risk Communication had not yet been elaborated. Due to political aspects of risk management and communication, and the current impasse, CCFL may not be able to resolve this dispute.

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68. To demonstrate the difficulties that can arise with non health-related standards, one may look at biotechnology (GM) labelling. This is one of the most difficult issues Codex has addressed, where there appear to be intractable differences between country positions (see Box 1) and progress (if any) has been painfully slow. While Codex has been deliberating, many countries have introduced national legislation on GM labelling (and the market has also responded with retailers and manufacturers taking GM ingredients out of their products in countries where consumers are opposed to them). [It is conceivable that mandatory labelling could be seen as a non-tariff barrier in breach of the TBT Agreement but, in the absence of a challenge, it should be assumed that this is not the case.] This particular issue reflects a broader difficulty in international harmonization when cultural differences among countries mean that consumers have different interests and priorities.

69. Contrast the position for labelling with that for risk assessment of foods derived from biotechnology (Box 2). Progress on agreeing to procedures for assessing health risks proved relatively straightforward. Several explanations have been given for this success including resources put into the process, the use of a task force approach and a strong chair. However, part of the explanation is undoubtedly that the issue was one of science not culture.

Box 2: Procedures for Assessment of Health Risks from Foods Derived From Biotechnology

In 2000, the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (TFFBT), hosted by Japan, began its four-year mandate. According to the terms of reference, TFFBT was obliged to take full account of existing work and it agreed that environmental risk was and should be addressed by other bodies such as the Cartagena Biosafety Protocol under the Convention on Biological Diversity, the International Plant Protection Convention and the Commission on Genetic Resources for Food and Agriculture. Moreover, the development,

adoption, acceptance and use of Codex standards on biotechnology had to be undertaken within the international regulatory framework, resulting in the definition of "modern biotechnology" being taken from the Cartagena Protocol.

TFFBT relied on three well-funded joint FAO/WHO expert consultations (plants, allergenicity, micro organisms [The proposed Joint FAO/WHO Expert Consultation on genetically modified animals has not been initiated.]) and three ad hoc working groups to develop texts (principles, plants and micro organisms (chaired by Japan); analytical methods (chaired by Germany); allergenicity (chaired by Canada)). The Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and the Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants have been advanced to Step 8 for adoption at the Codex Alimentarius Commission in 2003. As the safety assessment procedures for plants and micro organisms were the same, they were retained, wherever possible, for recombinant-DNA micro organisms. The Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Micro organisms has been advanced to Step 5. The ad hoc working group, chaired by Germany, revealed that different countries use different analytical methods for the detection or identification of foods or food ingredients derived from biotechnology and that there were no internationally validated methods available at present. The consensus on the list of validated methods of analysis, proposed by the working group, is expected to be approved at the next meeting of the Codex Committee on Methods of Analysis and Sampling in November 2002. Based on the proposals of the working group, chaired by Canada, and subsequent revisions, TFFBT agreed to advance the Draft Annex on the Assessment of Possible Allergenicity to Step 5 and recommended that the CAC also adopt the text at Step 8 with omission of Steps 6 and 7.

Risk assessment in the development of these texts focussed on the issue of "substantial equivalence", which, although questioned by Consumers International, was concluded to be a useful approach to risk assessment of foods derived from biotechnology (joint FAO/WHO expert consultation, 2000). Conversely, the risk management issue of "traceability" was more controversial. There was debate between the EU, who called for the inclusion of the issue in the Principles document, and the US delegations, who stated that the issue was more appropriately covered by the Codex Committee on General Principles. There was further dispute by Consumers International and Greenpeace International versus industry observers on the inclusion of "traceability". Nevertheless, TFFBT concluded that "traceability" was an important tool for the implementation and enforcement of risk management measures and, therefore, agreed on a compromise text on product tracing.

The development of these texts on principles, plants and micro organisms is an example of consensus building in a very short time period. The success of this case may be attributed to the chair who concentrated the discussion on procedures and did not allow it to move beyond science-based health considerations or to diverge from developing procedures into other aspects of potential GMO standards. The process also benefited from well-funded expert consultations and well-funded inter-meeting work of the ad hoc working groups. The scientific basis of risk assessment means that the established methods could be easily transferred to both the guidelines for plants and micro organisms. However, risk management remains at the abstract level due to various possible policy responses to risk assessment results, e.g. "traceability". Nonetheless, the overall success of TFFBT is undeniable and may be attributed to the restricted terms of reference, science-base of the discussion, established international definitions and methods of risk assessment, technical input resources and focus on food safety for human health.

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70. For the moment, Codex does not overtly prioritize between its twin objectives of protecting consumer health and ensuring fair practices in food trade. Food safety standards perform both functions, but commodity standards, product descriptors and informational (non-health related) labelling are targeted specifically at fair trade and informed consumer choice.

71. The evaluation team believes that, given ever-increasing demands, Codex now needs to prioritize in the use of scarce resources, putting health first. Product definition remains important but a lower priority is implied for commodity standards and product quality descriptors.

72. Codex will still work on issues such as informational labelling as, in this domain, Codex has proven to be in some cases, a valuable forum for international discussion, and such discussion can lead, over a period of time, to a convergence of opinions. Within the domain of food labelling it indicates higher priority for health-related aspects such as nutritional labelling, health claims and allergens than for non-health related issues such as, country of origin, religious and cultural labelling.

Recommendation 3: In determining its standard-setting work programme, Codex should prioritize as follows:

1) standards having an impact on consumer health and safety;
2) commodity standards responding to the expressed needs of developing countries;
3) commodity standards responding to the expressed needs of developed countries; and
4) informational labelling relating to non-health and non-safety issues.

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