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 labeling 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 labeling 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 labeling 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 labeling 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 labeling 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 labeling 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 6.1 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 24 rd 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 30 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 in Subsection 6.1, where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labeled 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, expressedits 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 labeled". 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 an/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 techniques[8], 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 6.1 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 labeling 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 labeled 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:

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 21 st Session of the Commission, 1995)

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 (Decision of the 24th Session of the Commission, 2001)

- 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; [55]

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

- 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[56] ; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

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

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.

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.

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 an/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 6.1 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 labeling 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)