[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"]

6.3 Where the presence of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering is declared on the label, the following would apply:

(a) In the case of single-ingredient foods, or where there is no list of ingredients, the information should appear clearly on the label of the food; or

(b) In the case of a food ingredient(s) in a multi-ingredient food, the information should be shown in the list of ingredients or in parentheses immediately following the ingredient(s). Alternately, the ingredient(s) may be identified by an asterisk and the required wording should appear in a statement immediately following the list of ingredients.

[7.0 IMPLEMENTATION

Consistent with the approach(es) adopted under Section 3, additional consideration should be given to procedures and methodologies for the identification of food and food ingredients produced using certain techniques of genetic modification/genetic engineering and verification of label declarations. These include, but are not limited to: development of validated detection methods; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure.]

ANNEX

[Optional Labelling: Without prejudice to the acceptance of the approach to method of production labelling as a —legitimate concern.* of governments in establishing their national legislation, the following is provided as optional considerations to member countries:] [*Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account]

2005 (33)

CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS): DEFINITIONS (Agenda Item 5a)
PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 5b)

46. The Committee recalled that the 32nd Session of the Committee had decided to return the Proposed Draft Guidelines to Step 3 for comments and consideration at the next session. The Committee exchanged general views on the proposed draft guidelines and considered Item 5b) before Item 5a).

47. Many delegations and observers supported retaining the current structure of the Proposed Draft Guidelines which had both provisions for health and safety-related labelling and for method of production labelling. These delegations and observers stressed that the purpose of food labelling is to provide consumers not only with health and safety information but also various useful information, as required. They also noted that when products had been subject to safety evaluation prior to authorization on the market, this did not preclude their declaration on the label, as in the case of food additives. In view of this, the Proposed Draft Guidelines needed to include method of production labelling since there was a strong demand from consumers to label genetically

modified foods based on method of production, in order to allow informed choices. It was also pointed out that many provisions in the General Standard for the Labelling of Prepackaged Foods were not related to health and safety and the Committee had already established method of production labelling such as organic and halal labelling.

48. Some delegations and observers recalled that the mandate given to the Committee by the Commission in 1991 was —to provide guidance on how the fact that a food was derived from "modern. biotechnologies could be made known to the consumers" (ALINORM 91/40, para. 90) and narrowing the scope would be against the Commission decision.

49. The Delegation of the European Community, supported by other delegations, proposed to restructure the guidelines into two parts; one for mandatory labeling provisions relevant to changes in nutrient content, product composition, end use and the other for optional labelling provisions linked to labelling of method of production, following the proposal by Canada (CRD 2). Several delegations also expressed the view that progress had been made as a result of earlier discussions in the Committee and stressed the need to continue work to achieve consensus.

50. Some delegations pointed out that clear labelling on the method of production would facilitate consumer acceptance of biotechnology and would ensure fair practices in international trade.

51. Several other delegations and some observers expressed their opposition to the inclusion of method of production labelling in the Proposed Draft Guidelines for the following reasons: such labelling did not address food safety issues and was not based on scientific evidence; it would not provide useful information to consumers but rather increase confusion; and it would create barriers to trade. These delegations proposed to focus on the provisions that reflected consensus on the need for mandatory labelling in cases where significant changes in the product composition, nutritional value or intended use existed. In this context, the Committee was reminded of the recommendation of the 55th CCEXEC to redefine or narrow the scope of the work when consensus was deemed difficult to achieve (see para. 10). Some delegations also indicated that in case of a possible dispute in the World Trade Organization, the Dispute Settlement Body would not establish any distinction between mandatory and voluntary provisions contained in a Codex standard. In this respect, the Delegation of Argentina pointed out that when mentioning mandatory and voluntary provisions in a Codex standard, reference is not made to the Codex standard per se, but to the modalities of its implementation at the national level in the countries that decide to adopt it. Consequently, the objective sought by including voluntary labelling provisions in these Guidelines would not be met.

52. Some of these delegations stated that the 43rd Session of the Executive Committee (1996) had expressed the view that the Four Statements of Principle should be closely adhered to in considering the guidelines for labelling of foods derived from biotechnology and that the consumers' claimed right to know was ill defined and could not be used by Codex as the primary basis for decision-making on appropriate labelling.

53. Several delegations and some observers stressed that the information on labeling should be accurate, verifiable and should not mislead consumers. In this respect, it was pointed out that labelling two identical products based only on method of production would convey misleading message that these products were different and many consumers would perceive this as a safety warning although safety evaluation had been conducted before these products were placed in the market. Some delegations also raised a question on the practicality of implementing method of production labelling, especially in developing countries.

54. With respect to the cost implications of method of production labelling, the Committee noted that different views were expressed. Some delegations indicated that mandatory method of production labeling would not result in an increase in the prices of the products. However, some other delegations pointed out that the method of production labelling might entail additional cost necessary to comply with the labeling requirements which would finally result in the increase in food prices, without providing additional benefits to consumers.

55. After a general exchange of views, the Committee considered how to proceed. Several delegations expressed their preference for considering the text section by section in detail. However, the Committee noted the difficulty to achieve agreement on the text in the present situation as major differences existed in the basic stance taken by members.

56. Several delegations supported the proposal made in the comments of Canada to consider two levels of labelling, including mandatory provisions in relation to changes in nutrition content, composition, end use, or concerns with allergens; and optional provisions linked to voluntary labelling of the method of production by the industry. The Delegation of the EC stated that the EC and its member states were prepared to assist Canada in "reconstructing" the Proposed Draft Guidelines provided that they remained at Step 3 until the Committee had decided to replace it with the "reconstructed" Proposed Draft Guidelines to be provided by Canada.

57. After some further discussion, the Committee decided that the text should be reconstructed, taking into account the discussion held at the present session and the comments received including those of countries not present in the session (Bolivia, Costa Rica, Peru and Zimbabwe) and considered at the next session. The Committee also confirmed that the revised text would include the same contents as the current Proposed Draft Guidelines, including provisions for both health and safety-related labelling and method of production labelling.

58. For this purpose, the Committee decided to establish an electronic working group led by Canada with the assistance of Argentina, Australia, Austria, European Community, Brazil, Germany, Ghana, Guatemala, India, Indonesia, Japan, Kenya, Malaysia, Norway, Papua New Guinea, Paraguay, Sweden, Switzerland, Thailand, United States, Bio and Consumers International. The Committee also noted that the working group would be open to all members and observers.

59. The Delegation of Mexico expressed its reservation on this decision as it objected to the Committee's decision to continue work on method of production labelling provisions, considering the implications that this would have in international trade. In addition, the Delegation pointed out that the decision had not been taken by consensus as several delegations had expressed contrary views and as all the recommendations of the 55th Session of the CCEXEC had not been considered. The Delegation highlighted the necessity to analyze the impact of this decision in trade and in particular in the relation of the Codex Alimentarius with WTO. The Delegation of Argentina supported the views of Mexico, and expressed its reservation on the possibility for a Codex standard to include a mandatory and a voluntary part, since this would not make any significant distinction in the context of the World Trade Organization. The Delegation of the United States supported the reservations expressed by the delegations of Mexico and Argentina.

60. The Delegation of Malaysia expressed its reservation on the decision not to consider the current text section by section at the present session as it was noted that many delegations wanted to proceed with the discussion of the current text.

Status of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain

Techniques of Genetic Modification/Genetic Engineering : Labelling Provisions

61. The Committee agreed to return the Proposed Draft Guidelines for redrafting by the above mentioned working group, comments at Step 3 and consideration at its next session.

Definitions

62. The Committee noted that the Draft Definitions at Step 7 had been retained as a draft amendment to the General Standard for the Labelling of Prepackaged Foods because the recommendations had been developed initially as an amendment to the General Standard. The recommendations had subsequently been redrafted as independent Proposed Draft Guidelines, that also included a section on definitions.

63. The Committee noted that in order to delete the Draft Definitions as Draft Amendment to the General Standard from the Agenda, discontinuation of work should be proposed to the Commission. Several delegations supported discontinuation of work and consideration of the text of the definitions only as part of the Proposed Draft Guidelines at Step 3. Other delegations and observers proposed to retain the Draft Definitions as a separate text at Step 7 and not to discontinue work at this stage, with the understanding that this question would be considered further at the next session.

APPENDIX III

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING) DEFINITIONS (At Step 6 of the Procedure)

SECTION 2. DEFINITION OF TERMS2

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[3], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. 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

[2] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[3] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[4] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

2006 (34)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING (Agenda Item 5)

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING): DEFINITIONS (AT STEP 7) (Agenda Item 5a)

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 5b)

82. The Committee recalled that its last session had agreed to return the Proposed Draft Guidelines for redrafting by an electronic Working Group led by Canada. The mandate of the Working Group was to reconstruct the Guidelines, including mandatory provisions for health and safety related labelling and optional method of production labelling provisions in the light of the comments made at the 33rd Session and received prior to the session.

83. The Delegation of Canada informed the Committee that it had redrafted the Guidelines as agreed at the last session, and circulated it twice for comments within the Working Group; however it had not been possible to reach consensus on a revised version of the Guidelines. The revised draft was provided in the report for information and consideration by the Committee.

84. Many delegations expressed their appreciation to Canada for its considerable work on the preparation of the document and for its continuous efforts to facilitate consensus on this issue in previous sessions.

85. Several delegations, while recognizing the efforts made by Canada to redraft the Guidelines, did not support the approach taken in the revision, especially the separation of the document into mandatory and voluntary provisions, or according to safety and other aspects, and stressed that the mandate of Codex was not to provide guidelines for the industry, but recommendations for governments.

86. The Chairperson recalled that although considerable efforts had been made since the Committee had undertaken work on this item, under consideration in the Step Procedure since 1997, including extensive consideration of all the issues involved in the Committee or in working groups, there was no consensus on further development of the Guidelines or on their content. The

Chairperson invited the Committee to consider whether work should be discontinued or suspended at this stage, with the understanding that work could be resumed as required in the light of new developments.

87. Several delegations indicated that they applied general mandatory labelling of foods derived from genetic modification at the national level and supported the same approach in the Proposed Draft Guidelines in order to ensure adequate consumer information. The Chairperson however recalled that the Committee was not discussing the content of the Guidelines at this stage but invited delegations to consider how the Committee should proceed further with its work.

88. Many delegations and some observers supported further discussion of this issue in view of its importance for consumers and as many governments had established regulations in this area, and recalled that the role of Codex was to provide guidance to governments, pointing out that the Committee and the Codex Alimentarius Commission would not comply with their mandate if they failed to develop relevant guidelines. These delegations therefore supported the establishment of a physical Working Group to discuss further all relevant issues, and noted that the considerable work carried out in previous sessions should be taken into account in the process. Several delegations proposed in particular to take into account the Proposed Draft Guidelines discussed in the Committee in 2004 (ALINORM 04/27/22 Appendix VI) and the work undertaken by Canada for the present session.

89. Several other delegations and some observers supported discontinuation or suspension of work as this issue had been discussed for many years and it was clear that there was no consensus and no prospect of further progress in the near future, and the resources of the Committee should be better used to address other issues. Some of these delegations highlighted the recommendations of the 55th Session of the Executive Committee concerning the options that should be considered when no consensus existed, and proposed either to discontinue work or to narrow the scope of Guidelines and focus on the areas that were not controversial. These delegations supported further work on labelling provisions addressing health, food safety and nutrition aspects of genetically modified/genetically engineered foods and noted that consensus could be achieved on the approach to such labelling. Some delegations expressed concern with the impact on trade of labelling provisions in this area.

90. Some delegations pointed out that foods derived from biotechnology were assessed in their countries for safety prior to approval for marketing and that labeling requirements did not relate to concerns for their safety but to the information of the consumer as to the nature of the product, and that the Committee needed to address the issue in this perspective. Some delegations and observers recalled that the Committee had a specific mandate from the Commission in this respect.

91. Some delegations stressed the importance of Codex recommendations in order to provide guidance to developing counties, as it would facilitate the establishment of national policy or requirements concerning labelling of GM/GE foods and therefore supported further work in this area.

92. The Chairperson noted that there was considerable support to continue work and to establish a physical Working Group for this purpose and proposed that it should consider all relevant issues in order to identify the main problems, and take into account the experience of the countries that had established relevant regulations, including communication aspects. The Committee agreed to hold a physical Working Group in Norway. After some discussion, the Committee agreed that the Working Group would be held in January 2007 in Norway, would be co-chaired by Norway, Argentina and Ghana, and would work in English, French and Spanish.

93. Some delegations expressed their concern with the role and mandate of such a Working Group in relation to the work under consideration in the Committee and stressed that it should not go beyond the mandate of the Codex. Some delegations stressed the need to take into account the work that had already been carried out in previous years, especially the Proposed Draft Guidelines.

94. Some delegations expressed the view that it was particularly important to take into account the general recommendations set forth in the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. Other delegations pointed out that this proposal was too restrictive and that all relevant Codex texts should be taken into account, especially as regards labelling, and that the focus of the discussion should remain on labelling issues, in conformity with the mandate of the Committee.

95. After some further discussion, the Committee considered the proposed terms of reference prepared by a group of countries[11] and agreed on the following objectives and terms of reference for the Working Group.

[11]United States, Canada, Thailand, India, EC and the co-chairs of the proposed working group, Norway, Argentina and Gh ana

96. The objective of the Working Group is to assist the Codex Committee on Food Labelling with guidance relating to the further development of the Draft Proposed Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification-Genetic Engineering.

Within the mandate of Codex, the Working Group shall address the following areas:

1. Consideration of the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
2. Identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
3. Identify Members practical experiences in applying/implementing mandatory and voluntary labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
4. Identify communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering with particular reference to how Members label these foods.
5. The output CCFL may require to respond to items 1-4 above.

97. The Committee agreed that in undertaking this work, the Working Group should take into account information presented in:

- Existing proposed draft texts on the labelling of foods and food ingredients obtained from certain techniques of genetic modification/genetic engineering prepared by the Codex Committee on Food Labelling, and associated comments and committee reports.
- Relevant Codex texts such as, but not limited to, the Codex Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Codex Working

Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, particularly those sections relating to risk management and risk communication.

- The WHO document 20 Questions on Genetically Modified (GM) Foods.

98. The Committee agreed that the Working Group would be held in January, 2007, and its report would be presented at the 35th Session of the CCFL. The Circular Letter requesting information on items 1 to 4 above should be issued to provide sufficient time for responses to be received in advance of the January, 2007 Working Group meeting.

99. The Committee noted that many delegations and observers expressed their interest in participation in the Working Group[12] and recalled that physical working groups were open to all members and observers. For practical reasons, it was recommended that delegations should not exceed two participants

Status of the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering): Definitions

100. The Committee agreed to retain the Draft Amendment at Step 7.

Status of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions

101. The Committee agreed to retain the Proposed Draft Guidelines at Step 4 pending consideration of the report of the Working Group established at the present session.

2007 (35)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING (Agenda Item 5)

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING): DEFINITIONS (AT STEP 7) (Agenda Item 5a)

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING: LABELLING PROVISIONS (Agenda Item 5b)[10]

[10] CX/FL 07/35/8 (report of the Working Group)

98. The Committee recalled that its last session had agreed to establish a physical working group co-chaired by Argentina, Ghana and Norway to be held in Norway between the sessions, and that the Draft Amendment and Proposed Draft Guidelines had been held respectively at Steps 7 and 4 pending consideration of the report of the working group.

99. The Delegation of Norway indicated that the Working Group had identified seven approaches to the labelling of GM/GE foods and considered the rationale for the members' approach to each individual approach. Some delegations had expressed the view that consideration should be given to the reasons why countries chose not to adopt a certain approach, and to the cost and benefit aspects of each approach. The Working Group had identified nine possible options for further action by the Committee but had not considered them in detail as this was for the plenary session to decide.

100. The Delegation of Ghana informed the committee that co-chairing the working group had been a very useful experience, and had allowed to raise awareness of Codex issues in Ghana.

101. The Delegation of Argentina expressed its appreciation to its co-chairs and to the working group and its satisfaction for the convening of the meeting and the mandate that was sufficiently broad to encompass the reasons for the different views regarding the labelling of foods derived from GM/GE, and noted that the discussion had been very useful in order to understand the rationale for the positions taken by governments on the labelling of GM/GE foods. The Delegation however pointed out that several questions had not been discussed, in particular the positive and negative aspects of each possible approach; technical and economic viability; and the costs of implementation, especially for developing countries.

102. Many delegations expressed their appreciation to Norway, Argentina and Ghana respectively for hosting and co-chairing the working group, as it had provided a very useful opportunity to discuss the fundamental approaches to the labelling of GM/GE foods as well as the practical experience of governments at the national level. Several delegations stated that although the working group had been a very useful forum, it had also served to further highlight the lack of consensus on approaches to GM/GE labelling.

103. The Committee had a general discussion on the outcome of the working group and considered how to proceed further with the consideration of this issue.

104. Some delegations informed the Committee that serious concerns were expressed in their countries regarding the safety aspects of GM/GE foods, and also concerning the social and economic consequences of their use in agriculture, especially for small farmers.

105. The Representative of WHO informed the Committee of the extensive work carried out by FAO and WHO as regards safety assessment of foods derived from biotechnology especially through the Joint FAO/WHO expert consultations on foods derived from recombinant-DNA (r-DNA) plants and microorganisms, and genetically modified animals. The Representative also drew attention to the report of the FAO/WHO Expert Consultation on Evaluation of Allergenicity of Genetically Modified Foods (2001) which was particularly relevant to the Committee.

106. The Chair of the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, Professor Yoshikura (Japan) informed the Committee that the Task Force had elaborated several texts subsequently adopted by the Commission (2003) to address risk analysis of foods derived from biotechnology, safety assessment of foods derived from recombinant-DNA plants, recombinant-DNA microorganisms, including assessment of possible allergenicity, and that these texts had been developed on the basis of the scientific advice provided by FAO and WHO. Professor Yoshikura also informed the Committee of the current work being undertaken by the Task Force related to low level presence of r-DNA plant material, foods derived from r-DNA animals, and r-DNA plants modified for nutritional or health benefits. He also noted that there was a possible discrepancy between the provisions of paragraph 4.2.2 of the *General Standard for the Labelling of Prepackaged Foods and paragraph 43 of the Guidelines for the Conduct of Food Safety Risk Assessment of Foods Derived from r-DNA Plants.*

107. The Secretariat recalled that, in conformity with the Codex mandate, several aspects of foods derived from biotechnology were

considered in the relevant committees and the above mentioned Task Force, including food safety, methods of analysis and sampling and labelling. The issues related to agricultural policy and economy were the competence of FAO and were addressed in the programmes developed by FAO to provide guidance to member countries concerning the various aspects of biotechnology in agriculture, including capacity building to allow countries to establish their national framework for policy or regulations.

108. Several delegations recalled that foods derived from biotechnology have to undergo a pre-market safety assessment in order to protect consumers' health and therefore the request for mandatory GM/GE labelling is not a food safety issue, but an issue related to consumer information. Some delegations expressed the view that labelling was also related to food safety in view of the potential risks to consumer's health. The Observer from 49P noted that a great proportion of GE foods being sold have not been subjected to any governmental safety assessments, and therefore labelling helped consumers make their own decisions about health and safety

109. Several delegations indicated that, in their countries, consumers had no objections in principle to the use of GM/GE foods, but that mandatory labelling was necessary in order to provide clear information to consumers and to allow them to make an informed choice. These delegations and some observers stressed the fundamental right of consumers to know the nature of the food they were consuming.

110. Taking into account the above arguments, many delegations supported further work on GM/GE food labelling in the Committee, in view of the importance of the subject for consumers and in order to provide guidance to governments. Many delegations pointed out that it was especially important as many developing countries relied on Codex recommendations to develop their national policy or regulations in this area. Some delegations recalled that the Committee had received a specific mandate from the Commission in this respect in 1991. It was underlined by several delegations that the consumer right to know and to make informed choices was an essential element of GM labelling. Several delegations further pointed out that the work on GM labeling was consistent with the mandate of Codex. The Delegation of Barbados, supported by the Delegation of Ireland, stated that Codex should not abdicate its responsibility to provide appropriate guidance on GM/GE labelling. The Observers from NHF and 49P expressed their views, based on the comments of the delegations of Norway and France, that since one of the Codex mandates is to ensure fair trade practices, developing guidelines on GM/GE food labelling would be appropriate.

111. Several other delegations expressed the view that mandatory method of production labelling of foods derived from biotechnology was not justified on the grounds of food safety or fair trade practices, and that the consumer's right to know was not one of the objectives of Codex, and referred to the view expressed by the Executive Committee in 1996 to the effect that "the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labeling" (ALINORM 97/3, para. 29). These delegations pointed out that governments had the possibility of requesting mandatory labelling in their national legislation if it fulfilled a legitimate objective but that it should not be imposed to all countries at the international level. In this respect, it was recalled that one of the Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principles was that "some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world wide"

112. Some delegations expressed the view that they supported mandatory labelling of GM foods only to address a food safety or public health issue such as allergenicity, or when a substantial change existed in composition or nutritional value.

113. Several countries expressed the view that this question had been discussed since 1997 in the Step Procedure without any progress, and that in view of the fundamental differences in the approaches taken to such labelling, it was not likely that progress would be made in the near future. These delegations therefore supported discontinuation of work, taking into account the general guidance provided by the Executive Committee in the framework of the Critical Review. Some of these delegations pointed out that consideration of this issue had taken up substantial resources of Codex although it was not related to health and safety and that it would be preferable to concentrate on issues such as the implementation of the Global Strategy in the CCFL. The Delegation of Canada recommended that the Committee refer this item to the Executive Committee for consideration under its Critical Review Process.

114. Several delegations expressed the view that the working group had been very useful but that is had not been able to complete its mandate and that further discussion would be necessary to clarify all the issues raised in the Oslo working group and at the current session, and therefore proposed to hold a new physical working group between the sessions, possibly with more time to allow for comprehensive discussion.

115. Several delegations, referring to one of the options proposed in the Working Group report, suggested considering the development of overarching principles which would be consistent with all approaches to GM food labelling presented by members.

116. The Delegation of the United States expressed that it had been giving consideration to the concerns from developing countries and indicated that there was no need for the development of new guidelines as current labelling texts contained a number of provisions that could be used by governments for the purpose of addressing the labelling of GM/GE foods. The United States therefore proposed to prepare a background paper that would identify such provisions, especially in the General Standard for the Labelling of Prepackaged foods and the General Guidelines on Claims.

117. After some further discussion, the Committee agreed to establish a physical working group between the sessions and agreed that its terms of reference would be the following:

1. The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:
   a. The rationale for adopting or not adopting a particular approach
   b. The communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.
2. The undertaking of an analysis of current Codex texts, particularly Codex labelling texts, to evaluate whether or not these texts supply sufficient guidance on the labelling of foods derived from genetic modification/genetic engineering.
3. The consideration of appropriate ways forward, taking into account the result of the analysis undertaken in 2 and the suggestion of the possible ways forward identified by the Oslo WG, (e.g. guidelines, principles or discontinuation of work).
4. The development of an outcome, appropriate to the findings of 2 and 3, taking into account the discussions of the 35th session of the CCFL, the needs identified by developing countries, including those expressed at the 35th session of the CCFL, and the mandate of Codex.

The Working Group will take into account:

a) The outcome of the Oslo Working Group including the report of the Working Group.
b) The report of the 35th session of the CCFL, including the written comments.
c) An informative background paper to be prepared by the United States, Canada and Nigeria on how current Codex texts relate to the labelling of Food and Food Ingredients obtained through certain techniques of genetic modification/genetic engineering.
d) Previous guidance on the labelling of foods derived from genetic modification/genetic engineering by the Codex Executive Committee and the Commission[11].

[11] ALINORM 91/40, para. 90; ALINORM 97/3, para. 29

e) Existing guidance provided in the Codex Procedural Manual relating to the Consideration of Other Factors referred to in the second Statement of Principle.
f) Any other relevant Codex, WHO or FAO texts.

118. The Committee agreed that the Working Group would take place in Ghana in early 2008, would be three days in length and complete its work in sufficient time for the report of the Working Group to be considered by the Codex members in advance of the next Session of the Committee; and that the languages of the meeting would be English, French and Spanish. For practical reasons, it was recommended that delegations should not exceed two participants.
119. It was further agreed that a Circular letter would be issued requesting comments on items 1, 2 and 3 of the terms of the reference. The background paper to be prepared by the US, Canada and Nigeria would be attached to the CL for information.
120. The Committee briefly discussed the status of the Draft Definitions and Proposed Draft Guidelines. Some delegations proposed to advance the Definitions to Step 8 as they were consistent with the definitions developed by the Task Force on Foods Derived from Biotechnology and included in the Cartagena Protocol. Other delegations pointed out that the definitions had not been discussed for several sessions, that there had been no consensus earlier to finalise them, and that they were also included in the Proposed Draft Guidelines, and should not be finalised separately. The Committee recognized that there was no consensus to advance the definitions to Step 8.

Status of the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods* (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering): Definitions

121. The Committee agreed to retain the Draft Amendment at Step 7.

Status of the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions

122. The Committee agreed to retain the Proposed Draft Guidelines at Step 4 pending consideration of the report of the Working Group established at the present session.
123. The Committee agreed that the time frame for the completion of this work was four years.

2008 (36)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING:
DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING): DEFINITIONS (AT STEP 7) (Agenda Item 5a)
DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING): LABELLING PROVISIONS (Agenda Item 5b)

75. The Committee recalled that its last session had agreed to establish a physical working group cochaired by Argentina, Ghana and Norway to be held in Ghana between the sessions and that the Draft Amendment on the Definitions and the Proposed Draft Labelling Provisions had been held respectively at Steps 7 and 4 pending consideration of the report of the working group.
76. The Delegation of Ghana introduced the report of the working group and expressed its thanks to its co-Chairs, Argentina and Norway, and to all participants for their active contribution to the discussion. The Delegation indicated that the working group had considered the rationale for different approaches to GM/GE labelling adopted by national governments, the communications strategies used in communicating information to the public on GM/GE foods; and an analysis of current Codex texts which may provide guidance on the labelling of GM/GE foods, as presented in a background paper considered by the working group (CL 2007/38-FL). Several key concepts derived from this paper were identified, modified and brought together in a draft document (Appendix III of CX/FL 09/36/8). The working group had discussed the possible title and proposed alternative texts for chapeau statements but had not reached consensus on the text. The Delegation of Argentina, as co-Chair, explained the process that the working group had followed to consider this subject, after identifying three main proposals in the course of its discussions.
77. The Committee expressed its appreciation to Ghana for its kind hospitality in hosting the working group and to the three Co-chairs, Ghana, Argentina and Norway for their chairmanship that had allowed the working group to make substantial progress on complex issues. The Committee considered how to proceed further in the light of the report of the working group.
78. Some delegations referred to their experience at the national level in the development of regulations on GM/GE labelling and noted that the background paper had been useful for this purpose or that they would use it in the future. The Committee expressed its appreciation to the delegations of the United States, Canada and Nigeria for this useful and excellent document.
79. The Delegation of the United States pointed out that the background paper was intended to address the need of member countries, especially developing countries, for guidance on the labelling of GM/GE foods and addressed four key issues: providing consumers with necessary health and safety-related information; providing consumers with information related to the significant differences in composition, characteristics, nutritional properties, or intended use of the food; protecting consumers from false and misleading labelling information; and ensuring truthful and non-misleading information to meet consumer demand. The Delegation further noted that in the working group held in Norway it was evident that countries had taken different approaches due to the different legal, regulatory and social frameworks. Such differences were an indication that such work should not be continued in Codex. The

Delegation indicated that it was possible to respond to the 1991 request of the Commission and therefore proposed that this document be forwarded to the Commission, as it could be used by governments as guidance regarding labelling of GM/GE foods and that the Committee should discontinue work on the development of a Codex text, as this item had been considered for many sessions and there was no prospect of reaching consensus. The Delegation stated that Appendix III was not an adequate basis for discussion as it was a simplification of the background document and included some areas where the Committee had failed to reach consensus. Several delegations and Observers supported this position.

80. Some delegations pointed out that mandatory labelling would substantially increase the costs of food production for the manufacturers and negatively affect the availability of foods, which would especially affect developing countries and low income consumers, especially in view of the increase in the price of food commodities at the international level.

81. Many other delegations and some observers supported further work on GM/GE food labelling, especially further consideration of Appendix III. These delegations underlined that although the two recent working groups came to the conclusion that no consensus was possible on a recommended approach to label GM/GE foods, they considered it was possible to agree on a list of principles or concepts to be taken into consideration by the countries willing to develop and implement rules on labelling of GM/GE foods. Such a document would address the requests expressed at the 34th and 35th sessions of the Committee by many delegations requesting Codex guidance on the labelling of GM/GE foods.

82. Some delegations and observers expressed the view that the consideration of this document was a first stage and that mandatory labelling of GM/GE foods should be required in order to ensure the right of consumers to be informed. The Observer from IFOAM supported further work and stressed the importance of mandatory labelling to allow consumer choice, and stated that as GM/GE crops are not allowed in the organic system, labelling of GM/GE foods is essential for the purposes of traceability and inspection in order to ensure the integrity of the organic system.

83. Some delegations and the Observer from NHF expressed the view that labelling of GM foods was necessary in order to address health concerns of consumers. Other delegations pointed out that all foods derived from biotechnology were subject to pre-market safety assessment, that unsafe foods should not be present on the market and therefore there was no justification to require mandatory labelling of such foods from the point of view of health protection.

84. The Chair drew the attention of the Committee to the requirements for safety assessment of foods derived from biotechnology prior to marketing in the countries where GM/GE foods were produced and to the work of Codex in this area.

85. The Chair of the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, Professor Yoshikura (Japan) informed the Committee that the Task Force had finalised three documents addressing food safety assessment of foods derived from Recombinant-DNA animals, Recombinant-DNA plants modified for nutritional or health benefits, and food safety assessment in situations of low level presence of Recombinant-DNA plant material in food. It had also been agreed that FAO would host a database for data and information sharing for the purpose of the Annex. The Chair of the Task Force also recalled that according to the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003, para. 19) "Risk management measures may include, as appropriate, food labelling conditions for marketing approvals and post-marketing monitoring".

86. The Delegation of Argentina expressed the view that safety and consumer health protection were priority aspects in the work of Codex; however in the discussion of the agenda items it perceived a contradiction in the fact that various member countries who supported labelling of GM/GE foods, which was not based on safety or health protection, were opposed to mandatory nutrition labelling, which was part of the WHO Global Strategy to reduce non communicable diseases, due to economic reasons, lack of understanding by consumers and excess of information on the labels.

87. As a compromise, some delegations proposed to limit further work to the consideration of Table 1 of Appendix III which provided only the list of relevant Codex texts without additional text, as it would provide useful guidance to governments and could be acceptable to all delegations. Some delegations, while not objecting to the consideration of Appendix III, indicated that it should be limited to those provisions on which consensus existed and that they would not support any modification beyond these areas of consensus.

88. The Committee recognized that there was large support for proceeding with work on the basis of Appendix III of CX/FL 08/36/8 and agreed that it would replace the text of the Proposed Draft Guidelines held at Step 4 in earlier sessions (ALINORM 04/27/22, Appendix VI). In view of the nature of the text, it was agreed that the title would refer to "Recommendations" instead of "Guidelines". It was further agreed that Appendix III should be considered in conjunction with the background document in CL 2007/38-FL.

89. The Delegation of the United States did not agree to the proposal for proceeding with work on Appendix III and noted that the areas of disagreement highlighted in Ghana and reiterated during the current session of CCFL were the same issues that had prevented the Committee from reaching consensus for the previous decade.

Definitions

90. The Committee considered how to proceed with the Draft Definitions currently at Step 7 in view of the above discussion.

91. The Delegations of the European Community and Switzerland, supported by other delegations, pointed out that the definitions had been held at Step 7 in earlier sessions pending the finalisation of the Proposed Draft Guidelines, and should be retained as they were essential to define the products under consideration. It was underlined that the fact that the definitions had reached Step 7 reflected a high level of consensus on these. Some other delegations proposed to delete the definitions as similar definitions already existed in the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003). The Committee did not consider the definitions in more detail.

Status of the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering): Definitions

92. The Committee agreed to retain the Draft Amendment at Step 7 (see Appendix VI).

Status of the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering

93. The Committee agreed to circulate the Proposed Draft Recommendations at Step 3 for comments and consideration at the next session (see Appendix VII).

APPENDIX VI

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING) DEFINITIONS (At Step 7 of the Procedure)

SECTION 2. DEFINITION OF TERMS[8]

For the purpose of the General Standard:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques[9], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[10]

beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[8] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[9] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[10] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

APPENDIX VII

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

(At Step 3 of the Procedure)

[[Chapeau 1

"Food labeling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other. Labelling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption. For additional assurance on safe and appropriate use of food, food labeling can be employed to provide consumers with essential information. It is recognized that consumers' expressed needs may vary in different regions of the world. These differences might lead to various levels of approaches regarding labelling of foods obtained by GM/ GE modifications.

The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts which are relevant for the labelling of foods obtained by GM/ GE techniques".

Chapeau 2

"The purpose of this document is to recall and assemble in a single document some important elements from Codex texts which are relevant for the labelling of foods obtained by GM/ GE techniques".]

1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:
   - The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985)
   - The Codex General Guidelines on Claims (CAC/GL 1-1979)
   - The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
   - Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
   - Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
   - Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms
   - Working Principles for Risk Analysis for Food Safety for Application by Governments
2. Codex labelling and other texts apply to foods sold in unpackaged/non-retail containers including those foods obtained through GM-GE techniques and sold in such manner. Labelling means "any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal".
3. Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption. Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose[11].

   [11] Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003).
4. The Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) states that the "transfer of genes from commonly allergenic foods . . . should be avoided unless it is documented that the transferred gene does not code for an allergen . . .".
5. The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed (section 4.2.2, GSLPF).
6. When the physical, chemical, or functional characteristics of a food are significantly altered through any means (production or processing), the labelling of such food be appropriately modified from its traditional labelling to ensure that the food is described or presented in a manner that is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect. The traditional name of such food may need to be changed or qualified with additional words or phrases to describe the true nature of the food and to avoid misleading or confusing the consumer.
7. In cases where GM/GE modifications result in a claim related to the nutritional properties of the food, the claim language should be consistent with the Guidelines for Use of Nutrition and Health Claims.
8. The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods.
9. Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences.
10. Any representations made on the label or in the labelling of GM/GE foods should be consistent with the GSLPF (Codex Stan 1-1985) and the General Guidelines on Claims (CAC/GL 1-1979).

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods

Mandatory Labelling Provisions

General Standard for the Labelling of Prepackaged Foods	
3.1	Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
3.2	Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.
4.1.1	The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.
4.1.2	There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.
4.2.2	The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Voluntary Labelling Provisions

General Standard for the Labelling of Prepackaged Foods	
7.1	Optional labelling –Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3 –General Principles.
General Guidelines on Claims	
1.2	The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
1.3	The person marketing the food should be able to justify the claims made.
2	Definition – For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.
3.3	Prohibited claims – Claims which cannot be substantiated.
3.5	Prohibited claims – Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.
4.1	Potentially misleading claims – Meaningless claims including incomplete comparatives and Superlatives.
5.1(iii)	Conditional claims – Terms such as "natural," "pure," "fresh," "home made," "organically grown," and "biologically grown" when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.
5.1(v)	Conditional claims – Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.
5.1 (vi)	Conditional claims – Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance: (b) is one which consumers would normally expect to find in the food; (d) is one whose presence or addition is permitted in the food.
Guidelines for Use of Nutrition and Health Claims	

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LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS: DEFINITIONS (at Step 7) (Agenda Item 6a)

88. Several delegations proposed discontinuation of the work on the definitions noting that they were linked to a paper that was no longer under discussion.

89. Several other delegations clarified that the definitions were an amendment for inclusion in the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) because 4.2.2 of the General Standard made reference to food or food ingredients obtained through biotechnology without defining this term. They proposed the definition be advanced to Step 8 for adoption.

90. The Delegation of Japan proposed two amendments. One is the first definition to read —food and food ingredients obtained through biotechnology. means food and food ingredients….. to be consistent with the GSLPF. To modify the third definition by stopping the sentence after the words modern biotechnology. The Committee however did not give consideration to this proposal, but agreed that it could be considered at the next session and to retain the draft amendment at Step 7.

Status of the Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods*: Definitions

91. The Committee agreed to retain the Draft Amendment at Step 7 (Appendix VI).

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (at Step 4) (Agenda Item 6b)

92. The Committee recalled the decision of its last session to replace the text of the Proposed Draft Guidelines (ALINORM 04/27/22, Appendix VI) with Appendix III of CX/FL 08/37/8, Proposed draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering and to circulate it at Step 3 for comments and consideration by this session of the Committee. It further recalled that the Draft Amendment to the General Standard for the Labelling of Prepackaged Foods: Definitions had been held at Step 7 pending further discussion on the proposed draft recommendations.

General remarks

93. Some delegations and some observers, were of the opinion that work on this issue should be discontinued noting that the matter had been discussed for almost two decades without consensus, that there was very little prospect of consensus in the future and considerable financial and human resources had been dedicated to this work over the years which could be better used to address more pressing health issues such as the implementation of the Global Strategy on Diet, Physical Activity and Health currently under discussion in the Committee. One delegation recalled that the first priority of Codex was protection of consumer health and food safety as asserted by the 25th Session of the Commission[13]. One delegation mentioned that Codex texts already gave sufficient guidance for the labelling of GM/GE foods and that identifying the method of production claims such as those related to GE should be a market driven decision of the private sector. One delegation noted that it was not clear that there is agreement within the committee on the nature of the work to be undertaken.

[13] ALINORM 03/25/5, para. 15

94. One delegation mentioned that governments were sovereign to adopt labeling provisions that they deem necessary to provide information to the consumer within the framework of their respective legislation and that therefore there was no reason for Codex to be involved in establishing specific provisions on this subject matter.]

95. Many other delegations and several observers expressed the view that some progress had been made over time and emphasized that especially many developing countries looked to Codex for guidance on approaches for the labelling of GM/GE foods and that the proposed draft recommendations could prove useful in this respect. One Observer recalled that Codex had a dual mandate to not only protect the health of consumers but also to ensure fair practices in the food trade and thus a failure to label GM/GE foods could in itself be considered misleading. Several delegations and observers expressed the need for mandatory labelling to allow consumer choice, noting that GM/GE foods were a sensitive issue for consumers in their respective countries and therefore stressed the importance of continuing this work. In addition many delegations and several observers expressed their view that one of the main conclusions of the work already carried out by several working groups was that several approaches for labelling of GM/GE foods were possible. One delegation indicated that their population preferred foods derived from GM/GE techniques because they were cheaper but while this was the case the consumers would still prefer the choice of being informed if the foods were derived from GM/GE techniques and therefore could not see the rationale for the discontinuation of this work.

96. In view of the large support to continue work, the Committee proceeded to discuss the proposed draft recommendations.

Chapeau 1 and 2

97. The Committee considered the two options for the chapeau as presented in ALINORM 08/31/22, Appendix VII as "chapeau 1" and "chapeau 2". As in the written comments there was no consensus on either of the chapeaux in the plenary discussion.

Different delegations proposed amendments to one or the other chapeau, which received varying degrees of support but no consensus could be reached on any of the versions proposed.

98. In view of the lack of consensus, the Committee considered a proposal by the Chairperson to delete the chapeau and to start the document with paragraph 1.

99. There was no agreement to the text as it stood without the chapeau and severa proposals were made to amend the first part of paragraph 1 to include that:

(1) any information or pictorial device may be displayed on labels of foods obtained from GM/GE techniques provided that these are not in conflict with Codex standards and guidelines (text adapted from the optional labelling provisions in CODEX STAN 107-1981); and

(2) to indicate that foods derived from GM/GE were not in any way different or less safe due to their method of production provided that they had undergone safety assessments consistent with relevant Codex guidelines.

100. However, no agreement could be reached on the text with these amendments.

101. In view of the lack of consensus, the Committee considered a proposal by the Chairperson to hold the work in abeyance for a

minimum of three sessions until more experience had been gained on labelling of GM/GE foods by member states and to allow for bilateral and multilateral exchanges and further discussion on this matter on an informal basis.

102. Many delegations and several observers did not support this proposal, reiterating their view that progress had been made, and that only a few members were not in agreement with the work done to date, and that the document could serve as a useful basis for further discussion and would provide useful guidance to developing countries in particular. Several delegations and observers underlined that suspension of the work on such an important labelling issue recognised by the majority of the consumers of the world would undermine the credibility of the Committee and require attention in other fora such as the regional coodinating committees.

103. Other delegations, while acknowledging the needs of developing countries but noting that not all developing countries supported continuation of work on this issue, supported the view that a pause could possibly allow common ground to develop among members to progress on the work in the future and that in the meantime the Committee could concentrate its efforts on the work to facilitate the implementation of the Global Strategy on Diet, Physical Activity and Health.

104. Noting the lack of support for the proposal, the Committee therefore agreed to retain the two original chapeau proposals, in addition to several of the proposals to amend them and the proposal for paragraph 1 as amended for comments at Step 3 and further consideration by the next session of the Committee.or

Status of the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering

105. The Committee agreed to circulate the Proposed Draft Recommendations at Step 3 for comments and consideration at the next session (Appendix VII).

APPENDIX VI

DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS - DEFINITIONS (At Step 7 of the Procedure)

SECTION 2. DEFINITION OF TERMS[1]

For the purpose of the General Standard:

"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified / engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.

"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.

"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.

"Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques[2], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[3] beyond the taxonomic family,

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

[1] The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels

[2] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion

[3] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family

APPENDIX VII

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (At Step 3 of the Procedure)

[Chapeau 1:

"Food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other. Labelling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption. For additional assurance on safe and appropriate use of food, food labeling can be employed to provide consumers with essential information. It is recognized that consumers' expressed needs may vary in different regions of the world. These differences might lead to various levels of approaches regarding labelling of foods obtained by GM/ GE modifications. The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods obtained by GM/ GE techniques".] / **or**

[Chapeau 2:

"The purpose of this document is to recall and assemble in a single document some important elements from Codex texts which are relevant for the labelling of foods obtained by GM/ GE techniques".] **/or**

[Chapeau 2 as amended by the USA:

"The purpose of this document is to recall and assemble in a single document some important elements from Codex LABELLING AND OTHER texts which are relevant for foods obtained by GM/GE techniques AS THEY ARE FOR ALL FOODS. THIS DOCUMENT IS NOT INTENDED TO SUGGEST OR IMPLY THAT GM/GE FOODS ARE IN ANY WAY DIFFERENT FROM OTHER FOODS SIMPLY DUE TO THEIR METHOD OF PRODUCTION".] **/or**

[Chapeau 2 as amended by Brazil:

"The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques. It also recognizes that each country can adopt different approaches regarding labelling of foods obtained by GM/GE techniques and that food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other".] / **or**

[Amendment to the first sentence of paragraph 1 as developed during the 37th Session of the CCFL as alternative to chapeau 1 and 2:

"1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE techniques. Any information or pictorial device may be displayed on labels of foods obtained from

GM/GE techniques provided that these are not in conflict with Codex standards and guidelines.

This document is not intended to suggest or imply that food obtained from GM/GE techniques are in any way different or less safe from other foods simply due to their method of production provided that they have undergone safety assessment according to the guidance of the Codex Alimentarius Commission".]

[Text as annexed to report of the 36th Session of the CCFL:

"1. The following Codex standards and related texts contain provisions applicable to the labeling of food products and may be applied to foods obtained by GM/GE:]

- The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985)
- The Codex General Guidelines on Claims (CAC/GL 1-1979)
- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
- Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms
- Working Principles for Risk Analysis for Food Safety for Application by Governments

2. Codex labelling and other texts apply to foods sold in unpackaged/non-retail containers including those foods obtained through GM-GE techniques and sold in such manner.
   Labelling means "any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal".
3. Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption. Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose[1].

   [1]Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003).
4. The Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) states that the "transfer of genes from commonly allergenic foods . . . should be avoided unless it is documented that the transferred gene does not code for an allergen . . .".
5. The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared.
   When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed (section 4.2.2, GSLPF).
6. When the physical, chemical, or functional characteristics of a food are significantly altered through any means (production or processing), the labelling of such food be appropriately modified from its traditional labelling to ensure that the food is described or presented in a manner that is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect. The traditional name of such food may need to be changed or qualified with additional words or phrases to describe the true nature of the food and to avoid misleading or confusing the consumer.
7. In cases where GM/GE modifications result in a claim related to the nutritional properties of the food, the claim language should be consistent with the Guidelines for Use of Nutrition and Health Claims.
8. The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods.
9. Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences.
10. Any representations made on the label or in the labelling of GM/GE foods should be consistent with the GSLPF (Codex Stan 1-1985) and the General Guidelines on Claims (CAC/GL 1-1979).

Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods

Section Mandatory Labelling Provisions

General Standard for the Labelling of Prepackaged Foods

3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

3.2 Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

4.1.1 The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.

4.1.2 There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared.
When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Section Voluntary Labelling Provisions

General Standard for the Labelling of Prepackaged Foods

7.1 Optional labelling Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3
- General Principles.

General Guidelines on Claims

1.2 The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

1.3 The person marketing the food should be able to justify the claims made.
2 Definition - For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

3.3 Prohibited claims - Claims which cannot be substantiated.

3.5 Prohibited claims - Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.

4.1 Potentially misleading claims Meaningless claims including incomplete comparatives and superlatives. 5.1(iii) Conditional claims - Terms such as "natural," "pure," "fresh," "home made," "organically grown," and "biologically grown" when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.

5.1(v) Conditional claims Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.

5.1(vi) Conditional claims Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:
(b) is one which consumers would normally expect to find in the food;
(d) is one whose presence or addition is permitted in the food.

Guidelines for Use of Nutrition and Health Claims"]

PART II
Short Summary and Some Questions

1. Introductory Phase

The 19th Session of Codex Alimentarius Commission in 1991 requested CCFL to provide guidance on the possibilities to inform the consumer that a food had been produced through modern biotechnology. In the 22nd Session of CCFL in 1993, the United States volunteered to prepare a discussion paper, which was submitted to the 23rd Session of CCFL in 1995.

Record of Discussion

1993 (22nd CCFL)

9. The Committee was informed of the request of the 19th Session of the Codex Alimentarius Commission that CCFL should provide guidance on the possibilities to inform the consumer that a food had been produced through "modern" biotechnologies.

10. The Committee welcomed the offer of the Delegation of the United States to prepare a discussion paper concerning this subject for circulation and government comments well before the next Session.

1995 (23rd CCFL)

114. The Committee expressed its appreciation to the Delegation of the United States for this comprehensive document and the presentation of current issues associated with biotechnology. It was also noted that, due to time constraints, the document had not been circulated with ample time for comments. Moreover, several delegations indicated that their scientific and legal authorities were considering this complex issue at the moment and that they would need additional time to examine in detail the questions the Committee was mandated to address.

2. Amendments agreed on sections related to allergenicity in General Standard for Labelling of Prepackaged Foods

CCFL agreed rather quickly (in total 4 sessions, 1997-2000) on allergenicity (See record of discussion in Ref. 1). The statement in the agreed document is as follows;

Section 4.2.2: The presence in *any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared.* When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

3. Organically Produced Food

CCFL agreed quickly on exclusion of genetically modified organisms or products thereof from the production of organically produced food without much debate. The agreed text relating to this particular issue is reproduced in Ref. 2.

4. Fourteen years' debate without any change in original positions of delegates (Ref. 3)

It is remarkable that members supporting labeling and those opposing have not changed their positions in the past 14 years.

Voices for labeling

1996: "the opinions of many delegations and observers which called for the mandatory and comprehensive labelling of all foods prepared with the aid of biotechnology on the basis of the consumer's right to know the origin and nature of the foods which they purchased and the right to make informed choices"

2007: "mandatory labelling was necessary in order to provide clear information to consumers and to allow them to make an informed choice. These delegations and some observers stressed the fundamental right of consumers to know the nature of the food they were consuming"

2009: "expressed the need for mandatory labelling to allow consumer choice, noting that GM/GE foods were a sensitive issue for consumers in their respective countries.

Voices against labeling

1996: "labelling should address the specific concerns of safety (including potential allergenicity), nutrition and food composition, all of which could be subject to scientific study and evaluation, and that labelling should be considered on a case-by-case basis"

2007: "mandatory method of production labelling of foods derived from biotechnology was not justified on the grounds of food safety or fair trade practices, and that the consumer's right to know was not one of the objectives of Codex.

2009: "work on this issue should be discontinued noting that the matter had been discussed for almost two decades without consensus, that there was very little prospect of consensus in the future"

Concern on the safety of foods derived from biotechnology is continuously expressed by the members requesting mandatory labelling, even five years after agreement on Guidelines on Foods Derived from Modern Biotechnology, which clearly mandated the pre-market risk assessment, e.g.,

2007: Some delegations expressed the view that labelling was also related to food safety in view of the potential risks to consumer's health. Some delegations informed the Committee that serious concerns were expressed in their countries regarding the safety aspects of GM/GE foods

Lasting claim from the party that supports mandatory labeling is "right to know of consumers";

1996: The Committee noted the opinions of many delegations and observers which called for the mandatory and comprehensive labelling of all foods prepared with the aid of biotechnology on the basis of the consumer's right to know the origin and nature of the foods which they purchased and the right to make informed choices based on a variety of considerations and personal values

2007: "request for mandatory GM/GE labelling is not a food safety issue, but an issue related to consumer information"

2009: expressed the need for mandatory labelling to allow consumer choice, noting that GM/GE foods were a sensitive issue for consumers in their respective countries

5. Several questions

1. Mandate given by Codex Alimentarius Commission

The sentence appearing in the 1991 Commission's report, "The Commission requested the Codex Committee on Food Labelling to provide guidance on how the fact that a food was derived from "modern" biotechnologies could be made known to the consumers., was continued to be referenced, e.g.,

2003: In this context, the delegation of Norway recalled that the mandate given to the Committee by the Codex Alimentarius Commission in 1991 "to provide guidance on how the fact that a food derived from "modern biotechnologies" could be made known to the consumers. still holds (Paragraph 90 ALINORM 91/41) (72).

2004: During the discussion, the Delegation of Switzerland, supported by the Observer from Greenpeace, recalled the mandate that had been given to the Committee by the Commission in 1991 "to provide guidance on how the fact that a food was derived from —modern. biotechnologies would be made known to the consumers" (ALINORM 91/40, para. 90) (83).

It is interesting to note that the request from Codex Commission was not "to provide guidance on labeling of a food derived from "modern biotechnologies", but "to provide guidance on how the fact that a food was derived from "modern. Biotechnologies" would be made known". *The Commission's request appears to allow wider options (not just labeling) for making consumers know the fact that a food was derived from "modern. Biotechnologies"*

2. Executive Committee recommended CCFL to adhere to the Statements of Principle Concerning the Role of Science in the debate on GM labeling (paragraph 52, 25th CCFL, 1997). The statements are;

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

The statement 1 requests sound scientific analysis.

According to the statement 2, Codex considers other legitimate factors relevant for the health of consumers and fair trade.

According to statement 3, while other legitimate factors being considered, role of labeling is in furthering the health of consumers and fair trade.

The statement 4 relates to allowance of abstention from the codex standards by member countries when they hold differing views about considerations that are other than the necessary level of protection of public health.

As regards statement 3, how can labeling further the objectives of protection of health and fair trade in the situation where foods derived from modern biotechnology are marketed after prior risk assessment?

As regards statement 4, what are "considerations that are other than the necessary level of protection of public health"?

How should CCFL use these four statements in the debate of GM labeling?

3. *"Right to know" has been frequently claimed by those requesting the mandatory labeling. The view expressed by the Executive Committee in 1996 was that "the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labeling" (ALINORM 97/3, para. 29).*

Is the "right to know" an issue unique to the foods derived from modern biotechnology? Consumers may want to know many things, such as producer's name, place and method of cultivation, animal husbandry, harvest, trade route, etc, even for conventional foods. The request may become endless. If "right-to-know" is used as a criterion of labeling, certain criteria of "right to know" may be necessary. How should "right to know" be handled in Codex in general?

4. *Divergence of different regulatory options taken by member countries regarding the GM labeling.*

In the 29th session in 2001;

67. Some delegations questioned the development of Guidelines which would provide different options according to the regulatory approach taken in member countries since this was not the usual approach in Codex and it was not clear how this would apply in case of trade disputes. These delegations indicated that Codex should rather give general recommendations that could be applied in all countries as a basis for international harmonization.

In the 32nd session in 2004, Cameroon indicated;

83. .... many countries had established national regulations.

Such statements were confirmed by countries' responses appearing in Appendix II of Report of the CCFL Working Group on Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering in

Oslo (CX/FL 07/35/8).

As the delegates themselves are regulating labeling according to the law of their own countries, it will be very difficult for them to accept publicly a scheme that does not fit their own law. The delegates may have no other choice than imposing their own labeling system to others. In such a situation, is it possible for codex to agree on any common guidelines (particularly if the delegates pursue a very descriptive guidance)?

5. *General Standard for the Labelling of Prepackaged Foods gives guidance on labeling of foods in general. Are there any sections that are not suitable or not applicable to foods derived from modern biotechnology in the present form?*

If all or nearly all of the provisions in the Standard apply to foods derived from modern biotechnology, is it necessary to replicate them in a separate document specially dedicated to the foods derived from modern biotechnology?)

6. *CCFL working group proposed the 35th session of CCFL the following options to advance the work in CCFL.*
   1. Discontinue work on this agenda item
   2. Distil common principles and themes which we could agree to take forward
   3. Develop general horizontal overarching principles which would be consistent with all the GM approaches presented by members.
   4. Refer back to the CAC
   5. Share the experience we have gathered in the Oslo workshop
   6. Continue working on the draft guidelines taking into consideration the outcome of the working group based on information shared by the working group members
   7. Discontinue work related to consumer information which should be based on national legislation
   8. Continue work related to consumer information.
   9. Focus on guidelines for labelling of GM foods where there is a significant difference from its conventional counterpart where only the significant difference is labelled.

The option 5 was useful in realizing different regulatory options already taken by member countries. The question is how CCFL takes this information into account.

The first option, discontinuing the work, could be a choice, because the regulatory systems are already different among countries and there could be no room for changing the countries' own rules in near future. The question is, however, how or in which way to discontinue the work without dissatisfying the party which wants labeling guidance.

How about option 2 or 3? What options other than the above nine are there?

7. *How can the agreements already obtained in codex be used for debate on GM labelling? For example, how can the consumers be informed that under the codex guidance pre-market safety assessment is prerequisite for placing the products on the market?*

6. Labelling appearing in the codex text produced by Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology

1. Allergen

Paragraphs related to allergenicity in General Standard for the Labelling of Prepackaged Foods and in Guideline for Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants are as follows;

General Standard for the Labelling of Prepackaged Foods (CCFL)

Section 4.2.2: The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Task Force of Biotechnology)

43. The transfer of genes from commonly allergenic foods and from foods known to elicit gluten-sensitive enteropathy in sensitive individuals should be avoided unless it is documented that the transferred gene does not code for an allergen or for a protein involved in gluten-sensitive enteropathy.

The Section 4.2.2 of the CCFL guidelines was agreed in 2000 and paragraph 43 of the Task Force was agreed in 2003. These two paragraphs are almost concordant but not entirely so.

Section 4.2.2 of the Prepackaged Guideline does not exclude the possibility of marketing of food or food ingredients that acquired allergen through biotechnology. It recommends declaration of their presence if they are present.

Meanwhile, paragraph 43 of the Task Force's guideline recommends avoidance of marketing of such products.

Among the products listed in Section 4.2.1.4, lactose and sulphite do not fit into the description in Section 4.2.2 as they are chemicals that contain no genes to be transferred.

2. Labelling (Ref. 6)

There is one paragraph directly referring to labeling. It is paragraph 19 of Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, 19. Risk management measures may include, as appropriate, labeling conditions for marketing approvals and post-market monitoring.

This paragraph recognizes that labelling is used as risk management.

3. Risk Management (Ref. 6)

How is "risk management" considered in the same document then? Paragraph 16 may be most relevant.

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

It is assumed that risk management measures (including labeling?) be based on the outcome of the risk assessment.

4. Other legitimate factors

The paragraph 16 also recommends to take into account "other legitimate factors.

According to STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT (Ref. 4),

2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

The statements recognize important role of labeling in furthering the health promotion of consumers and fair practices in food trade. How does labeling further these objectives if the products are already passed the safety assessment before being placed on the market?

Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle (Ref. 4)

Among eight criteria in "Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle., the following five criteria may potentially have relation to the labeling issue, i.e.,

- consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;
- only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex
- the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
- the integration of other legitimate factors in risk management should not create unjustified barriers to trade ; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

Should these criteria be considered in the labeling measures that are taken as risk management option?

5. WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS

Paragraph 16 recommends consideration of WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS (Ref.5)

The relevant paragraphs could be paragraphs 27 and 28. They are;

27. While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers.

Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.

28. Risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles.

Issues related to "differences in the level of consumer health protection to address similar risks in different situations. (paragraph 27 of the Working Principles for Risk Analysis) were discussed in The Task Force on Foods Derived from Biotechnology discussed in its third session. It appears in the following paragraph of the report;

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

The corresponding paragraph agreed finally by Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology reads;

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

How should WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX

ALIMENTARIUS be considered for labeling as a risk management measure?

Note: To the above issues, consideration of "like products" may be necessary. Note on "like products" is found in pages61-63 of this document.

REFERENCES

Ref. 1: Record of Discussion on allergenicity

1997 (25th CCFL): The Committee recalled that its last session had agreed that, subject to the advice of the Executive Committee, the Secretariat should initiate the preparation of guidelines to address the labelling issues associated with foods obtained through biotechnology. The Executive Committee had recommended that the Statements of Principle concerning the Role of Science9 should be closely adhered to and that the recommendations of the Joint FAO/WHO Expert Consultation on Food Safety and Biotechnology should be taken into account (52). The Secretariat indicated that the recommendations had been presented in the form of an amendment to the General Labelling Standard, following the approach taken for similar issues, and presented the conclusions of the Expert Consultation of particular relevance where labelling was concerned. The Committee noted that the elaboration of the recommendations had already been approved by the CCEXEC and that comments at Step 3 had not yet been requested in view of time constraints (53). The Committee agreed that the Proposed Draft Recommendations, as included in Appendix VI, should be circulated for government comments at Step 3, redrafted by the Secretariat, taking into account all comments received, for further consideration and thorough discussion in the plenary meeting at the next session (60).

APPENDIX VI: PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD OBTAINED THROUGH BIOTECHNOLOGY (PROPOSED DRADT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS) (At Step 3 of the Procedure)

Allergenicity

16. The Consultation considered the specific issues related to allergenicity in the case of biotechnology and made recommendations for the assessment of potential allergens, including a number of criteria to be applied in identifying potential allergenicity. It proposed that foods which would pose a health risk should not be released. It recommended that foods that fail to elicit positive results in in vitro or in vivo tests should be treated like any other foods in regard to allergenicity. The recommendations made by the CCFL concerning the labelling of potential allergens would therefore apply to foods obtained through biotechnology as to conventional foods.
17. As regards the possibility of transfer of allergenic properties to foods which normally are not allergenic, the Consultation made the following recommendations:
    - The transfer from commonly allergenic foods should be discouraged unless it can be documented that the gene transferred does not code for an allergen.
    - Foods which contain an allergen transferred from the organism which provided the DNA should not be considered for market approval unless they can be clearly identified in the marketplace and this identity would not be lost during distribution or processing. Labelling approaches may not be practical in these situations, and particular problems for consumers who cannot read, or who may not be provided with labels. Foods which are not presented on the market in a pre-packaged form and generally not labelled should be taken into account.
25. Recommendations relating to allergens should be considered in conjunction with the specific discussion on this subject, and the amendment of the General Standard, under Agenda Item 6 (Proposed Draft Recommendations for the Labelling of Foods that can cause Hypersensitivity).
27. The following amendments to the **General Standard for the Labelling of Prepackaged Foods** are therefore proposed as a basis for discussion and for consideration by the Committee:

Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology (Proposed Draft Amendment to the General Standard for the Labelling of Prepackaged Foods) (At Step 3 of the Procedure)

Recommendations concerning allergens

Two possible approaches are proposed:

[In view of the recommendations of the Consultation, it is not proposed at this stage to establish labelling requirements for material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population (especially allergens) as the preferred approach would be to discourage the marketing of such products.]

OR

[Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.3[5], shall be declared.]

1998 (26th CCFL): The Committee, recognizing the need to concentrate its efforts on the areas where consensus could be achieved, as proposed by the Chairperson, had an exchange of views on the definition of foods obtained through biotechnology.

The Committee noted the proposals 1) to replace "new" with "modern" biotechnology, and 2) to avoid using the term " biotechnology" as it might create confusion for the consumer. Taking into account the amendments to the definition proposed by Canada and the EC, the Committee agreed on a revised definition which clarified the scope of the text. The Committee also agreed to require the labelling of allergens transferred through genetic modification, as proposed in the current text (section 4.2.2.) (48). The Committee agreed to forward the amended Definition in square brackets and Section 4.2.2. (allergens) to Step 5 (see Appendix VII) and to return all other sections of the Proposed Draft to Step 3 for further comments and consideration by the next session (see Appendix VIII) (49).

Appendix VII

Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the

products listed in Section 4.2.1.4 shall be declared.
When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

2000 (28th CCFL): The Committee noted that no comments had been received at Step 6 on Section 4.2.2 concerning the declaration of allergens transferred from any of the products listed in Section 4.2.1.4, and agreed that it should be advanced to Step 8 for inclusion in the General Standard as a new section (36).

Section 4.2.2

The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in Section 4.2.1.4 shall be declared*.
When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Section 4.2.1.4

The following foods and ingredients are known to cause hypersensitivity and shall always be declared as such:
Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
Crustacea and products of these;
Eggs and egg products;
Fish and fish products; Peanuts, soybeans and products of these;
Milk and milk products (lactose included); Tree nuts and nut products; and Sulphite in concentrations of 10 mg/kg or more.

Ref. 2: The paragraphs related to genetically modified organisms appearing in the Guidelines for Organically Produced Food.

Section 1. SCOPE

1.5 All materials and/or the products produced from genetically engineered/modified organisms (GEO/GMO) are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

Section 2. DESCRIPTION AND DEFINITIONS

Genetically engineered/modified organisms. The following provisional definition is provided for genetically/modified organisms. Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Techniques of genetic engineering/modification include, but are not limited to:

recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.

B. LIVESTOCK AND LIVESTOCK PRODUCTS

Nutrition

15. Notwithstanding the above, where an operator can demonstrate to the satisfaction of the official or officially recognized inspection/certification body that feedstuffs satisfying the requirement outlined in paragraph 13 above are not available, as a result of, for example, unforeseen severe natural or manmade events or extreme climatic weather conditions, the inspection/certification body may allow a restricted percentage of feedstuffs not produced according to these guidelines to be fed for a limited time, providing it does not contain genetically engineered/modified organisms or products thereof. The competent authority shall set both the maximum percentage of non-organic feed allowed and any conditions relating to this derogation.

18. If substances are used as feedstuffs, nutritional elements, feed additives or processing aids in the preparation of feedstuffs, the competent authority shall establish a positive list/s of substances in compliance with the following criteria:

General criteria

a) substances are permitted according to national legislation on animal feeding;

b) substances are necessary/essential to maintain animal health, animal welfare and vitality; and

c) such substances:

. contribute to an appropriate diet fulfilling the physiological and behavioural needs of the species concerned; and

. do not contain genetically engineered/modified organisms and products thereof; and

. are primarily of plant, mineral or animal origin.

Specific criteria for feedstuffs and nutritional elements

19. Silage additives and processing aids may not be derived from genetically engineered/modified organisms or products thereof, and may be comprised of only:

. sea salt;

. coarse rock salt;

. yeasts;

. enzymes;

. whey;

. sugar; or sugar products such as molasses;

. honey;

. lactic, acetic, formic and propionic bacteria, or their natural acid product when the weather conditions do not allow for adequate fermentation, and with approval of the competent authority.

Species specific requirements

Beekeeping and bee products

64. The certification body or authority must identify zones where hives, that meet these requirements, should not be placed due to