codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5(b) **CX/FL 00/6**
February 2000

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD LABELLING
Twenty-eighth Session
Ottawa, Canada, 09-12 May 2000

RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY (PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS)

Governments and international organizations wishing to submit comments should do so in writing to the Secretary of the Committee, Mr. Ron Burke, Director, Bureau of Food Regulatory, International and Interagency Affairs, Health Protection Branch, Health Canada, HPB Bldg., Room 2395, Tunney's Pasture, Ottawa, K1A 0L2 (0702C1), Canada (Telefax No.: 613.941.3537, e-mail: codex_canada@hc-sc.gc.ca) with a copy to the Secretary FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, (Telefax No.: -39-06-570-54593, e-mail: codex@fao.org **before April 17, 2000**

Background

1. The 27th Session Codex Committee on Food Labelling (CCFL, April 27-30, 1999), considered the *Proposed Draft Recommendations for the Labelling of Foods Obtained Through Biotechnology* (ALINORM 99/22, APPENDIX VIII). In order to advance the work on the proposal, the Committee agreed to return the Proposed Draft Recommendations to Step 3 for redrafting by an *ad hoc* Working Group (WG) of interested member countries and international governmental and non-governmental organizations, coordinated by the delegation of Canada[1].

1 Alinorm 99/22A, para. 49

2. The WG was mandated to bring about a greater degree of general agreement and consistency in the wording of the draft document, *Section 5. Additional Mandatory Requirements* (ALINORM 99/22, APPENDIX VIII), for circulation and consideration by the CCFL at its 28th Session in May, 2000.

3. The full WG[2] comprised of 23 member countries, the European Commission and nine (9) international organizations. To facilitate the development of proposed revisions to the text in the most expedient manner, a smaller "Drafting Group" (DG) was also formed[3].

4. It is to be noted that Section 2 (Definition of Terms, *Proposed Draft Recommendations for the Labelling of Foods Obtained Through Biotechnology* (ALINORM 99/22, APPENDIX VII) was adopted by the Codex Alimentarius Commission (CAC) at Step 5, circulated for member comment and is currently on the agenda of the 28th Session of the CCFL for consideration at Step 6.

5. However, in order to fully consider and develop proposed revisions to Section 5, the WG found it necessary to also review and propose revisions to Section 2, Definition of Terms to both clarify and refine its proposed provisions and particularly, to ensure an essential accord between the texts of Sections 2 and 5. Accordingly, the DG proposed revisions to the texts of both Sections 2 and 5 taking into consideration comments received on draft texts from all WG members[4].

6. The proposed revised Sections 2 and 5 texts developed by the WG are now before the Committee for consideration at Step 3. Both Section 5 labelling options have been developed to the extent possible, keeping in mind the mandate of the WG. Each draft Section is also accompanied by a background document (Annex I pertains to Section 2 and Annex II pertains to Section 5) identifying the changes proposed by the WG from the texts of ALINORM 99/22, Appendix VII and ALINORM 99/22, Appendix VIII, including a rationale for the proposed changes. The texts have also been numerically cross-referenced to facilitate understanding of the changes that are being proposed.

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2 Argentina, Australia, Austria, Brazil, Canada, Chile, Denmark, Finland, France, Germany, Ireland, Japan, Korea, Malaysia, Norway, Romania, South Africa, Spain, Sweden, Switzerland, Thailand, United Kingdom, United States, EC, ASSINSEL, IFOAM, RAFI, Consumers International, ILSI, CIAA, COMISA, IACFO, ICGMA.

3 Australia, Brazil, Japan, United States, two representatives from the European Commission(Germany) and Canada.

4 Responses were received from 11 WG members (EC, Brazil, Denmark, Korea, South Africa, Switzerland, USA, Consumers International, ASSINSEL, CIAA and IFOAM).

SECTION 2

(1) **PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH MODERN BIOTECHNOLOGY (PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS)**

(At Step 3 of the Procedure)

Section 2. Definition of Terms

(2) **Food and food ingredients obtained through modern biotechnology**

For the purpose of the General Standard:

(3) **"Food and food ingredients obtained through modern biotechnology"** means food and food ingredients composed of or containing genetically [modified] / [engineered] organisms [obtained through gene technology], or food and food ingredients produced from, but not containing genetically [modified] / [engineered] organisms [obtained through gene technology].

(4) **"Organism"** means any biological entity capable of replication or of transferring genetic material.

(5) **"Genetically [modified] / [engineered organism]"** means an organism in which the genetic material has been changed [through gene technology] in a way that does not occur naturally by multiplication and/or natural recombination.

(6) Examples of these techniques[1] [used in gene technology] include but are not limited to:

(7) • recombinant DNA techniques that use vector systems

(8) • techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism[2]

(9) • [Cell fusion (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers,

1 The Working Group believes that these techniques are consistent with those identified in the definition of "modern biotechnology" in the *Draft Cartagena Protocol on Biosafety (final draft text submitted by the Legal Drafting Group-28 January 2000).*

2 [Examples of these techniques include, but are not limited to, micro-injection, macro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion.]

where the donor cells/protoplasts do not fall within the same taxonomic family.]

(10) Unless the donor/recipient organism is derived from any of the above techniques, examples of excluded techniques include but are not limited to the following:

- *in vitro* fertilization
- conjugation, transduction, transformation, or any other natural process,
- polyploidy induction
- mutagenesis

(11)

- [Cell fusion (including protoplast fusion) or hybridization techniques where the donor cells/protoplasts fall within the same taxonomic family]

(12) [**"[no longer equivalent]"/ "[differs significantly]"** means a food or food ingredient obtained through modern biotechnology where a scientific assessment demonstrates, through an appropriate analysis of data, that the characteristics assessed are different in comparison to those of the corresponding existing food or food ingredient, [having regard to accepted limits of natural variation for that food or food ingredient"]]

AGENDA ITEM NO. 5(B) **CX/FL 00/6 (ANNEX I)**

BACKGROUND DOCUMENT ON SECTION 2: DEFINITIONS OF TERMS

DETAILS ON PROPOSED TEXT CHANGES FROM ALINORM 99/22 APPENDIX VII

Background:

The following information details changes made to ALINORM 99/22, Appendix VII (Section 2) text by the Ad hoc Technical Working Group on the Labelling of Foods Obtained through Biotechnology between April 1999 and February 2000. It also addresses the comments received from individual Working Group members on the draft text during this process. The text is numerically cross referenced to the revised Section 2 draft text to facilitate understanding of the changes that have been proposed.

Details on Proposed Text Changes:

(1) -"modern" was added to the title to distinguish gene technology from traditional biotechnology and to track with May 1998 CCFL decision (para 48) and CCFL Report Appendix VII regarding Section 2.

-"and food ingredients" was added to ensure their coverage in the Proposed Draft Recommendations.

(2) -"Products" changed to "Food" to correspond with Section 5 and focus text specifically on "food". "food ingredients" and "modern" added.

(3) - Definition title was revised as per item (2) and the word "new" was deleted.

- Suggestions about replacing "biotechnology" with "gene technology," "genetically engineered"or "genetic modification" were not included in the definition "food and food ingredients obtained through biotechnology" because of the decision to include the term "modern" in (1) above.

- The Working Group accepted a comment to replace the square bracketed term "[obtained through recombinant DNA techniques]" with "[obtained through gene technology]" to clearly focus the definition on modern techniques of biotechnology, as identified in (7) - (9).

-The Working Group did not view the term "modern biotechnology" as discriminating against traditional methods, as one comment had suggested, but rather discriminating between them.

- A suggestion to specifically define "modern biotechnology" was not accepted as the term is always used within the definition of "food and food ingredients

obtained through modern biotechnology which is defined in the text."
- A suggestion to square bracket the second half of the definition beginning with "or food and food ingredients produced from , but not containing genetically [modified]/[engineered] organisms [obtained through gene technology]" was not accepted as the Working Group felt that the inclusion of the phrase was not considered conditional to a decision being made in Section 5 on Options 1 or 2.

- In reference to a comment suggesting that the definition has to be linked to the concept of "no longer equivalent / differs significantly," the Working Group believed that the linkage was established in Section 5.

(4) - The Working Group decided to remove square brackets from the definition of "organism" as there was agreement on the definition.

- A suggestion to add "when alive" to the definition of " organism" was not accepted because of the scientific debate as to what is alive, e.g. viruses are not necessarily considered alive, although they are capable of reproduction.

- A suggestion to add "without human intervention" to the definition of "organism" was not accepted as an organism is an organism whether or not there is human intervention in its genetic makeup.

(5) - "Genetically [modified] / [engineered] organism" term was maintained from the the ALINORM 99/22, Appendix VII (Section 2) text.

- A suggestion to include alternate language, i.e. "could not reasonably be expected to occur naturally" in place of " in a way that does not occur naturally," was not viewed as providing greater clarity, and was not accepted.

- A suggestion to add "and where such changed genetic material determines a novel trait" to the end of the definition of "Genetically [modified] / [engineered] organism" was not accepted as it was not viewed as further clarifying the definition. It was also believed that a definition for novel trait would also then be required.

- Because of these and other changes to the wording of the definition identified below, a suggestion to remove the square brackets within the definition was not accepted.

(6) - The Working Group included a footnote to indicate that in developing / refining the inclusion list, that it had considered the techniques identified in the definition of "modern biotechnology" included in the *Draft Cartagena Protocol on Biosafety (final draft text submitted by the Legal Drafting Group-28 January 2000)*. In this document,

"modern biotechnology" means the application of:

(i) In vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid in to cells or organelles,
(ii) Fusion of cells beyond the taxonomic family,

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

- The term "techniques [used in gene technology]" has replaced the term "modifications" to assure better consistency with the definition "genetically [modified]/[engineered] organism."

- In reference to a comment about the flexibility of the inclusion / exclusion lists, the Working Group believed that the inclusion and exclusion lists were flexible, providing examples and allowing room for new techniques, as appropriate.

(7) - Suggestions for the inclusion of more specific definitions of rDNA techniques, in the definition of "food and food ingredients obtained through modern biotechnology," "genetically [modified]/[engineered] organism," and in the list of examples of techniques included within the definition of "genetically [modified]/[engineered] organism," were not accepted as a more detailed definition was not viewed as necessary. It was also noted that the level of detail in (7) of the draft text was also reflected in the *Draft Cartagena Protocol on Biosafety (final draft text submitted by the Legal Drafting Group-28 January 2000)*, i.e. "in vitro nucleic acid techniques, including recombinant DNA"

(8) - re: "techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism...," "micro-injection and micro-encapsulation" have been moved from the text as some delegations were concerned that it was inappropriate to include specific examples, as they did not add further clarity to the main text. These techniques, along with other suggested techniques (macro-injection, chemoporation, electroporation and liposome fusion) were included in a square bracketed footnote as examples.

(9) -"cell fusion" text was further clarified in view of numerous suggestions received and the text of the *Draft Cartagena Protocol on Biosafety (final draft text submitted by the Legal Drafting Group-28 January 2000)* and square bracketed.

(10) -Sentence was reworded to "Unless the donor / recipient organisms..." to clarify exclusions.

-A suggestion to add "other than those produced by one of the techniques/methods listed below" to the end of the lead in sentence was not

accepted as the Working Group believed that the reworded introduction to the exclusion list provided clarity.

- A suggestion to add the technique of "self-cloning" as a further example to the exclusion list was not accepted by the Working Group because "self-cloning" was considered to be a method of gene technology.

(11) -"cell fusion" text was further clarified in view of numerous suggestions received and the text of the *Draft Cartagena Protocol on Biosafety (final draft text submitted by the Legal Drafting Group-28 January 2000)*.

(12) -the use of the term "substantial equivalence" description was moved from Section 5 to Section 2. The word "substantial" was crossed out as a result of a decision taken at the 1999 CCFL meeting. A definition for "[no longer equivalent]/[differs significantly] was proposed in its place in Section 2. Rationale: current Section 5 draft now employs the term "no longer equivalent" and this term would be consistent with that wording. The term "differs significantly" was added as some delegations believed that the term "no longer equivalent" may not be in accord with conventional approaches to labelling changes in food with respect to composition, nutritional value and intended use. Both terms were placed in square brackets

-Although numerous comments/suggestions were received, the Working Group decided to leave the wording of "[no longer equivalent] / [differs significantly]." Some members of the Working Group noted that with respect to changes in composition, nutritional value, and intended use, there has been an historical use of the concept "differs significantly" that has provided a framework with respect to decisions on labelling and to prevent misleading labelling. The concept of substantial equivalence was specifically introduced for the safety assessment of "genetically [modified]/[engineered] organisms" and being no longer equivalent triggered a specific labelling requirement for genetically [modified]/[engineered] organisms.

- Comments suggesting a rewording of "no longer equivalent/ differs significantly" because of vagueness due to the potential for foods to differ because of climactic conditions and farming practices during the food production stages were not incorporated. The Working Group believed that this situation was dealt with in the words "having regard to accepted limits of natural variation."

Final Note:

The Drafting Group of the Codex Ad hoc Technical Working Group on the Labelling of Foods Obtained through Biotechnology wishes to express its thanks to all members of the Working Group for their consideration of the draft interim text and for the valuable suggestions received.

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DRAFT DISCUSSION DOCUMENT

SECTION 5

(1) **PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH MODERN BIOTECHNOLOGY (PROPOSED DRAFT AMENDMENT TO THE GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS**)
(At Step 3 of the Procedure)

Section 5. Additional Mandatory Requirements

(2) **Food and food ingredients obtained through modern biotechnology**

(3) **Option 1**

1. When a food or food ingredient obtained through modern biotechnology, as defined in Section 2, [is no longer equivalent to] / [differs significantly from] the corresponding existing food or food ingredient, as regards:

   -composition; or
   -nutritional value; or
   -intended use

   the characteristics or properties which make it different from the corresponding existing food or food ingredient should be clearly identified in the labelling. In particular, the following requirements apply:

(4) a) If the composition of a food or food ingredient [is no longer equivalent to] / [differs significantly from] the corresponding existing food or food ingredient, the label should provide, in conjunction with, or in close proximity to, the name of the food or food ingredient, such additional words or phrases as necessary to inform the consumer as to its true composition, in conformity with Sections 4.1 and 4.2.2 of the General Standard.

(5) b) if the nutritional value of a food or food ingredient [is no longer equivalent to] / [differs significantly from] the corresponding existing food or food ingredient, the label should provide, in conjunction with, or in close proximity to, the name of the food or food ingredient, such additional words or phrases as necessary to inform the

consumer as to its changed 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.

(6) c) if the mode of storage, preparation or cooking [is no longer equivalent to] / [differs significantly from] the corresponding existing food or food ingredient, clear instructions for use should be provided.

(7) 2. If any food or food ingredient obtained through modern biotechnology contains an allergen transferred from any of the products causing hypersensitivity listed in Section 4.2.1.4, the allergen shall be declared.[1]

(8) 3. [The presence of substances that are absent in corresponding existing foods that may have implications for the health of certain sections of the population shall be labelled].[2]

(9) 4. [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.]

(10) 5. The presence in a food or food ingredient obtained through modern biotechnology of material from the sources referred to in Section 4.2.2.2 (pork fat, lard, and beef fat) which is not present in a corresponding existing food shall always be declared.

(11) *Text deleted - see details in Background Document*

(12) **<u>Option 2</u>**

(13) 1. The following foods or food ingredients obtained through modern biotechnology, as defined in Section 2, shall be labelled to declare the method of production:

- food or food ingredients composed of or containing a genetically [modified] / [engineered] organism; or

1 The Working Group observed that this provision concerns only allergens now identified in Section 4.2.1.4. However, it was noted that future additions to or deletions from the Section 4.2.1.4 list would be considered by the Codex Committee on Food Labelling (CCFL) taking into account advice received from the Joint Expert Committee on Food Additives and Contaminants (JECFA).

2 The Working Group considered that this requirement concerned the possible presence of food allergens as well as "substances" other than food allergens. As this matter concerns health implications, it is proposed that it be referred by the CCFL to the Codex Ad Hoc Interdepartmental Task Force on Foods Derived from Biotechnology. The Working Group also proposes that the CCFL also consider referring this matter to the JECFA for their consideration.

3 The Working Group considered that this provision is intended to ensure the existence of adequate controls to prevent the marketing of food(s) which may contain the allergens listed in Section 4.2.1.4. The Working Group suggests that this section could be considered for inclusion as a future amendment to Section 4.2.1.4 of the Codex General Standard.

- food or food ingredients produced from, but not containing, genetically [modified] / [engineered] organisms if :

- they contain protein or DNA resulting from gene technology; or
- they [are no longer equivalent to] / [differ significantly from] the corresponding existing foods or food ingredients

(14) Any food characteristic or property which makes the food or food ingredient [no longer equivalent to] / [differ significantly from] the corresponding existing food or food ingredient, as regards composition, nutritional value, or the intended use of the food, shall be declared. [Further, the following requirements would apply:

(15) (a) If the composition of a food or food ingredient [is no longer equivalent to] / [differs significantly from] the corresponding existing food or food ingredient, the label should provide, in conjunction with, or in close proximity to, the name of the food or food ingredient, such additional words or phrases as necessary to inform the consumer as to its true composition, in conformity with Sections 4.1 and 4.2.2 of the Codex General standard.

(16) (b) If the nutritional value of a food or food ingredient [is no longer equivalent to] / [differs significantly from] the corresponding existing food or food ingredient, the label should provide, in conjunction with, or in close proximity to, the name of the food or food ingredient, such additional words or phrases as necessary to inform the consumer as to its changed 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.

(17) (c) If the mode of storage, preparation or cooking [is no longer equivalent to] / [differs significantly from] the corresponding existing food or food ingredient, clear instructions for use should be provided.]

(18) 2. If any food or food ingredient obtained through modern biotechnology contains an allergen transferred from any of the products causing hypersensitivity listed in Section 4.2.1.4, the allergen shall be declared.[4]

(19) 3. [The presence of substances that are absent in corresponding existing foods that may have implications for the health of certain sections of the population shall be labelled].[5]

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4 The Working Group observed that this provision concerns only allergens now identified in Section 4.2.1.4. However, it was noted that future additions to or deletions from the Section 4.2.1.4 list would be considered by the Codex Committee on Food Labelling (CCFL) taking into account advice received from the Joint Expert Committee on Food Additives and Contaminants (JECFA).

5 The Working Group considered that this requirement concerned the possible presence of food allergens as well as "substances" other than food allergens. As this matter concerns health implications, it is proposed that it be referred by the CCFL to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology. The Working Group also proposes that the CCFL also

(20) 4. [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].[6]

(21) 5. The presence of substances that are absent in corresponding existing foods that may be the subject of ethical objections shall be labelled.

(22) 6. The presence in a food or food ingredient obtained through modern biotechnology of material from the sources referred to in Section 4.2.2.2 (pork fat, lard, and beef fat) which is not present in a corresponding existing food shall always be declared.

(23) 7. **[**Threshold Levels

The Working Group agreed that consideration should be given to the following[7]:

[- The establishment of a threshold level in food or food ingredients for the presence of food or food ingredients obtained from modern biotechnology, below which labelling would not be required[8]]

[- The establishment of a *de minimis* threshold level for adventitious or accidental inclusion in food or food ingredients, of food or food ingredients obtained through modern biotechnology] **]**

(24) 8. **[**The following label declaration(s) [should] / [may] be used to identify the presence of food or food ingredients obtained through modern biotechnology. Examples for consideration include, but are not limited to:

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consider referring this matter to the JECFA for their consideration.

6 The Working Group considered that this provision is intended to ensure the existence of adequate controls to prevent the marketing of food(s) which may contain the allergens listed in Section 4.2.1.4. The Working Group suggests that this section could be considered for inclusion as a future amendment to Section 4.2.1.4 of the Codex General Standard.

7 The Working Group observed that in order to establish a threshold it will be important for the CCFL to have advice from the Codex Committee on Methods of Analysis and Sampling (CCMAS) on an urgent basis for early international consideration of test methodologies to be used in detecting and quantifying DNA or protein resulting from gene technology. The Working Group believes that CCMAS should take into account work already underway in this area in other international fora and to consider the key question of test sensitivity. It was also considered that test methods should be consistent, accurate, quantitative and validated internationally for food and food ingredients. A further important consideration is that Codex work should not preclude the future development of testing methodology.

8 Consideration of a threshold must address existing provisions of the *Codex General Standard for the Labelling of Prepackaged Foods*, e.g. Section 4.2.1.3 (Compound Ingredients).

(a) [“Produced from genetically modified (naming the source)”, “genetically modified”] 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 from [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”]**]**

(25) 9. Where the presence of a food or food ingredient obtained through modern biotechnology is declared on the label, the following would apply:

(a) In the case of a food ingredient(s) in a multi-ingredient food, the wording in article (8) must 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 may appear in a statement immediately following the list of ingredients; or,

(b) In the case of single ingredient foods, or where there is no list of ingredients, the information must appear clearly on the label of the food.

AGENDA ITEM NO. 5(B) **CX/FL 00/6 (ANNEX II)**

BACKGROUND DOCUMENT ON SECTION 5: ADDITIONAL MANDATORY LABELLING

DETAILS ON PROPOSED TEXT CHANGES FROM ALINORM 99/22 APPENDIX VIII

Background:

The following information details changes made to the ALINORM 99/22, Appendix VIII (Section 5) text by the Codex Ad hoc Technical Working Group on the Labelling of Foods Obtained through Biotechnology in its work between April 1999 and February 2000. It also addresses the comments received from individual Working Group members on the draft text during this process. The text has been numerically cross referenced to the revised Section 5 draft text to facilitate understanding of the changes that have been proposed by the Working Group.

Details on Proposed Text Changes:

(1) -"modern" and "food and food ingredients" inserted in title to correspond with proposed changes to Section 2 definition of "food and food ingredients obtained through modern biotechnology".

(2) - Title changed as in item (1) and proposed designation as "Option 1"

(3) -"modern" inserted as per Section 2 change in item (1)

- "is no longer equivalent to" was placed in square brackets to be consistent with Section 2. "or differ significantly from" was added in square brackets, as per decision in Section 2. These changes were also made in paragraphs (4)-(6) and (13)-(17).

(4) A new paragraph was added to more clearly outline labelling requirements required for the clarification of "compositional" changes to a food arising from modern biotechnology. The current Codex draft provides no detail on this aspect. It is considered that such compositional changes would not include nutritional changes but would include changes in the food such as in the incorporation or removal of substances such as pH adjusting agents, preservatives, stabilizing agents, flavouring, colouring, changes in solids content (pulp in juices), etc.

- The Working Group agreed with comments that label information should comply with 4.1 and 4.2.2 of the General Standard.

- A suggestion to combine (4) and (5) was not accepted by the Working Group as it was believed that separate paragraphs provided further clarity in the text.

- A suggestion to delete the word "true" or substitute it with the word "new" was not accepted by the Working Group as the wording in this paragraphs was based on the text contained in 4.1.2 of the *Codex General Standard for the Labelling of Prepackaged Foods*.

(5) - The wording was changed from "nutrient content" to "nutritional value"

- "food and food ingredient" was added, and that "[no longer equivalent] / [differs significantly from]" replaced "significantly modified" to correspond with the wording in the Section 2 definitions, as per item (12) in the Background Document for Section 2.

- Additional wording was proposed to more clearly outline the specific labelling requirements needed to identify the nutrient content changes to a food which may arise from the use of modern biotechnology. Further, that label information should comply with 4.1 and 4.2.2 of the General Standard

(6) - "[is no longer equivalent to]/[differs significantly from]," replaced "significantly different."

(7) - Section 4.2.2 from Section 2 of the original ALINORM 99/22, Appendix VII, was moved to Section 5, and further reworded and clarified. In addition, the word "modern" was added to be consistent with Section 2.

- A footnote was added to indicate that future additions or deletions to the list in Section 4.2.1.4 of the Codex General Standard would be considered by the Codex Committee on Food Labelling (CCFL) taking into account advice received from the Joint Expert Committee on Food Additives and Contaminants (JECFA).

(8) - For consistency in both Options 1 and 2, the former "Alternative Proposal" provision, "The presence of substances that are absent in existing equivalent foods and may have implications for the health of certain sections of the population shall be labelled," was included in Option 1.

- The term "existing equivalent foodstuffs" was replaced with"corresponding existing food" to prevent confusion between the term "equivalent" and the definition of "no longer equivalent."

- A footnote was added to note that the Working Group believed: (i) that this requirement concerned the possible presence of food allergens and "substances" other than food allergens, and; (ii) that it should be proposed that

this matter be referred by the CCFL to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology (and that the CCFL also consider referring this matter to the JECFA for their consideration).

(9) -Moved from Section 2, paragraph 2 of Section 4.2.2. Note: this item has been square bracketed since the Working Group considered that as paragraph 2 does not deal specifically with labelling but rather at ensuring the existence of adequate controls, it should be considered for inclusion as a future amendment to Section 4.2.1.4, related to foods and food ingredients causing hypersensitivity, in the Codex General Standard (adopted at the 23rd Session of the Codex Alimentarius Commission in June 1999). This point was reflected in a footnote to this paragraph.

(10) - The last paragraph of Section 5 respecting Section 4.2.2.2 was included in "Option 1" and further clarified by the inclusion of the word "modern" and by the inclusion in parentheses of pork fat, lard and beef fat, as the sources being referred to.

- The term "existing equivalent foodstuff" was replaced with"corresponding existing food" to prevent confusion between the term "equivalent" and the definition of "no longer equivalent."

- A suggestion to establish a threshold in relation to this requirement was not accepted as the text is consistent with the Codex General Standard.

(11) -The paragraph: "[These requirements also apply to novel foods which are not obtained through biotechnology but are significantly different from the corresponding conventional food]," that appeared in the text of ALINORM 99/22, Appendix VIII, was removed as the Working Group believed that it did not contribute directly to the content of the subject text.

(12) - "Alternative proposal" title was replaced by the designation "Option 2."

(13) - Rewording for clarification, of the former "Alternative proposal", now designated as "Option 2", and insertion of, "[are no longer equivalent to]/[differ significantly from] provision as per item (12) of Details on Proposed Changes - Section 2, and to correspond with wording in "Option 1."

- Suggestions to remove reference to labelling the method of production were not accepted by the Working Group as labelling the method of production was a goal of Option 2.

- One comment received suggested that paragraph 13 had been significantly redrafted in the proposed revised text to change the emphasis of Option 2. Upon careful review, the Working Group concluded that all elements of the original

"Alternative Proposal" remained intact as contained in ALINORM 99/22, Appendix VIII.

- A suggestion to improve clarity in the document by including examples was not accepted as the Working Group believed that further revisions that were made to the text improved the overall clarity of the paragraph.

- One suggestion to delete further specifications as when to label food and food ingredients produced from but not containing genetically [modified]/[engineered] organisms was not accepted as the Working Group believed that it was outside of its mandate to make a change of this significance to the original ALINORM 99/22, Appendix VIII. The Working Group believed that such a request would introduce another option and therefore would be more appropriately discussed at the CCFL.

(14) - New paragraph inserted to parallel Option 1 provisions respecting changes to food characteristics or properties such as composition, nutritional value or intended use of the food.

(15) - Paragraph identified in item (4) above was also added to Option 2 for consistency.

- With respect to suggestions to delete (15), the Working Group agreed to maintain the text for consistency with Option 1.

(16) - Paragraph identified in item (5) above was also added to Option 2 for consistency.

- With respect to suggestions to delete (16), the Working Group agreed to maintain the text for consistency with Option 1.

(17) - Paragraph identified in item (5) above was also added to Option 2 for consistency.

- With respect to suggestions to delete (17), the Working Group agreed to maintain the text for consistency with Option 1.

(18) - The changes identified in paragraph (7) above were included.

- A suggestion for the deletion of this paragraph was not accepted as the Working Group believed that it provided clarity that this matter was covered for foods and food ingredients obtained through modern biotechnology.

(19) - The changes identified in paragraph (8) above were included.

- A suggestion for the deletion of this paragraph was not accepted as the Working Group believed that it provided clarity that this matter was covered for foods and food ingredients obtained through modern biotechnology.

(20) - The changes identified in paragraph (9) above were included.

- A suggestion to expand this paragraph to cover “any other substances that poses risk” was not accepted by the Working Group as this matter was covered in (19) above. It was suggested that this matter could be raised at CCFL, if further discussion on this point was desired.

- A suggestion for the deletion of this paragraph was not accepted as the Working Group believed that it provided clarity on this matter. A footnote to this paragraph, referred to in (9) above, addresses the text of the footnote in further detail.

(21) - A suggestion for the deletion of this paragraph was not accepted as the Working Group believed that it was outside of its mandate to make a change of this significance to the original ALINORM 99/22, Appendix VIII.

- Several questions were received regarding the interpretation / implementation of this provision. These comments were acknowledged by the Working Group as legitimate questions that may be clarified at the Codex Committee on General Principles in their discussion of “other legitimate factors.”

(22) - The changes and suggestions identified in paragraph (10) above were considered / included for this paragraph.

(23) - A new paragraph was included that considers the need for establishing threshold levels for labelling foods or food ingredients from modern biotechnology.

- The Working Group agreed with comments that the text recognizes both a general tolerance level for the deliberate inclusion of foods and food ingredients obtained through modern biotechnology, and a threshold for the adventitious inclusion of foods and food ingredients obtained through modern biotechnology.

- In addressing a suggestion to adopt a particular threshold, the Working Group concluded that the question of thresholds would require further consideration by the CCFL. The Working Group indicated that this matter could be raised at the next CCFL meeting.

- A footnote was included to this new paragraph to identify the Working Group's recommendation that in order to establish a threshold it will be important for the CCFL to have advice from the Codex Committee on Methods of Analysis and Sampling (CCMAS) on an urgent basis. This advice would allow for early international consideration of test methodologies to be used in detecting and quantifying DNA or protein resulting from gene technology. The Working Group believes that CCMAS should take into account work already underway in this area in other international fora and to consider the key question of test sensitivity. It was also considered that test methods should be consistent, accurate, quantitative and validated internationally for food and food ingredients.

- The Working Group also noted that, in considering a threshold level, attention should be given to maintaining consistency with other parts of the Codex General Standard, including Section 4.2.1.3 (the 5% rule for the labelling of compound ingredients), along with the accumulated experience gained through the implementation of threshold levels stipulated in national standards. A footnote identifying this consideration was included in the text.

- A suggestion received indicating that laboratory analysis should only be a supplement to "product flow analysis" was a point that the Working Group believed could be appropriately raised at CCFL.

(24) - A new paragraph was included to outline the specific label declarations that may / should be used in support of "Option 2". A range of possible examples were provided and further refined based on suggestions received in order to encourage discussion and to reflect a balanced range of possible examples. The Working Group considered that the list provides a series of options for label declarations, any number of which could be adopted, if desired, by national governments.

- The Working Group agreed with a comment received that, ideally, labelling statements should comply with both the Codex General Standard and a country's legal requirements.

- A proposal to include the following new suggestion was not accepted by the Working Group as the intent was not clear: "If an ingredient or substance in the list of ingredients or in the class name (trade description) is already identified as being produced from X, the label can be shortened to "genetically modified." The Working Group would suggest that, if desired, the example could be raised and further explained at the next meeting of the CCFL.

(25) - A new paragraph was added to specify the location on the label of the proposed label declarations. The Working Group believes that the text provides sufficient flexibility to permit the declaration: (i) of single ingredient foods obtained through modern biotechnology; (ii) of one ingredient obtained through modern biotechnology in a multi-ingredient food, and; (iii) of multiple ingredients obtained through modern biotechnology in a multi-ingredient food.

- In response to suggestions to further specify the proximity of messages, the Working Group noted that the existing text was based on text in the Codex General Standard.

Final Note:

The Drafting Group of the Codex Ad hoc Technical Working Group on the Labelling of Foods Obtained through Biotechnology wishes to express its thanks to all members of the Working Group for their consideration of the draft interim text and for the valuable suggestions received.