codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5(b) **CX/FL 01/7**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD LABELLING
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PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (PROPOSED DRAFT AMENDMENT TO THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS*)

(At Step 3 of the Procedure)

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 Products and Food 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 13, 2001**

Background

1. At its 28th Session, (May 9 - 12, 2000), the Codex Committee on Food Labelling (CCFL) considered the *Proposed Draft Recommendations for the Labelling of Food and Food Ingredients Obtained Through Biotechnology (ALINORM 99/22 Appendix VIII (CX/FL 00/6)*. During discussions, the Committee recognized the diversity of opinions among member countries regarding the two labelling options under consideration and, with the exception of specific provisions respecting the declaration of food allergens, agreed to return the text to Step 3 for redrafting. To assist in advancing this issue, the CCFL asked the *Ad hoc Working Group on the Labelling of Foods Obtained Through Biotechnology (WG)*, coordinated by Canada, to continue its work during 2000 - 2001. [1]

[1] Alinorm 01/22, para. 48

2. To facilitate the work of the full *Ad hoc* WG[2], the small drafting group (DG), originally established in 1999-2000, would continue to jointly "hold the pen". The DG now includes representatives from Australia, Brazil, Canada, Germany, European Commission, India, Japan, South Africa, Thailand and the United States.

3. In accordance with the direction provided by the CCFL, the WG continued in its deliberations to:

1) Combine the current texts of the draft labelling Options 1 and 2 (contained in CX/FL 00/6, *Section 5. Additional Mandatory Requirements*) into a single document, in the light of the proposal from Japan for the development of Codex Guidelines.

2) Consider in task (1) the proposal from Norway and India for comprehensive labelling.

3) Consider all key issues related to labelling discussed by the plenary session, including, as appropriate, the questions raised by the United States and others.

Codex Guidelines for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (At Step 3 of the Codex Procedure)

4. The DG developed an initial draft of the *"Codex Guidelines for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering"*. The draft *Codex Guidelines* were circulated to all members of the full WG for their detailed review and comment. All responses received were considered by the DG members and the draft *Codex Guidelines* text was further revised as appropriate.

5. Apart from the elimination of duplicative sections, all original provisions contained in both Options 1 and 2 have been retained in the proposed new draft *Guideline* text. Several footnotes which are no longer required have been removed and several words or phrases added to clarify the proposed draft text. The complete text of *Section 2. Definition of Terms*, (ALINORM 01/22 APPENDIX V) (now at Step 6) has also been included in this draft to ensure clarity and document completeness, and to indicate how the text of the completed Codex Guidelines would likely appear. As government comments have been requested by the Committee on *Section 2-Definitions* by way of Circular Letter 2000/16-FL, no changes have been made to its text by the WG. Finally, as

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[2] Argentina, Australia, Austria, Brazil, Canada, Chile, Denmark, Finland, France, Germany, India, 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.

directed by the CCFL, the draft Guideline makes provision for a comprehensive labelling approach to these foods as proposed by Norway and India.

6. The draft *Codex Guidelines* (Annex I)is also accompanied by a background document (Annex II), identifying the changes proposed by the WG from the text of ALINORM 99/22, Appendix VIII CX/FL 00/6 in the development of the guideline, including a rationale for the proposed changes. Both texts have been numerically cross-referenced to facilitate understanding of the changes that are being proposed.

7. The attached draft *Codex Guidelines* (Annex I) are now being circulated for comments and will be considered by the Committee at Step 3.

Issues Related to Method of Production Labelling Considered by the Working Group in the Development of the Codex Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering

8. A "Discussion Paper" entitled, *"Issues Related to Method of Production Labelling Considered by the Working Group in the Development of the Codex Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering"*, is also attached. This document is intended to serve as an information paper in response to the CCFL request that the WG consider all key issues related to labelling discussed by the Plenary Session, including, as appropriate, the questions raised by the United States and others.

9. This paper originated as a Conference Room Document, *"Practical Aspects of Labelling to Declare Method of Production for Bioengineered Foods"*, tabled at the 28th Session CCFL by the United States which was subsequently reviewed by the DG and further revised based on input received from the WG members.

10. The Discussion Paper reflects some of the major issues raised by the WG during their deliberations on the draft *Codex Guidelines* and is being circulated to member countries and international organizations to ensure that the CCFL is aware of, and can give adequate consideration to these matters in its decision process.

(1) **DRAFT CODEX GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING**

(2) **PURPOSE OF THE GUIDELINES**

To ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provides factual, understandable and non-misleading information to facilitate consumer choice.

These guidelines set out a number of approaches and related information that could be used for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

(3) ***1.0 SCOPE***

These guidelines recommend procedures for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.1 These guidelines apply to the labelling of such food and food ingredients:

1.1.1 when such food and food ingredients are [no longer equivalent to / differ significantly] from the corresponding existing food and food ingredients, as regards its: composition, nutritional value or intended use; and/or

1.1.2 when such food and food ingredients are labelled with information to indicate the method of its production

(a) when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or

(b) when they are produced from, but do not contain, genetically modified / engineered organisms, protein or DNA resulting from gene technology.

(4) ***2.0 DEFINITION OF TERMS***

(At Step 6 of the Procedure)

For the purpose of these guidelines:

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

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

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

Examples of these techniques used in gene technology include but are not limited to:

- recombinant DNA techniques that use vector systems
- techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism[1]
- cell fusion (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family.

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

- *in vitro* fertilization
- conjugation, transduction, transformation, or any other natural process,
- polyploidy induction
- mutagenesis
- cell fusion (including protoplast fusion) or hybridization techniques where the donor cells/protoplasts fall within the same taxonomic family

(5) [**"no longer equivalent"/ "differs significantly"** means food and food ingredients obtained through certain techniques of genetic modification/genetic engineering where a scientific assessment demonstrates, through an appropriate analysis of data, that the characteristics assessed are different in comparison to

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

those of the corresponding existing food and food ingredients, having regard to accepted limits of natural variation for that food and food ingredients"]

(6) ***3.0 LABELLING PROVISIONS***

(At Step 3 of the Procedure)

In adopting a specific approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering the following provisions could be used:

(7) 3.1 When food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, as defined in Section 2 are [no longer equivalent to / differ significantly] from the corresponding existing food and food ingredients, as regards:

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

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 6.l on label declarations.

(8) 3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification/genetic engineering of an allergen transferred from any of the products listed in Section 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991, Amended 1999) shall be declared[2]

(9) 3.3 [The presence of substances that are absent [or present in altered proportions having regard to accepted limits of natural variation] in corresponding existing foods that may have implications for the health of certain sections of the population [should] [shall] be labelled].[3]

(10) 3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques of genetic modification/genetic engineering as defined in Section 2, are labelled to indicate method of production, labelling declarations should apply (some examples of which are described in Subsection 6.2):

[2] This provision is at Step 8 for consideration by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

[3] The Working Group considered that this requirement concerned the possible presence of food allergens as well as "substances" or properties other than food allergens. This matter concerns health implications, and is being considered by the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. The Working Group also proposes that the CCFL consider referring this matter to the JECFA for their consideration.

(a) when they are composed of or contain a genetically modified / engineered organism or contain protein or DNA resulting from gene technology; and/or

(b) when they are produced from, but do not contain, genetically modified /engineered organisms, protein or DNA resulting from gene technology even when they do not differ in composition, nutritional value, intended use [and/or other parameters].

(11) 3.5 [Notwithstanding Section 4.2.2.2 of the General Standard[4]], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of ethical objections[5] [should] [may] be labelled. [Where such labelling is used, member countries should establish criteria on how labelling decisions, based on ethical considerations, will be decided and implemented in a manner that is fair, transparent and consistent.]

(12) ***[4.0 THRESHOLD LEVELS***

4.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, are labelled to declare the method of production, consideration may be given to:

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/genetic engineering, below which labelling would not apply[6]] and/or

[Establishment of a *de minimis* threshold level for adventitious or accidental inclusion in food and food ingredients, of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, below which labelling would not apply]**]**

(13) ***[5.0 EXEMPTIONS***

5.1 Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration

[4] Section 4.2.2.2 requires that pork fat, lard and beef fat shall always be declared by their specific names.

[5] The drafting group recognizes that the term "ethical objections" can have a variety of meanings and other terms such as "ethical, cultural and religious considerations" and "dietary restrictions" were suggested by different members of the drafting group.

[6] 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)

may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering.**]**

(14) ***6.0 LABEL DECLARATIONS***

In accordance with the *General Principles* section of the *Codex General Standard for the Labelling of Prepackaged Foods* and the *Codex General Guidelines on Claims*, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.

(15) 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.

(16) 6.2 In addition to the provisions in Subsection 6.1, where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

(a) [“Produced from genetically modified (naming the source)”] e.g. “produced from genetically modified soya”

(b) If the ingredient is already listed as produced from the source, [“genetically engineered (naming the food)”], e.g. “genetically engineered maize flour”

(c) [“Grown from seeds obtained through [modern] plant biotechnology”]

(d) If the ingredient is designated by the name of a category, ["contains (name of the ingredient) produced from genetically modified (source)"], e.g. starch ("contains starch produced from genetically modified maize")

(e) ["Genetically engineered (naming the characteristic) (naming the food)"] e.g. "genetically engineered high oleic soybean oil"

(f) ["Product of plant / animal biotechnology"]

(g) ["Naming the food/food ingredient (genetically modified)"] e.g. "soybean (genetically modified)"

(h) ["Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)"] e.g. "soybean (genetically modified soybean not segregated)"

(i) ["Product of gene technology"]

(17) 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.

(18) **[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[7]; establishment of verification (for example, documentation) systems;

[7] The Working Group observed that the Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology, as established by the Codex Alimentarius Commission in 1999 with the objective of elaborating standards, guidelines or other principles as appropriate for foods derived from biotechnology, has agreed to establish an *ad hoc* Working Group on " Analytical Methods" to be chaired by the Delegation of Germany. The initial work of the *ad hoc* Working Group is to compile a list of appropriate and available analytical methods for consideration by the Task Force, together with their performance characteristics and the status of their validation. A meeting of this group to discuss these issues will be held in Japan in March 2001. In addition, related activities may be undertaken by CCMAS.

and efforts for the development of supporting capacity and infrastructure.]

DETAILS ON PROPOSED DRAFT TEXT CHANGES FROM CX/FL 00/6 (ALINORM 01/22) IN THE DEVELOPMENT OF THE DRAFT CODEX GUIDELINES

BACKGROUND

The following information details changes made from the text of CX/FL 00/6 (ALINORM 01/22), Agenda Item No. 5(B), Section 5. Additional Mandatory Requirements, by the Codex Ad hoc Working Group (WG) on the Labelling of Foods Obtained Through Biotechnology, in its work between June 2000 and February 2001 in the development of the draft *"Codex Guidelines for The Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering"*. 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 text of the draft *Guidelines* document (Annex I), to facilitate understanding of the changes that have been proposed by the WG. This information is provided under the following section, "Details on Proposed Text Changes".

Note: During the course of its work, the DG/WG also developed the information document, *"Issues Related to Method of Production Labelling Considered by the Working Group in the Development of the Codex Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering"*. It was decided that this document, which identifies a number of the major issues which were raised by the WG during its deliberations, should proceed as a WG Discussion Paper (Attachment A) and would be circulated with the draft *Codex Guideline* document to provide information to Codex member governments in regard to method of production labelling. The United States opposed the DG decision to have the document proceed as a discussion paper, preferring that the document proceed as an Annex to the draft *Codex Guidelines* document to ensure adequate consideration of the information by countries in their national decisions respecting possible method of production labelling.

DETAILS ON PROPOSED TEXT CHANGES

The following points refer to the corresponding numbers in the proposed draft Codex Guideline document:

1) "Certain techniques of genetic modification/genetic engineering" - has been inserted into the title and throughout the document to replace the term "modern biotechnology", as agreed at the 2000 CCFL meeting.

   Comments received regarding a preference for one term over another were not considered since this matter relates to Section 2, Definition of Terms, now at step 6 and beyond the mandate of the drafting group. Specific concerns regarding Section 2 must be raised at the 29th Session of the CCFL in May, 2001.

2) "Purpose of the Guidelines" - added to introduce and clearly set out the intended purpose of the draft *Guideline*.

   The word "verifiable" was deleted from the earlier December 2000 draft of this section since it was considered that a label could not convey to consumers the method by which "verification" took place. It was also not felt necessary to further expand on the type of information. The statement, "...to facilitate consumer choice", was added to the end of the sentence. There was no general support to make further changes to the first paragraph. Finally, a second paragraph was added to indicate that the intent of the draft *Guideline* is to set out a number of approaches to labelling. This should provide flexibility to member nations regarding the labelling of these foods.

3) Section 1.0 "Scope" - a new section in the format and manner of Codex Guidelines to set out the application of the proposed draft *Guideline*. The "Scope" as drafted, takes into consideration the possibility of comprehensive labelling.

   The DG made no further changes to this section because it felt that the present wording, although considered repetitious by some WG members, provided for greater clarity and completeness. Also, suggested changes respecting the use of [no longer equivalent to/ differ significantly] from in the text of 1.0 received from some WG members could not be actioned because these terms are contained in Section 2, Definition of Terms and are outside the mandate of the WG.

4) Section 2.0 "Definition of Terms" - incorporates Section 2 of (ALINORM 01/22) APPENDIX V in the proposed draft Guideline discussion document for clarity and in order to allow the DG/WG to consider the draft *Guideline* as it would appear as a completed text. As Section 2 is now at Step 6 for further comment and consideration by member governments, no changes have been made to its text

apart from several very minor grammatical adjustments to ensure consistent wording throughout the proposed draft *Guideline.*

5) The definition, [no longer equivalent/differs significantly] from was raised during the DG/WG discussions by some member countries who suggested a lack of clarity in the definition and requested more precise wording.

However, because changes to the Section 2 definitions were not considered to be within the mandate of the WG, further discussions were deferred to the CCFL In this connection, it was noted that member countries may choose to raise their specific concerns in their Step 6 responses to Section 2, for further discussion at the 29th Session of the CCFL in 2001.

During DG discussions, it was also suggested that member countries should be prepared to clarify their criteria used to determine when food and food ingredients are [no longer equivalent/differs significantly] to/from their conventional counterparts.

6) Section 3.0 "Labelling Provisions" - has been created to combine Options 1 and 2 contained in CX/FL 00/6, *"Section 5. Additional Mandatory Requirements*", into a single draft Guideline text. As a proposed Codex Guideline, where possible, the word "shall" has been replaced by the square bracketed terms ["should"] ["shall"] or ["should"] ["may"] to allow a choice between these terms. India did not support the use of ["should"] ["shall"] in subsection 3.3 or ["should"] ["may"] in subsection 3.5, but preferred the terms "shall" and "should", respectively.

The subsections were re-ordered to group those provisions dealing with health and safety together. The United States also proposed that new section headings be established which would serve to create a clearer separation between labelling approaches. There was insufficient support for this change.

7) Subsections 3.1 and 3.4 - include former items (3) in Option 1 and items 13 and 14 in Option 2 in CX/FL 00/6, Section 5.

8) Subsection 3.2 - As agreed by the CCFL at its May 2000 Session, former items (7) in Option 1 and (18) in Option 2 respecting the declaration of allergens from products listed in Section 4.2.1.4, (re-Section 4.2.2 in Alinorm 01/22, Appendix III) were advanced to Step 8 for consideration by the Commission at its 24th Session. However, some countries felt strongly that as a key issue of concern, the subsection 3.2 reference to allergens should remain in the draft *Guideline* text. A reference to the *"General Standard for the Labelling of Prepackaged Foods"* is also included for clarity.

9) Subsection 3.3 - comprises former item (8) in Option 1 and (19) in Option 2. The WG generally felt that the text was unclear. Some WG members felt that the wording of the former items (8) and (19) was too restrictive and proposed the

addition of "...[or present in altered proportions....]". Others felt that such proposed wording would expand the meaning of the text to include provisions that are already dealt with by subsection 3.1, such as changes in nutritional value or composition. For the purpose of this draft, the subsection has been included in square brackets. A footnote references the *work of the "Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology*". It was also considered that this subsection might need to be revisited in future depending on Task Force recommendations. India did not support the retention of this subsection in square brackets.

10) Subsection 3.4(b) - takes into consideration the comprehensive labelling approach for these foods as proposed by Norway and India at the 28th session of the CCFL. To achieve this, the words "protein or DNA" have been added to the sentence. This would extend method of production labelling requirements to all such foods whether or not the product contains protein or DNA resulting from gene technology. A further phrase "even when they do not differ in composition, nutritional value, intended use [and/or other parameters]", has been added.

Note: Subsection 3.4 (formerly subsection 3.2 in an earlier December 2000 draft) was reworded by the DG to clarify the text.

Canada opposed the specific language adopted by the DG in subsection 3.4 on method of production labelling. Canada's strong preference was that in giving guidance on method of production labelling unrelated to final product characteristics, the text of the guideline should clearly articulate that this portion of the guideline is intended to be applied within the context of a voluntary labelling scheme. Such an approach leaves the choice of whether to indicate that the food or food ingredient was obtained through certain techniques of gene technology up to commercial partners, and is not mandated by government regulation.

11) Subsection 3.5 - combines the former items (10) in Option 1 and (21) and (22) in Option 2 respecting the provisions of Section 4.2.2.2 and that of "ethical objections". In accordance with the role and function of a Codex *Guideline* as an advisory text, the word "shall" has been changed to ["should"] ["may"].

Note: Some members felt that ethical objections should be given equal status to the provisions in Section 4.2.2.2 of the *General Standard* and that the wording for the subsection should remain as "shall". Other member countries questioned the appropriateness of ethical concerns being included in the draft *Guideline*. The revised text sections are indicated in square brackets. India did not support the retention of the entire subsection 3.5 in square brackets.

It was considered by DG members that member countries should be prepared to demonstrate the criteria used to govern labelling based on ethical considerations.

A second footnote was added to reflect DG/WG member discussion about the lack of clarity over the term "ethical objections".

12) Section 4.0 Thresholds - contains the provisions of former item (23) of Option 2. The WG felt it was not appropriate at this time to make any further recommendations regarding thresholds but recognized there is a need for further input and discussion by member countries. Accordingly, the section remains in square brackets. At its February meeting, the DG made a few minor wording changes to section 4.0 to improve clarity and consistency and also added the phrase, "below which labelling would not apply", to the end of the third paragraph of subsection 4.1.

India objected to the inclusion of Section 4.0 in the draft *Guidelines* as being contrary to the Indian position on comprehensive labelling.

13) Section 5.0 "Exemptions" - a proposed new section. A number of WG members felt the matter of possible exemptions from labelling must be included in the draft *Guidelines* and should be discussed further while others did not support its inclusion. India objected to the inclusion of Section 5.0 in the draft *Guidelines*. India felt that there could not be comprehensive labelling if exemptions were made. As the exemption concept is new, the proposed text is square bracketed. The phrase, "notwithstanding the provisions of Subsection 3.1 to 3.3", was added to the first sentence of subsection 5.1.

14) Section 6.0 "Label Declarations" - has been created to combine the specific labelling provisions of former Options 1 and 2 and includes an introductory paragraph re-affirming Codex prohibitions against misrepresentations in labelling. One WG member suggested that the introductory paragraph is unnecessary as prohibitions against misleading claims is already covered by the *Codex General Guidelines on Claims* which applies to all foods. However, there was support for its retention as a means to further emphasize the importance of truthfulness in the labelling of these foods.

15) Subsection 6.1 combines items (4), (5), (6), and (15), (16), (17) respectively, of the former Options 1 and 2. It was considered that consolidating these items into a single sub-section improved consistency and clarity. Because this subsection contained some repetitive elements, the formerly separate paragraphs dealing with composition and nutritional value were combined.

16) Subsection 6.2 - contains the provisions of item (24) of the former Option 2 which were square bracketed in CX/FL 00/6. Some WG members felt that leaving this section in square brackets was inappropriate while others wished to retain the brackets. India did not support the enclosure of this section in square brackets. At its February meeting, after further discussion, the DG decided to remove the square brackets around this subsection. However, it was also decided that all of the internal square brackets around the individual labelling examples would be

retained. A minor wording change to the introductory sentence was also made. A number of suggestions were received from WG members that certain labelling examples included in subsection 6.2 should be deleted. It was decided to defer further discussion of this to the CCFL.

17) Subsection 6.3 - contains the re-arranged provisions of item (25) of the former Option 2. A minor rewording of subsection 6.3 (b) from the earlier December 2000 draft text has been made.

18) Section 7.0 - "Implementation" - a new square bracketed Section proposed for further consideration. It was felt that, for the purposes of verifying label claims, consideration should be given to appropriate procedures and methodologies for the identification and/or verification of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

A number of WG members felt strongly that Section 7.0 should not be part of the *Guideline*s, as they considered it to go beyond the description of rules of when and how to label and is therefore not covered by the mandate of the DG. Alternately, other WG members strongly supported its inclusion in the *Guidelines* as it would raise awareness of the need for uniform procedures and methodologies to effectively support any labelling scheme selected for these foods.

Given the differing views, it was decided that it would be useful to include this section in the draft *Guideline* for the time being as the matter needed to be discussed further by the CCFL. The DG also significantly reworded this section from the earlier December 2000 draft to a shorter, much more general text.

General Notes:

1. One DG member felt that the *Guideline* text would be clarified if the various approaches to labelling were presented as distinct sections under separate sub-headings to clearly distinguish between labelling based on changes in composition, etc. (for which there is general consensus) and labelling based on method of production. This suggestion was further considered by the DG at its February meeting, but there was insufficient support for this change.

2. Several WG members strongly supported the inclusion of a section in the *Guidelines* to provide guidance for the labelling of food and food ingredients that have not been obtained through certain techniques of genetic modification/genetic engineering. eg. negative labelling such as "GM/GE free", "does not contain....", "not a product of....", etc. However, the WG did not undertake this initiative. As the current Codex/WG focus concerns the issue of positive product labelling, it was not considered to be within the current mandate of the WG to address the question of voluntary negative labelling and claims.

Final Note:

The Drafting Group of the Codex Ad hoc 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 of the *Guidelines* and for their valuable suggestions and comments which greatly assisted in the formulation of the final draft text.

DISCUSSION PAPER

Issues Related to Method of Production Labelling Considered by the Working Group in the Development of the Codex *Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering*[1]

I. INTRODUCTION

This document reflects some of the major issues which were raised by the Working Group (WG) during their deliberations on the development of the Draft *Codex Guidelines for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification /Genetic Engineering*.[2]

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[1] At the 28th Session of the CCFL in Ottawa in May, 2000, the United States tabled a Conference Room Document, *Practical Aspects of Labelling to Declare Method of Production for Bioengineered Foods* that raised a number of practical issues associated with method of production labelling of food and food ingredients obtained through certain techniques of genetic engineering/genetic modification. In response to the CCFL request that the Working Group (WG) consider all key issues related to labelling discussed by the Plenary Session, including, as appropriate, the questions raised by the United States and others, the Chair of the WG requested that an expanded version of that document be circulated to the small Drafting Group (DG) for discussion during their meeting in New Delhi in October, 2000. At that meeting, it was decided that the United States would revise the document based on the input from members of the DG. The revised document was circulated as a working draft for consideration by the larger WG as a possible annex to the draft *Guidelines for Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Engineering/Genetic Modification*. The DG met again in February 2001 and, based on input from the WG, the document was further revised and a decision taken to forward it to the CCFL as a Codex Discussion Paper for consideration at the CCFL meeting in May, 2001. This document is for information and discussion purposes and does not imply consensus on all aspects of the issues raised.

[2] For brevity in this document, food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are referred to as food and food ingredients produced using gene technology.

DISCUSSION PAPER

II. PURPOSE

This document discusses issues that will likely need to be considered in making decisions with regard to implementation of method of production labelling of prepackaged food and food ingredients produced from gene technology.

All of the issues discussed in this document relate to how governments and food producers can best provide information to the consumer so that the information is truthful and not misleading. This document will only address labelling of food and food ingredients produced using gene technology where labelling is based on the method of production. The issues relate to the practical implications of implementing such labelling so that reliable information is provided to the consumer in a way that does not unnecessarily impose burdensome requirements on agricultural and food production systems and trade. Many of the practical issues discussed here will apply whether method of production labelling is a mandatory requirement or a voluntary decision determined by market factors or consumer preference.

While the current issues reflected in this document focus on food and food ingredients derived from plants, the issues discussed herein generally would be applicable to food and food ingredients derived from microorganisms or animals.

III. BASIC PARAMETERS OF LABELLING

The most important function of a label on a food product is to convey information to consumers that is truthful and that will not mislead the consumer as to the properties of that product. A fundamental element of the label is to address consumers' demand for information. Labelling should provide a sound basis for consumers to make informed choices in relation to the foods they consume. This document will address issues associated with practical implementation of labelling of food products derived from gene technology based on the method of production. However, the same general requirements used for labelling all foods should apply to the labelling of foods derived through gene technology.

If food is labelled according to its production method it is important that this information is communicated on the label in a manner that is understandable, informative and is truthful or not misleading to the consumer. For example, the language used and the appearance of the label should not imply that there are implications for public health associated with the consumption of a food produced using gene technology that is not supported by a scientific safety assessment. Conversely, if a food is labelled as <u>not</u> containing ingredients produced using gene technology, this label should not imply that this food is any better than products that may contain food ingredients produced using gene technology. As with all other foods, the general parameters for food labelling described in the Codex General Guidelines on Claims, CAC/GL 1-1979 (Rev. 1-1991) apply to the labelling of food(s) and food ingredient(s) derived from gene technology.

DISCUSSION PAPER

IV. TRIGGERS FOR LABELLING

Any decision to label a food or food ingredient based on the method of production might include consideration of whether all food or ingredients derived from plant varieties modified using gene technology could be labelled, or whether there would be a mechanism that calls for the labelling of some products but not others. There are a number of possibilities that would have different implications for implementation and enforcement of labelling regulations.

The process of genetic modification/genetic engineering generally results in an organism (for example, a crop plant) that differs from the conventional variety of that organism by the presence of one or several new DNA sequences and one or several proteins that are not present in the corresponding existing varieties. This DNA or protein may or may not be present (or detectable) in a food product derived from the genetically engineered plant variety, depending on the nature of the food product and the degree of processing used in the production of that food or food ingredient.

Possible triggers for labelling of foods produced using gene technology include:

> A requirement that all food and any food ingredients produced using gene technology be labelled to denote this fact to satisfy the consumer demand for information. This would include foods such as highly processed oils and sugars that would not contain detectable DNA or protein resulting from the modification.
>
> Labelling could be triggered by the presence of new DNA or protein sequences in food produced using gene technology. If labelling is triggered by the presence of DNA or protein, having analytical methods in place would allow accurate, reliable detection of these substances in foods, including processed foods that may contain multiple ingredients in small quantities (see Testing and Documentation, below.)
>
> Decisions would be necessary as to whether to apply method of production labelling for minor ingredients such as flavoring, additives or processing aids that may be present in very small quantities.
>
> Labelling could also be triggered by ethical or religious concerns specific to a certain population or region.

If any specific factor is used to trigger labelling of food and food ingredients produced using gene technology, consideration could be given to the development of a "negatives" list that identifies products that would not require labelling and/or a "positives" list of products that will always require labelling. These lists could assist industry in complying with the labelling regulations as it would not be necessary to ascertain the specific content of every food product. For example, if the presence of DNA or protein is used as a trigger, a negatives list could include highly processed products such as refined oils and sugars, as the DNA and proteins would be

removed or destroyed during processing. Alternatively, a "positives" list could be developed that contains specific food and food ingredients produced using gene technology for which labeling would always be required. In either case, it would be necessary to update these lists regularly as new products enter the market or new food processing methods are developed or as new and more sensitive methods for detection of food produced using gene technology are introduced.

V. THRESHOLDS

Due to the nature of crop cultivation, food production, marketing and handling material derived using gene technology may be accidentally present in conventional products. For example, commodity products such as corn, canola, and soybeans are generally handled in bulk, meaning that different crop varieties of a product are mixed during harvest, eg., to achieve a certain grade. Furthermore, the use of the same trucks and containers to transport crops derived using gene technology and conventional crops sequentially, or the use of the same processing equipment to handle these products could result in the presence of small amounts of material derived from gene technology in a conventional crop shipment. Thus, workable policies for labelling prepackaged foods derived using gene technology might take into account threshold values, i.e., the amount of material derived through gene technology in a sample that would trigger the requirement to label the product as resulting from gene technology.

As method of production labelling of genetically engineered foods is not based on scientific evidence of nutritional or food safety concerns, but rather upon the desire of consumers to know certain facts about their food, criteria might need to be established on which to base the threshold value. Practically, threshold values could only be established for commodities or products if reliable quantitative detection methods are available (see Section V, Verification).

Several different criteria could be used to set threshold values:

> Threshold levels of material derived from gene technology could be based on the degree to which mixing of material derived or not derived from gene technology, is preventable. However, this value is likely to be different for different crops due to differences in production, handling and processing.
>
> Alternatively, the threshold level could be based on the limits of detection of the testing methodology employed to monitor the genetic status of a food product or ingredient. However, improvements in testing procedures could permit detection of increasingly smaller percentages of material and implies an effective "zero" tolerance.
>
> Scientific methods developed in several countries could be used to establish an internationally recognized threshold that would facilitate trade.

Should a comprehensive labelling approach be used, threshold levels may not apply in cases where there is assurance that foods or food ingredients are free from material derived from gene technology.

An additional factor for consideration is that processed foods often contain multiple ingredients; thresholds could be set for the percentage of total material derived using gene technology in the product, or as a percentage of material for each ingredient. In addition, consideration might be given to how thresholds for labelling would apply to additives, flavorings, or processing aids that may be present in processed foods in very small amounts.

VI. VERIFICATION

It will be necessary to have systems in place to verify the presence of material derived from gene technology in food or food ingredients. The method used will depend on the type and properties of the food product (for example the extent of processing) and the stringency required. Verification may be accomplished by documentation, testing, or a combination of both methods.

Testing:

If method of production labelling is to be triggered by the presence of DNA or protein resulting from the genetic modification, procedures that are accurate, reliable and reproducible should be available to test for the presence of these components. This includes procedures for sampling shipments of products, as well as laboratory methods for processing and testing individual samples. While testing methods are available that can detect the presence of either the recombinant DNA or the resulting new protein, at this time there are a number of technical issues that need further consideration outside of the CCFL. *(Note: the Codex Ad Hoc Intergovernmental Task Force is collecting information on methods for referral to the Codex Committee on Methods of Analysis and Sampling .)*

In order to assure that the tests are accurate and reliable, it will be necessary to develop and validate test methodologies. This would be an on-going project, as new test methods are introduced and new products (different crop varieties, new traits) enter the market. These new varieties are expected to present a large number of possible combinations of crop species and genetic material. This could require development and standardization of methods for each new variety. In addition, sampling and extraction procedures that work in one matrix may need to be modified for use in other matrices such as processed foods. It will be important to demonstrate consistency and reproducibility of test results from different laboratories within each country and between laboratories internationally, to minimize trade disruptions based on disputed test results.

An additional consideration regarding testing for the presence of materials derived using gene technology is that development of test methods, particularly for specific varieties derived using gene technology, or events, often requires the use of sequence information or genetic material

that companies consider proprietary, and it can be difficult for laboratories or regulatory agencies to obtain this material from companies.

There are currently two types of tests being used to determine if a food product has been produced using gene technology. These procedures test either for the presence of recombinant DNA or protein resulting from the genetic modification. For food or food ingredients in which the DNA or protein may have been lost or degraded during processing (such as refined oils, sugars, starches), these test methods will not work to determine whether these products are produced using gene technology.

Testing for DNA: The procedure most commonly used to detect the presence of specific DNA sequences in a food or food ingredient is called the polymerase chain reaction, PCR. However, PCR is technically complex and must be performed by trained personnel under precise laboratory conditions. The PCR test is highly sensitive, and can detect one or just a few molecules of DNA in a sample. Because the test is so sensitive, it can result in false positive results due to cross contamination.

Descriptions of the PCR technique and its use in identification of foods derived using gene technology can be found in recent publications by:

1. Saiki, R.K., D.H. Gelfand, S. Stoffel, S.J. Scharf, R. Higuchi, G.T. Horn, K.B. Mullis, and H.A. Erlich. 1988. Primer-directed enzymatic amplification of DNA with thermostable DNA polymerase. *Science* 239: 487-491.

2. C.W. Dieffenbach and G.S. Dveksler (eds.). 1995. PCR Primer: a laboratory manual. Cold Spring Harbor Laboratory Press (ISBN 0-87969-447-5).

3. Sachse, K., J. Zagon, H. Rüggeberg, L. Kruse, and H. Broll. 2001. Detection of genetic modifications in Novel Foods. Food International Reviews (in press).

Note that the technology is rapidly evolving and thus this information will need to be updated as new techniques are developed.

If PCR is to be used to detect the presence of material produced using gene technology in a sample for the purposes of labelling, there are a number of factors that should be considered that affect accuracy and reliability of these tests. For example:

-the need for specialized training of personnel in PCR techniques
-the need to physically separate different steps of the PCR process to prevent cross-contamination
-the need for special equipment (particularly for quantification)
-the choice of DNA primer and probe sequences
-choice of controls and availability of reference material for proper interpretation of results

In addition, if labelling provisions set a threshold value below which labelling would not be applicable, consideration should be given to the fact that the use of PCR as a quantitative method is in the very early stages. For quantitative PCR, it is essential that laboratories have access to reference materials with which to compare their results. Methods must be available to correlate data on the amount of DNA present with the percentage of biotech material in a sample. This can be difficult for products like Bt corn as different events can contain 1, 2 or more copies of the inserted DNA.

PCR testing becomes even more complex for processed food products that may contain multiple ingredients, often in very small amounts. As mentioned above, heat or chemical treatments associated with processing of food products may remove or degrade the DNA, and this will be variable for each processed product tested.

PCR testing can be expensive and time consuming. The need for specialized infrastructure and trained personnel is a specific consideration particularly for developing nations if they apply labelling provisions for foods produced using gene technology. In addition, a system should be implemented to resolve disputes based on discrepancies in test results between different laboratories or countries.

Testing for Protein: In addition to the PCR tests for detection of DNA, there are tests available to detect material derived using gene technology in food that are based on the presence of protein resulting from the genetic modification. These tests, often referred to as ELISA tests (enzyme-linked immunosorbant assay) use antibodies that bind to the specific protein and generally produce a colour reaction that can indicate the presence and/or the amount of the specific protein in the food. Two types of ELISA tests are currently commercially available: a rapid dipstick test that is mainly used to show the presence of material derived using gene technology in raw materials, and a microwell assay that can be used to quantify the specific protein in a product.

Protein assays can be problematic for quantification in a sample for several reasons. For example, the level of a particular protein produced or expressed can vary between plant varieties and even between individual plants under different growing conditions. It will also be important to consider the nature of the material to be tested. Protein is easily denatured or broken down by heat or chemicals into a form that would be unrecognizable by the antibodies, so ELISA tests would likely not work well for processed foods,

especially to detect ingredients present in very small quantities. Antibody-based protein assays may also be susceptible to false positives due to cross-reactivity of the antibodies with non-specific proteins. As with PCR tests, it is very important to have standardized material and reliable controls to ensure the test results are consistent for different types of material and between commercial testing facilities or test kits.

Documentation:

Another approach to verification of information on food labels regarding the presence of material derived from gene technology might be to base verification on a paper documentation system or certification processes at various stages in the food production chain. This applies particularly for products that would not contain detectable DNA or protein, such as highly processed oils, if these products require labelling. In addition, based on the difficulty of testing for the presence of a large number of varieties derived using gene technology, it may be a practical method of providing foods not produced using gene technology for consumers who prefer this type of product. Producers and processors could provide conventional products and with verification of proper identity preserved handling, it could be assumed that the level of materials derived using gene technology would not be more than an agreed-upon threshold value.

If labelling of foods based on the method of production is to be based on a verifiable process of production and handling, criteria might need to be established as to what that process will be and at what points documentation or testing will be required to verify that the process is being followed. Decisions will need to be made as to who will be responsible for verification/certification of the genetic status of a crop or processed food product, either by a government agency or a third party. And, if certification by private entities is allowed, it might be necessary to determine whether this would be accompanied by oversight or standardization of procedures by a government agency.

VII. COSTS OF LABELLING[3]

The costs to industry, regulatory agencies and ultimately consumers of labelling of food produced using gene technology and the distribution of these costs is a very complex topic. These costs will depend on a number of factors, including the nature of the food, and whether all foods, or a defined set of foods (i.e., foods containing detectable DNA or protein from the genetic modification) are subject to labelling. In addition, costs will be affected by supply and demand conditions for specific products in different markets. In adopting any of these approaches, consideration might be given to the capacity of

[3] The information on costs of labelling was provided by Australia, and is based on studies commissioned by the Australia/New Zealand Food Authority in 1999 and 2000. There are other independent and government-commissioned studies available on the costs of labelling. Some of these can be found online at www.anzfa.gov.au/GMO

industry and consumers to pay and the cost of enforcement incurred by regulatory agencies. Where the approach adopted for labelling of food or ingredients produced using gene technology is atypical of systems in effect internationally, consideration might also be given to cost impacts on trade in agricultural commodities and food products.

Where comprehensive method of production labelling is implemented, costs could accrue from the necessity to establish and continually monitor a system to track each food or ingredient produced using gene technology from its source of production to its point of inclusion in the final food product. Audit systems could require operators in the supply chain to be diligent in passing on information regarding the status of the food to enable appropriate labelling to be applied. Direct costs could accrue at all points of production and sale due to the requirement to implement information gathering, recording and transfer systems, and also from testing to verify the audit trail. Significant indirect costs would accrue through the establishment of segregation/identity preservation systems necessary to supply food and ingredients not derived from gene technology in response to market driven demand.

The necessity to track a multiplicity of minor food components, such as food additives and processing aids that are derived from gene technology, could contribute the largest costs associated with method of production labelling. The inclusion of these items differentially impacts on manufacturers of foods that comprise a large number of such components. Typically, this includes a significant number of small businesses.

Enforcement costs of full process labelling, especially where labelling is mandatory, are also likely to be high as extensive audit inspections and test systems would be required.

There are a number of additional factors that can affect the cost of method of production labelling. These factors include, but are not limited to: the need to develop and use validated sampling and testing methodologies at various points in the production chain; the establishment and maintenance of segregation systems; the use of exemptions from labelling for minor ingredients (e.g. processing aids, additives); and, the acceptance of small amounts of material derived using gene technology in conventional foods.

Any factor that affects the costs of labelling food and food ingredients produced using gene technology may have an impact on consumer information. Therefore, the results of a thorough cost-benefit analysis that considers these factors could be useful in developing provisions for method of production labelling.

VIII. NEGATIVE CLAIMS

Negative labelling statements or claims made regarding the absence of food or ingredients produced using gene technology arose during the discussions within the Drafting Group.

DISCUSSION PAPER

Negative labelling statements or claims are proliferating in a number of countries. Several members of the Drafting Group suggested that further discussion on this issue would be useful to provide clear, consistent guidance on the extent and limit of their use, as well as their relationship to the use of statements about the presence of food and food ingredients derived from gene technology.