codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7B **CX/FL 03/8-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Thirty-first Session
Ottawa, Canada, 28 April - 2 May 2003

DISCUSSION PAPER ON THE DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

PREPARED BY CANADA

The purpose of this paper is to describe a potential approach to facilitate progress of the Codex Committee on Food Labelling (CCFL) in developing the *Draft Guidelines for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering* (the draft Guidelines).

Advancement of the draft Guidelines through the Codex process has been a challenge for several years. Strong differences of opinion have polarized countries' views, resulting in a lack of consensus on various issues, particularly those related to method-of-production labelling (i.e. unrelated to health and safety). As a result, the draft guidelines have remained at Step 3 of the development process since 1996, and further progress on this document is unlikely.

In contrast, there has been strong consensus among Codex member countries in terms of health and safety risk management regarding foods derived through modern biotechnology. In the Codex Ad Hoc Intergovernmental Task Force on Foods from Biotechnology (CTFBT), agreement on the *Draft Principles for the Risk Analysis of Foods Derived from Biotechnology* was reached in unprecedented time. This document, which had been first considered in March 2000, is now at Step 8 of the development process.

In the recent "Report of the Evaluation of the Codex Alimentarius," and other FAO and WHO food standards work," it was recommended that the Codex Alimentarius Commission (CAC) make a priority those standards with an impact on consumer health and safety. This recommendation arose from considerable consultation among member countries. Further, at the Twenty-Fifth (Extraordinary) Session of CAC, held February 2003, to consider the Report of the Evaluation of Codex, the Commission reasserted that the first priorities in the development of Codex Standards were the protection of consumers'

health and food safety. In addition, recommendations as to prescribed time limits for standards/guidelines development (on the expiry of which the item would be removed from the agenda) point to the need to identify solutions when progress has stalled.

Considerable research is being done with respect to novel foods that exhibit nutritional and compositional modifications. As such, in light of the impending commercial availability of such foods, clear guidance is needed in respect of labelling as a risk management measure to protect consumers' health. There is, therefore, a need for Codex to address labelling for health and safety measures to foster international consistency.

Given the broad support for labelling as a risk management tool to protect health, and the benefit of clear Codex guidance in the application of such labelling, it may be beneficial to develop this element separately from method-of-production labelling. Health and safety labelling could then be permitted to develop on a track separate from that of method-of-production labelling, thereby improving opportunities for progress.

There may be several ways in which to achieve this separation, but the need for clear guidance for health and safety risk management must be addressed. To this end, a potential approach may be for the CCFL to split the draft Guidelines into two documents, as follows:

1) a draft standard for labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering that have an impact on consumer health and safety

2) a draft guideline for labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering to indicate method of production

The attached annexes, prepared by Canada using the current text at Step 3, illustrate how such a separation might be accomplished.

ANNEX 1

Draft - PROPOSED DRAFT STANDARD FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING THAT HAVE AN IMPACT ON CONSUMER HEALTH AND SAFETY

(At Step 3 of Procedure)

PURPOSE OF THE STANDARD

To provide guidance to ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering that have the potential to have an impact on consumer health and safety provides factual, verifiable, understandable and non-misleading information to protect consumers' health and to ensure fair practices in food trade.

These guidelines set out an approach and related information that should be used for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.0 SCOPE

This standard recommends procedures for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

1.1 This standard applies to the labelling of such food and food ingredients:

1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation[1];

2.0 DEFINITION OF TERMS[2]

(At Step 6 of the Procedure)

For the purpose of this Standard:

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

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

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

"Modern biotechnology" means the application of:

a. *In vitro* nucleic acid techniques[3], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

---

1 This would include products such as oils with altered fatty acid levels, but would not include products such as those with agronomic modifications which contain recombinant DNA and/or protein but no further overall change to composition, nutritional value or intended use.

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

b Fusion of cells[4] beyond the taxonomic family,

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

3.0 LABELLING PROVISIONS

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

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

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

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 4.l on label declarations.

3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification/genetic engineering of an allergen transferred from any of the products listed in Section 4.2.1.4 of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985 (Rev.1-1991, Amended 1999) shall be declared[5]

3.3 [The presence of substances which may result in physiological or metabolic disorders for certain sections of the population and that are absent in corresponding existing foods [should] [shall] be labelled].

4.0 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 likely to create an erroneous impression regarding its character or safety in any respect.

4.1 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*.

---

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

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

5 This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

(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.

[5.0 IMPLEMENTATION

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

ANNEX 2

Draft - PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING TO INDICATE METHOD OF PRODUCTION

(At Step 3 of Procedure)

PURPOSE OF THE GUIDELINES

To provide guidelines to ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provides factual, verifiable, understandable and non-misleading information to ensure fair practices in food trade. Food labelling plays an important role in providing information to consumers, thereby facilitating consumer choice.

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

1.0 SCOPE

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

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

1.1.1 when they are composed of or contain a genetically modified/engineered organism or contain protein or DNA resulting from gene technology[6]; and/or

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

2.0 DEFINITION OF TERMS[7]

(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 modern biotechnology, or food and food ingredients produced from, but not containing genetically modified/engineered organisms obtained through modern biotechnology.

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

---

6 [Gene technology: Means a collection of techniques which are used to alter the heritable genetic material of living cells or organisms in a way that does not occur naturally by multiplication and/or recombination.]

7 The terminology used in this section on definitions should not determine the terminology which is appropriate for use on food labels.

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

"Modern biotechnology" means the application of:

a. *In vitro* nucleic acid techniques[8], including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
b. Fusion of cells[9] beyond the taxonomic family,

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

3.0 LABELLING PROVISIONS

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

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

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

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

3.2 [Notwithstanding Section 4.2.2.2 of the General Standard[10]], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary considerations, will be decided and implemented in a manner that is fair, transparent and consistent.]

[4.0 THRESHOLD LEVELS

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

[Establishment of a threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification/ genetic engineering, below which labelling would not apply[11]] and/or

---

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

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

10 Section 4.2.2.2 requires that pork fat, lard, and beef fat shall always be declared by their specific names

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

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

[**5.0 EXEMPTIONS**

5.1 Notwithstanding the provisions of Subsection 3.1 and 3.2, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.]

6.0 LABEL DECLARATIONS

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

6.1 In accordance with Section 6.0, food labels should be meaningful to the [intended] consumer. Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

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

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

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

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

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

(f) [“Product of plant/animal biotechnology”]

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

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

(i) [“Product of gene technology”]

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

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

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

[7.0 IMPLEMENTATION

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