codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FL 04/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Thirty-second Session
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LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING

REPORT OF THE WORKING GROUP ON THE MANAGEMENT OF THE AGENDA ITEMS ON LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/ GENETIC ENGINEERING

REPORT OF THE MEETING OF THE WORKING GROUP ON OPTIONS TO ENHANCE THE MANAGEMENT OF THE AGENDA ITEMS ON THE LABELLING OF FOODS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING
Calgary, Alberta, Canada,
28th – 30th October 2003

Introduction

1. The 31st Session of the Codex Committee on Food Labelling agreed to a proposal from the Chairperson to establish a Working Group, hosted by Canada, to develop options for the management of the agenda items pertaining to the labeling of foods obtained through certain techniques of genetic modification/genetic engineering[1]. In response to this decision, the Canadian Secretariat circulated a letter to all members of the Commission and observer organizations soliciting proposals for ways to manage this issue.

2. The Working Group convened in Calgary, Alberta, October 28th – 30th, 2003 to consider the options submitted in response to the request for proposals. The Working Group consisted of 37 representatives from 18 member countries. The full list of participants is attached as Appendix I to this report.

CONSIDERATION OF PROPOSALS

3. A discussion paper (Appendix II) was prepared by the Canadian CCFL Secretariat and circulated to the Working Group members in advance of the meeting. The paper contained a summary of three options received in response to the call for proposals; one submitted by an Observer organization and the other two by a member country. Submissions received from two Observer organizations after the discussion paper was finalized were also made available to the Working Group (Appendices III and IV).

4. Although there were three options contained in the discussion paper, the Chair encouraged members to offer additional proposals. It was pointed out that all options should be considered, including dropping the item from the CCFL agenda or parking it for a period of time until global opinion is at the point to permit achievement of consensus. Another possibility would be to maintain the *status quo* and continue discussions at the Committee. The Chair indicated, nevertheless, that approaches to advance the issue should be the focus of the Working Group's considerations. The Chair also reminded the Working Group that their mandate was to consider management options and not to develop new text or revise existing text.

5. In considering the discussion paper, a number of underlaying issues were identified by various members of the Working Group, including:

- the need to be consistent with labelling text already adopted by Codex,
- priority should be given to protecting the consumer with respect to health and safety concerns and/or misleading information,
- labelling is about consumer information and, in many cases, not related to health and safety,
- regional differences should be taken into consideration with regard to what consumers need to know or are interested in,
- consideration respecting "when" and "how" to label,
- the mandate given to the CCFL by the Commission,
- WTO implications need to be taken into consideration but should not impede the work of Codex.

6. Members of the Working Group expressed the view that the CCFL should continue to consider this item and retain it on the agenda.

7. It was recognized that labelling for health and safety reasons was linked to science-based risk assessment. The Working Group also noted that certain other considerations could be science-based, yet not necessarily related to health and safety, such as composition and intended use.

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[1] ALINORM 03/22A, Report of the 31st Session of the Codex Committee on Food Labelling, 28th April – 2nd May 2003, Ottawa, Canada, paragraphs 69-74.

8. The proposal to split the document along "health and safety" considerations was examined by the Working Group as this was considered by some members as a possible option to progress the agenda item. Some members expressed the view that the health and safety aspects of labelling were already adequately addressed in the *Codex General Standard for the Labelling of Prepackaged Foods*, making a specific reference to sections 4.2.2 and 4.2.1.4 (allergenicity). Several members indicated that many countries can implement a pre-market approval process for foods obtained through certain techniques of genetic modification/genetic engineering and expressed the view that "unsafe" products would be precluded from the marketplace. They, therefore, questioned the validity of splitting the document along "health and safety" lines as proposed. They felt that labelling in most cases was not about health and safety but about providing other information to consumers to permit them to make informed choices.

9. Several members expressed the view that they did not favour splitting the document. Brazil shared this opinion but also indicated it would consider that approach as a possible means to achieve consensus on a way to progress this issue. However, should the document be split, it was important that both parts receive the same treatment and be advanced concurrently. Several members indicated that the split proposed by Canada was not really based on "health and safety" considerations but would more appropriately be referred to as product related characteristics.

10. There were aspects of labelling which the Working Group agreed should be considered as mandatory. These were identified as necessary to address health and safety concerns or changes in composition or intended use. Several members of the Working Group referenced Section 4.1.2 of the *Codex General Standard for the Labelling of Prepackaged Foods*, which highlighted the need to avoid misleading or confusing the consumer. It was further noted that other aspects of labelling were related to information, which the consumer considered to be important (e.g. method of production). It was recognized that there were regional differences in what consumers considered important and hence guidance needed to take these differences into account.

11. The Chair noted there was no consensus on splitting the document, but there appeared to be considerable interest in maintaining a single document, which contained mandatory elements, and other provisions, which were considered to be optional. The challenge was to determine how to address these optional elements, the application of which reflects regional differences. A number of members supported the suggestion to elaborate this single document by following the format of the *Codex General Standard for the Labelling of Prepackaged Foods*, as in this published document both mandatory and optional elements were already included.

12. It was noted that labelling provisions for foods obtained through certain techniques of genetic modification/genetic engineering, which do not address health and safety concerns, or changes in composition or intended use, such as labelling to indicate method of production, could be written in a way to facilitate a consistent approach. Therefore, it was suggested that the development of principles in this area should be given consideration, as these types of issues will reoccur. However, the Working Group did not discuss it further as a possible option.

13. Although the Working Group reached consensus on inclusion of a mandatory component, and while agreeing "optional" elements could also be included, concerns were expressed regarding how the term "optional" might be interpreted by a WTO panel, especially regarding disputes under the TBT Agreement. There were divergent views in the Working Group on how to address these concerns. Some members expressed the view that interpreting "optional" advice directed to governments as a requirement to implement may be contrary to the decisions taken at the 26th Session of the Codex Alimentarius Commission regarding the Codex mandate[2]. It was the view of some members that if these concerns were taken to the extreme, the work of Codex could be impeded.

14. The Working Group considered inclusion of a footnote or lead-in statement as a means to explain the "optional" elements as a way to accommodate regional differences in information the consumer considered important. The Working Group formed a drafting group to prepare sample text to facilitate their consideration of this approach. No final conclusions were drawn either on the text or its use but in the interest of transparency, this text is included in Appendix V.

15. The Working Group briefly discussed the "Definition of Terms" section of the draft guideline. It was noted that the Committee appeared to be close to a consensus on the definitions. It was suggested that

[2] ALINORM 03/41, Report of the 26th Session of the Codex Alimentarius Commission, paragraph 117.

consensus could be facilitated if there was a clear delineation of definitions for the purpose of interpreting the guidelines and definitions with respect to what was placed on the label.

Conclusions and Recommendations

16. The Working Group acknowledged the importance of the exchange of views and recognized that there were a variety of options with respect to managing work on this agenda item. The Working Group:

- # Expressed the view that CCFL should continue to consider this item and retain it on its agenda.
- # Expressed considerable interest in maintaining a single document with a mandatory component and other provisions which would be considered optional. The Working Group took note of the suggestion made to use the format of the *Codex General Standard for the Labelling of Prepackaged Foods.* (See paragraph 11).

17. Noting the concerns related to possible interpretations by a WTO Dispute Panel regarding "optional" elements of Codex texts, and the impact of these concerns on the work of Codex in general, it was suggested that the CCFL may consider it useful to bring this matter to the attention of the Commission and request the Commission seek an opinion from FAO, WHO and the WTO.

APPENDIX I

Ad Hoc Working Group Meeting on The Management of The Labelling of Foods Obtained Through Certain Techniques of Genetic Modification /Genetic Engineering

October 28-30, 2003, Calgary, Alberta, Canada

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APPENDIX II

Discussion Paper on
Proposals to Enhance the Management of the Agenda Item on the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/genetic Engineering

Prepared by the Canadian Secretariat to the Codex Committee on Food Labelling, Health Canada, Ottawa, Ontario - October 2003

BACKGROUND

1. "Foods Derived from Biotechnology" have been under consideration by Codex since the 35th Session (1988) of the Executive Committee.[1] The 19th Session (July 1991) of the Codex Alimentarius Commission requested the Codex Committee on Food Labelling (CCFL) to *"provide guidance on how the fact that a food was derived from "modern" biotechnology could be made known to the consumer.*[2]*"* At its 21st Session (July 1995), the Commission endorsed work on guidelines for labelling of foods derived from biotechnology[3] as one of the recommended strategies to achieve the objectives of the Medium-Term Plan 1993 – 1998.

2. The CCFL has had this item on its agenda since its 22nd Session (April 1993). Discussions at its 22nd, 23rd (October 1994) and 24th (May 1996) Sessions clearly demonstrated that a number of divergent views existed.

3. As there was no consensus, the 24th Session of the CCFL agreed to seek the advice of the Executive Committee on how the guidelines should be formulated, especially in view of the *Four statements of Principle on the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account*. The Committee also agreed that the Secretariat should initiate the preparation of proposed draft guidelines at Step 2 based on advice received from the Executive Committee.

4. The 43rd Session (June 1996) of the Executive Committee provided guidance to the CCFL[4] which contained three key messages:

- The Statements of Principle[5] were intended for guidance of all Codex Committees and thus should be closely adhered to by CCFL in preparing the draft guidelines;
- The CCEXEC did not accept the view that standards directed to ensuring fair practices in the food trade in areas other than the protection of consumers' health were excluded from the Commission's mandate.
- The CCEXEC noted that the "claimed right to know" was ill-defined and variable and in this respect could not be used by Codex as a primary basis for decision-making on appropriate labelling.

5. The Codex Secretariat, as directed by the 24th Session of the CCFL, and taking into consideration the guidance provided by the Executive Committee, presented the 25th Session (April 1997) of CCFL with proposed draft recommendations for the labelling of foods obtained through biotechnology in the form of an amendment to the General Standard for the Labelling of Prepackaged Foods. The draft proposals entailed an amendment to Section 2 (Definitions), Section 4 (Mandatory Labelling of Prepackaged Foods) and Section 5 (Other Mandatory Requirements). In preparing the paper, the Secretariat also took into account the Report of the FAO/WHO Expert Consultation on Food Safety Aspects of Biotechnology.

6. At its 25th, 26th (May 1998) and 27th (April 1999) Sessions, the CCFL could not reach consensus on the amendments to Section 5 of the General Standard. Some consensus, however, was achieved at the 26th

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[1] ALINORM 89/3, Report of the 35th Session of the Executive Committee, 4th – 8th July 1988, Geneva, paras 59 – 60.
[2] ALINORM 91/40, Report of the 19th Session of the Codex Alimentarius Commission, 1st – 10th July 1991, Rome, paragraph 90.
[3] ALINORM 95/37, Report of the 21st Session of the Codex Alimentarius Commission, 3rd – 8th July 1995, Rome, paragraphs 9 – 12.
[4] ALINORM 97/3, Report of the 43rd Session of the Codex Executive Committee, 4th – 7th June 1996, Geneva, paragraphs 27 – 30.
[5] Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account.

Session on the proposed revisions to Sections 2 (Definitions) and 4.2 (Listing of Ingredients – allergens) which were advanced to Step 5.

7. The 27th Session agreed to the establishment of a Working Group, chaired by Canada, which would develop text for consideration by the next Session.[6] In its report[7] to the 28th Session, the Working Group proposed two options. The first option recommended labelling when products obtained through biotechnology differ significantly from the corresponding food as regards composition, nutritional value, or intended use. The second option recommended the declaration of the methods of production for foods and ingredients composed of or containing genetically modified/engineered organisms, or food or food ingredients produced from but not containing GMO/GEOs if they contain protein or DNA resulting from gene technology or differ significantly from the corresponding food.

8. Consensus was reached on the amendment to Section 4.2 and the Committee advanced the section on allergenicity to Step 8. Consensus was not reached on Sections 2 and 5, thus the Committee requested the Working Group to combine the two options into a guideline format and present their recommendations to its 29th Session (May 2001).[8]

9. The resulting text developed by the Working Group allowed for different labelling options, including comprehensive labelling, and provided guidance in each case. Neither the 29th or the 30th Session (May 2002) could reach consensus on the guidelines. However, the 29th Session of the CCFL did agree to advance the section on definitions to Step 8, although several delegations expressed their reservations with this decision.[9]

10. The 24th Session (July 2001) of the Codex Alimentarius Commission adopted the amendments to Section 4.2 (Listing of Ingredients – Allergens) of the General Standard for the Labelling of Prepackaged Foods but returned the draft definitions back to the Committee.

11. At its 31st Session (May 2003), the Committee did not discuss the proposed draft guidelines but agreed to a proposal from the Chairperson to establish a Working Group to develop options for management of this agenda item. The Committee therefore agreed to hold the guidelines at their current step until the Working Group presents its recommendations to the next Session of the CCFL.[10]

12. The Working Group should note that while conducting the Joint FAO/WHO Evaluation of the Codex Alimentarius Commission and Other FAO and WHO Food Standards Work, the Evaluation Team devoted some of their time to examining the issue of "Labelling of Foods Derived from Biotechnology". Their report notes that "…the CCFL could have benefited from more focussed direction from the Codex Commission"[11] and that the "…CCFL did not have the benefit of an expert consultation on risk management or communication……..Due to political aspects of risk management and communication, and the current impasse, CCFL may not be able to resolve this dispute."[12].

PROPOSALS FOR CONSIDERATION BY THE WORKING GROUP

13. Acting on the decision of the 31st Session of the CCFL, the Canadian Secretariat circulated a letter to all members of the Commission and observer organizations soliciting proposals for ways to manage this issue. To facilitate discussion, respondents were requested to structure their proposal as follows:

[6] ALINORM 99/22, Report of the 26th Session of the Codex Committee on Food Labelling, 26th – 29th May 1998, Ottawa, Canada, paragraphs 41 – 48.
[7] CX/FL 00/6
[8] ALINORM 01/22, Report of the 28th Session of the Codex Committee on Food Labelling, 5th – 9th May 200, Ottawa, Canada paragraphs 30 – 48.
[9] ALINORM 01/22A, Report of the 29th Session of the Codex Committee on Food Labelling, 1st – 4th May 2001, Ottawa, Canada.
[10] ALINORM 03/22A, Report of the 31st Session of the Codex Committee on Food labelling, 28th April – 2nd May 2003, Ottawa, Canada paragraphs 69 – 74.
[11] *Report of the Evaluation of the Codex Alimentarius Commission and other FAO and WHO Food Standards Work*, paragraph 68 and Box 1, November 2002.
[12] Ibid.

introduction, brief description of the option, rationale for the option and benefits with the suggested approach. As of September 30th, one proposal had been received from a Member country and one from an International Non-Government Organization.

14. An Observer organization, the 49th Parallel Biotechnology Consortium, submitted a proposal recommending expanding the Working Group to include "voices not often heard from in the Codex process, such as a parliamentarian (a member of the (Canadian Parliament's) Standing Committee on Health) and individuals speaking from a public interest point of view who are known to want to see the Codex system work and not be an adjunct of the WTO". The Observer also suggested that the countries and special interest groups which are the cause of the problem should be identified and the burden of resolution should be placed on them. This proposal will be identified as Option 1. (Attachment 1).

15. Canada has offered two proposals for consideration by the Working Group. In its covering letter (Attachment 2), Canada draws the attention of the Working Group to statements contained in adopted Codex texts, specifically the *Codex General Standard for Prepackaged Foods* (Sub-section 3.1); the *Codex General Guidelines on Claims* (Subsections 3.3 and 3.5; paragraphs 5.1(v) and 5.1(vi)(b-d)) and the *Codex Guidelines on Nutritional Labelling* (Preamble). Canada expressed the opinion that these statements could benefit the Committee's work and should be considered by the participants when contemplating all management options.

16. One proposal from Canada is that the Guidelines for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering could be separated into two separate documents: (a) guidance for labelling of such foods where consumer health and safety are implicated and (b) guidance for labelling such foods to indicate method of production. Such a separation would permit the advancement of those elements of labelling guidelines where there is consensus and allow the Committee to further consider those areas where consensus still has not been reached. Canada points out that this approach is also consistent with the recent *Report of the Joint FAO/WHO Evaluation of the Codex Alimentarius and Other FAO and WHO Work on Food Standards*, recommendation that the CAC make a priority those standards which impact on consumer health and safety. This proposal will be identified as Option 2. (Attachment 3).

17. Canada's second proposal suggests establishing a small group or groups to work on specific sections of the draft Guidelines with a view to addressing unresolved issues (e.g. adventitious presence, tolerances, etc.). The group or groups, functioning in a fully transparent and inclusive manner, could be asked to gather information that would facilitate the informed discussion needed to resolve outstanding issues. The group(s) would interact with other international bodies, such as the OECD, FAO, WHO, and WTO, who may be discussing similar issues related to method-of-production labelling. This could be useful to the CCFL, enabling it to build on the work of others and possibly generate consensus through more informed discussions. The smaller group could also look at the results of other countries' domestic discussions on the technical aspects of the relevant issues. This proposal will be identified as Option 3. (Attachment 4)

18. Emphasizing that the focus of discussions will be on identifying possible ways to move this agenda item forward and not on text, the Working Group is invited to reflect on these Options and to develop recommendations for consideration of the next Session of the CCFL on how this agenda item can be managed.

Attachment 1

Proposal Received from the 49th Parallel Biotechnology Consortium

Brewster Kneen
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7 August 2003

Mr. Ron Burke
Canadian Secretariat, Codex Ctte on Food Labelling
Health Canada Building #7
Tunney=s Pasture, Ottawa

From: 49th Parallel Biotechnology Consortium (49P)

Re: Management of agenda items (ALINORM 03/22A para 73)

49P wishes to make two suggestions concerning the work of the AChair=s Advisory@ working group; A) participation in the group, and B) procedure.

A) Given the difficulties encountered in the past, we would like to suggest that the working group include voices not often heard from in the Codex process, such as a parliamentarian (a member of the Standing Committee on Health) and individuals speaking from a public interest point of view who are known to want to see the codex system work and not become an adjunct of the WTO.

B) On process, we would suggest the following:

1) Define the problem (obstacles to agreement)

2) Identify the countries and special interest groups (industry lobbies) that have been the cause of the problem.

3) Deconstruct the arguments used by those causing the problems, i.e. AScience-based@, Asound science@ etc.

4) Put the burden of resolution on those causing the problem, i.e., what changes are they prepared to make in their own demands and behaviour to recognize the will of the majority? If they are not prepared to change, then they need to be identified as the cause of the problem.

We think it is crucial for Codex to maintain its independence and integrity, as well as its consensus-based procedures.

Respectfully submitted, on behalf of 49P

Brewster Kneen

Attachment 2

Proposal from Canada
Cover Letter

Mr. Ron Burke, Director,
Bureau of Food Regulatory, International and Interagency Affairs,
Health Products and Food Branch
Health Canada

RE: Potential Management Option Proposals

Canada would like to present the following options to the Chair's Advisory Working Group meeting to discuss the management of the Codex Committee on Food Labelling (CCFL) agenda item on labelling of foods from biotechnology, from October 28th - 30th, 2003.

While Canada has not yet determined its official position, these proposals are intended to contribute to discussions that are to take place during the Working Group meeting. These management options describe possible approaches to facilitate progress in the CCFL to advance the discussion of the Draft Guidelines for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering.

The purpose of the Codex Alimentarius Commission is to protect the health of the consumers and ensure fair practices in food trade. While developing our proposals, it became clear to Canada that certain historical points of guidance may serve as a useful context for the Committee when contemplating the best management option. As listed below, Canada considers that these existing and adopted Codex statements could benefit the Committee=s work and should be considered by the participants when contemplating all management options at the Calgary meeting.

Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding the food=s character in any respect. (Subsection 3.1, Codex General Standard for the Labelling of Prepackaged Foods)

The following claim should be permitted subject to the particular condition attached to each:

Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.
(Paragraph 5.1(v), Codex General Guidelines on Claims[1])

The following claims should be prohibited:

Claims which cannot be substantiated.
(Subsection 3.3, Codex General Guidelines on Claims[1])

Claims which could give rise to doubt about the safety of similar food on which could arouse or exploit fear in the consumer should be prohibited
(Subsection 3.5, Codex General Guidelines on Claims[1])

Nutritional labelling should not deliberately imply that a food which carries such labelling/claims has necessarily any nutritional advantage over a food which is not so labelled. (Preamble, Codex Guidelines on Nutrition Labelling[1])

The following claims should be permitted subject to the particular condition attached to each: Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:

b. *is one which consumers would normally expect to find in the food;*
c. has not been substituted by another giving the food equivalent characteristics unless the nature of the substitution is clearly stated with equal prominence;
d. is one whose presence or addition is permitted in the food.

(Subparagraph 5.1(vi)(b-d), Codex General Guidelines on Claims[1])

At this time, Canada would like to thank Codex Canada for hosting this working group and the opportunity to propose the attached management options.

Thank you for your consideration.

Attachment:

Option A: Adapted from Canada=s discussion paper presented at the 31st Session of the Codex Committee on Food Labelling (CX/FL 03/8-Add.1)

Option B: Developing small groups to work on specific sections of the draft Guidelines with an approach to addressing unresolved issues.

Attachment 3

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD LABELLING
Chair's Advisory Working Group meeting

Calgary, Canada, 28–30 October, 2003

MANAGEMENT OPTION FOR THE DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

OPTION PROPOSAL (A) PREPARED BY CANADA

Introduction:
In April 2003, prior to the 31st Session of CCFL, Canada circulated the discussion paper CX/FL 03/8-Add.1, which describes a possible approach to facilitating progress of the Draft Guidelines for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (the draft Guidelines).

Canada is submitting this option in a revised format, as suggested by the Request for Proposals to Enhance the Management of the Agenda Item on the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering, dated June 25, 2003.

While Canada has not yet determined its official position as to the most appropriate management option, this proposal may serve to contribute to the discussions that are to take place during the Chair's Advisory Working Group meeting on the management of CCFL agenda item on labelling of foods from biotechnology.

Brief Description of Option:
To develop health and safety labelling, as a risk management tool, separately from method of production labelling, allowing both elements to advance independently, at their own appropriate pace, through the Codex process.

There may be several ways in which to achieve this separation; however, a potential approach may be for the CCFL to split the draft Guidelines into two documents:

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 voluntary 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 4, illustrate how such a separation might be accomplished.

Rationale for the option:
This management option would provide an opportunity for progress on the health and safety related components of this agenda item, as there is broad support for labelling as a risk management tool to protect health.

Unlike the method of production labelling, there has been strong consensus among Codex member countries in terms of health and safety risk management regarding foods derived through modern biotechnology. As an example, 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 was first considered in March 2000, was adopted at Step 8 at the 26th Session of the Codex Alimentarius Commission (CAC) in July 2003.

In addition, this proposal is consistent with the recent *Report of the Joint FAO/WHO Evaluation of the Codex Alimentarius and Other FAO and WHO Work on Food Standards*, recommendation that the CAC make a priority those standards which impact on consumer health and safety. Furthermore, at the Twenty-Fifth (Extraordinary) Session of CAC, held February 2003, the Commission reasserted that the first priorities in the development of Codex Standards were the protection of consumers' health and food safety.

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

This will also allow for more focussed discussion to take place on the method of production elements, which will facilitate appropriate progress of this type of labelling.

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 variation13;

2.0 DEFINITION OF TERMS[14]

(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 techniques15, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b Fusion of cells16 beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

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13 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.

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

15 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.

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

3.0 LABELLING PROVISIONS

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

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

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

the characteristics or properties which make it different from the corresponding existing food and food ingredients should be clearly identified on the label as described in Subsection 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 declared17

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*.

(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.**]**

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

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[18]; 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 TERMS19
(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 matrial.

"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 techniques20, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

[18] [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.]

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

b. Fusion of cells21 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 Standard22, 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 apply23] 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]**]**

[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

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[20] 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.

[21] 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

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

[23] 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)

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.]

Attachment 4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD LABELLING
Chair's Advisory Working Group meeting
Calgary, Alberta, Canada
28–30 October, 2003

MANAGEMENT OPTION FOR ADVANCING THE DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

OPTION PROPOSAL (B) PREPARED BY CANADA

Introduction:

This management option describes a possible approach to facilitating progress in the Codex Committee on Food Labelling (CCFL) that will advance the Draft Guidelines for the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (the draft Guidelines).

While Canada has not yet determined its official position as to the most appropriate management option, this proposal may serve to contribute to the discussions that are to take place during the Chair's Advisory Working Group meeting on the management of CCFL agenda item on labelling of foods from biotechnology.

The challenge of refining the draft Guidelines and advancing them through the Codex process has been characterized by a lack of consensus in regard to various issues such as those related to method-of-production labelling (i.e. labelling not related to inherent characteristics of the product with respect to health and safety).

Brief Description of Option:

This option involves the establishment of a small group to work on specific sections of the draft Guidelines with a view to addressing unresolved issues (e.g. adventitious presence, tolerances, etc.). In its work and membership, transparency and inclusiveness would be the operative considerations for this group. The group would interact with other international bodies discussing these issues, such as the OECD, FAO, WHO, and WTO.

The group could be asked to gather information that would facilitate the informed discussion needed to resolve outstanding issues. The group would work via e-mail and could hold a workshop or "learning event." The group would agree not to draw any conclusions, or make any recommendations, but would instead fully explore current thinking on the issue. A group could be assigned to each issue, or a single group could work on one issue at a time.

Following the draft Guidelines text, and considering any issues not yet discussed, information could be gathered on various issues, including, but not restricted to:

- threshold levels for adventitious presence or accidental co-mingling, below which labelling does not apply
- exemptions for specific categories of foods or food ingredients
- misleading claims
- implementation and verification (testing methodologies, verification systems)
- negative labelling

Rationale for the option:

Due to the fact that countries have differing views on developing the draft Guidelines among countries, discussions to date have left certain issues unaddressed, as evidenced by the number of square-bracketed items within the current draft. In addition, because of the broad scope and necessary time constraints, some issues, such as negative labelling, have not yet been discussed.

As described above, discussions on the above-noted issues are taking place in various other international fora, and at different levels. It is possible that this work could be useful in the CCFL's work on the draft Guidelines. In order to further help in the CCFL's work, the smaller group could also look at the results of Canada's and other countries' domestic discussions on the technical aspects of the issues.

Benefits to this approach:

This proposal, which involves building on the work of others, could be a way of generating more informed discussion and gathering information on those issues that have prevented the CCFL from reaching consensus. The ultimate result may well be the successful crafting of contentious sections of the draft Guidelines.

APPENDIX III

July 30, 2003

Mr. Ron Burke
Director, Bureau of Food Regulatory
International and Interagency Affairs
Food Directorate, Health Products and Food Branch
Health Canada
Building #7, Room 2395 (0702C1)
Ottawa, Ontario, K1A OL2

RE: BIO Response to Request for Proposals on Options to Manage Biotech Agenda Items in CCFL

Dear Mr. Burke:

On behalf of the Biotechnology Industry Organization (BIO) we appreciate the opportunity to provide a written response concerning your request for comments on the options to manage biotechnology agenda items in the Codex Committee on Food Labeling. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 US states and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

During the 31st Session of the Codex Committee on Food Labeling, the Committee Chair formed an advisory working group with the stated purpose to develop options for the management of the agenda items *Draft Recommendations for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (Definitions)* and the *Proposed Draft Guidelines for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering.*

One of the most important issues before the Codex Committee on Food Labeling (CCFL) at this time is the definitions and guidelines for labeling foods derived from modern biotechnology; these issues are particularly critical to the Biotechnology Industry Organization (BIO). In the ten years since the topic of aspects of labeling for biotechnology was introduced to CCFL, little progress has been possible to achieve in either developing definitions or consensus positions for criteria to use when considering labeling for products derived from modern biotechnology.

The recent FAO/WHO evaluation report well characterized the areas of disagreement on labeling for biotechnology as well as the differences in approach necessary when there is a scientifically based reason to label versus when no such rationale exists. **We support exploration of those differences as the primary goal of the Chair's Advisory "Working Group."**

We strongly believe that a systematic and sequential approach must be taken with respect to the elements of labeling of foods derived from modern biotechnology.

- We believe that the definition, currently at Step 6 of the Codex process, should be finalized and should become the definition upon which the subsequent guidelines are developed.
    - Significant progress has been made in developing the definition; the Step 6 document could be used for further work in development of guidelines or principles for labeling.
    - The definition developed could be applied for labeling whether given mandatory or voluntary guidelines for implementation of labeling.

- We believe that the proposal made by the Canadian government (31st Session of CCFL) to split the *Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering* into two separate documents.
    - In the same manner that the Codex Committee on General Principles was able to make significant and timely progress by separating the two elements of the Principles for Risk

Analysis (one for Codex and one for member governments), we believe that progress could be made.
    - We propose that work be managed sequentially in the full Committee.
    - In order to make progress, we propose that first priority would be given to the areas that would appear to have considerable support (consensus).

- We propose that Annex 1 of the Canadian proposal, "A draft standard for labeling of foods and ingredients obtained through certain techniques of genetic modification/ genetic engineering **that has an impact on consumer health and safety** be the subject of the initial discussion.
    - Considerable consensus exists on many elements of the Annex I proposed by the Canadian delegation.
    - Those areas that have achieved some agreement should be discussed in plenary and advanced as appropriate through the Step process.
    - When a draft standard can be agreed at Step 6 and combined with the existing Step 6 definition, we propose they be combined and sent to member governments for comment.

- We propose that Annex 2 of the Canadian proposal, "*A draft standard for labeling of foods and ingredients obtained through certain techniques of genetic modification/ genetic engineering* **to indicate the method of production** be considered for discussion after the first document and definition have been forwarded to the Commission.
    - We believe that significant controversy attends the document which is designed to require labeling when method of production is indicated. We strongly believe that this is the area that has held up the progress over the past years. For that reason, as part of the consideration of this second document in the process, we would ask that the Secretariat or the Chair request input on the following questions prior to initiation of further work in this area. Under the scenario where the labeling is intended to indicate the method of production:
        - What is the purpose of such labeling?
        - Under what conditions is such labeling necessary?
        - Under what conditions such would labeling be mandatory vs. voluntary?

We strongly believe that work on specific labeling language in this area should not be undertaken until agreement is achieved on the objectives for labeling and the criteria to be used for labeling.

We appreciate the opportunity to provide input on proposals for work in this area. We strongly urge the US government to actively participate in the working group and commit to holding a firm position regarding the need for a scientific basis in work on labeling definitions and criteria. In the same way that the US government provided strong leadership in the Codex Intergovernmental Task Force on Biotechnology, we believe it could effectively drive the group to development of strong criteria for developing a labeling scheme to address both areas where labeling for foods derived from modern biotechnology might be desired.

Sincerely,

Michael J. Phillips, Ph.D.
Vice President for Food and Agriculture
Science and Regulatory Policy

APPENDIX IV

October 2, 2003

Mr. Ron Burke, Director
Bureau of Food Regulatory , International and Interagency Affairs
Health Products and Food Branch
Health Canada, Bldg. No. 7, Room 2395
Tunney's Pasture, Ottawa K1A 0L2
Canada

Secretary
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme -- FAO
Viale delle Terme di Caracalla
00100 Rome
Italy

Dear Mr. Burke and Codex Secretary:

On behalf of the International Life Sciences Institute (ILSI), I am pleased to submit the attached comments to the "Friends of the Chair" Advisory Group of the Codex Committee on Food Labelling on the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions.

ILSI is a nonprofit, worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists from academia, government, industry, and the public sector to solve problems of broad implication for the well-being of the general public. ILSI receives financial support from industry, government, and foundations.

ILSI is affiliated with the World Health Organization as a nongovernmental organization and has specialized consultative status with the Food and Agriculture Organization of the United Nations. Thus, it is as a nongovernmental organization that we respectfully submit these comments.

If we can be of further assistance, please do not hesitate to call on us.

Sincerely,

Suzanne S. Harris, Ph.D.
Acting Executive Director

Attachment

Comments from the International Life Sciences Institute (ILSI) to the "Friends of the Chair" Advisory Group of the Codex Committee on Food Labeling on the Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions

The recent FAO/WHO evaluation report of FAO, WHO, and Codex activities characterizes the difference in approaches necessary to consider in determining requirements for labeling of foods derived from agricultural biotechnology when there is a scientifically-based reason to label versus when no scientific rationale exists.

Since Codex standards and guidelines are supposed to be scientifically sound so as to improve human health through improved food safety, it is appropriate for the CCFL Chair's advisory group to develop labeling requirements for which there is a scientific basis. It is, therefore, appropriate to develop labeling requirements for foods derived from agricultural biotechnology that are different in nutritional or other compositional factors, as demonstrated by scientifically valid and verifiable methods.

Labeling requirements should be based on scientifically substantiated differences of health or safety significance between products developed using modern biotechnology tools and those produced through traditional means.

Such work will require a common understanding of modern biotechnology for food and food ingredients. The CCFL has developed a scientifically sound definition, currently at Step 6 of the Codex process (ALINORM 03/22, Appendix III) that is in agreement with the recently adopted definition developed by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. This definition would be a reasonable starting point for the CCFL Chair's advisory group to start in developing guidelines for what and how to label when scientifically appropriate.

APPENDIX V

[Optional Labelling: Without prejudice to the acceptance of the approach to method of production labelling as a "legitimate concern"* of governments in establishing their national legislation, the following is provided as optional considerations to member countries:]

[*Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account]