codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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AGENDA ITEM NO. 5 (B) **CX/FL 02/06**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
THIRTIETH SESSION
HALIFAX, CANADA, 6 - 10 MAY 2002

Proposed Draft Recommendations for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering): Labelling Provisions (CL 2001/43-FL, Alinorm 01/22A – Appendix V)

Government Comments At Step 3

COMMENTS FROM:

ARGENTINA
BRAZIL
CANADA
COLUMBIA
MALAYSIA
POLAND
SPAIN
SWEDEN
UNITED STATES
URUGUAY
49TH PARALLEL BIOTECHNOLOGY CONSORTIUM (49P)
EUROPEAN COMMUNITY
INTERNATIONAL ASSOCIATION OF PLANT BREEDERS (ASSINSEL)
INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

CODEX AD HOC WORKING GROUP ON THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY

Working group member responses to
CL 2001/19-FL* (ALINORM 01/22A), *CL 2001/22-FL* and *CL 2001/43-FL

Index of Comments:

For ease of reference, the shaded boxes in this document contain the specific texts for each of the sections under review as they appear in ALINORM 01/22A, APPENDICES IV and V. In order to allow the document to be consolidated in a uniform way, references to footnotes that pertain to original texts have been omitted.

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

Columbia:

In the title of the Guideline: Change the term "**Modern Biotechnology**" by "Certain Techniques of **Genetic Modification/Genetic Engineering". .** Change the term throughput the document.

Include the word **ingredients** in the title"....**of food and food ingredients**...." The main ingredients in the formulation of a product obtained through gene modification should be covered by this requirement

European Community*:*

The European Community supports the use of the term "genetically modified" throughout the whole of the text and in the title. The European Community notes, however, that this terminology is not consistent with the terminology currently used in the work of the Codex Ad Hoc Task Force on Foods Derived from Biotechnology. At its Second Session, the Task Force maintained its preference for the use of the terms "foods derived from modern biotechnology" as it was of the opinion that consistency with other internationally agreed instruments (notably the Cartagena Biosafety Protocol) was critically important in this case. The Task Force recommended that the CCFL should give consideration to using the same definition in its work (ALINORM 01/34A, para. 23).

Recalling the extended discussion at the last Codex Committee on Food Labelling (CCFL) in Ottawa, May 1 – 4, 2001, it is obvious that the CCFL will have certain difficulties to achieve consensus on this issue. In general, the European Community is of the opinion that the Codex Alimentarius Commission and its subsidiary bodies should avoid using different terminology as a matter of principle. The CCFL shall however have full discretion for specifying and defining the terms to be used in the actual labelling of foods and to recommend the terms and definitions most appropriate from a labelling perspective. For labelling purposes, it is pertinent to use terms and definitions that are easier for consumers to understand.

Sweden:

Comments as expressed by the European Community.

(2) 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 relevant to protect consumer's health and to ensure fair practices in food trade. Food labelling plays an important role in furthering both of these objectives and 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.

Argentina:

[To provide guidelines to ensure that the labelling of food and food ingredients ~~obtained through certain techniques of genetic modification/genetic engineering~~ ***derived from modern biotechnology*** (a) provides factual, verifiable, understandable and non-misleading information relevant to protect ~~consumer's~~ ***the*** health ***of the consumer*** and to ensure ***the implementation of*** fair practices in food trade. Food labelling plays an important role in furthering both of these objectives ~~and 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~~ ***and to take advantage of the great opportunities to contribute to human welfare presented by modern biotechnology***

Note:
(a) *The same change should be applied throughout the document each and every time these terms are reiterated. We suggest introducing a general notification.*

Brazil:

We support the text as drafted

Columbia:

We agree, but including in the new wording the phrase "and to ensure fair practices in food trade"

The document reads: "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 **relevant to protect consumer's health and to ensure fair practices in food trade".**

For

"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**"

European Community:

The European Community supports the purpose of these guidelines and supports therefore the deletion of the brackets.

International Association of Plant Breeders (ASSINSEL):

ASSINSEL recommends to:

change the order between the first and second paragraphs;
add "where requested" at the end of the current second paragraph;
keep the first sentence of the current first paragraph and delete the second sentence of the same paragraph, or delete the whole paragraph.

According to the above, the section would read as follows:

*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**, where requested**.*

*[**These guidelines shall** ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provide factual, verifiable, understandable and non-misleading information relevant to protect consumer's health and ensure fair practices in food trade.]*

International Council of Grocery Manufacturers Associations (ICGMA):

ICGMA supports providing "factual, verifiable, understandable and non-misleading information" relevant to the protection of consumers' health and to ensure fair practices in food trade

Spain

We propose the following changes to improve the Spanish version:

- Change the title "Proposito de las directrices" for "Objeto de las directices"

- In the first paragraph, third line where it says: "...comprensible y no enganosa relevante para...", it should say: "...comprensible y no enganosa que sera util para...".

- In the first paragraph, fifth line where it says:"...para facilitar la opcion de...", it should say:"...para facilitar la eleccion de...".

49th Parallel Biotechnology Consortium (49P):

Regarding Appendix V, 2, Purpose of the Guidelines, the wording "factual, verifiable, understandable and non-misleading" sounds more nonsensical than meaningful. We would strongly urge the replacement of those four terms with "accurate and understandable." These words would be clearer in intent and more suitable to Guidelines.

Further, regarding Appendix V, 2, we urge the replacement of “to ensure fair practices in food trade” with “choice” and the deletion of the final sentence. The full paragraph, then, including suggestion in 8. above, would read:

> To provide guidelines to ensure that the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering provides accurate and understandable information relevant to the protection of consumer health and choice.

(3) 1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients obtained though 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 [no longer equivalent to/differ significantly] from the corresponding conventional counterparts, as regards its: composition, nutritional value or intended use; and/or

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

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

Argentina:

These guidelines recommend procedures for the labelling of food and food ingredients obtained though 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 [no longer equivalent ~~to/differ significantly~~] from the corresponding conventional counterparts, as regards its: composition, nutritional value or intended use; and/or

1.1.2 ~~when they are composed of or contain a genetically modified/engineered organism or contain protein or DNA resulting from gene technology; and/or~~ ***when they contain or are composed of genetically modified organisms or contain protein or DNA resulting from genetically modified organisms and that , according to the characteristics indicated in 3.3, are no longer equivalent to their conventional counterpart..***

1.1.3 ~~when they are produced from, but do not contain, genetically modified/engineered organisms, protein or DNA resulting from gene technology~~
when they are produced from, but do not contain, genetically modified organisms, nor proteins or DNA derived from genetically modified organisms and that, according to the characteristics indicated in 3.3, are no longer equivalent to their conventional counterpart.

Brazil:

We suggest to maintain the text as drafted, including the brackets in the text on Item 1.1.1;

Canada:

Canada believes that the scope of this guideline includes labelling to indicate two distinct types of information about food and food ingredients obtained through certain techniques of genetic modification / genetic engineering: i) product-related characteristics of such foods resulting from the use of modern biotechnology in their production, and ii) the fact that modern biotechnology was used to produce these foods. Canada strongly believes that the scope of the guidelines should clearly distinguish between labelling for these two reasons.

In addition, given that the definition of "no longer equivalent"/"differs significantly" is no longer found in the Definitions section, Canada believes that there is a need to include elements of that definition in the text of Subsection 1.1.1. For consistency with the terminology used by the CTFBT, we also suggest that the term "corresponding conventional counterparts" replace the term "corresponding existing food and food ingredients" found in the former definition.

The following is proposed text:

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

1.1.1 To indicate product-related characteristics, 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; and/or

1.1.2 To indicate non-product related method of production:

a) when they are composed of or contain genetically modified / engineered organisms 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.

Columbia:

Subsection 1.1.1

Change "..... when they **are no longer equivalent** to the corresponding food and food ingredients already in existence as regards to its composition, nutritional value or intended use; and/or".

By : ".....when they **differ significantly** from the corresponding food and food ingredients already in existence....."

When a scientific evaluation can demonstrate, through an appropriate analysis of the data, that the evaluated characteristics are different in comparison to their counterparts in food and food ingredients already in existence, taking into account the accepted limits of natural variation for such food or food ingredient.

European Community:

The European Community supports the new layout of this section to separate former section 1.1 into three sub-sections (1.1.1, 1.1.2 and 1.1.3) in order to make it clear that a number of approaches could be used by CODEX member countries and that all the three options presented are open to further considerations.

1.1.1. The European Community favours the term "no longer equivalent", and proposes the term "or differ significantly " to be deleted. The term "differ significantly" would be defined by "different in comparison" which seems illogical. "Equivalence", however, is a term widely used in the safety evaluation of genetically modified foods. This also affects item (7) 3.1 *and item (15) 6.1(a) and (b).*

1.1.2. The European Community notes that the term "gene technology" is not defined in Section 2.0 (Definition of Terms). This could be solved by adding "gene technology" as synonym term to "modern biotechnology" which is defined in 2.0. This also affects item (10) 3.4 a) and b).

International Association of Plant Breeders (ASSINSEL):

ASSINSEL reiterates that it is not in favour of option 1.1.2, and that it is strongly opposed to option 1.1.3 whose implementation would have important cost implications without benefit to consumer's health, would particularly affect developing countries, and would probably lead to the development of fraudulent acts.

Malaysia:

Subsection 1.1

Malaysia is of the view that the term "no longer equivalent to / differs significantly" is acceptable and the paragraph should be retained by removing all the square brackets.

Subsections 1.1.2 and 1.1.3

To be consistent with the new amendment to the definition of terms in Section 2.0, we propose to replace the words *"gene technology"* with "*modern biotechnology*" in these paragraphs and also throughout the document, wherever the words "gene technology" appears as the term *"modern biotechnology"* is already defined.

Spain:

We propose to eliminate the square brackets as it is in agreement with subsection 1.1.1

Sweden:

Sweden supports the new layout of this section to separate former section 1.1 into three sub-sections (1.1.1, 1.1.2 and 1.1.3) in order to make it clear that all the three options presented are open to further considerations.

Replace "corresponding existing food and food ingredients" with the term" conventional counterpart". Then the terminology will be consistent with those used by the Task Force and with the Report of a Joint

FAO/WHO Expert Consultation on Safety Aspects of Genetically Modified Foods of Plant Origin, held in Geneva, Switzerland, 29 May- 2 June 2000.

A reference to the definition of “conventional counterpart” in the Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, Section 2, para 8, should be made. This also affects item (7) 3.1 and (9).

Subsection 1.1.1. - Sweden favours the term “no longer equivalent “, and proposes the term “or differ significantly “ to be deleted. The term “differ significantly “ would be defined by “different in comparison” which seems illogical. “Equivalence”, however, is a term widely used in the safety evaluation of genetically modified foods. This also affects item (7) 3.1.

49th Parallel Biotechnology Consortium (49P):

The decision of the committee to use the term “conventional counterpart” (para. 76) is sound.

It is imperative that the suggestion made by Norway (para. 78) be accepted as the basis for the guidelines and therefore that the wording in Appendix V, 3.1, Scope, be endorsed as is.

(4) 2.0 DEFINITION OF TERMS (At Step 8 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.

"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, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
b. Fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Argentina:

For the purpose of these guidelines:

"Food and food ingredients ~~obtained through certain technologies of genetic modification / genetic engineering~~ ***derived from modern biotechnology*"** 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.
[1]

"Modern biotechnology" means the application of:

a. *In vitro* nucleic acid techniques[1], including recombinant deoxyribonucleic acid

[1]

(DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells[1] beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

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

Brazil:

(a) Brazil supports the text as drafted.

(b) Brazil suggests to include the definitions **"Gene Technology"** and **"Threshold Levels".**

(c) **Justification:** the expressions **Gene Technology** and **Threshold Levels** are being used in the Guidelines, without being defined. The inclusion of these definitions would clarify the understanding of the text.

European Community:

The European Community appreciates the considerable efforts that have been undertaken so far towards reaching international agreement on this difficult and complex issue.

The European Community supports the use of the term "genetically modified" throughout the whole of the text. The European Community notes, however, that this terminology is not consistent with the terminology currently used in the work of the Codex Ad Hoc Task Force on Foods Derived from Biotechnology. At its Second Session, the Task Force maintained its preference for the use of the terms "foods derived from modern biotechnology" as it was of the opinion that consistency with other internationally agreed instruments (notably the Cartagena Biosafety Protocol) was critically important in this case. The Task Force recommended that the CCFL should give consideration to using the same definition in its work (ALINORM 01/34A, para 23).

Recalling the extended discussion at the last Codex Committee on Food Labelling (CCFL) in Ottawa, May 1 B 4, 2001, it is obvious that the CCFL will have certain difficulties to achieve consensus on this issue. In general, The European Community is of the opinion that the Codex Alimentarius Commission and its subsidiary bodies should avoid using different terminology as a matter of principle. The CCFL shall however have full discretion for specifying and defining the terms to be used in the actual labelling of foods and to recommend the terms and definitions most appropriate from a labelling perspective. For labelling purposes, it is pertinent to use terms and definitions that are easier for consumers to understand.

Canada:

Notwithstanding the decision at the 24th session of the Codex Alimentarius Commission to return the Definitions to Step 6 for further comments and consideration by the 30th Session of the Codex Committee on Food Labelling in May 2002, Canada supports the Definitions as currently written.

Canada notes that the definition of ***Modern Biotechnology,*** as submitted to the Codex Alimentarius Commission, is identical to that found in both the *Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* being developed by the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology (CTFBT), as well as the *Cartagena Protocol on Biosafety* under the Convention on Biodiversity. With its adoption of this definition, the CTFBT recognized that while consistency between Codex texts is highly desirable, in this case, consistency with other internationally agreed instruments was critically important. It further recommended that the Codex Committee on Food Labelling give consideration to using the same definition in its work.

International Association of Plant Breeders (ASSINSEL):

"No Longer Equivalent" vs "Differs Significantly"

ASSINSEL considers the term "differs significantly" more appropriate since it refers to a scientific and statistical approach. On the contrary, the term "no longer equivalent" is quite vague, and its use could easily lead to the development of trade barriers.

International Council of Grocery Manufacturers Associations (ICGMA):

ICGMA opposes the proposed definition of biotechnology, which is inconsistent and at odds with the definition adopted by the Codex Ad Hoc Intergovernmental Task Force on Biotechnology (at Step 5 in the Codex process). Adopting a different term for labeling would set back the current effort within Codex to create a scientifically supportable and appropriate definition.

The Codex Commission established the Ad Hoc Task Force on Biotechnology to specially address issues for Codex on matters pertaining to biotechnology – including how it is to be defined. The Task Force provides a very precise definition of modern biotechnology that is consistent with the definition used in the Caratagena Biosafety Protocol.

The term "genetically modified/engineered organism," as used in the labeling document, is scientifically inaccurate for the following reasons: The term "genetic modification" is inaccurate because it technically applies to all forms of genetic manipulation that humans have been practicing on plants, animals, and microorganisms for centuries – including modern day traditional plant breeding.

The use of the terms "organism", "genetically modified organism", and "genetically engineered organism" suggest that living organisms of some unusual nature are present in food or food ingredients, and therefore, are confusing and likely to mislead consumers. With very few exceptions, (i.e. yogurt) food does not contain organisms.

Malaysia:

Malaysia is of the view that the definition for *"certain techniques"* should be included in the definition of terms so as to provide consistent understanding of the terms, since at the moment it is subject to interpretation. Although it is clear and understood by the scientific community, for clarity and understanding of the public, Malaysia proposes that the definition of *"certain techniques"* be included in the definition.

In this regard, Malaysia proposes that the definition which was proposed during the early discussions of this agenda item (ALINORM 01/22, Appendix V), be considered. The definition should read as follows:

"Certain techniques" 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[2]
- 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

<u>Spain</u>:

We have the following comment:

We propose to include the following definition regarding "no longer equivalent to/differ significantly", as in the context of the Proposed Draft Recommendations for the Labelling of Foods obtained Through Certain Techniques of Genetic Modification/Genetic Engineering, this concept is used and should therefore be defined.

We propose therefore the following definition:

"No longer equivalent to / differ significantly": Means a food or food ingredient obtained through modern biotechnology for which a scientific evaluation demonstrates, through an appropriate analysis of the data, that the evaluated characteristics regarding its composition, nutritive value, metabolism, intended usage and content of undesirable substances are different in comparison to their counterparts in foods ir food ingredients already in existence, taking into consideration accepted limits of natural variation for such foods or food ingredients.

<u>Uruguay</u>:

"Organism:" We fully agree with the proposed definition except for the word "reproduction" that is unnecessary. It is similar, in general terms, to the one givien under the Biosafety Protocol of the United Nations Environment Program (UNEP).

Genetically modified organism:

We propose using the following definition,

"Is an organism that has a new combination of genetic material obtained through the use of "modern biotechnology"

The proposal in the text is redundant with the definition of modern biotechnoloy regarding the overcoming of conventional reproductive barriers.

We do not agree with the expression "genetically engineered" as there is no definition of those terms and also because we do not understand how many techniques are covered under such expression.

Modern biotechnology:

The footnotes are considered unnecessary. Furthermore, footnote number 2 introduces two important modifications:

- Because protoplasts are not cells,
- Introducing the concept of hybridization which is not clearly explained (traditional hybridization between plants? of cells?)
- Footnote 2 look more like an option to sentence (b) than a footnote.

We recommend using the exact definition of the Biosafety Protocol:

"Modern Biotechnology" means the application of:

i. In vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acids into cells or organelles, or

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

"Foods or food ingredients obtained through certain techniques of genetic modification"

We do not understand why the word "certain" is used.

It means foods or food ingredients that contain or are made of genetically modified organisms, or foods or food ingredients that are produced from genetically modified organisms but that do not contain them.

We also suggest coordinating the definitions with the Chiba group and other pertinent Codex groups.

(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:

International Association of Plant Breeders (ASSINSEL):

In order to reflect the spirit of the draft recommendations, the chapeau should start with "Where…". We suggest the following wording:

***Where** a specific approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering **is adopted**, 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.I on label declarations.

Argentina:

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.I on label declarations

Canada:

- Consistent with our suggestion under Subsection 1.1.1, Canada believes that there is a need to include elements of the previous definition of "no longer equivalent"/"differs significantly" in the text of 3.1. The following is proposed text:

3.1 *When it is demonstrated, through an appropriate analysis of data, that composition, and/or nutritional value, and/or intended use of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering, differ in comparison to those of the corresponding conventional counterparts, having regard to accepted limits of natural variation, such changes should be clearly identified on the label as described in Subsection 6.I on label declarations.*

Malaysia:

To be consistent with comments in para 2.0 above, we propose to retain the term *"no longer equivalent / differs significantly "* by removing the square brackets.

Spain:

- We propose to add, on subsection 3.1, a new dash in the following text: *"-metabolismo".*

- In the last paragraph of subsection 3.1 and on subsections 3.3, 3.4 and 3.5, we propose to change the term *“should”* by the term *“must”* due to the importance that declaring foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering has for consumer information.

- Once the above mentioned correction takes place, we propose eliminating the square brackets on subsections 3.3, 3.4 and 3.5.

(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.

Argentina:

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

Columbia:

(Include the following article in the document):

The presence, in any food or food ingredient 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 STANDARD 1-1985 (Rev.1-1991, Amended 1999)~~ shall be declared"

International Association of Plant Breeders (ASSINSEL):

Paragraph 3.2 is not specific to food obtained through genetic engineering. ASSINSEL recommends that it be transferred to an appropriate place in the general principles section of the Codex standards for food labelling.

Malaysia:

Malaysia proposes that as Appendix III, Alinorm 01/22, had been adopted by the last 24th Session of the Commission, the adopted version be included for paragraph 3.2, which should include the sentence **"When it is not possible to provide adequate information on the presence of an allergen through labeling, the food containing the allergen should not be marketed"** as a second sentence in the paragraph which has been left out in the current draft. Malaysia also proposes that the Codex reference number be included in the Proposed Draft Recommendation for this paragraph

(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].

Argentina:

[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].

Brazil:

We suggest to maintain the text as drafted, including the brackets in the text, but using **"Shall"** instead of **"Should";**

Canada:

- Canada supports the intent of this subsection but believes it can be re-worded slightly to clarify its meaning, both in terms of the nature of the "substances" concerned and the suggested health implications.

- Canada also supports the use of the term "should" and therefore suggests the removal of the square brackets around "should".

- Canada therefore proposes that 3.3 be reworded as follows:

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 be labelled.*

Columbia:

We do not agree because wording is not clear. We request to improve the wording

Change: "The presence of substances that are absent in corresponding existing foods that may have implications for the health of certain sections of the population **should** be labelled."

By : "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 **shall** be labelled."

Triggers for Labelling

We propose to prepare a "negative list" identifying products which do not require labelling or a "positive list ", for products which will always require labelling

The requirement to label any food and food ingredient produced by the use of gene technology to indicate such a fact, with the objective of satisfying the information demands of the consumers. This

would include highly processed foods such as oils and sugars which would not contain detectable amounts of DNA or of protein resulting from the modification.
This labelling could be triggered by the presence of new DNA sequences or proteins.

Equally, an opinion is required about applying or not applying process labelling to ingredients such as flavouring agents, additives or processing aids, which may be present in very small amounts.

If any specific factor is used to trigger labelling of foods and food ingredients produced through the use of gene technology, consideration should be given to the development of a ***"negative"*** *list identifying products that would not require labelling, or of a* ***"positive"*** *list of products that will always require labelling.*

These lists could be of assistance to industry for the purpose of complying with the labelling regulations as it would not be necessary to find the specific content of each food product, i.e. If the presence of DNA is used as a trigger for labelling, highly refined products such as oils and sugars could be included in the ***"negative"*** *list, as the DNA and the proteins would be lost or destroyed during the process.*

As an alternative, a ***"positive"*** *list could be developed for products that contain specific foods or food ingredients produced through the use of gene technology and which would always require labelling.*

The lists will be brought up to date regularly as new products enter the market or new food processing methods are developed or new detection methods are introduced for foods produced through gene technology.

European Community:

The brackets as well as the internal brackets should be deleted. For reasons of consistency with 3.2 (Labelling of Allergens) the European Community favours "shall" and not "should".

Malaysia:

Malaysia is of the view that the whole paragraph should be retained by removing all the square brackets. This is due to the fact that other allergens might be transferred from other products not 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). We also propose to delete the word *"should"* and retain the word "shall" to ensure consumers are informed of the presence of such substances, which could have implications for the health of certain sections of the population.

Sweden:

Health implications: The brackets as well as the internal brackets should be deleted. For reasons of consistency with 3.2 (Labelling of Allergens) Sweden favours "shall" and not "should".

(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): (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].

Argentina:

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):~~

~~(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]~~.

Note: this paragraph is eliminated in line with the statements made under "General Comments" at the end of this document

Brazil:

We suggest to replace the expression **method of production** by "**method of production of the ingredient(s)". Justification:** this replacement is necessary considering that the expression, as drafted in the text can not allow the distinction between the method for the production of the raw material and the methods of production which define the presentation of the food to the consumer;

Subsection 3.4 (a) and (b)

We suggest to introduce the definition of **"gene technology";**

Subsection 3.4 (b)

We suggest to specify the parameters mentioned in the expression in brackets "**and/or other parameters";**

Canada:

- Canada does not support the specific language proposed in this subsection on method of production labelling.

- Canada strongly believes that this section should expressly indicate that labelling which is not based on product characteristics, but rather on method of production, should be implemented by the marketplace on a voluntary basis. As such, we suggest the following rewording:

3.4 *Except where the provisions of Subsections 3.1 through 3.3 apply, 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, it should be done voluntarily by the marketplace, and labelling declarations, taking into consideration Subsection 6.2, should apply:*

- Canada also suggests that further clarification be provided with regard to "other parameters" in 3.4(b).

International Association of Plant Breeders (ASSINSEL):

ASSINSEL is opposed to paragraph 3.4 that is a process-based labelling (see comments above).

International Council of Grocery Manufacturers Associations (ICGMA):

Paragraph 3.4 should delete the phrase "are labeled to indicate the method of production." In addition, paragraph 3.4(b) should be deleted as it endorses labeling of foods produced from, but not containing products of, modern technology. Paragraph 3.4(a) should be amended to include the phrase "that meet the criteria in 3.1" immediately after "from gene technology" to clarify that labeling should apply to a biotech food that substantially differ from its conventional counterpart.

Malaysia:

Malaysia is of the view that the whole paragraph should be retained by removing the square bracket in paragraph 3.4(b), which allows for other parameters to be included

(11)	3.5	[Notwithstanding Section 4.2.2.2 of the General Standard[3]], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of ethical objections[4] [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.]

Argentina:

3.5 [~~Notwithstanding Section 4.2.2.2 of the General Standard[5]], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of ethical objections[6] [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.~~]

The presence of substances absent from equivalent foods and food ingredients, and that are objectionable for dietetic reasons, should be indicated in the label.

Note:
We do not believe it is appropriate to consider ethical objections in this document. In the context it is presented, it would appear that the objections arise more from a dietary restriction (such as vegetarian diets) than from other issues, particularly given the reference made to section 4.2.2.2 of the General Standard and taking always into account it should not become a trade impediment.

Brazil:

We suggest to maintain the text as drafted without the brackets and to use **"Should"** instead of **"May",** in the text of the 1st sentence. **Justification:** this suggestion has the objective of giving consistency with the scope of the text of the item 3.5;

Canada:

- Canada strongly believes that the term "ethical objections" is too open-ended and could lead to an endless list of possible objections. Canada believes that the term "ethical objections" should be replaced with the term "dietary restrictions." Since the draft guideline deals with labelling of food/food ingredients it would seem reasonable to limit the focus of this section to objections related to the consumption of food based on religious considerations.

- We would also support the use of the term “may” and of the term “conventional counterparts” in this context, and we would therefore propose the following rewording:

3.5 Notwithstanding Section 4.2.2.2 of the General Standard[6], the presence of substances that are absent in corresponding conventional counterparts that could be subject to dietary restrictions may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on these considerations, will be decided and implemented in a manner that is fair, transparent and consistent.

Columbia:

We do not agree. We consider that labelling is a must.

Notwithstanding Section 4.2.2.2 of the General Standard , (which indicates: that pork fat, lard and beef fat should always be declared under their specific denomination), the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of ethical objections **must** be labelled.

Change by: "the presence . . . . of ethical objections (**should**) (**may**) be labelled."

The term "**ethical objections**" may have a wide variety of meanings, and, therefore, other terms are suggested, such as: **"ethical, cultural and religious considerations"** and "**dietetic restrictions "**

European Community:

The European Community believes that ethical objections that may go beyond the labelling of pork fat, lard and beef should be taken into account for labelling and therefore proposes the deletion of the first brackets and the deletion of [may]. The European Community also favours the deletion of the bracketed sentence [Where such labelling is used….] as this reflects practical considerations and goes beyond rules when and how to label.

International Association of Plant Breeders (ASSINSEL):

ASSINSEL recommends that paragraph 3.5 be either deleted or remain between brackets until: there is a clear definition of “ethical objections” and “may” is retained instead of “should”, since these kind of considerations should be subject to voluntary labelling only.

International Council of Grocery Manufacturers Associations (ICGMA):

Paragraph 3.5 should be deleted. Issues such as ethical and religious concerns are best addressed through voluntary labeling standards and have no scientific basis for mandatory labeling.

Malaysia:

As a multi-cultural and multi-religious country, Malaysia strongly feels that ethical, cultural and religious considerations should be taken into account when issues on the labelling of food and food ingredients obtained through certain techniques of genetic modification / genetic engineering are being discussed. Consumers should be given the right of choice.

However, Malaysia feels that the labelling requirements should be left to member countries to decide. In this regard, Malaysia proposes to amend paragraph 3.5 to read as follows :

3.5 Not withstanding Section 4.2.2.2 of the General Standard, the presence of substances that are absent in corresponding existing food and food ingredients may be labelled subject to national legislation.

Sweden:

Ethical objections: Sweden believes that ethical objections that may go beyond the labelling of pork fat, lard and beef should be taken into account for labelling and therefore proposes the deletion of the first brackets and the deletion of [may]. Sweden also favours the deletion of the bracketed sentence [Where such labelling is used....] as this reflects practical considerations and goes beyond rules when and how to label.

(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 [7]] 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]**]**

Argentina:

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 [8]] 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~~]**]**

Note:
We do not consider genetic engineering to be a method of food production but rather of genetic modification of the plant from which the food is derived; production methods are standard technologies accepted by use and have not been conceptually modified to adapt them to GMO's in the cases in which equivalence is not maintained. Establishing threshold levels would only make sense when the GMO origin determines that the food is no longer equivalent to its conventional counterpart. In those cases, the threshold shall be established as the value of the quantity of food or food ingredient derived from GMO's, below which it is not possible to verify differences with its conventional counterpart, regarding the characteristics indicated in 3.1, using analytic methods validated through the standards that have been established for that purpose.

Brazil:

We suggest to introduce a definition for the expression **"Threshold Level";**

We suggest to introduce the sub-item remarks **(a)** and **(b)** in the beginning of the paragraphs in brackets;

We suggest to maintain in brackets the two paragraphs as drafted;

Canada:

- Where method of production labelling is used, Canada strongly believes that there is a clear need to establish specific threshold level(s) in a food or food ingredient for the presence of food or food ingredients obtained through biotechnology, below which labelling would not apply.

Rationale for Threshold(s):

- Despite best efforts to maintain product identity and to apply rigorous segregation practices throughout the marketing chain, modern crop production methods and the necessity for multilevel handling, distribution and food processing practices as well as natural events, present a significant potential for some product mixing to occur. This mixing could be in excess of a possible *de minimus* level for adventitious or accidental inclusion. Not recognizing this reality could result in misleading and/or erroneous product label information being presented to consumers.

- In considering the application of thresholds to food and food ingredients from biotechnology, we suggest that existing Codex declaration thresholds, such as that for the identification of compound ingredients, found in section 4.2.1.3 of the *Codex General Standard for the Labelling of Prepackaged Foods* be considered.

Columbia:

- 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] 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

Comment:

We agree with the establishment of a threshold level. The difficulty lies in the verification, as validated analytical methods are required. However, it was argued that it would be possible to learn a value through the evaluation of suppliers, who should provide this information due to a solidarity principle.

Explanation:

Due to the nature of crop harvesting, production, marketing and food handling, ,a material obtained through the use of gene technology may be present accidentally in conventional products. i.e.: cereals

are handled in bulk, which means that different varieties of the product are commingled during harvest. The same trucks or containers used to transport crops derived from gene technology are used for conventional crops, and vice versa, potentially resulting in the presence in the conventional crop of small amounts of material derived from gene technology. Threshold levels should therefore be taken into account.

In practice, threshold levels could only be established for products if reliable quantitative detection methods are available. The scientific methods developed in several countries could be used to establish an internationally recognized threshold level which would facilitate trade.

European Community:

The European Community supports the establishing of a threshold value of adventitious or technically unavoidable presence of material of GMO origin in conventional foods and food ingredients. The European Community is not in favour of establishing a general threshold. Therefore delete bracketed second sentence and the brackets around third sentence of point 4.1.

International Association of Plant Breeders (ASSINSEL):

ASSINSEL considers that a threshold for adventitious presence of food ingredients obtained through genetic engineering is definitively necessary. In absence of such a threshold, the system would be unmanageable, since non-voluntary admixing in the food chain, at low level, is practically unavoidable.

The second proposed threshold (de minimis threshold), below which labelling would not be required, is welcomed. ASSINSEL recommends that it be kept.

Malaysia:

We are of the view that the whole paragraph is acceptable and the paragraph should be retained by removing all the square brackets.

Poland:

We suggest to establish a threshold level 1% below which labelling would not apply – like in Polish law.

Spain:

The Kingdom of Spain prefers the second of the 2 options presented, as it considers that a minimum threshold should be established for the inclusion in the labelling of the corresponding indicators.

Sweden:

Sweden supports the establishing of a threshold value of adventitious presence of material of GMO origin in conventional foods and food ingredients. Sweden is not in favour of establishing a general threshold. Therefore delete bracketed second sentence and the brackets around third sentence of point 4.1.

(13)	**[5.0**	**EXEMPTIONS**
	5.1	Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.**]**

Argentina:

~~**[5.0 EXEMPTIONS**~~

~~5.1 Notwithstanding the provisions of Subsection 3.1 to 3.3, consideration may be given to the exemption from labelling of specific categories (for example highly processed food ingredients, processing aids, food additives, flavours) of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering.**]**~~

Note:
There should be no exemptions as there are no reasons to exempt foods or food ingredients based on a quantitative criteria, particularly when it could be demonstrated that there is an equivalence to the conventional food or food ingredient counterpart.

Brazil:

To maintain the text in brackets as drafted, to allow better evaluation by the countries;

Canada:

- Canada believes that the draft Codex labelling *Guidelines* should provide for the possibility of limited exemptions from labelling and therefore supports the removal of the square brackets enclosing section 5.0.

Columbia:

We agree. This is a new article being proposed:

5.1 "Exemption from labelling of specific categories may be considered (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".

European Community:

The European Community is generally not in favour of exemptions of labelling and is of the opinion that the consumer should be informed when foods and food ingredients, including additives, *enzymes* and flavourings have been produced from GMO.

International Association of Plant Breeders (ASSINSEL):

ASSINSEL supports this section

Malaysia:

We are of the view that the whole paragraph is acceptable and the paragraph should be retained by removing all the square brackets.

Spain:

We propose this section be eliminated as we consider there should be no exemptions.

Sweden:

Sweden is generally not in favour of exemptions of labelling and is of the opinion that the consumer should be informed when foods and food ingredients, including additives and flavourings have been produced from GMO.

(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.

Argentina:

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~~ ***nature***.

The term "nature" is better in this paragraph to be in agreement with the statements of the General Principles section of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX 1-1985 (Rev. 1-1991).

Brazil:

To maintain the text as drafted. It was pointed out that if the word **"Modern**" is not adopted, it is necessary to redraft some examples;

Columbia:

6.0 We agree with this section (as drafted)

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.

<u>Argentina</u>:

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, a 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.

<u>Canada</u>:

- Consistent with our suggestions for sections 1.1.1 and 3.1, we would propose the following text:

(a) *if the composition or nutritional value of food and food ingredients is demonstrated through an appropriate analysis of data to be different in comparison to the corresponding existing food and food ingredients, having regards to accepted limits of natural variation, 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.*

Columbia:

We agree. New wording for *subsection 6.1* (a) is proposed:

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.

Malaysia:

6.1 (a) and (b)

> To be consistent with comments in paragraph 2.0 above, we propose to retain the term *"no longer equivalent / differs significantly"* by removing the square brackets.

Spain:

We propose eliminating subsection 6.1(b), as the indication regarding the mode of use is a generic indication that is included in the General Standard for the Labelling of Prepackaged Foods.

(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"]

Argentina:

~~(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"]~~

Note:
This paragraph is eliminated due to the reasons indicated in the "General Comments" section. The examples given have technical errors (ÿgenetically modified maize flour" should in any case be referred as "flour obtained from maize genetically modified through genetic engineering ÿ, which, aside from cumbersome for labelling purposes, could originate rejection by the consumers as it indirectly implies negative differential characteristics regarding the conventional counterpart food).

Canada:

- Canada supports the intent of this Subsection which is to set out acceptable examples of food label declarations to identify the presence of foods from biotechnology and thereby encourage consistency in the messages being conveyed to consumers. These declarations should be understandable, informative and not misleading.

Negative Labelling

- In addition, Canada strongly recommends that the draft guideline provide a framework for the use of negative labelling, and would support the inclusion of negative labelling statements in Section 6.0, given:

(i) the possible frequent use of negative labelling in Codex countries,

(ii) the recognition of negative labelling under the *Codex General Guidelines on Claims*, which is referenced in the chapeau to Section 6.0, and

(iii) the linkage of the concepts of thresholds and tolerances to negative labelling.

Columbia:

We agree. New wording for subsection 6.2 is proposed:

~~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~~ *the claim declarations will include:*

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. "contains starch produced from genetically modified maize"

(e) ~~["Genetically engineered (naming the characteristic) (naming the food)"]~~ *Name the genetically modified 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 *genetically modified* food/food ingredient ~~(genetically modified food/food ingredient)~~ (not segregated)"] e.g. "soybean (genetically modified soybean not segregated)"

~~(I) [Product of gene technology"]~~

European Community:

The European Community favours a greater harmonisation of label declarations and favours declarations mentioned in (a), (b), (d), (e), and (g) using the wording "genetically modified".

Consequently, the European Community proposes the deletion of the following labelling declarations:
(c) ["Grown from seeds obtained through [modern] plant biotechnology"] and
(f) ["Product of plant / animal biotechnology"]: "Biotechnology" is covering a broad range of techniques and is not restricted to gene technology; "modern biotechnology" is discriminating against traditional forms of biotechnology.
(h) ["Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)"] e.g. "soybean (genetically modified soybean not segregated)": Segregation is currently a term referring to foods from non-GMO origin and it is doubtful that consumers are familiar with the concept.
(i) ["Product of gene technology"]: This term is not specific enough as this could also encompass foods produced with the help of gene technology, including ~~processing aids derived from GMO~~ *food obtained from animals fed on GM feed.*

Poland:

We consider that in case of food containing genetically modified organisms or food ingredients produced from, the label should include statement that the product or the ingredient is genetically modified – in accordance with point 6.2.

Spain:

On subsection 6.2, we propose eliminating the expression "but are not limited" with the purpose of limiting the number of statements that can be used to declare the presence of a food obtained through genetic modification / genetic engineering.

We propose the elimination of indented points (c), (f) and (i) on subsection 6.2 as we consider they mislead consumers.

Sweden:

Sweden favours a greater harmonisation of label declarations and favours declarations mentioned in (a), (b), (d), (e), and (g) using the wording "genetically modified".

Consequently, Sweden proposes the deletion of the following labelling declarations:

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

(f) [”Product of plant / animal biotechnology”]: ”Biotechnology” is covering a broad range of techniques and is not specific for foods obtained through genetic modification; “modern biotechnology” is discriminating against traditional forms of biotechnology.

(h) [”Naming the food/food ingredient (genetically modified food/food ingredient (not segregated)”] e.g. “soybean (genetically modified soybean not segregated)”: Segregation is currently a term referring to foods from non-GMO origin and it is doubtful that consumers are familiar with the concept.

(i) [”Product of gene technology”]: This term is not specific enough as this could also encompass foods produced with the help of gene technology, including processing aids derived from GMO.

(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.

Argentina:

~~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.~~

Note: This paragraph is eliminated due to the reasons indicated in the "General Comments" section.

Columbia:

We agree

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

(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[9]; establishment of verification (for example, documentation) systems; and efforts for the development of supporting capacity and infrastructure. **]**

Argentina:

Consistent with the approach(s) 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.]

Note:

We believe that "additional consideration" of procedures and methods to identify foods and food ingredients derived from GMOs is not enough. The implementation of a labelling system will require the development and validation of identification and quantification methods for the presence of GMOs or of the proteins and/or nucleic acids that would allow to verify its origin, as they should provide the minimal conditions to ensure the labelling is verifiable.

Brazil:

To maintain the text as drafted

Canada:

- Canada strongly supports the intent of this section and supports its retention in the draft guideline.

- Canada strongly believes that the implementation of the draft guideline requires the identification of foods from biotechnology and the verification of label declarations. As a result the development of internationally validated detection methods, preferably through the Codex Committee on Methods of Analysis and Sampling, is critical.

Columbia:

We agree

(new section).

~~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.

It has been agreed to establish an Ad Hoc Support Working Group for analytical methods, to be chaired by Germany. Initially they will compile a list of appropriate and available analytical methods and their validation.

If labelling of the method of production is triggered by the presence of DNA or protein derived from the genetic modification, accurate, reliable and reproducible analytical methods to determine the presence of such components should be available

This includes sampling procedures as well as lab methods to process and analyse the individual samples. It will be important to demonstrate the consistency and capacity of reproducing the results of the analysis made in different labs within each country and between labs internationally.

Presently, the DNA analysis in foods or food ingredients is made through the polymerase chain reaction (PCR).

Several factors should be taken into account for its use as they affect the accuracy and reliability of the analysis:

- *Specialized training of the staff*
- *Prevent cross contamination*
- *Specialized equipment for quantification*
- *Selection of primer and probing DNA sequences*
- *Availability of reference material for the adequate interpretation of the results.*

For the protein analysis:

The ELISA (enzyme-linked immunosorbant assay) test is employed, which uses antibodies that bind to the specific protein and generally produce a color reaction that can indicate the presence and/or the amount of the specific protein in the food.

Commercially there are to types of ELISA tests: a fast dipstick test to demonstrate the presence of material derived from gene technology, and a microwell assay to identify the specific protein of a product.

Negative claims -

Negative claims made in the label indicating the absence of foods or food ingredients produced through gene technology are becoming common in several countries. It would be useful to promote further discussions on this subject to provide clear and consistent orientation regarding the scope and limits of application.

We agree, but we suggest to establish application limits in order to make such a declaration.

European Community:

The European Community welcomes the rewording of this paragraph. It reflects the efforts in the European Community on the development of validated detection methods and a harmonious approach across the Member States and the commitment of the European Community to introduce a legal system for traceability of foods containing, consisting or produced from GMO.

Malaysia:

Malaysia proposes to delete the whole paragraph in view that the implementation of guidelines is within the purview of member countries. Besides, additional consideration of the procedures and methodologies is being addressed by other Codex committee for member countries to follow.

GENERAL COMMENTS SECTION

This Section Contains the General Comments and Views Received from Respondents Which Do Not Directly Suggest or Propose Specific Changes to the Content or Wording of the Draft Texts under Review

ARGENTINA

We consider that the scope is too wide, and that within such a wide scope two labelling approaches are mixed (safety reasons labelling and production method labelling), which is not totally satisfactory to generate a fully coherent document.

In particular, due to several reasons, we do not believe that the differentiation by production methods is appropriate for labelling purposes. Essentially, this is due to the rights and obligations contracted under the World Trade Organization, where the agreements regarding the Application of Sanitary and Phytosanitary Measures (SPS), and about Technical Barriers to Trade (TBT) only justify the labelling of foods when the available scientific information demonstrates the noxious nature of the product for human health. We also think that such a differentiation by production methods, which is not applied to other production methods, could generate doubts about the safety of similar foods or could create fear in the consumers. Regarding this point, we also think that we would be making a claim that is explicitly in contravention of the prohibition indicated in point 3.5 of the "General Codex Guidelines for Claims" (CAC/GL 1- 1979, rev. 1-1991).

Nevertheless, having in mind that the market may request the labelling of production methods, Codex could provide general guidelines allowing labelling according to this criteria on a voluntary basis, as it is not a food safety problem, and taking into account that it would probably complicate fair trading practices if it is applied on compulsory basis. Regarding this point it is proper to indicate as well the important restrictions that developing countries could face, given their lack of resources, when having to implement a compulsory labelling system.

Based on this argument, we propose that the criteria to establish a labelling system for foods derived from GMOs should not be different from the labelling of any other food, keeping in mind its purpose is to inform consumers and not to substitute a solid regulatory framework to ensure the safety of foods that are allowed to be commercialised in the market place. Regarding this issue, compulsory labelling of foods which are no longer equivalent to their conventional counterparts could be developed, based on scientific evaluation factors and in the product characteristics, but not on its production method.

CANADA

General Background Comments:

- The labelling of foods obtained through biotechnology remains under discussion in Canada through a continuing public dialogue on the issue.

- Canada supports labelling that provides consumers with clear, meaningful, and credible information.

- Canada supports the advancement of the current health and safety-related labelling provisions of the draft guideline. Canada supports and has in place, mandatory requirements applicable to both conventionally produced foods and biotechnology-derived foods, that require, where there is

a significant change to nutritional content, composition, end use, or to indicate a concern such as the presence of an allergen, that the specific nature or character of the change must be indicated on the food label.

- Canada also believes that the decision to identify method of production on a label should be a voluntary decision by the private sector that is based on consumer demand.

- In Canada, where the food industry chooses to voluntarily label foods in response to consumer demand, there is guidance under the *Food and Drugs Act* that would apply. Where labelling is not false or misleading, and meets all other regulatory requirements, voluntary labelling provides a useful and consistent framework for manufacturers to identify foods and to effectively inform consumers.

- To facilitate the use of such labelling, the federal government is supporting the development of a national standard for the voluntary labelling of biotechnology-derived foods. A national committee, working under the guidance of the Canadian General Standards Board (CGSB), and representing over 100 major interest groups, is progressing toward the completion of a *National Standard for Voluntary Labelling and Advertising of Foods that are or are not Products of Gene Technology*. The proposed standard will set out principles for voluntary labelling as well as suggest acceptable declarations for labelling and advertising that are verifiable, understandable, informative and not false or misleading to consumers. As part of this standards development process, the CGSB released the Draft Standard for 60 days of public and World Trade Organization review which ended on October 17, 2001. It is expected that the Standard will be published in the Spring of 2002.

- A report recently released by the Royal Society of Canada Expert Panel on the Future of Food Biotechnology supported the current Canadian policy on the labelling of biotechnology-derived foods. The following are a few quotes from the report:

  > *"... there are not currently sufficient reasons to adopt a system of general mandatory labelling of GM foods."*
  >
  > *"Many of the concerns voiced in favour of mandatory labelling can be addressed, at least in part, by voluntary labels. This is true, not only of the social, ethical and political concerns, but also of some of the risk-related concerns, especially those related to uncertainties and even fears about unsubstantiated risks associated with GM foods."*
  >
  > *"The Panel believes that strong government support for voluntary labels is an effective way of providing consumer input into these issues, and encourages the Canadian regulatory agencies responsible to establish guidelines for the regulation of reliable, informative voluntary labels.*"

- The Canadian Biotechnology Advisory Committee, in its interim report released in August 2001, also supported the development of a voluntary standard for labelling of biotechnology-derived foods under the CGSB.
- More recently, the Ministers of Health, Agriculture and Agri-Food, Industry, and International Trade requested that the House of Commons Standing Committee on Health investigate the issue of labelling of genetically modified foods. The Standing Committee on Health will begin its study in February 2002. The Committee will be examining a range of issues related to labelling of genetically modified foods and will submit a report and recommendations on options for best meeting consumers' information needs.

EUROPEAN COMMUNITY

The European Community appreciates the considerable efforts that have been undertaken so far towards reaching international agreement on this difficult and complex issue.

The European Community welcomes that the guideline recognises labelling as a tool of consumer information. Labelling has to provide a sound basis for consumers to make informed choices in relation to the foods they consume.

The European Community is of the opinion that factual, understandable and non-misleading information on the fact that foods are containing, consisting or have been produced from genetically modified organisms will help resolving the current controversy concerning the application of gene technology in the food sector.

INTERNATIONAL ASSOCIATION OF PLANT BREEDERS (ASSINSEL)

ASSINSEL reiterates its position that there is no scientific ground for labeling a product according to the process it has been obtained. Labelling should be restricted to the characteristics or properties of the food product. This would include information on the composition, nutritional value or intended use.

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

ICGMA, a recognized NGO before the Codex Alimentarius Commission, represents the interests of national and regional associations who collaborate with all sectors of the consumer packaged goods industry. ICGMA promotes the harmonization of scientific standards and policies concerned with health, safety, packaging, and labeling, of foods, beverages and other consumer packaged goods. ICGMA also works to facilitate international trade in the sector by eliminating or preventing artificial barriers to trade.

General:

ICGMA recognizes the efforts and difficulty in working through this draft document. We believe the difficulty could be remedied if the focus were on elements supported by sound scientific principles and not the method of production. We are in agreement that Codex should endorse labeling standards for such foods that may contain potential allergen and/or materially differ from conventional crops with respect to composition and nutritional profiles.

ICGMA continues to oppose those components of labeling of foods obtained through techniques of modern biotechnology that are not based on sound science. Without the foundation of sound science, Codex will jeopardize its reason for being. Science, not politics, forms the basis for advancing standards that contribute to the protection of public health. Facilitating safe global food trade, not creating global trade barriers, should be the desired outcome in this debate.

Any erosion of sound science will undermine the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and our global food safety system. ICGMA is concerned that setting Codex standards based on political pressures will promote those same illegitimate barriers to agricultural trade that the SPS Agreement strives to proscribe.

ICGMA is supportive of advancing labeling standards for foods, whether developed through modern biotechnology or another method, if there is a change in nutritional composition or if an added component is toxic or allergenic. These regulations are based on the quantifiable chemical characteristics of the

food product and not the method of production. This type of standard is objective, science based, verifiable, and enforceable because the chemical properties of the food can be measured, confirmed and defended.

ICGMA continues to strongly oppose extending mandatory labeling to all products derived through the use of modern biotechnology. Such labeling violates the standard of being objective, verifiable or enforceable. Real hazards are found in the product and not in the process by which the product was made. Advancing Codex standards outside these sound scientific principles distracts attention from the legitimate health, safety and nutritional issues, particularly for developing countries, key areas in which Codex strives to emphasize and support.

ICGMA recalls that at the 28th Session of the CCFL, a Conference Room Document was submitted by the delegation of the United States that outlined a number of practical implementation issues associated with mandatory process based labelling. A Working Group was to convene to discuss and address these implementation issues. ICGMA requests the results of the Working Group findings and a full consultation of those results be discussed in full Committee. (**Attachment 1**).

Conclusion:

ICGMA Members Recognize that Labeling Serves Important Purposes

For consumers buying packaged foods, the label is their single most important information resource. Most importantly, it provides consumers with easy to find vital safety, health, and content volume information. For food manufacturers it contributes to consumers first impression about the product and it communicates information that helps them make their purchase decisions. It should be noted that today not all information is conveyed to consumers through a label as different consumers care about different things and label space is limited. Food manufacturers use 1-800 phone numbers, web based information, brochures and other forms of communication to address consumer specific needs.

In grocery stores, where hundreds and thousands of products compete for consumers' attention, labels must continue to provide those consumers with real health and safety information. They must be effective signals which can be easily read and understood. Unnecessary information on a label can drown out critical messages, or worse, confuse consumers.

Labeling Regulations Should Protect Consumers

Nearly a century of experience at regulatory agencies around the world has yielded the basic elements of successful consumer protection regulation. The legal system should prohibit product claims that deceive consumers and require that manufacturers have the evidence appropriate to support any claims they make. Regulatory standards should require disclosure of information that is necessary to inform consumers about such basics as the quantity, ingredients and safety of the contents of a package.

While the protection of the consumer requires essential information to be displayed on food labels, the effectiveness of the label requires that other claims remain voluntary, subject only to the requirement that they be accurate and substantiated. A food labeling standard that strikes this balance not only protects consumers but also preserves their ability to choose, because it permits manufacturers to communicate effectively to them.

POLAND

In our opinion food for infants and children up to three years old should not contain GMO ingredients.

SWEDEN

General comments

Sweden welcomes that the guideline recognises labelling as a tool of consumer information. Labelling has to provide a sound basis for consumers to make informed choices in relation to the foods they consume. Sweden is of the opinion that factual, understandable and non-misleading information on the fact that foods are containing, consisting or have been produced from genetically modified organisms will help resolving the current controversy concerning the application of gene technology in the food sector.

Negative Claims

Sweden recognises that several Codex member countries (ref. CRD1) have an interest in discussing the issue of negative claims such as “GM free”, etc. However, Sweden is of the opinion that the issue of negative claims (“GMO free”) should not be included in the future Codex guidelines for labelling of GM foods. Sweden therefor recommends that the complex issue of negative claim (GM-free) should be discussed carefully and in another context, e.g. reviewing Codex General Guideline on Claims.

UNITED STATES

The United States recognizes that the labeling of foods derived through certain techniques of genetic modification/genetic engineering (hereinafter referred to as modern biotechnology) is a complex and controversial area and, for these reasons, believes that the CCFL deliberations relative to any interests in providing for such labeling require deliberate and fully informed discussions as well as assurances that any provisions that might be adopted are both feasible and practicable. Therefore, the United States does not support advancing the current draft guidelines in the Codex process until these concerns are addressed and consensus is formed.

The United States notes that there appears to be consensus within the CCFL that labeling is needed to denote significant changes in composition, nutritional value or intended use of a food and agrees that it is important to provide such information to consumers. Therefore, the United States continues to support those parts of the current proposal that provide for labeling of foods derived from biotechnology that differ significantly from the conventional counterpart in relation to composition, nutritional value and intended use. Moreover, the United States notes, that the Codex Committee on Food Labelling (CCFL) has achieved a consensus on the labelling of allergens in foods derived from modern biotechnology and believes that such provisions provide considerable assistance to, and protection for, consumers. The United States therefore continues to support these previously adopted labeling provisions relating to the presence of allergens.

However, the United States cannot support provisions of the draft guidelines that relate to mandatory process-based labeling of foods derived from modern biotechnology. While recognizing that the United States has participated in the Working Group and the Drafting Group, the United States continues to have significant and serious concerns about substantive parts of the draft guidelines.

From an overall perspective, the United States continues to believe that a mandatory process-based label on genetically engineered food has the potential to be perceived by many consumers as a warning label that the product is unsafe, and therefore could be misleading and, consequently, inappropriate as a

mandatory international guideline. Foods derived from biotechnology are not inherently less safe than other foods.

The United States position is that the text of the draft guidelines under discussion fails to address the practical implications that must be considered by countries before mandatory process-based labeling is implemented. More specifically, the text fails to address many technical matters that are yet unresolved and are potentially problematic in the implementation of such labeling. The United States calls attention to Attachment A of CX/FL 01/7 which raises a number of significant issues of a practical nature. The United States believes CCFL should more carefully and more thoroughly explore and consider the numerous and potentially problematic implications of any process-based labeling before recommending such an approach for an international standard. Thus, the United States believes that it is premature for these draft guidelines to advance.

In summary, the United States believes that the Committee could advance Draft guidelines relating to labeling for reasons of significant changes in composition, nutritional value and intended use of foods derived from modern biotechnology. However, the United States strongly believes that the Committee should hold in abeyance any further discussion on mandatory process-based labeling until more comprehensive information is available regarding the implications of such labeling, particularly information relating the costs and impact on international trade.

49TH PARALLEL BIOTECHNOLOGY CONSORTIUM (49P)

The proposal made by Italy (para. 77) must be given time for thorough discussion at the next session. It would appear now that the food processing and distribution sector is moving rapidly – much more rapidly than predicted – to Identity Preserved systems and a demand for traceability. This is for reasons of market differentiation – the ability to gain market advantage by being able to deliver ingredients/components to meet exacting buyer specifications – and liability, among others. It is essential that Codex acknowledge this and include in its labelling guidelines provisions for ingredient/component labelling throughout the food chain in regards to genetic modification/genetic engineering. Consideration of this amplification does not need to hold up the guidelines if it is approached as an area of voluntary inclusion and not exclusion.

ATTACHMENT I
(ICGMA' s reference from pg. 46)

ICGMA SYNOPSIS OF ISSUES RAISED IN U.S. CRD 32 (28th Session, CCFL)

When consumers around the world ask for more information about their food, they turn to government regulators for the answers. Governments can give assurances that the food is safe, but are now asked to answer additional questions, such as how best to provide information to consumers in a way that is meaningful and reliable, how to provide food manufacturers with guidance to provide information that is truthful and not misleading, and how to avoid information that is confusing to consumers or that can be used in a discriminatory manner or as a barrier to trade.

Recently, several consumer, labour and environmental groups have expressed in other multilateral negotiations that their constituents want mandatory labels to indicate the process and production methods used to create manufactured products -- from cars to clothing, batteries to detergents -- so that consumers can choose to buy them or not. (We are unaware of any mandatory process and production method label yet agreed to.) As the CCFL is asked to consider process and production method labelling of food and food ingredients derived through modern biotechnology, government food safety regulators are now facing additional questions. These questions include whether process and production method information should be provided on food labels, which have traditionally focused on the end-product's compositional, nutritional and safety characteristics, and the degree to which governments should intervene to provide this information. Governments should also assess the costs incurred to industry, consumers and taxpayers, and weigh them against the benefits to the consumer. Governments may also compare these costs and benefits with those of other methods of supplying information, instead of or in addition to labelling, that is reliable, satisfy the consumer's need to know, and that is not a barrier to commerce.

The United States has initiated a process of identifying some preliminary questions that any government will likely consider before it makes decisions with regard to process and production method labeling of foods derived through biotechnology. Many of these questions apply in situations where labelling is mandated by a government, where a government is giving guidance to industry for a voluntary label, or where alternative methods of providing information are considered. The following list of questions is not definitive, nor has the United States yet determined how best to answer all these questions. Rather they are meant to be used as a basis for discussion and input by other governments and stakeholders interested in these issues. All of the questions relate to the process and production method labeling, measures to ensure that the information provided is truthful and not misleading, and the role governments play in providing process and production method information to the consumer.

Process and Production Method Labeling

- Of the many modern processes and production methods of biotechnology, which would be of interest to consumers and appear on the label?
- Which would not?
- Why not?
- Of the conventional (non-biotech) process and production methods, which would be of interest to consumers and appear on the label?
- Which would not?
- Why not?

Measures to ensure that the information provided is not misleading:

- How is the process and production method best communicated on the label in a manner that is not misleading to the consumer?
- What words would be used on the label?
- What is the level of understanding of consumers of these words?
- What would these words be intended to convey?
- How would processed foods with multiple ingredients be labeled?

Measures to ensure that the information is truthful:

- Would the process and production method label rely on testing?
- What testing methodology would be used?
- What is the reliability of this methodology?
- Would a threshold be established to accommodate unreliable test results?
- How would the threshold be determined?
- What are the costs of testing?
- How much time does testing take?
- Would the process and production method label rely on procedures alternative to testing, such as documentation?
- At what stages of food production, handling, and processing would documentation be required?
- What type of documentation would be required?

The role governments play:

- If process and production method testing is used, how will verification and accuracy be determined?
- Who will do the testing?
- How would tests be validated?
- How would labs be identified to certify testing?
- How would governments undertake compliance and enforcement?
- What degree of compliance would be taken?
- Would additional personnel need to be hired?
- Would personnel need to be trained?
- What would the costs of compliance and enforcement be?

- Costs to government?
- Costs to industry: farmers, handling and transport, processors?
- Costs to consumers?
- What impact on food costs would these measures have?
- Are these measures consistent with international trade obligations?