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 05/33/7-Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
THIRTY-THIRD SESSION
KOTA KINABALU, MALAYSIA, MAY 9 – 13, 2005

LABELLING OF FOODS AND FOOD INGREDIENTS 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

GOVERNMENT COMMENTS AT STEP 3

COMMENTS FROM:

CANADA
KENYA
UNITED STATES
CONSUMERS INTERNATIONAL (CI)
INSTITUTE OF FOOD TECHNOLOGISTS (IFT)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING:

5b) PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING : LABELLING PROVISIONS (ALINORM 04/27/22 – APPENDIX VI)

GOVERNMENT COMMENTS AT STEP 3

CANADA:

General Comments

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 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 supports guidelines which provide factual, verifiable, understandable and non-misleading information to protect consumers from fraudulent practices.

Canada also believes that the decision to identify non-health and safety related method of production information on a label should be a voluntary market driven decision by the private sector. 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 provide information while effectively informing consumers.

To facilitate the use of such labelling, the federal government supported the development of a 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, completed a *National Standard for Voluntary Labelling and Advertising of Foods that are or are not Products of Genetic Engineering* which outlines principles for voluntary labelling as well as suggests acceptable declarations for labelling and advertising that are verifiable, understandable, informative and not false or misleading to consumers. The standard was adopted earlier last year by the Standards Council of Canada, the national organization responsible for standardization.

Upon reflection of the current *Proposed Draft Recommendations for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/ Genetic Engineering* and Canada=s experience in developing a National Standard for the labelling of foods derived from biotechnology, Canada concludes that the current *Proposed Draft Guidelines For the Labelling of Food and Food Ingredients Obtained Through Certain Techniques of Genetic Modification*

/Genetic Engineering (*Draft Guidelines*) is incomplete and needs to be further elaborated to ensure that all claims are informative, understandable, verifiable and not false or misleading. Canada believes that the draft guidelines should include:

- guidance applicable to all claims
- guidance applicable to positive and negative claims
- criteria for claims made on the principal display panel
- practical and achievable threshold levels
- criteria to verify claims

As Canada is of the view that the decision to identify non-health and safety related method of production information on a label should be a voluntary market driven decision by the private sector, we suggest that the proposed *Draft Guidelines* should provide two levels of labelling. These include mandatory labelling provisions in relation to changes in nutrition content, composition, end use, or to indicate a concern such as the presence of an allergen; and optional provisions linked to labelling of method of production.

SPECIFIC COMMENTS

Canada would like to offer the following specific comments on the text of the document:

PURPOSE OF THE GUIDELINES

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

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

The CCFL *Discussion Paper on Misleading Claims (CX.FL 02/12)* describes truthful but misleading claims as those that are literally true, but that also lead consumers to make incorrect inferences about a food. Both the presence and absence of information can be relevant to determining whether labelling is misleading. The Discussion paper describes various types of misleading labelling, as well as some possible approaches to prevent misleading food labelling. Within this context, the paper provides useful information on the elaboration of standards that must be met before specific label claims can be made on a food. Canada would like to remind the Committee to consider these important concepts when setting out criteria for labelling of GE foods. Canada believes that the CCFL should endeavour to ensure that all claims made in accordance with the Guidelines are informative, understandable, verifiable, and not false or misleading.

1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering. [These guidelines also recommend procedures for the labelling of foods and food ingredients that do not contain ingredients obtained through certain techniques of genetic modification /genetic engineering.]

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

1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation[1]; 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[2]; 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.

[1.2 These guidelines apply to the labelling of such food and food ingredients that deliberately exclude food and food ingredients that are described by section 1.1.1, 1.1.2, and 1.1.3 to ensure fair practices in food trade, and thereby facilitate consumer choice].

Canada is supportive of the above provision, however we suggest that the CCFL elaborate these proposed draft Guidelines to include provisions outlining the use of negative claims and would support the inclusion of negative labelling statements in Section 6.0, given:

(i) the 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.

Canada believes that this additional guidance would greatly improve the clarity of the scope of the Guidelines.

3.0 LABELLING PROVISIONS

(At Step 4 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:

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

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

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

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

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

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[6]

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

Canada has concerns with this text as it implies that the GM/GE ingredient would result in, or in other words, cause, a physiological or metabolic disorder. We believe this was not the intention of this particular section. The intention was to identify, for certain individuals with preexisting conditions the presence in a food of a GM/GE ingredient that might be present in a food that individual had eaten without problems in the past. Consumption of this ingredient might either trigger the onset of symptoms or exacerbate existing symptoms. To provide clarification to this section, Canada suggests the following revision to the provision.

3.3 [The presence or absence of substance(s), in comparision to the corresponding existing food, which may trigger the onset or increase the severity of symptoms of pre-existing ~~which may result in~~ physiological or metabolic disorders for certain sections of the population ~~and that are absent in corresponding existing foods~~ [should] [shall] be ~~labelled~~ indicated].

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.

3.5 [Notwithstanding Section 4.2.2.2 of the General Standard[7]], the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of

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

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

dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on ethical considerations, will be decided and implemented in a manner that is fair, transparent and consistent.]

Section 3.4 and 3.5
Canada supports the provision as written, however believes that the decision to identify a method of production on a label should be a voluntary market driven decision by the private sector. For example, in Canada, voluntary labelling measures are used to label food and food ingredients that are the subject of dietary restrictions based on religious objections and requirements under the *Food and Drugs Act* 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 further describe foods and to effectively inform consumers. Canada would like the Committee to consider how the application of these provisions can be voluntary in nature.

[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[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]]

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

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.

We recommend the following maximum and minimum threshold levels of GE content, for the use of specific expressions:

- less than 5% adventitious GE content, is considered non-GE;
- between 5 and 95% GE content, is considered to be a mixture of GE and non-GE;
- more than 95% GE content is considered to be GE.

Also, claims may be made only on the principal display panel for ingredients that make up a significant portion of the final food product.

We encourage the Committee to establish levels which are practical and achievable across a range of commodity groups, thereby allowing a variety of foods to make acceptable and meaningful claims. In the production of field crops, adventitious material can be introduced by natural factors such as the wind, insects, and other animals spreading seeds from another crop, or by exposure to other crops through bulk handling systems. In Canada, a level lower than 5% would make it difficult for most field crops to qualify for a non-genetically engineered claim and would limit consumer choice of foods. A threshold level substantially lower than 5% would not be currently practical or achievable across a range of commodity groups under current production practices.

Canada would also like to reiterate to the Committee that a 5% threshold level would be consistent with current international practice for adventitious material of all sorts, such as the inclusion of other classes of wheat or barley in shipment of a single class offered for sale in the world market. In this example, like in the case of GE commodities, the classes are not visually distinguishable, thus requiring rigorous segregation techniques to ensure compliance.

Canada would also like to suggest that the CCFL elaborate these proposed draft guidelines to include provisions outlining the use of negative claims. In providing provisions for negative claims, the Committee would be supporting consumers= choice for foods or food ingredients that do not contain ingredients obtained through certain techniques of genetic modification/genetic engineering and alternative methods of production (e.g. organic). The addition of negative labelling provisions would ensure fair practices in food trade and also facilitate consumer choice. In order for consumers to choose to support, or not support, a particular method of production, Canada believes that negative claims are appropriate for foods in which the adventitious presence of food or food ingredients obtained through biotechnology is below a given threshold.

(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.]

Canada is supportive of this section as we believe that the *Draft Guidelines* should provide for the possibility of limited exemptions for specific categories of food which are not found to any substantial degree in the final food product and thus do not affect whether or not a food or food ingredient is considered GE.

Canada notes that this is a list of examples and is only meant to b an indicative list.

(14) **6.0 LABEL DECLARATIONS**

In accordance with the General Principles section of the Codex General Standard for the Labelling of Prepackaged Foods and the Codex General Guidelines on Claims, prepackaged food shall not be described on any label or in any labelling or presented in a manner that is false,

misleading or deceptive or is likely to create an erroneous impression regarding its character or safety in any respect.

(15) 6.1 Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to indicate final product characteristics, the following requirements should apply:

(a) if the composition or nutritional value of food and food ingredients is [no longer equivalent to/ differs significantly] from the corresponding existing food and food ingredients, the label should provide, in conjunction with, or in close proximity to, the name of the food and food ingredients, such additional words or phrases as necessary to inform the consumer as to its changed composition or nutrient content in conformity with Sections 4.1 and 4.2.2 of the General Standard. In addition, nutrient declaration should be provided in conformity with the Codex Guidelines on Nutrition Labelling.

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

(16) 6.2 In accordance with Section 6.0 and in addition to the provisions of subsection 6.1, food labels should be meaningful to the [intended] consumer. Where food and food ingredients obtained through certain techniques of genetic modification/genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but are not limited to:

(a) [AProduced from genetically modified[/genetically engineered] (naming the source)@] e.g. Aproduced from genetically modified soya@

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

(c) [AGrown from seeds obtained through [modern] plant biotechnology@]

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

(e) [AGenetically engineered (naming the characteristic) (naming the food)@] e.g. Agenetically engineered high oleic soybean oil@

(f) [AProduct of plant / animal biotechnology@]

(g) [ANaming the food/food ingredient (genetically modified[/genetically engineered])@] e.g. Asoybean (genetically modified[/genetically engineered])@

(h) [ANaming the food/food ingredient (genetically modified[/genetically engineered] food/food ingredient (not segregated)@] e.g. Asoybean (genetically modified[/genetically engineered] soybean not segregated)@

(i) [AProduct of gene technology@]

[(j) [Does not contain GM/GE material] and [Contains less than 0.1% GM/GE material]]

Canada also suggests adding 6.2 (j) in order to provide consumers with additional information.

In addition, Canada believes that this section is incomplete and needs further elaboration. The Committee should establish criteria for the labelling of GE foods to prevent the use of claims that are misleading. In addition to ensuring that claims are not misleading, guidance should be provided to ensure that claims are also informative, understandable and verifiable. All claims should adhere to the Codex General Guidelines on Claims (CAC/GL 1-1979 (Rev. 1-1991)).

In drafting labelling guidance, consideration should be given to the many types of misleading claims that are discussed in the CCFL *Discussion Paper on Misleading Claims (CX.FL 02/12)* tabled by United States at the 30th Session of the Codex Committee on Food Labelling in May 2002. First, the Committee in it=s deliberations needs to consider that claims can be truthful but misleading when there is a failure to disclose information that the consumer needs in order to correctly interpret statements on a label. Canada believes the Guidelines need to be further elaborated to include a number of provisions requiring the Adisclosure@ of information under circumstances where its absence could render the claim misleading. In addition, Canada believes that in order for a consumer to make an informed choice, general guidelines need to be included which require manufacturers/producers to include an explanatory statement if a claim is likely to lead to misunderstanding or misinformation.

Secondly, Canada would like to remind the Committee that claims could be misleading when they include word(s), phrase(s), or symbol(s) which cause consumers to misunderstand the label information. Canada proposes that a number of specific provisions meant to prevent the use of confusing language on labels be considered by the Committee, such as:

- requiring that all claims about multi-ingredient foods refer to the ingredient(s) rather than to the multi-ingredient food itself;
- establishing definitions for terms that may be used in label claims, including Agenetic engineering,@ AGE,@ and Aproduct of GE@;
- prohibiting claims that imply, directly or indirectly, an improvement that does not exist or that exaggerate the aspect of the food to which the claim relates;
- prohibiting the use of the terms Afree@ or A100%,@ since the committee recognizes that it is not possible to achieve 100% purity in food production;
- prohibiting the use of signs or emblems;
- providing guidance for the use of the terms Aentirely,@ Acompletely@ and Aabsolutely,@ as these terms negate the threshold levels that are established for the use of specific claims;
- providing an Appendix with additional guidance and examples of the use of many of the provisions in the Guidelines, to which claims must conform.

Finally, Canada would like to suggest that the Guidelines be re-formatted so guidance related to threshold levels and use of language, is found together within sections based on their applicability to the different types of claims. As a result, we suggest the Guidelines include sections which address:

- criteria for all claims,
- criteria for only positive claims, and
- criteria for only negative claims.

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.

Canada would like to remind the Committee that simply labelling a product as GE or Non-GE may not provide all of the information that might be relevant to consumers interested in the use of biotechnology in the production of food. As such, we suggest that provisions which require the claim refer to an external, readily accessible source of further information, such as a toll-free telephone number or a web page address of an internationally recognized organization or national company be included. These external sources may include information concerning:

- the method(s) used to verify claims,
- in the case of recombinant DNA technology, the origin of external genetic material (for example, plant, animal, fish, bacteria),
- the method(s) used to produce the genetic change (for example, recombinant DNA technology, cell fusion), and
- details of why genetic engineering was used.

In addition, Canada would like to point out that it is important, in order to prevent deception, that all claims be presented in a manner so that the claim is grouped together with any explanatory statements and sources of additional information.

[7.0 IMPLEMENTATION

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

Canada suggests revising the title AImplementation@ to read AVerification@.

In order to help ensure that claims provide information that is truthful, all claims should be verifiable. As such, Canada suggests that this section be further elaborated to include extensive criteria related to the verification of claims criteria to ensure that claims that cannot be verified are prohibited. The Committee should outline the steps involved in ensuring the verification of a claim, including but not limited to sampling protocols, testing, detection methods, certified reference material (CRM), inspection and audit. Canada supports the inclusion of this section on implementation and would like to provide the following suggestions:

- Criteria for Verification
  - e.g. securing data necessary for the verification of the claim
  - e.g. retention of documentation by claimant for the period that the claim is being made

- Criteria for Verification System
  - e.g. prepare a plan covering all the activities within the claimants control, and ensure that their supplier does the same

- Criteria for Testing

e.g. appropriate testing method is chosen for verification purpose, validated methods of sampling and analysis and CRM are to be used as appropriate for the product in question. It should noted that at the current time, there may not be an acceptable internationally recognized verification process(es) or method(s) for validating ingredient claims.

KENYA:

Kenya proposed the following

The purpose of labelling such food is to provide consumers with useful information and information regarding health and safety.

1) Food that contains genetically **Altered** (GA) DNA or protein must be labelled. This mean that any food, food ingredient, food additive, food-processing aid or flavouring, that contains genetically **altered** DNA or protein must be identified on the label as being genetically altered.

2) Food that has altered characteristics must be labelled. This means that if food is significantly different from its non-GM counterpart with respect to allergenicity, toxicity, nutritional impact or end use, it must be identified on the label as being genetically modified **(Altered).**

3) For packaged foods the words **"genetically modified"** shall be used in conjunction with the name of the food or in association with the specific ingredient within the ingredient list.

4) For unpackaged foods for retail sale, the words **"genetically modified"** shall be displayed in association with the food or in association with the particular ingredient within that food.

Kenya agrees with clauses but with a few amendments as follows:

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

3.1 When food and food ingredients obtained through certain techniques of genetic modification **through** genetic engineering, as defined in Section 2 are 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 6.1 on label declarations- **Kenya prefers this clause to be mandatory.**

3.2 The presence in any food or food ingredients obtained through certain techniques of genetic modification **through** genetic engineering of an allergen transferred form 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) shall be declared [13]

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 shall be labelled.

3.4 In addition to the provisions of Subsection 3.1 to 3.3, when food and food ingredients obtained through certain techniques through of genetic modification **through** 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 through engineered organism or contain protein or DNA resulting from gene technology; and/or – **Kenya prefers this clause to be mandatory.**

(b) When they are produced from, but do not contain, genetically modified through engineered organisms. Protein or DNA resulting from gene technology; even when they do not differ in composition, nutritional value and, intended use.- **Kenya prefers this clause to be Voluntary as long as the method of producing is known.**

3.5 Notwithstanding Section 4.2.2.2 of the General Standard[6], the presence of substances that are absent in corresponding existing food and food ingredients the are subject of dietary restrictions, based on religious objections or cultural practices, **shall** be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent- **Kenya prefers this clause to be mandatory.**

4.0 THRESHOLD LEVELS

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

(Establishment of threshold level in food and food ingredients for the presence of food and food ingredients obtained from certain techniques of genetic modification **through** genetic engineering, below which labelling would not apply[14]) 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 **through** genetic engineering, below which labelling would not apply) **Kenya prefers to use the word "through" instead of "slash".**

5.0 EXEMPTIONS

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

[13] This provison was adopted at step 8 by the Codex Alimentarius Commission at its 24rd Session (July, 2001)

techniques of genetic modification **through** genetic engineering – Kenya suggested that this be optional.

6.0 LABEL DECLARATION

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

6.1 Where food and food ingredients obtained through certain techniques of genetic modification **through** engineering are labelled to indicate final product characteristics, the following requirements should apply:

(a) If the composition of nutritional value of food and food ingredients "**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 o 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 .**Kenya prefers the word "differ significantly**" **from the word no longer equivalent to**

(b) If the mode of storage, preparation or cooking "**differs significantly"** from the corresponding existing food and food ingredients, cleat instructions fro use should be provided.

6.2 In accordance with Section 6.0 and in addition to the provisions in Subsection 6.1, food labels should be meaningful to the consumer. Where food and food ingredients obtained through certain techniques of genetic modification through genetic engineering are labelled to declare the method of production, examples of label declaration(s) include but not limited to: Kenya prefers to delete the word intended so the clause can cover all the consumers.

Kenya agrees with **6.2a, 6.2b, 6.2d, 6.2e, 6.2g,** and disagrees with **6.2c, 6.2f, 6.2h and 6.2i,** follows:-

(a) ("Produced from genetically modified (naming the source)") e.g. "produced from genetically modified soya".

(b) If the ingredients 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")- The clause is not very clear.

(d) If the ingredient is designated by the name of a category, ("contain (name of the ingredient) produced from genetically modified (source)"), e.g starch (contains such 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").-
(ii)

The disagreements of clause **6.2c, 6.2f, 6.2h and 6.2i** are due to insufficient information and the clauses are not very clear.

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

(a) In the case of single-ingredient foods, or where there is not 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). Alternatively, the ingredient(s) may be identified by an asterisk and the required wording should appear in a statement immediately following the list in ingredients. **Kenya agrees with the clauses mentioned above.**

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 **through** 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 is agreeable to Kenya for this clause to be part of the standard. You need a proper policy to ensure that consumers are protected.

UNITED STATES:

The following is the response of the United States Delegation to the Codex Committee on Food Labelling to Codex Circular Letter CL 2004/22-FL requesting comments on the *Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions.*

COMMENTS

General Comments

The United States appreciates the opportunity to provide comments on the *Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions.*

There was consensus to label foods derived from modern biotechnology when an allergen is introduced and provision for such labelling was adopted by the Codex Alimentarius Commission in 2001. There is also consensus within CCFL to label foods derived from modern biotechnology when there is a significant change to a product's composition, its nutrient content or its intended use, including handling, storage, or preparation requirements. The United States strongly supports the labelling of foods derived from modern biotechnology in such situations.

However, it is also clear there has been no consensus on the issue of labelling foods derived from modern biotechnology solely on the basis of their method of production ("process-based labelling"). The United States does not support the development of Codex guidelines for the labelling of foods derived from modern biotechnology solely because of their method of production and believes that CCFL needs to carefully consider the following points in relation to method of production labelling.

- Labelling of foods derived from modern biotechnology should not be the means to deal with issues concerning their safety. Unsafe foods should not be placed on the market.

- The Committee should not advance labelling proposals that are inconsistent with existing labelling standards. The *General Standard for the Labelling of Prepackaged Foods,* states; "Packaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect."

    - When two products are identical, the only difference being the mode of production, the label should not be used to convey the misleading message, even indirectly, that the two products are different. Foods derived from modern biotechnology that have undergone a safety assessment should be treated no differently than any other food and should not be burdened with negative labelling.

    - The U.S. is concerned that consumers will interpret method of production labelling statements as inferring that the food is inherently unsafe. In essence, consumers may perceive a method of production labelling statement as a warning statement.

Accordingly, the U.S. believes that method of production labelling will mislead or deceive many consumers.

- Food labels should provide important information that the consumer needs to basically identify the product and its ingredients, ensure its safe use, and prevent fraud or deception. CCFL should focus on labelling that provides information to consumers that has a consequence to consumers relative to health, how the product is to be used, or comparing the quality and quantity of one product to another. Food labelling should not focus on information that may be of interest to some consumers but which has no consequence to consumers in the preparation and consumption of the food.

- Codex is most successful in developing standards/guidelines when several governments have, over an extended period of time, practical experience in developing and implementing the same type of standards or guidelines. Such experience has been helpful for areas such as food hygiene and in the establishment of maximum residue levels (MRLs) for pesticides, veterinary drugs and maximum levels (MLs) for contaminants. The U.S. believes that the international community lacks sufficient practical experience in implementing method of production labelling for foods derived from modern biotechnology, especially experience relating to thresholds, record-keeping and appropriate analytical methods. As a result, the essential experiences that could serve as a basis for considering an international standard for method of production labelling are lacking.

- The United States does not believe that it is appropriate to develop an international guideline to address regional differences in the labelling of foods derived from modern biotechnology.

Most importantly, those who advocate mandatory method of production labelling of foods derived through modern biotechnology need to explain how such labelling will advance the Codex purposes of protecting consumers' health and ensuring fair practices in food trade. Method of production labelling neither relates to consumer protection nor facilitates fair practices in food trade. Therefore, the U.S. believes that this Committee should not advance any text on method of production based labelling.

The United States believes, that if there continues to be a lack of consensus regarding the issue of mandatory method of production labelling of foods derived from modern biotechnology, the CCFL should recommend to the Codex Alimentarius Commission that such work either be discontinued or suspended.

Specific Comments on the *Guidelines* (ALINORM 04/27/22, Appendix VI)

A strikeout version of the Draft Guidelines which reflects the suggested revisions the United States is recommending is attached as an Annex 1. Annex 2 shows the document that would result if all of the edits suggested by the United States were adopted.

Title

The United States believes that the term "Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering" should be replaced by the term "Derived from Modern Biotechnology"; this term has been accepted within Codex as a result of the work of the Codex *Ad-Hoc* Intergovernmental Task Force on Foods derived from Biotechnology and the phrase is an integral part of the title of the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*. As appropriate, this change should be made globally throughout the document.

Purpose of the Guidelines

The United States recommends that the second sentence of the first paragraph should be deleted as it does not provide guidance on the labelling of foods derived from modern biotechnology.

It is recommended that the second paragraph be deleted as it is unnecessary; it is evident from the following text that a number of approaches to the labelling of food derived from modern biotechnology are presented.

1.0. Scope

The United States believes that Section 1.1.1 provides important information that should be declared on the label of foods derived from modern biotechnology.

We believe that Sections 1.1.2 and 1.1.3 do not provide information that will be beneficial to consumers and would, in fact, as noted in our general comments above, convey misleading message. We believe that that these two sections of the scope should be deleted, including footnote 9.

3.0 Labelling Provisions

The United States believes that Section 3.1. does not make clear the types of changes in the composition of food or food ingredient that would necessitate a change in labelling. We suggest, therefore that Section 3.1. be rewritten as two provisions as follows:

a. When a food or food ingredient derived from modern biotechnology differs in composition as compared to the appropriate conventional counterpart such that a new common/usual name is required, the new name should convey the characteristics or properties which make the food or food ingredient different in a manner that is accurate and understandable, and/or;

b. When a food or food ingredient obtained through modern biotechnology differs from the conventional counterpart in nutritional value and/or intended use such that there is an identifiable consequence for the consumer, the characteristics or properties which make it different from the appropriate conventional counterpart should be clearly identified on the label as described in Section 6.1, label declarations.

The United States believes that Section 3.3 is unclear and potentially too broad. Clarity is needed as to the physiological and metabolic disorders, and the affected population groups, that would necessitate labelling.

The United States does not support current Section 3.4 and believes it should be deleted.

4.0 Threshold Levels

The United States notes that this section deals with method of production labelling and as such, believes the section should be deleted.

Regarding threshold levels, we believe that, depending on how threshold levels are constructed, there is potential for consumers to be misled by the information on the label. For example, if labelling based on thresholds suggests that a product is produced using modern biotechnology, it may not be clear to consumers whether the entire product or only certain ingredients are obtained through modern biotechnology. In addition, practical considerations must also be considered such as mixing of materials, ingredients, establishment of enforcement and verification mechanisms, reliability of testing methodology, developing of supporting capacity and infrastructure, and cost.

5.0 Exemptions

The United States believes this section should be deleted as the labelling of components such as highly processed food ingredients, processing aids and food additives should be handled in the same manner as any other food component.

6.0 Label Declarations

The United States recommends that Section 6.1 (a) be redrafted to be consistent with the changes proposed for Section 3.1 (see above).

The United States believes that, as Sections 6.2 and 6.3 deal with method of production labelling and consistent with our recommendation not to include such labelling provisions in the *Guidelines*, these Sections should be deleted. The U.S. believes that any of the suggested declarations may be misleading and that consideration must be given to what the message says and how consumers understand the message.

7.0. Implementation

We note that this Section relates primarily to method of production labelling and is not needed because method of production labelling should be removed from the *Guidelines*, as recommended above. If this section should be retained, it must be strengthened to ensure that a clear indication is given as to what is required to implement method of production labelling. In this regard the United States calls attention to a discussion paper entitled *Issues Related to Method of Production Labelling Considered by the Working Group in the Development of the Codex Guidelines for the Labelling of Foods and Food Ingredients Obtained Through Genetic Modification/Genetic Engineering.* Additionally, we call attention to the Paper *Practical Aspects of Labelling to Declare Method of Production for Bioengineered Foods*, presented to the 28th Session of the Committee; a copy of this paper is provided as a separate PDF file.

ANNEX 1

STRIKEOUT VERSION CONTAINING CHANGES RESULTING FROM UNITED STATES COMMENTS.

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD DERIVED FROM MODERN BIOTECHNOLOGY
(At Step 3 of the Procedure)

PURPOSE OF THE GUIDELINES

To provide guidelines to ensure that the labelling of food and food ingredients derived from modern biotechnology provides factual, verifiable, understandable and non-misleading information to protect consumer's health and to ensure fair practices in food trade. labellinglabelling

1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients derived from modern biotechnology.

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

1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in comparison to that of corresponding conventional counterparts, having regard to accepted limits of natural variation[8]; and/or
1.1.2 when an allergen is introduced into the food.[9]

[8] This would include products such as oils with altered fatty acid levels, but would not include products such as those with agronomic modifications which contain recombinant DNA and/or protein but no further overall changes to composition, nutritional value or intended use.
[9] ~~[Gene Technology: Means a collection of techniques which are used to alter the heritable genetic material of living cell or organisms in a way that does not occur naturally by multiplication and/or recombination.]~~

3.0 LABELLING PROVISIONS

In adopting a specific approach to the labelling of food and food ingredients derived from modern biotechnology the following provisions should be used:

3.1

3.1 (a) When a food and food ingredient derived from modern biotechnology differs in composition as compared to the appropriate conventional counterpart such that a new common/usual name is required, the new name should convey the characteristics or properties which make the food or food ingredient different in a manner that is accurate and understandable, and/or;

(b) When a food or food ingredient derived through modern biotechnology differs from the conventional counterpart in nutritional value and/pr intended use such that there is an identifiable consequence for the consumer, the characteristics or properties which make it different from the appropriate conventional counterpart should be clearly identified on the label as described in Section 6.1, label declarations.

3.2 The presence in any food or food ingredients derived through modern biotechnology 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 Food (CODEX STAN 1-1985 (Rev. 1-1991) shall be declared.[13]

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

labelling3.4 [Notwithstanding Section 4.2.3.2 of the General Standard, the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labeled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent.]

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4. 0 LABEL DECLARATIONS

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

4.1 Where food and food ingredients derived through modern biotechnology are labeled to indicate final product characteristics, the following requirements should apply:

(a) if the composition differs in comparison as compared with the appropriate conventional counterpart such that a new common/usual name is required, the new name should convey the characteristics or properties which make the food or food ingredient different in a manner that is accurate and understandable in accordance with Section 4.1 of the General Standard; and/or

[13] This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24th Session (July, 2001).

(b) if the nutritional value and/or intended use (including mode of storage, preparation or cooking) differs in comparison as compared with the appropriate conventional counterpart such that there is an identifiable consequence for the consumer, the characteristics or properties which make it different from the appropriate conventional counterpart should be clearly identified on the label.

ANNEX 2

VERSION CONTAINING CHANGES RESULTING FROM UNITED STATES COMMENTS.

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF FOOD AND FOOD INGREDIENTS DERIVED FROM MODERN BIOTECHNOLOGY
(At Step 3 of the Procedure)

PURPOSE OF THE GUIDELINES

To provide guidelines to ensure that the labelling of food and food ingredients derived from modern biotechnology provides factual, verifiable, understandable and non-misleading information to protect consumer's health and to ensure fair practices in food trade.

1.0 SCOPE

These guidelines recommend procedures for the labelling of food and food ingredients derived from modern biotechnology.

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

1.1.1 when it is demonstrated, through an appropriate analysis of data, that the composition, nutritional value, or intended use of the food or food ingredient differ in composition to that of the corresponding counterparts, having regard to accepted limits of natural variation[8]

1.1.2 when an allergen is introduced into the food.

3.0 LABELLING PROVISIONS

In adopting a specific approach to the labelling of food and food ingredients derived from modern biotechnology the following provisions should be used:

3.1 (a) When a food and food ingredient derived from modern biotechnology differs in composition as compared to the appropriate conventional counterpart such that a new common/usual name is required, the new name should convey the characteristics or properties which make the food or food ingredient different in a manner that is accurate and understandable, and/or;

(b) When a food or food ingredient derived through modern biotechnology differs from the conventional counterpart in nutritional value and/or intended use such that there is an identifiable consequence for the consumer, the characteristics or properties which make it different from the appropriate conventional counterpart should be clearly identified on the label as described in Section 6.1, label declarations.

3.2 The presence in any food or food ingredients derived through modern biotechnology 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) shall be declared.[13]

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

[13] This provision was adopted at Step 8 by the Codex Alimentarius Commission at its 24th Session (July, 2001)

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

3.4 [Notwithstanding Section 4.2.3.2 of the General Standard, the presence of substances that are absent in corresponding existing food and food ingredients that could be the subject of dietary restrictions, based on religious objections or cultural practices, may be labelled. Where such labelling is used, member countries should establish criteria on how labelling decisions, based on dietary restrictions, will be decided and implemented in a manner that is fair, transparent and consistent.]

4. 0 LABEL DECLARATIONS

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

4.1 Where food and food ingredients derived from modern biotechnology are labelled to indicate final product characteristics, the following requirements should apply:

(a) if the composition differs in comparison as compared with the appropriate conventional counterpart such that a new common/usual name is required, the new name should convey the characteristics or properties which make the food or food ingredient different in a manner that is accurate and understandable in accordance with Section 4.1 of the General Standard; and/or

(b) if the nutritional value and/or intended use (including mode of storage, preparation or cooking) differs in comparison as compared with the appropriate conventional counterpart such that there is an identifiable consequence for the consumer, the characteristics or properties which make it different from the appropriate conventional counterpart should be clearly identified on the label.

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 00/5-b-CRD.32**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
TWENTY-EIGHTH SESSION
OTTAWA, CANADA, 9 - 12 MAY 2000

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS OBTAINED THROUGH BIOTECHNOLOGY (SECTION 5) (ALINORM 99/22, APPENDIX VIII)

GOVERNMENT COMMENTS ON CX/FL 00/6 AT STEP 3

COMMENTS FROM:

UNITED STATES

CCFL
28th Session, Ottawa
To be tabled 9 May 2000

United States of America
Conference Room Document

Practical Aspects of Labelling to Declare Method of Production for Bioengineered Foods: The Need for Additional Deliberations of the Working Group

Background

Consumers throughout the world are increasingly interested in their diets and the foods they eat. This interest stems not only from the growing awareness of the role of diet in health, but also from the desire to "empower" consumers, thereby allowing them the option of making choices about the foods they eat. And bioengineered foods are no exception. Given this milieu, governments and national authorities charged with the responsibility of providing for the food label are faced with a significant challenge, including balancing a variety of considerations when making provisions for food labelling.

The United States has noted the difficult and complicated discussions surrounding Option 2 for labelling of bioengineered foods. In order to make the discussions about Option 2 more informed and meaningful, we believe that it would be useful to continue to explore the issues surrounding the practical aspects of mandatory provisions for the labelling of foods to declare method of production for bioengineered foods. It is important to take the time to understand the practical outcomes, ramifications, and specifics of the implementation and enforcement of any food labelling activity because consumers are better served, and the components of the implementation are transparent and well understood before they are put into place.

Considerations related to food labelling may be grouped into two major sets of activities. First, there is the need to ensure that the information provided on the food label is not only accurate and useful to consumers, but also not misleading. This set of activities also offers the opportunity to educate the consumer. Second, we need to explore whether the proposed requirements and specifications for labelling are technologically feasible, based on validated methods, reproducible, and within reasonable cost. In essence, the determinations about what, and how, to label foods should be made within a logical framework that includes relevant check-points and determinations for feasibility and practicality as well as studied considerations of consumer use of such label statements.

Application to Labelling of Bioengineered Foods, Section 5

The CCFL's on-going deliberations on the labelling of bioengineered foods under Section 5 have already reached the point where the underpinnings and practical framework for Options 1 and 2 are beginning to be explored. Specifically, the creation of the Codex Ad Hoc Technical Working Group on the Labelling of Foods Obtained through Biotechnology, which was charged with clarifying Section 5 but also addressed Section 2, has been a productive first step for this effort, particularly in terms of definitions of terms. Yet, we have noted that as part of its deliberations, the Working Group identified additional technological and implementation/enforcement issues (e.g. threshold levels) that require further clarification before CCFL can approximately proceed with provisions for method-of-processing labelling for bioengineered foods.

At this time, the Working Group could be re-established to further specify and address remaining key questions that are important to clarifying the practical implementation/enforcement of the various options for the Section 5 provisions. This is not necessarily a time-consuming or difficult task because much information is already available in existing technical documents as well as from existing and on-going research in areas ranging from analytical methods to consumer behavior. Once these efforts are brought forward, the CCFL would be better able to consider in what way to provide for labelling of bioengineered foods under Section 5. And it would allow for these discussions in an atmosphere where participants are fully informed and in which the outcomes and ramifications are as transparent as possible.

There are a number of ways in which the questions to be addressed could be identified and reviewed by the Working Group. One approach would be to organize the considerations by key categories inherent to provisions for any food labelling, for example:

- **IMPLEMENTATION / ENFORCEMENT INTERFACE:**

For example :

- What type of documentation or testing would be necessary to determine or establish whether a food or food ingredient is or is not derived through biotechnology?
- How would this documentation be tracked through agricultural production, food processing, and distribution?
- Who will verify the documentation, how will this be conducted, and would a third party be involved?
- Are there sufficient existing analytical methods to determine whether food products have been produced using bioengineering? Are they validated, reliable, and practical for in-field use?
- Have the methods been validated for both raw ingredients and processed products?
- How is a system for continual validation and updating of analytical methods put in place and maintained at an international level? Who is responsible?
- What responsibilities would be added to government regulatory authorities for labelling foods developed through biotechnology?
- What is the cost to the manufacturer to provide for the methods, verification, and labelling for foods developed through biotechnology?
- Can costs be compared and contrasted among different options for labelling of foods derived through biotechnology?

In addition, there is another category of practical considerations relevant to labelling that is not necessarily consistent with the work of the Working Group but which nonetheless should be clarified:

- **CONSUMER INTERFACE:**

For example:

- Is it possible that a statement on a food label can be factually correct but also misleading? How are such problems addressed?
- How do consumers interpret statements about processing methods in general and about bioengineered foods specifically?
- Are there some labelling statements that are more likely to engender fear or uncertainty in consumers, versus provide assurance to consumers, or help to educate them? Is this an important consideration for labelling?

- Do consumers need specific background information or education in order to appropriately use labels that declare the presence of bioengineered ingredients?
- How should label information be presented for issues that are currently the focus of considerable attention but that might be replaced or overshadowed in the consumer's mind by other emerging issues in the near future?

Recommendations

We suggest that CCFL re-convene the Ad Hoc Working Group to: (a) further identify the types of practical questions outlined above for Section 5, focusing, for example, on technological feasibility, implementation, and enforcement as well as on consumer needs, interpretation and impact; and (b) explore and review these underlying issues that would impact decisions about the labelling of bioengineered foods.

The United States is willing to participate in this effort. Additionally, our recently announced plans to refine the U.S. regulatory approach regarding foods derived through the use of modern biotechnology include provisions for the voluntary labelling of foods with and without the use of bioengineered ingredients. Therefore, we believe we will be able to offer, in the near future, more information about consumer interpretations, expectations and use of food label information related to bioengineered foods.

CONSUMERS INTERNATIONAL (CI):

Consumers International (CI) appreciates the opportunity to comment on the latest proposed Draft the Guidelines on Labelling of Foods Obtained by Genetic engineering/genetic modification (GE/GM).

Consumers International supports the draft guideline, and urges that it be advanced in the step process. We are particularly concerned that we have been discussing this issue for more than ten years and there has functionally been no movement on this document for more than two years. The mandate given to this Committee by the Codex Alimentarius Commission ***in 1991*** was: "to provide guidance on how the fact that a food derived from 'modern biotechnologies' can be made known to the consumers." The clearest way to make this fact known to consumer is via labelling of GE/GM foods. Since this Committee started discussion on this issue, many countries have passed laws requiring labelling of GE/GM foods. At present, more than 40 countries, which account for about a third of the world's population, have laws requiring the labelling of GE/GM foods. So, clearly such labelling is going on worldwide, in part because consumers want to know this information.

In addition, we note that the scope section, which lays out three options for labelling, is not in square brackets and so has been agreed upon by all. Thus there should not be fundamental disagreement about the basic thrust of the document. It should be possible to move this document forward and give countries advice on the various options they have when considering labelling of GE/GM foods. We point out that this Guideline does not require any country to label GE/GM foods. It only advises countries on the different labelling possibilities that exist. With more and more countries passing mandatory labelling laws, it would be desirable to have some Codex guidance on this clearly important issue. Consequently, we feel that it is urgent that CCFL move forward with this document and not allow a small handful of countries to block movement. CI's detailed comments follow.

Section 1.0 SCOPE

CI supports this section, which makes clear that there are three labelling options that Codex member countries can use. These options are (1) label only when there is a change in nutritional value or intended use (for example if an modified/engineered orange contains no vitamin C); (2) label only when the food contains modified/engineered protein or DNA (such food labels can be verified through testing*);* (3) label when the product is derived from a modified/engineered food, regardless of whether or not it contains modified/engineered protein or DNA (such labels can be verified through traceability systems). Option 1 roughly corresponds to the system employed in the United States; Option 2 corresponds to the system in Australia and Option 3 to the system in the European Union.

Section 2.0 DEFINITION OF TERMS

CI supports this section which is at Step 7 of the procedure.

Section 3.0 LABELLING PROVISIONS

Paragraph 3.3. This section calls for labelling if genetic modification/engineering results in "presence of substances which may result in physiological or metabolic disorders for certain sections of the population." We support this section, and urge that the square brackets around this section be removed, since this is an important health protection matter.

Paragraph 3.5. This section states that countries may require labelling when genetic engineering/modification results in presence in food of substances that are normally not present in the food and "that could be the subject of dietary restrictions, based on religious objections or cultural

practices." CI supports this section and urges that the square brackets around it be removed. Many cultures have strong religious and cultural preferences with regard to food. Vegetarians may well want to know if genes from animals were inserted into plants, resulting in the plant containing animal protein. Jews and Muslims may want to know if genes from pigs were inserted into a food. This section will address cultural and religious considerations of high importance to many consumers in the world in the context of genetic modification/engineering.

Section 4.0. THRESHOLD LEVELS

Consumers International believes that if there are any detectable residues of protein or DNA resulting from genetic engineering/genetic modification, the product should be labelled. Current tests can reliably detect GE/GM DNA down to levels of 0.1%. Therefore CI supports deletion of the square brackets around this section provided it is modified to read as follows:

"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 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, *that corresponds to the limit of detection for the modified/engineered food ingredient .*"

Further information/work on the issue of the limit of detection of GE/GM DNA could be referred to the Codex Committee on Methods of Sampling.

Section 5.0. EXEMPTIONS

We urge this section authorizing certain exemptions be deleted, since exemptions to basic rules will create confusion for consumers. However if the section is retained, we particularly object to the inclusion of "highly processed food ingredients" in the list of examples of food products that may be exempted from mandatory labelling. Highly processed ingredients often constitute virtually the entire contents of a food product--for example the corn in corn flakes. Exemption of highly processed ingredients could turn a labelling program into a meaningless effort, and one which was highly misleading to consumers.

If the intent of this section is to allow for exemptions of items that are present in extremely small quantities in processed food, then this should be made clear and would make this section more acceptable. In that case, delete "highly processed food ingredients" and insert the phrase "that are present in extremely small quantities" after the words "food and food ingredients" in line 3.

Section 6.0 LABEL DECLARATIONS

Section 6.2. This section suggests various alternative wordings for labels. In fact, the meaning of particular words in different cultures can vary widely, so it is difficult to establish guidelines in this area. However CI believes that the label declarations that are suggested here that include the terms "genetically engineered" or "genetically modified" will provide adequate information to the consumer. Thus, the square brackets should be removed from alternatives (a), (b), (d), (e), (g) and (h). However alternatives (c), (f) and (i)--which refer to products of biotechnology or gene technology--are unacceptably vague and indefinite and should not be recommended by Codex.

Section 7.0. IMPLEMENTATION

We support removing the square brackets from this entire section because, in our view, guidance in reference to implementation of GE/GM labelling guidelines may be helpful. CI recommends that the words "to facilitate product tracing/traceability" should be added to the second sentence so that it reads, "These include, but are not limited to: development of validated detection methods, establishment of verification (for example, documentation) systems *to facilitate product tracing/traceability*; and efforts for the development of supporting capacity and infrastructure." This addition should be made to make this document more consistent with the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44) adopted at the 2003 meeting of Codex Alimentarius Commission.

INSTITUTE OF FOOD TECHNOLOGISTS (IFT):

The Institute of Food Technologists (IFT) is pleased to offer comments on point B.6. of **CL 2004/22-FL** *("Proposed Draft Guidelines for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions"*) which will be considered at the 33rd Session of the Codex Committee on Food Labelling (CCFFL) May 9-13. IFT has been privileged to be present during many of the past discussions on this important topic and will be represented at the next Session of the Committee. IFT is an international scientific society with 26,000 individual members working throughout the food science and technology profession. IFT's mission is to advance the science and technology of food through the exchange of knowledge.

Labelling of foods derived from rDNA-biotechnology is an issue of tremendous scope and implication for international trade. If the Committee is to continue work in this area, IFT supports mandatory labelling only for significant objective, measurable, and verifiable differences (e.g., product composition, nutritional value, allergen presence, or end use) between r-DNA biotechnology-derived foods and their conventional counterparts.
IFT does not support mandatory labelling of food or food ingredients based solely on production (process-based labelling) from rDNA biotechnology, as there is not objective, verifiable means by which such labelling could be documented, and there is not health and/or safety concern or outcomes associated with such a labelling requirement.

Four years ago IFT convened a panel of distinguished scientists to address labelling, safety, and concerns about foods derived through modern (rDNA) biotechnology, subsequently producing the comprehensive IFT Expert Report on Biotechnology and Foods (http://www.ift.org/cms/?pid=1000380). This Expert Report describes the expert panel's conclusion that without reliable standardized analytical tests and sampling protocols, which do not yet exist, it is not possible to verify the accuracy of label declarations. To be effective, a labelling program must be based on well-defined, understandable, and non-misleading terminology and validated and standardized science-based sampling plans and testing methods. An Executive Summary of the report and accompanying backgrounder on labelling summarize key aspects of such important issues that factored into IFT's conclusions. These documents, accessible at http://www.ift.org/pdfs/expert/biotech/iftbiotechexsumm-b.pdf and http://www.ift.org/pdfs/expert/biotech/iftbiotechlabel-b.pdf, are incorporated herein by these references.