CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

AGENDA ITEM NO. 6(b) **CX/FL 11/39/12**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

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

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (CL 2010/19-FL)

Comments At Step 3

Brazil
Cameroon
Costa Rica
European Union
Iran
Japan
Kenya
Malaysia
New Zealand
Norway
Panama
United States
Biotechnogloy Industry Organization (Bio)
Consumers International
Croplife International
International Council Of Grocery Manufacturers Association (Icgma)
Institute Of Food Technologists (Ift)

BRAZIL

The Brazilian Delegation thanks for the opportunity to present the following comments on CL 2010/19-FL:

Comments:

Brazil supports the adoption of Chapeau 2 that was developed in the last session of the Codex Committee on Food Labelling.

We suggest updating the bullets of item 1 and the footnote of item 3 with the inclusion of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (CAC/GL 68-2008).

We understand that it is important to align the language in the text with that used in the Chapeau and other Codex texts. The words "foods derived from modern biotechnology" should be used instead of "foods obtained by GM/GE techniques".

CAMEROON

Cameroon like many African countries faces a lot of problems of food security, quality and safety.

WHO in the strategy for Food safety and Health urges member states among others to:

- Strengthen national laboratory capacity to monitor foods, especially food imports containing GMOS.
- While waiting for that to happen the food label is the only tool the country has to identify foods that contain GMOS.
- Cameroon has ratified a lot of treaties on the protection of the environment among which is the Bio safety law signed in 2003, the Cartagena protocol on biosafety. The African Union has also developed a model law of safety in biotechnology to address amongst other issues domestics GMOS, approve and label GMO foods. The precautionary principal is enshrined in both the biosafety protocol and the African model law. In addition a lot of foods such as corn, rice and soybeans are grown using seeds that have been genetically altered. There are a lot of other foods that have GMO ingredients that consumers purchase without discrimination as long as the prices are good.
- Bishop George Nkwuo of kumbo, Cameroon is one of those taking a leading role on GMOS and their impact on the human health and the environment.

  In view of all these concerns on GMOS, Cameroun maintains the same position as in the last CCFL which is the mandatory labeling of GMOS.

Comments:

We are equally of the opinion that Codex should issue recommendations on the labeling of GM foods. This guidance would in particular be extremely useful for our country as was largely expressed during the previous sessions of CCFL and also during the two specific working group meetings which took place in Oslo (February 2007) and Accra (January 2008).

In relation to the chapeaus, we support the Chapeau 2 as amended by Brazil: "The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts which are relevant for the labeling of foods obtained by GM/GE techniques. It also recognizes that each country can adopt different approaches regarding labeling of foods obtained by GM/GE techniques and that food labeling is the primary means of communication between the seller on the one hand and the purchaser and consumer on the other."

COSTA RICA:

Costa Rica welcomes the opportunity of providing the following comments to the circular letter CL 2010/19-FL:

Costa Rica supports the proposal regarding *["**Chapeau version 2**: Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are available, the purpose of this document is only to recall and assemble in a single document some important elements of guidance from existing Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.]*

Paragraph 2. Costa Rica proposes eliminating this paragraph.

2. ~~*Codex labelling and other texts apply to foods sold in unpackaged/non-retail containers including those foods obtained through GM-GE techniques and sold in such manner. Labelling means "any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal."*~~

Justification. It is understood that the term "food" includes all production methods, including those obtained through GM/GE techniques or any other production method. In that sense, it is unnecessary to differentiate between foods on the basis of their production method, as that would lead to have to mention other techniques as well, such as: organic, minimally processed or irradiated, among many others. Furthermore, the labelling definition quoted is already included in the Codex General Standard for the Labelling of Prepackaged Foods, Codex Stand. 1-1985 reference to which is later made in these proposed draft guidelines. For these reasons, Costa Rica considers that the inclusion of this paragraph is not justified.

Paragraph 3. Costa Rica proposes eliminating this sentence:

*3.***"** ~~*Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption.*~~

Costa Rica proposes the following wording for paragraph 3:

3. Codex has adopted several texts which address the safety aspects of GM/GE foods, such as the *"Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003)* and the *Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms (CAC/GL 46-2003)*", which are available to Member Countries for this purpose.

Justification: Product safety is guaranteed by Good Production Practices; it should be clear however that there are foods which due to their nature are not totally safe for some sectors of the population, such as: Foods that contain phenylalanine or that contain gluten and which are not safe, respectively, for phenylketonurics o for celiacs. Due to this reason the sentence on paragraph 3 *"only after the food has undergone appropriate assessments to deem it safe for human consumption"*, could create confusion or misinterpretations. It should be highlighted that the purpose of labelling is to appropriately **inform** consumers, and that this issue is clearly defined in point 4.2.2 of the General Standard for the Labelling of Prepackaged Foods and therefore this paragraph should not emphasize food labelling but food safety. For all of the above mentioned reasons, Costa Rica proposes that this paragraph should deal only with the issue of safety and not make reference to labelling. For this purpose we propose combining the foot note number 2 with the main text to read as shown in the proposed paragraph 3.

Costa Rica does not have any comments regarding **paragraph 4**.

Regarding **paragraph 5**, Costa Rica considers that the text has already been included in the Codex General Standard for the Labelling of Prepackaged Foods, Codex Stand. 1-1985 and, therefore, does not believe it would be relevant to include it this document.

Paragraph 6. Costa Rica proposes eliminating this paragraph.

~~6. *When the physical, chemical, or functional characteristics of a food are significantly altered through any means (production or processing), the labelling of such food be appropriately modified from its traditional labelling to ensure that the food is described or presented in a manner that is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect. The traditional name of such food may need to be changed or qualified with additional words or phrases to describe the true nature of the food and to avoid misleading or confusing the consumer.*~~

Justification: Regarding this issue, and as a developing country, we are concerned that this theme has occupied many years of debate without reaching consensus among the parties under the present trends of the draft proposal which, far from favouring the economies of developing countries, could create extreme limitations for our export expectations, if at the end the Codex were to establish food labelling guidelines based on the method of production, as that would determine that many of our micro, small and medium size enterprises would have to search for additional resources to declare such information in the label under known conditions, without guaranteeing that the food, or the ingredients subject to it, are or are not safe for consumption, in addition to confusing interpretations that could arise regarding the safety of these products. For this reasons, Costa Rica reiterates that it supports guidelines related to the safety assessment of these foods and ingredients but not about their method of production.

Due to the aforesaid, and acknowledging the debate at Codex, Costa Rica considers that the information available in the food labels should guarantee the duty of declaring the information in a clear and truthful manner to the consumer which, in the particular case we are discussing, would be when there is a significant difference in comparison to its conventional counterparts. By this we mean that labelling should be made only for the significant difference in relation to the conventional product characteristics and composition. Otherwise we would be labelling on the basis of the method of production, which is exactly what should be avoided.

Costa Rica does not have any comments regarding paragraph 7

Paragraph 8. Costa Rica proposes eliminating the paragraph.

8. ~~*The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods.*~~

Justification: Aside from the fact that there is a repetition in the sentence *"may be applied*", which generates confusion, all the paragraph is in itself a repetition of the idea expressed in paragraph 10 regarding the implementation of Codex standards related to the labelling GM/GE foods .Costa Rica suggests that sentences that may lead to erroneous interpretations regarding the issue" should be avoided in the text.

Paragraph 9. Costa Rica proposes eliminating the paragraph.

9. ~~*Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences.*~~

Justification: It is clear that the purpose of labelling is to appropriately **inform** consumers, as it has been established in the Codex standards. The objective emphasized in this draft proposal, which is *"to indicate that a food does or does not meet consumer preferences",* is not found in those standards. Costa Rica considers that this can lead to confusion o error and that it would go beyond the purpose of the present guidelines which is to "*recall and collect"* what has already been established regarding this issue. Furthermore, regarding the labelling purpose, reference to existing standards is sufficient, as mentioned on the following paragraph 10.

EUROPEAN UNION

The European Union and its 27 Member States (EUMS) appreciate the opportunity to comment on Circular Letter 2010/19-FL.

The EUMS welcome the fact that CCFL has supported continued work on the important issue of GM labelling, an issue which is a matter of concern or which raises questions for most consumers all over the world. That is undoubtedly a very good reason to devote Codex time and resources to this issue, even if consensus is difficult to obtain.

The EUMS believe it is useful at this stage to recall the exact mandate given by the 19th Session of the Codex Alimentarius Commission in 1991 (ALINORM 91/40 para.90): The Codex Alimentarius Commission "*noted that while consumers would benefit from "modern" food biotechnology, some consumers felt that this technology would pose certain problems. For example, individual consumers might, on ethical or other grounds, not wish to buy foods derived from "modern" biotechnology. The Commission requested the Codex Committee on Food Labelling to provide guidance on how the fact that a food was derived from "modern" biotechnologies could be made known to the consumers.*"

The text which was developed by the Working Group in Ghana on the basis of the Background Paper developed by the United States, Canada and Nigeria, represents a good starting point for the discussion.

Before detailing our comments on the text itself and as requested by paragraph 160 of the report from last session of CCFL, the EUMS would like to clearly state what are their objectives and their underlying rationales:

The **first objective** is that Codex should acknowledge that several approaches for GM labelling are conceivable, from total absence of labelling to full labelling. This was a clear outcome of the working group which took place in Oslo in February 2007 where 6 approaches[1] were identified:

1. Mandatory GM labelling as such of all foods derived from or containing ingredients derived from organisms produced using gene technology (food consisting of, containing or produced from GMOs);
2. Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food;

[1] Approach 7 : "Labelling requirements under development" is by definition a temporary status.

3. Mandatory GM labelling as such of GM food where it is significantly different from its conventional counterpart and where GM labelling is required in addition to the significant change;
4. Mandatory labelling of GM foods where it is significantly different from its conventional counterpart and where only the significant difference is labelled, but not the method of production;
5. Voluntary labelling (Voluntary labelling guidelines for foods that are or are not products of genetic engineering);
6. No special labelling requirements for bioengineered foods as a class of foods.

All these approaches aim at addressing consumers' needs and in some instances food producers willingness to provide information which may vary across the world and there are valuable arguments behind each of this approach. Every Codex member should be in a position to choose one of these approaches according to its policy and to the needs of its consumers. Informing the consumers about the nature of the food is totally in line with one of the two basic objectives of Codex which is to "ensure fair practices in the food trade".

The **second objective** is to give guidance to developing countries. This request was repeated at many occasions during the recent plenary sessions of CCFL. Several approaches are currently implemented all over the world in various countries. Many countries, including developing countries, have on-going reflections on the approach to follow and would welcome general guidance by Codex. This is really the basic mission of Codex: give guidance to its members. This guidance should take the form of an official Codex text; this essential task cannot indeed be delegated to another body or its content cannot be relegated in a "non-paper" or a background paper. Such guidance would define a general framework with the view to progress in the harmonization of requirements applied to foods and in doing so to facilitate international trade.

The **third objective** is to clarify that GM labelling is not directly linked to safety as such. Every food on the market has to be safe and Codex has developed guidance for the safety assessment of GM foods. Labelling is for consumer information to allow him/her to make informed choices (in line with the 2nd objective of Codex: ensure fair practices in the food trade).

The EUMS also want to make very clear that they do not have the intention nor the objective to impose GM labelling to the rest of the world. The European policy regarding GM labelling was designed to address the needs expressed by the European consumers who want to decide themselves whether or not they want to eat GM foods and make informed choices. This policy is widely supported by European citizens. It is also administered in a non-discriminatory manner and applies equally to domestic production and imports.

Appendix X of ALINORM 10/33/22:

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

(At Step 3 of the Procedure)

*~~[~~**Chapeau version 1:** The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. It also recognizes that each country can adopt different approaches regarding labelling of foods derived from modern biotechnology **and that food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other.** ~~This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.]~~*

Comment: The EUMS are in favour of a version close to the "Chapeau 2 as amended by Brazil" which states the essential message in a short text:

Chapeau 2 as amended by Brazil (discussed in May 2010):

"*The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques. It also recognizes that each country can adopt different approaches regarding labelling of foods obtained by GM/GE techniques and that food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other*."

The EUMS cannot accept the last sentence of chapeaus 1 and 2. Codex established a specific Taskforce on Foods Derived from Biotechnology and produced a series of texts addressing risk analysis and safety assessment of these foods since, for consumers, there is a difference between GM and conventional foods just as there is a difference between organic/non organic, irradiated/non irradiated, halal/non halal foods and that Codex members may wish to inform their consumers about

this difference to address their expressed needs. In addition, the fact that Codex established a specific Taskforce on Foods derived from Modern Biotechnology and produced a series of texts addressing risk analysis and safety assessment of these foods clearly demonstrates that the use of modern biotechnology is specific and deserves specific approaches in terms of risk analysis.

~~*[**Chapeau version 2:** Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are available, the purpose of this document is only to recall and assemble in a single document some important elements of guidance from existing Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.]*~~

[Text as annexed to report of the 36th Session of the CCFL:

1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:]

- The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985)
- The Codex General Guidelines on Claims (CAC/GL 1-1979)
- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
- Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
- Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms **(CAC/GL 46-2003)**
- **Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals (CAC/GL 68-2008)**
- Working Principles for Risk Analysis for Food Safety for Application by Governments **(CAC/GL 62-2007)**
- **The Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CAC/GL 32-1999)**

Comment: Within the framework of Codex, the voluntary labelling of organically produced foods already refers to GM material by stating that all materials and/or the products produced from genetically engineered/modified organisms are not compatible with the principles of organic production.

2. Codex labelling and other texts **also** apply to foods sold in unpackaged/non-retail containers including those foods obtained through GM-GE techniques and sold in such manner. Labelling means "any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal."

Comment: Codex labelling and other texts apply to both pre-packaged foods and foods sold in unpackaged/non retail containers depending on their specific scope.

3. Labelling of a food **is intended to provide essential information to the consumer** ~~is~~ **and placing on the market should only be** considered ~~only~~ after the food has undergone appropriate assessments to deem it safe for human consumption. Codex has adopted several texts, which address the safety aspects of GM/GE foods, ~~and~~ **which** are available to **Codex** Member**s** ~~Countries~~ for this purpose[2].

Comment: GM labelling is not directly linked to safety as such. Every food on the market has to be safe and Codex has developed complete guidance for the risk assessment of GM foods. Labelling is for consumer information to allow him/her to make informed choices (in line with the 2nd objective of Codex: ensure fair practices in the food trade).

3bis. The Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) state that risk management measures related to foods derived from modern biotechnology

[2] 2 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003).

"may include, as appropriate, food labelling conditions for marketing approvals and post-market monitoring" (para.19).

Comment: Food labelling requirements may be part of risk management measures. It is at the level of risk management carried out at national level that consumers' needs may be addressed.

4. The Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) states that the "transfer of genes from commonly allergenic foods . . . should be avoided unless it is documented that the transferred gene does not code for an allergen . . .".

5. The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed (section 4.2.2, GSLPF).

6. When the physical, chemical, or functional characteristics of a food are significantly altered through any means (production or processing), the labelling of such food **should** be appropriately modified from its traditional labelling to ensure that the food is described or presented in a manner that is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect. The traditional name of such food may need to be changed or qualified with additional words or phrases to describe the true nature of the food and to avoid misleading or confusing the consumer.

Comment: Paragraph 6 could be moved above paragraph 4 as it is of a more general nature than allergens. The structure would thus be: 1 alterations of all nature, 2 transfer of allergen as specific alteration for which precise rules already exist, 3 claims, 4: information regarding GM/GE origin.

7. In cases where GM/GE modifications result in a claim related to the nutritional properties of the food, the claim language should be consistent with the Guidelines for Use of Nutrition and Health Claims.

8. The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods.

9. Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences. **It can be decided to label food products as GM/GE foods when the products (or at least one ingredient) are obtained through certain techniques of genetic modification/genetic engineering, irrespectively of changes in the final product. In the case of pre-packaged products consisting of, containing or produced with, GMOs, the list of ingredients could indicate e.g. "genetically modified" or "produced from genetically modified [name of the organism]". In the case of products without packaging, these words could be clearly displayed in close proximity to the product (such as a note on the food store shelf).**

Comment: Several approaches are possible depending on the Codex Members' policy. The objective of these additions is to give an example on how GM labelling could materialise.

10. Any representations made on the label or in the labelling of GM/GE foods should be consistent with the GSLPF (Codex Stan 1-1985) and the General Guidelines on Claims (CAC/GL 1-1979).

Table 1. Provisions in existing Codex labelling texts that apply to the labelling of GM/GE foods

Section	Mandatory Labelling Provisions
	General Standard for the Labelling of Prepackaged Foods
3.1	Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
3.2	Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.
4.1.1	The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.

4.1.2 There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared.

When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

Principles for Risk Analysis of Foods Derived from Modern Biotechnology

Para. 19 Risk management measures may include, as appropriate, food labelling conditions for marketing approvals and post-market monitoring.

Section Voluntary Labelling Provisions

General Standard for the Labelling of Prepackaged Foods

7.1 Optional labelling – Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3 – General Principles.

General Guidelines on Claims

1.2 The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

1.3 The person marketing the food should be able to justify the claims made.

2 Definition – For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.

3.3 Prohibited claims – Claims which cannot be substantiated.

3.5 Prohibited claims – Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.

4.1 Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives.

5.1(iii) Conditional claims – Terms such as “natural,” “pure,” “fresh,” “home made,” “organically grown,” and “biologically grown” when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.

5.1(v) Conditional claims – Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.

5.1 (vi) Conditional claims – Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:
(b) is one which consumers would normally expect to find in the food;
(d) is one whose presence or addition is permitted in the food.

Guidelines for Use of Nutrition and Health Claims **]**

Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods

1.5 All materials and/or the products produced from genetically engineered/modified organisms (GEO/GMO) are not compatible with the principles of organic production (either the growing, manufacturing, or processing) and therefore are not accepted under these guidelines.

2.2 **The following provisional definition is provided for genetically/modified organisms. Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Techniques of genetic engineering/modification include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization.**

IRAN

Chapeau version 1 is more comprehensible and clear.

Text:

- **Para 1.**

A - The phrase " foods obtained by GM/GE" is not meaningful and different , so it is suggested to change the underlined phrase to the title or be changed as follows:

Foods derived from GM/GE techniques.

B - The standards and guidelines should be completed. For example the CAC for the sixth guideline is as follows:

" GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS PRODUCED USING RECOMBINANT-DNA MICROORGANISMS, **CAC/GL 46-2003**"

And the following guideline should also be added to the list:

"GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS, CAC/GL 68-2008"

- **Para 3:**

as far as we considered, the codex guidelines (CAC 45, 46 and 86) addressed the method of conducting risk assessment of foods derived form GM/GE techniques, not the **safety aspects** or any provisions for safety of these products, therefore it is suggested that the sentence be changed or deleted.

- **Para 5:**

The sentence is ambiguous!

As it is mentioned in Para 4, according to codex guidelines, transfer of genes from commonly allergens is not allowed unless it is documented that it doesn't code for an allergen, furthermore if any protein is found in new food which has a certain homology of proteins in new food with common allergens, the food would not be approved as a safe food. Such a food should not be marketed; therefore the sentence is not needed.

- **Para 6:**

The paragraph may not be applicable to GM products, since according to international guidelines, it should be proved that a GM product is **Equivalent** to its traditional non GM parents by SE method.

- **Table 1.**

The provisions mentioned in the table have been addressed in above paragraphs, so there is no need for an extra table. It might be confusing.

Para 4.2.2 is not necessary due to the reasons addressed in **para 5.**

The GM foods have their own obligations about allergens, so further provisions may lead to inconsistency.

JAPAN:

Japan would like to propose the amendment of draft recommendations. Point is as below.

1. No significant difference is found between Chapeau version 1 and 2. We recognize that Chapeau version 2 was the achievement of 38th CCFL facilitated lunchtime session. As a result, compare to Chapeau version 1, Chapeau version 2 includes more countries' point of view. Therefore, we would like to take up Chapeau 2. For details, see explanation in box No.1.

2. Original paragraph 1-10 only recall existing Codex standards and related text. Therefore, we would like to fuse together plural paragraphs and simplify the document. For details, see explanation in box No.2 and No.3.

3. We would like to insert new paragraph 5. Because labeling both "GM" and "cleared the safety assessment" will avoid misleading for consumers. For details, see explanation in box No.4.

4. To the foods that are deemed equally safe, all the codex labeling standards should be applied in an equitable manner irrespective of GM or non GM. Therefore, we would like to delete original table 1. For details, see explanation in box No.5.

Proposed changes to the documents

Below are our proposed addition (in underlined) and deletion (in struck-out). In box some explanatory notes on our proposals are presented in red.

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (At Step 3 of the Procedure)

~~*[**Chapeau version 1:** The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. It also recognizes that each country can adopt different approaches regarding labelling of foods derived from modern biotechnology. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.]*~~

*[**Chapeau version 2:** Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are available, ~~the purpose of~~ this document ~~is~~ only ~~to~~ recall**s** and assemble**s** in a single document ~~some~~ important elements of guidance from existing Codex texts, which are relevant for the labelling of foods derived from modern biotechnology. This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.]*

Box No.1
Comments: No significant difference is found between Chapeau version 1 and 2. We recognize that Chapeau version 2 was the achievement of 38th CCFL facilitated lunchtime session. As a result, compare to Chapeau version 1, Chapeau version 2 includes more countries' point of view. Therefore, we would like to take up Chapeau 2.
The Chapeau proposals are made for the sake of simplicity.

[Text as annexed to report of the 36th Session of the CCFL:

1. The **labeling of** ~~following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to~~ foods obtained by GM/GE **should be consistent with:**~~]~~
   - The Codex General Standard for the Labelling of Prepackaged Foods~~,~~ (Codex Stan 1-1985)
   - The Codex General Guidelines on Claims (CAC/GL 1-1979)
   - The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
   - **Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)**

2. Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose. They are;
   - Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003)
   - Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
     Annex 1 Assessment of Possible Allergenicity
     Annex 2 Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutrition or Health Benefits
     Annex 3 Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food
   - Guidelines for the Conduct of Food Safety Assessments of Foods ~~Derived from~~**Produced Using** Recombinant-DNA microorganisms **(CAC/GL 46-2003)**
     Annex Assessment of Possible Allergenicity

- **Guideline for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA Animals (CAC/GL 68-2008)**
  Annex Assessment of Possible Allergenicity
- ~~Working Principles for Risk Analysis for Food Safety for Application by Governments~~

Box No.2
Comments to the above two paragraphs:
1) The first part of the paragraph 1 in the present version is drafted to indicate that all the relevant guidelines listed apply to GM foods as well. It covers the first sentence of original paragraph 2 and paragraph 8.
2) The second sentence of original paragraph 2, paragraphs 4 of the original draft are deleted because they are copies of the definition of labeling and paragraph 4.2.2 of The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985).
3) Paragraph 4 in the original draft is deleted as it is the copy of paragraph 43 of Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003).
4) The second sentence of paragraph 3 in the original version is deleted as paragraph 2 in the present version covers it.
5) Paragraphs 7 and 10 of the original version are deleted because they just remind relevance of The Codex General Guidelines on Claims (CAC/GL 1-1979) and The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), which is already covered by paragraph 1 in the present version.

~~2. Codex labelling and other texts apply to foods sold in unpackaged/non-retail containers including those foods obtained through GM GE techniques and sold in such manner. Labelling means "any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal."~~

3. Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption. ~~Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose4.~~

~~4. The Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) states that the "transfer of genes from commonly allergenic foods . . . should be avoided unless it is documented that the transferred gene does not code for an allergen . . .".~~

~~5. The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed (section 4.2.2, GSLPF).~~

~~6~~**4.** When the physical, chemical, or functional characteristics of a food are ~~significantly~~ altered through any means **including use of modern biotechnology**~~(production or processing)~~ **in the way that may affect consumers' choice**, ~~the labelling of~~ such food**s can** be **labeled, where appropriate** ~~appropriately modified from its traditional labelling to ensure that the food is described or presented in a manner that~~ **only if it** is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect. ~~The traditional name of such food may need to be changed or qualified with additional words or phrases to describe the true nature of the food and to avoid misleading or confusing the consumer.~~

Box No.3
Comment: Paragraph 4 in the present version is the fusion of original paragraphs 6 and 9. The original paragraph 9 addresses the consumers' choice. As Chapeau already admits, member countries are taking different labeling measures as regards GM food, and as we know that the consumer choice affects the different decisions, the consumer choice should be addressed. However, the modification that may not concern consumers' choice may not need labeling. Therefore, it follows that "When the physical, chemical, or functional characteristics of a food are altered through any means including use of modern biotechnology in the way that may affect consumers' choice". However, even such labeling should be truthful; therefore it follows that "only if it is truthful and not misleading and not likely to create an erroneous impression regarding its character in any respect."

~~7. In cases where GM/GE modifications result in a claim related to the nutritional properties of the food, the claim language should be consistent with the Guidelines for Use of Nutrition and Health Claims.~~

~~8. The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods.~~

~~9. Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences.~~

~~10. Any representations made on the label or in the labelling of GM/GE foods should be consistent with the GSLPF (Codex Stan 1-1985) and the General Guidelines on Claims (CAC/GL 1-1979).~~

5. When foods are labeled as GM/GE, labeling may also include side by side a statement implying that such GM/GE foods have already cleared the safety assessment in compliance with the Codex guidelines on GM/GE foods, which will provide consumers with more correct information on nature and safety of GM/GE foods.

Box No.4
Comments: Paragraph 5 in the present version proposal logic is below

1) GM foods that have undergone appropriate assessment are deemed as safe as non-GM foods for human consumption.
2) Though GM labelling may satisfy the demands of consumer's right to know and such right may have to be respected, such labeling should not give misleading information as to the safety of GM foods.
3) In order to bridge a communication gap, parallel labeling of "GM" and "cleared the safety assessment" may be worthwhile exploring. The both labellings are factual and unbiased.

Box No.5
Comment: The entire Table 1 in the original version should be deleted. We do not find any necessity of providing GM/GE-specific guidelines if the provisions are the same for GM/GE and non-GM/GE. To the foods that are deemed equally safe, all the codex labeling standards should be applied in an equitable manner irrespective of GM or non-GM.

~~**Table 1. Provisions in existing Codex labelling texts that apply to the labeling of GM/GE foods**~~
~~**Section Mandatory Labelling Provisions**~~
~~***General Standard for the Labelling of Prepackaged Foods***~~
~~3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.~~
~~3.2 Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.~~
~~4.1.1 The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.~~
~~4.1.2 There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packaging medium, style, and the condition or type of treatment it has undergone; for example, dried, concentrated, reconstituted, smoked.~~
~~4.2.2 The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared.~~

~~When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.~~

~~**Section Voluntary Labelling Provisions**~~
~~***General Standard for the Labelling of Prepackaged Foods***~~
~~7.1 Optional labelling – Any information or pictorial device written, printed, or graphic matter may be displayed in labelling provided that it is not in conflict with the mandatory requirements of this standard and those relating to claims and deception given in section 3 – General Principles.~~
~~***General Guidelines on Claims***~~
~~1.2 The principle on which the guidelines are based is that no food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.~~
~~1.3 The person marketing the food should be able to justify the claims made.~~
~~2 Definition – For the purpose of these guidelines, a claim is any representation which states, suggests, or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, production, processing, composition or any other quality.~~
~~3.3 Prohibited claims – Claims which cannot be substantiated.~~
~~3.5 Prohibited claims – Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.~~

~~4.1 Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives.~~
~~5.1(iii) Conditional claims – Terms such as "natural," "pure," "fresh," "home made," "organically grown," and "biologically grown" when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.~~
~~5.1(v) Conditional claims – Claims that a food has special characteristics when all such foods have the same characteristics, if this fact is apparent in the claim.~~
~~5.1 (vi) Conditional claims – Claims which highlight the absence or non-addition of particular substances to food may be used provided that they are not misleading and provided that the substance:~~
~~(b) is one which consumers would normally expect to find in the food;~~
~~(d) is one whose presence or addition is permitted in the food.~~
~~*Guidelines for Use of Nutrition and Health Claims* "]~~

KENYA

General comment

Kenya would like to submit the following comments to the physical working group for consideration. We apologize for the delay and hope that our comment will be very helpful to the group and the forthcoming codex committee on food labelling to be held in May 2011.

Specific comment

We propose the title of the draft to be amended as indicated below to be in consistent with the body of the draft throughout the text.

PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS and food ingredients derived from modern biotechnology ~~**AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING.**~~

Specific Comment

Kenya has read the two different chapeau circulated to codex member countries and found chapeau 2 to be more appropriate with some amendment as indicated below. It was noted that the word 'only' and the last sentence need to be deleted for the reasons /justification mentioned herein.

We therefore indicate below how the chapeau 2 would finally read.

Chapeau version 2: *Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are available, the purpose of this document is to recall and assemble in a single document some important elements of guidance from existing Codex texts, which are relevant for the labelling of foods derived from modern biotechnology.*

*[**Chapeau version 2:** Acknowledging that different approaches regarding labelling of foods derived from modern biotechnology are available, the purpose of this document is ~~only~~*

Justification for deleting the word 'only'*:*
having the word 'only' weakens the recommendation and limits the document to the assembly) to recall and assemble in a single document some important elements of guidance from existing Codex texts, which are relevant for the labelling of foods derived from modern biotechnology.

Justification for deleting the last sentence:
~~*This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production.]*~~

This emphasis has been taken care of by the acknowledgement of availability of different approaches Furthermore food derived from modern biotechnology are not the same with conventional foods and that is why codex has developed risk assessment guidelines.

2.Text as annexed to report of the 36th Session of the CCFL:

Specific Comment
The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by foods derived from modern biotechnology ~~.by GM/GE:] –~~

Specific comment: ***Kenya proposes to replace the initial GM/GE with 'food derived from modern biotechnology' throughout the text/document.***

Specific Comment

Secondly, Kenya is in agreement with the codex text annexed to the report of 36th session of CCFL to be made reference to where applicable.

MALAYSIA

i) Chapeau version 1 and 2

Malaysia has no objection to both Chapeau version 1 and 2. However, Malaysia would like to propose the following amendments for consistency:

[Chapeau version 1*: The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods ~~derived from~~* ***obtained through*** *modern biotechnology. It also recognizes that each country can adopt different approaches regarding labelling of foods ~~derived from~~* ***obtained through*** *modern biotechnology. This document is not intended to suggest or imply that foods ~~derived from~~* ***obtained through*** *modern biotechnology are necessarily different from other foods simply due to their method of production.]*

*[****Chapeau version 2****: Acknowledging that different approaches regarding labelling of foods ~~derived from~~* ***obtained through*** *modern biotechnology are available, the purpose of this document is only to recall and assemble in a single document some important elements of guidance from existing Codex texts, which are relevant for the labelling of foods ~~derived from~~* ***obtained through*** *modern biotechnology. This document is not intended to suggest or imply that foods ~~derived from~~* ***obtained through*** *modern biotechnology are necessarily different from other foods simply due to their method of production.]`*

ii) Paragraph 5

Malaysia proposes to add a new paragraph after Para.5 (new Para. 5 Bis) to address concerns related to dietary restrictions based on religious concerns or cultural practices. This proposal is also in line with Para. 32 under item Risk Management of the the Proposed Draft Working Principles for Risk Analysis for Food Safety adopted at the 31st CAC:

"32. The decisions should be based on Risk Assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles as they relate to decisions at the national level. National Governments should base their sanitary measures on Codex standards and related texts, where available."

Hence, the Paragraph 5 shall read as follows:

"5. The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in section 4.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed (section 4.2.2, GSLPF). ***In cases where GM/GE modifications involve dietary restrictions, related to religious concerns or cultural practices, the label should clearly indicate the GM/GE modifications involved."***

NEW ZEALAND:

New Zealand is pleased to provide the following comments in response to CL2010/19-FL.

New Zealand has participated in the discussions on GM labelling over the past decade. We have been active members at all of the inter sessional workshops including Oslo (2007) and Ghana (2008). Although New Zealand did not and does not support continued work on this agenda item we did support the collation of Codex texts that were applicable to GM foods as a way of meeting the needs of those countries seeking extra guidance in managing GM labelling in their countries.

As an overall comment New Zealand believes that the essence of what is being proposed and what countries are expecting from the texts now under discussion may be at odds. Clarification is needed to ensure that all members are aware that the collation of texts is not a standard or guideline and does not

introduce any new text. It was merely proposed as a convenient way for members to work with relevant Codex texts (as of 2008).

The continuing discussions over last two sessions of CCFL to try and agree on an introductory chapeau now mean that the collation of Codex texts is already outdated.

New Zealand remains concerned that the efforts of the Committee would be better focused on issues where there is potential for a coordinated approach and for impact on global health and safety. We therefore restate our position that as the Committee is unable to come to a harmonised position on the labelling of foods or food ingredients obtained through genetic modification/genetic engineering that work should not continue on this agenda item. It is also worth noting that the Executive Committee stated as far back as June 1996 in the context of discussion on labelling of foods derived from biotechnology that the 'claimed right to know was ill defined and variable and in this respect could not be used by Codex as the primary basis of decision making on appropriate labelling. Furthermore the Commission's rules of procedure is clear that work should not proceed where no basis for consensus exists (see Procedural Manual, 19th Edition, *Measures to facilitate consensus*, p 183)

New Zealand strongly recommends that if discussions do continue on the texts currently under discussion, the Committee should clarify the purpose of the document. We believe that there may be some countries that understand that CCFL is working on new labelling guidance for GM foods and are not familiar with outcomes and history that underpin this work to date. If the collation of texts is not going to provide any useful practical assistance to countries and if there is not a process of keeping the collation current and up to date it would appear to serve no useful purpose for members.

We have made specific comments on the texts outlined in the circular letter should discussions progress to this level.

Regarding the chapeau New Zealand continues to prefer a simple statement of the purpose of the document. We do not support any reference to countries being able to **adopt** different approaches (as in chapeau 1) as it is not the purpose of Codex to determine what may be adopted at the national level.

We could however support chapeau 2 notwithstanding our reservations about it being unnecessarily wordy which only adds confusion to the purpose of the text.

New Zealand does not support the current name of the document and should work continue would recommend a change in name to reflect the content of the text.

There has been interpretation made of some of the Codex texts in the points outlined that is potentially ambiguous and would raise concerns for New Zealand and raises broader questions about the value of such a document that purports to provide guidance to members.

Under the points of the text:

1) Refers to a number of particular standards and related texts. This list is now out of date and **if** work progressed should be updated to include:

- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (CAC/GL 68-2008);
- Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for the Special Dietary Uses

There would also need to be an agreed process for keeping this list up to date or a statement to the effect that the list is up to date to a particular date.

6) Reference to "significantly altered" and "avoid misleading consumers" are also within the realm of different global interpretations. New Zealand does not support inclusion of this point.

9) New Zealand does not support inclusion of this dot point as it refers to the issue of most dissension regarding GM labelling – that of consumer choice. We would support deletion of (9) as it adds no substance to the guidance but adds to the confusion regarding a global approach to consumer choice.

NORWAY

Norway appreciates the invitation to comment on the Circular Letter 2010/19-FL and the fact that CCFL has supported proceeding with work on the basis of the draft Recommendations.

General Comments

Norway strongly believes that CCFL should fulfil the task as requested by the Codex Alimentarius Commission in 1991 and complete its work on these recommendations. Many countries and consumers world-wide, including many developing countries, have a great interest in Codex guidance on this topic. Some countries have already established labelling regulations, others are not interested in doing such, and many countries have not yet established labelling rules but intend to do so - but are still waiting for more specific guidance from Codex.

For us, the main objective for establishing Codex recommendations for labelling of GM foods, is that Codex should ensure fair practices in the food trade regarding labelling of GM foods. The draft Recommendations in CL 2010/19-FL contain **"**Text as annexed to report of the 36th Session of the CCFL", which is based upon a background paper produced by the United States of America, Canada and Nigeria, where the goal is to describe existing Codex standards and related texts that may be applied to GM foods. In the "Text as annexed to report of the 36th Session of the CCFL", different approaches are listed, but the list seems **incomplete** from our point of view. Norway does not find the present text fully sufficient for the purpose of ensuring fair practices in the food trade regarding labelling of GM foods.

We would like to highlight a very important issue, which is reflected in the "Chapeau version 1" of the draft – *the recognition of the fact that each country can adopt different approaches regarding labelling of GM/GE foods*.

Consumers' needs and preferences may vary in different regions of the world, and these differences might lead to a variety of approaches regarding labelling of GM foods.

We would like to call attention to one important labelling approach that we think is not described sufficiently in the present text in the draft Recommendations: Labelling based on the production method of the food, irrespective of changes in the final product, for instance detectable DNA or protein resulting from the genetic modification. This approach has been applied in Norwegian GM labelling regulations since 1997. The rationale for this approach is that our consumers require to be informed if GM techniques are used in the production of the food, and the Norwegian authorities recognize the consumers'right to make an informed choice.

A similar approach has been established in Codex with regard to "organically produced foods", the use of the term "halal", and also for "irradiated food".

In order to make a clear description of this approach, we would like to propose amendments in the "Text as annexed to report of the 36th Session of the CCFL", as described under "special remarks on the draft".

As regards the "Chapeau", the proposed draft Recommendations contain two different versions of the Chapeau. We would however prefer the following version (called "Chapeau 2 as amended by Brazil") proposed by Brazil at the CCFL meeting in May 2009:

" The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques. It also recognizes that each country can adopt different approaches regarding labelling of foods obtained by GM/GE techniques and that food labelling is the primary means of communications between the seller on the

one hand and the purchaser and consumer on the other."

Our main comments on the "Chapeau version 1"in the proposed draft Recommendations, are that it is not as clear as "Chapeau 2 as amended by Brazil" and the following sentence may also confuse the reader:

"This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production."

The confusion may arise from the word "different", as there exist at least two interpretations of the word "different".

One interpretation of the word "different" may be that GM foods are not **different from other food in quality/chemical composition**. In some cases this is true, as for instance certain oils derived from a GMO may not differ in chemical composition of, for instance, detectable DNA or protein resulting from the genetic modification. In other cases this it not true, as for certain GM food products with a changed quality and/or where they contain chemical constituents which originate from the genetic modification.

A second possible interpretation of the word "different" may be that GM foods should not be treated as **different regarding risk analysis**, compared to conventional food. We think that this second interpretation is totally wrong. In the "Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology"**,** Codex itself has treated GM foods as different in risk analysis for many years**.**

We do not support the text in the "Chapeau version 2" in the proposed draft Recommendations, mainly because the text does not include the recognition of the fact that each country can adopt different approaches regarding labelling of GM/GE foods.

But, for achieving consensus, and to build upon the compromise work done at the last CCFL meeting, we can however support "Chapeau version 1" in the proposed draft Recommendations, **but only under certain provisions** – as described under "special remarks on the draft".

Special remarks on the draft

Provided that the approach with regard to production method is described in the "Text as annexed to report of the 36th Session of the CCFL", Norway can support "*Chapeau version 1*" as it stands.

Our proposal for amending the text of the draft is as follows:

Amendment of paragraph number 9 to read (proposed new text is written in ***bold italics***):

"9. Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences. ***Some texts are established to meet the needs of certain consumers to be informed about use of specific production methods. This type of labelling approach is used, for instance, for "organically produced foods", for the use of the term "halal" and for "irradiated food". This approach may also be used in GM/GE labelling of food products obtained through certain techniques of genetic modification/genetic engineering, irrespective of changes and differences in composition and quality of the final product, compared to other conventional non GM/GE foods****."*

PANAMA

At the present time there is no consensus in Panama if the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering should be compulsory or voluntary.

However, we recognize the right of consumers to be informed about the products they consume and, as a Codex signatory country, we welcome its standards, guidelines and recommendations on our national legislation through Executive Order 331 of July 22, 2008 and Executive Order No. 11 of February 22, 2006.

In the evaluation of the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (ALINORM d10/33/22 paragraphs 159 to 161, Appendix X (Step 3), the national position would be focused in ensuring that this guideline does not establish a biased difference between (conventional) food products and those products obtained through modern technologies, which is the reason we consider that the reference guidelines must maintain for both cases the specific indications of nutritional and allergenic nature 4.2.1.4 and 4.2.2, or when the physical, chemical or functional characteristics have been significantly altered by any (production or manufacturing) means mentioned in the Draft Proposal.

It should be pointed out that Panama is a member of the Biodiversity Convention and of the Cartagena Protocol and that it counts with Act 72 of the 26 of December 2001 ratifying the Cartagena Protocol on Biosafety to the Convention on Biodiversity and with Act 48 of the 8 of August 2002 which creates the National Biosafety Commission for Living Modified Organisms (LMOs) and establishes other standards.

- Act 48 includes provision for health, agricultural and environmental sectoral committees.
- It also indicates the need of the country of capacity building for the analysis, evaluation and risk management, and identification techniques for LMOs and GMOs, as well as the need to strengthen administrative and standard setting structures to regulate this issue. It also points out the need of increasing human resource capacity at the government level as well as consumer education.
- To formally establish the National Biosafety Commission and thus nominate, at the national level, representatives from the private sector and from civil society.

- The formulation of a national integrated policy proposal is presently being evaluated for the development of biotechnology and biosafety, and for the integration of the country to the Latin American Network for the detection of LMOs.

UNITED STATES OF AMERICA

The United States is pleased to offer the following comments regarding the proposed draft Recommendations for the Labelling of Foods and Food Ingredients obtained through Certain Techniques of Genetic Modification/Genetic Engineering (ALINORM 10/33/22 paras. 159 to 161 and Appendix X).

In preparing comments the US reviewed the original objective of the Codex Alimentarius Commission for this work. In 1991, the Commission requested the Codex Committee on Food Labelling (CCFL) "to provide guidance on how the fact that a food was derived from modern biotechnologies could be made known to the consumers. The need to provide consumers with sound, scientifically based information which explained the application of biotechnology in food production and processing and clarified the safety issues was stressed." (ALINORM 91/40, paras. 90, 91).

The U.S. believes that to the extent possible within Codex this objective has been met. In the Codex *General Standard for the Labelling of Prepackaged Foods* (GSLPF, Codex Stan 1-1985), specific recommendations for the labelling of foods derived through modern biotechnology when such foods contain allergenic proteins have been included (GSLPF, Section 4.2.2). Additionally, CCFL reviewed a Background Paper[3] prepared by the United States, Canada, and Nigeria that explains how current Codex texts relate to the labelling of food and food ingredients obtained through certain techniques of genetic medication/genetic engineering. The paper explains, among other things, how Codex labelling texts contain provisions to protect consumers from false and misleading labelling information and provides advice to governments on the use of existing Codex text in this context.

Stopping work at this point is an appropriate action and logical step in the Codex process because CCFL can point to section 4.2.2 of the GSLPF and the Background Paper as ways that the original objective of the Commission for the work has been met. In this context the work that is feasible for Codex has been completed. Consensus was not reached on work by CCFL on a guideline for labeling foods derived through modern biotechnology, work which was discontinued in 2008. Additionally, CCFL has not been able to reach consensus on the current text which replaced the discontinued work. Guidance in the Codex *Procedural Manual* clearly states that work should not proceed where no basis for consensus exists.[4] . For these reasons the US restates its objections to continued work on this agenda item. It should be noted that there are other examples where Codex has discontinued work on certain standards and guidelines because consensus was not achievable (e.g. Parmesan cheese).

The US would comment that a key reason for the lack of the ability to reach consensus on Codex guidance for the labelling of foods derived from biotechnology lies in the different approaches to this area amongst countries, a fact that became clear in discussions that took place at the Oslo Working Group meeting held in 2008. In regards to this aspect, the US would call attention to the Codex *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle*[5], and, in particular, the following two factors: a) "recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide"; and, b) "only those factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex". The US would suggest that both of these factors have applicability to the Codex work on biotech labelling and support the discontinuation of work on this subject in CCFL.

The US recognizes interest from other delegations to continue work on the current document that summarizes key concepts from the Background Paper. However, we recommend that, if a need exists for a reference document, the Background Paper in its entirety be used as a more complete and useful document for national authorities. The document could also be used by FAO and WHO for development of outreach on labeling of foods. However, if the committee continues to work on the summary document, the US believes that the following objectives need to be achieved:

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[3] See CL 2007/39-FL, Annex 1: *Background Paper on the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering*

[4] Codex *Procedural Manual*, 18th ed., Guidelines to Chairpersons, p. 77; see also Measures to Facilitate Consensus, p. 183).

[5] Codex *Procedural Manual,*18th ed., pp. 180-181.

- The purpose of the document is to summarize existing Codex texts, not to introduce new concepts or principles.
- Statements in the document need to reference existing Codex texts and be consistent with those texts (i.e. Codex texts do not contain provisions for mandatory process/method of production labeling).
- That certain statements in the summary document were taken out of context from the Background Paper and need to be revised to provide relevant context.
- The document should not recognize, acknowledge, endorse or validate existing government approaches since such actions are not the purpose of Codex or within its scope.
- The title must be revised to be consistent with the nature of the text.
- If consumer preference is referenced in the document, it should only be in the context of claims, given the Codex Executive Committee opinion[6] that the claimed right to know is ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labeling.

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the above-referenced *Proposed Draft* document. BIO is the world's largest biotechnology organization, providing advocacy, business development and communication services for more than 1,100 members worldwide. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multinationals. We also represent state and regional biotechnology associations, service providers to the industry, and academic centers. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology. Many BIO members use biotechnology to improve the agronomic, nutritional, and other properties of plants and animals for food, feed, fiber and bioenergy.

BIO delegations have consistently participated in the work of Codex Alimentarius Committees, Working Groups and Tasks Force covering food and feed standards development related to agricultural biotechnology. We note that within almost two decades of discussion in the Codex Committee on Food Labeling (CCFL), no progress has been made to advance the status of guidance, recommendations or language associated with product labeling of foods obtained through certain biotechnology techniques, in spite of a number of targeted attempts to do so. In this time period, CCFL has convened five working groups, held inter-sessional discussions, and conducted prolonged intra-sessional discussions and dialogues without progress on issues pivotal to the development of guidance. Specifically, no consensus has emerged on the scope of the work, the rationale for conducting the work, or the objective of the work and potential guidance it might offer to consumers.

In November 2010, Codex is convening a working group for CCFL in a further attempt to make progress on this topic. In preparation for this meeting, the CCFL Chairman has specifically requested interested delegations to provide in their comments "a very clear rationale with respect to their objectives in relation to their proposals for changing text ……" We strongly support the Chairman in this approach since Step 3 text has been before CCFL for over 10 years with no progress on further elaboration. At the core of the process is fundamental disagreement on the scope of the work (circumstances under which labeling text might be used) and the objectives for developing such text in Codex. The rationale and intent for supporting a certain position must be fully explored before any progress might be made on text to further guide members in labeling of foods derived from modern biotechnology.

BIO proposes that CCFL discontinue work on this issue. Our rationale with respect to our objective for this proposal is very clear. The General Standard for the Labeling of Prepackaged Foods [Codex Stan 1-1985 (Rev. 1- 1991)] applies to the labeling of all prepackaged foods to be offered as such to the consumer. Terms within the Standard are defined, provisions for sharing of information detailed, and elements required for protection of consumer health and fair trade in foods elaborated. There is no fundamental difference in foods and food ingredients derived through the use of biotechnology from foods in the marketplace globally. Existing Codex standards, including the Codex Guidelines for Use of Nutrition and Health Claims [CAC/GL 23-1997 (Rev. 1-2004)] provide specific guidance for provision of information on food labels, as well as specific considerations when some type of nutrition or health claim is to be made by a food manufacturer. Therefore, existing Codex standards

[6] The Codex Executive Committee noted opinions that consumers may claim the right to know that foods had been prepared by certain techniques of genetic modification/genetic engineering. However, the Executive Committee stated that the claimed right to know was ill-defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling (ALINORM 97/3).

and related texts for labeling foods and food ingredients are appropriate for all prepackaged foods to be offered to the consumer, including those derived from modern biotechnology.

BIO continues to support those delegations that believe it is an inappropriate use of CCFL resources and time to continue work in this area when existing Codex text is appropriate for such labeling considerations. BIO strongly urges CCFL to discontinue work on this topic.

We appreciate the opportunity to provide these comments and very much look forward to active participation in the November 2010 discussions. However, we firmly believe that this area of work should be discontinued so that resources can be committed to priority areas where there is a demonstrated need, and also where consensus is possible.

CONSUMERS INTERNATIONAL

Summary

Consumers International (CI) appreciates the opportunity to comment on CL 2010/19-FL. CI welcomes the fact that the Codex Committee on Food Labeling (CCFL) has supported continued work on the important issue of labelling of foods derived from certain techniques of genetic modification/genetic engineering (GM/GE) and feel that the text elaborated by the Working Group in Ghana, which forms the basis for the *Proposed Draft Recommendations* put forward at Step 3, is a good starting document, with the suggested change of para 3 of that text, as noted in the detailed comments below.

The latest draft proposed recommendations are basically sound as written, with the changes CI proposes below, and should be advanced in the step process. CI has two main objectives in the comments we provide below. The first objective is to have CCFL issue some form of recommendations on the labeling of GE/GM foods to fulfill the mandate given to CCFL by the Commission in 1991: "to provide guidance on how the fact that a food derived from 'modern biotechnologies' can be made known to the consumers." The second objective is to obtain recognition that approaches to labeling in various regions of the world may differ for a variety of reasons, including differing religious/cultural reasons, but may still be consistent with existing Codex texts on food labeling.

In terms of our rationale for these two objectives, our analysis of Codex texts, particularly those associated with genetic engineering/genetic modification—the Principles for Risk Analysis of Foods Derived from Modern Biotechnology and Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 44, 45; 2003)—as well as Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account, demonstrates that labeling of foods and food ingredients obtained by genetic engineering/genetic modification can be undertaken either as a risk management measure, or to take account of "other legitimate factors" such as religious/cultural reasons, environmental factors, animal welfare, or public health.

Detailed comments

Of the two proposed Chapeaus developed during the 38th Session of CCFL, CI supports Chapeau 1, with the deletion of the third sentence (which we believe is not a true statement), because it clearly and succinctly states the purpose of the document and that there can be various approaches to labeling among member countries: *"The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques. It also recognizes that each country can adopt different approaches regarding labelling of foods derived from modern biotechnology."*

We believe that the third sentence in Chapeau 1—"*This document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production."*—should be deleted because we feel it is not true. First, GM/GE food is clearly different from conventional food, as can be seen from the fact that Codex has developed Guidelines for the safety assessments of such foods (e.g. CAC/GL 45-2003, CAC/GL 46-2003, and CAC/GL 68-2008). Although the Chair "clarified" that GM/GE foods that have been approved as a result of the use of the Codex safety assessment guidance are recognized to be as safe as their conventional counterparts, this does not mean that there are no differences GM/GE foods that could necessitate labeling. For example, if a gene from an animal was put into a crop plant (such as the Arctic flounder gene inserted into tomatoes, or the scorpion gene inserted into corn plants), labeling might be required so that vegetarians could avoid such foods. If a gene from pigs was engineered into plants, kosher Jews and halal Muslims would want to be made aware of that fact. So, it would be appropriate to label such foods for their source of proteins, even though such GM/GE foods would be considered to be as safe as their conventional counterparts, assuming they had been assessed according to the Codex Plant Guidelines. Since conventionally produced plants do not contain genes from pigs or other animals, such labeling would not be needed.

Labeling of foods and food ingredients produced via GE/GM due to religious/culture or ethical reason could be permitted due to so-called "other legitimate factors" (OLFs) in Codex. Codex texts clearly state that these "other legitimate factors" can be used during risk management phase and that labeling is a valid use for such OLFs. The Codex Alimentarius Commission's *Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors Are Taken into Account* states: "When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices if food trade. In this regard it is noted that food labeling plays an important role in furthering both of these objectives"[7]. Furthermore, the objectives of the Codex Intergovernmental Task Force on Foods Derived from Biotechnology includes consideration of such OLFs: "To develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and *having regard, where appropriate, to other legitimate factors relevant to the health of consumers and promotion of fair trade practices*"[8] *italics* added. Clearly, religious/cultural concerns constitute one such OLF. The labeling of GM/GE foods derived from plants with genes from animals would help further the "promotion of fair trade practices," as vegetarians assume the plant food they eat does not contain animal genes, while kosher Jews and halal Muslims assume the plants they eat contain no genes from pigs.

Second, we believe that two key Codex texts developed by the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Modern Biotechnology support/permit the labeling of foods derived from certain techniques of genetic modification/genetic engineering.

The Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) clearly state that labeling can be used as a risk management option to deal with scientific uncertainties associated with the risk assessment of GE/GM foods: "18. Risk managers should take into account the uncertainties in the risk assessment and implement appropriate measures to manage these uncertainties. 19. Risk management measures may include, as appropriate, food labeling, conditions for market approval and post-market monitoring" (pars 18, 19 in CAC/GL 44-2003).

Significant scientific uncertainty exists in the risk analysis of foods derived from GE/GM, and this is recognized in the Codex. In fact, the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants has a whole section on unintended effects which clearly states that they can have an unintended effect on human health: *"Unintended effects due to genetic modification may be subdivided into two groups: those that are "predictable" and those that are "unexpected" . . . A variety of data and information are necessary to assess unintended effects because no individual test can detect all possible unintended effects or identify, with certainty, those relevant to human health.*" italics added (paras 16 and 17, CAG/GL 45-2003). Furthermore, this section recognizes that the unintended effects could also be caused by changes in genes are expressed at the molecular level and how the gene products are processed: "Molecular biological and biochemical techniques (that) can also be used to analyse potential changes at the level of gene transcription and message translation that could lead to unintended effects" (para 16, CAG/GL 45-2003).

New data confirm unintended and unexpected effect from genetic engineering. Other studies in the last 5 years have found all sorts of unexpected changes/effects in GE/GM crops. A detailed molecular characterization of various GE/GM crops[9] (three different Bt maizes, an herbicide-tolerant maize, RoundUp Ready soybean, and a male-sterile canola) currently on the market, done in Belgium, has shown that of the transgenic lines looked at, all but one were found to have differences in the molecular characterization in products on the market compared to the original structure reported by the company. Except for the canola, all these reports found that the structure (e.g. molecular characterization) of transgenic inserts as reported by the companies in their initial submission were different than the structure found in subsequent studies. The differences in structure involved rearranged inserts, partial copies of genes inserted, multiple copies of transgenes inserted, scrambling of DNA near the border of the transgenic inserts, etc., suggesting that the

[7] pg. 164 Codex Procedural Manual, 16th Edition, available at: ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_16e.pdf

[8] pp. 148,149 in Codex Procedural Manual, 16th Edition, available at: ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_16e.pdf

[9] Dr. Moens, with the Service of Biosafety and Biotechnology (SBB) of the Scientific Institute of Public Health (IPH), a government agency reported on the molecular characterization of the genetic map for six transgenic crops: 3 different Bt maizes—Bt 176, Syngenta (www.biosafety.be/TP/MGC_reports/Report_Bt176.pdf); MON 810, Monsanto (www.biosafety.be/TP/MGC_reports/Report_MON810.pdf); Bt11, NorthrupKing (www.biosafety.be/TP/MGC_reports/Report_Bt11.pdf)—a herbicide tolerant maize (LibertyLink maize, Bayer)(www.biosafety.be/TP/MGC_reports/Report_T25.pdf) , glyphosate tolerant soybeans (RoundUp Ready soybeans, Monsanto) (www.biosafety.be/TP/MGC_reports/Report_MON810.pdf) , and a canola engineered for male sterility (Ms8 x Rf3, Bayer Cropscience).

transgenic lines are unstable and/or more likely to result in unintended effects. In fact, in virtually all the cases, the SBB/IPH recommends that further analysis "should be done to determine the presence of chimaeric open reading frames in the border integration sequences", e.g. an analysis should be done to see if there are any unexpected proteins being produced.

An Annex to the Codex Plant Guideline on the assessment of possible allergenicity states that no definitive test exists to accurately predict allergenicity of a given protein: "At present, there is no definitive test that can be relied upon to predict allergic response in humans to a newly expressed protein" (para 2, Annex, CAG/GL 45-2003). So there is scientific uncertainty around assessment of potential allergenicity of foods derived from GE/GM.

Thus, just based on the scientific uncertainty surrounding both the molecular characterization of GE/GM crops as well as the detection of potential allergenicity, there is more than enough uncertainty for a country to decide to require labeling of foods produced via GE/GM as a risk management measure as a way to identify unintended health effects that may occur post approval. If foods are not labeled as to GE/GM status, it would be very difficult to even identify that an unexpected health affect that results from a GE/GM food. Even if the food has undergone rigorous premarket safety testing, the scientific uncertainties associated with the risk analysis and the fact that when a large population (in the millions or tens of millions) is exposed to a GE/GM food, then rare unexpected health problems can appear. Take the case of Vioxx, a drug that was found to be safe in premarket testing but had to be removed from the market after adverse health effects were seen when the drug was used by large numbers of people.

Specific comments on text as annexed to report of the 36th Session of the CCFL

Para 3

In the first line insert the words "obtained from certain techniques of GM/GE" after "food" to clarify the meaning of the sentence (addition in **bold**):

"Labelling of a food **obtained from certain techniques of GM/GE** is considered only after the food has . . ."

CROPLIFE INTERNATIONAL

CropLife International (CropLife) would like to thank you for the opportunity to comment on the document mentioned above. CropLife is a global federation representing the plant science industry and works to address international developments in the areas of crop protection, agricultural biotechnology, and sustainable agriculture.

The discussions at the Codex Committee on Food Labelling (CCFL) have acknowledged that any standard for labelling of foods derived through biotechnology does not serve to address food safety-related issues (ALINORM 10/33/22, para. 140). Food safety is addressed as part of an appropriate risk assessment; regulatory analysis is completed prior to any consideration of labelling and product commercialization. We note that in June 1996, the Codex Executive Committee (CEC) stated that "while consumers may claim the right to know whether or not foods had been prepared by such means, it also noted that the claimed right to know was ill- defined and variable and in this respect could not be used by Codex as the primary basis of decision-making on appropriate labelling."

Codex Alimentarius has adopted several texts related to the safety assessment of genetically modified organisms and several valuable texts related to voluntary claims on pre-packed foods. A background document developed in 2008 by the United States, Canada, and Nigeria reviewed each of these documents and showed that they could be applied to labelling of biotechnology-derived foods, if countries choose to do so.

CropLife strongly urges Codex to discontinue the work on labelling of foods derived through biotechnology and to focus its efforts and resources on addressing issues of public health significance, such as those identified in the WHO Global Strategy on Diet, Physical Activity and Health. We would like to note that after the nearly two decades of debate, an agreement has not been reached in Codex or any other standard-setting body that process-based labelling of foods produced from biotechnology-derived crops is appropriate. Our rationale for support to discontinue this work includes the ample demonstration that Codex text already exists that can be used to inform consumers. CropLife believes that the lack of consensus, as well as the many different approaches to the labelling of biotechnology-derived products around the world — including the conclusion in many countries that labelling is not necessary — are symptomatic of the very politicized nature of the discussion on such labelling and do not permit the development of a common, international guideline.

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

The International Council of Grocery Manufacturers Associations (ICGMA) appreciates the opportunity to provide comments on the proposed draft *Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of GM/GE.* ICGMA, a recognized INGO before the Codex Alimentarius Commission, represents the interests of the consumer packaged goods industry including several hundred food companies that trade food products globally. In this regard, ICGMA strongly supports the work of Codex Alimentarius and promotes the harmonization of scientific standards and policies concerned with health, safety, packaging, and labeling of foods and beverages.

ICGMA member companies have participated in the work of the Codex Committee on Food Labelling (CCFL) for many years and in discussions related to labeling products derived from biotechnology for almost two decades, with no consensus emerging. ICGMA has previously stated that "CCFL should discontinue further work on this topic" and focus Codex' scarce resources on "those items more directly relevant to consumer health such as the implementation of the WHO Global Strategy." ICGMA notes the decision of the 25th Codex Alimentarius Commission and the *Evaluation of Codex Alimentarius Commission and other FAO and WHO Food Standards Work* which stated that Codex should work on issues related to the Protection of Consumer Health as a first priority[10] and that CCFL has recognized that "labelling of foods derived from biotechnology was not intended for health and safety as genetically modified products are evaluated for their safety before being placed on the market."[11]

The text presented in Appendix X of ALINORM 10/33/22 lists the Codex texts applicable to labeling of all food products- including those derived from biotechnology, demonstrating that existing Codex text is sufficient labeling guidance for national governments; further work on the current document would be of limited new value.

ICGMA refers to ALINORM 10/33/22, paragraph 160 which invites delegates to provide a "very clear rationale with respect to their objectives in relation to their proposals for changing text." In this regard, ICGMA questions the construct of the document in its entirety as it is neither a Codex Standard nor Codex Guidance. It is somewhat unclear how delegations would use "recommendations," or the specific status of "recommendations" within Codex. In fact, the text itself does not make specific recommendations or provide guidance on labeling.

Regarding the text within the Chapeaus, both (although in different words) defer to national "approaches." For this reason, ICGMA does not support either proposed chapeau. In comments filed in August 2010, related to Note 161, ICGMA stated, "the Codex system should not encourage government delegations to defer to national legislation without providing substantive reasons or technical justification." Deferring to national approaches undermines the scientific basis of Codex and the foundation of Codex as an international standard setting organization."

If an introductory chapeau is deemed necessary, ICGMA prefers to revert to the fact-based text originally introduced by the U.S.: "The purpose of this document is to recall and assemble in a single document some important elements from Codex texts which are relevant for foods obtained by GM/GE techniques as they are for all foods…."

ICGMA has no specific comments on the remainder of the text except to note that much of this text has been derived from a discussion document presented at the 2008 CCFL working group meeting in Ghana, and represents a reiteration of what exists in Codex text with respect to labeling provisions for prepackaged foods. As some of the text has been shortened and taken out of context, ICGMA believes the original background document presented in Ghana is a better informational tool for delegations than the text currently under consideration.

INSTITUTE OF FOOD TECHNOLOGISTS (IFT):

The Institute of Food Technologists (IFT) exists to advance the science of food. Ourlong-range vision is to ensure a safe and abundant food supply contributing to healthier people everywhere. Founded in 1939, IFT is a nonprofit scientific society with over 18,000 individual members working in food science, food technology, and related professions in industry, academia, and government. IFT champions the use of sound science across the food value chain through knowledge sharing, education, and advocacy, encouraging the exchange of information, providing educational opportunities, and furthering the advancement of the profession. As an international non-governmental organization with observer status with the Codex

[10] Report of the 25th session of CAC, July 2004

[11] ALINORM 04/27/22 Reports of the 32nd session of the CCFL, May 2004

Alimentarius Commission, IFT appreciates the opportunity to provide comment on the Proposed Draft Recommendations for the Labeling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/ Engineering.

IFT agrees with the Proposed Draft Recommendations for the Labeling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/ Engineering and recommends that Chapeau version 2 be accepted for the following reasons. IFT has been privileged to be present during many of the past discussions on this important topic. IFT does not support mandatory labeling of food or food ingredients based solely on the method of production (process-based labeling). IFT is also of the opinion that current Codex standards and texts presented as Table 1 in Appendix VII of ALINORM 09/32/22 sufficiently address the needs expressed by member countries with respect to the labeling of such food and food ingredients and clearly set forth how existing texts can protect consumers from false and misleading labeling information and the criteria for voluntary labeling.

As noted in prior Codex Committee on Food Labeling (CCFL) meetings, IFT reiterates support for mandatory labeling *only* for significant, objective, measurable, and verifiable differences between biotechnology-derived foods and their conventional counterparts. IFT convened a panel of distinguished scientists to address the issues of labeling, safety, and benefits and concerns regarding foods derived through modern biotechnology. An Executive Summary of the IFT Expert Report and other accompanying backgrounders are accessible at: http://www.ift.org/Knowledge-Center/Read-IFT-Publications/ScienceReports/Expert-Reports/Biotechnology-and-Foods.aspx

Given the lack of consensus during many years of deliberations, coupled with the lack of a scientific basis for mandatory labeling of food or food ingredients based solely on the method of production (i.e., genetic modification/ engineering process-based labeling), IFT believes it is time to discontinue work on this issue. Limited Codex resources can be more effective if devoted to public health priorities, such as the WHO Global Strategy on Diet, Physical Activity and Health. By doing so, CCFL will conform to the directives of the Codex Alimentarius Commission to work on issues related to the protection of consumer health as a first priority.