codex alimentarius commission





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AGENDA ITEM NO.6

CX/FL 09/37/10



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING THIRTY-SEVENTH SESSION CALGARY, CANADA, MAY 4 - 8, 2009

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 INGREDIENT OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (CL 2008/11-FL, ALINORM 08/31/22 – APPENDIX VII, & CL 2007/38/FL)

GOVERNMENT COMMENTS AT STEP 3

COMMENTS FROM:

AUSTRALIA
BRAZIL
COLOMBIA
EUROPEAN COMMUNITY
JAPAN
MEXICO
NEW ZEALAND
NORWAY
UNITED STATES

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

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 INGREDIENT OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING:

(CL 2008/11-FL, ALINORM 08/31/22 – APPENDIX VII, & CL 2007/38/FL)

GOVERNMENT COMMENTS AT STEP 3

AUSTRALIA:

Australia is pleased to submit the following comments to Part B, item 5 of CL 2008/11-FL.

Australia considers that national authorities should be responsible for the provision of labelling for consumer information. This allows the specific information needs of a population to be taken into account.

- Australia does not support the Chapeau 1 statement. These statements extend beyond the intent of the document and include assertions which did not achieve consensus when discussed by the Codex working group. Furthermore, in Australia's view the wording of the second sentence 'Labelling of food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption.' could be misleading. The statement refers to GM food, but implies that all food that is labelled is inherently safe.
- Australia prefers Chapeau 2 as it succinctly presents the purpose of the document and reflects
 the possible application of current Codex texts to the labelling of foods obtained by GM/GE
 techniques. . In order to add some clarity to the chapeau Australia would propose rewording
 it to read
 - 'The purpose of this document is to recall and assemble in a single document some important elements of existing Codex standards and texts that provide guidance to members regarding the labelling of foods and food ingredients obtained through certain techniques of GM/GE.'
- We suggest a final concluding point (point 11) stating that existing Codex standards and texts on labelling provide adequate guidance regarding labelling of GM foods.

BRAZIL:

The Brazilian Delegation thanks for the opportunity to present the following comments on CL 2008/11-FL.

Brazil recognizes the contributions provided by the Oslo and Accra Working Groups that were established in order to assist the Codex Committee on Food Labelling with guidance on the labelling of foods and food ingredients obtained through certain techniques of GM/GE.

We understand that no country should be prevented from taking measures necessary to ensure its food quality or for the protection of human health or for the protection of its essential interests such as the consumers' right to clear and accurate information.

Developing countries may encounter difficulties in the formulation of regulations related to the labelling of foods obtained through GM/GE. In this sense the Codex Alimentarius texts are important tools to guide countries in the formulation of their regulations.

We recognize the countries experiences and the legitimacy of the different approaches adopted in the labelling of GM/GE foods according to regulatory framework, cultural characteristics, and consumers' needs such as dietary restrictions.

Therefore we understand that the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of GM/GE should recognize these differences and should not prevent the utilization of different approaches.

We are in favour to insert a provision to provide certain flexibility to national governments. It would allow each country to adopt the most adequate labelling approach according to its reality.

We suggest the following text to the chapeau:

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.

COLOMBIA:

1. Document or Subject: Draft Amendment to the General Standard for the Labelling of Prepackaged Foods (Draft Recommendations for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering) Definitions (At Step 7 of the Procedure) ALINORM 05/28/22 APPENDIX III

PARAGRAPHS	POSITION PROPOSAL	OBSERVATIONS OR COMMENTS
"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified /	"Food and food ingredients obtained through certain techniques of genetic modification / genetic engineering" means food and food ingredients composed of or containing genetically modified /	We suggest that the definitions should as much as possible correspond to those already established in multilateral agreements or treaties such as the Cartagena Protocol or the
engineered organisms or their parts obtained through modern biotechnology, or food and food ingredients	engineered organisms or their parts obtained through modern biotechnology, or food and food ingredients	FAO glossary on biotechnology

produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.	produced from, but not containing genetically modified / engineered organisms obtained through modern biotechnology.	
"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material.		"Organism" means any biological entity capable of replication, reproduction or of transferring genetic material. (This definition of "organism" implies that just one cell of a multicellular organism is considered an organism. Thus, it is considered necessary to request a clarification about what is intended to be defined)
"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination.	"Genetically modified / engineered organism" means an organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination, as well as their parts, derivatives, or products that contain them, and that have the capacity of reproducing themselves or to transmit genetic information, and Novel products with more than one transformation event. This may be the retransformation of an existing transgenic line o the cross through conventional means of one or more transgenic lines	The proposed definition excludes events produced through conventional hybridizing where one of the parentals is conventional and the other one has been genetically modified, or those that are obtained by a conventional crossing of <i>de minimis</i> a genetically modified organism (Stacked events or a GMO event crossed with a conventional line). Furthermore, it is not consistent with the definitions for a genetic modified organism already established and internationally accepted. Due to the aforesaid we propose the definition shown in the previous column.

2. Document or Subject: Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (At Step 3/8)

PARAGRAPHS	POSITION PROPOSAL	OBSERVATIONS OR COMMENTS
[Chapeau 1	[Chapeau 2	Chapeau 2 is clear an concise,
"Food labelling is the primary	"The purpose of this	responds to the purpose of the
means of communications	document is to recall and	proposed recommendations
between the seller on the one	assemble in a single	being consistent with the
hand and the purchaser and	document some important	reference to the existing Codex

consumer the other. on Labelling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption. For additional assurance on safe and appropriate use of food, food labelling can be employed to provide consumers with essential information. It is recognized that consumers' expressed needs may vary in different regions of the world. These differences might lead to various levels of approaches regarding labelling of foods obtained by GM/GE modifications.

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."

Chapeau 2

"The purpose of this document is to recall and assemble in a single document some important elements from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques."]

Point Number 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

elements from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques."]

standards that would apply to the labelling of foods or food ingredients obtained through certain techniques o genetic engineering. Furthermore, points number 1 and 3 of the General Standard for the Labelling of Prepackaged Foods respond to the introduction statements made in Chapeau 1.

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We request updating the listing of point number 4.2.1.4 of the General Standard for the Labelling of Prepackaged Foods.

EUROPEAN COMMUNITY:

The European Community (EC) strongly believes that Codex must issue recommendations on the labelling of GM foods. This guidance in particular would be extremely useful for developing countries as was largely expressed during the last session of CCFL and during the two latest working groups (Oslo-February 2007 and Accra-January 2008).

The EC is of the opinion that the text elaborated by the Working Group in Ghana is a good starting point. The objective of this text is to gather in a single document overarching horizontal principles which have to be respected by any country wishing to put in place a legislative framework on GM labelling, while recognising that various approaches are envisageable. It is essential that this text be an official Codex document with appropriate legal relevance in the international context.

The EC wishes to suggest amendments to the proposed text as detailed in the Annex of this paper.

ANNEX: Outcome of the WG meeting

<u>Title of the document: Principles/Guidance for the Labelling of Foods and Food Ingredients obtained through certain Techniques of Genetic Modification/Genetic Engineering (GM/GE)</u>

Chapeau 1

"Food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other. Labelling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption. For additional assurance on safe and appropriate use of food, food labelling can be employed to provide consumers with essential information. It is recognized that consumers' expressed needs may vary in different regions of the world. These differences might lead to various levels of approaches regarding labelling of foods obtained by GM/GE modifications.

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."

Chapeau 2

"The purpose of this document is to recall and assemble in a single document some important elements from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques."

- 1. <u>The following Codex standards and related texts contain requirements provisions applicable to the labelling of all food products and may be applied therefore apply equally to foods obtained by GM/GE:</u>
 - The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985 (Rev. 1-1991))

- The Codex General Guidelines on Claims (CAC/GL 1-1979, Rev. 1-1991)
- The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997, Rev. 1-2004)
- 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
- Working Principles for Risk Analysis for Food Safety for Application by Governments
- 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 (Codex Procedural Manual).
- 2 Codex labelling and other texts <u>apply</u> can be applied to foods sold in unpackaged/in-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. <u>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 purpose (add references).</u>
- 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 of the General Standard for the Labelling of Prepackaged Foods 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).
 - 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 . . ."
- 6. When the physical, chemical, or functional characteristics of a food <u>are significantly altered</u> through any means (production or processing), the labelling of such food <u>should</u> 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. Differences in consumer's views on GMOs in different countries mean that different requirements may be needed to avoid misleading or confusing the consumer.

- 7. When the physical, chemical or functional characteristics of a food are significantly altered through any means (production or processing), 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.
- 8. 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.
- 9. The provisions in existing Codex texts can be applied to labelling statements related to GM/GE foods:
- 10. General Standard for the Labelling of Prepackaged Foods

Section 3.1

Section 3.2

Section 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

Section 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.

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

Section 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.

Section 3.3 Prohibited Claims - Claims which cannot be substantiated.

Section 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.

Section 4.1 Potentially Misleading Claims — Meaningless claims including incomplete comparatives and superlatives.

Section 5.1 Conditional Claims – Terms such as "natural," "pure," "fresh," "home made," (iii) "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.

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

Section 5.1 Conditional Claims — Claims which highlight the absence or non-addition of (vi) 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.

Codex labelling texts apply to representation used to provide information to enable consumer choice about the food they purchase and/or include several provisions which can be applied to determine the appropriateness of labelling when used as a means to satisfy consumers' demand for certain information about the food they purchase and/or when used by marketers to indicate that a food meets certain consumer preferences.

Any representations made on the label or in the labelling of GM/GE foods should be consistent with the Codex GSLPF and the Codex general guidelines on claims.

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

Section	Mandatory Labelling Provisions		
General S	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 S	tandard 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 C	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.
<u>5.1(v)</u>	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	

JAPAN:

Japan is pleased to submit the following comments on the Proposed Draft Recommendation for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of GM/GE.

The current proposed draft is concise and well elaborated as it stands, and gives a clear guidance for the development of GM/GE labelling provisions. Therefore, we believe we do not necessarily need the Table 1.

Having said that, if the WG agrees with keeping the Table 1 in the document, we would like to propose the following amendment;

In the General Standard for the Labelling of Prepackaged Foods (CODEX STAN1-1985) and the General Guidelines on Claims (CAC/GL1-1979), sections on General Principles are set out separately from "Mandatory Labelling", "Optional Labelling" and "Prohibited Claims". Therefore, Japan considers that 3.1 and 3.2 of the General Standard for the Labelling of Prepackaged Foods and 1.2 and 1.3 of the General Guidelines on Claims should be classified as General Principles.

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

Section	General Principles	
General Star	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.	
General Gui	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.		

4.1.1 4.1.2 4.2.2 Section General Stand 7.1	The name [of the food] shall indicate the true nature of the food and normally be specific and not generic. 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. 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. Voluntary Labelling Provisions
4.1.2 4.2.2 Section General Stand 7.1	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. 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. Voluntary Labelling Provisions
4.2.2 Section General Stand 7.1	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. 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. Voluntary Labelling Provisions
Section General Stand 7.1	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. Voluntary Labelling Provisions
Section General Stand 7.1	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. Voluntary Labelling Provisions
General Stand	
7.1	
	dard for the Labelling of Prepackaged Foods
	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 Guide	lelines on Claims
:	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.
2.2	Prohibited claims – Claims which cannot be substantiated.
	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.
	Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives.
1	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.
1	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	

MEXICO:

Mexico advances the following comments for the consideration of the Committee regarding those terms of reference

- 1. The further consideration of certain areas originally specified in the mandate of the Working Group, particularly:
 - a) The rationale for adopting or not adopting a particular approach

From a legal point of view, the basic argument is that Mexico has a Biosafety Law for Genetically Modified Organisms, which establishes the cases in which labelling is required for Genetically Modified Organisms (GMOs) and the products which contain them.

In those cases where their characteristics are significantly different from conventional products, explicit reference must be made to "Genetically Modified Organisms" indicating in the label the differences in food composition or nutritional characteristics in comparison to their conventional counterpart.

On the contrary, such legislation does not establish a labelling requirement when the GMO is not different from its conventional counterpart. Neither does it demand Production Process or Production Method labelling.

From a technical point of view, the policy followed by the health authorities in Mexico, regarding the food safety evaluation of foods that are or that contain GMOs for human consumption, has been the systematic evaluation, case by case and step by step, of the genetic events submitted by the developers, and to reach a positive decision only when, based on the available scientific evidence, it has been demonstrated that the food is as safe as its conventional counterpart.

Therefore, taking into account the health risk, labelling is only required when the genetic modification generates a product that is significantly different for its conventional counterpart, i.e. in those cases when the GMO presents significant changes in its composition or in its nutritional characteristics, or if it presents health risks for specific population groups in comparison to its conventional counterpart.

b. The communication strategies used in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

The Health Authorities, in their Internet Site (www.cofepris.gob.mx), have made available a positive list of GMOs authorized to be released in the market place. These products have already undertaken a safety evaluation process and can be considered appropriate to be consumed.

In addition, there is information on this subject from the *Comisión Intersecretarial de Bioseguridad de Organismos Genéticamente Modificados* (Interdepartmental Biosafety Commission for Genetically Modified Organisms), the *Procuraduría Federal del Consumidor* (Federal Consumers Advocacy bureau), and in Internet page of the Biosafety Clearing House of the Biodiversity Convention.

2. The undertaking of an analysis of current Codex texts, particularly Codex labelling texts, to evaluate whether or not these texts supply sufficient guidance on the labelling of foods derived from genetic modification/genetic engineering.

Mexico would like to thank the United States, Canada and Nigeria for their efforts in compiling the "Background Document for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification / Genetic Engineering" which is included as Annex I in the CL 2007/38-FL for the physical Working Group meeting that met in Ghana from January 28th to January 30th, 2008.

Throughout the more than 10 years of work regarding this subject within the framework of the Codex Committee on Food Labelling, Mexico has taken in consideration those texts as part of its efforts and deliberations to define its national position and does not detect any additional elements that would incline it to change its position. Therefore we reiterate that labelling is only required when the genetic modification generates a product that is significantly different from its conventional counterpart, i.e. in those cases when the GMO presents significant changes in its composition or in its nutritional characteristics, or if it presents health risks for specific population groups in comparison to its conventional counterpart.

3. The consideration of appropriate ways forward, taking into account the result of the analysis undertaken in 2 and the suggestion of the possible ways forward identified by the Oslo WG, (e.g. guidelines, principles or discontinuation of work).

During the years this issue has figured in the CCFL agenda, the different approaches of the Codex members have become obvious, resulting in opposing positions that would be very difficult to reconcile under the present circumstances to permit a consensual decision¹.

Therefore, Mexico supported suspending the discussions on this subject until more favorable circumstances exist to advance by consensus.

NEW ZEALAND:

New Zealand is pleased to submit the following comments in response to Part B, item 5 of CL 2008/11-FL.

CCFL has been considering this issue for almost two decades without reaching consensus on an international GM food labelling standard. As such, New Zealand believes that GM labelling for the purpose of providing consumer information should be left to national authorities to consider in association with their international obligations.

In relation to proposed draft recommendations, New Zealand supports Chapeau 2 which provides a simple introductory statement that captures the essential nature and purpose of the document. Chapeau 2 does not include statements on which members hold divergent views and is, therefore, likely to be acceptable to member countries. New Zealand considers that some of the statements in Chapeau 1 do not belong in a document that brings together existing Codex provisions relating to GM foods.

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¹ See the recommendations of the 55th session of the Executive Committee.

NORWAY:

Norway would like to thank you for this opportunity to submit comments to the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of GM/GE and we appreciate that the CCFL supported proceeding with work on the basis of this draft. We strongly believe that CCFL should fulfil its task from 1991 and finish its work on how the fact that a food has been derived from modern biotechnology should be made known to the consumer.

General remarks

Consideration of *The Proposed Draft Recommendations* as presented at step 3 is a good first stage to ensure the consumers right to be informed and to allow consumer choice. *The Draft* gives a good overview on how Codex texts relate to the labelling of foods; however it does not fully reflect how it may be made known to the consumer the fact that a food has been derived from modern biotechnology. In line with this, we would like to highlight a very important issue, which is now reflected in the chapeau (or introduction), of *the Draft* and may be elaborated further:

The recognition of the fact that consumers expressed needs may vary in different regions of the world and that these differences might lead to various levels of approaches regarding labelling of GM/GE foods.

This expressed recognition must be kept in the Recommendations and one reason for this point of view, is that in some regions of the world a product containing or derived from a GMO and not labelled as such, will be seen upon as having false and misleading labelling statement.

Special remarks

Para 3

To insert to the first sentence (underlined words to be inserted):

Labelling of a food obtained through GM/GE techniques is considered only after...

Para 5

This text is already in the table, the point is important; however it is made in the table and should therefore not be repeated. Suggest deleting this para.

Para 8

This is already reflected in para 1 and can be deleted.

To conclude, the Norwegian view is that current Codex texts do not cover labelling of GM foods as they where developed before this issue was raised by Codex for discussion, however this draft document with the inclusion of the recognition of the different approaches around the world, is a good first stage to recommend some principles or concepts within the Codex system for countries wanting to develop and implement regulations on GM/GE foods.

UNITED STATES:

The United States welcomes the opportunity to respond to CL 2008/11-FL regarding the **Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering.**

CCFL has spent nearly two decades on this subject without reaching consensus. Recent discussions at the physical working groups in Norway and Ghana clearly demonstrate that member countries have fundamentally conflicting legal and regulatory frameworks, views, and approaches on the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering (referred to as "GM/GE foods" in this document). The United States strongly believes that, given these conflicts, consensus at an international level is not possible and any new work will lead the Committee to the same impasse we have been at for nearly two decades.

Lack of Consensus – The Codex Statement of Principles and Criteria concerning Codex decision-making process clearly states that "only those other factors which can be accepted on a world-wide basis . . . should be taken into account in the framework of Codex" (page 165, Codex Procedural Manual, 16th edition). This point is critical as it is not possible to develop a common, international standard where member countries have conflicting legal and regulatory frameworks, views, and approaches on the labelling of GM/GE foods. CCFL has previously discontinued work on issues where there were fundamental differences among member countries; for example, guidelines on "vegetarian" and "natural" labelling terms and amendments to existing country of origin labelling provisions. Continuing work on an item that has no accepted world-wide basis is not consistent with this criterion. This is clearly the case with respect to the labelling of GM/GE foods.

Inadequate Basis for Mandatory Labelling – Thus far, Codex has not based any of its mandatory labelling provisions on consumer demand or preference alone. The 1997 Executive Committee opinion further stated that claimed consumer demand **could not** be the primary basis for labelling (ALINORM 97/3, para. 29). We believe that Codex mandatory labelling provisions are reserved for information that consumers need to know for health and safety aspects, functionality, or use of the food.

Inherently Misleading Labelling – Moreover, mandatory method-of-production GM/GE labelling would likely be inherently misleading. A mandatory method-of-production GM/GE labelling regime creates the impression that the labelled food is in some way different from or less safe than a comparable, unlabelled non-GM/GE food (for example, no requirements exist that all food be labelled to indicate the breeding technique used to produce it). As such, mandatory method-of-production GM/GE labelling would be inconsistent with the Codex General Standard for the Labelling of Prepackaged Foods, which states that foods shall not 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.

No Additional Guidance Needed – In areas where consensus does exist, there is sufficient guidance on those areas in existing Codex texts. The Background Paper, prepared by the US, Canada, and Nigeria, (CL 2007/38-FL) addresses the concerns that member countries have expressed at CCFL. The Background Paper explains how mandatory labelling provisions in Codex texts can be used to address 1) potential allergenicity and related safety concerns and 2)

the need to identify significant differences in essential characteristics of the food. In addition, the Background Paper explains how Codex mandatory and voluntary labelling provisions can be used to protect consumers from false and misleading labelling information. The Background Paper also notes existing Codex guidance on criteria for voluntary labelling. As explained in the Background Paper, the Codex *General Standard for the Labelling of Prepackaged Foods* (Codex Stan 1-1985 (Rev. 1-1991)), the Codex *General Guidelines on Claims* (CAC/GL 1-1979, Rev. 1-1991), and the Codex *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997, Rev. 1-2004) provide direction and guidance on mandatory and voluntary labelling of all foods in general and, therefore, apply equally to GM/GE foods.

Public Health Priorities – CCEXEC has asked committees to focus resources on priority issues in areas where consensus can be achieved. Along these lines, another factor to consider in the current setting is the request from FAO/WHO to assist with the implementation of the WHO Global Strategy on Diet, Physical Activity, and Health. The Committee has recently initiated work in this area and we believe that CCFL's time and resources are far better spent when devoted to these issues that relate directly to the purpose of Codex standards, i.e., to protect the health of consumers.

In summary, the United States records its strong objections to any new work on this agenda item based on the following:

- 1. any new work will lead the Committee to the same impasse we have been at for nearly two decades given that fundamental differences among member countries on any approach forward remain (as reflected in the discussions at the 36th CCFL and disagreement on the text itself as well as on the direction of future work² on the text in Appendix VII);
- 2. appropriate guidance is already available within existing Codex texts on this subject, as explained in the Background Paper prepared by the US, Canada, and Nigeria;
- 3. the Executive Committee provided its opinion in 1997 that "the claimed [consumer] 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, para. 29);
- 4. fundamental differences in legal and regulatory frameworks have resulted in conflicting labelling approaches among member countries, which do not permit the development of a common, international guideline;
- 5. the Procedural Manual as well as the Executive Committee have made clear that work should not proceed where no basis for consensus exists;
- 6. the Committee now has been requested to assist with the implementation of the WHO Global Strategy on Diet, Physical Activity and Health, an agenda item of immense public health significance and directly related to the purpose of Codex, i.e., to protect the health of consumers.

For the reasons stated above, the United States believes that it would be an inappropriate use of CCFL resources and time to continue work in this area. Therefore, the United States strongly urges CCFL to discontinue work on this agenda item.

² The United States reminds the Committee of the discussions at the 36th CCFL where although several countries supported continuing work on the text in Appendix VII, the stated reasons and approaches for this continued work varied widely underscoring the same differences that have prevented the Committee from reaching consensus on this

subject for the past decade.

However, should the Committee decide to continue to work in this area by considering the text in Appendix VII, in *Annex 1* below, the United States presents its views on the contents of an acceptable text. These revisions to the current draft are necessary to (a) ensure consistency with the principles and guidelines in existing Codex texts; and (b) clarify the intent and scope of the concepts as portions of the text are taken out of context of the fuller discussion presented in the Background Paper. These revisions are consistent with the Committee's decision to consider the text in Appendix VII in conjunction with the Background Paper in CL 2007/38-FL.

In addition, the United States submits that if work is to continue, that work must include a full discussion of the range of implications associated with mandatory method-of-production labelling of GM/GE foods, including economic and practical considerations. The cost of mandatory nutrition labelling was of particular concern to many developing countries at the last Committee meeting. Mandatory method-of-production labelling of GM/GE foods has similar cost implications, without any of the compensatory public health benefits provided by nutrition labelling, and presents additional enforcement challenges, particularly with respect to highly processed foods. The Committee should also consider the possibility that continuation of work in this area could create a precedent or impetus for having CCFL consider additional method-of-production labelling or labelling based on claimed consumer preferences. We believe that it is important for countries to be fully informed of the economic, policy, and logistical implications of implementation of new labelling regimes before deciding on the need for additional Codex labelling guidance (see *Annex 2*).

ANNEX 1 UNITED STATES' PROPOSED CHANGES TO APPENDIX VII (Additions in BOLD CAPS and deletions in strikethrough format)

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

COMPILATION OF ELEMENTS FROM CODEX LABELLING AND OTHER TEXTS THAT ADDRESS ISSUES RELEVANT TO FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING

Chapeau 1

Food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other. Labelling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption. For additional assurance on safe and appropriate use of food, food labelling can be employed to provide consumers with essential information. It is recognized that consumers' expressed needs may vary in different regions of the world. These differences might lead to various levels of approaches regarding labelling of foods obtained by GM/GE modifications.

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.

Chapeau 2

The purpose of this document is to recall and assemble in a single document some important elements from Codex LABELLING AND OTHER texts which are relevant for the labelling of foods obtained by GM/GE techniques AS THEY ARE FOR ALL FOODS. THIS DOCUMENT IS NOT INTENDED TO SUGGEST OR IMPLY THAT GM/GE FOODS ARE IN ANY WAY DIFFERENT FROM OTHER FOODS SIMPLY DUE TO THEIR METHOD OF PRODUCTION.

- 1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied **APPLY** to foods obtained by GM/GE:
 - The Codex General Standard for the Labelling of Prepackaged Foods (GSLPF; Codex Stan 1-1985 (REV. 1-1991));
 - The Codex General Guidelines on Claims (CAC/GL 1-1979, REV. 1-1991);
 - The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997, REV. 1-2004);
 - Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
 - Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003);
 - Guidelines for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46-2003); AND
 - Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)
- 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."
- 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 purpose (REFERENCES: CAC/GL 44-2003; CAC/GL 45-2003; CAC/GL 46-2003; AND CAC/GL 62-2007).
- 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 **OF THE GSLPF** 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 (**REFERENCE**: section 4.2.2, GSLPF).
- 6. SECTIONS 4.1.1 AND 4.1.2 OF THE GSLPF ADDRESS THE NAMING OF FOODS. CODEX LABELLING TEXTS DO NOT PROVIDE A BASIS FOR THE MANDATORY LABELLING OF FOODS OBTAINED BY GM/GE TECHNIQUES SIMPLY BASED ON THEIR METHOD OF PRODUCTION³. CONSISTENT WITH THESE SECTIONS, 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. (REFERENCE: SECTION 4.1.1 AND 4.1.2, GSLPF).
- 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.
- Codex labelling texts apply to ANY VOLUNTARY representation used IN THE LABELLING OF GM/GE FOODS to provide information to enable consumer choice about the food they purchase and/or when used by

³ MANDATORY GM/GE LABELING SIMPLY BASED ON THE METHOD-OF-PRODUCTION IS LIKELY TO CREATE THE IMPRESSION THAT THE LABELED FOOD IS IN SOME WAY DIFFERENT FROM OR LESS SAFE THAN A COMPARABLE, UNLABELED NON-GM/GE FOOD AND, AS SUCH, WOULD BE INCONSISTENT WITH THE GLSPF, WHICH STATES THAT FOODS SHALL NOT 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.

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marketers to indicate that a food meets certain consumer preferences (REFERENCES: SECTION 7, GSLPF; GENERAL GUIDELINES ON CLAIMS). A CLAIMED "RIGHT-TO-KNOW" CANNOT BE USED AS THE PRIMARY BASIS FOR DECISION-MAKING ON APPROPRIATE LABELLING (REFERENCE: ALINORM 97/3)⁴.

IN THIS CONTEXT, CODEX LABELLING TEXTS CONTAIN SEVERAL PROVISIONS TO PROTECT CONSUMERS FROM FALSE, MISLEADING, FRAUDULENT, DECEPTIVE, AND UNSUBSTANTIATED CLAIMS OR OTHER LABELLING STATEMENTS. Any representations made on the label or in the labelling of GM/GE foods should be TRUTHFUL, NOT MISLEADING, AND NOT LIKELY TO CREATE AN ERRONEOUS IMPRESSION REGARDING THEIR CHARACTER IN ANY RESPECT, consistent with the GSLPF (Codex Stan 1 1985) and the General Guidelines on Claims (CAC/GL 1 1979). (SEE TABLE 1).

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

Section	Mandatory Labelling Provisions		
General Sta	ral 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		
4.4.4	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		
4.2.2	undergone; for example, dried, concentrated, reconstituted, smoked. The presence in any food or food ingredients obtained through biotechnology of an allergen		
4.2.2	transferred from any of the products listed in section 4.2.1.4 shall be declared.		
	transferred from any of the products fisted in section 4.2.1.4 shan 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 Sta	undard 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 Gu	idelines 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 THE EXECUTIVE COMMITTEE STATED ITS OPINION "CLAIMING THAT WHILE CONSUMERS MAY CLAIM THE RIGHT TO KNOW WHETHER OR NOT FOODS HAD BEEN PREPARED BY SUCH MEANS [CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING], 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" (ALINORM 97/3).

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	Guidelines for Use of Nutrition and Health Claims	

ANNEX 2

Economic and other practical considerations related to method-of-production labelling of GM/GE foods

CCFL has been considering the agenda item on labelling of GM/GE foods for more than a decade. In the past two years, information has been shared on the labelling approaches (and rationales) adopted by different member countries, their legal and regulatory frameworks, experiences, and communication strategies. However, there has been little discussion on economic considerations and logistical implications associated with implementation and enforcement and costs and challenges that method-of-production labelling of GM/GE foods presents to consumers, companies, and government authorities.

The economic impact to public and private sectors associated with mandatory and/or voluntary method-of-production labelling of GM/GE foods has been estimated in some countries⁵. A careful analysis of the costs of implementation and enforcement requirements as well as the social and economic impacts should be weighed against any potential benefits.

⁵ Golder, G and Leung, F. Economic Impact Study: Potential Costs of Mandatory Labelling of Food Products Derived from Biotechnology in Canada. KPMG Consulting, Ottawa. January, 2000.

Economic Appraisal of Options for Extension of Legislation on GM Labelling. A final report for the Food Standards Agency (UK). May, 2001.

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De Leon, A; Manalo, A; and Guilatco, FC. The Cost Implications of GM Food Labeling in the Philippines. A socioeconomic impact study conducted by the Philippine Bureau of Food and Drugs. February, 2004.

Economic Considerations of Biosafety and Biotechnology Regulations in India. Proceedings of a Conference, New Delhi, India. August, 2006.

Bansal, S and Ramaswami, B. The Economics of GM Food Labels: An Evaluation of Mandatory Labelling Proposals in India. IFPRI Discussion Paper 00704. May, 2007.

Gruère, GP and Rao, SR. A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule. AgBioForum 10(1):51-64, 2007.

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For example, questions to be considered may include:

- What type of documentation or testing would be necessary to determine or establish whether a food or food ingredient is or is not obtained through certain techniques of GM/GE?
- How would this documentation be tracked through agricultural production, food processing, and distribution?
- Who will verify the documentation and how will this be conducted? Through government audits or third party certification?
- Do validated analytical methods exist that can reliably detect particular proteins or DNA sequences in the many different kinds of processed foods that may need to be tested, given the different kinds of food matrices that they may appear in and the different kinds of processing that they may have gone through?
- Are the analytical methods feasible and practical for in-field use? What are the methodological detection limits?
- What responsibilities would be added to government regulatory authorities if they need to monitor and enforce new method-of-production labelling requirements for GM/GE foods?
- What are the consequences to the credibility of the government if it is not able to adequately monitor and enforce new requirements?
- What is the cost to the manufacturer to provide for the methods, verification, and labelling of GM/GE foods?
- What is the cost to governments to implement and enforce method-of-production labelling of GM/GE foods?
- What is the cost passed on to consumers for method-of-production labelling of GM/GE foods?
- What are the costs and benefits associated with different labelling options?
- What measures are needed to ensure that labelling is not only accurate but also not misleading?
- Is there a need for education efforts to ensure that method-of-production labelling of GM/GE foods is appropriately understood and used by consumers? Who bears the responsibility and associated costs for such an education campaign?
- What effects do different labelling approaches have on consumer choice of foods in the marketplace? Does mandatory method-of-production labelling of GM/GE foods unnecessarily limit the availability of such foods because companies will choose to avoid marketing foods that are subject to onerous requirements?

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA):

The International Council of Grocery Manufacturers Associations (ICGMA) appreciates the opportunity to provide these 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 labelling 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 labelling products derived from biotechnology for well over a decade.

ICGMA believes that CCFL should discontinue further work on this topic and accept the background document prepared by the U.S., Argentina and Kenya for the working group meeting in Ghana, including Table 1 that clearly explains how existing Codex texts are applicable to labelling of products derived from biotechnology. 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 priority⁶ 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." ICGMA also fully recognizes Codex' scarce resources and the need to prioritize the work of CCFL to those items more directly relevant to consumer health such as the implementation of the WHO Global Strategy.

In going forward, ICGMA believes it may be useful for CCFL to have a substantive discussion on the background paper prepared for use by the Ghana working group. The discussion should address how this document and accompanying Table 1 can be used to provide guidance to national governments as they consider regulations relevant to mandatory or voluntary labelling of biotechnology-derived foods as well as to other process-based labelling. Beyond that, ICGMA is doubtful that a consensus can be achieved on the proposed draft recommendations and would support discontinuing this work in CCFL.

⁶ Report of the 25th session of CAC, July 2004

⁷ ALINORM 04/27/22 Reports of the 32nd session of the CCFL, May 2004