commission du codex alimentarius

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POINT 5(B) DE L'ORDRE DU JOUR *CX/FL 08/36/8*

F

PROGRAMME MIXTE FAO/OMS SUR LES NORMES ALIMENTAIRES

COMITÉ DU CODEX SUR L'ÉTIQUETAGE DES DENRÉES ALIMENTAIRES
TRENTE-SIXIÈME SESSION
OTTAWA (CANADA), 28 AVRIL – 2 MAI 2008

ETIQUETAGE DES ALIMENTS ET INGRÉDIENTS OBTENUS À L'AIDE DE CERTAINES TECHNIQUES DE MODIFICATION GÉNÉTIQUE/GÉNIE GÉNÉTIQUE*:* AVANT-PROJET DE DIRECTIVES CONCERNANT L'ÉTIQUETAGE DES ALIMENTS ET INGRÉDIENTS OBTENUS À L'AIDE DE CERTAINES TECHNIQUES DE MODIFICATION GÉNÉTIQUE/GÉNIE GÉNÉTIQUE*:* DISPOSITIONS D'ÉTIQUETAGE (À L'ÉTAPE 4)

RAPPORT DU GROUPE DE TRAVAIL DU CCFL SUR L'ÉTIQUETAGE DES ALIMENTS ET DES INGRÉDIENTS ALIMENTAIRES OBTENUS PAR CERTAINES TECHNIQUES DE MODIFICATION GÉNÉTIQUE / GÉNIE GÉNÉTIQUE

Rapport de la réunion du Groupe de travail du CCFL tenue à Accra, Ghana, du 28 au 30 janvier 2008

RAPPORT DU GROUPE DE TRAVAIL SUR L'ÉTIQUETAGE DES ALIMENTS ET DES INGRÉDIENTS ALIMENTAIRES OBTENUS PAR CERTAINES TECHNIQUES DE MODIFICATION GÉNÉTIQUE / GÉNIE GÉNÉTIQUE

1) Conformément à la décision prise à la 35e session du Comité du Codex sur l'étiquetage des denrées alimentaires[1], un groupe de travail (GT) physique sur l'étiquetage des aliments et des ingrédients alimentaires obtenus par certaines techniques de modification génétique / génie génétique s'est réuni à Accra (Ghana) du 28 au 30 janvier 2008. Le GT a été coprésidé par le Pr Josephine Nketsia-Tabiri (Ghana), le Dr Andrea Nilda Calzetta Resio (Argentine) et M. Kjetil Andreas Tveitan (Norvège) et 84 délégués représentant 25 pays membres, une organisation membre (CE), l'OMS et 5 organisations observatrices ont assisté à la réunion du groupe. La liste complète des participants se trouve à l'Annexe I du rapport.

2) Le Pr Samuel Sefa-Dedeh, vice-président du comité national du Codex pour le Ghana a ouvert la réunion. Les coprésidents du GT ont rappelé aux participants le mandat du GT, exposé dans la CL 2007/38-FL et les commentaires écrits reçus en réponse à la lettre circulaire (Annexe II). Ils ont attiré l'attention des participants du GT plus particulièrement sur les commentaires écrits du Costa Rica, du Mexique et de la Thaïlande qui n'étaient pas présents à la réunion.

Adoption de l'ordre du jour :

3) Les participants ont été invités à adopter l'ordre du jour provisoire. Bien qu'une modification proposée à l'ordre du jour ait été discutée, le GT est convenu d'adopter l'ordre du jour tel quel tout en limitant le temps réservé à la discussion des raisons qui avaient déjà été abordées à la réunion du GT à Oslo[2].

Examen des raisons des différentes démarches adoptées par les gouvernements nationaux concernant l'étiquetage de la MG / du GG

4) Après un échange de vues sur les raisons expliquant l'adoption de différentes démarches concernant l'étiquetage des aliments et des ingrédients alimentaires obtenus par certaines techniques de modification génétique / génie génétique, il a été admis que les pays avaient choisi diverses démarches à cause de leur cadre réglementaire respectif, des préférences de leurs consommateurs et d'autres facteurs. Ces démarches allaient de l'absence totale de déclaration, à la déclaration volontaire en passant par la déclaration obligatoire lorsque la composition ou l'usage de l'aliment présente d'importants changements, la déclaration obligatoire de tous les aliments et ingrédients alimentaires obtenus par certaines techniques de modification génétique / génie génétique et (ou) une combinaison de démarches. Il a été signalé que ce qui est applicable dans un pays peut ne pas être approprié dans un autre. Certaines délégations ont précisé que leur pays avait établi leur régime d'étiquetage à

[1] ALINORM 07/30/22, Rapport de la 35e session du Comité du Codex sur l'étiquetage des denrées alimentaires, para. 117.
[2] Oslo, Norvège, 6-7 février 2007

la suite de consultations approfondies et en tenant compte de divers facteurs comme la santé et la sécurité sanitaire, les autorités législatives, les préférences des consommateurs et les résultats d'analyses des coûts et avantages.

5) Il y a eu accord sur le fait que les régimes d'étiquetage ne remplacent pas l'évaluation de la sécurité sanitaire avant la mise sur le marché. Plusieurs pays ont en outre observé que les aliments MG / GG sont soumis à de rigoureuses évaluations de sécurité sanitaire avant l'autorisation de leur mise sur le marché.

Les stratégies de communication d'information au public au sujet des aliments et ingrédients alimentaires obtenus par certaines techniques de modification génétique / génie génétique :

6) Les membres ont échangé de l'information sur leurs stratégies et leurs outils de communication respectifs, notant que la communication devait être bidirectionnelle. Les outils comprenaient entre autres l'information sur Internet, les organes d'information, les brochures et les prospectus, l'éducation dans les écoles et les universités, les comités parlementaires, les consultations et les ateliers publics, les recherches d'opinion publique et les émissions radiophoniques, y compris les émissions téléphoniques. L'information communiquée portait notamment sur des aspects de l'étiquetage et sur la biotechnologie. L'information était originaire des gouvernements et des organisations non gouvernementales, notamment. La délégation de la Norvège a exprimé la vue que l'étiquette est l'outil sur lequel compte le consommateur pour faire des choix éclairés.

Présentation de l'analyse des textes Codex courants, particulièrement ceux traitant de l'étiquetage, afin de déterminer s'ils fournissent assez d'indications concernant l'étiquetage des aliments obtenus par certaines techniques de modification génétique / génie génétique :

7) Les États-Unis, le Canada et le Nigeria ont présenté un aperçu de leur analyse des textes Codex courants[3] (document d'information) qui fournissent peut-être des indications sur l'étiquetage des aliments et ingrédients alimentaires obtenus par certaines techniques de modification génétique / génie génétique. Dans leur présentation, ces pays ont observé que les textes Codex actuels contiennent plusieurs dispositions portant sur l'étiquetage des aliments, y compris les aliments MG/GG. Quatre grandes questions concernant les aliments MG/GG qui ont été soulevées durant les débats du CCFL, ont été soulignées : 1) fournir aux consommateurs l'information nécessaire relativement aux aspects santé et sécurité sanitaire de l'aliment (comme la présence d'allergènes); 2) fournir aux consommateurs l'information concernant les différences importantes dans la composition, les caractéristiques, les propriétés nutritionnelles et l'usage prévu de l'aliment; 3) protéger les consommateurs des informations fausses ou mensongères sur l'étiquette; et 4) garantir une information véridique et non trompeuse liée aux préférences des consommateurs.

[3] Annexe I de CL 2007/38-FL, Annexe II du présent rapport

8) Suite à la présentation, des délégations ont exprimé leurs vues sur l'analyse et sur le fait que les textes Codex actuels offraient des indications suffisantes concernant l'étiquetage des aliments MG/GG. Maintes délégations ont dit que le document d'information était très utile. On a généralement admis que les textes actuels du Codex offraient des indications suffisantes dans les cas où la modification génétique entraînait d'importants changements à la composition ou aux propriétés nutritionnelles ou l'introduction d'un allergène. Toutefois, les vues divergeaient sur le fait qu'ils offrent assez d'indications pour établir un régime d'étiquetage applicable aux aliments et ingrédients alimentaires obtenus par certaines techniques de modification génétique / génie génétique, particulièrement en réponse aux préférences des consommateurs.

9) Un certain nombre de délégations estimaient que le document d'information constituait un bon point de départ à la discussion et à l'examen des lacunes dans les textes Codex actuels. La délégation de la Norvège a dit que le droit de savoir des consommateurs n'avait pas été clairement abordé dans le document. D'autres délégations étaient d'avis que le document d'information correspondait aux sujets sur lesquels il y avait consensus et que les lacunes auxquelles ont fait référence d'autres délégations, sont celles qui sont présentes dans les textes Codex actuels, pas dans le document d'information. Également, elles ont dit craindre que la discussion des lacunes ne risque d'aborder des sujets qui avaient déjà été longuement discutés dans le passé sans parvenir à un consensus et dont la discussion aujourd'hui avait peu de chances de dégager un consensus.

Discussion des marches à suivre proposées

10) Plusieurs propositions ont été faites dont bon nombre portait sur la manière d'utiliser l'information du document d'information. Elles incluaient entre autres : extraire les idées principales du document d'information et des commentaires soumis en réponse à la CL 2007/38-FL, utiliser le document d'information pour élaborer des directives, recommander au CCFL que son rapport de 2008 comprenne un sommaire des textes courants du Codex qui sont applicables à l'étiquetage des aliments MG/GG, utiliser le document d'information pour établir un recueil des textes du Codex applicables, faire du document d'information un document officiel du Codex et combler les lacunes et recommander que la FAO et l'OMS rédigent des guides sur la manière d'établir des régimes d'étiquetage, y compris l'étiquetage des aliments MG/GG.

11) La délégation du Ghana, appuyée par plusieurs autres délégations, a exprimé l'avis que la compilation des textes du Codex offrant des indications sur l'établissement d'un régime d'étiquetage applicable aux aliments MG/GG serait souhaitable. La délégation a ajouté que des indications détaillées sur la manière d'étiqueter les aliments MG/GG, comme les mentions à employer, leur emplacement sur l'étiquette, etc. seraient utiles.

12) D'autres délégations toutefois ont observé qu'il serait difficile d'avancer des textes spécifiques en raison des démarches ou cadres réglementaires différents et de la diversité des préférences des consommateurs d'un pays à l'autre. Une délégation a

observé qu'une section de la Norme générale Codex pour l'étiquetage des denrées alimentaires préemballées (NGÉDAP) fournit des indications sur la présentation des mentions obligatoires d'étiquetage.

13) Les coprésidents ont résumé la discussion en présentant les trois principales propositions qui semblaient s'en dégager :

- Extraire les idées principales du document d'information et des commentaires reçus en réponse à la CL 2007/38-FL;
- Utiliser le document d'information comme point de départ et élaborer des indications ou principes sur la manière d'étiqueter les aliments et ingrédients alimentaires obtenus par certaines techniques de modification génétique / génie génétique ;
- Recommander que le rapport de la session de 2008 du CCFL inclue un condensé des textes d'étiquetage du Codex applicables aux aliments MG/GG.

14) Les coprésidents ont suggéré aux participants de réfléchir à ces propositions et de présenter un énoncé spécifique au GT qui l'étudiera. Ensuite, des notions fondamentales dérivées du document d'information ont été déterminées et rassemblées en un projet de document avec des éclaircissements additionnels portant sur l'étiquetage des aliments non emballés / non destinés à la vente au détail

15) Il a aussi été dit qu'un titre, un énoncé général et un objet devraient être attribués au texte. Des énoncés généraux ont été proposés et discutés et ont donné les deux énoncés présentés à l'Annexe III. Un certain nombre de délégations étaient favorables à l'énoncé général 1 parce qu'à leur avis il comprenait des notions importantes comme la reconnaissance des préférences des consommateurs et le fait qu'elles pouvaient varier d'un pays à l'autre. D'autres délégations se sont dites favorables à un énoncé général simple de l'objet comme l'énoncé général 2, observant que la sécurité sanitaire et les préférences des consommateurs étant déjà traitées dans le texte même, il n'était pas nécessaire de les mentionner dans l'énoncé général. Le GT n'est pas parvenu à un consensus concernant lequel de ces énoncés devrait former le préambule.

16) Les délégations du Canada et des États-Unis n'étaient pas favorables à l'inclusion du paragraphe 1 de l'énoncé général 1 parce qu'il contient des notions qui n'ont pas fait consensus dans le passé et qui ne feraient probablement pas consensus à l'avenir.

17) Après la discussion des énoncés généraux, les modifications proposées ont été apportées aux textes extraits du document d'information. Ces modifications sont reflétées dans l'Annexe III sous forme de texte souligné. Il a été observé que faute de temps, on n'avait pu examiner en détail le texte même. Par conséquent, les diverses modifications qui sont consignées à l'Annexe III, n'ont pas été pleinement discutées ou approuvées.

18) La délégation du Kenya a dit que les données scientifiques courantes permettaient d'affirmer que les techniques de modification génétique / génie

génétique pouvaient aussi créer des allergènes et a proposé d'ajouter une mention à cet effet soit dans le texte soit dans une note de bas de page dans le paragraphe 5 de l'Annexe III vu que le texte proposé était tiré de la Directive Régissant la Conduite de l'Évaluation de la Sécurité Sanitaire des Aliments Dérivés de Plantes à ADN recombiné (CAC/GL 45-2003) et ne fait référence qu'au transfert de gènes issus d'aliments communément allergéniques.

21) Observant que l'une des modifications proposées au texte extrait correspondait à la suppression de la référence aux *Déclarations de principes concernant le rôle de la science dans la prise de décisions du Codex et les autres facteurs à prendre en considération*, une organisation observatrice a exprimé l'avis que cette référence devrait être rétablie dans le texte parce qu'elle figure dans le manuel de procédure. Le Secrétariat a précisé que les textes dans le manuel de procédure, y compris les *Déclarations de principes concernant le rôle de la science dans la prise de décisions du Codex et les autres facteurs à prendre en considération*, sont destinés à servir d'indications aux comités du Codex et non à être appliqués par les gouvernements.

22) Le GT a en outre observé que le Codex pouvait recommander que la FAO et l'OMS rédigent des orientations ou des guides sur la manière d'établir un régime d'étiquetage qui inclurait des indications sur l'étiquetage des aliments MG/GG.

23) Quant au texte élaboré par le GT, la CE a dit préférer qu'il devienne un document officiel du Codex. La CE a également précisé que toutes ses interventions avaient été faites au nom de tous ses États membres présents à la réunion.

24) En réponse à des questions sur le résultat de la réunion et l'état du texte présenté à l'Annexe III, le Secrétariat a précisé que le résultat de la réunion serait transmis au CCFL aux fins d'examen, et que l'Annexe III est hors de la procédure par étapes du Codex. Il appartiendra au CCFL à sa 36^{e} session de décider s'il fera l'objet d'une discussion plus poussée et (ou) sera ultérieurement incorporé à la procédure par étapes.

25) Le GT a brièvement abordé l'état d'avancement de *l'avant-projet de directives pour l'étiquetage des aliments et des ingrédients alimentaires obtenus par certaines techniques de modification génétique / génie génétique*, en ce moment à l'étape 4, et décidé de ne transmettre aucune recommandation au CCFL à ce sujet.

Conclusion

26) L'Annexe III est transmise au Comité du Codex sur l'étiquetage des denrées alimentaires pour étude à sa 36^{e} session.

27) Les coprésidents et d'autres participants ont remercié le GT de son travail.

28) À la clôture de la réunion, les coprésidents et les participants du GT ont remercié le Ghana de son apport à titre d'hôte de la réunion et de sa remarquable hospitalité.

LISTE DES ANNEXES

Annexe I – Liste des participants

Annexe II – Commentaires soumis en réponse à la CL 2007/38-FL (Langue d'origine)

Annexe III – Résultat de la réunion du GT – Texte extrait du document d'information (Annexe I de la CL 2007/38-FL) avec ajouts suivants soulignés : Projets d'énoncés généraux et de modifications au texte extrait du document d'information conformes aux propositions de certaines délégations.

Annexe I

LISTE DES PARTICIPANTS

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Annexe II
Langue d'origine

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

Comments from:

AUSTRALIA
BRAZIL
CANADA
COSTA RICA
GHANA
JAPAN
KENYA
MEXICO
NEW ZEALNAD
NORWAY
RUSSIA
THAILAND
UNITED STATES OF AMERICA

CI – Consumers International
EC – European Community

AUSTRALIA

Australia wishes to provide the following comments in response to CL 2007/38-FL and would like to thank the United States, Canada and Nigeria for preparing the background paper to this Circular Letter.

1. **The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:**

   a. **The rationale for adopting or not adopting a particular approach**

One of the outcomes of the February 2007 Oslo working group was to identify seven different approaches taken by Member States and the rationale underpinning these approaches.

Labelling for consumer information in relation to method of production labelling (where there is no novel DNA or novel protein in the final food) is not deemed

appropriate by Australia for several reasons. Firstly, there is no issue with regard to health and safety. Second, there are no analytical methods to determine whether a food is GM-derived if no novel DNA or protein is present, and enforcement agencies would be reliant solely on comprehensive documentation of the method of production. Third, there is the potential for such labelling to become an unnecessary barrier to trade. The fourth reason is that Australia considers method of production labelling to be the responsibility of national governments or industry. It is not appropriate for international standards to mandate such labelling because of national differences in consumers' requirements for GM-labelling.

Australia supports the second and fourth approaches to GM labelling discussed by the Oslo Working Group, as these requirements are based on the GM status and altered characteristics of the final food, rather than based on the method of production where there is no novel protein or novel DNA in the final food.

Approach 2: Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food

Australia agrees with the following rationales provided by Member States in support of this approach:

- To allow consumers to purchase food based on its actual content, rather than the process by which it was made. It was argued that it prevents consumer deception by only requiring labelling when GM material is present in the final food and thus allows consumers to make an informed choice. The category provides adequate consumer information commensurate with national demands for information.
- It is enforceable because it avoids requiring labelling of food that does not contain novel DNA or protein which cannot be verified by analytical methods, since there is no current testing available for distinguishing between GM foods and non-GM foods when there is no novel protein or DNA present in the final food.
- It does not impose additional costs on industry and enforcement agencies due to tracking origin of ingredients which could not be justified on the basis of a cost benefit analysis.

Australia requires that genetically modified (GM) foods and food ingredients must be labelled if there is novel DNA and/or novel protein in the final food. The rationale for this regulatory approach is the provision of consumer information to allow informed food choice.

GM-derived foods which are produced from gene technology, but do not contain novel DNA and/or novel protein in the final food, are chemically indistinguishable from their conventional counterparts. At present, there are no analytical methods to determine whether a food is GM-derived (unless it contains novel DNA and/or novel protein).

Furthermore, the mandatory requirement to label GM food and food ingredients is not based on safety. Before entering the Australian food supply, a comprehensive pre-market assessment is undertaken to evaluate the safety of the GM food. This process ensures that GM foods are as safe as conventional foods and that there is no risk to public health and safety from the consumption of these foods.

The safety of GM foods is assessed in accordance with internationally established scientific principles and guidelines developed through the work of the Organisation for Economic Cooperation and Development (OECD), the FAO/WHO and the Codex Alimentarius Commission. Established analytical procedures are used to verify the presence of approved novel DNA and/or novel protein.

The absence of safety concerns relating to approved GM foods and that there are no currently agreed standards for export certification and traceability, are considered by Australia to be sufficient reasons for not requiring mandatory labelling on the basis of method of production (where there is no novel DNA or novel protein in the final food).

Approach 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

Australia agrees with the following rationales provided by Member States in support of this approach:

- The main rationale is food safety linked to labelling of the significant difference and not method of production. It does not require the words GM or GE on the label. It was argued that consumers should be informed about any change in the food and not the method of production. Some countries consider that the important element of information is the substantial difference a food may have as compared to its conventional counterpart.
- Novel foods and GM products are subjected to comprehensive health and safety requirements. If the assessment demonstrates that a GM product is found to have undergone a change in composition, nutrition, toxicity or allergenicity consumers need to be informed, and mandatory labelling informs about these changes. This approach informs consumers about material facts related to the use of the product without misleading the consumer when there are no differences between similar foods based on the method of production. It allows use of labelling as a measure to communicate possible risk to consumers, as a result of a scientifically based risk assessment of the food.
- This approach provides consumers with information to manage their diet and ensures transparency to garner consumer trust.
- This approach is consistent with existing Codex standards for mandatory labelling and is enforceable.

- It retains proportionality between the measure and the risk, and is technically and economically viable for developing countries.

Australia is in agreement that where a substantial difference exists between a GM food and its non-GM counterpart, the GM food should be labelled on the basis of providing information to the consumer relating to composition or intended use of the food. Australia requires that genetically modified (GM) foods and food ingredients in which there is novel DNA and/or novel protein remaining in the final food or have 'altered characteristics' must be labelled. This means that if the GM food is significantly different from its non-GM counterpart with respect to allergenicity, toxicity, nutritional impact or end use, it must be identified on the label as being 'genetically modified'. In addition, mandatory labelling is required where the genetic modification raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification.

1. The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:

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 communication strategies outlined below were submitted previously by Australia in response to the Circular Letter CL-2006/22-FL:

- A number of resources have been developed to assist industry implementation of the labelling requirements for GM foods, including business processes that should be in place to ensure compliance. The GM Standard came into effect in December 2001. Compliance requirements for labelling were included in industry and stakeholder education sessions in all jurisdictions during the transition period.
- The industry user guide '*Labelling Genetically Modified Food'* was published by FSANZ and developed by an intergovernmental working group representing enforcement agencies from the jurisdictions. This user guide outlines the labelling requirements of the Standard and provides information as to how industry can determine whether they have a labelling obligation and how they ensure ongoing compliance.
- In addition, FSANZ has worked with the New Zealand Food Safety Authority to develop fact sheets, which also outline the labelling requirements for GM Foods. FSANZ has an established telephone Advice Line that provides information to industry about the requirements of the Code, including those relating to GM foods.
- FSANZ published an information booklet entitled 'GM Foods: Safety Assessment of genetically modified foods', in 2005. The purpose of the document was to provide consumers with up-to-date information on the processes

undertaken by FSANZ for safety assessment and approval of GM Foods in Australia and New Zealand. The booklet includes information on the labelling requirements set out in Standard 1.5.2.

- Electronic versions of the *Australia New Zealand Food Standards Code*, User Guide to Standard 1.5.2, fact sheets and the 'GM Foods: Safety Assessment of genetically modified foods' booklet are available from the FSANZ Website at www.foodstandards.gov.au. Hard copies of these resources are also available on request.

Most of the strategies noted by the Oslo Working Group used in communicating information to the public on GM foods and GM food ingredients have been or are currently employed by Australia. It is evident from the diverse range of communication strategies used that the needs of each Member country are different and that modes of communication used to deliver information to the consumer are commensurate with the approaches taken for labelling of GM food.

Given that the Australian regulatory approach is based on the final food containing either novel DNA and/or novel protein, or significant changes with respect to allergenicity, toxicity, nutritional impact or end use, Australia considers that communication strategies restated above (in the response to Circular Letter CL 2006/22-FL) provide sufficient information to enable consumers to make informed food choices.

In addition, it is noteworthy that Australia (and New Zealand) consulted widely on the issue of labelling of GM food and consider that public health and safety concerns and consumers' information needs have been addressed by the current regulatory approach.

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.

Australia agrees with the analysis of the application of existing Codex texts to GM labelling. The following points were made about the responses prepared to the frequently raised questions (posed in the Background Paper, Annex 1 to CL 2007/38-FL).

Q1. Do existing Codex labelling texts include guidance with respect to the labelling of GM/GE foods?

Australia is in agreement with the comments made in the Background Paper that existing Codex labelling texts provide guidance for the labelling of GM/GE foods.

Q2. If the GM/GE food is significantly different from its conventional counterpart, what do Codex labelling guidelines require with respect to the labelling of this food?

The background paper has identified Sections 3.1, 3.2, 4.1.1 and 4.1.2 of the *General Standard for the Labelling of Pre-packaged Foods* (CAC/GL 1-1985, Rev. 1-1991) as applicable for determining the appropriate name of the food and any other labelling statements that may be required to inform consumers about the modified attributes of the GM/GE food.

Australia considers that existing Codex text in the General Standard adequately covers requirements for name of the food and any other labelling statements for informing consumers about the modified attributes of the GM/GE food – that is, where the final food is significantly different compared to its conventional counterpart. This is consistent with the regulatory approach taken by Australia. For example, the Australia New Zealand Food Standards Code requires that where the final food has altered characteristics, an additional statement is required to the effect that the food has been genetically modified. At present, there are two foods that must meet this requirement:

1. food derived from high lysine corn line LY038, in relation to increased levels of lysine; and
2. food derived from high oleic acid soybean lines G94-1, G94-19 and G168, in relation to high levels of oleic acid.

Q3. If the GM/GE food contains an allergen, what do Codex labelling guidelines require with respect to the labelling of this food?

Australia notes that the transfer of known allergens is covered by existing Codex labelling texts.

The first text identified by the Background Paper is Section 4.2.2 of the *General Standard for the Labelling of Pre-packaged Foods* (CAC/GL 1-1985, Rev. 1-1991), which includes specific recommendations for the labelling of foods derived from modern biotechnology when such foods contain allergenic proteins.

Australia notes that the reference to allergens in Section 4.2.2 is linked to those known allergens which are listed in Section 4.2.1.4. It appears, however, that other allergens are not captured under the existing Standard. For example, if the DNA is derived from a source which has an allergen which does not require labelling because it is not listed, then consumers may only be able to have adequate information if they are informed of the possible presence of the allergen. This issue may require further discussion. However, it is expected that this would be part of the safety assessment, which is adequately covered by Codex Guidelines, such as *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (Para 43, CAC/GL 45-2003).

Furthermore, Australia supports the comment made in the Background Paper, that this Guideline make no distinction between a food that is sold in pre-packaged form

or in another form and, accordingly apply to all GM/GE foods, whether in pre-packaged form or unpackaged and sold in non-retail containers.

Q4. If the GM/GE food is not significantly different from its conventional counterpart, what do Codex labelling guidelines require with respect to the labelling of this food?

Australia is in agreement with the comments made in the Background Paper, that additional labelling of GE/GM foods is not required unless such foods are significantly different from their conventional counterparts. Mandatory Codex labelling provisions (particularly the General Principles contained within Sections 3.1 and 3.2 of the *General Standard for the Labelling of Pre-packaged Foods* (CAC/GL 1-1985, Rev. 1-1991) are adequate to assure the dissemination of truthful and non-misleading information to consumers about safety and other significant characteristics of the food. Foods derived from modern biotechnology where there is novel DNA and/or novel protein or altered characteristics in the final food would be captured by these sections.

Q5. What types of GM/GE-related claims are permitted in the labelling of foods per Codex labelling guidelines?

Comments made in the Background Paper are supported by Australia. Whilst Codex labelling texts do not contain permissions for specific types of GM/GE-related claims, Section 7.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CAC/GL 1-1985, Rev. 1-1991) permits optional labelling where it does not contradict the mandatory requirements in this Standard, and those relating to claims and deception given in Section 3 – General Principles. Sections 1.2, 1.3, 2, 3.3, 3.5, 4.1, 5.1(iii), 5.1(v) of the *General Guidelines on Claims* (CAC/GL 1-1979, Rev. 1-1991) provide further guidance for voluntary claims about the GE/GM status of the food. Consequently, Australia considers that these labelling texts would be adequate for the purpose of making voluntary claims.

Q6. Do Codex guidelines include any criteria with respect to claims that describe modifications to the nutritional properties of a GM/GE food?

Australia considers that the GM status of a food is not in itself a claim in relation to modifications to the nutritional properties of a food, unless the nutritional characteristics of the final food have themselves been altered.
The Background Paper refers to the *Guidelines for use of Nutrition and Health Claims* (CAC/GL-1997, Rev. 1-2004) with regard to the appropriate use of nutrition claims in the labelling of all foods in general (section 1.2), which includes those obtained through modern biotechnology.

Given that Section 1.3 states these Guidelines are intended to supplement the *Codex General Guidelines on Claims* (CAC/GL 1-1979, Rev. 1-1991), where provisions for making voluntary claims reside, it seems reasonable to utilise them to determine the

appropriateness of voluntary statements to describe the altered nutritional properties of a GM/GE food compared to its conventional counterpart.

Text relating to nutrition labelling in Section 3 of the *Guidelines for use of Nutrition and Health Claims* (CAC/GL-1997, Rev. 1-2004), to which the Background Paper refers, states that "any food for which a nutrition claim or health claim is made should be labelled with a nutrient declaration in accordance with Section 3 of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985 (Rev. 1-1993)).

Q7. Do claims used in the labelling of GM/GE foods need to be substantiated? Do GM/GE-related claims in the labelling of non-GM/GE foods need to be substantiated?

Australia agrees that substantiation of GM/GE foods is required and the Codex labelling text identified in the Background Paper includes provisions for this. Section 1.3 of the *Codex General Guidelines on Claims* (CAC/GL 1-1979, Rev. 1-1991) states that the claims should be justified by the person marketing the food and Section 3.1 states that claims which cannot be substantiated are prohibited.

Voluntary GM/GE-related claims made for non-GM/GE foods should also be subject to verification requirements.

Q8. What guidance do Codex labelling texts offer with respect to claims about the method of production of a food, including a GM/GE food?

In the *General Standard for the Labelling of Pre-packaged Foods* (CAC/GL 1-1985, Rev. 1-1991), claim is defined as "…any representation which states, suggests or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality."

In the *Codex General Guidelines on Claims* (CAC/GL 1-1979, Rev. 1-1991), "a claim is any representation which states, suggests or implies that a food has particular characteristics relating to its origin, nutritional properties, nature, **production** [*bolding added*], processing, composition or any other quality."

Given that the reference to the production of a food resides in the definition of 'claim' within the *General Guidelines on Claims* (CAC/GL 1-1979, Rev. 1-1991), the emphasis should be placed on such labelling statements being made <u>voluntarily</u>. This would be in accordance with other Codex guidelines for voluntary method-of-production labelling terms, such as "Halal".

Australia suggests discussion on whether or not a <u>substance</u> that has been altered through biotechnology and is identified in the ingredient list as 'genetically modified' would be captured by existing Codex labelling text.

Q9. What guidance does Codex provide with respect to the use of food labelling simply to respond to consumer demand for information? How can the fact that

a food is or is not derived from modern biotechnology be made known to the consumer?

Australia agrees with the comments made in the Background Paper, that "Codex does not base its mandatory labelling provisions on consumer demand alone. Codex reserves the mandatory labelling for information specifically about the food itself and recommends that any additional voluntary labelling not be false, misleading or deceptive".

Mandatory provisions contained within the *General Standard for the Labelling of Pre-packaged Foods* (CAC/GL 1-1985, Rev. 1-1991)) encompass labelling requirements for the final food with regard to the use of an appropriate name and additional labelling statements to indicate modified attributes of the GM/GE food.

As discussed in the Background Paper, existing provisions for voluntary labelling statements, in the Codex Guideline documents and in the Standard, are sufficient to ensure that consumers are not misled or deceived. In addition, these provisions are available to provide consumers with 'clear, relevant, and accurate information so as to meet consumer and market needs that are based on personal preferences.'

Australia would like to draw to Working Group members' attention the following Codex text (from The Codex Alimentarius Commission – 15th Procedural Manual), noting it does not refer to consumer demand for information:

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

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. 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 the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

Further to the additional Codex texts provided in the Background Paper, on guidance with respect to GM/GE food labelling and consideration of consumer right to know as a basis for labelling, Australia wishes to bring to the attention of the Working Group other texts relating to previous discussion about the mandate of CCFL for GM labelling. In 1997, CCFL prepared the *Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology* (Alinorm 97/22 A, Appendix VI), shown below:

- "Although the CCFL is responsible only for labelling aspects of biotechnology, these should not be considered separately but in the wider context of ensuring food safety and preventing deceptive practices. It is also necessary to determine the issues related to biotechnology which can be addressed in the framework of Codex, as part of the Project Plan, and those which are outside its mandate" (Para 5).
- "A number of issues raised by the use of biotechnology cannot be addressed in the framework of Codex as they are not related to the food itself, but to the process or other factors which have no bearing on the safety and quality of the product as consumed…. Concerns which are not related to the properties of the food are sometimes put forward as justifying systematic labelling of all foods produced through biotechnology, whether or not they differ from conventional foods…It is therefore necessary to focus on the questions which are within the mandate of the CCFL, essentially labelling issues related to the characteristics of the food itself" (Para 6).
- "As regards the form in which recommendations should be made, the CCFL's mandate is limited to questions specifically related to labelling. It does not include establishing comprehensive recommendations concerning the production processes related to biotechnology, especially as this essentially involves considerations of food safety for which other Committees or Expert Groups are competent, and the Expert Consultation has already made specific recommendations in this area. Guidelines have been prepared or are under development by CCFL in areas where food safety considerations are not essential, such as organic agriculture or the use of the term "halal"….However, in the case of biotechnology, as the Committee is not responsible for food safety aspects, which are addressed elsewhere, it should focus only on the aspects related to labelling" (Para 7).
- "Section 4.1.2 of the General Standard requires the identification of production processes when it is necessary to identify the nature or type of the food (dried, concentrated, etc.). This relates to the treatment undergone by the food itself, but Codex provisions do not go into the production processes of raw materials at the level of agriculture or the mode of selection of plant or animal species. Only in the case of organic agriculture did the CCFL consider means of production because a specific claim was made concerning the type of agriculture and had to be defined. However, unless such a no claim is made, labelling requirements apply only to the nature of the food and not to the agricultural practices or selection processes. An indication relating to the selection and/or production process, as in the case of biotechnology, would go beyond the current area covered by labelling provisions, and this raises an issue of principle concerning the competence of the CCFL and Codex in this area" (Para 9).
- "Such a requirement should be clearly justified in the light of food safety concerns and the prevention of deceptive practices, as all foods put on the market should be clearly identified regarding their characteristics or composition. Any food obtained though biotechnology differing substantively from the corresponding food should be clearly identified as to its specific characteristics,

and any new food (with no existing equivalent) should be described. This is a general requirement which should also apply to any new food put on the market, irrespective of the production process. If the character of a food has been modified in any substantive way from the conventional food which is currently used by consumers, they should be informed of the nature of the changes" (Para 10).

- "The rationale for requiring additional information beyond what is usually covered by Codex is not the nature of the process, but the fact that the essential characteristics of the food have been modified. In order to be consistent with general Codex labelling policy, information on the process should apply only in relation to information on the product itself " (Para 11).
- "Any confusion between safety and labelling issues should be avoided and in particular, it should be clear that labelling is not intended to replace safety evaluation. It is sometimes proposed to label all foods produced through biotechnology as some of them might not be safe. However, the essential principle of any food legislation is to ensure that foods should not be available if they are not safe for consumption, whether conventional or produced through biotechnology. Labelling should provide the consumer with information on precautions for use if necessary, but the inherent safety of the product is a pre-requisite in any case" (Para 22).
- "It appears that recommendations concerning the labelling of foods produced through biotechnology should focus on the areas which are within the mandate of Codex and of the CCFL, and that is relating to the food itself, its safety, characteristics, nutritional composition or intended use, in order to provide clear information to the consumer for any new product obtained through biotechnology presenting specific characteristics not found in conventional foods. Reference to a particular food manufacturing or production process is not usual in Codex and could be relevant in the perspective of Codex objectives only if it is clearly linked to the food itself" (Para 24).

Q10. Do Codex labelling texts provide guidance on labelling related to religious preferences?

Australia agrees with the comments made that guidance on labelling related to religious preferences is provided as voluntary labelling statements. Section 5.1 of the *General Guidelines on Claims* (CAC/GL 1-1979, Rev. 1-1991) and the *General Guidelines for Use of the Term 'Halal'* (CAC/GL 24-1997) are specific texts identified in the Background Paper.

A labelling statement which indicates whether a food is or is not produced using GM/GE does not provide information about the religious acceptability of the food.

Q11. Do Codex labelling guidelines address the safety of GM/GE foods?

Australia notes the Codex texts identified that specifically address the safety aspects of GM/GE foods, and the references to allergenicity of GM/GE foods in Sections 4.2.1.4 and 4.2.2 of the *General Standard for the Labelling of Pre-packaged Foods* (CAC/GL 1-1985, Rev. 1-1991)) and is of the view that the Codex labelling guidelines do address the safety of GM/GE foods.

Q12. Do Codex labelling and other guidelines apply to GM/GE foods that may be sold unpackaged in non-retail containers?

Australia agrees with the comments made that those identified Codex texts identified in the Background Paper apply to GM/GE foods that may be sold unpackaged in non-retail containers.

Overall conclusion:

Australia believes the analysis presented in the Background Paper demonstrates existing Codex labelling texts are sufficient to ensure the safety of GM foods and to inform consumers of any modified characteristics.

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.

The Oslo Working Group listed nine possibilities:

1. Discontinue work on this agenda item
2. Distil common principles and themes which we could agree to take forward
3. Develop general horizontal overarching principles which would be consistent with all the GM approaches presented by members
4. Refer back to the CAC
5. Share the experience of the Working Group with CCFL
6. Continue working on the draft guidelines taking into consideration the outcome of the working group based on information shared by the working group members
7. Discontinue work related to consumer information which should be based on national legislation
8. Continue work related to consumer information (note: it was asked for deletion during our last session, however it was included in the transcript handed out during the WG and no one objected).

9. Focus on guidelines for labelling of GM foods where there is a significant difference from its conventional counterpart where only the significant difference is labelled.

At the 35th Session of CCFL, Australia commented that priority should be given to standard development related to health and safety which is likely to reach consensus and be progressed within a reasonable timeframe. Considering that the analysis indicates that requirements for labelling of GM foods is adequately addressed by existing texts, Australia thinks further consideration of this issue should be given low priority.

Australia notes the lack of consensus and traction to date of this issue over a number of years, and believes this provides a justification for discontinuing work on this guideline.

BRAZIL

The Brazilian Delegation thanks for the opportunity to present the following comments on CL 2007/38-FL and congratulates the delegations of United States, Canada and Nigeria for the excellent background paper elaborated.

1) The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:

a. The rationale for adopting or not adopting a particular approach

Brazilian Delegation position:

In Brazil, the labeling of foods and food ingredients containing or consisting of organisms obtained by certain techniques of genetic modification / genetic engineering is mandatory, as established in the Decree 4.680 of April 24, 2003.

This decree regulates the right to information, insured by the Law 8.078, of September 11, 1990, for foods and food ingredients destined to human or animal consumption that contain or are produced from genetically modified organisms. The Law 8.078/1990, also known as Code of Defense of the Consumer, disposes about the protection and defense of consumer.

In this sense, the main reason for the labeling of the foods and food ingredients obtained through certain techniques of genetic modification, in Brazil, is to guarantee the legitimate consumer right to information, in order to favor his/her conscious choice of foods.

This approach is contemplated in article 2.2 of the Agreement of Technical Barriers to Trade which states that "*…technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-*

fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; ***the prevention of deceptive practices****; protection of human health or safety, animal or plant life or health, or the environment".*

The warranty of this right is also in consonance with the second statement of principles of the Codex Procedural Manual, 15.Ed. - Appendix: General Decisions of the Commission: "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 in food trade".

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

Brazilian Delegation position:

Recently, the Brazilian Government instituted the Policy of Biotechnology Development, Decree 6.041 of February 8, 2007, which states in article 2 that "*it shall be established a communication and participation process to allow the Brazilian society to identify, assimilate, follow-up and make conscious options in the adoption of new technologies, through qualified information, transparency and a trustworthy relation among all stakeholders, in order to promote biotechnology with safety, efficacy, confidence and acceptability*".

Other communication strategies to the public have been developed by segments of the society, such as consumers´ organizations, academic institutions and the industry. These communications cannot mislead the consumer. The Government acts in order to prohibit misleading information and advertising.

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.

Brazilian Delegation position:

The Brazilian Delegation understands that the current Codex labelling texts supply some guidance on the labelling of foods derived from genetic modification/genetic engineering. However, Brazil has doubts about the interpretation of some provisions in the Annex 1 of CL 2007/38-FL. We believe that it is necessary to elaborate more specific provisions on the labelling of foods derived from genetic modification/genetic engineering, as there are for Organic and Halal Foods.

Presence of Allergens

Brazil understands that section 4.2.2 of the Codex General Standard for the Labelling of Prepackaged Foods is clear in relation to the labelling of foods derived from genetic modification/genetic engineering when such foods contain allergenic proteins.

However, the list of foods and ingredients known to cause hypersensitivity in section 4.2.1.4 of the standard should be actualized as new allergenic ingredients are identified. The national authorities may require the mandatory declaration of other allergenic foods and ingredients consumed locally and that are not listed in section 4.2.1.4.

Significant differences in composition, characteristics, nutritional properties, or intended use

The Brazilian Delegation asks for clarification in the interpretation of sections 4.1.1 and 4.1.2 of the Codex General Standard for the Labelling of Prepackaged Foods. We understand that these sections could be used in the labelling of foods derived from genetic modification/genetic engineering even if there is not significant differences in composition, characteristics, nutritional properties and intended use, as they state that *"…**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 packing medium, style, and the condition or type of treatment it has undergone…"*.

Protect consumers from false and misleading labelling information

The Brazilian Delegation considers that sections 3.1 and 3.2 of the Codex General Standard for the Labelling of Prepackaged Foods supply guidance to protect consumers from false and misleading labelling information in foods derived from genetic modification/genetic engineering.

Labelling related to consumer preferences

Brazil understands that the current Codex labelling texts do not provide sufficient guidance on the labelling related to consumers preferences. The labelling provisions to cover consumers' preferences should be established by national authorities.

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).

Brazilian Delegation position:

Brazil agrees with the elaboration of general provisions that are more specific to the labelling of foods derived from genetic modification/genetic engineering. Optionally, some sections of the Codex General Standard for the Labelling of Prepackaged Foods could be amended to attend the specific characteristics of these products.

We suggest that the provisions stats clearly that the requirements for the labelling of foods derived from genetic modification/genetic engineering related to consumer preferences should be established by the national authorities.

CANADA

Canada would like to thank Norway, Argentina and Ghana for co-chairing the upcoming physical working group meeting and is pleased to provide comments on the following areas agreed to at the 35th Session of the Codex Committee on Food Labelling.

1. **The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:**

    a. **the rationale for adopting or not adopting a particular approach for the labelling of food and food ingredients obtained through certain techniques of genetic modification/ genetic engineering.**

    The Government of Canada recognizes that regulation is an important tool for protecting the health and safety of Canadians, preserving the environment, and securing the conditions for an innovative and prosperous economy.

    The Government of Canada established a regulatory policy to ensure its regulatory powers are used in a manner that provides the greatest net benefit to Canadians. The policy has a number of requirements including an obligation for regulators to demonstrate that federal intervention is justified in order to manage a problem or a risk. The regulators must be able to show that a mandatory approach is the best alternative, taking into consideration that the benefit outweighs the costs associated with a regulation being implemented and the regulatory burden be minimized while respecting international obligations.

    While regulations are an important instrument, governments are now considering instruments other than regulation to achieve public policy outcomes. This is prompted by factors such as globalization, international competitiveness, increased emphasis on market solutions, and new philosophies of governance. Governments, including the Government of Canada, are seeking new or modified instruments that provide effective approaches to policy making which are least restrictive and more flexible. These considerations, in addition to the fact that health and safety components are addressed through regulations with respect to foods derived from biotechnology, impacted the policy tool Canada chose to address biotechnology labelling.

    The requirements for the pre-market notification under the *Food and Drug Regulations* for safety assessment of novel food products along with existing

labelling requirements in the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* and their respective *Regulations* affords Canada the leeway to adopt a voluntary approach to the labelling of food and food ingredients obtained through genetic modification.

The Canadian approach to biotechnology labelling consists of both mandatory labelling requirements, when there is a health and safety change or a significant change in nutrition or composition in the novel food (including products of genetic engineering), and voluntary labelling requirements for method of production labelling.

Novel foods, including those produced through biotechnology or genetic engineering, are subject to comprehensive health and safety requirements. The *Food and Drug Regulations* require that before a novel food can be advertised or sold, Health Canada be provided with sufficient accompanying information to enable it to undertake a safety assessment to demonstrate that the novel food is considered to be safe and nutritious as foods already on the Canadian marketplace.

In keeping with these regulatory requirements, Health Canada established a clear and stringent process for evaluating the safety of foods derived through genetic modification[4]. The specific criteria for the safety assessment of such foods are outlined in the Health Canada publication "Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms" (http://www.hc-sc.gc.ca/fn-an/legislation/guide-Id/nf-an/guidelines-lingesdirectrices_e.html).

In principle, food products derived from genetic modification that are demonstrated to be safe and nutritious are treated in the same manner as non-genetically modified foods with regard to labelling requirements. If the assessment demonstrates that a food product derived from genetic modification is found to have undergone a change in composition, nutrition, toxicity or allergenicity that the consumer needs to be informed of, then mandatory labelling is required to inform Canadians about these changes in the food. Health Canada, in consultation with the Canadian Food Inspection Agency (CFIA), would determine what type of information is needed on the label to highlight how the novel product differs from its non-modified counterpart.

Health Canada and the CFIA share the responsibility for food labelling policies under the *Food and Drugs Act*. Health Canada is responsible for developing policy and setting standards related to the health and safety aspects of labelling under the *Food and Drugs Act and Regulations*, whereas the CFIA applies these policies and enforces the regulations. The CFIA also has

[4] Genetically modified, as defined in Division 28 of the FDR, means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation.

the mandate to develop basic food labelling policies and regulations not related to health and safety. In particular, the CFIA is responsible for protecting consumers from misrepresentation and marketplace deception with respect to food labelling, packaging and advertising, and promoting fair market practices by prescribing and enforcing standards related to food labelling and advertising requirements.

For method-of-production labelling, such as biotechnology, the Government of Canada has traditionally supported market-driven initiatives. In this regard, food producers and manufacturers may voluntarily label their products, provided the label is truthful, not misleading, and in compliance with all domestic regulatory requirements set out in the *Food and Drugs Act and Regulations*, the *Consumer Packaging and Labelling Act and Regulations*, the *Competition Act* and all other relevant legislation.

This approach to labelling has been supported by a number of consultations, in which the Government of Canada has carried out and participated in, related to biotechnology labelling. The outcomes of these consultations[5] indicated that there was general consensus:

- to build on current food safety approach: mandatory labelling for health & safety, nutritional, compositional changes;
- that labelling is understandable, truthful and not misleading
- that the approach chosen must take into account domestic and international considerations
- that information for consumer choice can be facilitated through voluntary labelling by food manufacturers
- to permit voluntary positive and negative labelling on the condition that the claim is not misleading or deceptive and the claim itself is factual

All of these outcomes could be achieved within Canada's current regulatory framework for food.

This approach was supported by the Royal Society of Canada Expert Panel on the Future of Food Biotechnology, the Canadian Biotechnology Advisory Committee (CBAC) and the House of Commons Standing Committee on Agriculture and Agri-Food. In particular, the Royal Society of Canada's Expert Panel on the Future of Food Biotechnology identified that it did not, on the basis of scientifically established health hazards, find a justification for the

[5] Workshop on Regulating Agricultural Products of Biotechnology (Nov 1-10, 1993)
Technical Workshop on the Labelling of Novel Foods Derived Through GE (Nov 24-25, 1994)
Communiqué: Labelling of Novel Foods Derived through Genetic Engineering (Dec 1, 1995)
Food Biotech and Consumer Information: Do we need to label? (Dec 6-7, 1995)

mandatory labelling of biotechnology-derived foods. However, the Panel did call for the implementation of a reliable and informative system of voluntary labelling. In addition, CBAC recommended that the voluntary system be evaluated 5 years after its implementation to ensure adequate choice was provided for consumers.

This voluntary approach to biotechnology labelling offers Canada the opportunity to support and enable Canadian social, environmental and economic priorities, achieve high standards of protection for citizens and to enhance business confidence and public trust in Canada's regulatory system

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 with particular reference to how Members label their foods.

Canada's approach to communication has been to focus on biotechnology and the issues related to it, rather than biotechnology labelling itself. The communication strategies related to genetically engineered (GE) food have been shaped by numerous consultations and activities over the years. The Government of Canada's communication approach to GE foods has been one of continual improvement in understanding and responding to public and stakeholder information needs. These activities include:

Mechanisms Used to Collect Information

Public engagement through consultations has helped develop guidelines and regulations. The consultation process includes conducting workshops, convening multi-stakeholder meetings, and distributing draft documents for the general public's review and comment. Another form of consultation employed is the citizens' conference, also known as a consensus conference. This form of consultation provides Canadians with a forum to voice any concerns they may have with respect to policy or regulatory decisions which may be taken by the Government.

As an example, the Health Products and Food Branch (HPFB) of Health Canada have organized a Public Advisory Committee (PAC), comprised of 16 to 20 Canadians. The committee meets three times a year as a public / consumer involvement forum, to advise on issues and initiatives as requested by HPFB[6].

Public Opinion Research (POR) is another mechanism commonly used by the Government of Canada to gather information regarding important issues to stakeholders, including consumers.

[6] Minutes from previous the committee meetings can be found on the Health Canada website at: www.hc-sc.gc.ca/hpfb-dgpsa/ocapi-bpcp/index_e.html

Since 1999, the Canadian Biotechnology Secretariat and its partners have maintained a large-scale tracking program of public opinion research (POR). Results have been consistent since the inception of the research program. The cumulative research shows a clear upward pattern in Canadian support for biotechnology in general, with the caveat that people do not offer blanket support or opposition to any area of this technology. GE foods have lower support, and lower perceived overall benefits, than other biotechnology applications.

The program currently produces one wave of research each year. Each wave has a large tracking component, along with sections of more intensive inquiry into specific issues like genetic privacy, GE food, molecular farming, GE trees, and stem cell research.

The CBS Communications Working Group has published all of its POR reports on the Government of Canada's BioPortal website[7].

A more formal mechanism available to the Government of Canada is to request **expert advice** from various independent organizations.

In 1998, the CFIA funded an independent study by the National Institute on Nutrition (NIN), to see what type of information Canadians actually wanted on labels[8]. It is important to do such studies, to move beyond anecdotal "evidence." The knowledge garnered from the NIN study, set the stage for how the CFIA would communicate information to consumers about GE labelling, in order to assist them in their food choices. The key findings of the NIN study were that consumers wanted simple labels, linked to agriculture and government regulatory approval. The study also found that product labelling was not viewed as the only way to provide information.

In 2000, an expert panel was formed under the auspices of the Royal Society of Canada to study the future of food biotechnology and the federal regulatory capabilities and capacities to deal with these issues. The panel's report, titled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*[9] was made available to the Government of Canada for consideration and response.

The panel discussed Canada's labelling policy for genetically engineered food products. They conclude that there are not currently sufficient reasons to

[7] www.biotech.gc.ca or www.biostrategy.gc.ca/english/view.asp?x=524

[8] More details on the study can be found on the CFIA website, at "National Institute of Nutrition Study on Voluntary Labelling of Foods from Biotechnology": www.inspection.gc.ca/english/sci/biotech/labeti/ninintroe.shtml

[9] www.rsc.ca/index.php?page_id=119

adopt a system of general mandatory labelling of GM foods. They do not lead necessarily to the same conclusion about voluntary labelling. Many of the concerns voiced in favour of mandatory labelling can be addressed, at least in part, by voluntary labels.

The final independent organization that provided advice to the Government of Canada regarding labelling of biotechnology derived products was the Canadian Biotechnology Advisory Committee (CBAC), composed of external experts and laypersons. CBAC provides advice to federal ministers on social, economic, regulatory, scientific, ethical, regulatory, and environmental and health aspects related to biotechnology. In its report tabled in 2004 titled "*Improving the Regulation of Genetically Modified Foods and other Novel Foods in Canada*", CBAC made several recommendations[10] regarding labelling GE food.

The most formal mechanism available to the consumers to participate and for the Government of Canada to collect information is by participation in **parliamentary activities**.

The Government of Canada has participated in numerous hearings by Parliamentary Committees such as:

- the Standing Committee on the Environment and Sustainable Development
- the Standing Committee on Agriculture and Agri-Food
- the Senate Standing Committee on Energy, the Environment and Renewable Resources

The bulk of work done by Members of Parliament is in these standing committees. There they study and amend bills, and examine important issues and departmental spending plans (known as the Estimates) in depth. Committee work requires Members to read background documents and meet experts in various fields, including lawyers, economists, special interest groups, business persons and senior government officials. Committee work enables Members to study issues and legislation in greater detail than is possible in the Chamber. Minutes are made public via posting on the internet[11].

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[10] The report on food biotechnology, titled *Improving the Regulation of Genetically Modified Foods and other Novel Foods in Canada*, is posted at:
http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00186e.html *(html version)*
http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/Improving_Regulation_GMFoodAug02.pdf/$FILE/Improving_Regulation_GMFoodAug02.pdf *(pdf version)*

[11] Minutes from the Standing Committee on the Environment and Sustainable Development are found at: www.parl.gc.ca/35/Archives/committees352/sust/minutes/sust_issue-03_19-29/sust_03_covE.html
The report from the Standing Committee on Agriculture and Agri-Food, (June 2002) can be found at: www.parl.gc.ca/InfoComDoc/37/1/AGRI/Studies/Reports/agrirp23-e.htm

Though labelling of genetically engineered foods was discussed in the three Standing Committees listed above, the most significant recommendations came from the Standing Committee on Agriculture and Agri-Food. In their report titled "Labelling of Genetically Modified Food and its Impacts on Farmers: Report of the Standing Committee on Agriculture and Agri-Food contained four recommendations on labelling, as follows:

- That the government continue to develop a standard for the voluntary labelling of food derived from biotechnology. That standard should use a narrow definition of GMOs, as proposed in the draft standard produced by the Canadian General Standards Board.
- That the government intensify research into the benefits and risks to human health and the environment of agricultural products derived from biotechnology, and bring forward a public information program.
- That the government assess the additional costs, particularly for farmers and consumers, of implementing segregation and tracking systems, which are necessary for the labelling of GM foods, and report to the Committee and the House of Commons.
- That the government assess the trade implications of mandatory versus voluntary labelling of GM foods, and report the results of this assessment to the Committee and the House of Commons.

In addition, the Government of Canada responds to correspondence received from Canadians, on the topic of GE food labelling. While there has been a decline in the numbers of letters from the late 1990s, there is still a certain volume of letters received every year. By supporting the Minister of Agriculture and Agri-Food in his or her communications in the House of Commons, and in ministerial correspondence, the CFIA is able to explain labelling policy to the Canadian public.

The final mechanism is the **environmental petition process**. The petition process provides an opportunity for Canadians to ask the government questions concerning activities being undertaken by the government with respect to sustainable development.

The Government of Canada has responded to petitions regarding request for information concerning the Government of Canada position on labelling and transparency[12]. In Petition 23, the petitioners asked the federal government to review its laws, regulations, and policies on a number of fronts, and to adopt a series of suggested measures aimed at protecting the health, safety, and environment of Canadians from genetically modified organisms (includes

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Proceedings of the Standing Senate Committee on Energy, the Environment and Natural Resources can be found at: www.parl.gc.ca/36/2/parlbus/commbus/senate/Com-e/enrg-e/09cv-e.htm?Language=E&Parl=36&Ses=2&comm_id=5

[12] Petition 23: *Review of Federal Laws, Regulations and Policies on Genetically Modified Organisms* (9 May 2000): www.oag-bvg.gc.ca/domino/petitions.nsf/viewe1.0/099F91DB55C481EE85256C5600689A94

labelling). In addition, the government has responded to questions related to human, social, and environmental impact of genetic engineering, including questions about the production and licensing of GE crops, and the impact of GE crops on human health, biodiversity, and sustainable farming (includes labelling)[13].

Communication Strategies

As demonstrated above, the Government of Canada, through various activities, has gathered a great deal of information regarding Canadians views on issues related to genetically engineered foods. However the key design to effective communication strategies is taking that information and developing materials which provide information to a specific audience in a manner that they can understand and use to make decisions.

For instance the information gathered from the consultations the government participated in and conducted, and expert advice provided by the National Institute of Nutrition were used as a basis for the development of the Voluntary National Standard. Recognizing the importance of transparency and making the National Standard available, the CFIA established a five year web licensing agreement with the CGSB so the public and industry have free access to the voluntary standard. The voluntary standard is available via the Canadian General Standards Board web site at: http://www.pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html and is available, without charge, in hard-copy format. You can also request a copy from the: CGSB Sales Centre (Sales Centre, Canadian General Standards Board, Gatineau, Quebec, K1A 1G6).

In a second communication initiative, the government took into consideration the Royal Society of Canada and CBAC reports, as well as the labelling and biotechnology recommendations of the fourth and fifth reports by the Standing Committee of Agriculture and Agri-food. This communication strategy was developed to drive further work on transparency for biotechnology at the CFIA, some of which was about labelling in particular.

One transparency project undertaken provides a way for the public to look, in detail, at the assessment process for biotechnology-derived food crops, showing a product assessment's beginning, middle, and end. Each component is available on the CFIA website, in text and graphical form.[14] In the first component, the Biotechnology Notices of Submission Project, summaries of biotechnology-derived plant product submissions are posted to the CFIA website, and the public is invited to provide comments on the submissions[15].

[13] Petition 108: *Social, Health and Environmental Concerns of Genetic Engineering* (7 April 2004): www.oag-bvg.gc.ca/domino/petitions.nsf/viewe1.0/B8F93B1077687CAB85256FB40050F95A

[14] For all three projects, see the graphic "Looking inside the Assessment Process", at http://www.inspection.gc.ca/english/sci/biotech/trans/approve.shtml

[15] www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml

Other transparency work, which took into consideration public opinion research, recommendations from the Standing Committees and expert advice, included:

- Improvement of the shared Government of Canada information kit for GE foods
- Delivery of further information about CFIA regulation of biotechnology to consumers via development of fact sheets, and info kit and poster distribution
- delivery of public presentations, for example to the United Church of Canada, for some of its congregational consultations (the CFIA also provided information to the United Church for its consultations across Canada)
- delivery CFIA-wide training on biotechnology to our Operation staff
- focus testing of biotechnology factsheets and then applying what was learned when writing new factsheets
- development of the Biotechnology Highlights report which was made publicly available
- development of an educator's resource for post-secondary instructors titled *Regulation of Agricultural Biotechnology in Canada: Post-Secondary Educator's Resource*

In addition to these initiatives, the Government of Canada has developed communication material, which has resulted and benefited from the information gathering activities. Communication material on GE food labelling included:

- Information brochures
- Magazine supplement
- Information kits
- Posters
- Factsheets
- News releases

A key consideration in developing effective communication material is the principle of risk communication. Older views on how to communicate with the public about risk focussed on public misperception of risk and how to educate the public about the "real" risk. But more modern approaches stress the importance of factoring in public reaction to risk, and this has led to the view that there needs to be a real two way interaction between experts and lay people in order to achieve a common view on risk. These principles are considered at the root of all communication material produced by the Government of Canada.

Through the Government On-Line initiative, the Government of Canada committed itself to being the government that is the most connected to its citizens, with Canadians being able to access government information and

services on-line (www.ged-gol.gc.ca/rpt2006/rpt/rpt00_e.asp). Government of Canada departments and agencies put a great deal of their information on their websites, for public access.
In order to enhance the availability of information related to biotechnology, the Canadian Biotechnology Secretariat developed the Government of Canada BioPortal, a unique one-stop window to government and biotechnology. The portal has a section on labelling, and it also has a section on governments and international organizations (www.biotech.gc.ca).

Evaluating the effectiveness of communication strategies and material

Over the years, the Government of Canada has evaluated the effectiveness of these messages. For instance the CFIA had factsheets tested by the public in focus groups, and discussed by media experts, for clarity and comprehension. The focus testing indicated that readers want the following in factsheets:

- question and answer format
- clarity on definitions
- why the new product was developed
- risks and benefits
- how much research has been done
- how long the research took and where it took place
- who evaluates it (government, universities, or companies)
- long-term impacts
- other websites to go to for further information

Another way the CFIA has had its products evaluated is through a forum on the challenges of communicating science to non-scientific audiences. The forum, entitled "Biotechnology: Plain Language for a Complex Subject," brought together scientists, researchers, lab technicians, evaluators, policy officers, managers and communicators, along with three media panellists to discuss biotechnology communications. The forum gave scientists and researchers an opportunity to meet media panellists face-to-face, ask questions, and discuss issues and challenges that they face as government communicators and scientists. Panellists also had the opportunity to critique some of the CFIA's biotechnology news releases and fact sheets. While the panellists had praise for two of the factsheets, they had some advice on changing the CFIA news releases. The CFIA has used this advice to improve its information products.

These evaluations provide information that can be used to improve communication material being reviewed, and the findings are used in the development of subsequent communication material.

Conclusion

Communicating about GE foods and labelling in Canada has meant using a variety of methods to continually improve the understanding of the information needs of the public, stakeholders, and parliamentarians. It has also meant improving how the Government of Canada responds to those needs. Through this on-going work, the Government of Canada continues to contribute information to help Canadians make informed food choices.

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.

In preparing the informative background document with the United States and Nigeria, Canada had an opportunity to analyse whether current Codex texts can be related to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering. In undertaking this work and carrying out this analysis, Canada considers, given the discussion which has taken place and issues which have been raised at the Codex Committee on Food Labelling, that the current Codex texts sufficiently address the needs expressed by Member Countries with regards to genetic modification/genetic engineering labelling. Given this conclusion, Canada does not see the need to further elaborate specific guidelines for the labelling of foods derived from genetic modification/genetic engineering as we find that such a document would be duplicative.

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).

Given that current Codex texts sufficiently address the needs expressed by Member Countries with respect to the labelling of food and food ingredients derived through certain techniques of genetic modification/genetic engineering, Canada supports discontinuation of work under this agenda item.

Alternatively, Canada suggests that the Working Group make a recommendation to the CCFL to refer this agenda item to the Executive Committee for consideration under its Critical Review Process.

COSTA RICA

Costa Rica desea expresar sus comentarios en relación con el citado anteproyecto de directrices y extiende al Gobierno de Canadá su apoyo como país hospedante de los temas del CCFL. Asimismo manifestamos nuestro agradecimiento a los países

coordinadores del Grupo de Trabajo actual (Estados Unidos, Canadá y Nigeria) y anterior Grupo de Oslo (Noruega, Argentina y Ghana), por la incesante dedicación de brindar al resto de países miembros del Codex, orientaciones relevantes para el avance de los debates.

En relación con el inciso a del punto 1 de la carta circular, sobre los motivos para adoptar o no adoptar un enfoque en particular, Costa Rica considera que los debates para avanzar en un anteproyecto de directrices para el etiquetado de alimentos obtenidos por ciertas técnicas de la biotecnología moderna/ingeniería genética, ha creado un distanciamiento enorme entre lo que debe informarse al consumidor en relación con la inocuidad de estos alimentos e ingredientes obtenidos de la modificación genética/ingeniería genética y lo que requieren los Gobiernos, para orientar las mejores prácticas que permitan identificar elementos asociados para proteger la salud de los consumidores, además de velar por un trato justo en el comercio internacional.

En particular y como país en desarrollo, sentimos especial preocupación porque este tema ha llevado muchos años de discusión sin llegar a un consenso entre las partes bajo las tendencias actuales del anteproyecto, que lejos de favorecer las economías de países en desarrollo podría generar una limitación extrema a nuestras expectativas de exportación, si finalmente el Comité del Codex sobre Etiquetado de los Alimentos (CCFL), llega a establecer directrices para etiquetar alimentos por el método de producción, ya que de ello dependería que muchas de nuestras micro, pequeñas y medianas empresas, deban buscar recursos adicionales para declarar esta información en las etiquetas bajo las condiciones conocidas, sin que ello garantice que el alimento o los ingredientes bajo esta modalidad, sean o no inocuos para el consumo, agregando a esto interpretaciones confusas que podrían darse sobre la seguridad de estos productos. En este sentido apoyamos orientaciones relacionadas con la determinación de la inocuidad para estos alimentos e ingredientes y no con respecto a su método de producción.

Desde esta perspectiva, los debates del Codex han mostrado algunos puntos de consenso sobre los cuales se podría avanzar, sin dejar de lado otros asuntos que no han sido abordados por lo grupos de trabajo del CCFL, en particular la viabilidad técnica y económica, y los costos de implementación que significaría para los países en desarrollo (ALINORM 07/30/22, párrafo 102).

Ante lo anterior y reconociendo que los debates del Codex podrían continuar "per se", si el CCFL no decide una forma de avanzar en consenso, Costa Rica considera que la mejor manera podría ser enfocándose en un ***anteproyecto de directrices cuando hay una diferencia significativa en comparación a sus contrapartes convencionales y cuando solo se etiqueta la diferencia significativa***. Esta opción está respaldada por el consenso de los países, demostrando que la información que se disponga en las etiquetas garantizaría la obligación de declarar estos cambios significativos en relación con las características, la composición, el valor nutricional o el uso para el que se destine el alimento. Desde el punto de vista de los gobiernos se garantiza la información acerca de estos cambios y se fomentaría en las empresas

mayores investigaciones que favorezcan los efectos nutricionales de estos alimentos en relación con sus contrapartes convencionales. No obstante lo anterior, es nuestra opinión que sería importante una nueva propuesta en relación con las diferencias significativas de composición, características, valor nutricional o uso del alimento, debe aclarar cuál sería la mejor forma de presentar dicha diferencia a nivel del etiquetado, esto con el fin de evitar confusiones e interpretaciones subjetivas posteriores.

En relación con el inciso b del punto 1, Costa Rica no cuenta con estrategias de comunicación para informar al público acerca de los alimentos e ingredientes obtenidos por ciertas técnicas de modificación genética/ingeniería genética, sin embargo a nivel profesional si se reciben orientaciones sobre esta materia, a través de charlas, seminarios, conferencias, foros, talleres y cursos por medio de instituciones públicas, académicas o entidades internacionales.

Con respecto al punto 2 de la carta circular, Costa Rica manifiesta que analizó el informe preparado por Estados Unidos, Canadá y Nigeria y considera que este documento contiene una buena orientación para nuestros países y llena las expectativas de información con respecto a que Codex contiene normas y textos que recomiendan adecuadamente la actuación para desarrollar el análisis de riesgos y la evaluación de la inocuidad de los alimentos, así como orientaciones específicas sobre la mejor forma de aplicar los textos del Codex para el etiquetado de los alimentos e ingredientes obtenidos de ciertas técnicas de modificación genética/ingeniería genética.

En relación con el punto 3, el Codex no puede dejar de dar orientaciones a los países, y muchos países en desarrollo requerimos de estas orientaciones, en especial porque la información sobre el análisis de riesgos y la inocuidad de los alimentos se basan en criterios técnicos y científicos aceptados internacionalmente. Nuestra opinión radica en que ya se han abordado ampliamente los elementos que inciden en los procedimientos para evaluar el riesgo y garantizar la inocuidad de estos productos, pero no debe limitarse a ello, sin embargo bajo el informe de este Grupo de Trabajo y el Grupo de Oslo, se evidencia la necesidad imperante de concretar orientaciones consensuadas, de ahí que bajo nuestra perspectiva un documento de directrices podría ser el más apropiado para lograr alcanzar objetivos favorables para todos los países.

EUROPEAN COMMUNITY

The European Community and its 27 Member States (ECMS) appreciate the opportunity to provide comments on the "Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering" and respectfully wish to submit the following comments:

The rationale for adopting or not adopting a particular approach

Rapport de la réunion du Groupe de travail du CCFL tenue à Accra, Ghana, du 28 au 30 janvier 2008

The Working Group on Labelling of Foods and Food Ingredients obtained through certain techniques of Genetic Modification/Genetic Engineering that convened in Oslo, Norway on 6-7 February identified seven different approaches to GM labelling that were seen as representative among Codex member states.

Out of these seven approaches, the European Community (EC) has adopted the first one, i.e. *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)*.

According to this approach, all food that consists of, contains or is produced from GMO has to be labelled as such irrespective of the presence of modified protein or DNA. The objective of this legislation is to allow the consumer to make an informed choice about whether the food he is purchasing is GM or not. It is not the objective of this legislation to stigmatize GM food as being somehow unsafe. In fact, only GM food that has been thoroughly evaluated for its safety by the European Food Safety Authority may be placed on the market in the Community.

In the past, before the new legislative framework entered into force in the EC in 2003, the EC had adopted the second approach (*mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food*). However, based on demands expressed in numerous surveys by a large majority of consumers, the EC extended the labelling requirements to foods produced from GMO, irrespective of the presence of modified DNA or protein. This labelling facilitates informed choice and precludes potential misleading of consumers as regards the methods of manufacture or production of the food. It is in line with the general labelling requirements in the EC, that provide that labelling must not mislead the purchaser as to the characteristics of the foodstuff and among other things, in particular, as to its nature, identity, properties, composition, method of production and manufacturing.

It is further more in line with the Codex mandate from 1991 in which the Commission requested the CCFL to provide guidance on how the fact that a food was derived from modern biotechnologies could be made known to consumers.

The EC recognises thus the consumers' right to information and labelling as a tool for making an informed choice as regards genetically modified food.

It should be noted that the GM labelling as currently implemented in the EC is not the only example for a labelling based on production process. Codex itself has developed General Guidelines for use of the term "halal" that contains specific process-based criteria for the use of the term "halal" on food.

Also the labelling of irradiated food, as foreseen in the legislation of many Codex member countries, informs the consumer about a process applied to the food (i.e. irradiation) irrespective of whether or not this process has caused a material change in the food. In addition, there are a series of other voluntary labelling schemes that

achieve similar objectives, for instance labelling of food as organic, quality labels or labels indicating that a food has been produced with particular respect for animal health (dolphin safe) or animal welfare (eggs from free range hens).

Regarding approach number 5 (voluntary labelling guidelines for foods that are or are not products of genetic engineering) the ECMS would like to note that in preparation of the current legislation, the European Commission had examined the merits and disadvantages of a number of different labelling approaches, including the one that would complement the mandatory labelling provisions that were in force at the time (based on the presence of DNA or protein resulting from the genetic modification) with a Community-wide voluntary "GMO-free" (or similarly phrased) scheme.

The European Commission's preparatory work, including experiences in some Member States, revealed that voluntary "GMO-free" (or similarly phrased) schemes were beset by a number of technical, commercial and other difficulties. It also became evident that consumers in the EC were primarily interested in knowing whether their food was produced from GMOs or contained ingredients produced from GMOs. Consumers clearly prefer to be informed about what is in products and not about what is not in products. For this reason, the European Commission abstained from proposing a GMO-free labelling scheme at Community level. Some Member States have however introduced provisions at national level to make sure that when such a labelling is used, it is truthful and not misleading.

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

The ECMS believe that GM labelling is actually the first tool to provide the consumer with accurate information on the products he is purchasing enabling him to make a free choice. GM labelling enhances transparency throughout the food chain and might ultimately contribute to restore the consumer's confidence in the application of gene technology in the agro-food sector.

In addition, the EC has, via its Research Framework Programmes given financial support to a series of projects in the area of life sciences and biotechnology. One of these projects has lead to the establishment of a website www.gmo-compass.org on which independent science journalists give information about GM foods and bio-safety research.

The European Commission has placed information relating GM food on the website of the Commission Directorate-General for Health and Consumer Protection (DG SANCO) http://ec.europa.eu/food/food/biotechnology/index_en.htm. This website gives a comprehensive overview on the legislation on GM food (and feed) in place in the Community, as well as on the GM food (and feed) that are authorised. It also provides a document with questions and answers on GMO regulation in the EU.

Moreover, the national authorities attempt to provide objective information to consumers on techniques of genetic modification of food and food ingredients, their implications on health, the legal requirements regarding their production, marketing and labelling on their respective homepages and via informative brochures. Some EC Member States (e.g. Spain) have also put in place information modules in school programmes.

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

The EC and its Member States (ECMS) wish to thank the United States, Canada and Nigeria for their background paper on the Labelling of Foods Obtained through Certain Techniques of Genetic Modification / Genetic Engineering. This paper provides an overview on how current Codex texts relate to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering. The ECMS agree with the authors of the paper that the presence of an allergen in a GM food or any significant differences in composition, characteristics, nutritional properties or intended use should be labelled in accordance with the relevant Codex provisions.

However, as the analysis clearly shows, the existing Codex texts on labelling present two serious shortcomings: On the one hand, they leave GM labelling to the voluntary domain, and on the other hand, they do not give guidance about how the fact that a food has been derived from modern biotechnology should be made known to the consumer as requested by the Codex Commission in 1991. For these reasons the ECMS are of the view that existing Codex labelling texts do not supply sufficient guidance on the labelling of foods derived from genetic modification. The comprehensive analysis carried out by the United States, Canada and Nigeria represents a strong argument to focus the CCFL work on the above-identified shortcomings.

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

The ECMS are of the opinion that it would be very useful for Codex members, and especially for developing countries, to develop a list of overarching horizontal principles with the objective to provide guidance to those involved in the development of national legislations. These principles would not aim at establishing which of the seven approaches is the most appropriate. Even if some of these principles already exist, it would also be very useful to collect in a single document the relevant provisions contained in various Codex texts.

GHANA

We wish to congratulate Canada, the United States of America and Nigeria for the working group document.

1. The rationale for adopting or not adopting a particular approach

Ghana prefers the adoption of Approach 1: Mandatory GM labelling of all foods derived from or containing ingredients derived form organisms produced using gene technology (food consisting of, containing or produced from GMOs)

Rationale:

There is currently a general labeling regulation in Ghana, LI 1541, that provides for the labeling of prepackaged foods. The LI 1541 which was adopted from the Codex Standard on Food Labelling does not make any special provisions for the labeling of novel products. A Biosafety Bill has been placed before parliament that requires that products from GM/GE foods should be labeled as such. In the build up to the drafting of the Bill, there was a general consensus that Ghanaians would like to make informed choices regarding GMOs and that information should be provided on the label. This is against the backdrop of our lack of capacity to test for GMOs.
The ordinary consumer is therefore relying almost entirely on label information. Sometimes all that a consumer needs to know is whether a particular food or food ingredient has been made through GM/GE technology to help make a decision. There is also a perception that an absence of explicit labeling indicates a deliberate agenda by producers/manufacturers to keep vital information from the consumer and this only results in mistrust.

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.

Ghana's Biosafety Bill covers public awareness and participation and recommends measures in Article 42. Consequently a guideline on "Public participation, Information Sharing and Access to Justice" with respect to GMOs has been published. Ghana has also developed a strategic communication plan which among others uses a variety of communication channels and processes including print and electronic media to address the specific needs, concerns and expectations of the various target groups. A Biosafety Clearing House mechanism is also in place to facilitate exchange of information and experience with respect to GMOs. The Food and Drugs Board has a public awareness agenda which is being strengthened. Training for the media/journalists has been carried out whilst farmers and other relevant stakeholders are being educated through regional outreach activities.

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

Ghana notes the content of all relevant Codex labelling texts and Claims as outlined in the circular letter. At the time the Codex General Standards for Food Labelling were elaborated; irradiated foods, organic foods and food and food ingredients derived from certain techniques of genetic modification/genetic engineering may not have been anticipated and were not explicitly covered by Codex standards or texts. Codex has adopted mandatory labelling for irradiated foods and has developed guidelines for organic foods.

Therefore, Ghana is of the view that it is still necessary that Codex develops additional guidelines to provide uniformity in the labelling of genetically modified foods for countries that opt for labelling requirements for such foods.

3. The consideration of appropriate ways forward, taking into account the results of analysis of undertaken in 2 and the suggestion of the possible ways forward identified by the Oslo Working group

Ghana recommends that the current Codex provisions on labelling remain as they are but that additional guidelines are developed to help those countries who require mandatory labelling of GMOs.

JAPAN

We are pleased to respond to CL 2007/38-FL. We would like to express our appreciations for Ghana's hosting a physical working group on labelling of genetically modified foods as a chair. We would also like to thank the United States, Canada and Nigeria for preparing the discussion paper, which we believe is helpful for member countries to prepare their responses to the circular letter. We look forward to fruitful discussions at the physical working group in January 2008.

1. The further consideration of certain areas originally specified in the mandate of the Oslo working group:

a. The Rationale for Japan's Approach to the Labeling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering

We would like to reiterate that there are two rationales for Japan's introducing labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering (hereafter "GM foods") in 2000.

The primary rationale is to enable consumers to make informed choices, because the majority of them pleaded for labelling of GM foods in the situation that GM foods were expected to be imported and distributed in Japan. The second rationale is to

ensure that only GM foods which have been confirmed as safe by the mandatory safety assessment shall be distributed in Japan.

b. Communication Strategies used in Communicating Information to the Public on Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering

We believe that disseminating information of the labelling of GM foods is highly important so that consumers, as well as operators in charge of labelling, are better informed. We provide information to the public through websites and brochures.

Items subject to labelling in the labelling standards are reviewed annually, taking into account the distribution of GM foods in the world market, the advancement of detection technologies of DNA in foods and consumers' concerns. The public are provided with opportunities to make comments on the review itself and new items to be added before the amendment to the labelling standard is adopted. The public are able to get permissions to present and express their views at the committee for deliberating the standard.

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

We always take into account relevant Codex texts when we establish or revise technical regulations and voluntary standards on food labelling. Existing Codex labelling texts do not directly address the labelling of GM foods. Therefore, we introduced the labelling of GM foods and maintain the labelling system, taking into account the mandate of Codex and relevant provisions in *the General Standard for the Labelling of Prepackaged Foods*.

It might be difficult for the Codex to develop a labelling text on GM foods at this point, considering differing approaches to GM foods labeling in various countries and the discussions at the past CCFL sessions, but we believe that the establishment of the guidelines for labelling of GM foods will be helpful, especially for member countries which need Codex recommendations for framing their own labelling legislations.

3. The consideration of appropriate way forward, taking into account the result of the analysis undertaking in 2 and the suggestion of the possible ways forward identified by the Oslo WG.

We support the 6th option, "Continue working on the draft guidelines taking into consideration the outcome of the working group based on information shared by the working group members", among the possible ways forward identified by the Oslo WG . The labeling of GM foods in terms of providing consumers with informed choices is a matter of great interest for consumers in importing countries of foods,

including Japan, because GM foods production have been increasing and GM foods are likely to be continuously marketed in the whole world.

KENYA

Kenya honour and appreciate the good work of the working Group held between 34th session and 35th session in Oslo, Norway,6th -7th Feb 2007 and the paper prepared by United States, Canada and Nigeria for the 36th Session in Canada.

We have noted that the definition part of the Food Labelling standard is in step 7 yet the labelling provision is at step 4 for many years.

We would be pleased to see the whole standard moving collectively in the next CCFL meeting after taking into consideration the codex members comments and the view of the observers.

We are pleased to give our comments on CL2007/38 as follows:

Q1.a The rationale for adopting or not adopting a particular approach.

Our Response

We would like to adopt approach 4, which states as follows:

Approach 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.

Rationale

1.Kenya accepts this approach because it is based on safety and it is used on issues that are verifiable and enforceable in addition to the rationales given below (a, b and c).

a. It demonstrates that a GM product is found to have undergone a change in composition; nutrition, toxicity or allergenicity and consumers need to be informed. Such issues therefore require the mandatory labelling approach.

b. It demonstrates substantial difference a food may have as compared to its conventional counterpart.

c. It retains proportionality between the measure and the risk, and is technically and economically viable for developing countries.

Q1.b. The communication strategies we use in communicating information to the public on foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering are as follows.

1. Facilitate operationalisation of a secretariat for coordinating biotechnology awareness creation

2.Create mechanisms for establishment of national, provincial and district Biotech Information and Resource Centers (BIRCs) to serve as focal points for information provision, knowledge-sharing & rapid response

3.Facilitate production, packaging and dissemination of accurate, authoritative and timely biotech -Information, Education and Communication (IEC) materials to various stakeholders

4.Initiate mechanisms for mainstreaming of biotechnology into the curricula of schools and tertiary institutions of learning.

Q2. 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.

Kenya noted that the existing texts are sufficient as indicated in table 1 below but should allow countries to develop and enforce national guidelines on labelling of genetically modified foods when necessary.

Q3. 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).

Kenya fills that the possible way forward is item number 2 listed down by the CCFL working group that states: "distil common principles and themes which we could agree to take forward" We propose that the CCFL looks at the common principles which unite the codex member countries come up with the conclusion rather than dividing us. The work of GMO labelling has been going on for over 15 years so it is better to have some significant beneficial result out of it.

Reference For Question 2

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

Section	**Mandatory Labelling Provisions**	**Application to labelling of GM/GE foods**
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.	Labelling of all prepackaged foods, which includes those obtained through GM/GE, must be consistent with these principles.
3.2	Pre-packaged 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.	Where GM/GE results in a significant difference in the attributes of the food, this principle requires appropriate mandatory labelling to accurately reflect the basic nature and characteristics of the food. The following circumstances would be covered under sections 3.1, 3.2, 4.1.1 and 4.1.2: - Significant difference from the conventional counterpart such that the traditional name does not sufficiently describe the food - Significant difference in the intended use of the GM/GE food - Significant difference in nutritional properties of the GM/GE food
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.	Safety-related labelling of GM/GE foods is addressed through this provision Allergens introduced or present in a GM/GE food must be declared in the labelling of that food.

Table 1 (cont'd). Provisions in existing Codex labelling texts that can be applied to the labelling of GM/GE foods

Section	Voluntary Labelling Provisions	Application to labelling of GM/GE foods
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.	This provision applies to voluntary statements used in the labelling of all prepackaged foods, which includes those obtained through GM/GE
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.	A GM/GE-related claim can be voluntarily made by manufacturers provided such labelling is consistent with this principle
1.3	The person marketing the food should be able to justify the claims made.	The marketer of a food bearing a voluntary GM/GE-related claim should be able to substantiate the claim, such as through appropriate and adequate documentation

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.	This definition explicitly provides that voluntary statements and descriptors related to the method of production of a food are within the scope of these guidelines
3.3	Prohibited claims – Claims which cannot be substantiated.	A voluntary GM/GE-related claim that cannot be substantiated is prohibited
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.	A voluntary GM/GE-related claim that could arouse or exploit fear or could give rise to doubt of the safety of the food among consumers is prohibited
4.1	Potentially misleading claims – Meaningless claims including incomplete comparatives and superlatives.	A voluntary GM/GE-related claim that includes incomplete comparatives or superlatives may be misleading
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.	A voluntary GM/GE-related claim could be viewed similarly and used under the conditions specified in this provision
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.	A voluntary GM/GE-related claim may be made under the conditions specified in this provision
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.	A voluntary GM/GE-related claim may be made under the conditions specified in this provision
Guidelines for Use of Nutrition and Health Claims		These guidelines can be applied to the

(See Annex 1 of this paper) see	voluntary use of nutrient content and nutrient comparative claims in the labelling of all foods, including GM/GE foods

MEXICO

En seguimiento al acuerdo del Comité de Etiquetado de los Alimentos de establecer un Grupo de Trabajo Físico para considerar el tema del Etiquetado de Alimentos e Ingredientes Alimentarios Obtenidos por Ciertas Técnicas de Modificación Genética/ Ingeniería Genética, en el que se observarán los términos de referencia que señala el documento CL 2007/38-FL, México pone a la consideración del Comité los siguientes comentarios con respecto a dichos términos de referencia

1. **Mayor consideración de ciertas áreas especificadas originalmente en el mandato del Grupo de Trabajo, particularmente:**

    a) **motivos para adoptar o no adoptar un enfoque en particular**

Desde el punto de vista legal, el argumento fundamental es que México cuenta con una Ley de Bioseguridad de Organismos Genéticamente Modificados, que establece los casos en que es requerido el etiquetado de Organismos Genéticamente Modificados (OGM) y de productos que los contengan:

En aquellos casos en que sus características sean significativamente diferentes respecto de los productos convencionales. En estos casos, se deberá hacer referencia explícita a "organismos genéticamente modificados" y señalar en la etiqueta su composición alimenticia o propiedades nutrimentales diferentes de su contraparte convencional.

Por el contrario, dicho ordenamiento jurídico no establece la obligación de etiquetar en los casos en que el OGM no sea diferente de su contraparte convencional. Tampoco exige el etiquetado por Proceso o Método de Producción.

Desde el punto de vista técnico, la política seguida por las autoridades sanitarias en México, en cuanto a la evaluación de la inocuidad de alimentos que sean o contengan OGM para consumo humano, ha sido la evaluación sistemática, caso por caso y paso por paso de los eventos genéticos sometidos por los desarrolladores y dar dictamen positivo sólo cuando, con base en la evidencia científica disponible, se demuestre que el alimento es tan inocuo como su contraparte convencional.

En consecuencia, considerando el riesgo sanitario, sólo es necesario etiquetar cuando de la modificación genética derive un producto substancialmente diferente con

respecto a su contraparte convencional; es decir, en aquellos casos en que el OGM presente cambios significativos en su composición o en sus propiedades nutrimentales, o presente riesgos para la salud de grupos poblacionales específicos, con respecto a su contraparte convencional.

b. Las estrategias de comunicación utilizadas para comunicar informaciones al público, respecto de alimentos e ingredientes alimentarios obtenidos por medio de ciertas técnicas de modificación genética/ingeniería genética.

La Autoridad Sanitaria, tiene disponible a través de su portal de Internet (www.cofepris.gob.mx) la lista positiva de OGM liberados para la comercialización. Estos productos han pasado ya por un proceso de evaluación de seguridad, que pueden considerarse aptos para el consumo.

Adicionalmente, existe información sobre el tema por parte de la Comisión Intersecretarial de Bioseguridad de Organismos Genéticamente Modificados y la Procuraduría Federal del Consumidor, y en la página de internet del Biosafety Clearing House, del Convenio de Diversidad Biológica.

2. Emprender un análisis de los presentes textos del Codex, particularmente los textos de etiquetado del Codex, evaluar si estos textos proveen o no suficiente orientación sobre el etiquetado de los alimentos derivados de ciertas técnicas de modificación genética/ingeniería genética.

México agradece mucho el esfuerzo de Estados Unidos, Canadá y Nigeria para integrar el "Documento de antecedentes para el Etiquetado de Alimentos e Ingredientes Alimentarios Obtenidos por Ciertas Técnicas de Modificación Genética/ Ingeniería Genética" que aparece como anexo I del documento CL 2007/38-FL para la reunión del Grupo de Trabajo con presencia física que se reunirá en Ghana del 28 al 30 de enero de 2008.

México ha considerado estos textos como parte de sus trabajos y deliberaciones para definir su posición como país a lo largo de estos años más de diez años de trabajos en el marco del Comité de Etiquetado de los Alimentos y no encuentra elementos adicionales para cambiar su posición y reiteramos que, sólo es necesario etiquetar cuando de la modificación genética derive un producto substancialmente diferente con respecto a su contraparte convencional; es decir, en aquellos casos en que el OGM presente cambios significativos en su composición o en sus propiedades nutrimentales, o presente riesgos para la salud de grupos poblacionales específicos, con respecto a su contraparte convencional.

3. Considerar formas apropiadas de avanzar, tomando en cuenta el resultado del análisis emprendido bajo el punto 2 y la sugerencia de

posibles formas de avanzar identificadas por el Grupo de Trabajo de Oslo (por ejemplo, directrices, principios, o discontinuar el trabajo).

Durante los años que lleva este tema en la agenda del CCFL, han quedado evidenciados los distintos enfoques de los miembros del Codex, que derivan en posiciones encontradas que muy difícilmente son reconciliables en la circunstancia actual, como para permitir una decisión por consenso[16].

Por lo anterior, México apoyó suspender las discusiones sobre este tema hasta en tanto existieran circunstancias adecuadas para lograr avances por consenso.

NEW ZEALAND

New Zealand is pleased to submit the following comments in response to CL 2007/38 FL. As requested in the circular letter the following comments related to the three broad areas set out in points 1, 2 and 3.

1. ISSUES ARISING FROM THE OSLO WORKING GROUP MEETING

Discussion and analysis of options

In its comments on the draft report of the Oslo Working Group, New Zealand noted that the list of elements identified for GM labelling greatly oversimplified the situation and that the report did not capture the divergent opinion expressed at the meeting. New Zealand commented at the working group that the labelling regime that NZ adopted in 2001 under the joint Australia/New Zealand food standards setting system for application in both countries was implemented after a careful analysis of a range of options. The options were evaluated against a very rigorous regulatory impact analysis framework taking into account the benefits and costs of each option for consumers, industry and the Government. It should also be noted that no genetically modified foods (GMF) can be sold without a full safety assessment. The safety assessment and labelling of foods are distinctly different processes and labelling is not a substitute for safety assessment.

The options considered were as follows:

Option 1: label all genetically modified foods (i.e. where derived or developed from an organism which has been modified by gene technology); this option would required labelling based on the production process and raised a number of questions in terms of costs and international consistency.

[13] Ver las recomendaciones de la 55ª reunión del Comité Ejecutivo.

Option 2: label all GMF ingredients, which appear at concentrations of more than 1.0% of in-going weight. This option was also not favoured because of the balance of costs over benefits.

Option 3: Label for presence -label where genetically modified material is present and detectable in the final food or the food has altered characteristics. A 1.0% threshold for adventitious contamination of the final food; under this option specific labelling would only be required where the final product contained new genetic material.

Option 4: label all single ingredient GMFs and any GM ingredients which are present in a concentration of 1 % or greater in the final food.

The Government reviewed each option against the criteria for standards development including the need to take account of New Zealand's international obligations. On the basis of this analysis, the Government decided in favour of **Option 3** which was deemed to best meet the interests of consumers, industry and the government. It was also determined to be in line with New Zealand's international obligations.

New Zealand believes that it is important for the discussions within Codex on labelling options for GM foods be informed of the processes of national decision making and the considerations that went into the analysis and choice of options. Recognition and understanding of national processes are also important given the diversity of national situations and consumer expectations.

2. ANALYSIS OF CURRENT CODEX TEXTS

New Zealand welcomes the background paper prepared by the United States, Canada and Nigeria. New Zealand agrees with the analysis and comments contained in the background paper. It is clear from the analysis that there is already a large body of guidance available to members on labelling of foods including those derived from modern biotechnology. Specifically, Codex already has in place extensive and very specific guidance covering such critical areas such safety assessment, allergenicity, significant differences in composition, nutritional properties or intended use. In addition there are also various provisions that provide guidance on voluntary labelling that may be relevant to GM products.

As emphasised in the introductory commentary, '...labelling is considered only after the food has undergone appropriate assessment to deem it safe for human consumption'.

We support the analysis and conclusions presented in section three including the specific comments relating the 'protection of consumers from false and misleading labelling information.' Extensive guidance is already available in existing Codex texts both in respect of mandatory and voluntary aspects of labelling of foods including those derived from biotechnology.

New Zealand also concurs with the analysis and comments on the issue of labelling related to consumer preferences. We take particular note of the Executive Committee on the critical considerations that influence Codex decision making on labelling of foods based on production processes. The mandatory provisions already established by Codex address these critical elements while other provisions that are voluntary are available to members taking into account particular national circumstances.

3. CONSIDERATION OF WAYS FORWARD

The overwhelming conclusion that New Zealand would draw from the background paper is that there is already sufficient guidance available to members to address both the safety and non safety related attributes for labelling of all foods including those derived from biotechnology.

New Zealand believes that there remain significant differences on how to proceed on the issue of labelling of GM foods. The issue has been under discussion for well over a decade and the Commission is no closer to consensus particularly on those issues that are best addressed at the national level. In the circumstances, New Zealand would support suspension or discontinuation of work on developing specific guidelines for labelling of foods derived from biotechnology. This is in line with the Commission's new approach to standards management.

While we do not support continuation of the current work, we do believe that there is merit in compiling a consolidated document that brings together all existing labelling provisions relevant to labelling of foods derived from biotechnology. Such a document would have the advantage of meeting the needs of members for specific guidance on critical elements of labelling of foods derived from biotechnology while not entailing new work. The background paper prepared by the US, Canada and Nigeria brings together all the relevant information and should facilitate expeditious development of such a compendium.

NORWAY

Norway is pleased to provide comments to the Codex Circular Letter CL 007/38-FL regarding the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering. Norway would also like to thank the United States, Canada, and Nigeria for the prepared background paper.

As a general comment regarding food labelling we would like to explain that the Norwegian basis for labelling is **the consumers' right to know**. By acknowledging this right, we seek to secure transparency and openness and to gain consumers trust in food on the market. This approach facilitates fairness of transactions between seller and purchaser, which is regarded as a basic principal for fair practises in food trade. This principle has been implemented in our regulation on labelling of foods and food

ingredients obtained through certain techniques of genetic modification/genetic engineering (GM food).

Regarding the definition on health seen in connection with the general scope of Codex which is i.a. protection of health, Norway would also like to point out that some consumers may experience strong ethical, religious, emotional or other objections for purchasing specific foods. These perceived risks may influence the health and that this also has been recognized by the WHO in their definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". These aspects of health should also be considered when the needs for new standards are discussed.

In the following document we comment on questions 1- 4 as asked for in the CL.

1. The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:

a. The rationale for adopting or not adopting a particular approach

The Norwegian GM food labelling regulation complies with the first approach specified in the Oslo meeting (ref. CX/FL 07/35/8).

- *Mandatory labelling of all foods derived from or containing ingredients derived from organisms produced using gene technology (food consisting of, containing or produced from GMOs)*

We have had mandatory GM food labelling requirements since 1997, based on a parliamentary resolution from 1995. Members of the Parliament based their decision on the acknowledgment of the consumers' basic right to know, and the need for openness and transparency regarding many aspects related to labelling of food and food ingredients, e.g. ingredient list, allergens, food additives and new production methods. The labelling regulation apply to all GM foods including GMOs and food derived from GMOs, whether their properties or characteristics be different from those of comparable conventional food or not.

Our rationales for choosing this approach are also equivalent with the rationales put forward during the Oslo meeting;

I. *The main rationale behind this is based on the CAC mandate from 1991 ALINORM 91/40 paragraph 90 and the consumers' right to make an informed choice. The aim is to meet the demands expressed in consumer surveys, and it is the only approach which allows consumers to choose according to the method of production i.e. between GM and non GM foods.*

II. *This approach secures transparency and facilitates the consumer's right to informed choice. It is enforceable in combination with a traceability system and also in compliance with Codex Standards for labelling.*

III. *It was stated that the safety assessment is an integral part of the mandatory GM labelling requirements. These requirements are proportionate as they take into account the demands of consumers and the economic concerns of industry and they apply to both locally produced and imported foods.*

IV. *Mandatory GM labelling also highlights the intrinsic qualities of GM foods in comparison with their conventional counterparts (e.g. fewer pesticides).*

We would also like to add the following rationales:

- There has been developed Codex Guidelines in areas where food safety considerations are not the essential issue, such as organic agriculture or the use of the term "halal" and "irradiated food" [17]. This strengthen the role of labelling as a mean to ensure fair practices in food trade, and that requirements concerning various production processes have been and will be asked for in the future.
- A label on a food product indicating that it is containing or derived from a GMO food will easily be understood, since this is considered to be desired by the majority of consumers, whether they want GM foods or not.
- To label food according to different quality aspects, food processing methods and/or ethical values gives the consumer the basic knowledge for making informed choices.
- The label with information on whether a product consists of or is derived from a GMO can be verified by using GMO analysis and/or documentation control. Requirements on traceability are verified by documentation control for producers and distributors.
- Consumers are of the opinion that GM foods are different from conventional foods, simply because another production method (and hence not a traditionally production method) has been used. Consequently, the consumers want GM food to be labelled with this information (production method) irrespectively of the detectability of DNA or protein resulting from the genetic modification in the final product. Labelling of GM foods are the consumers' desire for making informed choices, which should be provided for by specific requirements on GM food labelling.

Approaches 2-6

Five other approaches were identified in the Oslo meeting;

- *"Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food.*

[14] Alinorm 97/22A, Appendix VI, point 7

- *Mandatory labelling of GM food only where it is significantly different from its conventional counterpart*
- *Voluntary labelling requirements for method of production, irrespective of whether the food or ingredients contains DNA or protein.*
- *Labelling requirements under development*
- *No special labelling requirements for bioengineered foods as a class of foods"*

Arguments used in favour of choosing one approach are likely to be the same used for not choosing another approach. Since our overall purpose for labelling GM foods is to inform the consumer that a product consists of or is derived from a GMO, then the other five approaches mentioned above will not fulfil this purpose.

1. The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:

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

Education and information are essential elements for making consumers able to make informed choices. Today's society has plenty of various information channels to use; as newspapers, television, internet, cinemas etc. On the other hand, and most important food labelling is the primary means of communication between the producer and seller of the food on one hand, and the purchaser and consumer o the other. Therefore, using information channels as mentioned above are valuable, but will never compensate for direct labelling on the product. Thus, Norway is of the opinion that the only accurate means to give information to the consumers, is by labelling the products.

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.*

The background paper carried out by United States, Canada, and Nigeria is a very useful background paper, and gives a good overview on how Codex texts relate to the labelling of foods. However, we will pinpoint some other aspects as well.

- The Norwegian view is that the consumers need for information and their right to know has not been clearly expressed or dealt with in this paper. The consumers interest may among several other aspects be based on safety, environmental or ethical values, and may influence the human health, either physically, mentally and/or social well-being as expressed by WHO's definition of health. Therefore, Norway would like it to be noted as a very important argument.
- Our understanding is that a product containing or derived from a GMO and not labelled as such, will be seen upon as having false and misleading

labelling statements. In our opinion GM foods versus conventional foods will never be the same product, and should therefore be labelled differently. We can not see that this has been clearly expressed.

- Having read current Codex texts on labelling GM foods and the background paper, we have seen that there are paragraphs in the Codex texts which can be read differently by different countries. The different understanding of a text can easily be misused and can even be used to mislead consumers. Our opinion is therefore that since existing standards and/or guidelines can be interpreted differently, there is a significant need to make a guideline for labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering.

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, and the consumer demands for information on GM foods has also increased after these existing texts where adopted. *We therefore conclude that existing texts do not provide sufficient guidance on the labelling of foods derived from genetic modification/genetic engineering.*

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).

If a country should choose to develop national requirements for the labelling of GM foods, we consider it to be very helpful to have some overarching principles as a framework and guidance. Such principles must comply with the provisions of Codex standards and related texts, in particular Codex Standards on Labelling.

There has been done a tremendous work regarding the existing Draft Guidelines. However, the drafted guidelines have not been discussed for almost two years and new information has been shared by Codex members. We therefore believe that a way forward might be to continue work on the Draft Guidelines.

With reference to above mentioned arguments and the nine suggested possible ways forwards in the Oslo meeting, Norway would at this point like to support further work as stated in point;

> *3. Develop general horizontal overarching principles which would be consistent with all*
> *the GM approaches presented by members*, and

In a longer perspective the way forward should be;

> *6. Continue working on the draft guidelines taking into consideration the outcome of the*
> *working group based on information shared by the working group members.*

RUSSIA

General horizontal principles for the labelling of foods obtained by genetic engineering/genetic modification

When developing national/regional requirements for the labelling of foods obtained by genetic engineering/genetic modification, Codex Members should take into account the following principles:

1. These requirements should fully comply with the provisions of Codex standards and related texts, in particular Codex Standards on Food Labelling;
2. The minimal requirements should address issues related to food safety, e.g. change in composition or nutritional properties, allergenicity;
3. Countries may use one or more of the following three approaches to GM labelling:

A. 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)

B. Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food.

C. 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. Monitoring data analysis of GMO-occurrence in food showed that GMO content at the levels less than 0.9% should be considered as occasional or technically unavoidable admixture so food products with such GMO concentrations should not be the subject of mandatory GM-labelling.
5. The basic rights of consumer for information enabling them to make informed choices should be strictly followed;
6. Appropriate control measures should be put in place to prevent against false and misleading labelling of foods obtained by genetic engineering/genetic modification;

THAILAND

Thailand would like to thank the drafting group consisting of the US, Canada and Nigeria for preparing the excellent background paper. In our point of view, we believe that the existing Codex texts provide adequate room to cover the issues proposed for the standard of the GM/GE foods labelling. The only issue which has not been adequately specified in the existing standards is the allergen from GM/GE foods. The most appropriate way forward is to revise the provision on allergens in

section 4.2 of the General Standard for the Labelling of Prepackaged Foods in order to cover the potential occurrence of allergens from GM/GE foods.

UNITED STATES OF AMERICA

The United States welcomes this opportunity to respond to CL 2007/38-FL regarding the labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering (GM/GE). Specifically, CL 2007/38-FL invited member countries to provide information on the following items identified in the CL:

1. The further consideration of certain areas originally specified in the mandate of the Oslo working group, particularly:

    a. The rationale for adopting or not adopting a particular approach.
    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.

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.

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).

1a. Rationale for adopting or not adopting a particular approach

As the United States previously noted in its response to CL 2006/22-FL (CX/FL 07/35/8, Appendix II), the United States does not have special labeling requirements for bioengineered foods as a class of foods. The labeling requirements that apply to all foods in general also apply to foods produced using biotechnology. Each food is required by law to bear a common or usual name or, in the absence of such a name, an appropriately descriptive term. In addition, the label of the food must reveal all material facts about the food. Thus:

- If a bioengineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.

- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made in the labeling to describe the issue.
- If a bioengineered food has a significantly different nutritional property, its labeling must reflect the difference.
- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed in the labeling.

All statements made on a food label or in the labeling of a food must be truthful and not misleading.

Rationale for not requiring mandatory labelling: As previously noted in a response to CL 2006/22-FL, the United States does not consider the methods used in the development of bioengineered foods to be "material" information. The United States considers the new methods of genetic modification to be extensions at the molecular level of traditional methods that will be used to achieve the same goals as pursued with traditional plant breeding. The United States is not aware of any information showing that bioengineered foods differ in any meaningful or uniform way, or, as a class, present any different or greater safety concern than foods developed by traditional plant breeding. In addition, scientific bodies in the United States as well as a FAO/WHO expert consultation have reported on the safety assessment of GM/GE foods. The United States is confident that the bioengineered plant foods on the U.S. market today are as safe as their conventionally bred counterparts. Manufacturers have a legal obligation to ensure that any food they market is safe. This applies equally to conventional foods and bioengineered foods. (Refer to the United States' response to CL 2006/22-FL for additional information, including legal considerations (CX/FL 07/35/8, Appendix II)).

1b. Communication strategies

As the United States also previously noted in its response to CL 2006/22-FL, the U.S. Government communicates with its stakeholders in a number of ways, including through the internet (the United States Regulatory Agencies Unified Biotechnology Website at http://usbiotechreg.nbii.gov and FDA's activities related to bioengineered foods at http://www.cfsan.fda.gov/~lrd/biotechm.html) where comprehensive information about the regulation of biotechnology products in the United States is provided. The U.S. federal rulemaking process offers ample opportunity for the public to provide their comments and bring to the forefront any concerns they may have on any issue related to the rule in question. In addition, for technical regulations and sanitary and phytosanitary measures within the scope of the WTO TBT and SPS Agreements, notification of proposals are made to WTO members, and inquiry points for information are established as required by these Agreements. Additionally, FDA communicates with consumers through its official magazine, *FDA Consumer*, which reports on current FDA activities related to the products the agency regulates, including foods. FDA previously informed consumers about the safety and labeling of genetically engineered foods and, as appropriate, responded to consumer inquiries

through publications in the *FDA Consumer* (Available on the Internet at: http://www.fda.gov/fdac/). (Refer to the United States' response to CL 2006/22-FL for additional information (CX/FL 07/35/8, Appendix II)).

2. Analysis of current Codex texts

The United States reviewed existing Codex texts, including Codex labelling texts, to evaluate whether or not these texts supply sufficient guidance on the labelling of GM/GE foods. The United States also reviewed other documents such as FAO/WHO reports that are relevant to issues surrounding the labelling of GM/GE foods. The Background Paper attached to CL 2007/38-FL, prepared by the United States, Canada, and Nigeria, elaborates on the provisions in various Codex texts that address safety, labelling, and other issues related to GM/GE foods. The United States believes that the issue of labelling of GM/GE foods should be viewed in light of concerns which member countries have expressed at CCFL. Such concerns include: 1) potential allergenicity of the GM/GE food and related safety concerns; 2) need to identify significant changes to the basic identity or essential characteristics of the food; 3) need to protect consumers from false and misleading labelling information; and 4) need to provide information to satisfy consumer demand consistent with consumer preferences.

As explained in the Background Paper, existing Codex labelling texts contain provisions that address each of these concerns. Specifically, 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 foods in general and, therefore, apply equally to GM/GE foods.

In addition, the Codex guidelines for the safety assessment of foods derived from modern biotechnology, specifically CAC/GL 45-2003 and CAC/GL 46-2003, include specific guidance with respect to the assessment of possible allergenicity of these foods. Further, Codex developed several principles and guidelines in texts relating to food import and export inspection and certification systems that apply to all foods in general, which include GM/GE foods; these principles ensure that foods and their production systems meet certain requirements necessary to protect consumers against food-borne hazards and deceptive marketing practices and facilitate trade on the basis of accurate product description. Finally, the FAO and WHO have published several reports of expert consultations which carefully reviewed safety aspects related to GM/GE foods.

The United States believes that existing Codex texts provide adequate guidance to member countries on various questions related to the labelling of GM/GE foods (see section V of the Background Paper, Frequently raised questions about the labelling of GM/GE foods). These existing texts should be examined and issues/elements specific to GM/GE foods that may not be adequately addressed in these existing texts

should be identified prior to determining what, if any, appropriate CCFL actions are necessary.

3. Consideration of appropriate ways forward

As explained above, an analysis of existing Codex texts shows that potential allergenicity concerns related to GM/GE foods is adequately addressed in Codex labelling texts. In addition, Codex has adopted several texts specifically on risk analysis and safety assessment of these foods. Issues relating to the import and export of such foods are addressed by the Codex texts on import and export certification systems that apply to all foods, which include GM/GE foods. With respect to providing truthful and non-misleading information to consumers about these foods, Codex labelling texts provide sufficient direction and guidance for the presentation of mandatory as well as optional information in food labelling.

The United States considered the comments and concerns expressed by developing countries in recent CCFL discussions. We believe that these concerns either are explicitly covered or can be addressed through general provisions in existing Codex labelling and other texts. Based on the analysis described in the Background Paper, the United States believes that existing Codex texts provide sufficient overall direction and guidance to address member countries' needs and concerns related to the labelling of GM/GE foods.

With respect to appropriate ways forward, the United States asks member countries to consider the following:

1. The United States welcomes comments from member countries on whether there are other Codex texts or FAO/WHO reports that are not included in the Background Paper and that provide additional guidance on issues relevant to the labelling of GM/GE foods. Further, the United States seeks input from member countries on whether the Background Paper accurately interprets the application of existing Codex texts to GM/GE foods.

2. The United States urges member countries to consider whether there are any issues, needs or concerns, particularly those of developing countries, that are not adequately addressed in the Background Paper and/or existing Codex texts[18]. If so, which of these needs are within the scope and mandate of CCFL?

   Alternatively, are there any issues, needs or concerns outside the scope and mandate of CCFL that are more appropriately addressed in other contexts or

[15] For example, member countries may have specific questions related to economic issues pertaining to the labelling of GM/GE foods. An evaluation of the economics of mandatory labelling of GM/GE foods in India was recently published by the International Food Policy Research Institute (IFPRI Discussion Paper 00704, May 2007). Similarly, these types of concerns can be appropriately addressed through other institutions with relevant expertise.

fora? For example, is there a need for expanded outreach or educational efforts related to risk assessment evaluations of GM/GE foods from FAO/WHO to further assist member countries?

3. Another factor to consider is whether current Codex labelling provisions identified in the Background Paper need additional clarification with respect to their application to GM/GE foods. For example,

- Several provisions identified in the Background Paper, particularly provisions in Codex labelling texts, are general provisions that apply to all foods and, therefore, are applicable to GM/GE foods. Is there a need to clearly specify within the scope of Codex labelling texts that the provisions contained in those texts apply to all foods, including those obtained through any novel production or processing technologies?

- An area that may need clarification is the application of the principles of Codex labelling texts to bulk foods or foods sold in non-retail containers. Is there a need to clearly specify that the principles underlying the labelling of prepackaged foods, i.e., that all labelling should be truthful and non-misleading, should apply to information disseminated during the marketing of foods in bulk or in non-retail containers?

CONSUMERS INTERNATIONAL

Summary

Consumers International (CI) appreciates the opportunity to comment on CL 2007/38-FL. In particular, we would like to comment on the following items in the terms or reference for the working group: 2) analysis of current Codex texts, 3) consideration of an appropriate way forward and 4) a proposed outcome—namely draft general horizontal principles for the labelling of foods obtained by genetic engineering/genetic modification.

CI supports continued discussion of the issue of labelling of foods obtained by genetic engineering/genetic modification (GE/GM). 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 labelling 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.

CI supports discussion and adoption of the *Draft Proposed Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification-Genetic Engineering.* Consumers International supports comprehensive labelling of GMOs. The *Draft Guideline* outlined three options for mandatory labelling, including the option of comprehensive labelling.

An alternative way forward for the Codex Committee on Food Labelling (CCFL) would be to discuss general horizontal principles for labelling of foods obtained via GE/GM. We propose text below for these horizontal principles, based on the output of the Oslo Working Group report.

Codex Risk Analysis texts support labelling of foods derived from GE/GM

CI notes that the background paper prepared by the US, Canada and Nigeria does a good job of listing/discussing all the Codex texts that may relate to labelling of foods obtained through certain techniques of genetic modification/genetic engineering. However, we believe that the most import Codex texts to look at are those that directly address biotechnology that were developed by the Codex AdHoc Intergovernmental Task Force on Foods Derived from Modern Biotechnology—especially the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) and Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003)—as well as the 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. All these documents support/permit the labelling 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). These principles clearly state that labelling 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 labelling, 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).

A number of recent scientific studies have pointed out such unexpected effects in genetically modified crops and have shown that they can lead to potential adverse health effects. For example, a 2005 animal study on transgenic peas found that the genetic engineering/genetic modification process unexpectedly turned a protein that is relatively "safe" into one that causes adverse health effects and increased the potential for adverse effects in other proteins[19]. A group of Australian scientists looked at the transfer of a gene from beans into peas. The gene codes for a protein, α-amylase inhibitor (αAI), that confers resistance to certain weevil pests. The αAI in raw beans inhibits the action of amylase, an enzyme that degrades starch. So αAI in raw beans can cause gastrointestinal problems in humans. When beans are cooked, the αAI is easily digested and causes no problems. However, when the gene for αAI was inserted into peas, the resultant protein had the same amino acid sequence as the bean αAI, yet the structure of the protein had been subtly altered (through a process called post-translational processing), causing an immunological reaction in mice fed the transgenic peas, but not in mice fed normal beans. The adverse/immunological reaction to the transgenic pea αAI was not mitigated by boiling the peas. The mice fed transgenic peas, in addition to developing an immunological reaction to the pea αAI, also developed an immunological reaction to a number of proteins normally found in peas; mice fed these same proteins from non-engineered peas developed a far smaller immunological response, thus demonstrating that the transgenic pea αAI acts as an adjuvant to increase the immunogenicity of native pea proteins.

This new study involving αAI is extremely important. This study found that moving the same gene between two relatively closely related plants (common beans and peas) can result in a protein that, although it contains the exact same amino acid sequence, is relatively safe in the donor plant (common beans), but is potentially harmful in the recipient plant (peas) and can increase the potential hazardousness of other proteins found in peas. These are all clearly unintended and unexpected effects that clearly result in an adverse health effect.

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[20]

[19] Prescott, VE, Campbell, PM, Moore, A, Mattes, J, Rothenberg, ME, Foster, PS, Higgins, TJV and SP Hogan. 2005. Transgenic expression of bean α-amylase inhibitor in peas results in altered structure and immunogenicity. *Journal of Agricultural and Food Chemistry*, 53: 9023-9030.

[20] 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

(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 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.

A paper reviewing the food safety issues associated with genetically modified/genetically engineered crops listed a range of documented unintended effects and concluded that "The development and validation of new profiling methods such as DNA microarray technology, proteomics, and metabolomics for the identification and characterization of unintended effects, which may occur as a result of the genetic modification, is recommended."[21]

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. Furthermore, a study done by Dutch scientists, using a modified, and more conservative, methodology for screening transgenic proteins for potential allergenicity (e.g. the analysis of sequence homology to known food and environmental allergens) as laid out in the Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology (January, 2001), found that a number of transgenic proteins have significant sequence homology to known allergens and recommended further study for a number of these proteins: "Many transgenic proteins have identical stretches of six or seven amino acids in common with allergenic proteins. Most identical stretches are likely to be false positives. As shown in this study, identical stretches can be further screened for relevance by comparison with linear IgE-binding epitopes described in the literature. In the absence of literature values on epitopes, antigenicity prediction by computer aids to select potential antibody binding sites that will need verification of IgE

(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).

[21] Kuiper, HA, Kleter, GA, Notebom, HPJM and EJ Kok. 2001. Assessment of food safety issues related to genetically modified foods. *The Plant Journal*, 27(6): 503-528.

binding by sera tests. **Finally, the positive outcomes of this approach warrant** [papaya ringspot virus coat protein, acetolactate synthase GH50, and glyphosate oxidoreductase] **further clinical testing for potential allergenicity[22] bold** added. Another study done by Dr. Steven Gendel of the US Food and Drug Administration found that there was significant sequence similarity between a gene in Bt maize and Bt cotton (e.g. Cry1Ab or Cry1Ac) and an egg yolk allergen and recommended further study: "the similarity between Cry1A(b) and vitellogenin might be sufficient to warrant additional evaluation"[23].

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 labelling 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.

OLFs as Basis for Labelling

Labelling of foods and food ingredients produced via GE/GM can also be undertaken as a result of considering issues such as religion/culture or ethics—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 labelling 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 labelling plays an important role in furthering both of these objectives"[24]. 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

[22] Kleter, GA and ACM Peijnenburg. 2002. Screening of transgenic proteins expressed in transgenic food crops for the presence of short amino acid sequences identical to potential, IgE – binding linear epitopes of allergens. *BMC Structural Biology*, 2: 8. Accessed at: http://www.biomedcentral.com/1472-6807/2/8

[23] Gendel, S.M. 1998b. The use of amino acid sequence alignments to assess potential allergenicity of proteins used in genetically modified foods. *Advances in Food and Nutrition Research,* 42: 44-61

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

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*"[25] *italics* added.

One obvious OLF is religious/cultural concerns. For example, if a gene from an animal was put into plants (such as the artic flounder gene inserted into tomatoes, or scorpion genes put into corn plants); vegetarians would want to know such information so as to 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. In sum, labelling GE/GM plants for OLFs helps to further "promotion of fair trade practices."

In sum, the Codex texts associated with foods derived from GE/GM as well as the Codex 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* clearly support the labelling of foods or food ingredients derived from GE/GM.

Potential Way Forward

Given that the Codex texts on biotechnology, along with the Codex 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* clearly support the labelling of foods or food ingredients derived from GE/GM, CI suggests that the Working Group build on the work from the meeting held in Oslo in February, 2007. CI suggests the following text as the basis for discussion:

General horizontal principles for the labelling of foods obtained by genetic engineering/genetic modification

When developing national/regional requirements for the labelling of foods obtained by genetic engineering/genetic modification, Codex Members should consider the following principles:

1. These requirements should comply with the provisions of Codex standards and related texts, in particular Codex Standards on Food Labelling;

2. The safety assessment should inform the GM labelling requirements;

3. The minimal requirements should address issues related to food safety, e.g. change in composition or nutritional properties, allergenicity;

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

4. Countries may wish to utilize one or more of the following four approaches to GM labelling:

A. 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)

B. Mandatory GM labelling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food.

C. 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

D. 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. The basic rights of consumer for information enabling them to make informed choices should be respected;

6. Appropriate control measures should be put in place to prevent against false and misleading labelling of foods obtained by genetic engineering/genetic modification;

7. The limitations of developing countries should be taken into account.

Rapport de la réunion du Groupe de travail du CCFL tenue à Accra, Ghana, du 28 au 30 janvier 2008

Annexe III

Résultat de la réunion du GT – Texte du document d'information (Annexe I de CL 2007/38-FL) **avec les ajouts suivants soulignés : Énoncés généraux et modifications suggérées par certains participants du GT au texte extrait du document d'information**

[Énoncé général 1

« L'étiquetage des denrées alimentaires est le premier moyen de communication entre le producteur et le vendeur de denrées alimentaires d'une part, et l'acheteur et le consommateur d'autre part. L'étiquetage d'un aliment n'est étudié qu'après que l'aliment a été jugé sans danger pour la consommation humaine au moyen des évaluations de sécurité sanitaire indiquées. À titre de garantie additionnelle de l'usage sûr de l'aliment, l'étiquetage peut servir à fournir des informations essentielles aux consommateurs. Il est admis que les besoins exprimés des consommateurs peuvent varier suivant les régions du monde. Ces différences peuvent donner lieu à des démarches à divers niveaux concernant l'étiquetage des aliments obtenus par modification génétique / génie génétique.

L'objet du présent document est de rappeler et d'assembler en un seul document des éléments importants des indications fournies dans les textes Codex qui sont applicables à l'étiquetage des aliments obtenus par les techniques de modification génétique / du génie génétique. »

Énoncé général 2

« L'objet du présent document est de rappeler et d'assembler en un seul document des éléments importants des indications fournies dans les textes Codex qui sont applicables à l'étiquetage des aliments obtenus par les techniques de modification génétique / du génie génétique. »]

1. [Les normes et les textes apparentés suivants du Codex contiennent des ~~conditions~~ dispositions applicables à l'étiquetage des ~~tous les~~ produits alimentaires et~~, par conséquent, s'appliquent également~~ peuvent être appliqués aux aliments obtenus par certaines techniques de modification génétique / génie génétique :

   - La norme générale Codex pour l'étiquetage des denrées alimentaires préemballées (CODEX STAN 1-1985 (Rév. 1-1991));
   - Les directives générales Codex concernant les allégations (CAC/GL 1-1979, Rév. 1-1991);
   - Les directives pour l'emploi des allégations relatives à la nutrition et à la santé (CAC/GL 23-1997, Rév. 1-2004);

- Les Principes pour l'analyse des risques liés aux aliments dérivés des biotechnologies modernes (CAC/GL 44-2003);
- La Directive régissant la conduite de l'évaluation de la sécurité sanitaire des aliments dérivés des plantes ADN recombiné (CAC/GL 45-2003);
- La Directive régissant la conduite de l'évaluation de la sécurité sanitaire des aliments produits à l'aide de microorganismes à ADN recombiné
- Principes de travail pour l'analyse des risques en matière de sécurité des aliments destinés à être appliqués par les gouvernements
- ~~Déclarations de principes concernant le rôle de la science dans la prise de décisions du codex et les autres facteurs à prendre en considération (Manuel de procédure du Codex).~~

2. Les textes Codex et d'autres textes s'appliquent ~~peuvent être appliqués~~ aux aliments vendus non emballés / dans des contenants non destinés à la vente au détail, y compris ceux obtenus par certaines techniques de modification génétique / génie génétique. On entend par étiquetage « tout texte écrit ou imprimé ou toute représentation graphique qui figure sur l'étiquette, accompagne le produit ou est placé à proximité de celui-ci pour en promouvoir la vente ».

3. Un aliment doit d'abord avoir été jugé sans danger pour la consommation humaine au moyen des évaluations indiquées avant que son étiquetage ne soit étudié. Le Codex a adopté plusieurs textes portant sur la sécurité sanitaire des aliments MG/GG et ces textes sont mis à la disposition des pays membres à cette fin[26].

4. La Directive Régissant la Conduite de l'Évaluation de la Sécurité Sanitaire des Aliments Dérivés de Plantes à ADN recombiné (CAC/GL 45-2003) dit que le « transfert de gènes issus d'aliments communément allergéniques … devrait être évité à moins que ne soit documenté le fait que le gène en question ne code pas pour un allergène … ».

5. La présence dans tout aliment ou ingrédient alimentaire obtenu à l'aide des biotechnologies d'un allergène transféré à partir de n'importe quel produit énuméré dans la section 4.2.1.4 doit être déclarée. Lorsqu'il n'est pas possible de fournir, au moyen de l'étiquetage, des renseignements appropriés concernant la présence d'un allergène, l'aliment contenant l'allergène ne doit pas être commercialisé (section 4.2.2 de la NGÉDAP).

   ~~La Directive Régissant la Conduite de l'Évaluation de la Sécurité Sanitaire des Aliments Dérivés de Plantes à ADN recombiné (CAC/GL 45-2003) dit que le « transfert de gènes issus d'aliments communément allergéniques … devrait être~~

[26] Directive Régissant la Conduite de l'Évaluation de la Sécurité Sanitaire des Aliments Dérivés de Plantes à ADN recombiné (CAC/GL 45-2003); Directive régissant la conduite de l'évaluation de la sécurité sanitaire des aliments produits à l'aide de microorganismes à ADN recombiné (CAC/GL 46-2003).

~~évité à moins que ne soit documenté le fait que le gène en question ne code pas pour un allergène … ».~~

6. Lorsque les caractéristiques physiques, chimiques ou fonctionnelles d'un aliment sont sensiblement modifiées par quelque moyen que ce soit (production ou transformation), l'étiquetage de cet aliment doit être modifié pour le différencier de l'étiquetage du produit traditionnel de référence pour faire en sorte que l'aliment soit décrit ou présenté de manière véridique et non trompeuse et non susceptible de créer une impression erronée au sujet de sa nature véritable. Le nom du produit traditionnel de référence appliqué à cet aliment devra peut-être être modifié ou accompagné de qualificatifs additionnels pour en décrire la nature véritable et éviter de tromper ou d'embrouiller le consommateur.

7. ~~Lorsque les caractéristiques physiques, chimiques ou fonctionnelles d'un aliment sont modifiées sensiblement par quelque moyen que ce soit (production, transformation), le nom du produit traditionnel de référence appliqué à cet aliment devra peut-être être modifié ou accompagné de qualificatifs additionnels pour en décrire la nature véritable et éviter de tromper ou d'embrouiller le consommateur.~~

8. Dans les cas où les modifications MG/GG aboutissent à une allégation concernant les propriétés nutritionnelles de l'aliment, la formulation de l'allégation devrait être conforme aux Directives pour l'emploi des allégations relatives à la nutrition et à la santé.

9. Les dispositions des textes courants du Codex sur l'étiquetage peuvent être appliquées aux mentions d'étiquetage des aliments MG/GG :

10. ~~Norme générale Codex pour l'étiquetage des denrées alimentaires préemballées~~
    ~~Section 3.1~~
    ~~Section 3.2~~
    ~~Section 7.1 Mentions d'étiquetage facultatives - Tout texte écrit ou imprimé (renseignements) ou toute représentation graphique (images) peuvent figurer sur l'étiquette à condition de ne pas aller à l'encontre des dispositions obligatoires de la présente norme ni des dispositions relatives aux allégations et aux déclarations mensongères figurant à la Section 3 - Principes généraux.~~

    ~~Lignes directrices générales Codex concernant les allégations~~

    ~~Section 1.2 Le principe sur lequel s'appuient les lignes directrices est le suivant: aucun aliment ne devrait être décrit ou présenté de façon fausse, trompeuse, mensongère ou susceptible de créer une impression erronée au sujet de sa nature à tous égards.~~

    ~~Section 1.3 La personne qui commercialise l'aliment devrait être en mesure de justifier les allégations avancées.~~

~~Section 2 Définition - Aux fins des présentes lignes directrices, le terme "allégation" s'entend de toute mention qui affirme, suggère ou implique qu'une denrée possède des caractéristiques particulières liées à son origine, ses propriétés nutritives, sa nature, sa production, sa transformation, sa composition ou toute autre qualité.~~

~~Section 3.3 Allégations interdites - Les allégations qui ne peuvent pas être justifiées.~~

~~Section 3.5 Allégations interdites - Les allégations qui pourraient faire naître des doutes sur la sécurité d'aliments analogues, susciter la crainte ou exploiter ce sentiment chez le consommateur.~~

~~Section 4.1 Allégations pouvant induire en erreur - Allégations vides de sens, notamment comparatifs et superlatifs incomplets.~~

~~Section 5.1 (iii) Allégations conditionnelles - On peut utiliser des expressions telles que "naturel", "pur", "frais", "fait maison" et "cultivé biologiquement" à condition qu'elles soient conformes aux usages nationaux du pays où le produit est vendu. L'emploi de ces expressions doit être compatible avec les interdictions indiquées à la Section 3.~~

~~Section 5.1 (v) Allégations conditionnelles - On peut indiquer qu'un produit a des propriétés spéciales, alors que tous les produits de cette nature ont les mêmes propriétés, à condition que ce fait soit évident dans l'allégation.~~

~~Section 5.1 (vi) Allégations conditionnelles - On peut souligner l'absence ou la non-adjonction d'une substance particulière à un aliment, à condition que cette allégation ne risque pas d'induire en erreur et:~~

~~(b) qu'il s'agisse d'une substance que le consommateur s'attend normalement à trouver dans l'aliment;~~

~~(d) que sa présence ou son addition soient autorisées par la loi.~~

Les textes Codex sur l'étiquetage s'appliquent à toute mention utilisée pour fournir de l'information qui permettra au consommateur de choisir les aliments qu'il achète et (ou) ~~comprennent plusieurs dispositions qui peuvent être appliquées pour déterminer l'opportunité de l'étiquetage utilisé comme moyen de répondre à la demande des consommateurs de certaines informations au sujet des aliments qu'ils achètent ou~~ utilisée par les marchands pour indiquer qu'un aliment correspond aux préférences des consommateurs.

Toute mention sur l'étiquette ou dans l'étiquetage des aliments MG/GG doit être conforme à la NGÉDAP du Codex (Codex Stan 1-1985, Rév. 1-1991) et aux Lignes directrices générales Codex concernant les allégations (CAC/GL 1-1979, Rév. 1-1991).

Rapport de la réunion du Groupe de travail du CCFL tenue à Accra, Ghana, du 28 au 30 janvier 2008

Tableau 1. Dispositions des textes courants du Codex sur l'étiquetage qui s'appliquent à l'étiquetage des aliments MG/GG

Section	Mentions d'étiquetage obligatoires
Norme générale pour l'étiquetage des denrées alimentaires préemballées	
3.1	L'étiquette apposée sur les denrées préemballées ne devra pas décrire ou présenter le produit de façon fausse, trompeuse, mensongère ou susceptible de créer d'une façon quelconque une impression erronée au sujet de sa nature véritable.
3.2	Les denrées préemballées ne devront pas être décrites ou présentées sur l'étiquette ou dans l'étiquetage par des mots, des images, ou de toute autre façon se référant ou faisant allusion directement ou indirectement à un autre produit avec lequel elles pourraient être confondues, ou d'une manière qui laisse à penser à l'acquéreur ou au consommateur que l'aliment est apparenté avec cet autre produit.
4.1.1	Le nom [de l'aliment] doit indiquer la nature véritable du produit et il doit normalement être spécifique et non générique.
4.1.2	L'étiquette devra porter en liaison avec le nom du produit, ou à proximité immédiate de celui-ci, les mots ou groupes de mots nécessaires pour éviter que le consommateur ne soit induit en erreur en ce qui concerne la nature et les conditions véritables de l'aliment, y compris son milieu de couverture, son mode de présentation, ainsi que l'état dans lequel il se trouve ou le type de traitement qu'il a subi, par exemple: déshydraté, concentré, reconstitué, fumé.
4.2.2	La présence dans tout aliment ou ingrédient alimentaire obtenu à l'aide des biotechnologies d'un allergène transféré à partir de n'importe quel produit énuméré dans la section 4.2.1.4 doit être déclarée. Lorsqu'il n'est pas possible de fournir, au moyen de l'étiquetage, des renseignements appropriés concernant la présence d'un allergène, l'aliment contenant l'allergène ne doit pas être commercialisé.

Section	Mentions d'étiquetage facultatives
Norme générale pour l'étiquetage des denrées alimentaires préemballées	
7.1	Étiquetage facultatif – Tout texte écrit ou imprimé (renseignements) ou toute représentation graphique (images) peuvent figurer sur l'étiquette à condition de ne pas aller à l'encontre des dispositions obligatoires de la présente norme ni des dispositions relatives aux allégations et aux déclarations mensongères figurant à la Section 3 – Principes généraux.
Lignes directrices générales concernant les allégations	
1.2	Le principe sur lequel s'appuient les lignes directrices est le suivant: aucun aliment ne devrait être décrit ou présenté de façon fausse, trompeuse, mensongère ou susceptible de créer une impression erronée au sujet de sa nature à tous égards.
1.3	La personne qui commercialise l'aliment devrait être en mesure de justifier

	les allégations avancées.
2	Définition – Aux fins des présentes lignes directrices, le terme «allégation» s'entend de toute mention qui affirme, suggère ou implique qu'une denrée possède des caractéristiques particulières liées à son origine, ses propriétés nutritives, sa nature, sa production, sa transformation, sa composition ou toute autre qualité.
3.3	Allégations interdites – Les allégations qui ne peuvent pas être justifiées.
3.5	Allégations interdites – Les allégations qui pourraient faire naître des doutes sur la sécurité d'aliments analogues, susciter la crainte ou exploiter ce sentiment chez le consommateur.
4.1	Allégations pouvant induire en erreur – Allégations vides de sens, notamment comparatifs et superlatifs incomplets.
5.1 (iii)	Allégations conditionnelles – On peut utiliser des expressions telles que «naturel», «pur», «frais», «fait maison» et «cultivé biologiquement» à condition qu'elles soient conformes aux usages nationaux du pays où le produit est vendu. L'emploi de ces expressions doit être compatible avec les interdictions indiquées à la Section 3.
5.1 (v)	Allégations conditionnelles – On peut indiquer qu'un produit a des propriétés spéciales, alors que tous les produits de cette nature ont les mêmes propriétés, à condition que ce fait soit évident dans l'allégation.
5.1 (vi)	Allégations conditionnelles – On peut souligner l'absence ou la non-adjonction d'une substance particulière à un aliment, à condition que cette allégation ne risque pas d'induire en erreur et: (b) qu'il s'agisse d'une substance que le consommateur s'attend normalement à trouver dans l'aliment; (d) que sa présence ou son addition soient autorisées par la loi.
Directives pour l'emploi des allégations relatives à la nutrition et à la santé	

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