codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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AGENDA ITEM NO. 6(B) **CX/FL 10/38/12**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING
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LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENT OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING (CL 2009/15-FL, ALINORM 09/32/22 – APPENDIX VII)

GOVERNMENT COMMENTS AT STEP 3

COMMENTS FROM:

AUSTRALIA
BRAZIL
COLOMBIA
COSTA RICA
EUROPEAN UNION
MALAYSIA
BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)
INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA)

LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENT OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION/GENETIC ENGINEERING: (CL 2009/15-FL, ALINORM 09/32/22 – APPENDIX VII)

GOVERNMENT COMMENTS AT STEP 3

AUSTRALIA:

With regard to the *Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering*:

Australia's Overall Position

If there continues to be agreement/consensus at the 38th CCFL to proceed on this issue, then of the draft recommendations proposed, Australia would support Chapeau 2 as amended by Brazil.

Rationale for Position

The main reasons for Australia's position can be summarised as follows:

- Chapeau 2 succinctly presents the purpose of the document and reflects the possible application of current Codex texts to the labelling of foods obtained by GE/GM techniques. However for clarity, Chapeau 2 still requires further modification/amendment.

Australia considers that the amendments to Chapeau 2 as proposed by Brazil provide the additional clarification that is needed, namely that:

- it is not the role of Codex to mandate labelling for consumer information - this is the role of national authorities, taking account of the information needs of the population, cost-benefit analyses and other considerations.

BRAZIL:

The Brazilian Delegation thanks for the opportunity to present the following comments on CL 2009/15-FL

Brazilian comments:

In relation to the chapeaus, we support the Chapeau 2 as amended by Brazil:

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

In order to achieve consensus, we could also support the chapeau 1 with the elimination of the following sentence: *"For additional assurance on safe and appropriate use of food, food labelling can be employed to provide consumers with essential information"*. We understand that the labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption.

COLOMBIA:

Colombia wants to express its thanks to all countries that have worked in the development and structuring of the working document titled PROPOSED DRAFT RECOMMENDATIONS FOR THE LABELLING OF FOODS AND FOOD INGREDIENTS OBTAINED THROUGH CERTAIN TECHNIQUES OF GENETIC MODIFICATION / GENETIC ENGINEERING (Step 3 of 8) for which comments were requested from the countries in the Report of the Thirty-Seventh Session of the Codex Committee on Food Labelling (ALINORM 09/32/22).

Colombia would like to present its comments to the above mentioned Proposed Draft Recommendations to support the Chapeau as amended by the delegation of the United States, as it considers it to be clear and concise as well as responding to the existing *Codex* standards that would apply to the labelling of foods and food ingredients obtained through certain techniques of genetic engineering. Furthermore, it combines the different elements proposed by other delegations or those proposed during the previous sessions of the Codex Committee on Food Labelling which took place in 2008 and 2009,

This chapeau also includes the position that Colombia presented during the Thirty-sixth Session of the Codex Committee on Food Labelling and the comments it later sent for the Thirty-Seventh Session of the same Codex Committee.

Colombia maintains that the labelling of foods obtained through certain techniques of genetic modification / genetic engineering must respond to the same principles established by the Codex regarding food safety and communications between the seller and the buyer/consumer.

Although we back the proposal made by the United States, we also want to rescue the statement included in the Chapeau proposal made by Brazil, regarding recognition of the sovereignty of countries to adopt different approaches for the labelling of foods obtained through certain techniques of genetic modification / genetic engineering, without disregarding through this statement that the Codex standard is a fundamental guide for the development of appropriate standards for each country.

COSTA RICA:

Costa Rica supports Chapeau 2 with the inclusion of the comments of the United States and Brazil, under the approach that a wording that supplements both proposals should be negotiated.

EUROPEAN UNION:

The European Union and its 27 Member States (EUMS) are pleased to submit their comments on Part B, item 5 of Codex Circular Letter CL 2009/15-FL "Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering".

The EUMS strongly believe that Codex should issue recommendations on the labelling of GM foods. This guidance would in particular be extremely useful for developing countries as was largely expressed during the previous sessions of CCFL and also during the two specific working group meetings which took place in Oslo (February 2007) and Accra (January 2008).

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

While maintaining their view on the necessity of providing consumers with a clear information on the nature of products containing, consisting or produced from GMOs, the EUMS are pleased to announce the starting, in June 2009, of an evaluation of the existing legislative framework on GM food and feed.

The evaluation has been launched five years after the entry into force of Regulation (EC) 1829/2003 on GM food and feed and will be conducted by an external contractor to ensure a wide range of view and an impartial collection of data. Through surveys, interviews and case studies the exercise will cover all the 27 Member States as well as the major stakeholders (biotech providers, importers and traders, food and feed industry, NGOs).

The scope of this evaluation covers the major aspects of the legislative framework. One of the pillars of the evaluators' work will thus be the existing labelling regime and its possible evolution in the near future.

The launching of this exercise shows - once again - the need for some Codex guidance to steer the approach of Codex members on such an important issue.

The EUMS will be happy to provide the details of this exercise in the CCFL meeting of May 2010 and to keep Codex members immediately informed of the outcome of this evaluation whose results are due in by June 2010. The EUMS are committed to formally submit the evaluation report to the Codex Secretariat as soon as available and to present the results and follow up of the exercise to the CCFL meeting immediately following the conclusion of the exercise.

Chapeau of the document: the EUMS support Chapeau 2 as amended by Brazil because it states clearly the purpose of the document and underlines the principle of various possible approaches.

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

~~**[Chapeau 1:**~~
~~*"Food labelling is the primary means of communications between the seller on the one hand and the purchaser and consumer on the other. Labelling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption. For additional assurance on safe and appropriate use of food, food labelling can be employed to provide consumers with essential information. It is recognized that consumers' expressed needs may vary in different regions of the world. These differences might lead to various levels of approaches regarding labelling of foods obtained by GM/GE modifications.*~~
~~*The purpose of this document is to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant for the labelling of foods obtained by GM/GE techniques."*~~**]** ~~/~~
~~**Or**~~

~~**[Chapeau 2:**~~
~~*"The purpose of this document is to recall and assemble in a single document some important elements from Codex texts which are relevant for the labelling of foods obtained by GM/GE techniques."*~~**]** ~~/**or**~~

~~**[Chapeau 2 as amended by the USA:**~~
~~*"The purpose of this document is to recall and assemble in a single document some important elements from Codex LABELLING AND OTHER texts which are relevant for the labelling of foods obtained by GM/GE techniques AS THEY ARE FOR ALL FOODS. THIS DOCUMENT IS NOT INTENDED TO SUGGEST OR IMPLY THAT GM/GE FOODS ARE IN ANY WAY DIFFERENT FROM OTHER FOODS SIMPLY DUE TO THEIR METHOD OF PRODUCTION."*~~**]** ~~/**or**~~

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

~~**[Amendment to the first sentence of paragraph 1 as developed during the 37th Session of the CCFL as alternative to chapeau 1 and 2:**~~
~~"1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE techniques.~~
~~Any information or pictorial device may be displayed on labels of foods obtained from GM/GE techniques provided that these are not in conflict with Codex standards and guidelines.~~
~~This document is not intended to suggest or imply that food obtained from GM/GE techniques are in any way different or less safe from other foods simply due to their method of production provided that they have undergone safety assessment according to the guidance of the Codex Alimentarius Commission."~~**]**

[Text as annexed to report of the 36th Session of the CCFL:
"1. The following Codex standards and related texts contain provisions applicable to the labelling of food products and may be applied to foods obtained by GM/GE:]

• The Codex General Standard for the Labelling of Prepackaged Foods, (Codex Stan 1-1985)
• The Codex General Guidelines on Claims (CAC/GL 1-1979)
• The Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997)
• Principles for Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003);
• Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA plants (CAC/GL 45-2003)
• Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA
microorganisms
• Working Principles for Risk Analysis for Food Safety for Application by Governments

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

3. Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption. Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose[1].

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

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

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

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

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

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

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

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

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

Section Mandatory Labelling Provisions
General Standard for the Labelling of Prepackaged Foods
3.1 Prepackaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

3.2 Prepackaged food shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

4.1.1 The name [of the food] shall indicate the true nature of the food and normally be specific and not generic.

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

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

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

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

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

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

3.3 Prohibited claims – Claims which cannot be substantiated.

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

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

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

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

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

MALAYSIA:

GENERAL COMMENTS

Malaysia would like to reiterate our view that labelling of foods and food ingredients obtained through certain techniques of genetic modifications/genetic engineering should be made mandatory for both consumers and health concerns **AND** to indicate their methods of production in order to allow consumers to make informed choices.

SPECIFIC COMMENTS

i) Chapeau 1

Malaysia would like to propose the second and third sentence of the Chapeau 1 to be deleted and replaced by a new amended sentence to take into account the safety and other factors to provide information for consumers, as follows:

"Labelling of a food is considered only after a food has undergone appropriate safety assessment and to provide other essential information to the consumer."

As such, the final Chapeau 1 (amended) would read as follows:

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

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

ii) Paragraph 3

Malaysia proposes to delete paragraph 3 in view that the Chapeau 1 already addresses the same issue. (Redundancy)

~~["3. Labelling of a food is considered only after the food has undergone appropriate assessments to deem it safe for human consumption. Codex has adopted several texts which address the safety aspects of GM/GE foods and are available to Member Countries for this purpose[11].]~~

iii) Malaysia proposes to add a new paragraph between Para.5 and Para.6 to address concerns related to dietary restrictions based on religious concerns or cultural practices. This proposal is also in line with Para. 32 under item Risk Management of the Proposed Draft Working Principles for Risk Analysis for Food Safety adopted at the 31st CAC:

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

New proposed paragraph

"In cases where GM/GE modifications involve dietary restrictions, related to religious concerns or cultural practices, the label should clearly indicate the GM/GE modifications involved."

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO):

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the above-referenced Proposed Draft document. BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,200 members worldwide. Corporate members range from entrepreneurial companies developing their first product to Fortune 100 multinationals. We also represent state and regional biotechnology associations, service providers to the industry, and academic centers. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology, and many BIO members use biotechnology to improve the agronomic, nutritional and other properties of tree, fruit, vegetable, and field crops.

BIO delegations have consistently participated in the work of Codex Alimentarius Committees, Working Groups and Tasks Force covering food and feed standards development related to agricultural biotechnology. We note that within the last nearly two decades of discussion in the Codex Committee on Food Labelling (CCFL), no progress has been made to advance the status of guidance, recommendations or language associated with voluntary or mandatory product labelling of foods 'obtained through certain techniques of GM/GE,' in spite of a number of targeted attempts to do so. In this time period, CCFL has convened five working groups, held intra-sessional discussions, and conducted prolonged inter-sessional discussions and dialogues without progress on issues pivotal to development of guidance, including the scope and objective of the guidance.

BIO delegations have actively participated in the various meetings and deliberations, and have worked with other delegations to try to reach some consensus on the fundamental concerns of when and how to label such foods and food ingredients. However, BIO members believe that consensus on such fundamental issues will not be possible. We strongly support discontinuation of further work in CCFL on labelling for foods derived from modern biotechnology.

The CL2009/15-FL requests comments on text provided as well as four options (chapeau) for the introduction to the guidance/principles found in ALINORM 09/32/22 Appendix VII. During the course of the discussion referenced in the outcomes of the CCFL meeting (ALINORM 09/22/22, paras 88-104) it became clear that consensus could not be reached on the proposed options. The Chair proposed (paragraph 101), that the work might be held in abeyance for a specific time until more experience could be gained on labelling; that recommendation also was not agreed as no consensus could be reached.

Fundamental differences in approach to labelling continue to exist among CCFL delegations and consequently BIO continues to believe that consensus will not be reached; progress on this work is not possible at this time. **We therefore continue to support those delegations that propose discontinuation of work on labelling of foods derived from modern biotechnology.**

In response to the specific request in the circular letter (CL2009/FL-15), we have reviewed the four wording options open for consideration of 'chapeau language.' BIO strongly believes that the language in Chapeau 2, intended to inform member governments and others of existing Codex texts which cover all of the issues associated with labelling of foods derived from modern biotechnology, would be the only option viable at this point. From Chapeau #2 language, leading

into the text developed in the paper developed for the working group meeting held in Ghana in 2008, specific citations for Codex text provide information needed by governments to consider how best to label foods generally. These provisions also provide any relevant information for manufacturers to voluntarily label foods derived from modern biotechnology.

We appreciate the opportunity to participate in these important discussions, but also we believe that this area of work should be discontinued by CCFL, and resources better committed to areas where there is demonstrated need and where consensus is possible.

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS (ICGMA):

The International Council of Grocery Manufacturers Associations (ICGMA) appreciates the opportunity to provide these comments on the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained through Certain Techniques of GM/GE. ICGMA, a recognized INGO before the Codex Alimentarius Commission, represents the interests of the consumer packaged goods industry including several hundred food companies that trade food products globally. In this regard, ICGMA strongly supports the work of Codex Alimentarius and promotes the harmonization of scientific standards and policies concerned with health, safety, packaging, and labelling of foods and beverages. ICGMA member companies have participated in the work of the Codex Committee on Food Labelling (CCFL) for many years and in discussions related to labelling products derived from biotechnology for almost two decades.

ICGMA refers to the report of the 37th Session of the CCFL[2], and recalls extensive efforts by the Chair to find consensus on suggested amendments to chapeau language in the text. Lacking consensus, the chair proposed to hold the work in abeyance for a minimum of three sessions to allow more experience with the labelling and informal discussion among delegations. The committee found no consensus on the Chair's proposal. As a result, CCFL is now seeking comments on Appendix VII that offers four possible chapeaus on which consensus could not be found.

In comments filed in 2008, ICGMA stated that "CCFL should discontinue further work on this topic" and focus Codex' scarce resources on "those items more directly relevant to consumer health such as the implementation of the WHO Global Strategy." ICGMA noted the decision of the 25th Codex Alimentarius Commission and the *Evaluation of Codex Alimentarius Commission and other FAO and WHO Food Standards Work* which stated that Codex should work on issues related to the Protection of Consumer Health as a first priority[3] and that CCFL has recognized that "labelling of foods derived from biotechnology was not intended for health and safety as genetically modified products are evaluated for their safety before being placed on the market."[4]

The text presented as Table 1 in Appendix VII clearly explains that existing Codex texts are applicable to labelling of all food products including those derived from biotechnology. This existing Codex text is sufficient guidance for national governments.

[2] ALINORM 09/32/22, paragraphs 92 – 105

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

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

As clearly demonstrated after almost two decades of discussion, including at the 37th session of the CCFL, ICGMA does not believe it possible to find consensus on this issue and supports discontinuing the work. Alternatively, ICGMA could support the recommendation of the Chair to hold the work in abeyance for several sessions while national governments gather more experience and CCFL completes work related to the Global Strategy.