codex alimentarius commission

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FBT 07/7/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX *AD HOC* INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Seventh Session

Chiba, Japan, 24 – 28 September 2007

PROPOSED DRAFT ANNEX TO THE GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS ON LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL AT STEP 4

Comments at Step 3, in response to Circular Letter CL 2007/17-FBT rev., by Australia, Brazil, Canada, Japan, Kenya, Malaysia, New Zealand, Philippines and United States of America

AUSTRALIA

Australia would like to congratulate the Working Group for their excellent work in developing the proposed draft annex, and in particular notes the high level of consensus that was achieved.

Australia would like to make the following comments in response to CL 2007/17-FBT rev.

General comments

Australia is generally satisfied with the proposed draft annex that has been developed and believes it to be consistent with the objectives originally outlined in the project proposal. At this stage, Australia does not have a strong preference for which version of the annex is ultimately pursued by the Task Force.

Specific comments

Formatting

The formatting of the long version of the annex (attachment 1; CL 2007/17-FBT rev) makes it difficult to know when the text in the annex flows into the copied sections from the plant guideline, and back again; e.g. paragraph numbering and section headings. If this version of the annex is ultimately preferred by the Task Force, it may be easier to follow if text copied directly from the plant guideline is distinguished somehow from the new text. This is not an issue with the short version of the annex.

Australia also notes that in the long version of the annex, paragraph 37 from the plant guideline begins by saying "For reasons described in Section 3,……..". This is a reference to Section 3 of the plant guideline, however given that there is also a Section 3 in the proposed draft annex, Australia believes there is potential for confusion. If the long version of the annex is the version ultimately preferred by the Task Force, Australia would like to propose that the copied paragraph 37 be amended as follows:

37. For reasons described in Section 3 of the Plant Guideline, conventional toxicology studies may not be considered necessary…….

Section 3 – Data and Information Sharing

Paragraph 13 refers to nonviable reference material being made available for event specific detection. Australia understands that reference to "nonviable" was made to address concerns relating to the provision of viable material without appropriate guarantees of protection of commercial interests. However, as written, this paragraph seems to exclude the possibility of providing viable reference material, should that be acceptable to the product applicant. Australia would therefore like to propose the following amendment to paragraph 13:

13. The product applicant shall make all reasonable efforts to provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method, as specified by the Codex Member, and appropriate ~~nonviable~~ reference materials [insert footnote].

(Footnote text – nonviable material would be acceptable)

BRAZIL

Brazil agrees with the proposed report and considers the 2nd version of proposal to the Annex (Attachment 2) as the best, once its structure presents only the modified paragraphs and addresses to those of the Guideline that apply to the issue in question.

CANADA

Canada welcomes this opportunity to provide input on the proposed *Draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-Level Presence of Recombinant-DNA Plant Materials*. We are pleased to submit the following comments for consideration.

Canada recognizes that the low level presence of recombinant-DNA (rDNA) plant material in the food supply is an important issue for regulatory authorities. Due to increased development of rDNA plants globally, it is desirable for regulatory authorities to apply an internationally accepted approach which is based on science to assess the risk presented by the low level presence of material from rDNA plants that have been authorized in some countries but not in the country where the rDNA plant material has been identified in the food supply.

Canada would like to thank the United States for hosting the physical working group meeting in March and believes that the meeting was a good first step towards ensuring that Member Countries have tools available to address the low level presence of unauthorized rDNA plants in food. Canada would like to provide the following specific comments on the sections found within the Annex.

Canada supports Sections 1 and 2 of the proposed Draft Annex. After reviewing the options for the possible structure of Section 2 of the Draft Annex, we note that reproducing all of the relevant paragraphs may be preferable to allow the Draft Annex to be used as a stand-alone document. This would eliminate the need for a risk assessor to repeatedly refer back to the guidelines, making the Draft Annex user-friendly in presentation.

With regard to Section 3 of the Draft Annex, Canada is of the view that developing mechanisms to share information between Codex member countries would be highly beneficial in the risk assessment and management of unauthorized rDNA plant products. For example, a database of approved rDNA plants could assist countries if any of these plants are identified in their food supply prior to authorization. It should be noted that sufficient information must be available to regulatory authorities to utilize Section 2 of the Draft Annex. Canada believes that the meeting with the Working Group Co-Chairs and representatives of the biotechnology industry is a good first step towards ensuring that countries have the ability to access the necessary data to conduct a risk assessment.

JAPAN

First, we would like to express our appreciation to the Co-Chairs and the members of the Working Group for its successful completion of the Proposed Draft Annex to the Plant Guideline on Low-Level Presence of r-DNA Plant Material. The Government of Japan is pleased to provide the following comments in response to CL 2007/17-FBT rev.

We are generally satisfied with the Section 1 "Preamble" which well reflects the purpose and the scope described in the Project Document upon which we agreed at the last session of this Task Force.

In this proposed draft Annex, the term "assessment of food safety considerations" has been newly introduced to replace "food safety assessment". We would like to suggest keeping the original term "food safety assessment" throughout the document, which is fully defined in the paragraphs 9-13 of the original Plant Guideline. This is because changing the terms here may give a wrong message to readers that we are going to take a new approach which is different from the approach taken in the original Plant Guideline. Moreover, if we were to choose a new terminology here, this change should be reflected in all other existing Codex documents on foods derived from modern biotechnology, that we think should be avoided.

Regarding the format of the document, the Attachment 1 would be preferable for us as it can be read as a stand-alone document. For convenience of referring back to the Plant Guideline, however, for paragraphs copied from the Plant Guideline, the original paragraph number in the Plant Guideline can be indicated, for example, at the end of the paragraph.

KENYA

Kenya commends the working group for the elaboration of the proposed draft annex.

Comment

Kenya has no strong preference for any of the versions presented. However, for use of the annex as a stand alone document, the longer version is preferred.

MALAYSIA

General comments

Malaysia prefers to have a more complete document that can stand alone without other documents referred. In this regards, Malaysia selects Attachment 1 as the Annex.

Specific comments

ATTACHMENT 1, SECTION 3 – DATA AND INFORMATION SHARING

Malaysia feels that Section 3 is too obligatory. Member countries would already have in place certain procedures for obtaining information on importation of food products. Hence, Malaysia suggests the following:

1. **Paragraph 10, Pg 12**
   Malaysia proposes to change the word 'shall make available' to 'are encouraged' in that sentence.
2. **Paragraph 11, Pg 13**
   Malaysia proposes to change the word 'shall' to 'will' in that sentence.
3. **Paragraph 12, Pg 13**
   Malaysia proposes to change the word 'shall make available' to 'are encouraged' in that sentence.
4. **Paragraph 11, Pg 13**
   Malaysia proposes to change the word 'shall' to 'should' in that sentence.

NEW ZEALAND

New Zealand would like to thank the Working Group for its commendable work in producing the proposed draft annex to the plant guideline (CAC/GL 45-2003). New Zealand notes that low-level presence of unapproved material is a horizontal issue, and causes difficulties irrespective of whether the material is microbiological or chemical in nature, or derived from rDNA plants. New Zealand would like to make the following comments in response to CL 2007/17-FBT rev.

New Zealand is comfortable with either of the proposed approaches to the Annex and believes that both would provide useful guidance in instances of low-level presence.

New Zealand notes that there would need to be some re-numbering of sections if the longer version were adopted by the Task Force.

Although New Zealand believes that Section 3 - Guidance on Data and Information Sharing is useful, we think there could be some explanation of its relationship with the rest of the Annex. We look forward to discussions at the Task Force, which should clarify how Section 3 fits with other sections.

PHILIPPINES

1. Proposed Draft Annex Format.

   - The Philippines supports the adoption of the Proposed Draft Annex presented as Attachment 1 (Stand alone approach), containing all the relevant paragraphs from the Codex Plant Guideline, with modifications as warranted.

   - *Rationale*. The stand alone format of the Proposed Draft Annex shall suit and be appropriate for regulators that are not well versed with the current Guidelines and shall eliminate the inconvenience of cross reference to other documents.

2. Assessment of Food Safety Considerations

   - Item 46. Evaluation of Metabolites:

     The Philippines wishes to be clarified on the 'metabolites' of concern as indicated in the paragraph:

     "Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food…Assessment of food safety considerations arising from low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food…."

     If possible, the Philippines would like specific examples of such metabolites to be elaboration in this section.

UNITED STATES OF AMERICA

The United States expresses its appreciation to the Working Group for its extremely cooperative and productive efforts in developing the *Proposed Draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-Level Presence of Recombinant-DNA Plant Material.*

The United States supports progression of the Annex in the Codex Step procedure and believes it will provide helpful guidance to governments in developing and implementing a risk-based approach to the handling of the low-level presence of r-DNA plant materials that have passed a food safety assessment according to the Codex *Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* in one or more countries but that may, on occasion, be present in food in importing countries in which the food safety of the relevant r-DNA plants has not been determined. The United States also notes that the inclusion of a section on data and information sharing, in combination with the development of a central database pursuant to that section, will help facilitate use of the Annex.

The United States notes that two forms of the Annex are presented in CL 2007/17-FBT, one form (attachment 1) that provides all applicable paragraphs of the Guideline and can be used as a stand-alone text, and one (attachment 2) that provides only those paragraphs of the Guideline that have been modified and cross-references all other applicable paragraphs. The United States believes that the form of the Annex in attachment 1 may be somewhat easier to use, but also recognizes that the form of the Annex in attachment 2 may be closer to the format more commonly used in Codex annexes. The United States encourages the Task Force to make a determination on the format based on that structure which is considered most helpful to users of the Annex.