codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 1 **October 2006**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Sixth Session

Chiba, Japan, 27 November – 1 December 2006

PROVISIONAL AGENDA

On 3 October 2006, the Codex Secretariat received a communication from the United States of America, reproduced below.

In accordance with Rules VII.5 and XI.11 of the Rules of Procedure of the Codex Alimentarius Commission, the item "Discussion paper on Food Safety Assessment of Low Level Presence of Recombinant-DNA Plant Material in Food Resulting from Asynchronous Authorizations" is hereby placed on a supplementary list.

The discussion paper is attached to the present document.

The United States requests the inclusion of a new item to the provisional agenda for the Sixth Session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, in conformity with Rule VII.5 (Agenda), respecting matters of an urgent nature. We propose that the subject matter for this new agenda item be: Discussion paper on Food Safety Assessment of Low Level Presence of Recombinant-DNA Plant Material in Food Resulting from Asynchronous Authorizations.

The U.S. Codex Office will submit within a week this Discussion Paper, in English, French, and Spanish, and will request that it be dispatched to all Members of the Commission.

The United States considers discussion of this paper a matter of an urgent nature because the Sixth Session represents a unique opportunity for consideration of new work with the expectation that such new work could be completed before the end of the term approved for the Task Force.

Ed Scarbrough

F. Edward Scarbrough, Ph.D.

U.S. Manager for Codex

Discussion Paper on Food Safety Assessment of the Low Level Presence of Recombinant-DNA Plant Material in Food Resulting from Asynchronous Authorizations

(Submitted by United States)

Background

1. At the Fifth Session of the Task Force, the United States had proposed new work to address low level presence in food of unauthorized recombinant-DNA plant materials (see ALINORM 06/29/34, paragraphs 53-57, for discussion).

2. At that session, the United States stated that the development of an annex to the Plant Guideline would assist member countries in situations in which they had to conduct food safety assessments of low levels of recombinant DNA plant materials originating from new varieties undergoing field testing or from older varieties coming off the market.

3. The European Community stated that a low level presence of unauthorized recombinant-DNA plants was often attributable to differences in the approval status of recombinant-DNA plants among countries. The European Community further stated that an annex to the Plant Guideline could be developed to provide guidance on how to deal with the low level presence of unapproved recombinant-DNA plants developed for food use, resulting from asymmetrical approvals.

4. After an exchange of views, the Task Force realized that there were different views among delegations on the appropriate scope of the proposed work and therefore decided not to start such new work at that time.

5. The United States indicated that it wished to study this issue further to decide whether to revisit the subject at a future session of the Task Force.

6. The United States has studied the issue further, and continues to believe that the Task Force should as a high priority take on new work to address this issue.

7. The United States has taken into account the comments of the European Community and agrees that the focus of such new work should be to address the problems created by asynchronous (asymmetric) authorizations of rDNA plants for commercialization for food use.

8. The United States, working with other interested countries, has developed a paper for discussion at the upcoming meeting of the Task Force. The paper proposes that the Task Force take on new work to develop an annex to the Plant Guideline that would focus on the food safety assessment appropriate for the low level presence in food of material from rDNA plants that have been authorized for commercialization for food use in one or more countries, but not in the country of import in which it unintentionally occurred. The discussion paper is an Annex to this document.

ANNEX

PROJECT DOCUMENT

Proposal for Future Work: Annex to the *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* on "Food Safety Assessment of the Low Level Presence of Recombinant-DNA Plant Material in Food Resulting From Asynchronous Authorizations."

Prepared by: United States

1. Purpose and scope of the proposed work

The purpose of the proposed work is to provide guidance on the food safety assessment of foods derived from recombinant-DNA (rDNA) plants in which those plants have already been authorized in one or more countries for commercialization for food use based on an assessment according to the Codex *Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) (the Plant Guideline), but are unintentionally present in low levels in food in countries in which the rDNA plants are not authorized.[1] To provide such guidance, the proposed work would identify the sections of the Plant Guideline essential to the food safety assessment of such foods, and put them into an Annex to the Plant Guideline.

The scope of the proposed work is the food safety assessment of foods from rDNA plants when those foods have satisfactorily completed a food safety assessment in one or more countries according to the Plant Guideline, and an importing country has not made a determination of food safety, and are found to occur at low levels in food in an importing country.

The proposed Annex would not constitute a substitute for a full food safety assessment under the Plant Guideline for any rDNA plant foods that would be marketed in a country. Similarly, while the proposed Annex would be a useful risk assessment tool to assess the food safety of the low level presence of food derived from rDNA plants, it would be up to countries to decide when and how to make use of it within the context of their regulatory systems, including their approval and enforcement procedures. It thus would not address risk management measures.

Countries will not be able to use the proposed Annex if they do not have access to requisite information. However, by specifying the needed information, the proposed Annex would indicate that the international community expected developers, or possibly countries that had authorized food use of the rDNA plant, to provide the information to the importing country.

2. Relevance and timeliness

An increasing number of rDNA plants are being authorized for commercialization. However, they are authorized at different rates in different countries. As a consequence of these asynchronous authorizations,

[1] The guidance would not be intended for an rDNA plant that was not authorized in an importing country as a result of that country's food safety assessment.

low levels of food derived from rDNA plants that have passed a food safety assessment in one or more countries may on occasion be present in food in countries in which the food safety of the relevant rDNA plants has not been determined. This Annex is intended to aid countries that want to determine the food safety of an rDNA plant food under such circumstances or in advance preparation for such potential circumstances.

3. The main aspects to be covered

This Annex will provide recommendations on performing a food safety assessment in low level situations in which the food has already been found to be safe by one or more countries through an assessment performed according to the Plant Guideline, but the importing country has not determined its food safety. It will identify the sections of the Plant Guideline that are essential to the food safety assessment of foods derived from an rDNA plant in such a low level situation.

It is proposed that this work would not address how a country should decide when an rDNA plant food is present at a level low enough for this Annex to be appropriate. It recognizes that such a decision may depend on the characteristics of the rDNA plant food, as well as how countries wish to use the Annex as part of their risk management strategies in any particular situation. Thus, it leaves the decision of when to use the Annex to countries to decide on a case-by-case basis.

4. Assessment against the *Criteria for the establishment of work priorities*

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries:

The project would provide additional guidance for countries to use in assessing the food safety of the low level presence of unauthorized rDNA foods, thus establishing the underlying safety of the food and appropriate protection of consumers. The project could particularly assist countries that have limited experience with food safety risk assessments.

Diversification of national legislations and apparent resultant or potential impediments to international trade: The project would provide internationally recognized scientific guidance that countries may use to establish individual standards or guidance. Such internationally agreed guidance can help ensure consistent approaches for the food safety assessment for such foods.

Scope of work and establishment of priorities between the various sections of the work: The scope of the work relates to work previously undertaken by the Task Force on a high priority basis.

Work already undertaken by other organizations in this field: The project does not duplicate work undertaken by other international organizations, and is an extension of work developed in the first Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology.

5. Relevance to Codex Strategic Objectives

This proposal is consistent with the following strategic goals presented in the Codex Draft Strategic Plan 2008-2013:

- Promoting Sound Regulatory Frameworks; and,

- Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis;

6. Information on the relation between the proposal and other existing Codex documents

The work product would be an Annex that complements and extends the Codex *Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants* (CAC/GL 45-2003).

7. Identification of any requirement for and availability of expert scientific advice

None identified.

8. Identification of any need for technical input to the standard from external bodies that this can be planned for

None identified.

9. The proposed timeline for completion of the new work, including start date, the proposed date for adoption at Step 5 and the proposed date for adoption by the Commission; the timeframe for developing a standard should not normally exceed 5 years

It is expected that the work can and should be completed within the remaining timeframe for the Task Force.

If the proposed new work is recommended by the 6th Session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (November, 2006) and adopted as new work by the 30th Session of the Codex Alimentarius Commission (July, 2007), a proposed draft Annex would be presented to the Task Force at its next Session (2007) for consideration at Step 3.