

Indian Delegation Report

6th Session of Codex Ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, Chiba, Japan, 27th November – 1st December 2006

Introduction

The Sixth Session of Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology was held at Chiba, Japan, from 27th November to 1st December 2006, by courtesy of the Government of Japan. The session was presided over by Dr. Hiroshi Yoshikura, Adviser, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare. The session was attended by a total of 176 delegates from 40 member countries alongwith 5 intergovernmental and 12 non-governmental observer organizations.

The team of Indian delegation, attending the above session comprised of the following members:-

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Opening of the Session

The Session was opened by Mr. Naohito Takahashi, Director-General, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, who welcomed the participants to the meeting and wished a pleasant stay at Chiba. The Representatives of FAO and WHO also welcomed the participants.

Adoption of the Agenda (Agenda Item 1)

The Task Force agreed to include a new agenda viz. food safety assessment of the low level presence of recombinant-DNA plant material in food resulting from asynchronous authorizations submitted by US. Accordingly the agenda were renumbered as new Item 10 through 12.

Review of the Work by International Intergovernmental Organizations Related to Foods Derived from Biotechnology (Agenda Item 3)

The Codex Secretariat informed the task force that the Third meeting of the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol (COP-MOP 3) had agreed for the requirements of documentation accompanying shipments of living modified organisms intended for direct use as food or feed, or for further processing. The Secretariat also informed that COP-MOP3 requested the Executive Secretary of CBD to continue intensifying cooperative arrangements with several international organization including Codex.

The Representative of FAO highlighted activities carried out by FAO or jointly with WHO, which included the development of several tools, such as an FAO/WHO document in order to assist countries to implement Codex food safety assessment guidelines, technical assistances to countries, as well as the development of public-private networks for information exchange regarding Biosafety.

The Representative of WHO conveyed the role of WHO in the field of biotechnology and human health in relation to food production. Organization of the Economic Cooperation and Development (OECD) highlighted some of the activities undertaken by the OECD Task Force for the Safety of Novel Foods and Feeds. These works included consensus documents including launching of a new version of OECD's database of products of modern biotechnology approved for commercial application. The Representative of the World Organization for Animal Health (OIE) informed that the OIE ad hoc Group on Biotechnology had started work on reproductive animal biotechnologies and on veterinary vaccine production. The ad hoc Group revised guidelines on the animal health risks arising from somatic cell nuclear transfer (SCNT) cloning of production animals and guidelines for new vaccine technologies, monitoring of developments on nanotechnology and advising the OIE.

Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (Agenda Item 4) prepared by the physical working group, co-chaired by Australia and Japan circulated for comments at Step 3.

The Delegation of Australia informed that the working group agreed to use the existing plant guideline as a template in elaborating the proposed draft guideline, limit the approach of deviations from the plant guideline only when scientifically justified on the basis of biological differences between plants and animals and focus on developing a guideline for recombinant-DNA animals in general rather than addressing any specific species-related issues.

The Task Force was in the opinion of using the phrase “used as food or for food production” in place of “used as food” through out the text.

Various delegates evaluated various options of the proposed draft guideline provided in the document to select the most appropriate one. The delegates felt the need for avoiding inclusion of provision for animals developed for pharmaceutical or other non-food uses. Delegations also felt that there was no rationale to discriminate between plant and animal in the guideline.

After a lengthy discussion, the Task Force agreed for Option 5 by deleting the word “additional” from the chapeau part and deleting the third bullet point to define the scope of the guideline. The amended version of the guideline thus read as follows:-

“. The development, raising and use of animals for human purposes, and in particular, or use for food, raise a variety of issues beyond food safety. Without prejudice to their legitimacy or importance, or to whether or how the use of recombinant-DNA methods in developing animals for food use might affect those issues, this Guideline addresses only food safety and nutritional issues. It therefore does not address:

- *animal welfare;*
- *ethical, moral and socio-economical aspects;*
- *environmental risks related to the environmental release of recombinant-DNA animals used in food production;*
- *the safety of recombinant-DNA animals used as feed, or the safety of animals fed with feed derived from recombinant-DNA animals, plants and microorganisms.”*

The Task Force considered in para 16 that the Working Group was of the view that consideration of second metabolites was not always required in the context of recombinant-DNA animals. The Task Force also agreed to retain the first sentence and delete the second sentence, as proposed by the Representative of OIE.

In paragraph 37C several delegations suggested full molecular characterization of inserted materials while others proposed that the provisions should remain as the same as in the plant guideline. The Task Force made several editorial amendments in paragraphs 38, 39, 42 and 63 to made the documents technically relevant.

The Delegation of the European Community expressed the view that the use of marker genes should be excluded in the production of recombinant-DNA animals due to the risk of integration of transgenes derived from inserted marker genes into the animal genome.

The Task Force noted, with satisfaction, that all sections of the propose draft guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNT Animals were finalized and were ready, in principle, for adoption by the Commission, with the exception of the section of the Use of Antibiotic Resistance Marker Genes (paragraphs 64-67).

Proposed draft Annex to the guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants modified for Nutritional or Health benefits (Agenda Item 5)

The Delegation of Canada introduced the report of the electronic working group and briefly explained the prospective value of the proposed draft and agreed to further proceed with the work, preferably through the establishment of a physical working group. A number of delegations specially those from developing countries expressed concern on stability of the level of expression of a particular trait in varying agro-ecological conditions in various countries. The Delegation of Argentina, speaking as Coordinator for Latin America and the Caribbean, proposed that the Annex should address not only staple crops but all crops. The Delegation of the European Community highlighted the importance of (1) comparative animal feeding study and (2) selection of the most appropriate comparator. The Delegation of Mexico emphasized the need of post-market monitoring while the delegation of New Zealand pointed out that since the target of Annex was to develop safety assessment guideline the emphasis should be on risk assessments.

Comparative Food Composition Analysis of Staple Foods (Agenda Item 6): Submitted by INDIA

The Delegation of India explained the background, objectives and expected benefits of the proposal. The Delegation submitted that there were the limitations in existing knowledge on compositional analysis of genetically engineered staple crops, namely macro- and micro-nutrients, inherent plant toxins, anti-nutrients, plant metabolites and allergens. The Delegation was of the view that the absence of globally acceptable analytical methods for food consumption analysis constituted an obstacle to conducting these analyses. The Representative of OECD informed the Task Force that the OECD had already produced a number of consensus documents containing compositional and other relevant information for the staple crops although these documents need to be updated. The Representative welcomed increasing participation of non OECD members in the work of the OECD Task Force on consensus documents. The Representative of FAO informed about various food composition tables produced by FAO using data from different parts of the world that could be available to all members of FAO. After some

discussion, the Task Force decided not to initiate new work in this area pending further consideration in order to avoid duplication of work.

Sanitary Surveillance after Placing of the Market of Foods Derived from Biotechnology (Agenda Item 7): Submitted by Mexico

The Delegation of Mexico explained the objective of the proposed new work towards monitoring of effects on specific human groups consuming nutritiously enhanced foods. However, the Task Force decided not to initiate new work since the matter could be covered by another ongoing work of the Task Force (Agenda Item 5).

Discussion Paper on Safety Assessment of Foods Derived from Animals Exposed to Protection against Diseases through Gene therapy or Recombinant-DNA Vaccines (Agenda Item 8): Submitted by Kenya

This proposal by Kenya stressed the need for assessment of possible risks to human health by the application of these techniques. The Task Force conveyed that the subgroup of vaccine established under the OIE ad hoc Group on Biotechnology was already engaged in this area which included food safety aspects related to animal health. Some delegations felt that the proposed work would be more appropriately done by OIE. After some discussion, the Task Force decided not to initiate the new work and agreed to monitor the progress of the ongoing work by OIE.

Discussion Paper on Food Safety Assessment of the Low-Level Presence of Recombinant- DNA Plant Material in Food Resulting from Asynchronous Authorization (Agenda Item 9): Submitted by United States

The Delegation of the United States provided a brief account of the proposal. Some delegations objected to the use of the term “asynchronous” since the term implied that the recombinant DNA plant in question and proposed the term “asymmetric authorization”. Several delegations including European Community stressed for the need for establishment of mechanisms for data sharing and information exchange regarding detection methods, molecular characterizations and testing protocols.

The Task Force agreed to establish an in-session physical working group which submitted a revised project document which was accepted by the Task Force.

Date and Place of the Next Session (Agenda Item 11)

The 7th Session of the Task Force was tentatively scheduled to take place from 24-28 September 2007 in Chiba, Japan, subject to further confirmation by the host government in consultation with the Codex Secretariat.

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