

**REPORT OF THE INDIAN DELEGATION ON THE FIFTH
SESSION OF THE CODEX AD HOC INTERGOVERNMENTAL
TASK FORCE ON FOOD DERIVED FROM BIOTECHNOLOGY
Chiba, Japan, 19-23 September, 2005**

PART I INTRODUCTION

The Codex Intergovernmental Task Force on Foods Derived from Biotechnology held its fifth Session in Chiba, Japan, from 19 to 23 September, 2005, 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 152 delegates representing 50 members of the Commission and 4 international intergovernmental and 15 non governmental observer organization.

1. Shri Chaman Kumar Head of Delegation
Joint Secretary
Department of Women & Child Development

2. Dr. Debasish Chattopadhyaya
Assistant Director General, Prevention of Food
Adulteration Division, Department of Health,
Ministry of Health & Family Welfare

PART II BACKGROUND

1. BACKGROUND OF THE MEETING

- The 26th session of the Codex Alimentarius Commission considered the proposal to establish a new Task Force on Foods Derived from Biotechnology and requested Japan to submit a proposal on the new Task Force.
- The 53rd Session of the Executive Committee agreed that Japan would prepare a project document in the form of Draft Terms of Reference for a new Ad Hoc Task for with a list of potential areas of work.
- Circular letter (CCL 2004/7-FBT) seeking comments on the Draft Terms of Reference and invite Project Proposals for the New Ad Hoc Intergovernmental Task Force, was issued in March, 2004.

2. COMMENTS RECEIVED FROM THE MEMBER GOVERNMENTS AND INTERNATIONAL ORGANISATIONS COVERED FOLLOWING AREAS FOR THE PROPOSED TASK FORCE.
 - i. Foods derived from animals
 - Transgenic animals, including fish
 - Cloned animals
 - ii. Foods derived from plants
 - Plants expressing bioactive substances or nutritionally-enhanced plants.
 - Plants with “stacked” genes (i.e. several genes conferring different traits in the same plants)
 - Biopharming
 - Plants expressing pharmaceuticals or other non-food substance
 - iii. Low level presence of unauthorized genetically engineered foods in authorized foods
 - iv. Comparative food composition analysis.
3. The 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Food derived from Biotechnology with understanding that its final report should be submitted to commission in 2009.
4. The Commission agreed that a Circular Letter be issued to solicit specific proposal for new work and to define priorities and that the comments received would be distributed as a working document for consideration by the first session of the Task Force. Accordingly, circular (CL2005/2-FBT) was issued in February, 2005 soliciting specific proposals on new work to be undertaken by the Task Force. Proposals were to be made covering the following aspects:
 - a. the rationale
 - b. the scope
 - c. the need for additional specific advice,
 - d. any questions to be answered by experts concerning the proposed issues,
 - e. information on the relation between the suggested issues and other existing Codex and other pertinent documents, and

- g. the expected outcome, such as guideline, annex to any of the existing or forthcoming documents, etc. with supplementary explanation on technical terms where necessary and inter-se priority to be set among the proposals;

Proposals were submitted by us and included in the Conference Room Document (CRD)-7 in the session. A copy of CRD-7 is at Annexure – 1.

THE TERMS OF REFERENCE OF THE AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY

Objectives

To develop standards, guidelines or recommendations, as appropriate, for food derived from modern biotechnology or traits introduced into foods by modern 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 the promotion of fair practices in the food trade.

Time frame

The Task Force shall complete its work within four years and should submit a full report in 2009.

Terms of Reference

- a. To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from modern biotechnology, taking account, in particular, of the Principles for the Risk Analysis of Food derived from Modern Biotechnology;
- b. To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from modern biotechnology; and
- c. To take account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international for a.

PART III REPORT

OPENING OF THE SESSION

The Session was opened by Mr. Toshikazu Togari, Vice-Minister of Health, Labour and Welfare, who welcomed the participants to Chiba, Japan. He stressed the importance of developing science based international guidance on issues related to the safety of the foods derived from biotechnology.

On behalf of FAO, Mr. Ezzeddine Boutrif, Chief, Food Quality and Standards Service, highlighted the importance of biotechnology and suggested reviewing of safety assessments undertaken by different parties in order to assess their conformity with Codex guidelines. The Representative also emphasized the need to assist developing countries to build their capacity in the safety assessment of foods derived from biotechnology.

On behalf of the WHO, Dr. Jorgen Schlundt, Diorector, Department of Food Safety, Zoonoses and Food borne Diseases, expressed appreciation for the Government of Japan for the success of the first four-year period of the Task Force to the efficient management of the process of the Japanese Government who managed to obtain a collaborative spirit between participating Member States.

AGENDA ITEM 1: ADOPTION OF THE AGENDA

- (a) The Task Force agreed, time permitting, to the proposal of Kenya to discuss the issue of foods derived from animals receiving gene therapy or recombinant-DNA vaccines for protection of various diseases under agenda Item 5 (other business).
- (ii) The Task Force adopted the Provisional Agenda as the Agenda of this Session.

AGENDA ITEM 2: MATTERS REFERRED TO THE TASK FORCE BY THE COMMISSION AND THE OTHER CODEX COMMITTEES

The Task Force noted the information presented in document CX/FBT 05/5/2 containing the matters arising from the Codex Alimentarius Commission and the other Codex Committes viz. **Methods of Analysis and Sampling and on Food Labelling**.

AGENDA ITEM 3 REVIEW OF THE WORK BY INTERNATIONAL ORGANIZATIONS ON THE EVALUATION OF THE SAFETY AND NUTRITION ASPECTS OF FOODS DERIVED FROM BIOTECHNOLOGY

- (i) The Representative of the Convention on Biological Diversity (CBD) mentioned that the third session of the Conference of the Partners serving as the meeting of the Partners to Cartagena Protocol on Biosafety (COP-MOP) would be held in March 2006. In addition a separate Technical Expert Group on Risk Assessment established by the COP-MOP, to be held in November, 2005, would examine the existing approaches identifying gaps and capacity building needs and forward recommendations to Cop-Mos-3. A document would also be prepared on the needs and modalities of standards with reference to paragraph 3 of the Article 18 including identification, handling, packaging and transport practices for Living Modified Organisms (LMO).
- (ii) The Representative of the Organisation for Economic Cooperation and Development (OECD) informed of the recent activities by the OECD Task Force on Novel Foods & Feeds especially elaboration of series of Consensus Documents on food and feed safety.
- (iii) The Representative of FAO referred to the FAO's 2004 publication "The State of Food and Agriculture". The Representative indicated that work was in progress on the development of training materials on the safety assessment of GM foods based on Codex adopted guidelines.
- (iv) The WHO Representative informed, inter alia, about a report titled "Modern Food Biotechnology, Human Health and Development: an evidence-based study, an outcome of a three-year study". He mentioned how GM Foods can promote human health and economic development, provided it is properly evaluated from the angle of human health, environment, social and ethical aspects.

AGENDA ITEM 4: CONSIDERATION OF THE ELABORATION OF STANDARDS, GUIDELINES OR OTHER TEXTS FOR FOODS DERIVED FROM BIOTECHNOLOGY

General

Task Force took note, inter alia, of situation of developing countries in relation to the prevalence of malnutrition and nutrient deficiency diseases as well

as their needs for capacity building on the safety assessment of foods derived from biotechnology.

Recombinant-DNA Animals

- (i) There was a distinct division of opinion among the delegates on this issue. Many delegations e.g. Canada supported this work due to potential benefit from the angle of commercialization of recombinant-DNA animals, especially fish. Many delegations, especially from developing countries, considered it as a low priority compared to other important projects.
- (ii) Many delegations considered work on cloned animals as out of the scope of the Task Force. The Task Force agreed not to undertake new work on cloned animals, but may accept work on recombinant-DNA animals.
- (iii) The Delegation of European Community, Iran and Egypt stressed the need for ethical, environmental and animal welfare considerations. However delegation of Canada felt that the Task Force should consider solely scientific aspects related to food safety assessment.
- (iv) The Task Force decided to forward the Project Document, as agreed, to the 58th Session of the Executive Committee for critical review and 29th Session of CAC for approval as new work (Annexe 2).
- (v) It was decided to establish a physical working group to prepare Proposed Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, co-chaired by Australia and Japan. Many members and observers expressed their interest in participating in this working group.
- (vi) The Task Force decided to frame the draft guidelines in relation to the safety of viral and other vectors used to generate recombinant-DNA animals and parameters are important to consider and how should the appropriate animals health comparators be selected for different classes of animals.

Recombinant-DNA plants modified for nutritional or health benefits

- (i) Several delegations, including India, stated that development of nutritionally enhanced crops might have significant impact on health of consumers in developing countries and suggested that the Task Force start new work related to comprehensive safety assessment of there new crops.

- (ii) Several delegations, however, felt that there was no justification to apply additional safety assessment to recombinant-DNA plants only. However, nutritional consequences of the nutritionally enhanced plants due to excessive intake of nutrients in certain populations was also an issue of concern for many delegates including the European Community.
- (iii) It was finally agreed to initiate new work in the form of an annex to the Plant Guidelines and to proceed with further scoping of the work based on CRD 16 and CRD 17 prepared by Canada. The Task Force also agreed to establish an electronic working group led by Canada to formulate a proposed draft document (scoping) in this regard.

Comparative composition analysis

- (i) Several delegations proposed to give high priority to this work on comparative composition analysis of recombination DNA plants including staple crops of developing countries.

The Delegation of India, referring to its written comment, proposed that the Task Force should start new work on comprehensive analysis of nutrient, anti-nutrients as well as methods of toxicity studies because quantitative and qualitative analytical methods would be necessary tools to conduct safety assessment of recombinant-DNA plants.

The Task Force agreed to invite India to submit a discussion paper on this subject for further consideration by the next session of the Task Force. The Task Force observed that the work undertaken by the Codex Committee on Methods of Analysis and Sampling and other relevant international organizations should be fully taken into account while assessing the need for future work on the subject.

Plants with Stacked Genes

- (i) The Task Force observed that the term ‘stacked genes’ was understood in different ways by different delegations. Hence the first and foremost responsibility of the task force was to arrive at a consensus about the concept of the term stacked gene. Several delegates considered this difference in concept as the main barrier for developing the guidelines for safety assessment.

Low Level (Adventitious) presence of Unauthorized Recombinant-DNA Plant Materials

- (i) The Delegation of USA stated that development of a new guidance document would assist member countries in conducting safety assessment of low level adventitious presence recombinant-DNA plant materials originating from new varieties in the development or field testing or from oldest varieties coming off the market. The delegation of European Community attributed it to differences in approval status of recombinant-DNA plants among countries. Many delegations, however, stated that term “low level” or “unauthorized” as well as scope of work required further clarification and the subject falls in the category of “risk management” rather in safety assessment.
- (ii) Some delegations like CI stressed that there should be no room for the term low so long it is “unauthorized”.
- (iii) The Delegation of the United States decided to revisit the subject, if required, at a future session of the Task Force.

Plants producing pharmaceutical or bioactive substances

- (i) Several delegations pointed out that the issues related to plants producing pharmaceutical or bioactive substances were the beyond the mandate of Codex.
- (ii) The delegation of Norway considered the issue as relevant from the angle of food safety and consumers’ health, in the event of these plants reaching the food chain.
- (iii) Due to lack of consensus, the Task Force agreed not to start new work on this subject.

Post market surveillance

Due to the late availability of the written proposal, the Task Force agreed that Mexico should submit a discussion paper in the next session of the Task Force with respect to post market surveillance for foods derived from biotechnology.

AGENDA ITEM 5: OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF THE NEXT SESSION

The Delegation of Kenya proposed safety assessment of foods derived from animals exposed to protection against disease through gene therapy or recombinant-DNA vaccines. The Task Force invited Kenya to submit a discussion paper to the next session of the Task Force.

Some of the areas considered for future work included :

- (i) The Task Force noted that the following items would be considered at its next session:
 - 1. Comparative Food Composition Analysis of Staple Foods (led by India) ;
 - 2. Post market safety surveillance of GM food/food ingredients (led by Mexico)
 - 3. Safety evaluation of animals receiving recombinant vaccines and gene therapy against diseases (led by Kenya)
 - 4. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (led by Australia and Japan);
 - 5. Guideline for the Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits (led by Canada);

Date and Place of the Next Session of the Task Force

- (i) The 7th Session of the Task Force was tentatively scheduled to take place from 27th November to 1st December 2006 in Chiba, Japan.