codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7 **CX/FBT 06/6/7**

September 2006

E

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

DISCUSSION PAPER ON SANITARY SURVEILLANCE AFTER PLACING ON THE MARKET OF FOODS DERIVED FROM BIOTECHNOLOGY

(Submitted by Mexico)

Background[1]

1. At the Fifth Session of the Task Force, Mexico proposed to start new work on post market surveillance with the aim of obtaining scientific information which could support and complement risk assessment of foods derived from biotechnology.

2. The Task Force agreed that Mexico submit a discussion paper to the Sixth Session of the Task Force with respect to the sanitary surveillance after placing on the market of foods derived from biotechnology.

3. The Paper submitted by Mexico is in the Annex to this document.

[1] ALINORM 06/29/34, paras 61-62

ANNEX

1. During the Fifth Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (TFBT), which took place in Chiba, Japan, from September 19 to 23, 2005, in response to national interests, the Mexican delegation requested the approval of a new work on surveillance after placing foods derived from biotechnology in the market, with the objective of collecting scientific information that sustains and complements their risk assessment.

2. The Task Force, whilst agreeing with the Mexican request, prompted the presentation of a discussion paper at its sixth Session.

3. During the discussions in the Task Force, several concerns were raised on nutritionally improved crops, such as:

- That development of nutritionally enhanced crops might have significant impact on the health of consumers, especially in developing countries. Attention was drawn to the need to improve capacities of developing countries for conducting safety assessment of these plants. (ALINORM 06/29/34, para.28)
- That nutritionally enhanced staple crops might lead to excessive intake of enhanced nutrients in certain populations and that risk management measures might become necessary for the protection of consumers' health and that food and nutrient intake study might be necessary in order to monitor health effects where nutritionally enhanced plants were used because the availability and perceived benefits of such plants could change food consumption patterns of the population. (ALINORM 06/29/34, para. 30)
- Those considerations on post marketing monitoring systems should be an essential element of the work on this item because consumptions of nutritionally enhanced plants may cause significant changes in dietary intake patterns. (ALINORM 06/29/34, para. 31)

4. Recognizing the existence of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003, hereinafter referred to as the Guideline on Plants), related with nutritional aspects, as part of the food safety assessment offer guidance regarding the intended nutritional modifications.

5. Expressing however, that these guidelines are ambiguous and do not offer detailed information regarding the safety and nutritional considerations (e.g. the studies to determine bioavailability or the determination of the physiologic function of the modification), and

Expecting that new works should be undertaken to provide additional guidance regarding the evaluation of these new crops,

Recalling that the Task Force was invited to prepare an Annex to the Guideline on Plants (CAC/GL 45-2003), and decided to establish an Electronic Working Group, led by Canada, in charge of drafting an Annex (scoping document ("Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits"), and present it to the next session of the Task Force,

Noting the agreements reached at the Fifth Session of the Task Force, and in accordance to the twentieth paragraph of the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003),

Also noting that Mexico in its discussion paper, aimed to solve some national concerns to determine the cases in which it is appropriate to establish a sanitary surveillance program after placing in the market of foods derived from biotechnology, particularly of foods obtained from recombinant-DNA plants modified for nutritional or health benefits, in order to attain the following objectives:

- Determining the existence of a scientific-based risk hypothesis derived of a risk assessment, verification of which requires to accurately estimate the risk exposure, nutrimental effects or any other consequence, clearly identified as resulting from the consumption of such food.

- To adopt a specific safety surveillance method must be made based on a case-by-case principle in order to verify conclusions about the absence or the possible occurrence, impact and significance of potential consumer health.
- Monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.

6. Considering these objectives and underlining that they are reflected in the concerns that leads to the development of the annex on “Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits”,

Recognizing that both the Mexican document and that derived from the Canadian proposal intend to address uncertainties on the risk assessment of foods derived from nutritionally enhanced plants,

Accepting that the draft document led by Canada, matches the Mexican interests in scope and that by adding to it on the technical elements to be included,

Mexico considers that it is not appropriate to work on another document related with the subject; at least not until being able to analyze the results of the discussions on the draft annex on “Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits”.