codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION

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TO: Codex Contact Points
Interested International Organizations

FROM: Secretary,
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **Request for proposals for new work to be undertaken by the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology**

DEADLINE: **30 April 2005**

COMMENTS:

To:
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BACKGROUND

1. 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 Force with a list of potential areas of work.

2. In accordance with this decision, the Circular Letter appended with Draft Terms of Reference and Project Document: Proposal for New Work on Foods Derived from Biotechnology (CL2004/7-FBT) was issued. In response to this Circular Letter, comments on the potential areas for work were received from Argentina, Australia, Canada, Hungary, Indonesia, Iran, Mexico, New Zealand, United States of America, Venezuela, European Community, Biotechnology Industry Organization, Croplife International, 49th Parallel Biotechnology Consortium and Greenpeace International (CAC/27 LIM.9 & LIM.11).

The comments received covered areas as follows :

1) Foods derived from animals
   - Transgenic animals, including fish
   - Cloned animals

2) 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 plant)
- Biopharming
- Plants expressing pharmaceutical or other non-food substance

3) Low level presence of unauthorized genetically engineered foods in authorized foods

4) Comparative food composition analysis

3. The 27th Session of the Codex Alimentarius Commission agreed to establish a new Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology with understanding that its final report should be submitted to Commission in 2009. It adopted the Terms of Reference of the Task Force (ALINORM04/27/41 APPENDIX VIII). The Commission noted the willingness of the delegation of Japan to host the new Task Force subject to confirmation of availability of funds (ALINORM04/27/41, para. 90).

4. The Commission agreed that a Circular Letter be issued to solicit specific proposals for new work and to define priorities and that comments received would be distributed as a working document for the consideration by the first session of the Task Force and noted that the issues concerning potential areas for future work including "cloned animals" and "bioactive substances" would be clarified and discussed in the new Task Force (ALINORM 04/27/41, paras 89 and 91).

In accordance with the decisions of the Commission, the present Circular Letter is hereby distributed to solicit specific proposals for new work to be addressed by the Task Force.

REQUEST FOR COMMENTS

5. Governments and international organizations are requested to make comments on the issues to be addressed by the Task Force (particularly from among, but not limited to the list of areas shown in paragraph 2) with;

1) Sufficient clarification on the suggested issues, including
   - the rationale,
   - the scope,
   - the need for additional scientific advice,
   - any questions to be answered by experts concerning the proposed issues,
   - information on the relation between the suggested issues and other existing Codex and other pertinent documents, and
   - the expected outcome, such as guideline, annex to any of the existing or forthcoming CTFBT documents, etc.,

   with supplementary explanation on technical terms where necessary;

2) Priorities to be set among the proposals;

3) Any other considerations.

Where appropriate, comments may incorporate project document(s) (see Elaboration Procedures, Part 2 Critical Review, in the Procedural Manual, 14th Edition) for issues proposed.

6. Governments and international organizations wishing to submit comments should do so in writing, preferably by email to the above address **before 30 April 2005**. The comments received will be compiled and distributed as a working document of the forthcoming session of the Task Force.

Note: For information, the Terms of reference of the Task Force agreed in the 27th Session of the Codex Alimentarius Commission (ALINORM 04/27/41 Appendix VIII), the contents of the "Principles for the Risk Analysis of Foods derived from Modern Biotechnology (CAC/GL 44-2003)" and the "Guideline for the Conduct of Food Safety Assessment of the Foods derived from Recombinant-DNA Plants (CAC/GL 45-2003)" developed by the previous Task Force, and the "Questions for a Joint FAO/WHO Expert Consultation" addressed in the first meeting of the previous Task Force are reproduced in Annex, which may assist in the above consideration.

ANNEX

A. The Terms of Reference of the Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology (ALINORM 04/27/41 Appendix VIII)

Objectives

To develop standards, guidelines or recommendations, as appropriate, for foods 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. The Task Force 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 Foods 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 fora.

B. The Contents of the Principles and Guidelines developed by the previous Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology

PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY (CAC/GL 44-2003)

1. Introduction
2. Scope and Definitions
3. Principles
   - Risk Assessment
   - Risk Management
   - Risk Communication
   - Consistency
   - Capacity Building and Information Exchange
   - Review Processes

GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS (CAC/GL 45-2003)

1. Scope
2. Definitions
3. Introduction to Food Safety Assessment
   - Unintended Effects
   - Framework of Food Safety Assessment
4. General Considerations
   - Description of the Recombinant-DNA Plant
   - Description of the Host Plant and its Use as Food

Description of the Donor Organism(s)
Description of the Genetic Modification(s)
Characterization of the Genetic Modification(s)
Safety Assessment
Expressed Substances (non-nucleic acid substances)
Assessment of possible toxicity
Assessment of possible allergenicity (protein)
Compositional Analyses of Key Components
Evaluation of Metabolites
Food Processing
Nutritional Modification
5. Other considerations
Potential Accumulation of Substances Significant to Human Health
Use of Antibiotic Resistance Marker Genes
Review of Safety Assessments

ANNEX TO "GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS (CAC/GL 45-2003)":

ASSESSMENT OF POSSIBLE ALLERGENICITY

1. Introduction
2. Assessment Strategy
3. Initial Assessment
   3-1.Source of the Protein
   3-2. Amino acid Sequence Homology
   3-3. Pepsin Resistance
4. Specific Serum Screening
5. Other Considerations

C. THE QUESTIONS FOR AN EXPERT CONSULTATION RAISED BY THE PREVIOUS AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY AT ITS FIRST SESSION (2000)

QUESTIONS FOR A JOINT FAO/WHO EXPERT CONSULTATION (ALINORM 01/34, Appendix III)

1. What over-arching scientific principles should be applied to safety and nutritional assessment?
2. What is the role and limitation of substantial equivalence in safety and nutrition assessment? Are there alternative strategies that should be used for safety and nutrition assessment?
3. What scientific approach can be used to monitor and assess possible long term health effects or unintended/unexpected adverse effects?
4. What scientific approach can be used to assess potential allergenicity?
5. What scientific approach can be used to assess the possible risks arising from the use of antibiotic resistance marker genes in plants and micro-organisms?