

Overview of Codex Activities in Food Biotechnology

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Codex Alimentarius Commission (CAC)

- The “Joint FAO/WHO Food Standards Programme” was established in 1963 to “guide the world’s growing food industry and to protect the health of consumers.”
- The Codex Alimentarius Commission is mandated to develop international food standards to:
 - protect the health of consumers
 - ensure fair practices in the food trade
- coordinate all food standards work at the international level

2

Codex Alimentarius Commission (CAC)

The Codex Alimentarius Commission (Codex)

- It is an intergovernmental body
- Currently consists of 172 members (October 2004)
- Members vs. Observers
- Commission meets annually at the present time
- Meetings alternate between Rome and Geneva
- Permanent Secretariat based in Rome
- The *Codex Alimentarius*

Codex Alimentarius Commission (CAC)

Scope of the Codex Alimentarius

- Includes standards for all principle foods, whether processed, semi-processed or raw, covering:
 - food additives,
 - pesticides residues, contaminants,
 - food hygiene,
 - labelling and presentation,
 - methods of analysis and sampling
- Also includes provisions of an advisory nature, including codes of practices, guidelines, and other recommended measures.

Codex Alimentarius Commission (CAC)

Codex and the World Trade Organization

- Codex standards are reference “benchmark” under the Sanitary and Phytosanitary (SPS) Agreement
- Obligation of WTO members to participate “within the limits of their resources” in the relevant international standard setting organizations, in particular Codex, OIE and IPPC
- Members adopting measures that conform to Codex standards are presumed to meet the obligations of SPS Agreement

5

Codex Alimentarius Commission (CAC)

Subsidiary Bodies

- Codex develops its standards, guidelines and recommendations through the use of subsidiary bodies.
- Codex has four types of subsidiary bodies, each hosted by a member country, established to carry out its work:
 - General subject or “Horizontal” Committees such as Codex Committee on Food Labelling [CCFL] or Codex Committee on Food Hygiene [CCFH].

Codex Alimentarius Commission (CAC)

- Commodity specific or “Vertical” Committees such as the Codex Committee on Milk and Milk Products [CCMMP] or the Codex Committee Meat Hygiene [CCMH].
- *Ad Hoc* Intergovernmental Task Forces
- FAO/WHO Regional Coordinating Committees. (Canada is a member of the Regional Coordinating Committee for North America and the South-West Pacific.)

Codex Alimentarius Commission (CAC)

Elaboration of Codex Standards and Related Texts

- When a subsidiary body of the Commission is considering elaborating a standard or related text it will prepare project documentation.
- The elaboration procedure follows either an 8 step or a 5 step process. Regardless of the process used, the principles of transparency, inclusiveness and scientific soundness prevail.

Codex Alimentarius Commission (CAC)

- Once the Commission approves new work (1), a proposed draft is prepared (2) and circulated to member governments and observer organizations for comments (3). The comments are considered by the relevant Codex subsidiary body and the text is revised accordingly (4).
- The revised text is submitted to the Commission for adoption as a draft standard (5).

Codex Alimentarius Commission (CAC)

- The draft standard is circulated to Members and Observers for another round of comments (6) and the relevant Committee considers the comments and revises the text as appropriate (7).
- The revised standard is submitted to the Commission for adoption and incorporation into the *Codex Alimentarius* (8).
- In the “accelerated” procedure (5 steps) the second round of comments is omitted.

Codex Alimentarius Commission (CAC)

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Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology

- Established in 1999 to develop standards, guidelines or recommendations for foods derived from biotechnology
- Hosted by the Government of Japan
- 4-year mandate to reach an agreement toward the modality of safety assessment of food derived from biotechnology
- Reports of the four sessions of the Task Force available at www.codexalimentarius.net

FAO/WHO Expert Consultations

- Consultation on Specific Aspects of Genetically Modified Foods of Plant Origin (*Geneva, June 2000*)
- Consultation on Allergenicity of Genetically Modified Foods (*Rome, January 2001*)
- Consultation on Food Derived from Modern Biotechnology – Genetically Modified Microorganisms (*Geneva, September 2001*)
- Consultation on Safety Assessment of Foods Derived from Genetically Modified Animals including Fish (*Rome, November 2003*)

Codex Task Force's Highlights

First Session (Chiba, Japan - March 2000)

- Decision to proceed with the elaboration of two major texts:
- Broad principles for risk analysis of foods derived from biotechnology, including matters such as:
 - science-based decision-making,
 - pre-market assessment,
 - transparency;
 - post-market monitoring [including traceability], and
 - other legitimate factors as appropriate

14

Codex Task Force's Highlights

First Session (Chiba, Japan - March 2000) (cont.)

- Specific guidance on the risk assessment of foods derived from biotechnology, including such matters as:
 - food safety and nutrition,
 - substantial equivalence,
 - potential long-term health effects; and
 - non-intentional effects
- Also agreed to compile a list of appropriate analytical methods, together with their performance characteristics and validation status

Codex Task Force's Key Achievements Third Session (Yokohama, Japan – March 2002)

Matters for final adoption by the CAC in 2003:

- Draft Principles for the Risk Analysis of Foods Derived from Modern biotechnology
- Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Draft Annex on the Assessment of Possible Allergenicity

16

Codex Task Force's Key Achievements Third Session (Yokohama, Japan - March 2002)

Other matters:

- Agreed to advance the Proposed Draft Guidelines for the Conduct of Food Produced using Recombinant-DNA Microorganisms to Step 5
- Agreed to forward the list of validated methods for the detection or identification of foods or food ingredients derived from biotechnology to the Codex Committee on Methods of Analysis and Sampling for its consideration

Codex Task Force's Key Achievements Fourth Session (Yokohama, Japan - March 2003)

Matters for final adoption by the CAC in 2003:

- Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms

Other Matters:

- The Task Force had an exchange of opinions on potential future work on the safety assessment of foods derived from biotechnology

Principles for the Risk Analysis of Foods Derived from Modern Biotechnology

- The Principles provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology.
- The Principles recognize the need for consistency with the Codex Working Principles for Risk Analysis and therefore address risk assessment, risk management, risk communication, consistency, capacity building and information exchange and the need for review processes to address new scientific knowledge.

Guideline for the Conduct of Food Safety Assessment of Foods Derived from rDNA Plants

- The safety of foods derived from new plant varieties, including recombinant-DNA plants, is assessed relative to the conventional counterpart having a history of safe use, taking into account both intended and unintended effects.

Guidelines – Framework of Food Safety Assessment

The evaluation follows a stepwise process of addressing relevant factors that include:

- 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);

Guidelines – Framework of Food Safety Assessment (cont.)

Safety assessment:

- a) expressed substances (non-nucleic acid substances);
 - assessment of possible toxicity
 - assessment of possible allergenicity (proteins)
- b) compositional analyses of key components;
- c) evaluation of metabolites;
- d) food processing;
- e) nutritional modification

Guidelines – Framework of Food Safety Assessment (cont.)

Other considerations:

- potential accumulation of substances significant to human health
- use of antibiotic resistance marker genes

New Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology

- Establishment of a new *Ad Hoc* Task Force in 2004
- First session in September 2005
- Work to be completed in 2009
- Potential topics of work already identified:
 - foods derived from transgenic animals and from cloned animals,
 - foods derived from plants expressing bioactive substances, and
 - low level presence of unauthorized genetically engineered food in the food supply

24