

# **CODEX** **ALIMENTARIUS**

## **Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food**



**World Health  
Organization**



**Food and Agriculture  
Organization of  
the United Nations**

# CODEX was established to

- Protect the health of consumers
- Ensure fair practices in the food trade
- Coordinate all food standards work done by IGOs and NGOs
- Create and update the Codex Alimentarius

# CODEX: A Result and A Forum

- **185 + 1** members and **220** observers
- **100%** member driven, inclusive and transparent
- Based on science
- WTO SPS reference
- **100s** of food standards, guidelines and codes,
- **1000s** of safe limits for pesticides and veterinary drugs residues, contaminants and food additives
- **20** technical meetings per year allowing exchange and learning from each other, building international relations and building consensus



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# Codex Alimentarius Commission

## Executive Committee

Secretariat

### Horizontal/ general Committees

General Principles (France)	Food Labelling (Canada)
Import and Export Inspection and Certification Systems (Australia)	Residues of Veterinary Drugs in Foods (United States)
Food Additives (China)	Pesticide Residues (China)
Contaminants in Foods (Netherlands)	Food Hygiene (United States)
Methods of Analysis and Sampling (Hungary)	Nutrition and Foods for Special Dietary Uses (Germany)

### Vertical/commodity Committees

active	
Fish and Fishery Products (Norway)	Processed Fruits and Vegetables (United States)
Fats and Oils (Malaysia)	Fresh Fruits and Vegetables (Mexico)
Sugars (Colombia)	Spices and culinary herbs (India) <b>NEW</b>
adjourned sine die	
Cereals, Pulses and Legumes (United States)	Meat hygiene (New Zealand)
Natural Mineral Waters (Switzerland)	Vegetable Proteins (Canada)
Milk and Milk Products (New Zealand)	Cocoa Products and Chocolate (Switzerland)

### Ad-hoc intergovernmental task forces

active	
Animal Feeding (Switzerland)	
dissolved	
Fruit Juices (Brazil)	Foods derived from Biotechnology (Japan)
Processing and Handling of Quick Frozen Foods (Thailand)	Antimicrobial Resistance (Republic of Korea)

### FAO/WHO Coordinating Committees

Africa (Cameroon)	Asia (Japan)	Europe (Netherlands) <b>NEW</b>	Latin America and the Caribbean (Costa Rica)	North America and South West Pacific (Papua New Guinea)	Near East (Lebanon)
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# Task force: Objectives and Facts

- **Objectives:** *Develop guidance for foods derived from biotechnology or traits introduced into foods by 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 trade practices.*
- Worked from 1999-2003 and 2004-2008 – hosted by Japan
- Developed principles and three guidelines
- Coordinated with other Codex Committees as appropriate and took into account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

# Task force: Results

- Principles for the risk analysis of foods derived from modern biotechnology (CAC/GL 44-2003)
- Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003, Annex II and Annex III 2008)
- Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms (CAC/GL 46-2003)
- Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals (CAC/GL 68-2008)

# Annex 3:

## Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food

### What it is intended for

- **Scope:** Low levels of recombinant DNA plant materials;
  - which have passed a food safety assessment according to the Codex Plant Guideline in one or more countries
  - which are present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined
  - as a consequence of asymmetric authorization in different countries

## **Annex 3: What it is NOT intended for**

- For a recombinant-DNA plant that was not authorized in an importing country as a result of that country's food safety assessment.
- The guideline does not;
  - address risk management measures, which are under National authorities' responsibility
  - preclude national authorities from conducting a safety assessment according to the Codex Plant Guideline
  - eliminate the responsibilities of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant requirements, including in relation to unauthorized recombinant-DNA plant material.



## Annex 3: Principle of approach

- Combination of
  - Food safety assessment in situations of or in advance preparation for such potential circumstances; and
  - Data and information sharing mechanisms to facilitate utilization of the guideline and to determine whether it should apply.
- (Annex paragraphs 2 and 3)

## Annex 3: Principle of approach

- **Food Safety Assessment:** Only certain elements of the Codex Plant Guidelines will be relevant as the dietary exposure will be significantly lower. (Annex paragraph 5)
- In order for Codex Members to use the Guideline, it is essential that they have access to requisite data and information.(Annex paragraph 27)
- **Data sharing:** Codex members shall make available to publicly accessible central database to be maintained by FAO information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline.

## Annex 3: Principle of approach

- name of product applicant
- summary of application
- country of authorization
- date of authorization
- scope of authorization
- unique identifier
- links to the information on the same product in other databases maintained by relevant international organizations, as appropriate;
- summary of the safety assessment, which should be consistent with the framework of food safety assessment of the Codex Plant Guideline;
- where detection method protocols and appropriate reference material (non-viable, or in certain circumstances, viable) suitable for low-level situation may be obtained<sup>14</sup>; and
- contact details of the competent authority(s) responsible for the safety assessment and the product applicant.

*This information may be provided by the product applicant or in some cases by Codex members. (Annex paragraph 28)*

## **If further Codex work is needed ...**

- Project document
- Discussion in CCEXEC and CAC
- Eventually New Task force
- Codex Standard setting process (8 Steps)