



## 2. Concepts and principles of safety assessment of food derived from recombinant-DNA plants (within international frameworks)

### Introduction

Modern biotechnology broadens the scope of genetic changes that can be introduced into organisms used for food. However, it does not inherently result in foods that are less safe than those produced by more conventional techniques (OECD, 1993; US NAS, 2004). This principle has important ramifications for the safety assessment of GM foods. It means that a new or different standard of safety is not required, and that previously established principles for assessing food safety still apply. Moreover, introducing specific genetic changes should enable a more direct and focused assessment of safety.

While countries may differ in statutory and non-statutory approaches to regulating foods derived from recombinant-DNA plants, the criteria used to assess the safety of these products is generally consistent from one country to another (World Bank, 2003). This reflects the concerted efforts that have been made internationally to harmonize the risk assessment of foods derived from modern biotechnology (Table 2.1). The outcomes of these consultations have contributed significantly to the development of internationally accepted approaches to assessing the safety of foods derived from biotechnology, as articulated in two important documents published in 2003 by the Codex Alimentarius Commission (CAC)<sup>5</sup>: *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (hereinafter referred to as “Codex Principles”; see Appendix 1) and *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants CAC GL 45-2003* (hereinafter referred to as “Codex Guideline”; see Appendix 2).

These documents acknowledge the inadequacy of applying already established risk assessment principles to foods, which by nature are complex compounds and not single chemicals that can be investigated individually. Nevertheless, the documents describe the safety assessment of foods derived from recombinant-DNA plants as a process within the established framework of risk assessment. Safety assessment is in essence the first step in identifying any hazards that may be associated with the food, after which the risks to human health are evaluated.

### Role of Codex Alimentarius Commission (CAC) in setting food safety standards

The CAC was created in 1963 by FAO and the World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this programme are protection of the health of consumers and ensuring fair trade practices in the food trade, and promoting harmonization of all food standards work undertaken by international governmental and non-governmental organizations<sup>6</sup>. The 23rd Session of the CAC agreed to establish the *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (TFFBT) under the following Terms of Reference:

- to elaborate standards, guidelines or other principles, as appropriate, for foods derived from biotechnology;

<sup>5</sup> At the same time, the Codex Alimentarius Commission also published a third document, *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms*.

<sup>6</sup> [http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp)

- to coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as related to foods derived from biotechnology;
- to take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.

The Task Force successfully completed its work within the original four-year time frame, culminating with the publication of the Codex Principles and Guideline.

**Table 2.1.** Some key international consultations addressing the safety assessment of foods derived from recombinant-DNA plants (1990-2006)

Year	Organization	Title and link (where available)
1990	FAO/WHO	Strategies for assessing the safety of foods produced by biotechnology, a joint FAO/WHO consultation. Geneva, Switzerland, 5–10 Nov. 1990. ( <a href="http://www.who.int/foodsafety/publications/biotech/1990/en/index.html">http://www.who.int/foodsafety/publications/biotech/1990/en/index.html</a> )
1990	IFBC	Biotechnologies and food: assuring the safety of foods produced by genetic modification. Regulatory Toxicology and Pharmacology, 12: S1–S196.
1993	WHO	Health aspects of marker genes in genetically modified plants. Report of a WHO Workshop. Copenhagen, Denmark, 21–24 Sept. 1993.
1994	WHO	Application of the principles of substantial equivalence to the safety evaluation of foods or food components from plants derived by modern biotechnology. Report of a WHO Workshop, Copenhagen, Denmark, 31 Oct.–4 Nov. 1994.
1996	FAO/WHO	Biotechnology and food safety. Report of a Joint FAO/WHO Consultation, Rome, Italy, 30 Sept.–4 Oct. 1996. FAO Food and Nutrition Paper No. 61.
1996	ILSI	ILSI Allergy and Immunology Institute (AI) guidance for assessing the allergenic potential of foods derived from biotechnology.
1997	OECD	Safety assessment of new foods: results of an OECD survey of serum banks for allergenicity testing, and use of databases. ( <a href="http://www.olis.oecd.org/olis/1997doc.nsf/LinkTo/sg-icgb(97)1-final">http://www.olis.oecd.org/olis/1997doc.nsf/LinkTo/sg-icgb(97)1-final</a> )
1998	OECD	Report of the OECD workshop on the toxicological and nutritional testing of novel foods. ( <a href="http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/sg-icgb(98)1-final">http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/sg-icgb(98)1-final</a> )
2000	FAO/WHO	Report of a Joint FAO/WHO Expert Consultation on foods derived from biotechnology – safety aspects of genetically modified foods of plant origin. WHO Headquarters, Geneva, Switzerland, 29 May–2 June 2000. ( <a href="http://www.fao.org/ag/agn/agns/biotechnology_expert_2000_en.asp">http://www.fao.org/ag/agn/agns/biotechnology_expert_2000_en.asp</a> )
2000	CAC	First session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Chiba, Japan, Mar. 2000. ( <a href="http://www.who.int/foodsafety/publications/biotech/ctf_march2000/en/index.html">http://www.who.int/foodsafety/publications/biotech/ctf_march2000/en/index.html</a> )
2001	FAO/WHO	Allergenicity of genetically modified foods, a joint FAO/WHO consultation on foods derived from biotechnology. Rome, Italy, 22–25 January 2001.
2001	CAC	Second session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Chiba, Japan, Mar. 2001. ( <a href="http://www.who.int/foodsafety/publications/biotech/ctf_march2001/en/index.html">http://www.who.int/foodsafety/publications/biotech/ctf_march2001/en/index.html</a> )
2002	OECD	Report of the OECD Workshop on the nutritional assessment of novel foods and feeds. ( <a href="http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)6">http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)6</a> )
2002	CAC	Third session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Yokohama, Japan, March 2002. ( <a href="http://www.who.int/foodsafety/publications/biotech/ctf_march2002/en/index.html">http://www.who.int/foodsafety/publications/biotech/ctf_march2002/en/index.html</a> )
2002	WHO	The stakeholders' meeting on WHO draft document "WHO – modern food biotechnology, human health and development: an evidence-based study". WHO, Geneva.
2003	CAC	Fourth session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Yokohama, Japan, March 2003. ( <a href="http://www.who.int/foodsafety/publications/biotech/july2003/en/index.html">http://www.who.int/foodsafety/publications/biotech/july2003/en/index.html</a> )
2003	OECD	Report on the questionnaire on biomarkers, research on the safety of novel foods and feasibility of post-market monitoring. ( <a href="http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/env-jm-mono(2003)9">http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/env-jm-mono(2003)9</a> )
2006	FAO	FAO expert consultation on biosafety within a biosecurity framework: Contributing to sustainable agriculture and food production. 28 February–3 March 2006, Rome, Italy. ( <a href="http://www.fao.org/ag/agn/agns/meetings_consultations_2006_en.asp">http://www.fao.org/ag/agn/agns/meetings_consultations_2006_en.asp</a> )



## List of international consultations on food safety

Several international organizations have identified the need to convene experts in order to address the scientific and other issues raised regarding the safety aspects of foods derived from recombinant-DNA plants or the consequence of their release into the environment, to rationalize the large number of discussions taking place on the topic in different countries to which these products are being targeted. Organizations such as FAO, WHO, OECD, ILSI and IFBC played an important role in the 1990s by facilitating and supporting several expert consultations on the subject, which were followed by the establishment of the Codex Alimentarius Commission in 2000. The major references are listed in the Table 2.1 ●