International Organizations: Implications for rDNA Animals

Second International Workshop for Regulation of Animal Biotechnology

August 2014

Luc Bourbonnière,
Section Head, Novel Foods,
Health Canada

Jim Louter, Ph.D.
Manager, Biotech Section
Environment Canada

Canada

Outline

- ✓A) Codex Alimentarius Commission (Luc)
  - ✓Raison d'être / Rationale for an International Food Standard setter : Codex Alimentarius Commission
  - ✓**Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology**
  - ✓**Codex guidelines**
- ✓B) OECD
  - ✓i) Task Force on Novel Foods and Feeds (Luc)
  - ✓ii) Working Group on Harmonization of Regulatory Oversight in Biotechnology (Jim)

CODEX: History and Rationale

Foods without Borders:

- Food products are amongst the most traded commodities
- Foods are important contributors to health of consumers internationally
- Information about risks and benefits associated with foods is provided by many sources

CODEX ALIMENTARIUS

1963-2013

Need for a reference body to guide food standard development internationally




Codex Alimentarius Commission : Raison d'être

- **Established in 1963 by FAO and WHO: intergovernmental body that elaborates food standards under the joint FAO/WHO Food Standards Programme:**
  - Develops harmonized international food standards, guidelines and codes of practice with the objective :
    - ✓ **To protect consumers' health**
    - ✓ **To ensure fair practices in the food trade**
  - Promotes coordination of all food standards work by international governmental and non-governmental organisations
- **An international focal point for informed discussions on food related issues**

Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology (TFFBT) 1999-2008

- To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from modern biotechnology, taking into account, in particular, of the Principles for the Risk Analysis of Foods derived from Modern Biotechnology;
- To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from modern biotechnology; and
- To take into account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.




Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
CAC/GL 44-2003

- " *A safety assessment is characterized by an assessment of a whole food or a component thereof relative to the appropriate conventional counterpart:*
  - *A) taking into account both intended and unintended effects;*
  - *B) identifying new or altered hazards;*
  - *C) identifying changes, relevant to human health, in key nutrients*."
- *Risk management measures for foods derived from modern biotechnology should be proportional to the risk…*
- *Risk communication should include transparent safety assessment and risk management decision-making processes.*
  - *These processes should be fully documented at all stages and open to public scrutiny, whilst respecting legitimate concerns to safeguard the confidentiality of commercial and industrial information*




Output: Guidelines

- Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA plants (2003)
- Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms (2003)
- Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA animals (2008)




Architecture

- The safety assessment of a food derived from a recombinant-DNA organism follows a stepwise process of addressing relevant factors that include:
  - A) Description of the recombinant-DNA organism;
  - B) Description of the host plant and its use as food;
  - C) Description of the donor organism(s);
  - D) Description of the genetic modification(s);
  - E) Characterization of the genetic modification(s);
  - F) Safety assessment:
    - a) expressed substances (non-nucleic acid substances);
    - b) compositional analyses of key components;
    - c) evaluation of metabolites ;
    - d) food processing;
    - e) nutritional modification; and
    - Health status of the recombinant-DNA animal;
  - G) Other considerations.




Organisation for Economic Co-operation and Development

- The OECD work programme aims to promote international harmonisation in the risk/safety assessment of :
  - novel foods and feeds.
  - products of modern biotechnology (environmental/biosafety)
- A number of non-OECD member economies and observer organisations are partners in this work (Brazil, Argentina, Chile and others).
- The major outputs of the programme are Consensus Documents that provide information on critical parameters for biosafety and for food/feed safety and nutrition.
- Another part of the programme is its outreach activity, including the development of BioTrack Online for disseminating the information worldwide and promoting harmonised biosafety frameworks. In addition to the consensus documents, Biotrack provides links to regulatory contacts in OECD countries, as well as to information on products of modern biotechnology which have been released to the environment or food/feed.





OECD Task Force for the Safety of Novel Foods and Feeds

- Established in 1999
- Focus its work on the development of science-based consensus documents
- In the area of food and feed safety, consensus documents are being published on the nutrients, anti-nutrients or toxicants, information of the product's use as a food/feed and other relevant information
- Maize, soybean, canola, cotton, sugarbeet, sugarcane, papaya, sweet potato, grain sorghum, tomato, cassava, sunflower, alfalfa, barley, wheat, rice, potato, 2 mushrooms
- Foods of animal origin: points to consider (initial work)
- Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants
- Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology (with Working Group on Harmonisation of Regulatory Oversight in Biotech.)

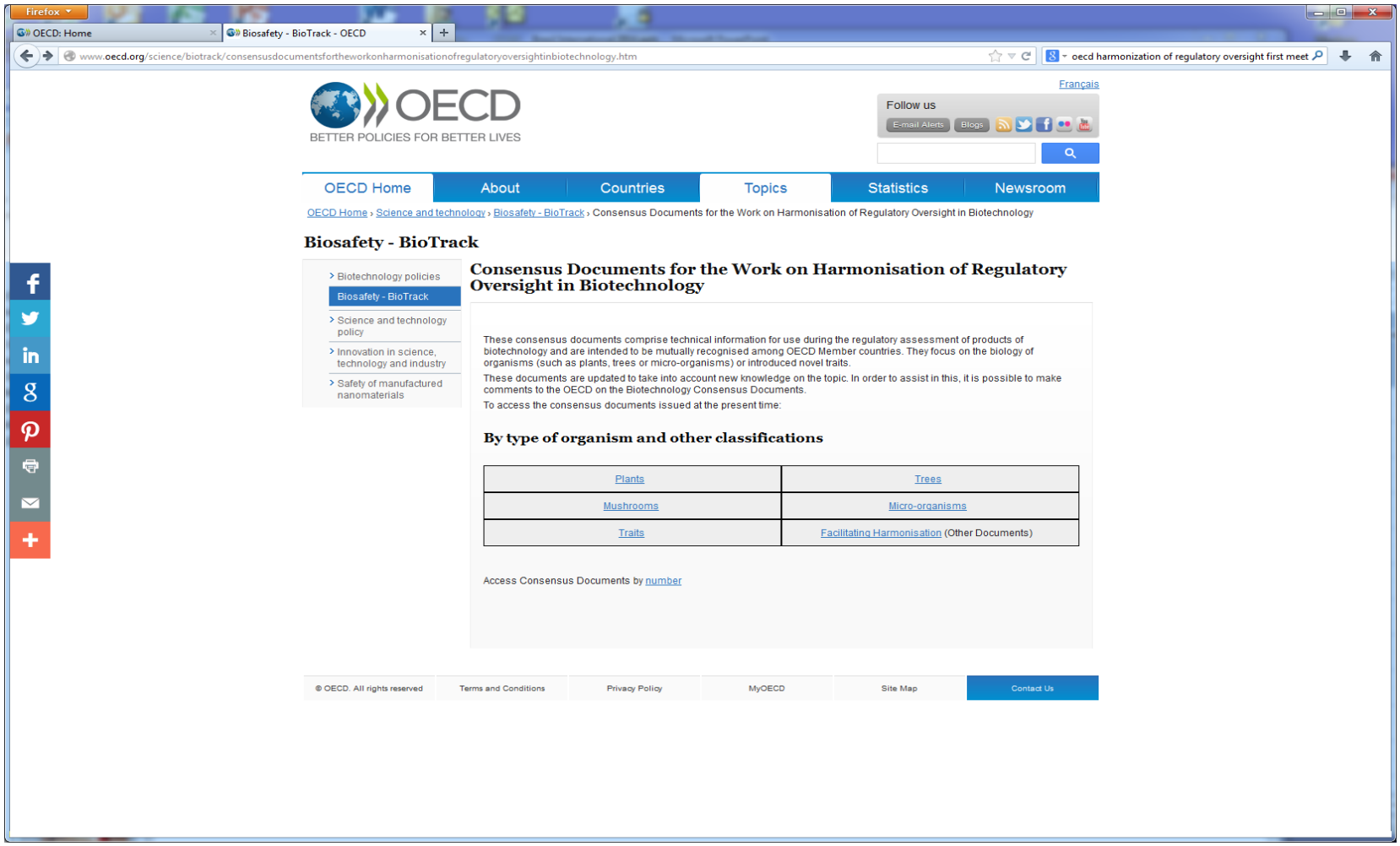



Working Group on Harmonisation of Regulatory Oversight in Biotechnology

- First established in the 1980s as the 'Group of National Experts' when biotechnology was first identified as an emerging science; *Recombinant DNA Safety Considerations* (*Blue Book)* was published in 1986.
- Early 1990s became 'WG on Harmonization of Reg. Oversight in Biotech'
- Consensus documents comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognised among OECD Member countries.
- They focus on the biology of organisms (such as plants, trees or micro-organisms) or introduced novel traits.
- 15 crops species, 1 mushroom species, 12 trees species
- 3 bacterial genera and 1 baculovirus
- 5 traits in GM crops (herbicides tolerance, Bt)
- Biology of Atlantic salmon consensus document is in draft; also one on mosquitoes.




OECD biosafety consensus documents



Cassava (Manihot esculenta Crantz) *		2014
Sugarcane *		2013
Brassica Crops (Brassica spp.) *		2012
Cucurbita L. (Squashes, Pumpkins, Zucchinis and Gourds)		2012
Bananas & Plantains (Musa spp.)		2009
Cotton (Gossypium spp.) *		2008
Chili, Hot & Sweet Peppers (Capsicum annum)	Chinese/中文	2006
Papaya (Carica papaya) *		2005
Sunflower (Helianthus annus) *		2004
Maize (Zea mays subs. Mays) *	Japanese/ 日本語 Chinese/中文	2003
Sugar Beet (Beta vulgaris)		2001
Soybean (Glyxine max) *	Japanese/ 日本語 Russian/ русском Chinese/中文	2000
Rice (Oryza sativa) *	Japanese/ 日本語 Chinese/中文	1999
Wheat (Triticum aestivum) *	Chinese/中文	1999
Potato (Solanum tuberosum subsp. Tuberosum) *	Russian/ русском	1997





고맙습니다
谢谢
תודה!
mahalo
děkuji
Thank You
شكرا
köszönöm
gracias
Ευχαριστώ
merci
どうもありがとう
danke