OECD's Work on Environmental Considerations for Risk/ Safety Assessment

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OECD's Biosafety Team

http://www.oecd.org/biotrack/

organised in two programmes:

1) **OECD's Working Group for the Harmonisation of Regulatory Oversight in Biotechnology**
   (Environmental safety of transgenic organisms)

2) **OECD's Task Force for the Safety of Novel Foods and Feeds**
   (foods/feeds derived from transgenic organisms)

Participation of the OECD countries and of some Non-member economies:

- Argentina
- Brazil
- Cameroon
- China
- Chile
- India
- Latvia
- Philippines
- Russian Federation
- Slovenia
- South Africa
- Thailand

Who participates?

- **Working Group:** delegates from ministries/ agencies responsible for environmental risk assessment of transgenic organisms (competent authorities);
  - Observers and invited experts: UNEP, CBD Secretariat, UNIDO, other stakeholders.
- **Task Force:** delegates from ministries/ agencies responsible for risk assessment of novel foods and feeds (competent authorities);
  - Observers and invited experts: FAO, WHO, Codex secretariat, other stakeholders.

The purpose of these programmes is threefold:

- To assist OECD countries evaluate the potential risks of transgenic products to ensure high standards of safety;
- To foster communication and mutual understanding of the regulatory processes in different countries; and
- To reduce the potential for non-tariff barriers to trade.

The work undertaken by the two programmes focuses on the four main areas:

- Creating a common base of scientific information by identifying the potential risks that the products of modern biotechnology may pose to human and animal health as well as the environment.
- Dissemination of information relevant to the risk/ safety assessment of products of modern biotechnology, mainly through a website: BioTrack Online.
- Involves organising workshops and meetings where experts from OECD member countries as well as non-member countries.
- Similarities and differences in regulatory frameworks among countries.

Food/ Feed Safety Consensus Documents

- Food/ feed risk/ safety assessment of transgenic varieties follows a comparative approach;
- In other words, is a new food as safe as a traditional counterpart?
- Include information (for use in food/ feed safety risk assessment of new varieties) on key:
  - Nutrients
  - Anti-Nutrients
  - Toxicants
  - Allergens
  - Secondary metabolites

Some Published Food/ Feed Safety Consensus Documents

- Soybean *(under review)*
- Canola/ Oilseed Rape *(under review)*
- Potato
- Sugar Beet
- Maize
- Sunflower
- Alfalfa and Other Temperate Forage Legumes
- Bread Wheat
- Considerations for safety of animal feeds
- Rice
- Cotton
- Barley
- Cultivated mushroom *Agaricus bisporus*
- Tomato

Food/ Feed Safety Consensus Documents in preparation

- Cassava
- Sweet Potato
- Papaya
- Sugarcane
- Sorghum

Working Group
Biosafety Consensus Documents

- Include a wealth of information (for use in risk assessment) on the ***biology*** of crops and traits:
  - The use of the crop/ trait in agriculture practice
  - Taxonomy
  - Reproduction
  - Wild relatives – hybridisation
  - Centre of origin and diversity
  - Weediness

Some Published Biosafety Consensus Documents

- **Crops:** maize, oilseed rape, potato, bread wheat, rice, soybean, sugar beet, cotton, sunflower, peppers, papaya, etc.
- **Traits:** tolerance to glyphosate herbicide, tolerance to phosphinothricin herbicides, virus resistant through coat protein gene-mediated protection, Bt resistance, etc.
- **Trees:** Norway spruce, white spruce, poplars, Douglas fir, Sitka spruce, lodgepole pine, Eastern white pine, European white birch, larches, etc.
- **Micro-organisms:** *Acinobacter, Pseudomonas,* baculoviruses, Taxonomy in Risk Assessment, Detection methods, etc.
- **Unique identifier for transgenic plants:** Guidance used by many organisations and databases (OECD, CBD, industry…)

Other Biosafety activities, and main Consensus Documents in preparation

- Cucurbita spp.
- Black spruce
- Brassica spp.
- Tomato
- Atlantic salmon
- *Fusarium*, etc.

- **Environmental Considerations** for Risk/Safety assessment for the release of transgenic plants
- **Molecular Characterisation** of transgenic plants…
- **Low level presence** of transgenic material in seeds and commodities

Three recent innovations related to preparation of Consensus Documents

- 1) An Introduction to the Biosafety Consensus documents
  - Describes Regulatory Harmonisation
  - A common approach to risk/ safety assessment
  - Why consensus documents
  - Their purpose
  - How they are used (intended users)
  - How they are drafted and brought to publication

Three recent innovations related to preparation of Consensus Documents

- 2) Guide for Preparation of Consensus Documents (process)
  - The role of the secretariat
  - The role of the lead country
  - The role of other stakeholders
  - Sources of information
  - Style, Layout, Nomenclature

Three recent innovations related to Consensus Documents

- 3) Points to consider for consensus documents
  - Species of taxonomic group
  - Reproductive Biology
  - Genetics
  - Hybridisation and Introgression
  - Interactions with other organisms
  - Human health and biosafety
  - Additional information

Examples of points to consider

Reproductive Biology

Generation time and duration under natural circumstances, and where grown or managed

Rationale: *The generation time and duration are indications of the terms in which environmental effects may occur. Precocious generation times and shorter durations in agriculture affect the likelihood of outcrossing with free-living (wild) relatives, and give a general indication of when outcrossing may first occur.*

Examples of points to consider

Reproductive Biology

Reproduction (production of flowers or cones, fruits, seeds, and vegetative propagules)

Rationale: *The reproductive capabilities of a plant determine the means by which the plant can produce progeny and spread or disperse. Both the plant and its progeny may affect the environment, including other organisms, and thus the time frame and geographic area over which effects might occur*

Examples of points to consider

Reproductive Biology

Pollination (wind, insects, both, etc.), pollen dispersal, pollen viability

Rationale: *Pollen biology is an important component in the assessment of potential for gene flow, and in the evaluation of a need for and the type(s) of pollen confinement strategies such as buffer rows or isolation distances.*

Environmental Considerations

- Weediness and Invasiveness
- Gene Flow and its consequences
- Effects on Organisms and Food Webs
- Effects on Soil Function
- Changes in Management Practices
- Effects on Plant Health, and Incidental Exposure to Animals and Humans
- Effects on Biodiversity

Weediness and Invasiveness: Information Elements

- Weediness or invasiveness of the unmodified plant species
- Potential for cultivation/growth of the transgenic plant beyond the cultivation/growth area for the unmodified species
- Changes in the modified species' reproductive characteristics
- Changes in the modified species' vegetative characteristics
- Changes in the modified species' susceptibility to biotic or abiotic stresses
- Changes in interactions with other plant species (e.g. allelopathy)
- Current cultivation practices used for the unmodified species in cropping systems in the receiving environment
- Anticipated changes in cultivation practices after introduction of the transgenic plant in cropping systems

Effects on Organisms and Food Webs: Information Elements (1)

- Mode of action of the novel protein/metabolite
- Spectrum of activity of the novel protein/metabolite
- Expression pattern of the novel protein/metabolite in the transgenic plant (i.e. concentration in various tissues over time)
- Change in composition of the transgenic plant, compared to unmodified species
- Change in phenotypic characteristics of the transgenic plant, compared to unmodified species
- Potential for cultivation of the transgenic plant beyond the current cultivation area of the unmodified species
- Presence of species of conservation concern in the receiving environment
- Organisms interacting with the unmodified species
- Organisms (individual species or groups) likely to be exposed to the novel protein/metabolite

Effects on Organisms and Food Webs: Information Elements (2)

- Routes and level of exposure of organisms to the novel protein/metabolite
- Toxicity and sub-lethal effects of the novel protein/metabolite on organisms (or surrogate species)
- For transgenic plants with pesticidal properties: level of efficacy on target organisms
- Anticipated cultivation practices (e.g. insecticide use) for the transgenic plant, compared to unmodified species
- Potential impact of changes in cultivation practices (if any) on organisms and food webs

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