International Consensus on Environmental Risk Assessment of GE Crops: Contributions from the Organization for Economic Cooperation and Development

South Asia Conference on Current Approaches to Environmental Risk Assessment of Genetically Engineered Crops, May 16-18, 2011 New Delhi, India

OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology
Dr. Sally McCammon, Chair
33 Member Countries of OECD

- Australia
- Austria
- Belgium
- Canada
- Chile
- Czech Republic
- Denmark
- European Commission
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Israel
- Italy
- Japan
- Korea
- Luxembourg
- Mexico
- Netherlands
- New Zealand
- Norway
- Poland
- Portugal
- Slovak Republic
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- United Kingdom
- United States
OECD Regulatory Harmonization in Biotechnology

- Working Group for the Harmonization of Regulatory Oversight in Biotechnology
  - Environmental

- Task Force for the Safety of Novel Food and Feed
  - Food
Working Group Observers

• **Formal**
  – Argentina
  – Russia
  – OECD Business and Industry Advisory Committee

• **Ad hoc**
  – Brazil
  – Cameroon
  – China
  – Egypt
  – India
  – Philippines
  – South Africa
Other Working Group Observers

- CBD Secretariat
- CERA
- FAO
- ICGEB
- UNEP
- UNIDO
- IFPRI (International Food Policy Research Institute)
WG Harmonization

• Differences between countries
  – New Laws or not
  – Regulation endpoints based upon adverse effects or defined risks
  – Combined or separate environmental or food/feed safety reviews
  – Triggers- novelty, GE/GMO, combination
  – Adverse effects
  – Number of ministries involved in regulation (and in developing positions for international discussions)
Harmonization and the WG

- To ensure that the information used in environmental risk/safety assessment of transgenic organisms, as well as the methods used to collect such information, is as similar as possible among countries.
  - Develop a common way of thinking for regulators and safety assessors
  - Provide technical documents to support risk assessment
  - Capacity building
  - Link with non-member countries
Working Group

- Technical documents that support risk assessment for environmental release
- Rationales for importance to risk/safety assessment
- Mutual recognition of or acceptance of data, assessments
Criteria

- Science Basis for approaches to environmental assessment
- Leverage collective expertise in environmental assessment of biotechnology products
- Economies of scale
- Credibility of Working Group
WG Harmonization

• Similarities between countries
  – Risk assessment paradigm
    • Biology + trait + environment X interaction
    • Use of familiarity
    • Comparative
    • Step-by-step, case-by-case
Assessment Paradigms

Established in OECD - 1993

• Concept of Familiarity (environmental safety)-Basis of assessment
  • Biology X Trait X Environment + Interaction
  • Hazard identification and safety assessment

• Substantial Equivalence (food safety)-Basis of assessment
Concept of ERA Developed within OECD: History

  - Industrial, agricultural and environmental applications
  - Confined Field tests
  - Large-scale field tests
OECD Blue Book (1986)

- Agriculture
- Risk assessment includes evaluating
  - Donor and recipient organisms
  - Techniques for developing organism
  - Properties of resulting organism
- General considerations included
  - Survival and multiplication
  - Interactions with other species
  - Effects on environment
OECD Blue Book (1986)

• Stepwise
  Laboratory > Greenhouse > Small-scale field trial > Large-scale field trial > (unconfined release)

• Case-by-Case
  – Individual review of proposal against assessment criteria relevant to the particular proposal;
  – not intended to imply that every case will require review since classes of proposals may be excluded.
1993 Scale-up: Familiarity

- **Knowledge and experience**
  - Unmodified plant > basis for comparative risk assessment

- **Hazard identification and risk assessment**
  - Safety issues
  - Safety concerns > product specific
  - Assessing potential adverse effects

- **Applying risk management including**
  - When standard cultural practices are adequate
  - When additional management practices are needed
  - When increases in scale not appropriate

- **More information needed**
1993 – Scale-up

• Background in plant breeding and performance trials for the development of new plant varieties.

• Safety issues that could give rise to a concern
  – Gene transfer,
  – Weediness,
  – Trait effects,
  – Genetic and phenotypic variability,
  – Biological vector effects and genetic material from pathogens,
  – Worker/human safety
Familiarity (1993)

• Information available before assessment
  – The crop plant
  – Agricultural and surrounding environment
  – Specific traits introduced
  – Previous basic research in greenhouse and small-scale field trials
  – Scale-up of plant lines with traits developed by traditional techniques
  – Scale-up of similar plant lines (transgenic)
  – Presence of related sexually compatible plants in the environment
  – Interactions between the crop/trait/environment
Working Group
Organisms in the Environment

Plants
Micro-organisms
Animals
I. ‘Consensus Documents’ – biology and trait
II. Information Dissemination and Outreach
III. Facilitating Harmonization: Emerging Issues
OECD Working Group

• Funding-Extramural
• Projects developed by Member Countries
  – Proposal > Draft operational plan > steering group > document

• Bureau (Board of Directors)
  – Australia, Japan, Finland, Mexico, Netherlands, United States + the Secretariat (Canada)
Environmental Risk Assessment
Plants
I. Consensus Documents—Biology of Crop Plants (27)

- *Zea mays* (Maize)
- *Beta vulgaris* L. (Sugar Beet)
- *Glycine max* (L.) Merr. (Soybean)
- *Oryza sativa* (Rice)
- *Triticum aestivum* (Bread Wheat)
- *Solanum tuberosum* subsp. *tuberosum* (Potato)
- *Brassica* spp. (5)(2011)  
  - *Brassica napus* L. (Oilseed rape)
- Bananas and Plantains (2009)
Plant Biology Consensus Documents

- *Carica papaya* (Papaya)
- *Capsicum annuum* complex
- *Helianthus annus* (sunflower)
- Cotton
- Trees (13)
  - Forest
  - Pulp
  - Fruit
Plant Biology Consensus
Documents in the Pipeline

• Cucurbits (Mexico)
• Tomato (Spain and Mexico)
• Sugarcane (Australia)
• Eucalyptus (Australia)
• Sorghum (South Africa and the United States)
• Compositional Considerations: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants

• Examples
  – Bread Wheat (*Triticum aestivum*)
  – Maize (*Zea Mays*)
  – Potatoes
  – Sugar Beet
  – Soybean
  – Low Erucic Acid Rapeseed (Canola)
  – Papaya
Guidance for Development of Biology Documents

• Introduction to Biosafety Consensus Documents (2005)
• Points to Consider (2006)
• Guidance for Preparation (2008)
  – Lead country
  – Lead authors
  – Working Group review
  – Secretariat
Points-to-Consider

• Points to Consider for Consensus Documents on the Biology of Cultivated Plants
  – Guide to revising documents
  – Guide to developing new documents

• Descriptions of sections and sub-sections e.g.
  – Taxonomy
  – Related and sexually compatible species
  – Cultural practices

• Rationales
  – Why relevant
  – Not how used in risk/safety assessment

• Examples – OECD consensus documents
Consensus Documents-Traits

- Virus Resistance (coat protein)
- Glyphosate Herbicide Tolerance
- Phosphinothricin Herbicide Tolerance
- Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants
- *Bacillus thuringiensis* - Trait
Use of Consensus Documents

• By applicants for submissions
• By regulators for assessments
• By public for understanding
II. Outreach Activities

• Biotrack Online  www.OECD.org/biotrack
  – OECD Publications-finalized ‘consensus documents’
  – Links to Member Country Websites
  – Product database

• Unique Identifiers – plants (2003), stacked genes (2007)

• International Symposia for Biosafety of GMOs – 3 Workshops (Korea, New Zealand and Argentina)
ISBGMO and OECD

• Korea (2006) – Twentieth anniversary of the “Blue Book”
• New Zealand (2008) – Harmonization
• Argentina (2010) – Current work in harmonization

• Goals
  – Share work
  – Provide views of participating countries on projects – why important and usefulness
  – Receive input from audience regarding projects and potential future work
  – Answer questions
III. Facilitating Harmonisation

- Molecular Characterization
- Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants
- Low Level Presence – Seed/commodities
- (Biology of Atlantic salmon)
Molecular Characterization

- One component of ERA and Food Safety Assessment for commercial use
- Understanding of genetic material introduced and expressed
  - Transformation method
  - The inserted DNA, insertion site, and expressed material
  - Inheritance and genetic stability
- Rationales as to why this information may be useful for risk/safety assessment
  - Case by case
Environmental Considerations

• Collective experience gained in 18 years since the Scale-up document for unconfined release of plant products

• 7 considerations under discussion
  – Persistence, weediness & invasiveness
  – Gene flow
  – Organisms and food webs
  – Effects on soil function
  – Crop management practices
  – Effects on plant health, & incidental exposure to animals & humans
  – biodiversity
Environmental Considerations

• Consideration
  – Overview
  – Rationale
  – Information elements of use in evaluation

• Considerations evaluated depend upon case
  – Product attributes
  – Legislative endpoints; Protection goals
  – Hazards identified
OECD
Suite of Documents for ERA

**Paradigm**
- Blue Book (1986)
  - Organism
  - Step-by-step
  - Case-by-case
- Confined field trials (1992)
- Large scale field trials (1993)
  - Familiarity
  - Plant, trait, environment
  - Environmental issues
- Traditional Crop Breeding Practices-a baseline (1993)

**Technical**
- Biology documents
- Points to Consider with biology
- Trait documents
- Molecular Characterization
- Environmental Considerations
- ERA and information for LLP in seed & commodities
Thank You