



ORGANISATION FOR ECONOMIC  
CO-OPERATION AND DEVELOPMENT



# OECD Project on Low Level Presence in Seed and Commodities

**BIGMAP SYMPOSIUM**

**Ames, Iowa**

**April 27-28, 2010**

# 30 Member Countries of OECD

- **Australia**
- Austria
- Belgium
- **Canada**
- Czech Republic
- Denmark
- European Commission
- Finland
- France
- Germany
- Greece
- Hungary
- **Iceland**
- Italy
- **Japan**
- **Korea**
- Luxembourg
- **Mexico**
- Netherlands
- **New Zealand**
- Norway
- Poland
- Portugal
- Slovak Republic
- Spain
- Sweden
- **Switzerland**
- **Turkey**
- United Kingdom
- **United States**

# Regulatory Harmonization

- **Working Group for the Harmonization of Regulatory Oversight in Biotechnology**
  - Environmental
- **Task Force for the Safety of Novel Food and Feed**
  - Food

# Formal Observers

- **Argentina**
- **Russia**
- **Slovenia**
- **OECD Business and Industry  
Advisory Committee (BIAC)**

# *Ad Hoc Observers*

- **Brazil**
- **Cameroon**
- **Chile\***
- **China**
- **Egypt**
- **India**
- **Philippines**
- **South Africa**

\*In Accession  
Process

# Other Working Group Observers

- **CBD Secretariat**
- **ILSI-CERA**
- **UNEP**
- **UNIDO**
- **International Food Policy Research  
Institute – IFPRI**

# HARMONIZATION

- **Goals of Harmonization**
  - **Develop a common way of thinking for regulators and safety assessors**
  - **Provide documents for risk assessment**
  - **Capacity Building**
  - **Link with Non-Member Countries**

# WG Harmonization

- **Similarities between countries**
  - **Environmental 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**
    - **Safety Considerations for Biotechnology: Scale-up of Crop Plants, OECD, Paris.**
      - **Biology X Trait X Environment + Interaction**
      - **Hazard identification and safety assessment**
  - **Substantial Equivalence (food safety)-Basis of assessment**

# 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**
  - **Adverse effects**
  - **Number of ministries involved in regulation (and in developing positions for international discussions)**

# 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**

# Organisms in the Environment

- **Plants**
- **Micro-organisms**
- **Animals**

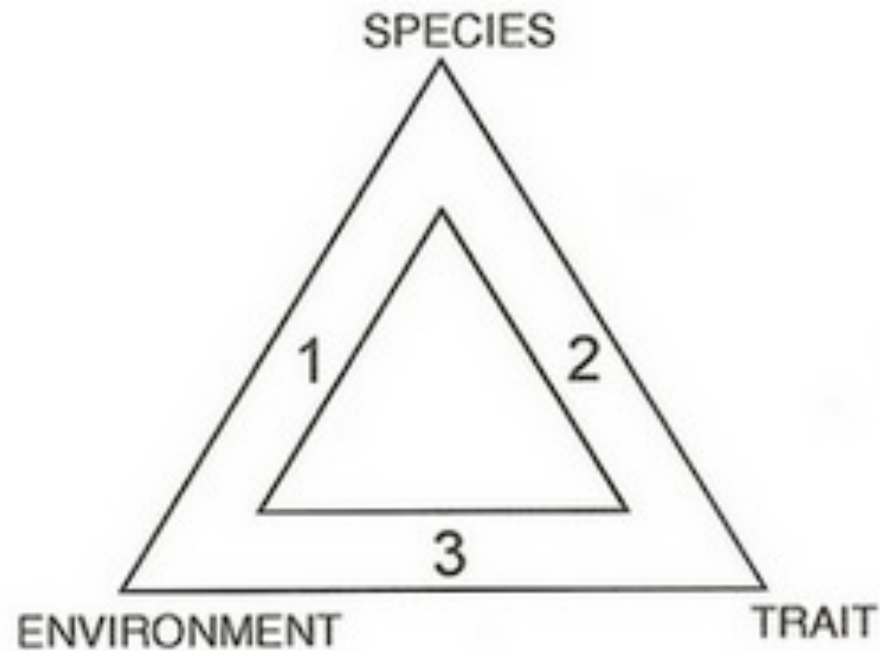
# Terms of Reference 2009-2012

**I. Consensus Documents –  
biology and trait**

**II. Information Dissemination and  
Outreach**

**III. Facilitating Harmonization:  
Emerging Issues**

# Environmental Risk Assessment Plants



# I. Consensus Documents- Biology of Crop Plants (24)

- *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 napus* L.  
*Bananas and Plantains*
- *Carica papaya* (Papaya)
- *Capsicum annuum* complex
- *Helianthus annuus* (sunflower)
- Cotton (2008)
- Trees (10)
  - Forest
  - Pulp
  - Fruit

# Guidance for Development of Biology Documents

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

# 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* (2007)- 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](http://www.OECD.org)**
  - **OECD Publications-finalized consensus documents**
  - **Product database**
    - **CODEX/FAO LLP database**
    - **CBD BioSafety Clearinghouse – UID Registry**
  - **Links to Member Websites**
- **Unique Identifiers – plants (2003), stacked genes (2007)**

# III. Facilitating Harmonisation

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



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International  
Low Level Presence Risk Assessment  
Activities

**CODEX Alimentarius**

**Organization for Economic  
Cooperation and Development**

# Sources of LLP

- **Asynchronous approvals**
  - Products that are approved in one country, and appear as LLP in a country where it is unapproved.
- **Research material**
  - Products that should be contained in laboratories, greenhouses or field trials, but appear unexpectedly in the marketplace. May not have approvals in any country.
- **Approved products**
  - Products that pose no health or safety concerns. May be time-limited approvals.

# CODEX - Low Level Presence

- **LLP - term developed in CODEX because “Adventitious Presence” already had too many existing meanings**
- **Assumes approval of product in at least one country**
- **Allows for information sharing – summaries of assessments will be available on FAO database**

# CODEX LLP Project

## Food and Feed

- **Annex to the CODEX *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants***
- **LLP annex adopted in 2008**
  - Addresses food and feed safety
  - not a substitute for full food safety assessments
- **Does not address risk management measures**
- **Importing country decides when and how to use the guidelines within the context of their regulatory systems**

# OECD LLP Project Environment

- **OECD Low Level Presence of unapproved biotech material in seed**
  - **Proposed by BIAC - February 2007**
  - **Project advanced by ISF and ASTA**
  - **Technical Focus - environmental risk assessment for LLP in Seed**
  - **Compliments CODEX guidelines**

# Low Level Presence of Unapproved Biotech Material in Seed – Project Development

- **Intercessional workshop proposed to focus on potential development of LLP project October 2007**
- **Workshop held in Paris, April 2008**
  - **27 Participants from 11 countries and BIAC:**
    - Argentina, Belgium, Canada, Germany, Finland, Japan, Mexico, Netherlands, Turkey, the United States, and The European Commission

# Conclusions from LLP Workshop

- **LLP is an important topic**
- **A project on LLP in seed would be different than the Codex project**
- **Potential Scope of Low Level Presence Project**
  - **Scientific risk assessment**
  - **Familiarity with crop biology and new traits**
  - **Information-sharing**
    - **Where can appropriate information be found**

# Regulatory Response

- **Either in anticipation of possible LLP situations or actual circumstances, regulatory response can be triggered**
- **First step = Risk assessment**
  - **Safety of environment is the priority**
  - **Case-by-case approach with remedial actions commensurate with identified risks**

# Full Approval vs LLP

- **Full Approval**
  - Risk assessment assumes 100% exposure over a long period of time
- **LLP**
  - Determination of the level of risk that an unauthorized product may pose is based on potential exposure and hazards identified
  - Risk assessment does not result in an authorization – it represents an assessment of a situation

# Risk Assessment and Information

- **Fundamentally, risk assessment elements and considerations are identical with both scenarios**
- **However, information (data) requirements may be different because of potential differences in the level of exposure**
- **Risk assessment in LLP situations can inform decisions on mitigating exposure to the product**

# Environmental Risk Assessment Considerations

- **Familiarity\* provides the basis for risk assessment**
- **Familiarity Includes knowledge of/experience with:**
  - **same or similar plant species**
  - **same or similar gene/protein**
  - **same or similar phenotype**
- **Available supporting data to confirm/characterize LLP event**
- **In cases where familiarity cannot be confirmed, more data may be necessary**
- **Strictly a technical approach - distinct from any legal consideration posed by domestic frameworks**

# Other Issues

- **Non-compliance**
- **Mitigation and management**
- **Zero tolerance**
- **Legal framework**
- **Trade implications**

# Project Proposal for LLP in Seed and Commodities in the Context of Environmental Safety

- **Working Group decides to move forward on project proposal – June, 2008**
- **Proposal developed for February, 2009**
- **Commodities added to proposal**

# LLP Project Outline

- **Background and History**
- **Purpose and Scope**
- **Summarize Working Group Experience**
  - **Information Acquisition and Use**
  - **Environmental Risk/Safety Assessment in LLP Situations**
    - Commonalities
    - Practical approaches to resolving situations
- **Annex**
  - **Participant Scenarios/Case Studies (Questionnaire)**
- **References**

# LLP Outline – Background and History

- **Background and History**
  - **What – the WG is taking up a project on LLP**
    - Why the issue is important
    - How the issue relates to remit of WG
  - **What is LLP and sources of LLP**
  - **Relationship to Codex Plant Guideline Annex on food safety assessment and LLP situations**

# Purpose and Scope

- **Provide an aid to risk assessors and regulators regarding LLP**
  - Information acquisition and use
  - Environmental risk assessment
- **Situation of low level presence in commercial seed and/or commodities of transgenic plant material that have received approval and been commercialized in at least one country but have not received approval or authorization in the country of import.**

# Purpose and Scope continued

- **Commercial seed used intentionally for planting**
  - **Produced to meet certain quality standards**
- **Commodities (e.g. grains and oilseeds)**
  - **Unintentionally released into the environment during handling and transport**
  - **Intentionally used for planting**
  - **Harvested for food, feed or processing**
- **Only relates to LLP situations in the environment**

# Purpose and Scope cont'd

- **Principles of risk/safety assessment**
  - **OECD paradigm**
  - **LLP – same as other applications of risk assessment**
  - **Use of knowledge, familiarity, and experience**

# Criteria

- **The project will:**
  - **Fit into the remit of the Working Group, whose terms of reference focus on scientific and technical aspects of environmental risk/safety assessment;**
  - **Assume a product approval of the transgenic material present as LLP in one or more countries;**
  - **Assume that countries themselves determine what low level presence is, and how to respond to it;**
  - **Relate to LLP in seed including commodities that can function biologically as seed; and**
  - **Facilitate risk/safety assessment**

# Criteria

- **The project would not:**
  - **Address risk management or indicate how regulatory authorities should manage incidents of LLP, make decisions, or define what LLP is legally;**
  - **Conflict with existing international agreements on the topic of LLP;**
  - **Conflict with case-by-case approaches;**
  - **Preclude a national authority from undertaking a risk/safety assessment within the context of its regulatory system.**
  - **A project should not interfere with legal frameworks of participant countries or imply a short cut for commercial approval.**

# Working Group Experience Questionnaire Developed

- **LLP situations relating to the environment**
- **Availability of data and information needed to define and analyze LLP situation e.g. risk**
- **Approaches taken to identify and assess any potential risk**
- **Mitigation of situation**

# Questions

- **Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?**
- **How has your country addressed these LLP situations; if your country conducted a risk assessment related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?**
- **What lessons were learned?**
- **Other comments**

# Questionnaire

- **Circulated to Participating Countries**
  - **OECD Members**
  - **Observers**
- **Responses received**

# Responses

- **Argentina**
- **Australia**
- **Belgium**
- **Canada**
- **Czech Republic**
- **Japan**
- **Netherlands**
- **New Zealand**
- **Turkey**
- **United States**
- **Business Industry  
Advisory  
Committee**



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**Thank You**