



Organization for Economic Cooperation and Development

BEYOND THE BLUE BOOK

Framework for Risk/Safety

Assessment of Transgenic Plants



Recombinant DNA Safety Considerations - 1986

- First international agreement on approaches to evaluating environmental releases of transgenic organisms
 - Plants and microbes
- Proactive
- Governments, scientists and other stakeholders
- Blue cover



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 and feed



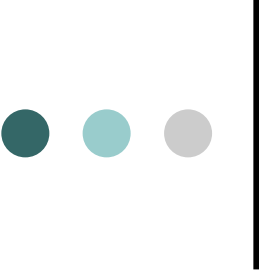
Working Group Observors

- Argentina
- Russia
- Slovenia
- OECD Business and Industry Advisory Committee
- CBD Secretariat
- UNEP, UNIDO
- Brazil
- Cameroon
- Chile
- China
- Egypt
- India
- Philippines
- South Africa



Working Group

- History-1994
 - Group of National Experts
 - G8 Report
 - LMO Conference
 - Biosafety Protocol
- Terms of Reference
 - Facilitating Harmonization: Emerging Issues
 - Consensus Documents
 - Information Dissemination and Outreach



Group of National Experts (GNE) -Assessment Paradigms

- Established in OECD
 - 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



GNE → Working Group

- 1993 – Ad Hoc Group on Biotechnology under Joint Working Party of the Agriculture and Environment Policy Committees
- 1994 – Working Group under EPOC and Environment Directorate
- 2001- Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology
 - Environment Directorate



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



G8 Report 1999-2000

- “In light of the increasing importance of issues concerning food safety we invite the OECD Working Group....and the OECD Task Force...to undertake a study of the implications of biotechnology and other aspects of food safety.”



G8 Report 1999-2000

- Ad Hoc Food Safety Group formed with a report – precaution, risk management
- Two reports from Working Group and Task Force
 - Identified areas of interest for environmental work
- Two Conferences
 - Edinburgh – Food
 - Bangkok – Social aspect
- LMOs and the Environment-Symposium - 2001



Working Group and the Cartagena Protocol on Biosafety

- Pilot Phase of Biosafety Clearinghouse
 - OECD Product Database
- Unique Identifiers for Transgenic Plants - 2003



Working Group

- Funding-Extramural
 - Funding by participating countries
 - Japan-MAFF
- Bureau
 - Canada, Germany, Japan, Netherlands, United States + the Secretariat
- Projects developed by Member Countries



Workshop Objectives

- History and evolution of conceptual framework for transgenic plants in the environment
- Current work by the OECD Working Group for the Harmonization of Regulatory Oversight in Biotechnology
- Current risk assessment challenges and the role of OECD



Outcomes

- Use results to inform agenda of Working Group
- Speakers Talks to be published in the EBR Journal



Program Committee

- Chair: Ervin Balazs
- Marc Auer
- Hans Bergmans
- Hyun-Suk Cho
- Janet Collins
- Helmut Gaugitsch
- Peter Kearns
- Dong-Hern Kim
- Masatoshi Kobayashi
- Sally McCammon
- Terry Medley
- Elizabeth Milewski
- Marja Ruohonen-Lehto
- Joachim Schiemann
- Stephen Yarrow
- Lisa Zannoni



Working Group and Task Force

- Secretariat & Rapporteurs
 - Peter Kearns
 - Masatoshi Kobayashi
- WWW.OECD.ORG
 - Biotrack
- Search for 'Consensus Documents'