

Challenges for Risk Assessment

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Harmonization of Regulatory
Oversight in Biotechnology

Identification of Challenges

- OECD G8 Report - 2000
- LMOs and the Environment - 2001
- Washington Workshop - 2003

G8 Report

- Working Group to OECD Council
 - Council formed of ambassadors from member countries
 - 6 months-short time for international document
- Recommendation to continually review and approve assessment methods and approaches

G8-Improvements in Risk/Safety Approaches

- **Capacity Building**
 - lack of infrastructure to do assessments
- **New Scientific and Technical Developments**
 - New ge organisms
 - New issues
- **Broader Policy Objectives**
 - Risk assessments don't occur in a vacuum

Capacity Building: Challenges for Risk Assessment

- Local geography, biota, climate, soil
- Centers of origin
 - Wild relatives
 - Land races

New Scientific and Technological Developments

- Range of ge organisms will increase
 - Plants, micro-organisms, animals
 - Establishment of familiarity more difficult
 - Methods to assess and monitor needed
- Increased number of traits
 - Stacked genes
 - Genes from new sources & new combinations

New Scientific and Technological Developments

- Short term effects more clear cut
- Long-term effects and possible need for ecological models

Linkage of Assessment to Broader Policy Objectives

- Minimize adverse effects on environment
- Agriculture has detrimental effects on environment—policies may be to
 - Enhance environmental effects of agriculture
 - Promote sustainable development
 - Economic
 - Ecological
 - Life cycle assessments

New Scientific and Technological Developments

- Need to streamline existing risk/safety assessments
 - Focus resources on new products
 - Use experience with existing products with little or no concern

*OECD Workshop on Review
of Consensus Documents
and Future Work in
Harmonization*

**Priority Setting
Washington, D.C.
October, 2001**

Future Work in Harmonization

Categories of Topics

- **Definitions and Concepts**
- **Information Elements**
- **Evaluation of Hazards**
- **Risk Assessment Methodologies**

Definitions and Concepts

- Substantial Equivalence
- Familiarity
- Real Environmental Terms
- Environmental Harm
- Regional Strategies
 - Centers of Origin
 - Agricultural

Information Elements & Evaluation of Hazards

- **Information Elements**
 - Clarity on what basic information collected for risk assessments
 - Environmental Parameters for Risk/Safety
- **Evaluation of Hazards**
 - Clarity on those factors that may constitute a hazard to the environment.

Risk Assessment Methodologies

- Protocols and processes for measuring impact
 - Tests to gather information
 - Lab tests
 - Non-target organism tox testing
 - Germination dormancy tests
 - Field tests
 - Fitness in the environment
 - Non-target organisms toxicity in the environment
 - Models

Risk Assessment Methodologies

Cont'd

- Methodologies for use of information in decision-making
 - Environmental risk/safety assessment methodologies
 - Clarification of decision thresholds

Future Consensus Documents

- Fava beans
- Plantain
- Alfalfa
- Sweet potato
- Pomme fruits
- Safflower
- Eucalyptus
- Turf and forage grasses
- Cassava*
- Sorghum
- Cabbage
- Tobacco
- Grape
- Barley

Potential Traits

- Pharmaceutical compounds
- Stacked genes
- Gene silencing
- Modified chemical composition
- Stress tolerance*
- Fungal disease resistance
- Male sterility

Next Generation of Biotech-Derived Plants

- Crop Plants
 - Biopharming and increased exposure
 - Drought tolerance (how tropical countries develop baseline)
 - Impact on rhizosphere
 - Review of new impact traits
 - Phytoremediation
 - Impact of increased fitness on risk assessment
 - Gene stacking
 - Neutraceuticals
 - Centers of Origin or Diversity

Points to Consider

- Consensus documents on the biology of crop plants

Next Generation of Biotech-Derived Fish

- Biology of Atlantic salmon
- Two workshops
 - Moscow & Norway
 - Identify environmental issues and develop outline of document for unmodified Atlantic salmon
 - Baseline
 - Use experience with plants
 - Steering group
 - First draft being developed

Prioritization Criteria

- Significant Experience
- Promotes Harmonization
- Promotes Capacity Building
- Unique Contribution of OECD
- Reasonable Time Frame
- Addresses Regulatory Needs for Conducting Environmental Risk Assessments
- Resources
- Builds upon/complements current body of work of OECD and other organizations

OECD Working Group is Unique

- Harmonize to provide aid in environmental risk/safety assessment of ge organisms
- Produced by regulators
- Identification and articulation of key questions, information and tools to be considered by regulators
- Technical documents from a regulator's perspective.

OECD Working Group is Unique

- ‘Environment’ is the organizing concept
 - Into which the organism introduced
 - Interaction with organism and trait
 - Issues depend upon region
 - Agricultural + associated ‘natural’ environment
 - Some environments especially important
 - Definition of environment critical