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 gene 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 genetically engineered 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