



ISBR

*International Society
for Biosafety Research*

9th ISBGMO

Session I

**Biosafety Research and Risk
Assessment**

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Regulatory Systems

- The structure of the system varies from country to country due to specific economic, social and environmental factors
- Challenges
 - Scope and boundaries of authorizing legislation
 - Quality and quantity of data that will be necessary and sufficient
 - Hard to respond to values
 - What is acceptable risk?

Regulatory Systems

- Risk assessment methodologies have common approaches across countries
 - Details vary
- Most assessments are qualitative
 - Not less credible than quantitative
 - Long term data sets not available

Regulatory Systems and Data

- Relevance of Data
 - Credible, reliable, available
 - Expertise and resources needed to understand and apply in risk assessment
 - Is it sufficient?
 - Reduce uncertainty

Uncertainty

- A credible risk assessment should be faithful to the assumptions and kinds of uncertainty embedded in it.
 - Defined and identified at start
- Different kinds of uncertainty
 - How take into account in risk assessment
 - Vagueness of language
 - ‘large-scale’, high, medium and low-problems at boundary
 - Qualitative risk assessments- more important because can’t eliminate
- If no information-use best/worse case bounds

Relevance to Risk Assessment

- Examine what sources of uncertainty are
 - Make explicit - clear up and express
 - Definition
 - How reduce
 - What is cost of reduction and does it serve the purpose?
 - Concise and clear language
 - Do more experiments
 - How deal with

Uncertainty

- Models can allow understanding of variability and uncertainty
- Variety of models: statistical, process, qualitative
 - Model uncertainty is the 800 lb. gorilla
 - Sensitivity analysis has been used for transgenic fish to look at daily viability and mating advantage
- Models are hard to translate=case specific
- Not many quantitative studies dealing with uncertainty for gm—may be because of tendency to do assessments qualitatively.

International Approaches

- Fundamental definitions for risk assessment
 - Terminology varies-concepts the same
 - UNEP, IPPC, EFSA, OECD, Biosafety Protocol
- All the accepted guidance uses same fundamental principles
 - What constitutes a risk assessment
 - What it should do
- Risk assessment is not opposite of precaution
 - Functional risk assessments
 - Precaution can come at the decision-making level
 - Level of risk aversion based contextual values

International Approaches

- Iterative process
 - Quick and dirty
 - Tiering of detail based on initial assessment
 - Re-estimate risk based on mitigation measures
 - Baselines change over time
- Multiple sources of information – scientific
 - Weight of evidence for most steps- e.g. hazard, mitigation, assessment
- Roster of Experts

Research Priorities

- United States AGRA design to link regulatory and public research agencies for research priorities in risk analysis
 - General principles
 - Current or imminent commercialization
 - Critical to address evolving regulatory issues – new products & questions
- Identify opportunities for further investment
 - Weediness and invasiveness
 - Allergenicity and toxicity
 - Bring in the scientists for their opinion of priorities
 - Industry data –there should be an overview—how account for data generated that addresses topics
- ISBR Survey-need to know vs nice to know

- EC research funding – 21 years – funding fewer but larger projects- consortia
- Complementary to testing & regulatory requirements
 - Risk assessment an informal part of biotech research
 - Regulation, research and management
- What issues have we closed through our research?
 - Funding is moving away because of inability of research to resolve issues—what are endpoints of research?
 - How help decision-making?

- EC Conclusions about biosafety
 - Gm not inherently safe or unsafe
 - No new risks
 - Food safety clarified
 - Questions about conventional agriculture
 - Concerns remain about the environment
 - Biotech has allowed elaboration of new knowledge about molecular biology, environmental impacts and ecology
 - Need to get predictive
 - Communication still a challenge

- Risk assessment research in developing countries – Program for Biosafety Systems
- Structure/function/goals
 - Goals of research
 - Develop knowledge base to establish a regulatory agency
 - Risk assessment
 - Post-commercialization monitoring
 - Animals and vaccines – not funded
 - Projects
 - Gene flow-Africa
 - Outcrossing
 - Non-target Brazil and Philippines

- Is there any evidence of any harm from gmos anywhere?
 - Important for Developing Countries (DC's)
 - Who pays for risk assessments?
 - Companies generate data
 - Public – more generalized research
- DC's have no one to pay for packages – done be state or research orgs.—not for profit

- CBD database Roster of Experts (ROE)
 - How get on ROE
 - Can be done
 - Should try-national authority
 - Developing countries