



**ISBR**

*International Society  
for Biosafety Research*

# 9th ISBGMO

## Identifying and Defining Hazards and Potential Consequences, Part I

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# New Structure for Conclusions

- **Concepts** for problem formulation and non-target RA: A.Raybould, T.Nickson, J.Romeis, D.Andow, A.Varma
- **Modelling** as a tool for predicting invasiveness of GM plants: D.Hoftmann, P.Caley, R.Hales
- Two **case-studies** of ERA of large scale release: M. Heard, B.Lu
- **Lessons learned** for ERA from a commercialized GM plant: D.Gonsalves
- **Monitoring** of unintended release of Bt maize in Mexico: A. Alvarez

# Relevance to Risk Assessment: Concepts

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1. ERA framework is a structured (tiered) process (problem formulation, hazard + exposure assessment, risk characterization, **risk management, risk communication**)
2. Problem formulation
  - concept of familiarity: comparative plant characterization (pre-existing knowledge on GM and parental plants), assessing experimental data and interpretation of detected differences
  - trait characterization (e.g. nature and expression of protein)

# Relevance to Risk Assessment: Concepts

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## Problem formulation continued:

- characterization of receiving environment (ecological, agronomic characterization, multi-trophic interactions)
- species selection (adopting surrogate/indicator species concept)
- formulation of risk hypotheses and assessment endpoints that reflect “protection goals” and are meaningful
- construction of analysis plan for testing risk hypotheses incl. definition of measurement endpoints (that relate to effect in the field and interpretable by risk assessors)

# Relevance to Risk Assessment: Concepts

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3. Hazard and exposure assessment (methods development, testing, analysis and interpretation)
4. Risk characterization/estimation (risk = likelihood of effect x magnitude of effect if exposure occurs)

# Use by Risk Assessors

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- Proposed concepts adopt principles of existing RA frameworks used for other environmental stressors and adapts them to the needs of GM plants
  - Precursor information (plant and trait characterization, agronomic and ecological characterization of receiving environment) determines the scope of experimental testing of hazard and exposure
  - Tiered approach provides decision endpoints
  - “Open end” approaches are not useful and would delay deregulation without giving higher confidence

- **Surrogate (indicator species) concept in species selection for laboratory testing is accepted if selection criteria are respected (ecological functions in receiving environment, taxonomic groups, stressor information, amenability, availability of methods, unambiguous taxonomic recognition)**

# Next Steps in Research

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- Conceptual studies for species selection coupled with case-studies for different receiving environments
- Development of validated standard methods for lab. testing of selected non-target organisms (GLP)
- Studies that relate effects assessed in laboratory (measurement endpoints) to ecological significance (non-targets, geneflow)
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# General Conclusions

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1. **Problem formulation is the important starting point for ERA and is focusing resources on issues with potentially greatest effect and uncertainties**
2. **Consensus on relevant principles of ERA (tiered approach, surrogate species) between risk assessors, industry and public research scientists achieved**
3. **Communication between industry and risk assessors/regulators is crucial for a transparent and efficient deregulation of GM plants**