



# The ERA from an applicant's perspective

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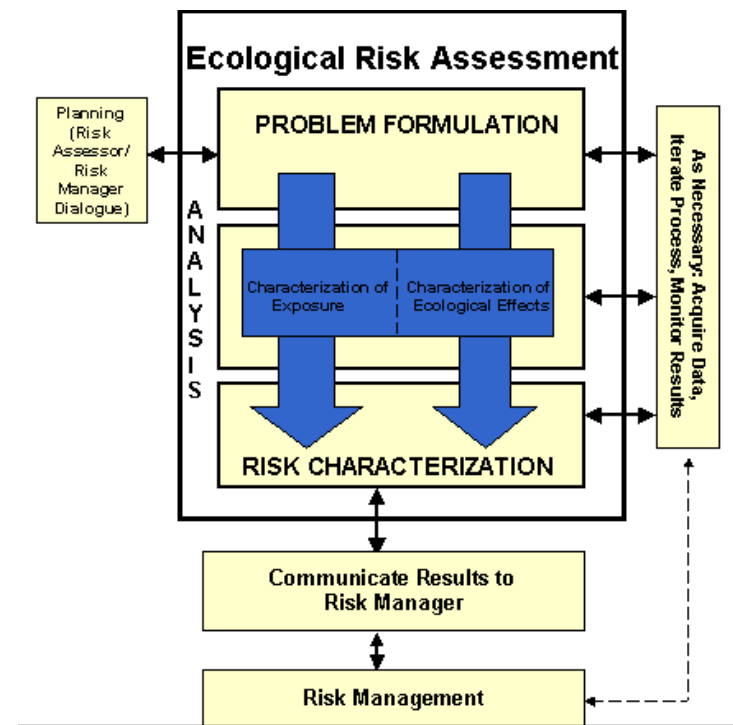


# ★ ★ Applicants' perspective

- Risk assessment approach
- Harmonisation
- Transparency and consistency
- Based on
  - Science
  - Concept of familiarity
  - Concept of equivalence (comparative approach)
- Organised data collection
- Allows decision to be taken

# Process of risk assessment

- Problem formulation
  - Data gathering
- Analysis
  - Characterisation of exposure
  - Characterisation of effects (determine hazard)
  - Iterative process
- Risk characterisation
- Decision making





# Problem formulation

- Review available information
  - Characteristics of GM plant
  - Ecosystem context
- Identification of potential risk
  - What constitutes harm?
  - What are we trying to protect?
  - What are the exposure pathways?
  - What organisms might be exposed?
- Formulation of testable hypothesis
  - Identification of potential risk
- Determine analysis plan
  - Design studies to determine exposure and hazard and test the hypothesis



# Available information

- Directive 2001/18/EC Annex IIIB
- Annex II
  1. More persistent in agricultural habitats or more invasive in natural habitats
  2. Selective advantage or disadvantage
  3. Potential for gene transfer and selective advantage or disadvantage
  4. Immediate and/or delayed environmental impact resulting from direct/indirect interactions with TOs
  5. Immediate and/or delayed environmental impact resulting from direct/indirect interactions with NTOs
  6. Immediate and/or delayed effects on human health
  7. Immediate and/or delayed effects on animal health
  8. Immediate and/or delayed effects on biogeochemical processes
  9. Immediate and/or delayed, direct and indirect environmental impacts of specific cultivation techniques



# Definition of harm

- Subjective
- Cannot be discovered scientifically
- Derived from legal instruments and reflects e.g. policy goal, societal value, protection goals
- Change *per se* is not harm

A discussion about what is a harmful effect may be more useful than more research to predict effects

# Endpoints

- Assessment endpoints
  - Explicit expression of the actual environmental value to be protected
  - Linked to protection goals
- Measurement endpoints
  - Measurable responses to a stressor that are related to the assessment endpoints



# Formulate hypothesis

- Clear hypotheses of no harm: Corroboration or falsification should help decision-making
- Simple hypotheses that make semi-quantitative predictions (no more than, no less than etc.)
- Complex hypotheses that make precise predictions are not useful unless decisions depend on exact quantification

Establishing thresholds for an indicator of harm may be more useful than more research to increase the precision of predictions of that indicator



# Analysis plan

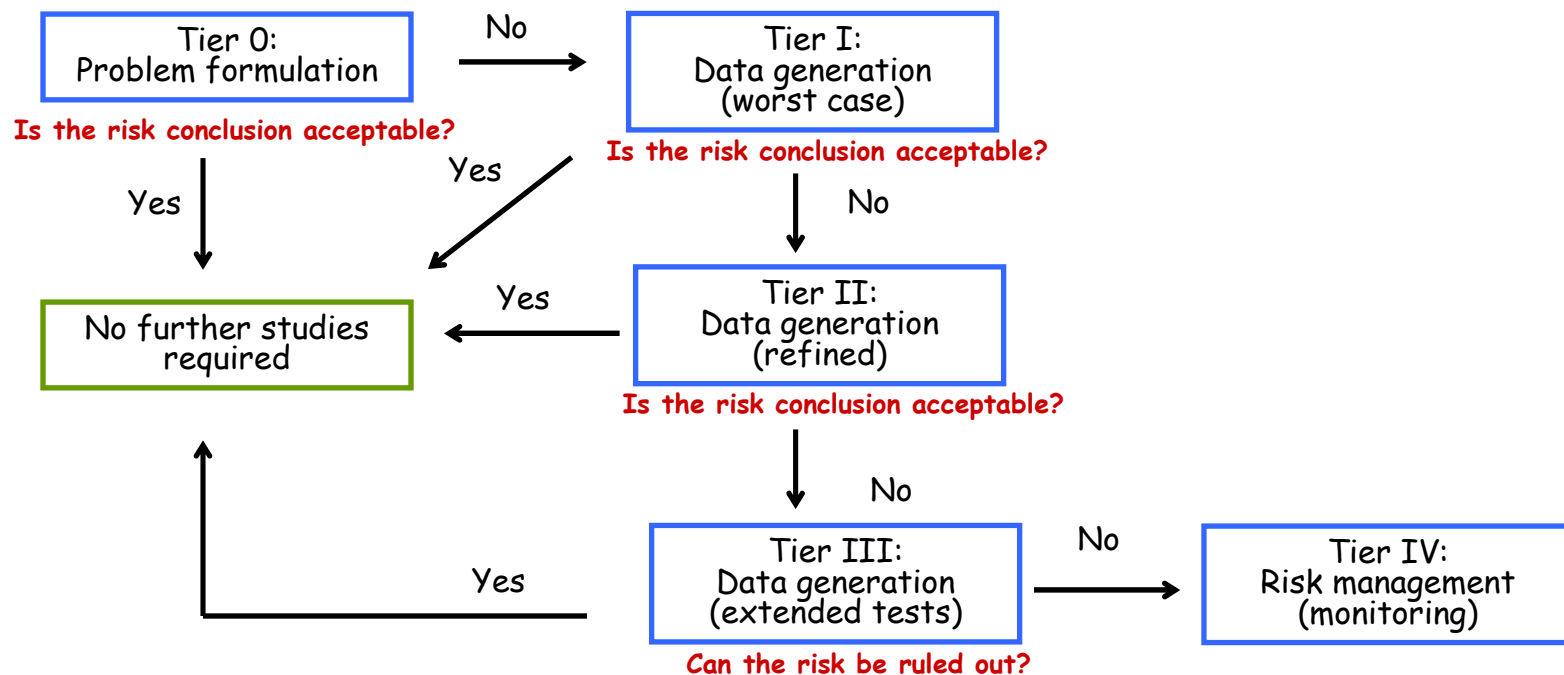
- Based on identified differences (intended and unintended) with biological relevance
- Well defined laboratory studies often provide a more rigorous test than do field studies
- Search for harmful effects, don't collect harmless ones
- If uncertainty in the level of risk is still too great after laboratory testing, further laboratory testing may be more useful than an extensive programme of field research

# Need to know vs. Nice to know

- Assessing a risk and dealing with concerns are not the same as doing a study
- The adequacy of a risk assessment is not judged by the amount of data provided
- Confidence derives from the rigour of the test based on the risk hypothesis, not the amount of data supporting it
- If existing data adequately assess the risk, further research will not increase certainty

# The tiered approach

- A tiered risk assessment is a logical progression of tests to evaluate potential risks
  - Provides practical organisation of data generation
  - Allows rational **science-based decision-making** by both applicants and risk assessors



A landscape illustration with rolling green hills, a blue sky with white clouds, and a single tree in the foreground. The text "Thank you!" is written in a green, italicized font across the center of the image.

*Thank you!*



For more information visit:  
Green Biotechnology Europe on the EuropaBio website:  
[www.europabio.org](http://www.europabio.org)

EuropaBio Workshop “ Environmental Risk Assessment for cultivation of GM crops”