OVERVIEW OF THE RISK ASSESSMENT - METHODOLOGY

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RISK ASSESSMENT – WHY?

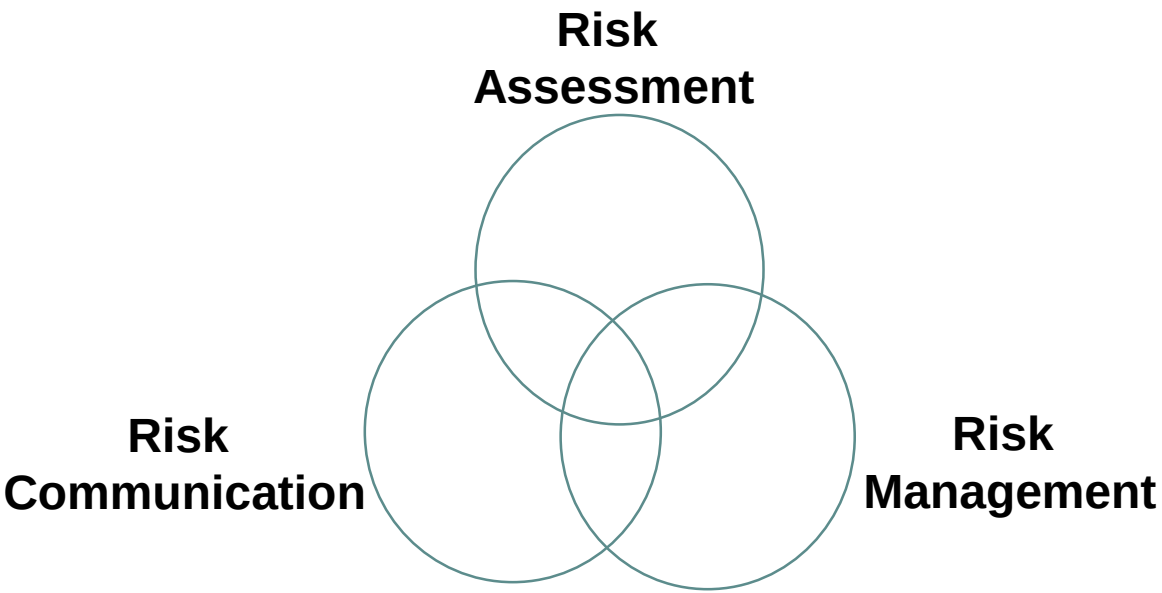
- LMOs differ from conventionally bred organisms
  (methodology of development, traits, transgenes)
- New characteristics – potential new risks
- Gene transfer beyond natural species boundaries
- Enable informed decisions

→ requirement in many regulatory frameworks and regional & international agreements (e.g. CPB, Art. 15 & Annex III)

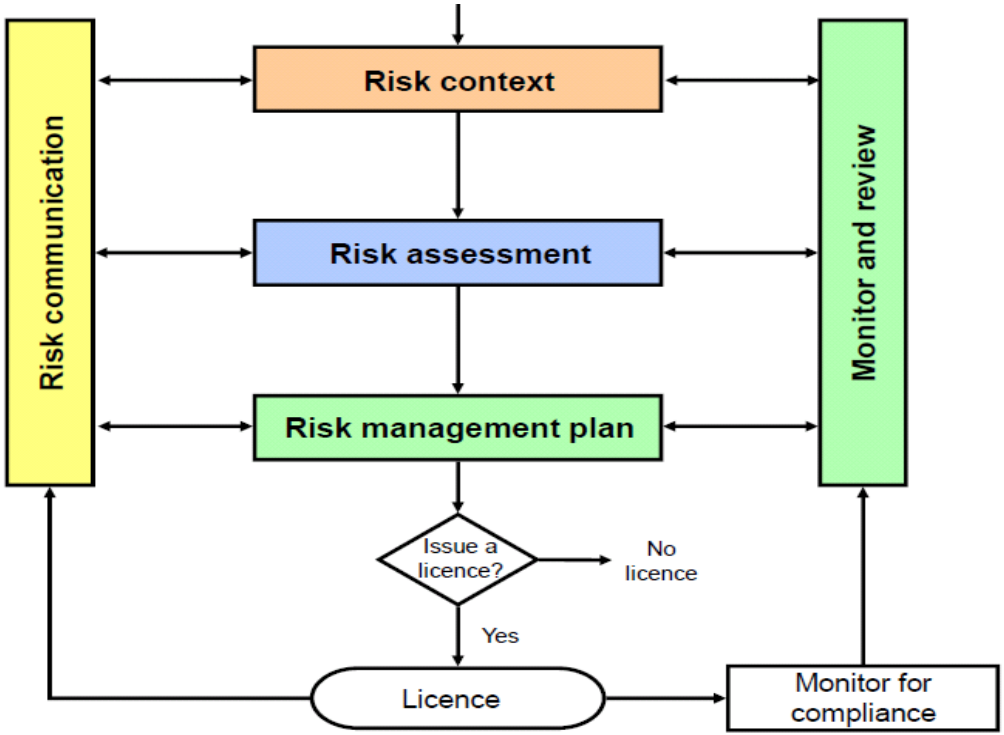
→ pre-requisite for authorization

RISK ANALYSIS FRAMEWORK

Risk Analysis = Risk Assessment + Risk Management + Risk Communication



IMPLEMENTATION OF RISK ANALYSIS



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DEFINITION OF RISK

- Risk is often described as the combined evaluation of

HAZARD x EXPOSURE

- “Hazard” is defined as the potential of a stressor to cause harm to a biological system (e.g. a species) (UNEP/IPCS, 1994).
- “Exposure” means the contact between an agent and a receptor. Contact takes place at an exposure surface over an exposure period (WHO, 2004).
- Risk = the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences will occur.

RISK ASSESSMENT – GENERAL PRINCIPLES (CPB, ANNEX III)

- RA must be carried out in a scientifically sound and transparent manner
- conducted on a case-by-case basis
- conducted in a stepwise process and an iterative manner
- risks of LMOs should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment
- lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk

TRANSPARENCY TO ENSURE SCIENTIFIC SOUNDNESS

Transparency is needed in all parts of risk assessments, including:

- the objective and scope
- the source, nature and quality of the data, detailed methods, explicit assumptions, variabilities, identified uncertainties and their significance for the outcome
- the output and conclusions

A transparent risk assessment should be

- Clear - need of stakeholders to understand the basis for risk assessment
- Understandable - allowing an informed debate on scientific issues
- Reproducible - providing a consistent framework

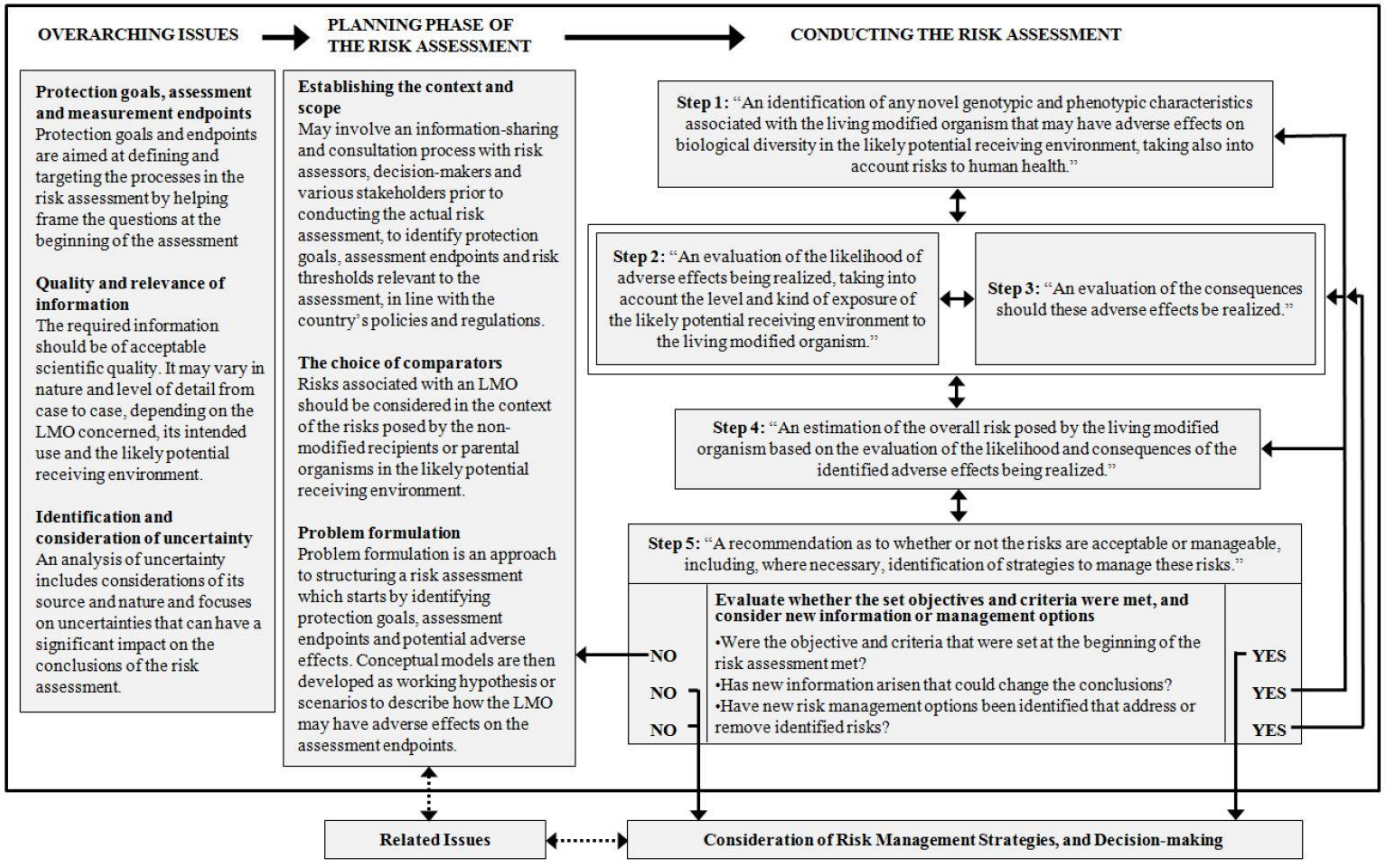
RISK ASSESSMENT - THE PROCESS

- Planning the RA - defining context & scope of the RA
- Conducting the RA
- Drawing conclusions & taking decision
- Objective of RA
  - Identify and evaluate potential adverse effects
  - Consider direct, indirect, immediate, delayed and cumulative effects
  - Identify need for risk management measures

RISK ASSESSMENT – THE PLANNING PHASE

- establish the context to identify protection goals
- establish the scope to define the extent and limits of the RA
- formulate the problem to structure/frame the RA and to develop an analysis plan
- select adequate comparators to conduct a meaningful assessment

THE ROADMAP FOR RISK ASSESSMENT



RISK ASSESSMENT – METHOD (CPB, ANNEX III)

- **Step 1**: “An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health.”
- **Step 2:** “An evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism.”

RISK ASSESSMENT – METHOD (CPB, ANNEX III)

- **Step 3**: “An evaluation of the consequences should these adverse effects be realized.”
- **Step 4**: “An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized.”
- **Step 5**: “A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks”

RISK ASSESSMENT – STEP 1

- What could go wrong, why and how?
- Look for links between LMO and potential adverse effects considering
  - the characteristics of the LMO and its use
  - the potential receiving environment and it's interaction with the LMO
  - direct, indirect, immediate and delayed effects
  - various risk areas
    (e.g. effects on target organisms and non-target organisms, potential gene transfer, persistence and invasiveness)

→ Identify scientifically plausible risk scenarios and risk hypothesis

RISK ASSESSMENT – STEP 2

- How likely is it to happen?
- characterize pathways of exposure considering
  - handling and use of LMO
  - expression levels
  - dose and env. fate of the transgene products
  - Various routes of exposure (e.g. oral, respiratory, dermal pathways)

→ identify the intensity of contact (spatial and temporal extent of exposure)

RISK ASSESSMENT – STEP 3

- Would it be a problem?
- evaluate the consequences of the adverse affects considering
  - Duration of the effect (short or long-term)
  - The scale (local, national, regional)
  - The mechanism of the effect (direct or indirect)
  - Potential for recovery in event of an adverse effect
  - Ecological scale of the effect (indiv. organism, population)

→ identify the severity of a potential adverse effect

RISK ASSESSMENT – STEP 4

- What is the risk?
- Characterize the overall risk considering
  - The likelihood and consequences of the identified adverse effect being realized
  - Interaction among indiv. risks (e.g. synergism)
  - Risk management actions
  - Cumulative effects (e.g. changes in human activities, presence of other LMOs)

→ determine the risk

RISK ASSESSMENT – STEP 5

- Is the risk acceptable or manageable?
- evaluate risk management options considering
  - Risk thresholds
  - Uncertainties regarding the level or risk
  - Need, feasibility and efficacy of risk management options

→ Provide recommendations for risk management

RISK MANAGEMENT STRATEGIES

- CPB, Art. 16: ‘to regulate, manage and control risks identified in the RA’
- Administrative risk management
  - Authorization & decision making
  - Conditions laid down in decisions on release (e.g. time limited consent, monitoring plan)
  - Information of the public and people exposed (e.g. announcements, labelling)
- Technical risk management
  - E.g. containment, buffer strips, isolation distances, prevention of flowering, volunteer management
  - Monitoring to gain long term data feeding into the RA and as a basis for modelling

DECISION MAKING

- Taken by national competent authorities
- In line with national and international obligations
- Based on outcome of the RA
  (e.g. identified risks, technical risk management measures, monitoring obligations)
- In practice also based on other reasons
  (e.g. general policy, public opinion, stakeholder pressure, economic considerations)
- Possibility for review and withdrawal of decisions

CONCLUSIONS

- Risk assessment is a complex process involving different authorities, scientists and stakeholders
  - Assessors from different fields (e.g. molecular biology, toxicology, ecology)
- A thorough assessment is necessary, but should be well planned in order to focus on important issues (i.e. thoroughly define context and scope)
- Protocols and guidance for risk assessment are available for various purposes (e.g. food/feed RA, ERA)
- Basis for decision making and risk management actions