RISK ASSESSMENT – THE PLANNING PHASE

HELMUT GAUGITSCH

ENVIRONMENT AGENCY AUSTRIA umweltbundesamt

THE PLANNING PHASE OF THE RISK ASSESSMENT

WHY?

→ in order to arrive at a case-specific assessment in line with general requirements

- 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

→ may involve an information sharing and consultation process

ESTABLISHING THE CONTEXT – 1

WHY?

→ in order to identify protection goals

→ in order to identify general assessment requirements

- Regulatory requirements and international obligations
  (e.g. Cartagena Protocol on Biosafety, EU Directive 2001/18/EC, national genetic engineering law)
- Environmental and health policies (e.g. reduction in use of PPPs)
- Guidance (e.g. in EU: EFSA GD on ERA, EFSA GD on RA for GM food & feed)

→ **protection goals**
(e.g. human health, environment, biodiversity, protected species & habitats, ecosystem functions & services, socio-economic aspects)

PROTECTION GOALS

- environmental policy protection goals (e.g. biodiversity) often too vague & general to be useful for RA
- need to be translated to assessment endpoints in order to be operational
  (e.g. protected species, pollinator, soil function)
- e.g. Ecosystem Services approach used by EFSA
  - identifying potential ES impacted by the use of the LMO
  - identifying structural or functional components of biodiversity that provide or support ecosystem services (= services providing unit)
  - specifying the level of protection for service providing unit

→ communication with stakeholders to reach agreement on operational protection goals!

ESTABLISHING THE CONTEXT - 2

- Identification of methodological and analytical requirements
  - Molecular characterization
    (bioinformatics data: sequencing data, southern plots etc.)
  - Comparative assessment
    (e.g. agronomic and phenotypic analysis, compositional analysis)
  - Toxicological assessment
    (e.g. heat stability & digestibility studies, acute & sub-chronic toxicity studies, feeding studies)
  - Allergenicity assessment
    (e.g. amino acid sequence homology comparison between the newly expressed protein and known allergens)
  - Nutritional assessment
    (e.g. nutritional relevance of newly expressed proteins or changes in nutritional constituents, potential alterations in the total diet for the consumers/animals)

ESTABLISHING THE CONTEXT - 3

- Baseline information of the potential receiving environment
  (ecosystem type and its use, e.g. type of agricultural production system, climatic and geographical conditions, existence of protected species etc.)
- Criteria to characterize the likelihood and magnitude of consequences of individual risks
  (e.g. risk determination matrix)

		Likelihood of adverse effect			
		Highly likely	Likely	Unlikely	Highly unlikely
Consequence of adverse effect	Major	High	High	Moderate	Moderate
	Intermediate	High	Moderate	Moderate	Low
	Minor	Moderate	Low	Low	Negligible
	Marginal	Low	Low	Negligible	Negligible

Source: http://bch.cbd.int/database/record.shtml?documentid=110899.

- Identification and Consideration of Uncertainty

UNCERTAINTY ANALYSIS

- identify uncertainties
  (e.g. sampling uncertainty, missing data, assumptions, statistical estimates, ambiguity)
- describe the quality of existing data & indicate absence of data
- quantify uncertainty as far as possible for each step of the RA
  (e.g. EFSA recommends the use of probability)
- combine the individual uncertainties
- assess the overall uncertainty

DEFINING THE SCOPE -1

WHY?

→ in order to define extent and limits of RA

→ in order to define information & data requirements for the specific case

- Define the ‘case’

  case = LMO, its new characteristics and the receiving environment

  - The LMO (crop plant, biology/ecology of the recipient organism)
  - The novel trait relating to its intended effect and phenotypic characteristics of the LMO
  - The potential receiving environment relating to its intended use

DEFINING THE SCOPE - 2

Take into consideration….

- The scope of the notification - scale and duration of exposure
  (e.g. field testing, commercial use as food & feed or cultivation)
- Experience and history of use with non-modified recipient or parental organism
  (taking into account its ecological function)
- Information from previous RA of the same or similar LMOs and modified traits in other types of LMOs
- Proposed limits and controls to restrict the spread and persistence of the LMO
  (in particular for field trials)

DEFINING THE SCOPE – 3

…de facto an iterative process of 3, non-separate activities/actions

1. Select relevant assessment endpoints or representative species on which to assess potential adverse effects
2. Establish baseline information on receiving environment as reference for estimating effects of the LMO or its use
3. Establish appropriate comparators

1. SELECTING RELEVANT ASSESSMENT ENDPOINTS

WHY?

→ in order to have a measure indicating a potential adverse effect of the LMO on a protection goal

= species representative for an ecological function, a (non-) target organism etc.

important selection criteria:

- relevance to protection goals
- well-defined ecological function
- accessibility to measurement
- level of potential exposure to LMO

Example 15 – Questions asked when selecting representative species for assessing effects of Bt plants on non-target organisms

- Which variant of the Bt protein are we dealing with?
- Where is it expressed (in the leaves, pollen or only in the roots)?
- Is it produced in the plant throughout its life or only during particular growth phases?
- Which insects come into contact with the Bt protein?
- Is this contact direct and long-term or only occasional?
- Which insects ingest the Bt protein through their prey?

Source: GMO Safety (website).

2. ESTABLISH BASELINE INFORMATION ON THE RECEIVING ENVIRONMENT

WHY?

→ in order to have a reference for estimating effects of the LMO or its use

- Description or measurement of existing conditions of the environment (without LMO)
  - quantitative information
    (e.g. number of organisms, variability of abundance, percentage of a certain health condition in a population)
  - qualitative information (e.g. agricultural practices, protection status)
- include info on assessment endpoints or selected representative species

3. ESTABLISH APPROPRIATE COMPARATORS -1

WHY?

→ comparative approach is a general principle (acc. Annex III of the CPB)

→ in order to assess if the LMO presents a greater, lesser or equivalent risk compared to the non-modified recipient or parental organism used in a similar way and in the same environment

- ideal comparator = near isogenic line
- ideally evaluated at the same time and location and
  under similar environmental & management conditions as the LMO

3. ESTABLISH APPROPRIATE COMPARATORS - 2

- additional comparators may be considered useful
  (e.g. non-modified organisms with characteristics as close as possible to LMO)
- Consider standard management practices applied (e.g. pesticide regimes)
- If suitable comparator is not available
  (e.g. abiotic stress tolerant LMO which cannot be grown in same environment as the non-GM organism)
  - the LMO may be considered an entire new genotype in the particular environment (similar to alien species) and
  - the RA should then be primarily based on the evaluation of the characteristics of the LMO plant and derived products

IN PRACTICE - PROBLEM FORMULATION

WHY?

→ in order to structure and frame the RA & to develop an analysis plan

PF = combination of establishing context & scope with 1. step of the RA
(i.e. identification of potential adverse effects of the LMO)

- Identify protection goals and assessment endpoints
- Identify potential adverse effects
- Develop conceptual models
  (e.g. outline hypothetical scenarios & pathways on how the LMO may cause harm to protection goals)
- Establish risk hypotheses
  (e.g. Which novel characteristics of the LMO may affect specific assessment endpoints?)
- Develop an analysis plan & identify adequate methods
  (e.g. How can the identified scenarios and pathways be tested?)

CONCLUSIONS

- A lot of information can be collected beforehand
  and some issues can be discussed case-independent
- A lot of work has been done by various international and national bodies
  - Cartagena Protocol on Biosafety (www.cbd.int)
  - OECD (www.oecd.org)
  - Codex Alimentarius Commission (www.codexalimentarius.net)
  - European Food Safety Authority (www.efsa.europa.eu)
- A good planning of the RA reduces efforts in data requirements
  and allows to focus the RA on the most relevant risks