Item 5.4: Conducting the risk assessment

Marja Ruohonen-Lehto

September 25

2.30 – 3.30 pm

Central and Eastern European Training Course on Risk Assessment of Living Modified Organisms

24.-28.9.2018

Minsk, Belarus

SYKE

Conducting the risk assessment (1)

Let us start!

- Have all your data and information available
- Have your notes and summaries ready – prepared in a logic and organized manner
- Start with an open mind
- Do not do conclusions in advance
- Do not discard any possible adverse effect because you think that it is not likely to cause a risk – conclude at the end of the exercise
- Step by step – structured and integrated process
- Iterative – certain steps may need to be repeated

SYKE

Conducting the risk assessment (2)

Step 1: Identification of any novel genotypic or phenotypic characteristics associated with the LMO that may have adverse effects

- On biological diversity
- In the likely potential receiving environment
- Taking into account human health

“Potential adverse effect/harm reflects an undesirable condition involving damage or injury”

SYKE

Conducting the risk assessment (3)

Step 1 can also be referred to as:

- Hazard identification
- A part of problem formulation
- What could go wrong -step

- Case-by-case risk assessment
  - The LMO itself
  - The likely potential receiving environment
  - The intended use

SYKE

Conducting the risk assessment (4)

The LMO

- Characterization of the recipient organism:
  - Taxonomic status, Common name, Biological characteristics, Origin, Centres of origin and centres of genetic diversity, Ecosystems and habitats where the recipient organisms is known to be native
- Description of the genetic modification
  - Donor organism(s), Modified genetic elements, Vector, Transformation method, Characteristics of the modification
- Identification of the LMO

SYKE

Conducting the risk assessment (5)

- Likely potential receiving environment(s)
  - Range of environments (ecosystem or habitat, including other organisms) – intentionally introduced as well as other environments likely to be exposed
  - Where exposure levels to the LMO will be the highest
  - Ecological characteristics, including physical location/geography, climate, soil, biological entities and their interactions (help in the selection of assessment endpoints), management status
  - Potential pathways for dispersal, habitats where the recipient/parent organism(s) may persist or proliferate
  - The nature of the LMO in question and its use

SYKE

Conducting the risk assessment (6)

- Intended use
  - Large scale – commercial releases
  - Small scale – field trials, more contained release
  - Management practices
  - Change in use: human consumption vs pharmaceutical or industrial use

SYKE

Conducting the risk assessment (7)

Some examples on possible adverse effects

The EU Directive 2001/18

- Disease to humans including allergenic or toxic effects
- Disease to animals or plants
- Effects on the dynamics of populations of species in the potential receiving environment -> may lead to decrease of biodiversity
- Effects on biogeochemical cycles – particularly carbon and nitrogen recycling

SYKE

Conducting the risk assessment (8)

More examples of possible adverse effects

- Transgenes escaping from cultivars into wild relatives, protected species (possible decrease of genetic diversity)
- Pests to evolve resistance to the toxins produced by the LM crops (change in population dynamics)
- Toxins affecting non-target organisms

- Direct, Indirect, Immediate, Delayed

SYKE

Conducting the risk assessment (9)

An example of FAO

Potential adverse effects from weediness in plants

- Competitive exclusion of other plants
- Reduction in yield/biomass of other plants
- Reduction in quality of products/services
- Restriction of physical movement (e.g. water, people, animals)
- Harm to human and/or animal health
- Altered ecosystem processes

SYKE

Conducting the risk assessment (10)

- We have now identified possible changes in the LMO(s)
- We have information on the potential likely receiving environment, exposure levels and routes
- We have information on the use
- We have identified possible adverse effects – and already in the previous scoping phase our assessment endpoints (deriving from ours specific protection goals)

SYKE

Conducting the risk assessment (11)

Now it is time to construct risk scenarios and risk hypotheses – that will help in the following steps (estimating the likelihood and consequences of the adverse effects)

- **Develop conceptual models/Risk scenarios**
  (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?)

From slides of Helmut Gaugitsch on “Problem Formulation”

SYKE

Conducting the risk assessment (12)

Example of a risk scenario:

- The possibility that growing Bt corn may kill ladybird beetles due to ingestion of the Bt protein when preying on insects feeding on the LM corn, thereby reducing the abundance of coccinellids in the agroecosystem and increasing the incidence of pests.

(Hokanson and Quemada 2009)

- Toxic effects on pollinators – reduction in abundance - effect on pollination services (a vital ecosystem service)

SYKE

Conducting the risk assessment (13)

An example of a pathway:

The LM plant expresses a novel compound →

the novel compound exerts a direct toxic effect on a protected species →

The protected species is exposed to the LM plant or parts of it →

The direct toxic effect leads to decreased abundance, reproduction or fitness of the protected species →

The abundance of the protected species is negatively affected by cultivation of the LM plant in the likely potential receiving environment

SYKE

Conducting the risk assessment (14)

Step 2: Evaluation of the likelihood

- Likelihood i.e. probability of the adverse effect occurring, taking into account the level and kind of exposure
- Analysis of the likelihood and consequence (Step 3) -> with respect to the identified assessment endpoints
- In Annex III of the Protocol two separate steps, sometimes in reverse order, sometimes simultaneously

- Qualitatively - High, Moderate, Low, Negligible
  Quantitatively as a relative measure of probability
  - From zero to one, where zero represents impossibility and one certainty

SYKE

Conducting the risk assessment (15)

Step 2 can also be referred to as:

- Exposure assessment
- Change or probability of a harm being realized
- How likely is it to happen –step

Example one:

- Outcrossing with a non-modified plant is determined to be possible
  - The likelihood of the outcrossing
  - The likelihood of the LM progeny to persist or proliferate
  - Affecting fitness level of the progeny?
  - Positive fitness effect vs negative fitness effect
  - High or low likelihood of the resulting population to increase

SYKE

Conducting the risk assessment (16)

Example two:

- LM plant potentially toxic to a herbivorous insect
  - The likelihood of the insect to be present
  - The likelihood that the insect will feed on the LM plant
  - The likelihood that the insect will digest a sufficient quantity to suffer an adverse effect
  - Probabilities at an individual level or on a population level or both

Example three:

  - Likelihood of introgression
  - Measurements of hybridisation rates, assumed selective advantage of inserted gene, fitness measurements of parent plants, and plants from first and second back-cross generations

SYKE

Conducting the risk assessment (17)

Step 3: Evaluation of the consequences

- The consequence of an adverse effect is the outcome, extent and severity of an adverse effect associated with the exposure to an LMO, its handling and use
- May consider effects on individuals (mortality, enhanced or reduced fitness etc.) or populations (increase or decrease in number, change in structure, behaviour etc.)
- To consider the consequences of each adverse effect
- High, Moderate, Low, Negligible consequences

SYKE

Conducting the risk assessment (18)

Step 3 can also be referred to as:

- Effects assessment
- Assessment of severity of effects if they occur
- Hazard characterization
- Stressor-response assessment
- Would it be a problem –step

An example:

- Gene flow and introgression could lead to a potential adverse effect
  - The presence of transgene could have an impact on biodiversity
  - Depends on the effects of the transgene on individual fitness

SYKE

Conducting the risk assessment (19)

Continues:

- Depends on the importance of that species relative to protection goals
- If a protected species – impact of the transgene on the population
- If not – possible indirect effects
- Progeny with the transgene could produce more seeds (resistance to a stressor), increases the frequency of the transgenes in the protected species, reduces the genetic diversity and abundance of the protected species

SYKE

Conducting the risk assessment (20)

Step 4: Estimation of the overall risk

- Compiles the likelihood and consequence of each of the individual risks identified
- Takes into account any relevant uncertainty
- This step can also be referred to as:
  - Risk characterization
  - Risk evaluation
  - Characterization of risks based on the evaluation of the likelihood and consequences of the identified adverse effects being realized
  - What is the risk -step

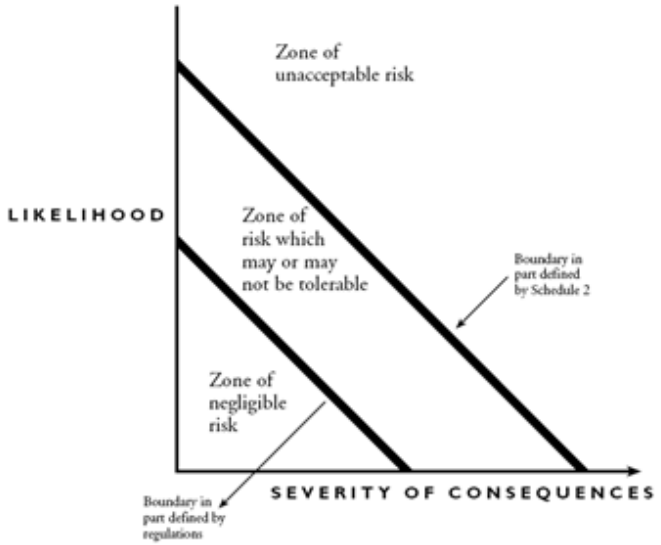
SYKE

Conducting the risk assessment (21)

- In rare cases risk characterization results in quantitative value (6% of a species population exposed to a stressor, half of that percentage will die)
- Quantitative – High, Medium, Low, Negligible

An example of estimation:

Figure 8 – Estimation of overall risk



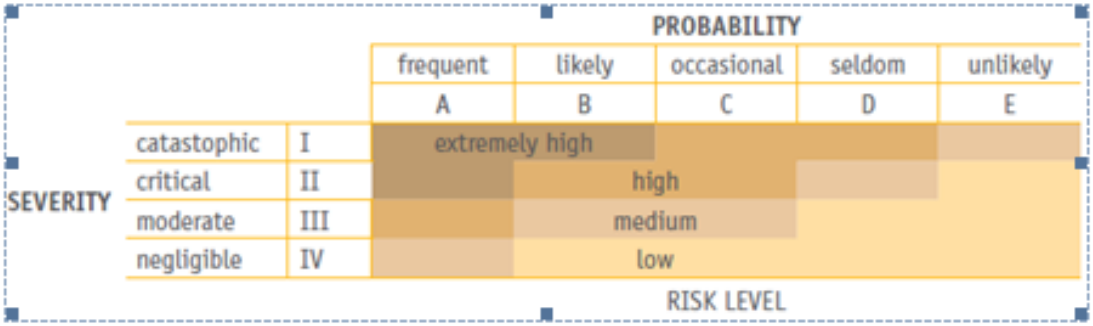
Source: ERMA NZ (1998)

SYKE

Conducting the risk assessment (22)

An other example of classification of risk:

Figure 9 –Classification of risk



Source: FAO (2011b).

SYKE

Conducting the risk assessment (23)

Step 5: Acceptability of risk and identification of risk management and monitoring strategies

- This step can also be referred to as:
  - Mitigation options
  - Application of risk management strategies
  - Identification of strategies to manage risks

  - Acceptability of risks -> I will talk about this under Item 6.1 on 26 September (4-5 pm)

SYKE

Conducting the risk assessment (24)

Technical risk management

- To reduce or control risks that have been identified in the risk assessment
- To reduce the likelihood – preventive measures
- To reduce the consequences of potential adverse effects – mitigation measures
- Examples: minimum distance from sexually compatible species, destruction of seeds remaining in the field or volunteers after harvest, restrictions from introduction into specified receiving environments etc.

SYKE

Conducting the risk assessment (25)

Monitoring

- A strategy, a plan to monitor the receiving environment for adverse effects after the release
- The level of uncertainty
- Some accepted risks/negligible risks
- For all LMOs, for particular LMOs
- Detecting changes
- May be designed based on protection goals
- General surveillance (Beneficial insects)
- Case-specific monitoring (Resistance development in insect pests)

SYKE

Conducting the risk assessment (26)

- Potential adverse effects such as delayed, cumulative, combinatorial or indirect effects
- ➢ May be considered in the post-release monitoring strategies
- The level of specificity depends on the LMO, the intended use and/or the likely potential receiving environment(s)
- The methodology may include:
  - Frequency
  - Locations and methods of sampling
  - Methods of analysis

SYKE