



Umweltbundesamt GmbH

CASE STUDY 1 – CONDUCTING THE ASSESSMENT

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OVERVIEW

- Short repetition of the tool ‘problem formulation’
- We will identify
 - protection goals in Belarus
 - characteristics of the LMO capable of causing potential adverse effects (hazards)
 - possible pathways of exposure
 - potential adverse effects
- Formulate specific risk hypotheses
- Develop an analysis plan
- Evaluate the risk

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 & assessment endpoints
- Identify potential adverse effects
- Develop conceptual models
(e.g. outline hypothetical scenarios & pathways on how the LMO may cause harm to PGs)
- 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?)

PROTECTION GOALS IN BELARUS

- Protection goals in national gene law?
- Protection goals in nature protection laws? (national and/or regional)
- Protection goals in agricultural production?
- Any protection goals resulting from national policies or policy instruments?
- Protection of human and animal health and the environment
- Protection of biodiversity
- Protection of rare or endangered species
- Protection of endangered habitats
- E.g. good agricultural practices, reduction in pesticide use, specific production systems
- E.g. ecosystem services, red list species, socio-economic aspects, prevention of development of antibiotic resistances

OPERATIONALIZATION OF PROTECTION GOALS

protection goals

(e.g. biodiversity, protected species, ecosystem function)



assessment endpoints

(e.g. representative species)



measurement endpoints

(e.g. abundance, mortality)



limits of concern

(i.e. maximum tolerable change)

CHARACTERISTICS OF THE LMO CAPABLE OF CAUSING POTENTIAL ADVERSE EFFECTS (HAZARDS)

- **Herbicide tolerance (HT) trait**
- Antibiotic resistance (AR) trait
- In combination with specific biological characteristics:
 - Small seeds, which can easily be lost
 - Persistence in the seed bank
 - Existence of cross-pollination partners

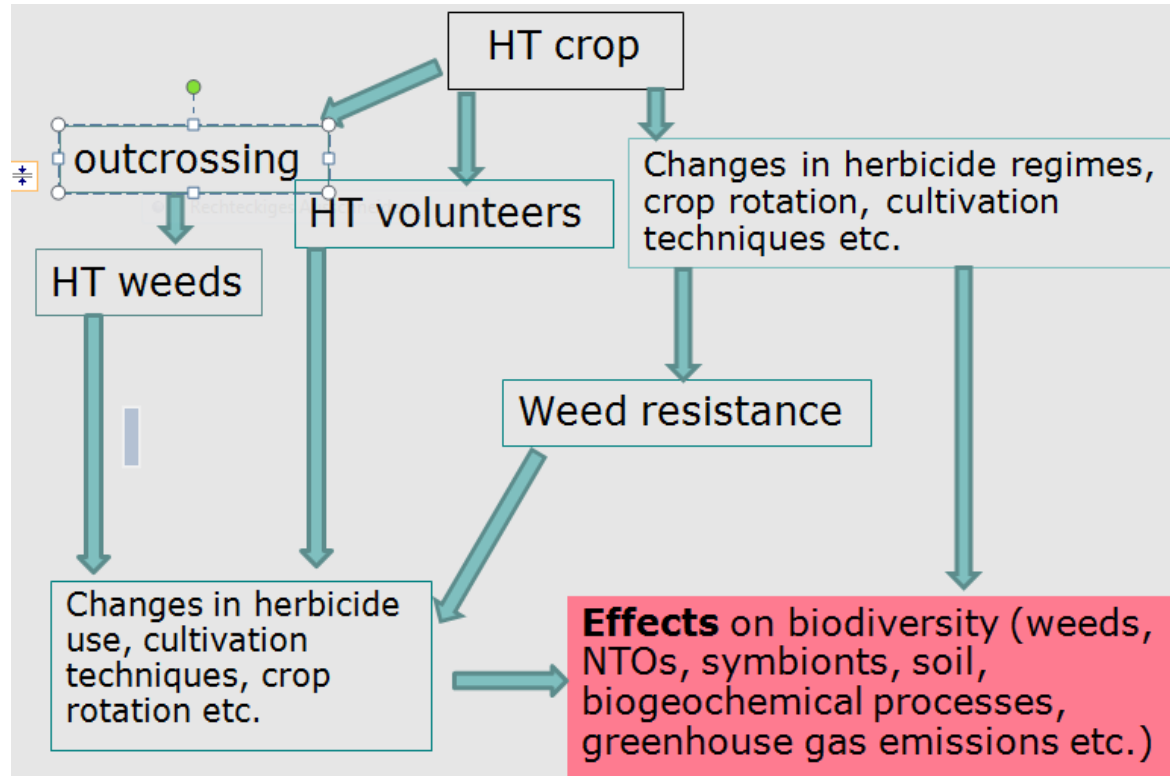
POSSIBLE PATHWAYS OF EXPOSURE - HT TRAIT

- Loss and spillage during transport and handling
- Establishment of feral GM OSR HCN92, in particular in areas where glufosinate is frequently applied
- Persistence in the seed bank

POTENTIAL ADVERSE EFFECTS – HT TRAIT

- GM OSR HCN92 may establish feral populations and be more persistent or invasive than *B. napus*. Thus leading to the replacement of other feral plant species, potentially endangered or protected species
- The HR trait may outcross to wild relatives and hybrid offspring may become more weedy and invasive or suffer from decreased fitness (e.g. out-breeding depression)
- CULTIVATION: HT trait may cause management problems in fields

SCENARIOS OF ADVERSE EFFECTS ON BIODIVERSITY IN CASE OF CULTIVATION



SPECIFIC RISK HYPOTHESIS – HT TRAIT

- Loss and spillage of GM OSR HCN92 during transport and handling as well as enhanced fitness of the GM OSR HCN92 may lead to the establishment of feral GM OSR HCN92 populations which are more persistent than feral *B. napus* populations
- Feral GM OSR HCN92 may form hybrids with wild relatives leading to the introgression of the HR genes into the gene pool of protected species or decreased fitness of hybrid offspring leading to a local decline in wild relatives (out-breeding depression)
- CULTIVATION: Volunteer GM OSR HCN92 may cause management problems in fields (e.g. multiple herbicide resistant weeds) and lead to the use of other, potentially more harmful herbicides

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POSSIBLE PATHWAYS OF EXPOSURE - AR TRAIT

- Horizontal gene transfer to gut bacteria and pathogens of livestock fed GM OSR HCN 92

POTENTIAL ADVERSE EFFECTS – AR TRAIT

- AR trait may compromise medical therapies with antibiotics in livestock

SPECIFIC RISK HYPOTHESIS – AR TRAIT

- Horizontal gene transfer of the *nptII* gene to gut bacteria of organisms consuming GM OSR HCN92 and potentially to pathogens may compromise medical treatments with the antibiotics neomycin and kanamycin

ASSESSMENT ENDPOINTS - EXAMPLE BY EFSA

EXPOSURE OF HONEYBEES TO PLANT PROTECTION PRODUCTS

protection goals

(regulating service: pollination, food production)



assessment endpoints

(colony and foraging population of a colony)



measurement endpoints

(e.g. survival of the colony, abundance and foraging behavior of foraging populations, biomass, reproduction)



limits of concern

(e.g. no effect on colony size greater than 7%)

Source: Guidance to develop specific protection goals options for environmental risk assessment, in relation to biodiversity and ecosystem services (EFSA 2016)

ASSESSMENT ENDPOINTS - EXAMPLE BY EFSA

EXPOSURE OF NON-TARGET LEPIDOPTERA TO BT MAIZE POLLEN

protection goals

(cultural services: e.g. species of conservation concern, species of aesthetic value
regulating service: pest regulation)



assessment endpoints

((meta)population of particular species of Lepidoptera)



measurement endpoints

(e.g. abundance, within & between species diversity)

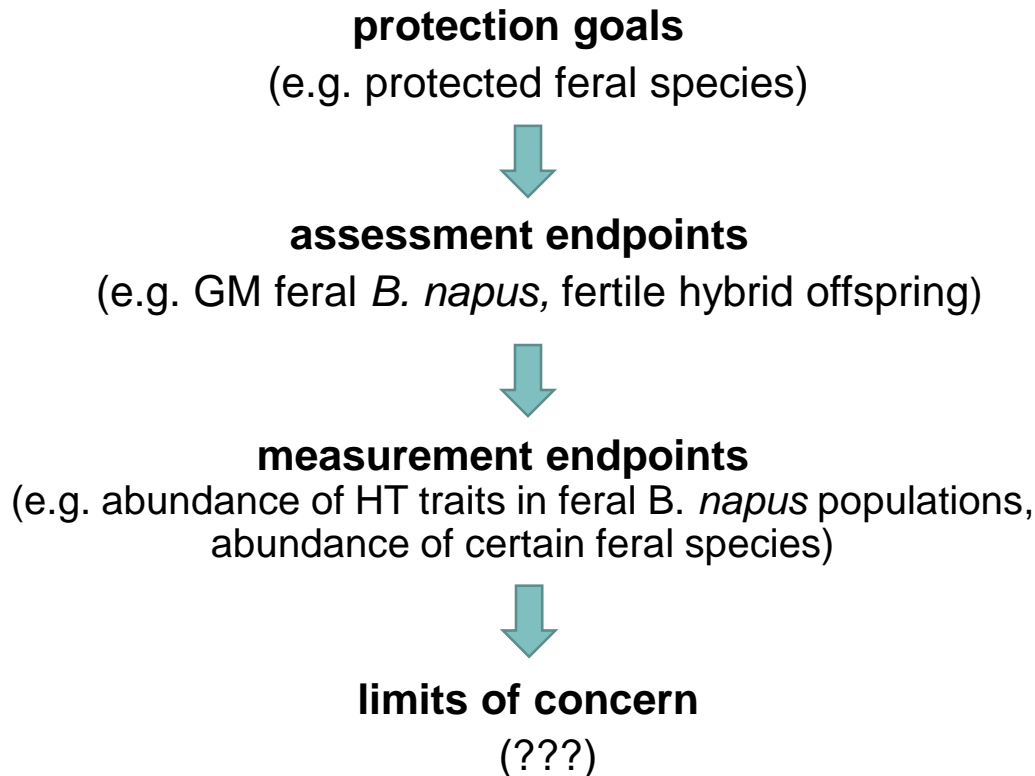


limits of concern

(e.g. no more than 1% reduction in abundance
of adults over a single year in a region)

Source: Guidance to develop specific protection goals
options for environmental risk assessment, in relation to
biodiversity and ecosystem services (EFSA 2016)

ASSESSMENT ENDPOINTS - CASE STUDY GM OSR HCN92



EXAMPLE FOR A CONCEPTUAL MODEL APPLIED BY EFSA: STAGED APPROACH

- Can the GM plant reproduce and hybridize with compatible wild relatives? Are there any unintended differences in the hybridization potential in comparison to the conventional counterpart? → YES!
- Will the GM plant be more persistent than conventional counterparts? → YES, if complementary herbicide is applied!
- Can the GM plant form feral populations? → YES!
- Will the GM trait alter the fitness or range of feral plants or compatible relatives in semi-natural habitats? Will it change their size? → ???

RISK ASSESSMENT – CONSEQUENCE & LIKELIHOOD

- Consequences?
- Likelihood?
- Risk?

		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>.

RISK OF ESTABLISHMENT OF GM OSR HCN92

- Consequences?
- Likelihood?
- Risk?

		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>.

RISK OF OUT-CROSSING TO WILD RELATIVES

- Consequences?
- Likelihood?
- Risk?

		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>.

RISK OF GM OSR HCN92 CAUSING MANAGEMENT PROBLEMS IN FIELDS

- Consequences?
- Likelihood?
- Risk?

		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
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RISK OF HORIZONTAL GENE TRANSFER TO GUT BACTERIA AND PATHOGENS

- Consequences?
- Likelihood?
- Risk?

		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

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CHARACTERIZATION OF OVERALL RISK

- Consequences?
- Likelihood?
- Risk?

		Likelihood of adverse effect			
		Highly likely	Likely	Unlikely	Highly unlikely
Consequence of adverse effect	Major	High	High	Moderate	Moderate
	Intermediate	High	Moderate	Moderate	Low
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RECOMMENDATIONS REGARDING THE MANAGEMENT OF POTENTIAL RISKS

● Conditions of consent?

- in general limited consent in the EU (10 years)

● Monitoring requirements?

- mandatory post-market monitoring plan in the EU (incl. general surveillance)
- some EU Member States favor case-specific monitoring, some do not (e.g. fate of transgenes in the environment, assessment of GM OSR volunteers)

● Policy consequences?

- commercial cultivation of GM OSR in the EU unlikely (only for breeding purposes)
- phasing out of the use of antibiotic resistance markers

CONCLUSIONS

- complex exercise
- iterative process
- different from case to case
- different expertise
- different opinions



Thank you for your attention & participation!