Living Modified Organisms

Implementation of the Biosafety-Protocol requirements according to the Federal Agency for Nature Conservation

General Principles of an Environmental Risk Assessment (ERA)

Environmental risk assessments of LMOs (Living Modified Organisms) undertaken pursuant to the Biosafety-Protocol shall be carried out in a scientifically sound manner and following the precautionary principle, in accordance with Annex III and taking into account recognized risk assessment techniques (Figure 1 and 2).

General Principles of an ERA
- scientifically sound and transparent manner
- precautionary approach should be applied
- carried out case-by-case
- long term effects should be considered

Figure 1: General principles of an environmental risk assessment according to annex III of the Biosafety-Protocol

Steps of an ERA
- Identifying any characteristics that may pose adverse effects
- Evaluating the likelihood of the adverse effects
- Evaluating the consequences
- Estimating the overall risk
- Recommending whether the risks are acceptable and manageable
- In case of missing knowledge further information can be requested

Figure 2: Steps of an environmental risk assessment according to annex III of the Biosafety-Protocol

Objectives of an ERA of LMOs

The risk assessment aims to identify and evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity in the likely receiving environment, taking into account risks to human health.

Elements of the ERA of the Federal Agency for Nature Conservation

To adequately assess the environmental impact of LMOs in the receiving environments we recommend collecting data over several growing seasons and from different biogeographic regions in Europe and support an improved concept of ecotoxicological testing of LMOs. Special consideration should be given to protected areas such as “Natura 2000” and distance regulations.

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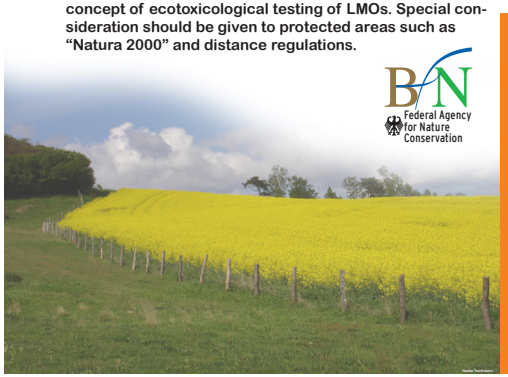

Living Modified Organisms

Ecotoxicological testing

Current situation

To date, ecotoxicological tests developed and standardised for the assessment of chemicals are used also for the environmental risk assessment of living modified organisms (LMOs). In most cases these include acute toxicity testing of the specific transgene product only. These concepts are met with criticism as they do not adequately address the provision put forward in European regulations of comprehensive testing including indirect, long-term and cumulative effects.

Improved concept for ecotoxicological testing

We support a concept that explicitly addresses the whole transgenic organism and the transgene product. Ecotoxicological testing of LMOs has to take into account the ecology of the LMO and its interactions with non-target organisms and ecosystem functions in the relevant receiving environment.

Selection of meaningful test species and functions

In order to select the ecologically most relevant test species and function a number of questions are asked which reduce the number of candidate test species or functions in a systematic, transparent and step-wise fashion.

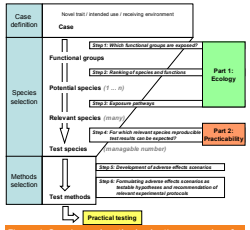

Figure 1: Species and method selection procedure for ecotoxicity testing of GMO proposed by Hilbeck et al. (2008)

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Living Modified Organisms

Impacts on Protected Areas

Network “Natura 2000”

“Natura 2000” is a network of legally protected areas to ensure biodiversity by conserving natural habitats and wild fauna and flora in EU Member States. Council Directive 92/43/EEC provides that a project or plan, which is likely to have a significant effect on a Natura 2000 site, shall be subject to an impact assessment.

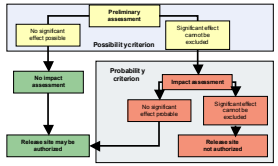

Figure 1: Procedure of the assessment.

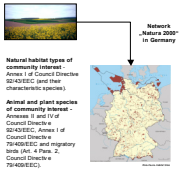

Figure 2: LMO release/cultivation and the network “Natura 2000” in Germany.

Prevention of adverse effects

German law specifies the need of an impact assessment for experimental release of LMOs in and nearby a Natura 2000 site, and for commercial use of LMOs in Natura 2000 sites. Projects, which may have a significant adverse effect on conservation objectives or integral parts of a site, are prohibited.

Impact assessments

- consider effective area of the project, distance from site, active range of protected species, etc.
- follow the Precautionary Principle,
- are based on standardised information on a site, field maps and management plans,
- are conducted on a case by case basis.

Effective distance regulations between Natura 2000 site and LMO release/cultivation might be determined for impact mitigation.

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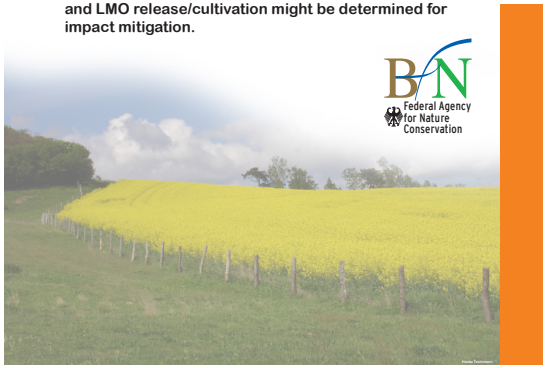
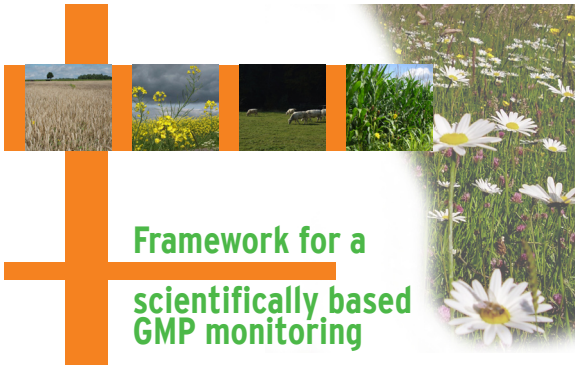




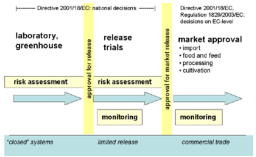
Framework for a scientifically based GMP monitoring

Harmonised and scientifically based monitoring

According to Directive 2001/18/EC the commercial cultivation of genetically modified plants (GMPs) in EU has to be monitored to identify potential adverse environmental effects. Many details of GMP monitoring and its implementation are still at an initial stage of development. However, there are key issues for GMP monitoring that should be targeted and agreed upon to ensure an internationally harmonised and science based approach.

The priciple of stepwise release

The principle of stepwise scale increase of GMP releases based on risk assessment results is essential. However, it is not yet implemented in a satisfactory manner. To ensure this principle, sufficient data during pre-commercial releases must be collected, which enables a solid environmental risk assessment and a design for the monitoring during subsequent cultivation.



'Step by step' principle for release of GMOs

GM oilseed rape escaped from cultivation

A systematic and consistent monitoring approach

Suitable monitoring parameters and methods must be chosen on a case-by-case approach, which is hypothesis-driven and related to specified protection targets. Likewise, there are criteria for selecting suitable monitoring sites and for integrating GMO monitoring with existing environmental monitoring programmes.

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Standard methods for the monitoring of genetically modified organisms (GMOs)

Comparability of monitoring data

According to Directive 2001/18/EC a monitoring plan is mandatory in all applications for deliberate release of GMOs. Since an approved monitoring plan of genetically modified organisms will be effective in all European Member States, data will be collected in different regions and by different parties. To ensure high quality as well as comparability of these data, standard methods should be used if available.

Standardisation of methods for GMO monitoring

On national level, the Association of German Engineers (VDI) works with the support of scientific experts on standardising specific methods for the monitoring of environmental effects of GMOs. In order to obtain a standardised methodology on European level, the European Organisation for Standardisation (CEN) has started its work in 2007 on the basis of VDI guidelines.

Guideline series VDI 4330	Monitoring the effects of genetically modified organisms (GMOs)
Part 1	Monitoring the ecological effects of genetically modified organisms; Genetically modified plants; Basic principles and strategies
Part 3	Pollen monitoring; Pollen sampling using pollen mass filters (PMF) and Sigma-2 samplers
Part 4	Biological sampling of pollen; Bee hives as biological pollen samplers
Part 7	Qualitative methods for the detection of genetically engineered nucleic acids in the environment
Part 9	Assessment of the diversity of ferns and flowering plants; Vegetation survey
Part 13	Standardised monitoring of butterflies and moths (Lepidoptera); Transect method, light trap, and recording of larvae

Tab.1: Standard methods for the environmental monitoring of genetically modified organisms (finalised).

Guideline series VDI 4330	Monitoring the effects of genetically modified organisms (GMOs)
Part 2	Sampling for pollen monitoring
Part 5	Sampling of plant material for the detection of genetically engineered nucleic acids in the environment
Part 6	Extraction methods for the detection of genetically engineered nucleic acids in the environment
Part 10	Floristic mapping
Part 11	Molecular ecology/soils; ELISA
Part 12	Molecular ecology/soils; Microbial communities
Part 14	Effects of GMO on soil organisms

Tab.2: Standard methods for the environmental monitoring of genetically modified organisms (in progress).

Availability of VDI guidelines

The VDI guidelines are published in the series VDI 4330 and are consolidated in the VDI manual Biotechnology Volume 1: Monitoring (www.vdi.de/gmo). The guidelines are printed bilingually (German and English).

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Assessment of environmental damages caused by genetically modified organisms

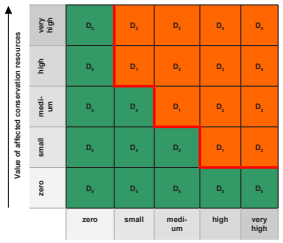
Legal framework

According to the EU Deliberate Release Directive (2001/18/EC), measures have to be taken to avoid environmental damages resulting from the release of genetically modified organisms. For the implementation of this regulation, it is necessary to define damages and to set up a standardised procedure for the assessment of damages.

Definition and identification of environmental damages

An environmental damage occurs when a relevant conservation resource (e.g. a rare species) is significantly adversely affected. The identification comprises the magnitude of the adverse effect (e.g. decline in certain genotypes) and the value of the affected resource (e.g. high value of an endangered species).

Table 1: Steps of the standardised procedure for the assessment of environmental damages caused by genetically modified organisms (GMO)	
(1)	It has to be estimated which environmental changes can be originated by a GMO or its use in agriculture.
(2)	It must be identified which of the estimated environmental changes adversely affects conservation resources.
(3)	The value of affected conservation resources has to be assessed.
(4)	The intensity of adverse effects must be evaluated.
(5)	The significance of the adverse effects is evaluated by combining the intensity of the adverse effects with the value of affected conservation resources (see matrix). Only a significant adverse effect is classified as a damage and can be further quantified into four different grades.



The matrix indicates the significance of adverse effects: Beyond the red line four different grades of damages D_1 to D_4 can be distinguished.

Application of standardised criteria

The value of an affected conservation resource is assessed by means of criteria such as "rareness and endangerment". The magnitude of an adverse effect is reviewed with criteria such as "effects on non-target organisms". In order to combine the resource value with the magnitude of the effect, an explicit matrix has been developed.

This poster is based on results of a BfN research project carried out by the Technical University Berlin (I. Kowarik, R. Bartz, U. Heink).

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