

Steps towards
a comprehensive

post market

environmental monitoring

of genetically

modified organisms

A position paper of the European Network of the Heads of Environment Protection Agencies (EPA) and the European Network of the Heads of Nature Conservation Agencies (ENCA)
Oktober 2013

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This paper is supported by:

Danish Environmental Protection Agency (Danish EPA)
Environment Agency Austria (EAA)
Finnish Environment Institute (SYKE)
German Federal Agency for Nature Conservation (BfN)
Institute for Environmental Protection and Research (ISPRA)
Norwegian Environment Agency
Swiss Federal Office for the Environment (FOEN)

This paper is approved by:

EPA network plenary (21th EPA plenary meeting in Berlin, September 2013)
ENCA network plenary (13th ENCA plenary meeting in Bonn, October 2013)

Impressum:

Cover photo + layout: Bernadette Guenot

Key Messages of this Position Paper

The current implementation of post market environmental monitoring (PMEM) requires improvement.

Monitoring possible changes due to the cultivation of genetically modified plants is highly important to protect our environment. The obligatory pre-release risk assessment of GMO products might not address all open questions and possible effects, due for instance to the complexity of receiving environments. Post market environmental monitoring (PMEM) (see figure) of GMO-induced changes is therefore crucial for the protection of the environment and mandatory in most European countries. However, the currently implemented PMEM plans do not meet the standards set by legal bases and existing guidelines, and need substantial improvement.

PMEM must be appropriate to monitor environmental impacts of GMOs.

To achieve this goal, scientifically sound PMEM based on reliable data should be implemented in all receiving environments that might be affected by GM plants. The monitoring design, sampling methodology and data analysis have to comply with fundamental quality criteria like correctness, comparability and reproducibility. Authorisation holders as well as developers of PMEM guidelines need to consider all relevant protection goals (biodiversity, water and soil) in order to warrant a complete and comprehensive monitoring.

The potential of case specific monitoring (CSM) is not fully exploited.

The aim of case specific monitoring (CSM) is to address the risks and uncertainties identified during environmental risk assessment (ERA), and to assess whether the conclusions from the ERA are valid. CSM may for instance investigate interactions between a specific GM crop and non-target organisms which cannot be sufficiently addressed by the ERA (e.g. because laboratory results are not fully comparable with the field situation). Currently, authorisation holders evaluate most risks as being negligible during ERA, and therefore only implement few, if any, CSM measures. However, CSM should be performed nonetheless to make sure that the ERA's assumptions about risks and uncertainties indeed hold true in the field.

All exposed environments must be addressed by PMEM.

A GMO's long-term persistence in the environment and its uncontrolled long-distance spread might lead to unforeseen and unpredictable environmental impacts. Therefore, the study of both the environmental exposure routes (dispersal, hybridisation,...) as well as the possible presence

of GMO in the environment (persistence, accumulation,...) are crucial steps of PMEM. Studies should take into account the dispersal and presence not only of entire GMOs, but also of GMO parts (e.g. pollen, plant residues) and products (e.g. Bt-toxin). Knowledge about exposure routes is a prerequisite for the selection of appropriate monitoring sites and parameters, and is fundamental to detect causal effects. Exposure monitoring should be an integral part of PMEM.

The main responsibility for PMEM lies with the authorisation holder.

The responsibility of the authorisation holders is not restricted to limited aspects of PMEM such as monitoring measures at the farm-level (e.g. farmers questionnaires). Authorisation holders should also assume responsibility for the holistic monitoring of environmental impacts according to the submitted monitoring plans. However, monitoring measures do not necessarily need to be carried out by the authorisation holder themselves. If PMEM is performed in collaboration with third parties, specialists and institutions with the necessary practical expertise and access to existing data should be involved in order to ensure a scientifically sound PMEM.

Legal requirements need to be respected and enforced.

When implementing PMEM, authorisation holders should fully comply with the requirements of the relevant legal framework as well as the monitoring conditions specified in the authorisation decision. Furthermore, the existing EFSA (European Food Safety Authority) guidance for PMEM should be applied as a minimal standard. In addition, it is important that the competent authorities at the national and European level chaperone the work of the authorisation holders to ensure the PMEM's quality. The authorities should evaluate the monitoring results reported by the authorisation holders critically and address any shortcomings or deficiencies by rapidly enforcing improvements.

Application for the deliberate release of GMO

ERA *Environmental Risk Assessment*

The aim of the ERA is to identify and evaluate potential adverse environmental effects of the GMO's placing on the market on a case by case basis.

PMEM plan *Post Marketing Environmental Monitoring plan*

GS

General surveillance

The aim of GS is to identify the occurrence of adverse effects of the GMO or its use on the environment which were not anticipated by the ERA.

CSM

Case specific monitoring

The aim of CSM is to validate assumptions taken during the ERA regarding the occurrence and impact of potential adverse effects of the GMO or its use on the environment, and to address remaining uncertainties associated with ERA.

Risks and uncertainties found during ERA

Relationships between environmental risk assessment (ERA) and post market environmental monitoring (PMEM).

An application for the deliberate release of a GMO needs to include both an environmental risk assessment (ERA) as well as a post marketing environmental monitoring (PMEM) plan. The ERA provides the basis for the monitoring plans to be developed on a case by case basis, taking into account the modified characteristics, the intended use of the GMO and the receiving environment. PMEM consists of a general surveillance (GS), which serves to identify unexpected effects of the GMO release, and a case specific monitoring (CSM), which directly addresses risks and uncertainties identified during ERA.

1. Introduction

In the EU and other European countries, the monitoring of environmental impacts caused by the placing on the market and the subsequent environmental release of genetically modified organisms (GMOs) is mandatory.

The discussion of a useful implementation of post marketing environmental monitoring (PMEM) involves many partners, such as the European Commission, the European Food Safety Authority (EFSA), authorities of each European country, academia, industry and non-governmental organizations (NGOs).

PMEM needs to generate high quality data and has to be conducted in a comparable way throughout Europe in order to yield meaningful results. The ENCA EPA interest group on risk assessment and monitoring of GMOs (IG GMO) was founded in 2008 to strengthen the international exchange between experts. This interest group is set up by the Environmental Protection Agencies

(EPA) and European Nature Conservation Agencies (ENCA) and offers a platform for cooperation at a European level (for details see Chapter 6 of this position paper).

The IG GMO has written this position paper to present its view on PMEM. The current implementation of PMEM plans leaves much to be desired, but at the same time existing guidelines are vague or ambiguous. This paper thus emphasizes the requirements for a well-rounded approach to PMEM and aims at strengthening environmental aspects in the ongoing discussion on the implementation of GMO monitoring. Its recommendations are based on the broad experience of the member institutions regarding GMO monitoring and general environmental monitoring. The paper is also based on a policy paper published by the National Environment Agencies in Austria and Switzerland and the Federal Agency for Nature Conservation in Germany (BfN-FOEN-EAA 2011).

2. Regulatory Background

The requirements for PMEM are specified in the existing EU-level regulations, notably in Directive 2001/18/EC, its Annex VII, and the supplementing guidance notes for implementation (2002/811/EC). European non EU-member states often define requirements for PMEM in their national legislation. For instance, monitoring after a GMO's placing on the market is demanded in the Swiss Gene Technology Act (SR 814.91) and Release Ordinance (SR 814.911).

According to the Directive 2001/18/EC, the applicant has to develop a post market environmental monitoring (PMEM) plan based on a detailed environmental risk assessment (ERA) (see Figure on p. 5).

The ERA should provide a detailed analysis of the risks posed by the respective GMO and its use for human and animal health as well as for the environment. It should include the description of potential adverse effects, an evaluation of their consequences, and the likelihood of their occurrence. Based on an

overall risk estimation, the applicant has to propose an appropriate risk management strategy.

PMEM is defined as “the systematic measurement of variables and processes over time (...) to examine potential changes with respect to certain baselines” (2002/811/EC). It should serve as an early warning system for adverse effects caused by GMOs, thus allowing the rapid reassessment and implementation of mitigation measures in order to reduce damage to the environment (2002/811/EC). This is necessary because results obtained from laboratory or small-scale field experiments might not reflect the complex situation in large-scale agricultural use appropriately. PMEM should help identify any adverse effect on human and animal health or the environment after the marketing authorization. Possible effects that should be considered include but are not limited to: direct or indirect, immediate, delayed, cumulative, long term or unanticipated consequences.

According to Annex VII of the Directive, the PMEM plan should consist of:

- **Case specific Monitoring (CSM)**, to validate the ERA's assumptions about the occurrence and impact of potential adverse effects of the GMO, and to address any remaining uncertainties associated with ERA.
- **General Surveillance (GS)**, to identify adverse effects of the GMO or its use which were not anticipated in the ERA.

These documents have to be submitted to the competent authority for approval prior to the placing on the market and the environmental release of a GMO. The EFSA has elaborated a

specific guidance for PMEM based on the above-mentioned legal framework (EFSA 2011). Furthermore, relevant policy documents addressing monitoring issues have been published by national institutions from several European countries (e.g. ACRE 2004, COGEM 2011, BfN-FOEN-EAA 2011, etc.).

3. Recommendations for a comprehensive post market environmental monitoring

The implementation of a comprehensive and meaningful PMEM for GMO applications is of the utmost importance for the protection of the environment. The PMEM strategy should allow to monitor the environmental effects of GMO releases. This highly complex and challenging task should be performed in a scientifically sound way using appropriate methods, and involve specialists with the necessary scientific expertise.

Adequate guidance is needed to help applicants develop monitoring plans and to

assist regulators in evaluating them. The current EFSA guidance document provides a general framework for PMEM (EFSA 2011). However, more specific and detailed guidance is missing and the existing general guidance needs to be improved. Both the EFSA and authorities of the IG GMO member states have identified a substantial number of serious deficiencies in existing PMEM plans and reports. Thus, the current implementation of PMEM needs to be considerably improved.

PMEM should be planned with the following requirements in mind:

- GMOs are able to reproduce, spread and persist in the environment. In addition, parts of GMOs (e.g. pollen, plant residues) or their products (e.g. Bt-toxins) can persist and accumulate in the environment. The long-term persistence of GMOs in the environment as well as their uncontrolled long-distance spread might have unforeseen and unpredictable environmental impacts. Therefore, PMEM should take into account not only intended but also unintended effects of a certain GMO or its products on the environment. Monitoring should take place in all areas that are exposed to a GMO or its products (receiving environments including adjacent areas, soils and aquatic ecosystems). Therefore, environmental exposure to waste materials and sewage as well as accidental spillage need to be considered when

authorizations for the use of GMO are applied for. All possible pathways for environmental exposure should be taken into account for the design of the monitoring approach and the selection of monitoring objectives. For every monitored environmental compartment, measures need to be adapted depending on the expected exposure levels and the capability of the GM material to propagate and persist in the environment.

- Causal relationships between an observed environmental change and the release of a GMO can only be established if a meaningful baseline is available for comparison. The status of the environment either before GMO cultivation or in areas without GMO cultivation can serve as a baseline (comparison of environmental states over time or in space). The choice of suitable comparators depends on the parameters that are to be observed. The use of “historical knowledge” (e.g. farmer’s experiences) can provide a useful additional source of information, but cannot substitute data generated by scientific methods.
- PMEM plans should ensure appropriate interaction between ERA, CSM and GS and prevent gaps in the overall monitoring strategy. The boundaries between CSM and GS in particular have to be considered. For instance, it is difficult to assess whether a parameter like the environmental impact of hybridisation with wild relatives should be monitored for CSM, for GS, or for both approaches simultaneously. Therefore, the separation between CSM and GS should be handled in a flexible manner, so that every parameter can be assigned to CSM or GS on a case-by-case basis.
- PMEM needs to be implemented in an adaptable and dynamic way throughout the whole monitoring period. Adequate reporting and review at regular intervals enables the improvement and / or amendment of the monitoring strategy during the whole monitoring period. The respective competent authorities at the national and European level should enforce any necessary improvements without undue delay to ensure that the monitoring is adequate and meaningful.
- According to Directive 2001/18/EC, the overall responsibility for PMEM lies with the authorization holder. This comprises both the field and the landscape level of PMEM, including the whole range of potential adverse effects from direct to long-term and cumulative effects on the environment. Any restriction of the monitoring scope, e.g. focusing on the field level only, is unacceptable. However, authorization holders do not need to carry out all monitoring measures by themselves and may cooperate with external institutions or partners that have the necessary expertise.

4. Recommendations for case specific monitoring

CSM is currently implemented for a few authorized GMOs only (e.g. MON810). Current CSM plans are based on the conclusion that most of the risks identified through ERA are negligible. For example, the only notable risk identified in the case of MON810 was that the target organisms might develop mechanisms counteracting the toxins produced by the insect resistant GM crop. Consequentially, this was the only issue monitored in the frame of CSM. However, CSM should also be used to make sure that the ERA's assumptions about risks and

uncertainties can be confirmed in complex receiving environments.

To decide whether CSM measures should be implemented to address an issue, one has to take into account the level of uncertainty regarding a given risk, the amount and quality of available data, the scale of the release (large versus small) as well as the consequences and irreversibility of a potential adverse effect. Moreover, it is important to consider long-term and cumulative effects as well as effects that might only become apparent at a certain scale of application.

CSM should be planned with the following requirements in mind:

- CSM should complement the uncertainties and general limitations of an ERA. For example, the ERA, amongst other things, may be based on results from small-scale field release experiments or from experiments in contained systems, which cannot easily be extrapolated to the large field releases that are expected to follow authorization. Likewise, only a limited number of potential non-target organisms can be tested prior to the GMO release. Thus, the limited scope of the experimental methods that can be employed for an ERA will fail to reflect the complexity of environmental interactions upon GMO release. Therefore, CSM is a crucial complement of ERA and should investigate whether all of the ERA's assumptions regarding potential adverse effects arising from the GMO and its use are correct. Moreover, CSM is necessary to verify whether all of the ERA's suggested measures are appropriate to reduce identified risks. Furthermore, scientifically sound CSM should address missing information and uncertainties from the ERA independent of whether the identified risks are deemed significant or negligible.
- Every GMO has distinct characteristics that result from the organism itself, from the genetic modification introduced, from their combination and finally from the

possible interactions between the GMO and the specific receiving environments. The content and parameters of each CSM measure therefore have to be selected on a case-by-case basis for every GMO.

- Finally, a comprehensive CSM is particularly important for GM crops with a high outcrossing potential (such as oilseed rape), for GM crops with traits that may increase the fitness of the GM plant (e.g. tolerance to environmental stressors), as well as for plants with possible toxic effects on non-target organisms (e.g. producing Bt-toxin).

5. Recommendations for a general surveillance

GS is mandatory in order to detect adverse effects which were not anticipated during the ERA, and is especially important to identify indirect, delayed, long term and/or cumulative environmental effects. GS should allow the rapid detection of relevant changes in the environment. If changes are observed, further in depth studies are necessary to distinguish between changes caused by GMOs and variations that occurred independently of GMO release.

It is generally accepted that implementing specific measures to monitor all possible effects in all environmental compartments

(e.g. air, water, soil, terrestrial habitats) and at all ecological scales (species/populations, ecosystems, landscapes) is impossible for practical reasons. Thus, a significant challenge of GS is to identify parameters and key environmental indicators that appropriately reflect adverse effects of GMOs on the environment and provide robust datasets (Sukopp 2004, DEFRA 2007). Currently, GS plans are mainly based on farmer questionnaires and other measures such as the review of scientific literature and company stewardship programs (management of a product from its inception to its use by the company).

GS should be planned with the following requirements in mind:

- GS should include both a general observation, which does not specifically focus on a given GMO, as well as parameters selected based on the specific GMO's traits and use. The following aspects should be taken into account when selecting

appropriate parameters and indicators for GS: (1) cause-effect hypotheses established by biosafety research, (2) existing knowledge about the GMO and its traits as well as general ecological knowledge; (3) modeling and geo-statistical extrapolation to determine potential long-term, delayed and combinatory effects, and (4) representation of objects to be protected and protection goals by adequate indicators.

- The individual monitoring tools employed in GS should be used according to their strengths and weaknesses. For instance, farmers' questionnaires may be valuable for collecting data on management practices of a GM crop as they report data on agronomic issues like the frequency of pests, the application of pesticides or the occurrence of weeds. However, while such approaches may assist monitoring, they cannot replace a scientific investigation of a given GMO's environmental effects at the field level.
- Directive 2001/18/EC recommends cooperation with existing environmental surveillance programs, like for instance biodiversity monitoring, to facilitate GS. However, current GS plans merely include general suggestions to analyse information from currently implemented environmental observation programs. They do not define clear strategies and neither specify the involved programs nor the precise monitoring objectives or methods. A first attempt at using existing national surveillance programs for the monitoring of GM maize MON810 in Germany in 2008 failed for several reasons. For instance, no agreement about the access to data was settled beforehand and the suitability of the selected programs to detect adverse effects of MON810 had not been assessed (BfN-FOEN-EAA 2011). Therefore, a detailed and systematic analysis of existing monitoring schemes is essential in order to determine their suitability for GS (ACRE 2013, Glandorf 2012).
- Appropriate tools and surveillance systems need to be optimized or developed for the study of impacts on exposed organisms and environments that cannot be surveyed adequately by existing observation programs. A range of reliable and validated monitoring methods have been developed and should be applied to GS (e.g. VDI Guidelines, Lang and Bühler 2011, Pascher et al. 2011).

6. Activities of the IG GMO related to GMO-Monitoring

Most members of the EPA and ENCA networks are directly involved in the evaluation of monitoring plans and reports from applicants. Indeed, they consist of agencies responsible for the authorization of GMO releases as well as public institutions that advise national administrations in this process. Many of them are also involved in the development of concepts for the environmental monitoring of GMOs and participate in ongoing research projects at the national and EU level.

Because of their responsibilities in environmental protection and nature conservation, this paper's author institutions are also involved in various other issues of general environmental monitoring. A number

of these issues are addressed through joint activities in the working groups of the EPA and ENCA networks. Such activities include the exchange of knowledge and experience between member institutions, the harmonization of existing or newly developed approaches in environmental monitoring (e.g. remote sensing), or collaborations to identify key problems and opportunities associated with environmental monitoring.

The author institutions support the current efforts to establish an appropriate framework for GMO monitoring in Europe by contributing their competence and their vast experience with environmental monitoring activities in different regulatory fields.

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