

Long-term and large-scale effects of genetically modified organisms require specific environmental monitoring designs

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Abstract: Within the European Union monitoring is compulsory after the placing on the market of genetically modified organisms (GMOs). It aims firstly at confirming assertions made in the environmental risk assessment regarding the occurrence and impact of potentially adverse effects of the GMO or its use and secondly at identifying effects which are not anticipated in the environmental risk assessment. GMO monitoring has to be specific on GMO characteristics, modified traits and on the intended use of the GMO. In order to design GMO monitoring different steps have to be carried out and three identified monitoring areas have to be considered. In this article specific attention is given to the identification of potential adverse effects of GMOs on the environment, the selection of appropriate methods and the suitability of existing programs for GMO monitoring.

Introduction

According to Directive 2001/18/EC monitoring of adverse effects of GMOs after placing on the market is compulsory. Monitoring is required to follow the precautionary principle and to cope with incompleteness of knowledge and uncertainties about the impact of GMOs and their use on human health and the environment. The aim of GMO-monitoring is to serve as an early warning system: “The data which will be monitored should be relevant to and suitable for a rapid assessment and implementation of measures to reduce any consequences to the environment” (Council Decision 2002/811/EC). The objective is, on a case-by-case basis, to detect direct, indirect, immediate, delayed, long term and cumulative as well as unanticipated adverse effects of the GMO to the environment.

To design monitoring that is appropriate to fulfil this task is a real challenge since potential adverse effects are not limited in time and space, may occur on different ecological and trophic levels and might appear in different environmental media (Züghart et al. 2007). The following steps have to be carried out when developing a GMO monitoring plan: 1. identification of potential adverse effects, 2. determination of relevant and suitable parameters, 3. selection of appropriate methods, 4. specification of monitoring areas, 5. establishment of suitable baseline data. In this article some of these elementary steps will be further elaborated.

How to determine monitoring parameters

A first step in the design of GMO monitoring is to identify potential adverse effects of the GMO on the environment. For this step different complementary procedures can be applied. One approach is to evaluate existing data of biosafety research. Usually they are limited in time and space. Therefore additional tools are needed. Another approach is the involvement of modelling and geo-statistical extrapolation. Models are useful for instance to extrapolate the results of biosafety research to further levels of time and space. A main tool for the identification of potential adverse effects are cause-effect-hypotheses derived from research results as well as from existing knowledge of ecology and ecosystem theory. Together these approaches allow identifying the areas and topics of observation where the relatively highest probability of adverse effects and potential environmental impacts of the GMO exist. With regard to the point that it may not be possible to monitor all identified effects at all ecological levels the next important step is to prioritise the identified effects. After this step parameters that are appropriate to address the selected potential adverse effects can be determined.

When designing GMO monitoring three core areas have to be covered (Züghart & Breckling 2003):

Documentation of exposure

The first area is the documentation of the dissemination of the GMO, parts of it or of GMO products into the environment and furthers the documentation of their persistence and accumulation. This is important particularly for the assessment of long-term effects, large scale processes and cumulative effects.

Monitoring the impact of the specific GMO

A second area is the monitoring of the impact of the specific GMO. This is directly related to the characteristics of the GMO, the genetically modified trait and the intended use, and the extent of actual use. This core area covers for instance effects on non-target organisms or the ecological behaviour of GM hybrids outside fields.

Large scale and long term effect relationships

The third area to be considered when designing a monitoring plan is closely linked to area one and two. It focuses especially on larger scale and long-term effects. Subjects are for instance alterations of landscape structures, indirect and complex food chain effects or cumulative effects.

The decision, whether a potential effect should be monitored in case specific monitoring (CSM) or general surveillance (GS) depends on the outcome of the environmental risk assessment. It is obvious that effects, which are identified as a risk, belong to the CSM and effects that are not anticipated in the risk assessment are part of GS. However, for some effects potential hazards for the environment may have been identified, but their risk is difficult to predict or assess. These effects can either belong to CSM, GS or to both at the same time. This has to be decided on a case-by-case basis.

Standardised monitoring methods

According to Council Decision 2002/811/EC standard methodology should be followed where appropriate. Standardisation ensures the compliance with fundamental quality criteria such as correctness, comparability and reproducibility (VDI 2006). Because GMO monitoring will take place all over Europe, monitoring data from different regions or EU member states should be comparable.

On the national level the Association of German Engineers (VDI) develops standard methods appropriate for GMO monitoring. The overall aim is to reach standardization on the European level. In 2007 the European organisation for standardisation (CEN) started its work based on the VDI guideline on pollen monitoring.

Integrating environmental monitoring programs

Directive 2001/18/EC recommends for GS to make use of already existing agricultural and environmental monitoring programs, if appropriate. However, the suitability of existing programs for GMO monitoring depends on different aspects, as there are: the monitoring objectives, parameters and frequencies, the monitoring area or the availability of data. In many cases the suitability may be limited (Graef et al. 2005). Therefore at first a systematic evaluation of the considered programs is required. If existing programs are not suitable new and specifically targeted monitoring tools have to be established.

Present state of monitoring plans

Applicants mostly disregard important requirements for the design of the environmental monitoring of GMO. Currently provided monitoring plans are undetermined and incomplete. The documentation of exposure and the monitoring of the environmental impact of the specific GMO are normally not addressed; monitoring parameters and monitoring methods are not specified. Furthermore, the use of appropriate existing monitoring programs or networks is considered, but not rendered more precisely. At present state these monitoring plans are not appropriate to ensure a scientifically sound early warning system.

Also the EFSA guidance document on risk assessment (2006a) requires monitoring plans which “describe in detail the monitoring strategy, methodology, analysis, reporting and review as laid down in Council Decision 2002/811/EC” and which “describe the processes and criteria that will be used for selecting and evaluating existing monitoring systems for supplying data...”. Nevertheless, the EFSA Scientific panel on GMO declared the current monitoring plans as being sufficient (e.g. EFSA 2005a, b, 2006b).

In the monitoring plan for MON810 in Germany (Monsanto 2007a) it is suggested that five nationwide environmental monitoring programs are used. According to Monsanto (2007b, c), it is intended “to analyse on an annual basis the reports published by these selected networks to establish whether any potential adverse effects as a result of MON810 cultivation can be identified”. However, it is evident that the suitability of these programs was not sufficiently evaluated beforehand. Some of these programs do not publish any reports, and data are not publicly available. No arrangements were made how to get access to relevant monitoring results. Coordinators of these programs were neither involved in nor informed about the intended use of their data. An in depth evaluation of their ability to detect adverse effects of MON810 and their explanatory power is still outstanding.

Conclusions

GMO monitoring plans should be appropriate to detect effects on the environment at an early stage. For this reason the monitoring design has to take place on a case-by-case basis and should be scientifically sound. The elementary steps of designing GMO monitoring stated above should be followed and agreed upon to ensure an internationally harmonised and scientifically correct approach.

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