Concepts for the coordination and harmonisation of monitoring data exchange regarding GM crops.

Contents

1 Introduction

1.1 Legal framework

Neither the Directive 2001/18/EC[1] nor any other legal basis foresees a specific coordination and harmonisation of GMO monitoring data between EU Member States (MS). Article 31 of Directive 2001/18/EC merely regulates the creation of national registers for GMO cultivation, which may be used for monitoring.

Other regulations don't refer to GMO monitoring data but have implications on information or data exchange such as during the notification process (Decision 2002/812/EC[2]), for the structure of results from deliberate releases into the environment (Decision 2003/701/EC[3]), in

[1] *Official Journal L 106 , 17/04/2001 P. 0001 - 0039*
[2] *Official Journal L 280 , 18/10/2002 P. 0037 - 0061*
[3] *Official Journal L 254 , 08/10/2003 P. 0021 - 0028*

the context of transboundary movements of GMOs (Regulation No 1946/2003[4]) and for a system of unique identifiers of GMOs (Regulation No 65/2004[5]).

1.2 Monitoring Working Group (MWG) terms of reference

Since coordination and harmonisation of GMO monitoring data is not regulated in the European context, "the possibility of EU-wide coordination and harmonisation of data resulting from post-market monitoring of GMOs" is one of the main issues in the terms of reference of the MWG.

1.3 Definitions

Data coordination for the purpose of this document refers to the process of GMO monitoring data collection and storage from different sources. *Data coordination* requires an infrastructure (staff, the necessary hard- and software) and may take place at different stages of GMO monitoring (data collection methods → spatio-temporal design of data collection → data collection → data storage → data processing and analysis →data exchange).

Data harmonisation refers to the process of setting common standards for GMO monitoring. These standards may be set at different stages of GMO monitoring such as methods and spatio-temporal design for data collection; data quality; data and file types and structure; data storage and analysis; and data exchange.

GMO monitoring data relates to both a) case specific monitoring (CSM) and general surveillance (GS) data collected by applicants and third parties and to b) data from external agro-environmental monitoring programmes according to preamble 44 of Directive 2001/18/EC. Data coordination and harmonisation may refer to both types of monitoring data.

2 Purpose of data coordination and harmonisation

2.1 General aims

The main purpose of GMO monitoring data coordination and harmonisation is to manage data from different sources using a common structure preferably a information system (IS), thus enabling comparability of the analysed sample sets. In this way extrapolation of local monitoring results to larger areas and different regions will be enabled which increases the explanatory power and representativeness of analysed data.

2.2 Enhancing EU-wide data interpretability: spatio-temporal data collection design

GMO monitoring can be designed and the data analysed on different spatial and temporal levels. For every GMO event the monitoring design and data analyses should be based on a specific scale, quality and quantity of data to be representative and interpretable. Monitoring every GMO event everywhere is neither necessary nor feasible and data analysis may also

[4] *Official Journal L 287 , 05/11/2003 P. 0001 - 0010*
[5] *Official Journal L 010 , 16/01/2004 P. 0005 - 0010*

lead to adjustment of the overall number of representative monitoring sites. An intelligent monitoring design can be representative for large areas if adequately designed.

The Farm Scale Evaluations in the UK as a large scale biosafety research programme can be potentially used for designing monitoring and statistical analysis. About 60 field sites per crop were examined for the whole of UK, based on pilot studies and the known variance of the measured variables.

2.3 Harmonising indicator species and collection methods

Different potential adverse effects of GM crops may require monitoring a range of different indicator species. It is likely that, for example, indicator species or environmental conditions vary across MS, and surveillance networks used by either the applicant or MS use different survey methodologies. Selected indicator species will probably not cover all representative GMO cultivation areas as they may have a specific spatial distribution depending on ecological site requirements. Many methods are specific to selected organisms and their spatial distribution, which might require establishing individual monitoring designs. Furthermore, selected monitoring sites should be representative for the area of GMO cultivation. Monitoring data sets should therefore include appropriate information on geographical distribution and biometric analyses (e.g. number of sites, spatial distribution, and standard deviation of measured organisms). In the end this enables GMO monitoring programmes to achieve results with a tolerable error probability comparable between the MS. At present most (if any) of this information is not available, as there are currently no GM crops cultivated in the EU that would legally require a monitoring plan. However, some are close to approval. Maize cultivars containing the MON810 event can be cultivated but do not need a specific monitoring plan.

2.4 Harmonising data analysis

If EU-wide GMO monitoring data is coordinated and harmonised, selected data can be shared for aggregated analyses, for up-scaling results to larger or unsurveyed areas within EC and for modelling and validation of prognoses. The technical tool for data sharing and systematic reproducible analysis is an information system (IS). The opportunity for analysis of GMO monitoring data on an EU-level will enable to both assess the assumptions of the risk assessment and provide information on unforeseen environmental effects on a broader basis. They can also inform regulators about the effectiveness of the monitoring programmes.

2.5 Summary

From a scientific point of view the purpose of EU-wide data coordination and harmonisation is to:

a) provide a basis for subsequent establishment of an EU-wide GMO monitoring information system (IS) for analysing the monitoring reports and supplementing raw data.

b) upscaling of interpretation because more monitoring data become accessible that may enable a more reliable and representative extrapolation to both unsurveyed EU areas and additional potentially affected environmental factors.

c) reduce the overall monitoring and analysis efforts due to synergistic effects of an EU-wide coordinated monitoring data analysis system.

3 Current state of GMO monitoring, data coordination and agro-environmental monitoring programmes in the MS and the EU

Monitoring data in the context of GMO monitoring may originate from two essentially different sources: a) The *GMO monitoring data* according to Annex VII of Dir. 2001/18/EC are collected by *the applicants* from own surveys or from contracted third parties and b) monitoring should make use if possible of *monitoring data* from *existing agro-environmental monitoring programmes* as recommended by preamble 44 of Directive 2001/18/EC and Council Decision 2002/811/EC[6]. It should be noted that EFSA supports the idea of a reporting and scientific analysis mechanism in the EU[7].

3.1 GMO monitoring and coordination of the applicants' GMO monitoring data in the MS and the EU

Currently there are no GM crops approved for cultivation purposes in the EU under Directive 2001/18/EC or Regulation 1829/2003[8]. The only approved GM crop for cultivation purposes in EU has been Bt-Maize (MON 810 and Bt176) approved under Directive 90/220/EEC[9], which have been cultivated e.g. in Spain. A number of GM crop products have been approved for importation but not for cultivation purposes.

Concepts for GMO monitoring and the coordination of the applicants' GMO monitoring data are being discussed but so far they focus on national level, even though both the spatial monitoring design inherent to the submitted monitoring plans and the cultivated GMOs may extend to large parts of the EU-territory. The upcoming monitoring plans to be submitted by the applicants for GMO cultivation are presumed to differ highly in complexity and quality especially in comparison to import.

There is currently only little focus on how the generated GMO monitoring data may be harmonised on the EU-wide basis. Little focus also is put on the need to harmonise the monitoring plans.

3.2 National agro-environmental monitoring programmes

EU MS have various agro-environmental monitoring programmes in place some of them have a long data collection tradition. Most of these programmes including their generated data are coordinated individually and are poorly interrelated. There are large differences in and between the MS in the availability and types of existing data that may be used as background data for interpreting GMO monitoring results. Especially in the context of General Surveillance some of these monitoring programmes are being discussed, but no programme would currently satisfy the needs of a GMO monitoring programme.

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[6] *Official Journal L 280 , 18/10/2002 P. 0027 - 0036*

[7] *Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental Monitoring (PMEM) of genetically modified plants, The EFSA Journal (2006) 319, 1-27*

[8] *Official Journal L 268 , 18/10/2003 P. 0001 - 0023*

[9] *Official Journal L 117 , 08/05/1990 P. 0015 - 0027*

3.3 EU agro-environmental monitoring programmes

It should be noted that there are EU Directives with respect to environmental protection with an obligation to monitor environmental parameters. For some of those Directives monitoring programmes have been developed with a potential applicability to GMO monitoring including data coordination and harmonisation, for instance a) the Habitats Directive on the conservation of natural habitats and of wild fauna and flora (92/43/EEC[10]), b) the Birds Directive on the conservation of wild birds (79/409/EEC[11]) and c) the Water Framework Directive (2000/60/EC[12]):

a) The Habitats Directive and subsequent decisions of an EU-WG include aspects on how to standardize data forms to be delivered by the MS. Standard tables include defined species and details on their range, population and habitat. The data forms include aggregated value classes (low- medium –high).

b) The Birds Directive foresees only reports with highly condensed information by the MS without using standard data forms.

c) The Water Framework Directive requires that a complex methodology for monitoring and data coordination and harmonisation must be developed. It includes standards for water body types, ecological regions in the EU and numerous indicator parameters. Measurements have to be carried out according to ISO standards. The monitoring design is standardised with respect to site location and site numbers. Data coordination is obligatory on both national and EU wide information systems, for instance the Water Information System for Europe (WISE). The shared data are aggregated among value classes (low- medium –high) that represent predefined thresholds for the measured parameters.

3.4 Summary

In summary, the concepts for coordination of the applicants' GMO monitoring data in the MS and the EU are still at an initial stage. Harmonisation of GMO monitoring plans and GMO monitoring data must be agreed by MS. A central data analysis should be used as a focal point.

There are some agro-environmental monitoring programmes in the MS and the EU where data are centrally coordinated and harmonised, many of which are valuable, especially in the context of GS as a monitoring data source or as baseline or reference data. Some of them might also provide baseline or reference data for parameters identified for CSM. Some of those agro-environmental monitoring programmes utilise certain aspects that may be applicable to GMO monitoring data coordination. Although no monitoring programme would be currently suitable to integrate GMO monitoring data without any adaptation, some of those programmes might need only minor adaptations.

4 Options for central data coordination, harmonisation and analysis

[10] *Official Journal L 206 , 22/07/1992 P. 0007 - 0050*
[11] *Official Journal L 103 , 25/04/1979 P. 0001 - 0018*
[12] *Official Journal L 327 , 22/12/2000 P. 0001 - 0073*

In considering options for central data coordination and harmonisation one has to distinguish between a) GMO monitoring data collected by applicants or third parties and b) data from external agro-environmental monitoring programmes of the MS or the EU that could be used to supplement the GMO monitoring data collected by applicants. These programmes could be extended to include different aspects of GMO monitoring, but it would be necessary to harmonise data type, measuring methods and data quality to a certain level for EU-wide data coordination and interpretation. Also the complexity of those programmes in space and contents should be related to the needs of GMO monitoring programmes.

The coordination of GMO monitoring data requires the need for information systems (IS) to be used for managing monitoring data from different sources within a common structure for subsequent analysis. There are three basically different options for GMO monitoring IS, each of which has to integrate GMO monitoring data of the applicants and if applicable the data from external agro-environmental monitoring programmes of the MS or the EU:

1) national IS that manage the monitoring data within the MS only;

2) one central EU wide IS that manages the monitoring data from all MS;

3) a combination solution of national and EU wide IS that manages the monitoring data within both MS and EU. Considering combination solutions is necessary, because coordination and harmonisation within and between MS and EU would be an adaptation process spanning over years. A national monitoring IS may be more easily realised compared to a central EU wide monitoring IS.

Between the three approaches there are transitions of functions and features possible. The options are discussed and characterised below and a distinction is made whether the monitoring plans and the collected data should be harmonised or not.

4.1 Option 1: National GMO monitoring IS

a) National GMO monitoring IS in each MS could be operated with EU wide standards for the data provided by the applicants and to a limited extent, also for data from external agro-environmental monitoring programmes of the MS and the EU. The standards should be set out in terms of storage media, files types, processing stage, quality, etc. so that the data provided are comparable on the MS level.

→ This option requires efforts in national data coordination and EU wide data harmonisation. The collected data could be analysed on the MS level and later on the results be shared using an EU wide platform for information exchange. For an EU-wide scientifically based analysis, however, this data cannot be used due to different data aggregation and data analysis methods between the MS.

b) National GMO monitoring IS could be operated without any standards for the data provided by the applicants and by external agro-environmental monitoring programmes of the MS or the EU.

→ This option only requires efforts in national data coordination. Without standards, the collected numerical data would not be comparable or scientifically interpretable on national and EU level. Final monitoring results from different applicants, however, could

still be shared on a higher information (meta)level of the MS and later on also on an EU wide platform of information exchange.

4.2 Option 2: Central EU wide GMO monitoring IS

a) A central EU wide GMO monitoring IS could be operated with EU wide standards for data provided by the applicants and to a limited extent, also for data from external agro-environmental monitoring programmes of the MS and the EU. Standards should be set out in terms of storage media, files types, processing stage, quality, etc. so that the data provided are comparable on the EU level.

→ This option initially requires more efforts in EU wide data coordination and harmonisation. But it produces scientifically reliable and comparable GMO monitoring data and results on the EU level.

b) A central EU wide GMO monitoring IS could be operated without any standards for the data provided by the applicants and by external agro-environmental monitoring programmes of the MS and the EU.

→ This option requires effort in EU wide data coordination but no effort in data harmonisation. Without standards the numerical data would not be comparable. Final monitoring results from different applicants could still be shared on a higher information (meta)level of the EU. For instance, different applicants may state adverse effects in their surveyed regions, but will not be able to correlate them.

4.3 Option 3: Combination of national and EU wide GMO monitoring IS

a) A combination of national and EU wide GMO monitoring IS could be operated with EU wide standards for data provided by the applicants and to a limited extent, also for data from external agro-environmental monitoring programmes of the MS and the EU. Standards should be set out in terms of storage media, files types, processing stage, quality, etc. so that the data provided are comparable on both national and EU level.

→ This option aims at implementing national monitoring IS and integrating this in parallel with an EU wide monitoring IS. It requires effort in both national and EU wide coordination and harmonisation. The collected monitoring data would be scientifically reliable and comparable on both MS and EU level.

b) A combination of national and EU wide GMO monitoring IS could be operated without any standards for the data provided by the applicants and by external agro-environmental monitoring programmes of the MS and the EU.

→ This option requires effort in EU wide data coordination but no effort in harmonisation. Without standards, the incoming numerical data would not be comparable and scientifically interpretable on the national and EU level. Final monitoring results from different applicants, however, could still be shared on a higher information (meta)level of the MS and the EU.

4.4 Summary

Coordination and harmonisation of monitoring data from the applicants and external agro-environmental monitoring programmes will take time for implementation in the MS and EU.

National solutions (Option 1) are more likely to be functional in the short term. Hence, in spite of the advantages in data interpretability of a central EU wide GMO monitoring IS (Option 2) it is necessary to consider also a combination of national and EU wide GMO monitoring IS (Option 3).

5 Recommendations

1. The present concepts on exchange of information and data of monitoring GMOs placed on the market in the Directive 2001/18/EC need to be supplemented with rules enabling the operational data coordination and harmonisation at EU level for EU wide data analysis.
2. A common strategy and time schedule for the implementation of data coordination and harmonisation should be elaborated and agreed upon.
3. The submission of monitoring plans and monitoring data provided by the applicants should be based on standards for storage media, files types, processing stage and quality.
4. Monitoring data provided by the applicants should include, if requested, standardised numerical raw data ready to be analysed with an IS.
5. With respect to data quality it is necessary to standardise data specifications such as expected variability, type I error, type II error, number of replications, types of statistical tests. Applicants or MS may then select, if existing, standard monitoring methods applied to local species, habitats and geographical regions.
6. It should be advocated to establish a system for coordinating and exchanging monitoring data. The functionalities and extent of this system would have to be further elaborated.
7. There are overall advantages in GMO monitoring data coordination and analysis at EU level. Out of three possible implementation options we recommend that option No. 3 (Combination solution of national and EU wide GMO monitoring IS) should be discussed further. This option aims at implementing national monitoring IS and integrating this in parallel with an EU wide monitoring IS.