Harmonised Post Market Environmental Monitoring Plan for cultivation in the EU

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EuropaBio Monitoring Working Group

1 Introduction

A scientific environmental risk assessment (ERA) of Product X has been carried out and concluded that, subject to appropriate management measures; Product X cultivation is unlikely to have any adverse effect on the environment.

The Post Market Environmental Monitoring (PMEM) plan proposed by the authorisation holder consists of two parts:

1. **Case Specific Monitoring (CSM)**: case-by-case basis, depending on the outcome of the ERA.

2. **General Surveillance**: The General Surveillance plan is based on the following 4 pillars: (1) Farmer Questionnaire; (2) use of existing surveillance networks; (3) literature review; (4) company stewardship programmes.

2 Responsibilities

The authorisation holder is responsible for ensuring that the PMEM plan is put in place and properly implemented in accordance with the conditions of the authorisation and that unanticipated adverse effects if identified are investigated immediately and reported to the Commission and rapporteur Competent Authority.

The authorisation holder shall be in the position to give evidence as requested by the Commission and the competent authorities of the Member States that the PMEM plan has been implemented. The authorisation holder is responsible for reporting the results of the CSM and General Surveillance (GS) to the Commission and the rapporteur Competent Authority.

3 Case Specific Monitoring

When risks linked to the GMO have been identified in the ERA, then case-specific monitoring should be carried out after placing on the market, in order to confirm assumptions made in the ERA and to further inform the ERA. Therefore, case-specific monitoring is hypothesis-driven and should be targeted at the assessment endpoints and protection goals highlighted in the ERA conclusions.

Option 1
The ERA performed for cultivation of Product X has concluded that there is no anticipated adverse effect (immediate, delayed, direct, or indirect) on human health or the environment. In consequence, case-specific monitoring is not required. End Option 1

Option 2
The ERA performed for cultivation of Product X has concluded that there is no anticipated adverse effect (immediate, delayed, direct, or indirect) on human health or the environment. In consequence, case-specific monitoring is not required. Product X is, however, commercialised alongside company stewardship programmes such as the IRM plan presented in *Reference*. As part of this stewardship programme, a hypothesis-based monitoring effort will be conducted specific for this product. End Option 2

Option3
The ERA performed for cultivation of Product X could not exclude a potential adverse effect at the commercial scale. Therefore, case-specific monitoring is proposed.
Complete for the specific case End Option 3
End Option Section

4 General surveillance

The objective of General Surveillance (GS) is to identify the occurrence of unanticipated adverse effects on the environment that may be due to the cultivation of the genetically modified plant, including biodiversity and ecosystem services and functions. By nature, the prediction of unanticipated effects does not lend itself to the formulation of defined scientific hypotheses.

4.1 Approach

The GS plan focuses on the geographical regions within the EU where Product X is grown, and takes place in representative environments, reflecting the range and distribution of farming practices and environments exposed to Product X plants and their cultivation.

GS is comprised of the following elements:

- Farmer Questionnaire.
- Existing Monitoring networks.
- Review of Literature.
- Company Stewardship Programme.

4.2 Time-period

The time-period for GS is in line with the period of consent, *i.e.* maximum 10 years, in areas where Product X is cultivated during the monitoring season.

4.3 Farmer questionnaire – monitoring the GM crop and its production sites

Farms present, in practical terms, the smallest unit where monitoring characteristics can be observed and where the influencing factors (as defined below), especially cultivation practices, can be assumed to be comparable. Questionnaires, directed at farms or productions systems where genetically modified plants are grown and utilised, are considered a useful method for collecting first hand data on the performance and impacts of a genetically modified plant and its cultivation for comparison with the cultivation of conventional plants[1]. In cases where an adverse effect is observed, the data can be used to establish if there is a correlation and to separate GM crop effects from adverse effects observed as a result of other environmental and cultivation factors.

4.3.1 Design of the farmer questionnaire

The farmer questionnaire has been designed to seek specific information on previous and current cropping and management practices and to provide comparisons between Product X and an equivalent non GM cultivar.

4.3.2 Conventional reference for comparison between GM and conventional crops

The reference for comparison can be:

- Simultaneous growing of conventional crops by the same farmer.
- Historical experience of growing the same conventional crop on the same farm.

4.3.3 Sampling

A minimum sample size of 2500 questionnaires over the 10 year period of authorisation is required (i.e. 250 questionnaires for each cultivation year). If, due to low uptake of Product X, fewer than 250 farmers per year are identified, the maximum possible number of farmers will be surveyed. If at the end of the authorization period less than 2500 questionnaires are done the test statistics will be evaluated for power.

The sampling procedure ensures that the monitored area will be proportional to and representative of the total regional area under GMO cultivation. Monitoring will focus on cultivation areas with a high uptake of the GM crop. The area of cultivation (ratio of country and total area) will be the first

[1] EFSA Scientific Opinion Guidance on the Post Market Environmental Monitoring (PMEM) of genetically modified plants 2011

subdivision factor. The product situation[2] within the countries will also be taken into consideration and the number of questionnaires per country adjusted accordingly to reflect this. Within each stratum (per year and country) the determined numbers of farmers are selected randomly where each farmer has the same chance to be surveyed. The procedure for the identification of participating farmers for interview might vary by country. Customer lists or lists developed by local associations might be used for identification. The final number of units per country may be adapted according to availability and willingness of farmers. The questionnaires will be collected after every growing season during the consent period.

4.3.4 Collecting information via questionnaires

The personal data of the farmer will be handled in accordance with applicable data protection legislation such as Directive 95/46/EC on the protection of individuals with regard to the processing of personal data (EC, 1995). The questionnaires will be encoded to protect farmers' identity in the survey and confidentiality agreements will be put in place between the different parties (*i.e.* authorisation holders, licensees, interviewers and analysts). The identity of a farmer will only be revealed to the authorisation holders if an adverse effect linked to their trait has been identified and needs to be investigated.

The response rate of the survey and reasons for non-completion will be specified yearly.

4.3.5 Data analysis

Each monitoring characteristic will be analysed according to the following scheme:

1. Calculation of the frequencies of the farmers' answers for the three categories and the corresponding confidence intervals (CI)
2. Comparison of the frequencies 'More' and/or 'Less' answers and their corresponding 99% upper confidence bounds with the threshold of 10% (binomial test).
3. Interpretation of the test result (effect/ adverse/ beneficial)
4. In case of identified effects: review possible causes
5. In case of GM crop being identified as the cause of the effect: further explanation of possible mechanism, as far as supported by the collected information.

The authorisation holder will conduct a statistical analysis with all pooled data every 5 years depending on the level of uptake and at the end of the authorisation period.

4.3.6 Quality control

Before the data are analysed, they will be subject to:

- Completeness check: Certain database fields are defined as mandatory because they are indispensable for the analysis.

- Validity check: Quantitative values have to vary within a plausible min-max range, qualitative values have to meet only acceptable parameter values

- Plausibility check: Data values have to be logical (e.g. the harvest date has to be after the sowing date). Possible logical connections between the questions have to be identified and inquired.

In case of missing or wrong data, queries will be sent to the farmer in order to complete the database. If a questionnaire is excluded it will be conserved in the raw data and noted as such.

4.3.7 Responsibilities

The authorisation holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

- That the farmer questionnaire as specified in the monitoring plan is available in the farmers' local language for each region.
- That the farmers were interviewed by qualified, specially trained independent interviewers either in person or by phone.

[2] Product Situation takes into account the GM adoption degree of the different countries.

The authorisation holder is responsible for:

- Developing and adapting in light of experience and in response to recommendations the content of the farmer questionnaire and any accompanying documentation.
- Identifying reliable infrastructure to support the collection of information integrating:
  (i) The authorisation holder's own organisation, particularly when acting as seed suppliers;
  (ii) Seed distributors;
  (iii) Sales representatives and promoters;
  (iv) Growers of; or other users of Product X;
  (v) Identification of independent interviewers.
- Reporting the results as requested in the Decision. This may include engaging an independent expert third party for data handling and statistical analysis. The report will include at least:
  (1) details of the farmer questionnaire
    (a) details of the implementation of the farmer survey (*e.g.* number and geographical distribution of participating farmers)
    (b) Data analysis

4.4 Existing monitoring networks

Council Decision 2002/811/EC (EC, 2002a) specifies that "General Surveillance should, when compatible, make use of established routine surveillance practices such as monitoring of agricultural plants, variety/seed registration, plant protection, plant health and soil surveys as well as ecological monitoring and environmental observations."

4.4.1 Existing environmental surveillance networks

4.4.1.1 Approach - Identification and selection of existing environmental networks

Four categories of existing networks are identified: *governmental* networks that are official initiatives focused on particular policy areas; *academic* networks that provide platforms for scientific communications on particular projects or research; *trade* networks that address specific professional issues; and *environmental* networks that educate, promote and collect information on observations of diverse components of nature.

The authorisation holder will make use of existing inventories of environmental monitoring networks at the European level and/or the following sources to identify existing environmental networks suitable for the purposes of monitoring Product X:

- Identification by the Competent Authorities under Directive 2001/18/EC of the different Member States where Product X will be grown,
- Identification by EuropaBio members and their representatives in European Member States of any network that would be expected to provide relevant information in the framework of general surveillance,
- Internet searches,
- Suggestions from third parties (*e.g.* from other networks, other stakeholders …).

For each network that is identified, the following information shall be recorded:

- network name(s);
- country(ies) where it is active;
- protection goals studied;
- website;
- general description;
- access to information.

This enquiry provides an initial set of existing networks potentially relevant for general surveillance.
The first screening is based on the information collected in the basic record. In particular the following aspects are taken into account:

- Relevance for general surveillance: Networks are selected to cover the environmental protection goals in the geographic regions in which the GM crop will be introduced. The information on networks will be collected throughout the consent period.

- Availability of information:
  For some existing networks it is not possible to access information on the network and their observations.

The authorisation holder will make this database available as part of the annual PMEM.

In case of an indication of an unexpected adverse effect via any other source (farmer questionnaire, literature,...) the information of the existing networks covering the specific protection goal will be reviewed and the existing network may be contacted to investigate if there is any indication of the adverse effect occurring in the environment where the GMO has been cultivated. The results of this analysis will be communicated as part of the PMEM report.

4.4.1.2 Baseline

Each existing network has developed its own methodology and related baselines. In most cases historical information is used as a reference for establishing trends over time.

4.4.1.3 Collecting information

Information on the selected networks information is collected, as it becomes publically available. This includes publications, journals, reports, information on websites and other communications. The analysis of this information provides the justification of the selection of networks and their entry in a ready-to-consult database.

On a regular basis, the information on each network will be verified in order to keep the listing up-to-date. Whenever new networks are identified the same documentation and selection process will be followed.

4.4.1.4 Analysis

The analysis is initially focussed on a structured, systematic selection of environmental networks that may be informative for PMEM.

4.4.1.5 Quality control

The existing network selection is performed in a standardized way and all actions are properly recorded. Data collection only includes information that can be supported by a publication or communication of the existing network. Any statement or conclusion will be fully attributed.

4.4.1.6 Responsibilities

The authorisation holder is responsible for:

- Scouting for existing networks that address relevant protection goals,
- Selection and keeping an up-to-date database of existing networks that may be relevant for PMEM.
- Taking the necessary actions to verify with existing networks in case of an indication of an adverse effect relating to Product X and its cultivation

4.4.2 National Routine Surveillance Programmes and networks

Companies selling Product X hybrids have an extensive network of technicians and retailers in the areas where products are sold and planted, and together with farmers using the Product X seeds would detect any potential unintended adverse effect. This is guaranteed by company stewardship programmes that cover the whole product cycle from the gene discovery until product discontinuation. These programmes contain solid complaint systems that allow any stakeholder involved in seed distribution up to planting and beyond to report any unexpected findings. In addition, national seed associations make strong efforts to inform farmers about the GM crop, the specific management requirements, the importance of the monitoring programme and the importance of reporting any unanticipated adverse effect during (and after) the cultivation of the GM crop and act as "*de facto*" national surveillance programmes. Therefore, any such unanticipated adverse effect will be handled through the company's stewardship programme as described in Section 4.6.

4.5 Review of scientific literature

4.5.1 Approach

A review of peer-reviewed literature will be performed based on generally recognised high quality databases. The authorisation holder will report the name of the searched databases, the corresponding web address, and the relevance of the database(s) to GMO risk assessment.

The search strategies are designed to retrieve a broad range of studies relevant to authorised cultivation of Product X. The authorisation holder shall provide in the annual PMEM report the following information:

- The complete search strategy or syntax used, including all the search terms and the logical association between the search terms (Boolean operators and parentheses).
- The time span of the search (e.g. yearly basis or through weekly/monthly alerts).
- Any limits applied to the search (*e.g.*, publication types or language).

The selection process of relevant publications follows two steps:

1. An initial assessment based on the title and/or abstract in order to exclude entries which are not pertaining to the safety or lack of risk of the intended use of Product X.
2. A detailed assessment based on the full-text publication.

The reasons for excluding a paper shall be recorded at each stage of the process.

For each of the relevant publications, the authorisation holder will endeavour to obtain within a reasonable time frame a copy of the full article. If this is not possible it shall be noted in the results.

4.5.2 Baseline

The overall baseline for the verification of an adverse effect will be the ERA and the assumptions underlying the ERA.
In addition, each study will have used its own baseline and/or experimental controls. While this is beyond the responsibility of the authorisation holder, it is important that this is checked in order to determine the validity and relevance of the study.

4.5.3 Timeline

The search will be conducted every year during the reporting period.

4.5.4 Analysis

The results of this analysis will be presented in a table as per the Appendix of the Commission Decision 2009/770/EC (EC, 2009). The selected publications are sorted by their relevance to each area of the risk assessment (*e.g.*, human and animal health). Full-text documents of the relevant publications will be provided in electronic format. If the document is not in one of the official EU languages, a summary of the relevant parts shall be provided.

For each relevant publication, the authorisation holder will:

- List, summarise and provide details on the scientific content,
- Put the results into the context of the original ERA by relating each study to the respective area of risk to be addressed in the ERA, and
- Consider the implications of the results; in particular if this literature indicates any potential adverse environmental impacts associated with the GM crop and its cultivation and whether these findings alter the conclusions of the ERA, the requirements for risk management or the PMEM plans.

4.5.5 Quality control

Each stage of the study selection process will be well documented, in order to make it assessable and reproducible.

4.5.6 Responsibilities

The authorisation holder is responsible for ensuring that the review is set-up and conducted. This includes:

- Defining the framework for the review (databases, search terms).
- Performing the selection of the references. If a third party performs the selection and review, then proper contractual arrangements will be in place.
- Collecting the detailed information on relevant publications.
- Putting the results into the context of the original ERA for Product X and its cultivation.
- Communicating as part of the PMEM reporting the selection process, the relevant publications and the results from the analysis.

4.6 Company stewardship programmes

Stewardship programmes for farmers are based on good agricultural practices to:

- Facilitate compliance with the authorisation conditions,
- Ensure that the products are used responsibly in a way that has similar or less environmental impacts compared to conventional crop cultivation, and
- Ensure the sustainable use of the technology.

4.6.1 Approach

In order to adhere to company-internal stewardship standards, the authorisation holder will:

- Develop a Technical Guide of Good Farming Practices for the farmers including the conditions of the Decision, and will inform growers, seed suppliers, processors and other stakeholders about the GM crop and its management and in particular the importance of the implementation of the measure to delay insect resistance.
- Promote the networks of the sales and technical organisations, through their routine visits to the farmers, ensuring a continuous and efficient communication link from the grower to the technology provider, especially in relation to complaints about product performance, difficulties with product management, compliance implementation and unexpected effects.
- Provide farmers with contact details and directions on where they can obtain more information and/or report any unexpected finding related to the GM crop and its cultivation.

4.6.2 Timeline

The stewardship programme will continue throughout the life cycle of the product as it is integrated in the commercial effort of the authorisation holder. Any information that may have an impact on the ERA or that is relevant for PMEM will be included in the regular reporting.

5 Reporting and review

5.1 Reporting adverse effects

In accordance with Article 20 of Directive 2001/18/EC, should any new information become available, from the users or other sources, with regard to the risks of the GMO(s) to human health or the environment after the written consent has been given, the authorisation holder shall:

- Immediately take the measures necessary to protect human health and the environment,
- Inform the competent authority thereof, and
- Revise the information and conditions specified in the notification.

Any indication of a possible adverse effect will be immediately reported to the Commission irrespective of the regular scheduled PMEM reports.

Where an unusual effect linked with the cultivation of the GM crop is observed, for which it is not certain that it should be classified as adverse; the authorisation holder will contact the Commission and the competent authority in order to establish the most appropriate course of action.

5.2 Format of reporting

The authorisation holder will submit annual monitoring reports to the Commission. At the same time the raw data shall be provided in order to allow different analyses and interrogation of the data by the European Commission and EFSA. The results will be presented in accordance with the standard reporting formats established by Commission Decision 2009/770/EC (EC 2009).

If required the authorisation holder will provide intermediary reports at 5 yearly intervals that provide an accumulative analysis of all pooled data from previous years. The authorisation holder will provide a report of all pooled data after a period of 10 years of PMEM.

5.3 Review and adaptation

The PMEM plan and associated methodology may be updated or adapted as necessary.