Environmental Monitoring Plan

1. Case-specific monitoring

An environmental risk assessment of NK603 × MON 810 maize was undertaken for import of NK603 × MON 810 maize and use in the E.U. as any other maize, excluding the cultivation NK603 × MON 810 maize varieties .

The GMO Panel has carried out the scientific assessment of the genetically modified maize NK603 x MON810 and considered that NK603 x MON810 maize is unlikely to have any adverse effect on human and animal health or the environment in the context of its intended uses.

The GMO Panel has evaluated the environmental monitoring plan proposed by the authorisation holder and considered that there is no need for a case-specific monitoring since no adverse effects were identified. The monitoring plan consisting in a general surveillance plan is in line with the intended uses for the GMO since the scope does not include cultivation.

2. General Surveillance

Any potential adverse effects of the GMO on human health and the environment, which were not anticipated in the environmental risk assessment., can be addressed under the general surveillance. The proposed plan in this section ensures that any unanticipated adverse effects associated with the placing on the market of NK603 × MON 810 maize, which come to the attention of the authorisation holder through existing company and external networks, will be reported, so that any reports can be further investigated by the appropriate authorities.

This chapter of the monitoring plan describes the general principles and methodology of general surveillance for unanticipated effects, and the reporting of surveillance information. In addition, specific examples of general surveillance actions are listed for NK603 × MON 810 maize, which are in accordance with the proposed plan.

2.1. General principles

General surveillance is largely based on routine observation and implies the collection, scientific evaluation and reporting of reliable scientific evidence, in order to be able to identify whether unanticipated, direct or indirect, immediate or delayed adverse effects have been caused by the placing on the market of a genetically modified (GM) crop in its receiving environment. By its nature, the prediction of unanticipated effects does not lend itself to the formulation of clear scientific hypotheses, and therefore it will be difficult to apply classical scientific methods to general surveillance.

The essential elements of the surveillance plan are:

i. The best possible chance of detecting an unanticipated adverse effect would be ensured by having an adequate number of people, with relevant experience, involved in the surveillance process. It follows, therefore, that those persons or organizations normally involved in the handling, storage, processing and use for animal feed of a GMO, or whose activities are connected with the receiving environment and human and livestock health, will be in the best position to

participate in a general surveillance plan.

ii. In order to allow detection of the broadest possible scope of unanticipated adverse effects the general surveillance will be performed by either selected, existing networks, or by specific company stewardship programs, or by a combination of both. Such networks are already in place in the majority of E.U. countries.

iii. While the principles for the entire E.U. should be the same, the intensity of surveillance activities is unlikely to be the same in each of the different E.U. countries since, for example, the GM crop may not be imported, processed and used in all Member States. Instead, the approach to surveillance should include the concept of general observation in representative environments and should be responsive to indications of possible adverse effects. Finally, the availability, extent and composition of existing networks in the different E.U. countries will have a direct influence on the existence and availability of baseline and surveillance information.

iv. Where there is scientifically valid evidence of a potential adverse effect (whether direct or indirect), linked to the genetic modification, then further evaluation of the consequence of that effect should be science-based and compared with baseline information. In many cases it may not be possible to establish a causal link between a potential adverse effect and use of a particular GM crop.

v. The surveillance plan should be focused and should not attempt to include all research, stewardship or other programs ongoing during the commercialization of the GM crop. It is recognized that independent research and other programs will be undertaken which are not associated with the detection of unanticipated adverse effects.

2.2. Areas of post-marketing surveillance for unanticipated effects

The people and their networks participating in the surveillance plan would tend, although not exclusively, to be those best suited to surveying particular aspects of the receiving environment (See practical examples in Section 2.5 of this monitoring plan).

Receiving environment

Those people and networks best suited to surveillance of the broader receiving environment where the GM crop is handled, processed and used would be those whose day-to-day work gave them regular experience of this environment.

Human and livestock health

Those people and networks having regular contact with handlers, processors, users and farm livestock, are best suited for surveillance of any unanticipated human occupational health and livestock health effects.

2.3. Methodology

The authorisation holder will ensure that awareness of the GM crops is made widely available by providing key information, for example:

o In accordance with the requirements of Directive 2001/18/EC, the authorisation holder shall provide international traders with the necessary information to comply with statutory requirements relating to the Placing on the Market of the

GM crop.

o Product briefings to selected networks

o Technical literature (e.g. product-specific information, company contact details)

In addition, further information on the product and relevant legislation will be available from a number of sources, including industry and government websites, official registers and government publications.

Primary sources of surveillance information

As discussed above, the use of existing networks to provide surveillance information is seen as a key aspect of ensuring that sufficient observers are available to identify and report possible unanticipated adverse effects, as well as ensuring methodological consistency and optimizing the expenditure of resources. This would include existing observation programs in the receiving environment, occupational health and livestock welfare. (See practical examples in Section 2.5 of this monitoring plan).

Other sources of surveillance information

Although not a formal part of the surveillance plan, it is appropriate to note that there is an extensive information network, with global reach, which will provide additional information on possible adverse effects arising from the use of GM crops. These include new and rapid means of access to information from across the globe through telecommunications, the media and Internet access. Through these means, many groups, including agronomists, ecologists, health professionals, and the general public now have unprecedented access to reports on the use world-wide of GM crops. In addition, electronic discussion sites, for example those of WHO, OECD, FAO, and consumer organizations, are valuable sources of information and communication for professionals and, in many cases, the general public.

Information collection and analysis

Surveillance information shall be collected from two primary sources:

1. Feedback from selected networks

2. Ongoing record keeping of reported potential adverse effects and other relevant information received via direct contacts with the authorisation holder

Evaluation of potential adverse effects

Where scientific evaluation of the observation confirms the possibility of an unanticipated adverse effect, this will be investigated further to establish a correlation, if present, between the use of the GM crop and the observed effect. The evaluation shall consider the consequence of the observed effect and remedial action.

2.4. Reporting

2.4.1. Responsibility

The authorisation holder is responsible to inform the Commission of the results of the surveillance.

This report shall clearly state which parts of the report is considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003.

Confidential parts of such report shall be submitted in separate documents.

2.4.2. Information that does not change the risk assessment

Frequency

Direct and immediate effects refer to primary effects on human health and the environment that, if they occur, are likely to be observed during the period of release of the GM crop. Market introduction of a specific GM crop, however, is a gradual process and the placing on the market might be very small during the initial time period of the consent. General surveillance reports shall be submitted on an annual basis, following placing on the market (first import). A final report will be made at the end of the consent.

Indirect effects refer to a causal chain of events with an effect on human health and the environment. Observations of indirect effects might, in some cases, be delayed. Since surveillance will also include the observation of potential indirect and/or delayed effects, a report covering potential indirect or delayed effects shall be submitted at the stage of re-evaluation or at the end of a given authorisation in the case where the authorisation holder does not apply for a renewal. An evaluation of the need for additional, post-consent surveillance will be included in such a report.

Content

The authorisation holder will submit a General Surveillance Report containing information obtained from participating networks.

2.4.3. Confirmed potential unanticipated adverse effects

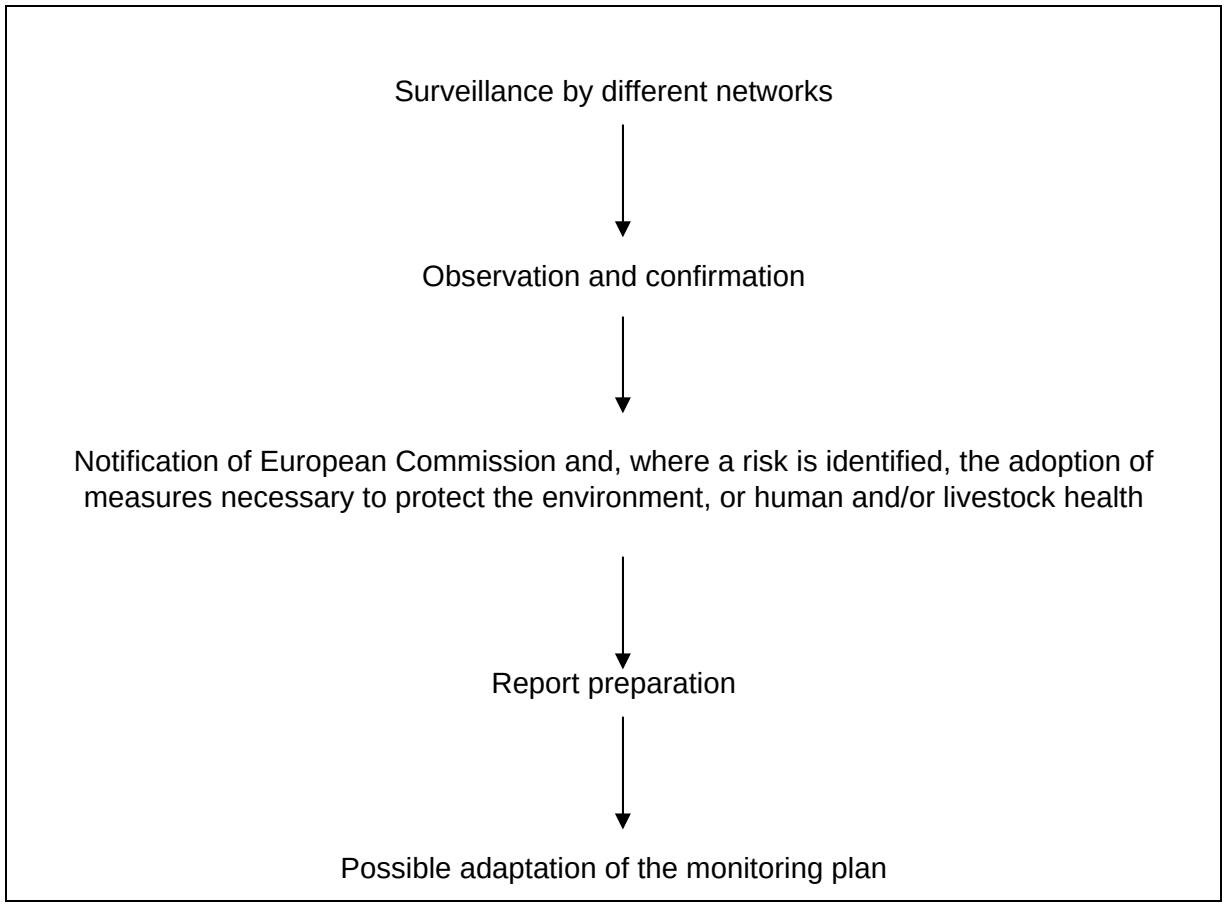
Frequency

If information indicates an adverse effect which might alter the existing risk assessment becomes available to the authorisation holder from users or other sources, the authorisation holder is required immediately to inform the Commission and, if necessary, to take proportional measures necessary to protect human or livestock health and/or the environment.

Content

Without prejudice to Articles 9(3) and 21(3), the authorisation holder will submit a Report, consisting of a scientific evaluation of the potential adverse effect and a conclusion on the safety of the product. The report will also include, where appropriate, the measures that were taken to ensure the safety of human or livestock health and/or the environment. These procedural steps are summarized in Figure 1.

Figure 1. Summary of procedures for the observation, analysis, reporting and management of an unanticipated adverse effect



2.5. Practical examples of actions according to the general surveillance plan for NK603 × MON 810

Annual imports of maize grain into the E.U. are market-driven but typically limited to about 2.5 million tonnes, the majority of which is imported into Spain and Portugal, given the annual tariff quotas applicable in these Member States. Annual tariff quotas in Spain and Portugal are announced and assigned by the E.U. Commission. Imports of maize from third countries into other E.U. Member States typically are small. Usually, a small number of large traders participate in the maize import market, which is strongly price-driven. Nearly all of the imported grain in Spain and Portugal is used for processing. Use of imported maize as unprocessed whole-grain is exceptional. On the basis of this information, the focus of the proposed general surveillance plan is considered adequate for monitoring of potential unanticipated adverse effects of the placing on the market of NK603 × MON 810 maize in the E.U. Based on the data presented, the proposed surveillance plan is considered appropriate for the type of market and proportionate to the expected scale of release for this maize.

The authorisation holder shall inform, through the relevant trade associations, all operators involved in the handling and use of viable NK603 x MON810 maize of the safety and general characteristics of the NK603 x MON810 maize and of the conditions as to general surveillance together with the requirement to report to the authorisation holder any adverse effect arising from handling and use of viable NK603 x MON810 maize.

- Following the approval of this maize in the E.U., the authorisation holder shall approach key stakeholders and key networks of stakeholders of the product (including international grain traders, maize processors and users of maize grain for animal feed) and inform them that the product has been authorised and may be present in grain shipments. The authorisation holder shall request key stakeholders and networks for their participation in the general surveillance of the placing on the market of this maize, in accordance with the provisions of Directive 2001/18/EC and the consent. Key stakeholders and networks will be requested to be aware of their use of this maize and to inform the authorisation holder in case of potential occurrence of any unanticipated adverse effects to health or the environment, which they might attribute to the import or use of this product. Appropriate technical information on NK603 × MON 810 maize shall be provided to them.

Between six months and one year after the first information regarding the regulatory approval of the product and the invitation to participate in the general surveillance plan has been sent, key stakeholders and key networks of stakeholders will be reminded of the recent approval of the product and the possibility of its presence in maize shipments. The request to report to the authorisation holder any adverse environmental effects that can be attributed to the use of the product will be repeated.

- In their communication, the authorisation holder shall request that participants in general surveillance report any adverse observations in a timely fashion, so that decisive (if necessary re-mediating) action can be taken, including risk-reducing measures where necessary. The authorisation holder shall investigate and record the details of such observations. In the main markets where the product will be used, stakeholders will also be given other options of communication, such as a local telephone number, in order to maximize the possibility to respond if necessary.

- In addition, the authorisation holder experts shall actively monitor existing information sources such as official websites and expert reports on GMOs in order to identify, collate and follow-up on potentially adverse observations made for this maize or any other relevant information, in particular with respect to occupational health, animal feed safety or putative ecological effects of the release of this maize.

Any recorded observations of adverse findings that are linked to the import and/or

use of this maize, which come to the attention of the authorisation holder, shall receive careful analysis in real time and re-mediating action where applicable. Adverse reports will be discussed in the mandatory general surveillance report. The general surveillance reports shall be sent to the European Commission. Given the limited volumes of grain imported into the E.U. and given the annual tariff quotas applicable to the two main markets, Spain and Portugal, general surveillance reports will be prepared on an annual basis, except any adverse findings that need immediate risk mitigation, which will be reported the E.U. Commission in accordance with Articles 9(3) and 21(3) of Regulation (EC) No 1829/2003.

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

- that the monitoring networks as specified in the monitoring plan collect the information relevant for the monitoring of NK603 x MON810 maize;
- that the members of these networks have agreed to make available that information to the authorisation holder before the date of the submission of the monitoring report.