

## **ENVIRONMENTAL MONITORING PLAN**

### **1. GENERAL**

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 the proposed monitoring plan for 1507xMON810xMIR162xNK603 maize has been developed according to the principles and objectives outlined in Annex VII of Directive 2001/18/EC and Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. The structure of the monitoring plan also takes into account the guidance on presentation of applications provided in the Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2006).

### **2. INTERPLAY BETWEEN ENVIRONMENTAL RISK ASSESSMENT AND MONITORING**

The scope of this application is the authorisation of 1507xMON810xMIR162xNK603 maize for import, processing, food and feed use in the European Union (EU) under Regulation (EC) No. 1829/2003. The scope of the application does not include authorisation for the cultivation of 1507xMON810xMIR162xNK603 maize seed products in the EU.

An environmental risk assessment (ERA) was carried out for 1507xMON810xMIR162xNK603 maize according to the principles laid down in Annex II to Directive 2001/18/EC and Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC. The scientific evaluation of the characteristics of 1507xMON810xMIR162xNK603 maize in the ERA (Section 5 of Part II of this application) has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of 1507xMON810xMIR162xNK603 maize relative to:

1. Persistence and invasiveness
2. Selective advantage or disadvantage
3. Potential for gene transfer
4. Interactions between the GM plant and target organisms
5. Interactions of the GM plant with non-target organisms
6. Effects on human health
7. Effects on animal health
8. Effects on biogeochemical processes
9. Impacts of the specific cultivation, management and harvesting techniques
10. Potential interactions with the abiotic environment.

### **3. CASE-SPECIFIC GM PLANT MONITORING**

As discussed in Section 2, the scientific evaluation of the characteristics of 1507xMON810xMIR162xNK603 maize in the ERA has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of 1507xMON810xMIR162xNK603 maize. It is therefore considered that there is no need for case-specific monitoring.

### **4. GENERAL SURVEILLANCE FOR UNANTICIPATED ADVERSE EFFECTS**

#### **4.1. APPROACH**

General surveillance is not based on a particular hypothesis and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the ERA

The scope of this application is the authorisation of 1507xMON810xMIR162xNK603 maize for import, processing, food and feed uses. The scope of the application does not include authorisation for the cultivation of 1507xMON810xMIR162xNK603 maize seed products.

Therefore, exposure to the environment will be limited to unintended release of 1507xMON810xMIR162xNK603 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity including 1507xMON810xMIR162xNK603 maize destined for processing into animal feed or human food products. Exposure can be controlled by clean up measures and the application of current practices used for the control of any adventitious maize plants, such as manual or mechanical removal and the application of herbicides (with the exception of glyphosate or glufosinate herbicides).

However and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, general surveillance on 1507xMON810xMIR162xNK603 maize will be undertaken for the duration of the authorisation. The general surveillance will take into consideration, and be proportionate to, the extent of imports of 1507xMON810xMIR162xNK603 maize and use thereof in the Member States.

In order to increase the possibility of detecting any unanticipated adverse effects, a monitoring system will be used, which involves the authorisation holder and operators handling and using viable 1507xMON810xMIR162xNK603 maize. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable 1507xMON810xMIR162xNK603 maize.

A detailed description of the methodology proposed for general surveillance of 1507xMON810xMIR162xNK603 maize is provided in Section 4.6.

## **4.2. BASELINES**

Since the intended use of 1507xMON810xMIR162xNK603 maize is the same as that of any other commercial maize, the procedures for the import, handling and processing of 1507xMON810xMIR162xNK603 maize will be the same and have been considered in the development of the monitoring plan. The baseline and controls for general surveillance will rely on the historical knowledge and experience with non-GM maize as comparable reference where necessary.

## **4.3. TIME-PERIOD**

General surveillance of 1507xMON810xMIR162xNK603 maize will be undertaken for the duration of the authorisation period for 1507xMON810xMIR162xNK603 maize for import and processing.

## **4.4. ASSIGNING RESPONSIBILITIES**

The authorisation holder is responsible for ensuring that the monitoring plan is put in place and properly implemented in accordance with the conditions of the authorisation.

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

1. That the monitoring networks as specified in the monitoring plan collect the information relevant for the monitoring of 1507xMON810xMIR162xNK603 maize.
2. 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.

The third parties involved in the general surveillance will report any potential unanticipated adverse effects to the authorisation holder, who will immediately investigate and inform the European Commission in accordance with Regulation (EC) No 1829/2003, as described in Section 5.

## **4.5. EXISTING SYSTEMS**

### **Primary sources of information**

The authorisation holder is not involved in commodity trade with 1507xMON810xMIR162xNK603 maize. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable 1507xMON810xMIR162xNK603 maize. They are exposed to the imported viable 1507xMON810xMIR162xNK603 maize and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use. The routine surveillance is based on the HACCP principles as outlined in Annex I.

Since traders may commingle 1507xMON810xMIR162xNK603 maize with other commercial maize, including authorised GM maize, the authorisation holder is working together with other members of the plant biotechnology industry within the European Association of Bioindustries (EuropaBio) and

trade associations representing the relevant operators in order to implement a harmonised monitoring methodology. The following networks are currently involved:

*1. Importers / Traders*

- a. COCERAL is the European association representing the cereals, rice, feedstuffs, oilseeds, oils and fats and agro-supply trade in the European Union. Its members are the national trade organisations that represent collectors, distributors, exporters, importers and agribulk storers of the above mentioned commodities in the majority of Member States. The main importers of cereals and feedstuffs into the EU are members of COCERAL.
- b. Also see: <http://www.coceral.com/cms/beitrag/10010169/227870>.

*2. Silo Operators*

- a. UNISTOCK is the European association representing professional storekeepers for agribulk commodities within the EU. It regroups representatives from 11 Member States and is itself a member of COCERAL. Commodity imports enter the EU by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.
- b. Also see: <http://www.coceral.com/cms/beitrag/10010260/232602>

*3. Processors*

- a. FEDIOL, the federation of the EU Oil and Protein Meal Industry, represents the interests of the European crushers of oilseeds meals producers and vegetable oils producers/processors. Its members represent 80% of the EU industry and hold 147 oilseeds processing and vegetable oils and fats production facilities across Europe.
- b. Also see: <http://www.fediol.be/1/main1.php>.

These associations represent the majority of European operators importing, handling and processing viable maize commodity. They work closely together with a continuous and efficient flow of communication between them, particularly, through the documentation that needs to accompany any shipment containing GMOs in accordance with the labelling and traceability requirements of Regulation (EC) No 1830/2003, and are therefore best placed to observe and report any unanticipated adverse effects.

Other networks consisting of operators further down the food and feed chain have not been selected for the general surveillance of viable 1507xMON810xMIR162xNK603 maize, because they focus on processed, non-viable material.

**Additional sources of information**

In addition to the aforementioned existing monitoring systems, extensive independent research by scientists with a wide range of expertise is another valuable source of information on potential adverse effects arising from the use of GMOs. The authorisation holder will actively screen relevant reports and peer-reviewed publications on the use of 1507xMON810xMIR162xNK603 maize, in order to identify potential unforeseen adverse effects linked to 1507xMON810xMIR162xNK603 maize.

#### 4.6. MONITORING METHODOLOGY

The authorisation holder, together with other members of the plant biotechnology industry and EuropaBio, will implement general surveillance of viable GM maize, including 1507xMON810xMIR162xNK603 maize, with the help of the selected networks described in Section 4.5.

The different parties agreed on a general framework for monitoring of GMOs, including 1507xMON810xMIR162xNK603 maize, as follows:

1. The authorisation holder represented by EuropaBio will:
  - a. Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
  - b. Inform operators concerning the authorisation, safety and general characteristics of 1507xMON810xMIR162xNK603 maize and of the conditions as to general surveillance
  - c. Set up and maintain a website dedicated to operators including detailed information on 1507xMON810xMIR162xNK603 maize. The website, hosted on the EuropaBio website under <http://www.europabio.org/information-operators>, contains the following information:
    - i. An introduction to the purpose of the website
    - ii. A table giving an overview of all currently approved GM plant products subject to general surveillance
    - iii. A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU
    - iv. A contact point at EuropaBio for information exchange on any of the GM plant products
    - v. The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.
  - d. Contact the selected networks of operators annually reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).
2. The selected networks of operators (European trade associations) will:
  - a. Inform and remind their member organisations and companies on an annual basis:
    - i. to monitor for potential unanticipated adverse effects
    - ii. that, in the framework of their management or safety standards (ISO, HACCP, ...), procedures must be in place and implemented to limit losses and spillage of viable maize and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential adverse effects
    - iii. to inform and remind their own member companies of this requirement
    - iv. to report back any adverse effect reported to them to the European trade associations
  - b. Report to the authorisation holders directly or via EuropaBio
    - i. at least annually, regardless whether an adverse effect was observed or not
    - ii. immediately any adverse effects reported to them.

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL will notify EuropaBio of the results of the general surveillance on an annual basis. EuropaBio will forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission, as described in Section 5.

The general surveillance information reported to and collected by the authorisation holder from the European trade associations or other sources will be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and 1507xMON810xMIR162xNK603 maize can be established. If the investigation establishes that 1507xMON810xMIR162xNK603 maize was present when the adverse effect was identified, and confirms that 1507xMON810xMIR162xNK603 maize is the cause of the adverse effect, the authorisation holder will immediately inform the European Commission, as described in Section 5.

## **5. REPORTING THE RESULTS OF MONITORING**

In accordance with Regulation (EC) No 1829/2003, the authorisation holder is responsible to inform the European Commission of the results of the general surveillance.

If information that confirms an adverse effect of 1507xMON810xMIR162xNK603 maize and that alters the existing risk assessment becomes available, the authorisation holder will immediately investigate and inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, will define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

The authorisation holder will submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report will contain information on any unanticipated adverse effects that have arisen from handling and use of viable 1507xMON810xMIR162xNK603 maize.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of 1507xMON810xMIR162xNK603 maize and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

The report will also clearly state which parts of the provided information are 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.

## **6. REVIEW AND ADAPTATION**

The monitoring plan and associated methodology will be reviewed and updated or adapted as necessary.