Application for authorisation to place on the market MON 87769 × MON 89788 soybean in the European Union, according to Regulation (EC) No. 1829/2003 on genetically modified food and feed

Monitoring report

Data protection.
This application contains scientific data and other information which are protected in accordance with Art. 31 of Regulation (EC) No 1829/2003.

11. Environmental monitoring plan

11.1 General

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No. 1829/2003 the proposed monitoring plan for MON 87769 × MON 89788 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[1].

11.2 Interplay between environmental risk assessment and monitoring

The scope of this application is the authorisation of MON 87769 × MON 89788 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 MON 87769 × MON 89788 seed products in the EU.

An environmental risk assessment (E.R.A.) was carried out for MON 87769 × MON 89788 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 MON 87769 × MON 89788 in the E.R.A. (*see* Section D.9 and D.10) 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 MON 87769 × MON 89788 relative to:

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

11.3 Case-specific GM plant monitoring

As discussed in Section D.11.2, the scientific evaluation of the characteristics of MON 87769 × MON 89788 in the E.R.A. 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

[1] EFSA: http://www.efsa.europa.eu/cs/BlobServer/Guidance_of_Panel/gmo_guidance_derived_feed_food.pdf?ssbinary=true - Accessed June 7, 2010

uses of MON 87769 × MON 89788. It is therefore considered that there is no need for case-specific monitoring.

11.4 General surveillance for unanticipated adverse effects

11.4.1. Approach

In accordance with Council Decision 2002/811/EC, 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 E.R.A.

Exposure to the environment will be limited to unintended release of MON 87769 × MON 89788, which could occur for example via substantial losses during loading/unloading of the viable commodity including MON 87769 × MON 89788 destined for processing into animal feed or human food products. However, such exposure is highly unlikely to give rise to an adverse effect and can be easily controlled by clean up measures and the application of current practices used for the control of any adventitious soybean plants, such as manual or mechanical removal and the application of herbicides. Furthermore, unintended environmental effects due to the unintended release of MON 87769 × MON 89788 will be no different than that of other commercialsoybean.

However and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the E.R.A., general surveillance on MON 87769 × MON 89788 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 MON 87769 × MON 89788 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 MON 87769 × MON 89788. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable MON 87769 × MON 89788.

A detailed description of the methodology proposed for general surveillance of MON 87769 × MON 89788 is provided in Section D.11.4.6.

11.4.2. Baselines

Since the intended use of MON 87769 × MON 89788 is the same as that of any other commercial soybean, the procedures for the import, handling and processing of MON 87769 × MON 89788 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 soybean as comparable reference where necessary.

11.4.3. Time period

General surveillance of MON 87769 × MON 89788 will be undertaken for the duration of the authorisation period for MON 87769 × MON 89788 for import and processing.

11.4.4. Assigning responsibilities

The authorisation holder is responsible for ensuring that the monitoring plan included in the application is put in place and properly implemented in accordance with the conditions of the authorisation. 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 D.11.5.

11.4.5. Existing systems

Primary sources of information

The authorisation holder is not involved in commodity trade with MON 87769 × MON 89788. 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 MON 87769 × MON 89788. They are exposed to the imported viable MON 87769 × MON 89788 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 MON 87769 × MON 89788 with other commercial soybean, including authorised GM soybean, 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:

⇒ *Importers / Traders*

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.

Also see: http://www.coceral.com/cms/beitrag/10010169/227870 - Accessed July 14, 2010

⇒ *Silo Operators*

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.

Also see: http://www.coceral.com/cms/beitrag/10010260/232602 - Accessed July 14, 2010

⇒ *Processors*

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.

Also see: http://www.fediol.be/1/main1.php - Accessed July 14, 2010

These associations represent the majority of European operators importing, handling and processing viable soybean 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 MON 87769 × MON 89788, 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 applicant will actively screen peer-reviewed publications relevant to MON 87769 × MON 89788 by the scientific community.

11.4.6. Monitoring methodology

The authorisation holder, together with other members of the plant biotechnology industry and EuropaBio, will implement GS of viable GM soybean, including MON 87769 × MON 89788, with the help of the selected networks described in Section D.11.4.5.

The different parties agreed to collaborate on the following basis:

⇒ The authorisation holder represented by EuropaBio will:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
- Inform the operators in a timely fashion of any newly approved GM plant products for import and processing under Regulation (EC) No. 1829/2003 or Directive 2001/18/EC subject to general surveillance
- Set up and maintain a website dedicated to operators including detailed information on MON 87769 × MON 89788. The website, hosted on the EuropaBio website under www.europabio.org/InfoOperators, (Accessed July 14, 2010) contains the following information:
  - An introduction to the purpose of the website

- A table giving an overview of all currently approved GM plant products subject to general surveillance
- 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
- A contact point at EuropaBio for information exchange on any of the GM plant products

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.

- Contact the selected networks of operators annually, providing them with an update on the approved GM plant products subject to general surveillance and reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).

⇒ The selected networks of operators (European trade associations) will:

- Inform and remind their member organisations and companies on an annual basis:
  - to monitor for potential unanticipated adverse effects
  - to inform and remind their own member companies of this requirement
  - to report back any adverse effect reported to them to the European trade associations
- Report to the authorisation holders directly or via EuropaBio:
  - at least annually, regardless whether an adverse effect was observed or not
  - 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 D.11.5.

The current approach used for the collection of general surveillance information may still be adjusted in the future based on experience gained by the selected networks of operators with current and future GM plant products.

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 MON 87769 × MON 89788 can be established. If the investigation establishes that MON 87769 × MON 89788 was present when the adverse effect was identified, and confirms that MON 87769 × MON 89788 is the cause of the adverse effect, the authorisation holder will immediately inform the European Commission, as described in Section D.11.5.

11.5 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 MON 87769 × MON 89788 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 MON 87769 × MON 89788.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MON 87769 × MON 89788 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.

11.6 Review and adaptation

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

ANNEX I

to

Monitoring Plan conforming with Annex VII to Directive 2001/18/EC

Scope

The purpose of this document is to describe the principles operators shall comply with by enforcing their food and feed safety obligations and responsibilities as operators. As such, the Annex describes the principles the operators apply for all the commodities they deal with (GM and non-GM).

Being provided as complement to Section 4.5 "*Existing systems*" of the monitoring plan, this document exempts operators from any additional duty which is not foreseen by the hereunder recalled and collected legislation.

General principles

According to the monitoring plan,

- *The monitoring methodology needs to be predominantly based on collaboration with third parties, such as importers/traders; silo operators and processors.*

  Ports, silos and processing facilities are identifiable as the receiving environments and, consequently, the areas in which the general surveillance should be principally carried out.

- *Operators involved in the import, handling and processing are exposed to the imported GM commodities 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 activities of the operators are carried out within the areas of interest, identified as the receiving environments.

- *Exposure to the environment will be limited to unintended release of the viable GM commodity destined for processing into animal feed or human food products, which could occur for example via substantial losses during loading/unloading. Such exposure is highly unlikely to give rise to an adverse effect and can be easily controlled by clean up measures and the application of current practices used for the control of any adventitious plants such as manual or mechanical removal and the application of appropriate herbicides.*

Additional Information on the existing systems and routine practices

The following information on the existing systems and routine practices supplements the monitoring plan, particularly its Section 4.5:

By means of Articles 3(3) and (6) of Regulation (EC) No 178/2002 (General Food Law – GFL) importers / traders, silo operators and processors are "food and feed business operators" and thus identified as the natural or legal persons responsible for ensuring that the requirements of food/feed law are met within the food and feed business under their control.

Specifically, importers/traders, silo operators and processors are responsible for ensuring that the requirements of the laws, regulations and administrative provisions governing food (and feed) in general and food safety in particular are met, whether at Community or national level, covering *any stage of production, processing and distribution,* respectively and distinctively, within the ports, silo and processing facilities.

Without prejudice to Regulation (EC) No. 1829/2003, Directive 2001/18/EC and its Annexes, to Council Decision 2002/811/EC and to the monitoring plan for the general surveillance of GM crop, above all the operators shall comply with the food and feed safety legislation (and related acts) at any stage of the activity they carry out, *i.e.* production, import, processing and distribution.

Specifically, importers/traders, silo operators and processors and their respective activities are subjected by law to:

- **Regulation (EC) No 178/2002** of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Chapter II of this Regulation lays down general principles of food/feed safety horizontally applicable independently from the commodities the operators are dealing with;

- **Regulation (EC) No 852/2004** of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuff, laying down general rules for food business operators on the hygiene of foodstuff, and **Regulation (EC) No 183/2005** laying down requirements for feed hygiene which both stipulate that:

    - Food/feed business operators shall put in place, implement and maintain a permanent written procedure or procedures based on the Hazard Analysis of Critical Control Point (HACCP) principles which consist of:

        (a) Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;

        (b) Identifying the critical control points at the stop or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

(c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

(d) Establishing and implementing effective monitoring procedures at critical control points;

(e) Establishing corrective actions when monitoring indicates that a critical control point is not under control;

(f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and

(g) Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).