Application for renewal of the authorisation of Bt11 maize import in the European Union under Articles 11 and 23 of Regulation (EC) No 1829/2003

ENVIRONMENTAL MONITORING PLAN

This document is complete as of September 2018. Since it is submitted as one part of a regulatory application, which is subject to an on-going regulatory review, it may be subject to later amendment or replacement. The information may also be supplemented with additional material requested by regulatory authorities. As such, it may only be considered properly with reference to those later amendments or supplementary materials and in the context of the dossier as a whole.

ENVIRONMENTAL MONITORING PLAN

1 General

According to Article 4 of the Commission Decision 2009/866/EC (EC 2009) on Bt11 maize, a monitoring plan for environmental effects should be put in place and implemented. Since the placing on the market of Bt11 maize, a post-market environmental monitoring (PMEM) plan has been successfully implemented and no unanticipated adverse effects have been detected. The results of the monitoring plan therefore confirm the previous conclusions of the risk assessment and since no modification to the use of Bt11 is foreseen there is no *a priori* reason to modify the PMEM as a result of characteristics of the product.

However, it should be noted that the format of the current harmonised Industry monitoring plan has been updated and this current plan reflects those changes.

As required by Article 5(5)(b) and 17(5)(b) of Regulation (EC) No 1829/2003 the proposed Post-Market Environmental Monitoring (PMEM) plan for Bt11 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 PMEM plan also takes into account the approaches and conclusions provided in the Scientific Opinion on guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants (EFSA, 2011).

2 Interplay between environmental risk assessment and monitoring

The scope of this application is the renewal of the authorisation of Bt11 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 Bt11 maize seed products in the EU.

An environmental risk assessment (e.r.a.) provided for the authorization of Bt11 maize was carried out for 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 Bt11 maize 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 uses of Bt11 maize. No information has become available since that time, which would impact the previous conclusions on the safety of Bt11 maize for human and animal health or the environment, and no modification to the use of the product is foreseen, therefore no specific product related change to the existing environmental monitoring plan for Bt11 maize products is proposed. However it should be noted that the latest plan has been modified to reflect the latest Industry harmonised PMEM plan.

3 Case-specific GM plant monitoring

As discussed in the environmental risk assessment (e.r.a.) provided for the authorization of Bt11 maize, the scientific evaluation of the characteristics of Bt11 maize 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 uses of Bt11 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 Genetically Modified Organism (GMO) or its use for human and animal health or the environment that were not predicted in the e.r.a.

The scope of this application is the renewal of the authorisation of Bt11 maize for import, processing, food and feed uses. The scope of the application does not include authorisation for the cultivation of Bt11 maize seed products.

Therefore, exposure to the environment will be limited to unintended release of Bt11 maize, which could occur for example via substantial losses during loading/unloading of the viable commodity including Bt11 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.

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 Bt11 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 Bt11 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 Bt11 maize. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable Bt11 maize.

A detailed description of the methodology proposed for general surveillance of Bt11 maize is provided in Section 4.6.

4.2 Baselines

Since the authorized and still intended use of Bt11 maize is the same as that of any other commercial maize, the procedures for the import, handling and processing of Bt11 maize will be the same and have been considered in the development of the PMEM 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 Bt11 maize will be undertaken for the duration of the authorisation period for Bt11 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:

- That the monitoring networks as specified in the monitoring plan collect the information relevant for the monitoring of Bt11 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.

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 of this PMEM.

4.5 Existing systems

Primary sources of information

The authorisation holder is not involved in commodity trade with Bt11 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 Bt11 maize. They are exposed to the imported viable Bt11 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 reflected on the website of the trade associations representing the operators involved in the PMEM (see below).

Since traders may commingle Bt11 maize with other commercial 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:

⇒ *Importers / Traders*
COCERAL is the European association of trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agro supply. It represents the interests of the European collectors, traders, importers, exporters and port silo storekeepers of the above mentioned agricultural products. The main importers of cereals and feedstuffs into the EU are members of COCERAL.
Also see: http://www.coceral.com/

⇒ *Silo Operators*
UNISTOCK is the European association representing professional storekeepers for agri-bulk commodities in the EU. UNISTOCK full and extraordinary members are present in

twelve countries and UNISTOCK is itself a full 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.unistock.be/

⇒ *Processors*
FEDIOL, the federation of the EU vegetable Oil and Protein Meal Industry, represents the interests of the European crushers of oilseeds meals producers and vegetable oils producers/processors. Its members represent 85% of the EU industry.
Also see: http://www.fediol.eu/

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 Bt11 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 Bt11 maize, in order to identify potential unforeseen adverse effects linked to Bt11 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 Bt11 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 Bt11 maize, as follows:

⇒ 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 PMEM plan.
- Inform operators concerning the authorisation, safety and general characteristics of Bt11 maize and of the conditions as to general surveillance
- Set up and maintain a website dedicated to operators including detailed information on Bt11 maize. The website, hosted on the EuropaBio website under http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information/introduction, 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 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
  - 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 Bt11 and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential 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 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 Bt11maize can be established. If the investigation establishes that Bt11maize was present when the adverse effect was identified, and confirms that Bt11maize 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 Bt11 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 confirmed 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 unanticipated adverse effects, if any, that have arisen from handling and use of viable Bt11 maize.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of Bt11 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 PMEM plan and associated methodology will be reviewed and updated or adapted as necessary.

REFERENCES

EC, 2009. Commission Decision of 30 November 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2009) 9399). (2009/866/EC). Official Journal of the European Union. L314, 102-105. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32009D0866&from=DE (EN)

EFSA, 2011. Guidance on the post-market environmental monitoring (PMEM) of genetically modified plants. The EFSA Journal 2011, 9(8) 2316, 40 pp.