2019 Annual Report on the General Surveillance of A2704-12 Soybean in the EU

BASF Agricultural Solutions Seed US LLC
Represented by
BASF SE

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ANNUAL REPORT ON THE GENERAL SURVEILLANCE OF A2704-12 SOYBEAN IN THE EU

1. General Information

1.1 Crop/trait(s): A2704-12 Soybean / Glufosinate-ammonium herbicide tolerance

1.2 Decision authorisation number pursuant to Directive 2001/18/EC and number and date of consent pursuant to Directive 2001/18/EC: NA[1]

1.3 Decision authorisation number and date of authorisation pursuant to Regulation (EC) No 1829/2003: Commission Decision 2008/730/EC of 8 September 2008

1.4 Unique identifier: ACS-GMØØ5-3

1.5 Reporting Period from: July 2018 to June 2019

1.6 Other monitoring reports have been submitted in respect of Cultivation: No

2. Executive Summary

On 8 September 2008, Commission Decision 2008/730/EC[2] (as amended by Commission Implementing Decision (EU) 2019/1195[3] addressed to BASF SE) authorised the placing on the market of A2704-12 soybean pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. This authorisation covers the following products:
a) foods and food ingredients containing, consisting of, or produced from A2704-12 soybean;
b) feed containing, consisting of, or produced from A2704-12 soybean;
c) products other than food and feed containing or consisting of A2704-12 soybean for the same uses as any other soybean with the exception of cultivation.

In accordance with Directive 2001/18/EC and Article 4 of Commission Decision 2008/730/EC, the authorisation holder for A2704-12 soybean, shall ensure that the monitoring plan, contained in the application and consisting of a general surveillance plan, is put in place and implemented. In addition, Article 4 of Commission Decision 2008/730/EC stipulates that the authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan.

In view of the obligation to submit annual monitoring reports for A2704-12 soybean, the authorisation holder has undertaken a number of general surveillance activities accompanying the placing on the market of A2704-12 soybean in the EU. An updated status on these activities is given in this annual monitoring report.

[1] NA: not applicable.
[2] Commission Decision of 8 September 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2008/730/EC). Official Journal of the European Union L 247/50, 16.9.2008.
[3] Commission Implementing Decision (EU) 2019/1195 of 10 July 2019 amending Decisions 2008/730/EC, 2008/837/EC, 2009/184/EC, 2011/354/EU, Implementing Decisions 2012/81/EU, 2013/327/EU, (EU) 2015/690, (EU) 2015/697, (EU) 2015/699, (EU) 2016/1215, (EU) 2017/1208 and (EU) 2017/2451 as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean, cotton, oilseed rape and maize. *Official Journal of the European Union* L 187/43, 12.7.2019.

To date, the general surveillance accompanying the placing on the market of A2704-12 soybean indicates that there have been no adverse health or environmental effects associated with the importation or use of A2704-12 soybean. Therefore, no revisions to the general surveillance plan are considered necessary for A2704-12 soybean.

3. Uses of GMOs Other Than Cultivation

3.1 Commodity imports into the Community

3.1.1 Commodity crop (GM + non-GM) imports into the Community by country of origin (actuals for the reporting period of July 2018 to June 2019)[4]

Country of origin[5]	**Quantity[6] (tons)**
United States*	9.116.610,2
Brazil*	4.840.173,1
Ukraine	362.208,4
Canada*	249.674,1
Uruguay	175.657,8
Argentina*	9.009,3
All Other Countries	305.073,8
TOTAL extra-EU	**15.058.406,7**

[4] Source: Eurostat (2019)
[5] Data are provided for the main exporting countries, which combined make up approximately 98% of total soybean imports. Data for exporting countries where A2704-12 soybean is authorised for cultivation is marked with "*".
[6] The quantities are total EU-28 imports.

3.1.2 Commodity Crop (GM + non-GM) imports into the Community by country of destination (actuals for the reporting period of July 2018 to June 2019)[4]

Destination country	**Quantity[6] (tons)**
Netherlands	4.109.405,8
Spain	3.392.808,3
Germany	2.315.458,4
Italy	1.685.146,2
Portugal	1.070.678,4
United Kingdom	701.870,6
Belgium (and Luxembourg)	587.966,1
France	564.835,7
Greece	305.996,2
Romania	169.840,9
Poland	67.498,2
Hungary	25.952,6
Finland	25.191,0
Ireland	11.254,4
Denmark	9.208,3
Sweden	6.111,4
Czech Republic	4.857,1
Austria	2.942,4
Lithuania	1.290,6
Slovakia	45,8
Bulgaria	36,2
Malta	12,1
TOTAL	**15.058.406,7**

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The authorisation holder, via EuropaBio, has collected EUROSTAT data on soybean imports into the EU for the period of July 2018 to June 2019. According to this data, total extra-EU imports of soybean was 15.058.406,7 tons and the main exporters of soybean to the EU were the United States, Brazil, Ukraine, Canada and Uruguay which together accounted for 98% of total extra-EU soybean imports.

For the period of July 2018 to June 2019, A2704-12 soybean was authorised for cultivation in the United States, Canada, Argentina and Brazil. The total EU soybean imports from the United States, Canada, Argentina and Brazil were 9.116.610,2, 249.674,1, 9.009,3 and 4.840.173,1 tons, respectively. During the period of July 2018 to June 2019, United States, Canada, Argentina and Brazil soybean exports to the EU accounted for around 94% of total extra-EU soybean imports (**Table 3.1.1**).

Table 3.1.2 summarizes the total soybean imports from outside the EU-28 by destination. The main import countries for soybean in the EU during the period of July 2018 to June 2019 were the Netherlands, Spain, Germany and Italy. They are accounting together for nearly 76% of the total soybean imports. Other main import markets of extra-EU soybean were Portugal, the United Kingdom, Belgium (and Luxembourg) and France.

3.2 General Surveillance

3.2.1 Description of General Surveillance

The current approach used for general surveillance represents the consensus between all authorisation holders within EuropaBio and has been endorsed by the operators involved in the trade of viable soybean commodity (listed in Section 3.2.2).

The authorisation holder is not involved in commodity trade with A2704-12 soybean. 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 A2704-12 soybean. They are exposed to the imported viable A2704-12 soybean 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.

Since traders may commingle A2704-12 soybean 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 different parties agreed to collaborate on the following basis:

⇒ The consent holder represented by EuropaBio shall:

- 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 that provides an overview and detailed information on approved GM plant products subject to general surveillance. The website, hosted on the EuropaBio website under

  https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information, 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 Decisions(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) shall:

- 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 consent holders directly of via EuropaBio
  - at least annually, regardless of whether an adverse effect was observed or not
  - immediately any adverse effects reported to them

Consequently, the European trade associations shall notify EuropaBio of the results of the general surveillance on an annual basis. The report shall cover all approved GM plant products subject to general surveillance. EuropaBio shall forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission.

The general surveillance information reported to and collected by the authorisation holder from the European trade associations or other sources shall 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 A2704-12 soybean can be established. If the investigation establishes that A2704-12 soybean was present when the adverse effect was identified, and confirms that A2704-12 soybean is the cause of the adverse effect, the authorisation holder shall immediately 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, shall 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.

As described in the bullet points above, the authorisation holder shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report shall contain information on any unanticipated

adverse effects that have arisen from handling and use of viable A2704-12 soybean.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of A2704-12 soybean and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

3.2.2 Details of industry, environmental, food and/or feed related surveillance networks used during General Surveillance

The authorisation holder, together with other members of the plant biotechnology industry and EuropaBio, will implement general surveillance of viable GM soybean, including A2704-12 soybean, with the help of the selected networks described below, according to the methodology outlined in the authorisation holder's general surveillance plan and as detailed in Section 3.2.1. 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 agrosupply. 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 agribulk commodities within 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, meal producers and vegetable oil producers/processors.

Also see: http://www.fediol.eu/

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 A2704-12 soybean, because they focus on processed, non-viable material.

3.2.3 Details of information and/or training provided to importers, traders, handlers, processors, etc.

The authorisation holder directly informed the selected network of operators (i.e. COCERAL, UNISTOCK and FEDIOL) that A2704-12 soybean was authorised pursuant to Regulation (EC) No 1829/2003 by Commission Decision 2008/730/EC and that a website dedicated to operators that provides an overview and detailed information on the authorised A2704-12 soybean has been made available as described below.

Specific information concerning the safety, general characteristics and the general surveillance conditions for A2704-12 soybean was uploaded in a website dedicated to trade associations representing the relevant operators that import, handle and process viable soybean commodity in the EU, providing an overview and detailed information on approved GM plant products subject to general surveillance. The website, hosted on the EuropaBio website under http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information , 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. The document providing documentation on characteristics and safety for A2704-12 soybean is attached as Appendix 1 to this annual monitoring report.

-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.

3.2.4 Results of General Surveillance

The reporting by the trade associations takes place at the end of their business year, *i.e.* end of June. Therefore, EuropaBio reminded the trade associations to provide their annual report on any occurrence of unanticipated adverse effects arising from the approved GM products, including A2704-12 soybean placed on the market during the period from July 2018 to June 2019.

The trade associations implemented the monitoring in the framework of their routine surveillance of the commodities (GM and non-GM) they handle and use. As required in the monitoring plan, they reminded their members "*to monitor for potential unanticipated adverse effects; that, in the framework of their management or safety standards (ISO, HACCP, etc), procedures must be in place and implemented to limit losses and spillage of viable GMOs 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; and to report back any adverse effect reported to them to the European*

trade associations;" .

COCERAL, UNISTOCK and FEDIOL members have in place Good Hygiene Practices and Good Manufacturing Practices in their daily operations, at the level of imports, storage, handling, and internal transport of grains and oilseeds commodities, as well as at the level of oilseed crushing and vegetable oil refining, irrespective of the botanical species of the commodity. Such practices form the pre-requisite programmes which are the foundation upon which their HACCP systems are built. Measures implemented in this context to limit losses and spillage of viable grains and oilseeds, as well as clean-up and eradication measures (in case of accidental spillage), allow trade associations to report any adverse effect that would be considered as "unusual" or "unanticipated" and potentially attributable to GMOs.

The trade associations informed EuropaBio in a format that reiterates the terms of the agreement of the general surveillance system and reports on the outcome of the monitoring. The format allows the authorisation holder to comply with the requirement to give evidence to the Commission and the Competent Authorities that the system is in place; that the trade associations are aware of the requirement to monitor; and, that they are providing information on any observed unanticipated adverse effects, if any.

The reports received from COCERAL, UNISTOCK and FEDIOL indicate that no adverse effects were reported from their members, thus implying that no adverse effects were linked to the presence of A2704-12 soybean in the time period from July 2018 to June 2019 (see Appendix 2 and Appendix 3). Furthermore, no incidents in relation to the placing on the market of A2704-12 soybean have been reported to EuropaBio or the authorisation holder since July 2018 to date.

3.2.5 Additional Information

Not applicable since no adverse or unanticipated effects were reported.

3.2.6 Review of peer-reviewed publications

The authorisation holder actively monitors peer-reviewed scientific literature related to its products. In the light of the 2019 annual general surveillance report for A2704-12 soybean, a literature review was performed for the A2704-12 soybean and the newly expressed protein PAT/*pat*. A broad literature search was performed using a comprehensive collection of bibliographic databases, covering a database entry period from October 1, 2018 to September 30, 2019. Additional sources of information, such as web pages of food safety, agriculture, and biotechnology-related organizations were searched for the period of October 1, 2018 to September 30, 2019, along with the bibliographies of relevant reviews. The references identified were evaluated for potential relevance according to pre-defined criteria.

This literature search identified a total of 123 unique references, which were subject to rapid assessment to exclude obviously irrelevant references. A total of 12 references were progressed for detailed assessment. All 12 references were determined to be not relevant after detailed review. No new publication contained new data on molecular characterization of A2704-12 soybean and the newly expressed PAT/*pat* protein, nor did they suggest any potential adverse effects on human and animal health or on the environment.

Therefore, this literature search and review of the retrieved publications identified no relevant references that would contradict the existing safety assessment of A2704-12 soybean or the newly expressed PAT/*pat* protein (Annex I_A2704-12 Literature Review).

3.3 Case-Specific Monitoring

3.3.1 Description and results of Case-Specific Monitoring (if applicable)

The scientific evaluation of the characteristics of A2704-12 soybean in the environmental risk assessment (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 A2704-12 soybean. It is therefore considered that there is no need for case-specific monitoring.

3.3.2 Processing (if applicable)

Not applicable.

3.3.3 Monitoring and reporting of adverse effects resulting from accidental spillage (Not applicable)

3.4 Concluding remarks

The information reported to and collected by the authorisation holder within the frame of the general surveillance accompanying the placing on the market of A2704-12 soybean in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of A2704-12 soybean. The reports received from COCERAL, UNISTOCK and FEDIOL show that no adverse effects linked to the presence of A2704-12 soybean were recorded and no adverse findings from independent research relating to A2704-12 soybean have been published.

4. Summary of Results and Conclusions

To date, the general surveillance accompanying the placing on the market of A2704-12 soybean in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of A2704-12 soybean.

Taking into account:

a) the favourable scientific evaluations by scientists and regulatory agencies around the world;
b) our experience with this product;
c) the reports from the European trade associations (operators involved in the import, handling and processing of viable A2704-12 soybean) who are selected as the most appropriate participants in the general surveillance network;
d) the lack of adverse findings from independent research, available through the public literature;
e) the fact that no adverse effects for A2704-12 soybean have been reported to the authorisation holder

there is, to the best of our knowledge, no information available that questions the conclusion that A2704-12 soybean does not pose any greater risk to health or the environment than conventional soybean.

5. Adaptation of the Monitoring Plan and Associated Methodology for future years

In view of the results given in this report, no revisions to the general surveillance plan are considered necessary for A2704-12 soybean.

Signed: **BASF**

Date: **19th December 2019**