2023 Annual Report on the General Surveillance of A2704-12 soybean

Submitted by

BASF Agricultural Solutions Seed US LLC
Represented by
BASF SE

Submitted on

4 December 2023

ANNUAL REPORT ON THE GENERAL SURVEILLANCE OF A2704-12 SOYBEAN

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 Implementing Decision (EU) 2019/2084 of 28 November 2019

1.4 Unique identifier: ACS-GHØØ5-3

1.5 Reporting Period from: July 2022 to June 2023

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. On 28 November 2019, Commission Implementing Decision (EU) 2019/2084[4] renewed authorization of the said product.
The authorisation is addressed to BASF Agricultural Solutions Seed US LLC, represented in the Union by BASF SE and 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 5 of Commission Implementing Decision (EU) 2019/2084, 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 5 of Commission Implementing Decision

[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.
[4] Commission Implementing Decision (EU) 2019/2084 of 28 November 2019 renewing the authorisation for 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. *Official Journal of the European Union* L 316/74, 6.12.2019.

(EU) 2019/2084 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.

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 EU and the UK by country of origin

Country of origin[5]	Quantity[6] (EU imports in tons)	Quantity[7] (UK imports in tons)
Brazil*	5.577.766,3	636.549,2
United States *	5.273.406,1	189.049,3
Ukraine	1.318.631,0	0
Canada*	837.207,1	35.258,1
Uruguay*	117.048,1	0
Argentina*	32.222,1	0
All Other Countries	**512.544,2**	**2.908,1**
TOTAL	**13.668.825,0**	**863.764,7**

[5] Data are provided for the main exporting countries and countries where A2704-12 soybean is authorised for cultivation, which combined make up approximately 96% of total soybean imports from outside the EU and nearly 100% of total soybean imports from outside the UK. Data for exporting countries where A2704-12 soybean is authorised for cultivation are marked with "*". For the full list of exporting countries and detailed information on commodity types please refer to 2023_2052657 and 2023_2052658.

[6] Source: Eurostat (2023) data covers 27 EU Member States (July 2022 to June 2023). Data October 2023, collected by CropLife Europe (refer to 2023_2052657).

[7] Source: HMRC/AHDB (2023) data for the UK covers Great Britain and Northern Ireland (July 2022 to June 2023) as it is not possible to extract the data for Great Britain separately. Data extracted October 2023, collected by CropLife Europe (refer to 2023_2052658).

3.1.2 Commodity Crop (GM + non-GM) imports from outside the EU and the UK by country of destination

Destination country	Quantity[8] (tons) July 2022 - June 2023
Netherlands	3.640.130,3
Spain	3.214.215,0
Germany	2.114.292,4
Italy	1.963.322,4
Portugal	948.356,6
United Kingdom	863.764,7
Slovenia	403.925,8
France	368.351,6
Belgium	224.807,4
Romania	217.909,8
Greece	211.960,2
Poland	142.800,8
Hungary	112.697,3
Slovakia	39.324,0
Austria	29.658,1
Ireland	15.959,7
Sweden	6.162,5
Czechia	5.916,6
Latvia	4.082,0
Bulgaria	1.883,6
Denmark	1.767,7

[8] Sources: Eurostat (2023) data covers 27 EU Member States (July 2022 to June 2023). HMRC/AHDB (2023) data for UK covers Great Britain and Northern Ireland (July 2022 to June 2023). Quantities below 0,1 tons are indicated as 0 and marked with "*".

Destination country	Quantity[8] (tons) July 2022 - June 2023
Finland	668,8
Croatia	568,1
Lithuania	62,9
Malta	1,2
Luxembourg	0,3
Estonia	0*

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The authorisation holder, via CropLife Europe, has collected data on soybean imports (GM and non-GM) into the EU and the UK for the period of July 2022 to June 2023.

For the EU, according to this data, total imports of soybean were 13.668.825,0 tons and the main exporters of soybean to the EU were Brazil, the United States, Ukraine, and Canada which together accounted for approximately 95% of total extra-EU soybean imports.

A2704-12 soybean was authorised for cultivation in Argentina, Brazil, Canada, the United States, and Uruguay. The total EU soybean imports from Argentina, Brazil, Canada, the United States, and Uruguay were 32.222,1, 5.577.766,3, 837.207,1, 5.273.406,1 and 117.048,1 tons, respectively. Argentina, Brazil, Canada, the United States, and Uruguay soybean exports to the EU accounted for around 87% of total extra-EU soybean imports (**Table 3.1.1**).

The main import countries for soybean in the EU were the Netherlands, Spain, Germany, and Italy. They are accounting together for nearly 80% of the total soybean imports. Other main import markets of extra-EU soybean are Portugal, Slovenia, and France. (**Table 3.1.2**).

For the UK, according to this data, total extra imports of soybean were 863.764,7 tons and the main exporters of soybean to the UK were Brazil, the United States, and Canada which together accounted for nearly 100% of total extra-UK soybean imports (**Table 3.1.1**).

A2704-12 soybean was authorised for cultivation in Argentina, Brazil, Canada, the United States, and Uruguay. The total UK soybean imports from Brazil, Canada, and the United States were 636.549,2, 35.258,1 and 189.049,3 tons, respectively. Brazil, Canada, and the United States soybean exports to the UK accounted for nearly 100% of total extra-UK soybean imports (**Table 3.1.1**).

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 CropLife Europe 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 industry within CropLife Europe 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 CropLife Europe 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 CropLife Europe website under

  https://croplifeeurope.eu/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 CropLife Europe 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 or via CropLife Europe:
  - 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 CropLife Europe of the results of the general surveillance on an annual basis. The report shall cover all approved GM plant products subject to general surveillance. CropLife Europe shall forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission and UK's Food Standards Agency.

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 and UK's Food Standards Agency. The authorisation holder, in collaboration with the European Commission and UK's Food Standards Agency 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 industry and CropLife Europe, 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 and the UK are members of COCERAL.

Also see: http://www.coceral.com

⇒ *Silo Operators*

UNISTOCK is the European association representing professional storekeepers for agribulk 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 and the UK 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 European 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 Commission implementation Decision (EU) 2019/2084 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, providing an overview and detailed information on approved GM plant products subject to

general surveillance. The website, hosted on the CropLife Europe website under https://croplifeeurope.eu/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 to this annual monitoring report (refer to 2023_2051624).

-A contact point at CropLife Europe 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, CropLife Europe 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 2022 to June 2023.

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 CropLife Europe 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 2022 to June 2023 (refer to 2023_2052354 and 2023_2052360). Furthermore, no incidents in relation to the placing on the market of A2704-12 soybean have been reported to CropLife Europe or the authorisation holder since July 2023 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 2023 annual general surveillance report for A2704-12 soybean, a scoping review was performed for the A2704-12 soybean and its newly expressed protein, PAT/*pat*. The objective of this scoping review was to determine if there were studies about the molecular characterization of A2704-12 soybean, its effect on food and feed safety or environmental safety, that might require in-depth examination. A set of broad literature searches was performed using several bibliographic databases covering scientific literature from July 1, 2022 to June 30, 2023. Additional sources of information, such as web pages of food safety, agriculture, and biotechnology-related authorities were searched for the same time window, along with the bibliographies of relevant reviews. The references identified were evaluated for potential relevance to the scoping review questions according to pre-defined criteria.

These literature searches identified a total of 178 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 8 publications were progressed for detailed assessment.

No new relevant publications were found that contained data on the molecular characterization of A2704-12 soybean and its newly expressed protein PAT/*pat*. Similarly, no publications were found that suggested any potential adverse effects of A2704-12 soybean on human health, animal health, or the environment. No issues or topics were identified that would warrant conducting a systematic review.

Therefore, these literature searches and review of the retrieved articles identified no publication that would adversely impact the existing safety assessment of A2704-12 soybean (refer to 2023_2054083).

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 (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 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 and the UK 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 and the UK 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: **4 December 2023**