

**Annual general surveillance report in 2020/2021 season for
genetically modified soybean products* authorised in accordance with**

Commission Implementing Decisions

**2012/82/EU¹, 2012/83/EU², 2012/347/EU³, (EU) 2015/686⁴, (EU) 2015/696⁵,
(EU) 2015/700⁶, (EU) 2016/1216⁷, (EU) 2016/1217⁸, (EU) 2019/1309⁹, (EU)
2019/2083¹⁰, (EU) 2020/1360¹¹, (EU) 2021/66¹²**

Bayer Agriculture BV

Dept. Regulatory Science

Legal address

Scheldelaan 460, 2040 Antwerp, Belgium

Postal address

Jan Emiel Mommaertslaan 14, 1831 Diegem, Belgium

VOLUME 1 OF 1

October 2021

* 40-3-2¹, MON 87701², MON 87701 × MON 89788³, MON 87769⁴, MON 87705⁵, MON 87708⁶, MON 87708 × MON 89788⁷,
MON 87705 × MON 89788⁸, MON 87751⁹, MON 89788¹⁰, MON 87708 × MON 89788 × A5547-127¹¹, MON 87751 × MON 87701 ×
MON 89788 × MON 87708¹²

Data protection.

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

© 2021 Bayer Group. All Rights Reserved.

This document is protected under national and international copyright law and treaties. This document and any accompanying material are for use only by the regulatory authority to which it has been submitted by Bayer CropScience LP and its affiliates, collectively “Bayer Group”, and only in support of actions requested by Bayer Group. Any other use, copying, or transmission, including internet posting or scientific peer-reviewed publications, of this document and the materials described in or accompanying this document, without prior consent of Bayer CropScience LP, is strictly prohibited; except that Bayer CropScience LP hereby grants such consent to the regulatory authority where required under applicable law or regulation. The intellectual property, information and materials described in or accompanying this document are owned by Bayer Group, which has filed for or been granted patents on those materials. By submitting this document and any accompanying materials, Bayer CropScience LP and the Bayer Group do not grant any party or entity any right or license to the information, material or intellectual property described or contained in this submission.

Table of contents

1. General Information.....	3
1.1 Crop/trait(s)	3
1.2 Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC.....	3
1.3 Decision authorisation number and date of authorisation under Regulation (EC) No 1829/2003.....	3
1.4 Unique identifier.....	3
1.5 Reporting period.....	3
1.6 Other monitoring reports have been submitted in respect of cultivation.....	3
2. Executive Summary	6
3. Uses of GMOs Other Than Cultivation	7
3.1 Soybean imports into the EU and UK ²	7
3.1.1 Soybean seed (GM + non-GM) imports into the EU and UK by country of origin from countries where Bayer GM soybean is cultivated (2020/2021).....	7
3.1.2 Soybean seed (GM + non-GM) imports into the EU and UK by country of destination (2020/2021).....	9
3.1.3 Analysis of data provided in Tables 3.1.1 and 3.1.2.....	10
3.2 General Surveillance	11
3.2.1 Description of General Surveillance	11
3.2.2 Details of industry, environmental, food and/or feed related surveillance networks used during General Surveillance.....	13
3.2.3 Details of information and/or training provided to importers, traders, handlers, processors, etc.	14
3.2.5 Additional Information	15
3.2.6 Literature search	16
3.3 Case-Specific Monitoring.....	16
3.3.1 Description and results of Case-Specific Monitoring (only applicable for MON 87769, MON 87705, and MON 87705 × MON 89788).....	16
3.3.2 Processing (if applicable).....	17
3.3.3 Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable).....	17
3.4 Concluding remarks	17
4. Summary of Results and Conclusions.....	17
5. Adaptation of the Monitoring Plan and Associated Methodology for future years	18
ANNEX: EUROSTAT and HMRC/AHDB data showing all soybean exporters into the EU and UK	
Appendix 1: Annual report on general surveillance of genetically modified organisms in 2020/2021 season from COCERAL, UNISTOCK, FEDIOL	
Appendix 2: Adverse effect reporting form	
Appendix 3: Literature search for annual monitoring on the general surveillance of Bayer GM soybean products in the EU and GB	

1. General Information					
1.1 Crop/trait(s) ¹	1.2 Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC	1.3 Decision authorisation number and date of authorisation under Regulation (EC) No 1829/2003^{2,3}	1.4 Unique identifier	1.5 Reporting period	1.6 Other monitoring reports have been submitted in respect of cultivation
Soybean 40-3-2	N/A	Commission Implementing Decision of 10 February 2012 (2012/82/EU)	MON-Ø4Ø32-6	July 2020 – June 2021	No
Soybean MON 87701	N/A	Commission Implementing Decision of 10 February 2012 (2012/83/EU)	MON-877Ø1-2	July 2020 – June 2021	No
Soybean MON 87701 × MON 89788	N/A	Commission Implementing Decision of 28 June 2012 (2012/347/EU)	MON-877Ø1-2 × MON- 89788-1	July 2020 – June 2021	No
Soybean MON 87769	N/A	Commission Implementing Decision (EU) 2015/686 of	MON-87769-7	July 2020 – June 2021	No

¹ Hereafter, referenced as Bayer GM soybean products.

² EU: The decisions have been amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 and Commission Implementing Decision (EU) 2021/184 of 12 February 2021, as regards the representative of the authorisation holder.

³ GB: All Commission decisions adopted prior to 31 December 2020 have been transposed into GB legislation.

1.1 Crop/trait(s) ¹	1.2 Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC	1.3 Decision authorisation number and date of authorisation under Regulation (EC) No 1829/2003^{2,3}	1.4 Unique identifier	1.5 Reporting period	1.6 Other monitoring reports have been submitted in respect of cultivation
		24 April 2015			
Soybean MON 87705	N/A	Commission Implementing Decision (EU) 2015/696 of 24 April 2015	MON-877Ø5-6	July 2020 – June 2021	No
Soybean MON 87708	N/A	Commission Implementing Decision (EU) 2015/700 of 24 April 2015	MON-877Ø8-9	July 2020 – June 2021	No
Soybean MON 87708 × MON 89788	N/A	Commission Implementing Decision (EU) 2016/1216 of 22 July 2016	MON-877Ø8-9 × MON- 89788-1	July 2020 – June 2021	No
Soybean MON 87705 × MON 89788	N/A	Commission Implementing Decision (EU) 2016/1217 of 22 July 2016	MON-877Ø5-6 × MON- 89788-1	July 2020 – June 2021	No

1.1 Crop/trait(s) ¹	1.2 Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC	1.3 Decision authorisation number and date of authorisation under Regulation (EC) No 1829/2003^{2,3}	1.4 Unique identifier	1.5 Reporting period	1.6 Other monitoring reports have been submitted in respect of cultivation
Soybean MON 87751	N/A	Commission Implementing Decision (EU) 2019/1309 of 26 July 2019	MON-87751-7	July 2020 – June 2021	No
Soybean MON 89788	N/A	Commission Implementing Decision (EU) 2019/2083 of 28 November 2019	MON-89788-1	July 2020 – June 2021	No
Soybean MON 87708 × MON 89788 × A5547-127	N/A	Commission Implementing Decision (EU) 2020/1360 of 28 September 2020	MON-87708-9 × MON- 89788-1 × ACS-GM006-4	July 2020 – June 2021	No
Soybean MON 87751 × MON 87701 × MON 89788 × MON 87708	N/A	Commission Implementing Decision (EU) 2021/66 of 22 January 2021 ⁴	MON-87751-7 × MON- 87701-2 × MON-87708-9 × MON-89788-1	July 2020 – June 2021	No

⁴ GB application under review

2. Executive Summary

In accordance with Directive 2001/18/EC and the product specific Commission Implementing Decisions as mentioned in section 1.3, the authorisation holder Bayer, is accountable for general surveillance of the placing on the market of genetically modified (GM) soybean products in the EU and GB for the duration of the validity of the consent.

In view of the obligation to submit annual monitoring reports for viable GM soybean products, Bayer has undertaken a number of general surveillance activities accompanying the placing on the market of each Bayer GM soybean product in the EU and GB and the status on these activities is given in this annual report.

This annual general surveillance report for the 2020/2021 season presents the monitoring results of Bayer GM soybean products as listed in Section 1 of this report. During the last year, taking into account our extensive experience with these products; the lack of adverse findings from independent research, available through the public literature; and the fact that no reports of adverse effects of these products have been communicated; there is, to the best of our knowledge, no information available that questions the conclusion that any Bayer GM soybean product as referred to in this monitoring report does not pose any risk to health or the environment greater than conventional soybean.

Therefore, the general surveillance accompanying the placing on the market of Bayer GM soybean products in the EU and GB indicates that, to date, there have been no adverse health or environmental effects associated with the importation or use of any Bayer GM soybean product in the EU and GB.

3. Uses of GMOs Other Than Cultivation

3.1 Soybean imports into the EU and UK²

3.1.1 Soybean seed (GM + non-GM) imports into the EU and UK by country of origin from countries where Bayer GM soybean is cultivated (2020/2021)

Table 3.1.1 Soybean seed (GM + non-GM) imports into the EU and UK by country of origin

Soybean products	Soybean imports into the EU and UK from where Bayer GM soybean was cultivated and approximate share of Bayer GM soybean cultivation in the country of origin						Total soybean imports from the countries where Bayer GM soybean was cultivated	Total soybean imports from GM and non-GM soybean cultivating countries
	Brazil	USA	Canada	Argentina	Paraguay	Uruguay		
GM + non-GM imports into the EU ¹ /UK ²								
2020/2021 (Quantity 10 ³ tonnes)	7 593 / 412	5 246 / 188	1 292 / 165	70 / 2	30 / 0	9 / 0	14 240 / 767	14 933 / 782
Share of GM cultivation in 2020 ³								
40-3-2							NA	NA
MON 87701								
MON 87701 × MON 89788								
MON 87769								
MON 87705								
MON 87708								
MON 87705 × MON 89788								
MON 87708 × MON 89788								
MON 87751								
MON 89788								
MON 87708 × MON 89788 × A5547-127								
MON 87751 × MON 87701 × MON 89788 × MON 87708								

¹ Source: EUROSTAT (2021) data covers 27 EU Member States (July 2020 to June 2021). Data are obtained through CropLife Europe (CLE) in October 2021 and show total soybean imports into the EU in 2020/2021 from countries where Bayer GM soybean was also cultivated in 2020. The EUROSTAT data showing all soybean exporters into the EU are provided as an Annex to this document.

- ² Source: HMRC/AHDB (2021) data for UK cover Great Britain and Northern Ireland (July 2020 to June 2021). Data are obtained through CLE in October 2021 and show total soybean imports into the UK in 2020/2021 from countries where Bayer GM soybean was also cultivated in 2020. The HMRC/AHDB data showing all soybean exporters into the UK are provided as an Annex to this document.
- ³ Bayer is not an operator directly involved in the import of soybean into the EU and UK. Therefore, Bayer is not in a position to report directly on globally traded volumes of GM soybean products. However, in order to provide an idea of the amount of GM soybean products that could possibly be imported into the EU and UK, the approximate share of cultivation in the country of origin is provided, expressed as “-“ (no cultivation), 0-20%, 20-40%, 40-60%, 60-80% or 80-100%. It must be kept in mind that information on approximate share of cultivation are estimates only, and that the amount of GM soybean that will be exported to the EU and UK will only represent a portion of the cultivated amounts.

NA = Not applicable

3.1.2 Soybean seed (GM + non-GM) imports into the EU and UK by country of destination (2020/2021)

Table 3.1.2 Soybean seed (GM + non-GM) imports into the EU and UK by country of destination

Country of destination	Quantity (10 ³ tonnes) in 2020/2021
Netherlands	4 410
Spain	3 207
Germany	2 415
Italy	2 249
Portugal	1 214
France	530
Belgium	303
Greece	259
Romania	184
Hungary	55
Austria	29
Slovenia	24
Finland	15
Poland	13
Sweden	13
Croatia	5
Denmark	3
Lithuania	3
Czech Republic	4
Slovakia	1
Bulgaria	0
Estonia	0
Ireland	0
Cyprus	0
Luxembourg	0
Malta	0
Latvia	0
TOTAL EU	14 933
TOTAL UK	782

Sources: EUROSTAT (2021) data cover 27 EU Member States. HMRC/AHDB (2021) data for UK cover Great Britain and Northern Ireland. Period covers July 2020 to June 2021.

3.1.3 Analysis of data provided in Tables 3.1.1 and 3.1.2

The soybean seed (GM and non-GM) import data from suppliers to the EU and UK from outside the EU and UK is presented in **Tables 3.1.1** and **3.1.2**.

Extra-EU/UK soybean imports vary from year to year depending on several factors (*e.g.* EU soybean harvest, weather conditions, commodity price).

For the **EU**, total extra-EU soybean imports in 2020/2021 were approximately 14.9 million tonnes.

In 2020/2021, the suppliers of extra-EU soybean to the EU were Brazil, USA, Canada, Ukraine and Serbia⁵. Of these, Brazil, USA and Canada cultivated Bayer GM soybean products in 2020 (**Table 3.1.1**).

Table 3.1.2 summarizes the total soybean imports into the EU by country of destination. These data indicate that Netherlands, Spain, Germany, Italy, Portugal and France are the main importers of extra-EU soybean in the EU in 2020/2021, accounting for over 93 % of the total soybean import volume.

For the **UK**, total soybean imports in 2020/2021 were approximately 0.8 million tonnes.

In 2020/2021, the main suppliers of soybean to the GB were the Brazil, USA, and Canada⁶. All three countries cultivated Bayer GM soybean products in 2020 (**Table 3.1.1**).

Table 3.1.2 summarizes the total soybean imports into the UK.

Bulk shipments of soybean entering the EU and UK are usually processed into compound animal feed, whereby the processed animal feed is unlikely to contain whole soybean kernels. The handling of the shipments is the same across Europe and UK; upon arrival, the shipments are unloaded into silos at the port of the importing (Member) State and transferred from there to the feed processing plant present at the port.

Regulation (EC) No 178/2002 regarding the general principles and requirements of food law and food safety procedures, Regulation (EC) No 852/2004 on the hygiene of foodstuffs, and Regulation (EC) No 1831/2003 regarding feed hygiene, and their amendments, contain operational rules and standards applicable to the handling of soybean imports. In accordance with these Regulations, the principles of HACCP (Hazard Analysis and Critical Control Points) apply.

⁵ According to EUROSTAT 2021 data, the suppliers of extra-EU Soybean to the EU in 2020/2021 were by decreasing order of importance: Brazil, USA, Canada, Ukraine, Serbia, Togo, Argentina, Paraguay, India, Cameroon, Kazakhstan, Uganda, Uruguay, Bosnia and Herzegovina, Benin, Burkina Faso, Moldova, Ethiopia, Libya, Turkey, Vietnam, Ghana, Switzerland, Russia, Indonesia, Mexico, Iran, Taiwan, Japan, United Arab Emirates, South Korea, Sri Lanka, Thailand, Kenya, Nepal, Mauritius, Morocco, Nigeria, Lebanon, Australia, Hong Kong, Singapore, Colombia and Myanmar. The EUROSTAT data showing all Soybean exporters into the EU are provided as Annex to this document.

⁶ According to HMRC/AHDB 2021 data, the suppliers of soybean to the UK in 2020/2021 were by decreasing order of importance: Brazil, USA, Canada, Ukraine, China, Argentina, India, Singapore, Mongolia, Sri Lanka, Hong Kong, Indonesia, Nepal, Vietnam, South Korea, Thailand and Japan. The HMRC/AHDB data showing all soybean exporters into the UK are provided as Annex to this document.

3.2 General Surveillance

3.2.1 Description of General Surveillance

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

Bayer is not involved in commodity trade with GM 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 GM soybean. They are exposed to the imported viable GM 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 as reflected on the website of the trade associations representing the operators involved in the PMEM (*see* below).

Since traders may commingle GM soybean with other commercial soybean, including authorised GM soybean, Bayer is working together with other members of the plant biotechnology 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 website⁷ 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

⁷ CropLife Europe - <https://croplifeeurope.eu/product-information/> - Accessed on 22 October 2021.

- 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
 - 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 soybean and to routinely eradicate adventitious populations on their premises - any such adventitious populations, resisting routine eradication procedures, shall be treated as a potential adverse effect
 - 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 COCERAL, UNISTOCK and FEDIOL, 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 consent holders for inclusion in their annual report to the European Commission and to FSA.

The general surveillance information reported to and collected by the consent 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 consent holder shall immediately investigate to determine and confirm whether a significant correlation between the effect and a specific GM soybean can be established. If the investigation establishes that a specific GM soybean is the cause of the adverse effect, the consent holder shall immediately inform the European Commission and FSA. The consent holder, in collaboration with the European Commission and FSA and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human 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 consent holder shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the consent. The report shall contain information on any unanticipated adverse effects that have arisen from handling and use of viable GM soybean.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of GM 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

Bayer, together with other members of the plant biotechnology industry and CropLife Europe, implements the general surveillance of viable GM soybean, with the help of selected networks, according to the methodology outlined in Bayer'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 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 and GB are members of COCERAL.

Also see: <http://www.coceral.com> - Accessed on 22 October 2021.

⇒ Silo Operators

UNISTOCK is the European association representing professional storekeepers for agribulk commodities in the EU and GB. 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 GB by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.

Also see: <http://www.unistock.be> - Accessed on 22 October 2021.

⇒ Processors

FEDIOL, the federation of the EU vegetable Oil and Protein Meal Industry, represents the interests of the European crushers of oilseed meal producers and vegetable oils producers/processors. Its members represent 85% of the EU industry and hold more than 180 oilseeds processing and vegetable oils and fats production facilities across Europe.

Also see: <http://www.fediol.eu> - Accessed on 22 October 2021.

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 GM 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.

Following the Commission Implementing Decisions regarding the placing of Bayer GM soybean on the market pursuant to Regulation (EC) No 1829/2003, Bayer informs the operators in the EU and GB who handle and process bulk mixtures of imported soybean seed of the regulatory progress made in the EU and GB. This notice also included a description of the establishment of a general surveillance plan.

Additionally, specific information concerning the safety, general characteristics and the general surveillance conditions for each of Bayer GM soybeans were uploaded on the website dedicated to trade associations representing the relevant operators that import, handle and process viable soybean commodity in the EU and GB, providing an overview and detailed information on approved GM plant products subject to general surveillance. The website^{Error! Bookmark not defined.}, hosted by CropLife Europe, contains the following information for each Bayer GM soybean:

- A fact sheet
- A contact point
- The EFSA Opinion for food and feed uses, import and processing
- The Commission Decision concerning the placing on the market
- A link to the entries in the Community Register for GM Food and Feed

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 Bayer GM soybean products as listed in Section 1 placed on the market during the period from July 2020

to June 2021.

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(s) to comply with the requirement to give evidence to the European Commission, FSA 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 Bayer GM soybean products as listed in Section 1 in the time period from July 2020 to June 2021 (see **Appendix 1**). Furthermore, no incidents in relation to the placing on the market of Bayer GM soybean products as listed in Section 1 have been reported to CropLife Europe or the authorisation holder since July 2020 to date.

3.2.5 Additional Information

Operators in the food and feed supply chain and/ or any other person wishing to report a potential adverse effect associated with the import or use of Bayer GM soybean in the EU and GB, can refer to a contact point at CropLife Europe website⁷. This contact will record any reports of potential adverse

effects by means of a standardised adverse effect reporting form (**Appendix 2**). Reports of adverse effects would be analysed in the annual general surveillance report. Additionally, the Bayer Product Stewardship Safety page offers a global contact point for reporting any safety concern⁸.

To date, no adverse effects associated with the import or use of any Bayer GM soybean products in the EU and GB and in other parts of the world have been reported.

3.2.6 Literature search

As part of the general surveillance requirements for Bayer GM soybean products, a literature search that complies with the recommendations outlined in the 2019 EFSA explanatory note on literature searching⁹ has been conducted on a quarterly basis covering the time span June 2020 – May 2021 and is provided along with the Appendix E – completeness checklist in **Appendix 3**.

Bayer confirms that the literature search, conducted in accordance with the 2019 EFSA explanatory note on literature searching and within the context of the general surveillance for the Bayer GM soybean in the EU and GB, identified no relevant publications that would invalidate the initial conclusions of the risk assessment for Bayer GM soybean products as listed in Section 1.

3.3 Case-Specific Monitoring

3.3.1. Description and results of Case-Specific Monitoring (only applicable for MON 87769, MON 87705, and MON 87705 × MON 89788)

The scientific evaluation of the characteristics of Bayer GM soybean products 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. It is therefore considered that there is no need for case-specific monitoring, except for the Bayer soybean MON 87769, MON 87705 and MON 87705 × MON 89788 (unique identifiers MON-87769-7, MON-87705-6 and MON-87705-6 × MON-89788-1) where, in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003, the European Commission has included specific post market monitoring conditions for the placing on the market of, use or handling of these GM soybean products (Decision 2015/686/EU¹⁰, Decision 2015/696/EU¹¹ and Decision 2016/1217/EU¹²).

As authorisation holder, Bayer collaborates with third parties, such as farmers, crushers and all exporters involved in the production and trade of MON 87769, MON 87705 and MON 87705 × MON 89788 soybean oil or MON 87769, MON 87705 and MON 87705 × MON 89788 soybean for crushing into oil, to collect, as required by the Commission

⁸ Bayer - <https://www.bayer.com/en/product-stewardship.aspx> - Accessed on 22 October 2021.

⁹ EFSA - <https://www.efsa.europa.eu/en/supporting/pub/en-1614> - Accessed on 22 October 2021.

¹⁰ European Commission - [Commission Implementing Decision \(EU\) 2015/686/EU](#) - Accessed on 22 October 2021.

¹¹ European Commission - [Commission Implementing Decision \(EU\) 2015/696/EU](#) - Accessed on 22 October 2021.

¹² European Commission - [Commission Implementing Decision \(EU\) 2016/1217/EU](#) - Accessed on 22 October 2021.

authorisation decisions 2015/686/EU, 2015/696/EU and 2016/1217/EU, information on the quantities of MON 87769, MON 87705 and MON 87705 × MON 89788 soybean oil and MON 87769, MON 87705, and MON 87705 × MON 89788 soybean for oil extraction, imported in the EU and GB for the placing on the market as or in products for food.

On the basis of this information and as required by Commission authorisation decisions 2015/696/EU, 2015/686/EU and 2016/1217/EU, the authorisation holder confirms that during the Post-Market Monitoring (PMM) reporting period ending 30 June 2021, no MON 87769, MON 87705 and MON 87705 × MON 89788 soybean oil or MON 87769, MON 87705 and MON 87705 × MON 89788 soybean for crushing into oil was exported to the EU for the placing on the market as or in products for food. This concludes our PMM reporting for 2020/2021. Monitoring will continue as required and subsequent reports will be provided in 2021.

3.3.2 Processing (if applicable)

Not applicable, see Section 3.3.1.

3.3.3 Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable)

Not applicable, see Section 3.3.1.

3.4 Concluding remarks

To date, the general surveillance accompanying the placing on the market of any Bayer GM soybean products in the EU and GB indicates that there have been no adverse health or environmental effects associated with the importation or use of Bayer GM soybean products.

4. Summary of Results and Conclusions

In accordance with the Commission Implementing Decisions for the Bayer GM soybean products presented in Section 1, the consent holder for the Bayer GM soybean products, Bayer, is accountable for general surveillance during placing on the market of these GM soybeans in the EU and GB for the duration of the validity of each consent.

Taking into account a) the favourable scientific evaluations by scientists and regulatory agencies around the world; b) our extensive commercial experience with these products; c) the lack of adverse findings from independent research, available through the public literature; and d) the fact that no reports of adverse effects of these products have been communicated; there is, to the best of our knowledge, no information available that questions the conclusion that any Bayer GM soybean product as referred to in this monitoring report does not pose any risk to health or the environment greater than conventional soybean.

Therefore, the general surveillance accompanying the placing on the market of Bayer GM soybean

in the EU and GB indicates that, to date, there have been no adverse health or environmental effects associated with the importation or use of Bayer GM soybean products in the EU and GB.

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 any Bayer GM soybean products.

October 2021

ANNEX. EUROSTAT and HMRC/AHDB data showing all soybean exporters into the EU and UK, respectively

EUROSTAT data showing all soybean exporters into the EU

July 2020 until June 2021 EU Soy Imports by Member State and by MAIN Exporter in tons (CN 12019000)

Reporter/Period	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czechia	Denmark	Estonia	Finland	France	Germany	Greece	Hungary
Brazil	2,5	66.660,7							79,5	234.819,8	801.167,7	96.424,4	
United States		17.450,0	115,0				0,1		324,2	176.952,6	1.465.833,7	95.354,2	
Canada	10,6	188.938,0	20,2		0,5	459,6		20,4	14.302,1	43.023,9	61.173,1	19.186,8	
Ukraine	10.438,1	1.821,2	22,0			404,4				21.972,6	31.856,9	48.044,8	20.472,9
Serbia	18.240,2	1.476,6	2,0	373,2		40,5					49.513,9		33.927,5
Togo	203,6	9.001,5				0,2	572,0			36.103,5	3.124,1		
Argentina											0,6		
Paraguay											0,2		
India	0,2	13.163,4			0,2		0,5			1.119,8	4,8	0,8	
Cameroon		2.920,5				2,0	1.149,2			374,2	2.493,4		122,0
Kazakhstan							928,6						
Uganda		880,0								3.894,6			
Uruguay		75,5											
Bosnia and Herzegovina				4.670,0									930,1
Benin										6.522,9			
Burkina Faso										5.549,0			
Moldova, Republic of	132,0		303,2										
Ethiopia													
Libya								206,1					
Turkey													
Viet Nam		120,2			0,6	2,0							
Ghana										0,4			
Switzerland	3,3										79,3		
Russian Federation													
Indonesia										3,0			
Mexico										19,0			
Iran, Islamic Republic of	2,4										31,3		
Taiwan													
Japan		0,1								0,2	13,4		
United Arab Emirates		10,0											
Republic of South Korea											4,6		
Sri Lanka							0,7			0,1	0,5		
Thailand										2,2			
Kenya													
Nepal		1,7											
Mauritius										2,3			
Morocco										1,8			
Nigeria													
Lebanon											1,2		
Australia										0,4			
Hong Kong											1,0		
Singapore										0,5			
Colombia													
Myanmar (Burma)													
Total	29.032,9	302.519,4	462,4	5.043,2	1,3	908,7	2.651,1	226,5	14.705,8	530.362,8	2.415.299,7	259.011,0	55.452,5
Source: Eurostat, October 2021													

Commodity Code CN 12019000 Soya beans, whether or not broken

Ireland	Italy	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Total
	1.249.330,4					2.201.257,1		813.673,7	109.925,0		57,0	2.020.012,1		7.593.409,9
	442.823,4					1.713.450,2		360.201,9	25.000,0			948.221,7	40,0	5.245.767,0
170,1	449.834,3		61,1			320.819,5	153,6	40.121,1		142,8		153.745,5	199,9	1.292.383,1
	77.015,1		2.471,7			120.446,3	4.935,8		30.968,4		13.050,5	27.506,0		411.426,7
						1.044,7			14.835,8	600,1	8.303,2	81,5		128.439,2
	7.626,0					15.710,4						2.720,3		75.061,6
	12.397,4					34.366,5	7.857,4					15.450,0		70.071,9
								52,3				29.644,8		29.697,3
0,7	9,7			0,2		32,1		3,2					0,4	14.336,0
1,0	1.202,9					2.947,2	52,9	40,6				1.416,8	694,1	13.416,8
													11.746,4	12.675,0
												6.032,1		10.806,7
	8.538,6					0,3								8.614,4
											2.542,5			8.142,6
												22,0		6.544,9
	15,0													5.564,0
						86,0			2.827,5					3.348,7
												2.050,0		2.050,0
			4,2			4,0								214,3
	26,8					110,0								136,8
						0,3							2,4	125,5
	112,2					0,3								112,9
													0,2	82,8
			66,0											66,0
						59,1								62,1
												18,8		37,8
						3,4							0,2	37,3
						1,2						21,6		22,8
	1,1					7,1					0,1			22,0
												10,0		20,0
						3,0							5,7	13,3
						4,1								5,4
												2,2	0,3	4,7
						2,8								2,8
0,1								0,6						2,4
														2,3
												0,1		1,9
						1,4								1,4
														1,2
						0,7								1,1
														1,0
														0,5
						0,4								0,4
												0,2		0,2
171,9	2.248.932,9	0,0	2.603,0	0,2	0,0	4.410.358,1	12.999,7	1.214.093,4	183.556,7	742,9	23.953,3	3.206.955,7	12.689,6	14.932.734,7

HRMC/AHDB data showing all soybean exporters into the UK

July 2020 until June 2021 - UK Soyabean Imports in tons (CN 12019000)

Reporter/Period	United Kingdom
Brazil	412.053,1
USA	188.075,9
Canada	164.840,5
Ukraine	11.106,7
China	3.093,5
Argentina	2.330,0
India	49,6
Singapore	30,6
Mongolia	16,0
Sri Lanka	8,0
Hong Kong	6,7
Indonesia	4,1
Nepal	3,5
Vietnam	1,9
South Korea	1,1
Thailand	0,9
Japan	0,2
Total	781.622,1

Source: HMRC, via the Agriculture and Horticulture Development Board
<https://ahdb.org.uk/cereals-oilseeds/trade-data>

Commodity Codes:

CN 12019000: Soya beans, whether or not broken