Annual general surveillance report in 2018/2019 season for genetically modified soybean products* authorised in accordance with Commission Decision 2008/933/EC[1], Commission Implementing Decisions 2012/82/EU[2], 2012/83/EU[3], 2012/347/EU[4], (EU) 2015/686[5], (EU) 2015/696[6], (EU) 2015/700[7], (EU) 2016/1216[8], (EU) 2016/1217[9]

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*** MON 89788[1], 40-3-2[2], MON 87701[3], MON 87701 × MON 89788[4], MON 87769[5], MON 87705[6], MON 87708[7], MON 87708 × MON 89788[8], MON 87705 × MON 89788[9]**

Data protection.

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

Table of contents

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**	**1.4 Unique identifier**	**1.5 Reporting period**	**1.6 Other monitoring reports have been submitted in respect of cultivation**
Soybean MON 89788	N/A	Commission Decision of 4 December 2008 (2008/933/EC)	MON-89788-1	July 2018 – June 2019	No
Soybean 40-3-2	N/A	Commission Implementing Decision of 10 February 2012 (2012/82/EU)	MON-Ø4Ø32-6	July 2018 – June 2019	No
Soybean MON 87701	N/A	Commission Implementing Decision of 10 February 2012 (2012/83/EU)	MON-877Ø1-2	July 2018 – June 2019	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 2018 – June 2019	No

[1] Hereafter, referenced as Bayer GM soybean.

1.1 Crop/trait(s) [2]	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[3]	1.4 Unique identifier	1.5 Reporting period	1.6 Other monitoring reports have been submitted in respect of cultivation
Soybean MON 87769	N/A	Commission Implementing Decision (EU) 2015/686 of 24 April 2015	MON-87769-7	July 2018 – June 2019	No
Soybean MON 87705	N/A	Commission Implementing Decision (EU) 2015/696 of 24 April 2015	MON-877Ø5-6	July 2018 – June 2019	No
Soybean MON 87708	N/A	Commission Implementing Decision (EU) 2015/700 of 24 April 2015	MON-877Ø8-9	July 2018 – June 2019	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 2018 – June 2019	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 2018 – June 2019	No

[2] Hereafter, referenced as Bayer GM soybean.

[3] The decisions have been amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 as regards the representative of the authorisation holder.

2. Executive Summary

In accordance with Directive 2001/18/EC and the product specific Commission 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 for the duration of the validity of the consent.

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

This annual general surveillance report for the 2018/2019 season presents the monitoring results of Bayer GM soybean: MON 89788, 40-3-2, MON 87701, MON 87701 × MON 89788, MON 87769, MON 87705, MON 87708, MON 87708 × MON 89788 and MON 87705 × MON 89788. During the last year, taking into account our extensive commercial 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 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 indicates that, to date, there have been no adverse health or environmental effects associated with the importation or use of any Bayer GM soybean in the EU.

3. Uses of GMOs Other Than Cultivation

3.1 Soybean imports into the Community

3.1.1 Soybean seed (GM + non-GM) imports into the Community by country of origin from countries where Bayer GM soybean is cultivated (2018/2019)

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

Soybean products	Soybean imports into the EU 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
	USA	Canada	Brazil	Paraguay	Argentina	Uruguay		
GM + non-GM imports into the EU*								
2018/2019 (Quantity 10^3 tonnes)	9 117	250	4 840	155	9	176	14 546	15 058
Share of GM cultivation in 2018**								
40-3-2	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	NA	NA
MON 87701	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
MON 87701 × MON 89788	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
MON 87705	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
MON 87705 × MON 89788	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
MON 87708	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
MON 87708 × MON 89788	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
MON 87769	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
MON 89788	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		

* Source: EUROSTAT [obtained through European Association of Bioindustries (EuropaBio) in October 2019]. Data show total soybean imports into the EU in 2018/2019 from countries where Bayer GM soybean was cultivated in 2017. The EUROSTAT data showing all soybean exporters into the EU are provided as Annex to this document.

** Bayer is not an operator directly involved in the import of soybean into the EU. 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, 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 will only represent a portion of the cultivated amounts.

NA = Not applicable

3.1.2 Soybean seed (GM + non-GM) imports into the Community by country of destination (2018/2019)

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

Country of destination	Quantity (10^3 tonnes) in 2018/2019
The Netherlands	4 109
Spain	3 393
Germany	2 315
Italy	1 685
Portugal	1 071
United Kingdom	702
Belgium	588
France	565
Greece	306
Romania	170
Poland	67
Hungary	26
Finland	25
Ireland	11
Denmark	9.21
Sweden	6.11
Czech Republic	4.86
Austria	2.94
Lithuania	1.29
Slovakia	0.05
Bulgaria	0.04
Malta	0.01
Croatia	-
Cyprus	-
Estonia	-
Latvia	-
Luxembourg	-
Slovenia	-
TOTAL	**15 058**

Source: EUROSTAT [obtained through European Association of Bioindustries (EuropaBio) in October 2019].

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 from outside the EU-28 (extra-EU) is presented in **Tables 3.1.1** and **3.1.2**.

Total extra-EU soybean imports in 2018/2019 were approximately 15 million tonnes. Extra-EU soybean imports vary from year to year depending on several factors (*e.g.* EU soybean harvest, weather conditions, commodity price).

In 2018/2019, the largest suppliers of extra-EU soybean to the EU were the USA and Brazil[4]. Together, they accounted for over 92 % of total extra-EU soybean imports into the EU in 2018/2019. Both countries cultivated Bayer GM soybean in 2018 (**Table 3.1.1**).

Table 3.1.2 summarizes the total soybean imports into the EU by country of destination. These data indicate that the Netherlands, Spain, Germany, Italy and Portugal are the main importers of extra-EU soybean in the EU in 2018/2019, accounting for over 83 % of the total soybean import volume.

Bulk shipments of soybean entering the EU 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; 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) No183/2005 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.

[4] According to EUROSTAT 2019 data, the suppliers of extra-EU Soybean to the EU in 2018/2019 were by decreasing order of importance: US, Brazil, Ukraine, Canada, Uruguay, Paraguay, China, Togo, India, Uganda, Argentina, Moldova, Kazakhstan, Burkina Faso, Ethiopia, Switzerland, Turkey, Indonesia, Benin, Hong Kong, Taiwan, Iran, Bosnia and Herzegovina, Norfolk Island, Japan, Singapore, Kenya, South Korea, Thailand, Nepal, Sri Lanka, Peru, Vietnam, Costa Rica, Israel, Myanmar, South Africa, Malaysia, Morocco and Chile. The EUROSTAT data showing all Soybean exporters into the EU 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 consent/authorisation holders within European Association of Bioindustries (EuropaBio) 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 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[5] 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)

[5] EuropaBio - http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information - Accessed on 22 November 2019.

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
  - 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 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 COCERAL, UNISTOCK and FEDIOL, 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 consent holders for inclusion in their annual report to the European Commission.

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 GM soybean can be established. If the investigation establishes that GM soybean is the cause of the adverse effect, the consent holder shall immediately inform the European Commission. The consent 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 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 EuropaBio, 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 are members of COCERAL.

Also see: http://www.coceral.com - Accessed on 22 November 2019.

⇒ *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 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 November 2019.

⇒ *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 November 2019.

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 Community decisions regarding the approval of Bayer GM soybean pursuant toRegulation (EC) No 1829/2003, Bayer informs the operators in the Community who handle and process bulk mixtures of imported soybean seed of the regulatory progress made in the EU. This notice also included a description of the establishment of a general surveillance plan.

Specific information concerning the safety, general characteristics and the general surveillance conditions for 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, providing an overview and detailed information on approved GM plant products subject to general surveillance. The website[Error! Bookmark not defined.], hosted by EuropaBio, 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, EuropaBio reminded the trade associations to provide their annual report on any occurrence of unanticipated adverse effects arising from the approved GM products, including including MON 89788, 40-3-2, MON 87701, MON 87701 × MON 89788, MON 87769, MON 87705, MON 87708, MON 87708 × MON 89788 and MON 87705 × MON 89788 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(s) 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 MON 89788, 40-3-2, MON 87701, MON 87701 × MON 89788, MON 87769, MON 87705, MON 87708, MON 87708 × MON 89788 or MON 87705 × MON 89788 soybean in the time period from July 2018 to June 2019 (*see* **Appendix 1**). Furthermore, no incidents in relation to the placing on the market of MON 89788, 40-3-2, MON 87701, MON 87701 × MON 89788, MON 87769, MON 87705, MON 87708, MON 87708 × MON 89788 or MON 87705 × MON 89788 soybean have been reported to EuropaBio or the authorisation holder since July 2018 to date.

3.2.5 Additional Information

Operators in the food and feed supply chain, wishing to report a potential adverse effect associated with the import or use of Bayer GM soybean, can refer to a contact point at Europabio website**Error! Bookmark not defined.**. 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 concern[6].

To date, no adverse effects associated with the import or use of any Bayer GM soybean in the EU 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, a literature search that complies with the recommendations outlined in the 2017 EFSA explanatory note on literature searching[7] has been conducted on a monthly basis covering the time span June 2017 – May 2018 and is provided along with the checklist for literature search (Annex 2) in **Appendix 3**.

Bayer confirms that the literature search, conducted in accordance with the 2017 EFSA explanatory note on literature searching and within the context of the general surveillance for the Bayer GM soybean in the EU, identified no relevant publications that would invalidate the initial conclusions of the risk assessment for 40-3-2, MON 87701, MON 87705, MON 87708, MON 87769, MON 89788, MON 87701 × MON 89788, MON 87705 × MON 89788 and MON 87708 × MON 89788 in the EU.

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 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-877Ø5-6 and MON-877Ø5-6 × 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 (Decision 2015/686/EU[8], Decision 2015/696/EU[9] and Decision 2016/1217/EU[10]).

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

[6] Bayer - https://www.bayer.com/en/product-stewardship.aspx - Accessed on 22 November 2019.
[7] EFSA - https://www.efsa.europa.eu/en/supporting/pub/en-1207 - Accessed on 22 November 2019.
[8] European Commission - Commission Implementing Decision (EU) 2015/686/EU - Accessed on 22 November 2019.
[9] European Commission - Commission Implementing Decision (EU) 2015/696/EU - Accessed on 22 November 2019.
[10] European Commission - Commission Implementing Decision (EU) 2016/1217/EU - Accessed on 22 November 2019.

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 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 2019, 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 2018/2019. Monitoring will continue as required and subsequent reports will be provided in 2020.

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 in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of Bayer GM soybean.

4. Summary of Results and Conclusions

In accordance with the Commission Decisions for the Bayer GM soybean presented in Section 1, the consent holder for the Bayer GM soybean, Bayer, is accountable for general surveillance during placing on the market of these GM soybeans in the EU 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 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 indicates that, to date, there have been no adverse health or environmental effects associated with the importation or use of Bayer GM soybean in the EU.

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.

December 2019

ANNEX

EUROSTAT data showing all soybean exporters into the EU

July 2018 until June 2019 EU Soy Imports by Member State and by MAIN Exporter in tons (CN 12019000)

REPORTER/PERIOD	AUSTRIA	BELGIUM (an	BULGARIA	CROATIA	CYPRUS	CZECHIA (C	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY (incl DD	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOU	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM	TOTAL
UNITED STATES		249957,4							24088,8	320204,5	2150413,8	97435,7			981340,3					2566906,1		647959,5	113477,3			1573223,6	40,3	391562,9	9116610,2
BRAZIL		167899,7							530	202477,9	113497,8	43120,8			541646,6					1399936,7		308077,4	50700			1724266,6		288019,6	4840173,1
UKRAINE	1216,4					1589,2				48436	97026,6	25835,4			53606,6		358,5			682,2	67121,9		595,5			65740,1			362208,4
CANADA	462,9	145218,5	20,2			351,9			362,1	1200,5	993,5		20	11254,4	63678,8		61,2			7159,3	367,2			45,8		1532,9	163,1	16781,8	249674,1
URUGUAY												16234,2			5000					117039		37384,6							175657,8
PARAGUAY										505,3	0,4	52178,3			17657							77160,5				7718,5			155220
CHINA	2,1	3600,6	16				9197,5			353,7	1901,9		97		7004,2				12,1	15493,1	9	90,5				1460,2	1050,6	5403,1	45691,6
TOGO										29171,3					3682,5					1931						4458,9			39243,7
INDIA		21248,3								3418,9	3,6	0,6			4					25,7	0,1					4136,3		20	28857,5
UGANDA										2112					440											6644			9196
ARGENTINA											0,7				9000											8,6			9009,3
MOLDOVA, REPUBLIC OF	1221										0,1												5068,1						6289,2
KAZAKHSTAN									210								870,9										4845		5925,9
BURKINA FASO (UPPER VOLTA -> 1985)										5016,7																			5016,7
ETHIOPIA (incl. ERITREA ->1993)										210,5																3582			3792,5
SWITZERLAND (incl. LI->1994)	37					2916				5,5	162,5																0,2		3121,2
TURKEY															2060													2,8	2062,8
INDONESIA (ID+TP from 77,excl. TP -> 2001)		41,4									0,2									187,3								1	229,9
BENIN (DAHOMEY -> 1976)										154,3																			154,3
HONG KONG											19,7									20,3		5,9				20,5		1,2	67,6
TAIWAN																				1						7,4		25,6	34
IRAN, ISLAMIC REPUBLIC OF	2,1										25									1,3							0,1		28,5
Bosnia and Herzegovina															25,1														25,1
NORFOLK ISLAND																												20,4	20,4
JAPAN		0,1					10,4			2,2										0,6								4,6	17,9
SINGAPORE											0,2				0,1												0,1	17,2	17,6
KENYA										0,2										16									16,2
KOREA, REPUBLIC OF (SOUTH KOREA)	0,9												0,2														11,7		12,8
THAILAND							0,1			2	0,4				1					0,9						5,9	0,1		10,4
NEPAL																												8,4	8,4
SRI LANKA (ex CEYLAN)							0,3				0,4									3,5									4,2
PERU																										2,2			2,2
VIETNAM									0,1																		0,2	1,9	2,2
COSTA RICA											2																		2
ISRAEL (GAZA and JERICHO->1994)																				1,2									1,2
MYANMAR																										0,6			0,6
SOUTH AFRICA																				0,5								0,1	0,6
MALAYSIA											0,2									0,1									0,3
MOROCCO										0,2																			0,2
CHILE		0,1																											0,1
TOTAL	2942,4	587966,1	36,2			4857,1	9208,3		25191	564835,7	2315458,4	305996,2	25952,6	11254,4	1685146,2		1290,6		12,1	4109405,8	67498,2	1070678,4	169840,9	45,8		3392808,3	6111,4	701870,6	15058406,7

Source: Eurostat