

Annual report on the implementation and the
results of the monitoring activities for 305423
and 305423 x 40-3-2 soybeans authorised by
Commission Implementing decisions (EU)
2015/698 and (EU) 2017/2448, respectively

December 2019

© 2019 Pioneer Hi-Bred International, Inc. All Rights Reserved.

This document is protected by copyright law and under Art. 31 of Regulation (EC) No 1829/2003. This document and material is for use only by the regulatory authority for the purpose that it is submitted by Pioneer Hi-Bred International, Inc., member of Corteva Agriscience group of companies ("Pioneer"), its affiliates, or its licensees and only with the explicit consent of Pioneer. Except in accordance with law, any other use of this material, without prior written consent of Pioneer, is strictly prohibited. The intellectual property, information, and materials described in or accompanying this document are proprietary to Pioneer. By submitting this document, Pioneer does not grant any party or entity not authorized by Pioneer any right or license to the information or intellectual property described in this document.

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 under Regulation (EC) No 1829/2003	3
1.4	Unique identifier.....	3
1.5	Reporting period from.....	3
1.6	Other monitoring reports have been submitted in respect of cultivation:.....	3
2	EXECUTIVE SUMMARY	4
3	USES OF GMOs OTHER THAN CULTIVATION.....	6
3.1	Commodity imports into the Community	6
3.1.1	Commodity crop (GM and non-GM) imports into the Community by country of origin	6
3.1.2	Commodity crop (GM and non-GM) imports into the Community by country of destination	7
3.1.3	Analysis of data provided in tables 3.1.1 and 3.1.2	8
3.2	General surveillance	9
3.2.1	Description of General Surveillance.....	9
3.2.2	Details of industry, environmental, food and/or feed related surveillance networks used during General Surveillance	11
3.2.3	Details of information and/or training provided to importers, traders, handlers, processors, etc	11
3.2.4	Results of General Surveillance	12
3.2.5	Additional information.....	13
3.2.6	Review of peer-reviewed publications	13
3.3	Case-Specific Monitoring.....	14
3.3.1	Description and results of Case-Specific Monitoring (if applicable)	14
3.3.2	Processing (if applicable)	14
3.3.3	Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable)	14
3.4	Concluding remarks.....	14
4	SUMMARY OF RESULTS AND CONCLUSIONS.....	15
5	ADAPTATIONS OF MONITORING PLAN AND ASSOCIATED METHODOLOGY FOR FUTURE YEARS.....	16
	REFERENCES.....	17
ANNEX 1	EU Soybean Imports by Member States and Exporters, as collected by EuropaBio (source EUROSTAT, 2019)	
ANNEX 2	2019 Annual report on general surveillance of genetically modified organisms from COCERAL and UNISTOCK	
ANNEX 3	2019 Annual report on general surveillance of genetically modified organisms from FEDIOL	
ANNEX 4	Review of literature of 305423 and 305423 x 40-3-2 soybeans in the scope of their authorisations for food and feed uses, import and processing in the EU (2019 update)	

1 GENERAL INFORMATION

1.1 Crop/trait(s)

Soybean / high oleic acid and herbicide tolerance traits

305423 soybean and 305423 x 40-3-2 soybean – also referred to as Plenish® high oleic soybean with increased monounsaturated fat and reduced polyunsaturated fats¹ in the commercial context

1.2 Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC

Not applicable

1.3 Decision authorisation number and date under Regulation (EC) No 1829/2003

- 305423 soybean : Commission Implementing Decision (EU) 2015/698² of 24 April 2015 (EC, 2015)
- 305423 x 40-3-2 soybean : Commission Implementing Decision (EU) 2017/2448³ of 21 December 2017 (EC, 2017)

1.4 Unique identifier

- 305423 soybean : DP-3Ø5423-1
- 305423 x 40-3-2 soybean : DP-3Ø5423-1×MON-Ø4Ø32-6

1.5 Reporting period from

July 2018 - June 2019⁴

1.6 Other monitoring reports have been submitted in respect of cultivation:

Yes ☐ No ☒

¹ Plenish® technology by Pioneer Hi-Bred; Plenish® is a registered trademark of Pioneer Hi-Bred International, Inc.

² Article 4 (1) and (2) of Decision (EU) 2015/698 requires the implementation and annual reporting on the results of the monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC which is publicly available on the EU Register for Food and Feed: http://ec.europa.eu/food/dyna/gm_register/monitoringplan305423.pdf

Article 5 (1) and (2) of Decision (EU) 2015/698 requires the implementation and annual reporting on the results of the post-market monitoring plan of the DP-3Ø5423-1 soybean oil, as set out in point (g) of the Annex to the Decision.

³ Article 4 (1) and (2) of Decision (EU) 2017/2448 requires the implementation and annual reporting on the results of the monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC which is publicly available on the EU Register for Food and Feed: http://ec.europa.eu/food/dyna/gm_register/305423%20x%2040-3-2_Monitoring%20plan.pdf

Article 5 (1) and (2) of Decision (EU) 2017/2448 requires the implementation and annual reporting on the results of the post-market monitoring plan of the DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean oil, as set out in point (g) of the Annex to the Decision.

⁴ Submission dates and reporting periods of all the Pioneer monitoring reports are aligned with those of the rest of the plant biotechnology industry as of end of December 2008.

2 EXECUTIVE SUMMARY

Genetically modified (GM) 305423 soybean and 305423 x 40-3-2 soybean (hereafter referred to as 'these GM soybeans') have been developed by Pioneer Hi-Bred International, Inc. as represented by Pioneer Overseas Corporation in the European Union (EU), hereafter referred to as Pioneer⁵.

After the assessment made by the European Food Safety Authority (EFSA) (EFSA, 2013), 305423 soybean received full European Union (EU) approval for import and use as or in food, feed and processing in April 2015 in accordance with:

Commission Implementing Decision (EU) 2015/698 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

After the assessment made by the EFSA (EFSA, 2016), 305423 x 40-3-2 soybean received full European Union (EU) approval for import and use as or in food, feed and processing in December 2017 in accordance with:

Commission Implementing Decision (EU) 2017/2448 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 x 40-3-2 (DP-3Ø5423-1 x MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Pioneer is the authorisation holder for the authorisations for the placing on the market of these GM soybeans for food and feed uses, import and processing. The purpose of this report is to provide information on the implementation and results of monitoring activities carried out by the authorisation holder in accordance with Directive 2001/18/EC (EC, 2001), Regulation (EC) No 1829/2003 (EC, 2003a), Decision 2009/770/EC (EC, 2009) and as required under Commission Implementing Decisions (EU) 2015/698 (EC, 2015) and (EU) 2017/2248 (EC, 2017).

The monitoring requirements outlined in Commission Implementing Decisions (EU) 2015/698 (EC, 2015) and (EU) 2017/2448 (EC, 2017) consist primarily of the implementation and reporting on the results of the environmental monitoring plan that was prepared and submitted by the authorisation holder in accordance with Annex VII to Directive 2001/18/EC (EC, 2001). In addition, post-market monitoring (PMM) in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003 is required by article 5 of Commission Implementing Decisions (EU) 2015/698 (EC, 2015) and (EU) 2017/2448 (EC, 2017). Monitoring applies for the duration of the authorisation, *i.e.* ten years.

Monitoring activities for these GM soybeans, in particular general surveillance, were carried out in accordance with the monitoring plan for environmental effect and in line with the conditions laid out in the Decisions (EC, 2015 article 4; EC, 2017 article

⁵ Pioneer Hi-Bred International, Inc. and Pioneer Overseas Corporation are members of Corteva Agriscience group of companies

4). The results of the monitoring confirm **no adverse effects on human and animal health or the environment have arisen from the import of these GM soybeans into the EU for this annual reporting period.**

In addition, during the current PMM reporting period ending 30 June 2019, no 305423 or 305423 x 40-3-2 soybean oil or 305423 or 305423 x 40-3-2 soybeans for crushing into oil were exported to the EU for the placing on the market as or in products for food. This concludes our PMM reporting for 2019. Monitoring will continue as required and subsequent reports will be provided in 2020.

3 USES OF GMOs OTHER THAN CULTIVATION

3.1 Commodity imports into the Community

3.1.1 Commodity crop (GM and non-GM) imports into the Community by country of origin

Country of origin ¹	Quantity (tonnes) 2018-2019 ³	Estimated data of potential share of these GM soybeans in imports (where not possible approximate share of cultivation in the country of origin), for each specified product ⁴
United States of America²	9 116 610	0-10%⁵
Brazil	4 840 173	NA
Ukraine	362 208	NA
Canada	249 674	NA
Uruguay	175 658	NA
Paraguay	155 220	NA
China	45 692	NA
Togo	39 244	NA
Other countries	113 172	NA
Total from countries cultivating these GM soybeans (GM and non-GM soybean)	9 116 610	
Total from all countries (GM and non-GM soybean)	15 058 407	

¹ Main countries exporting soybean to the EU, which combined make up > 99% of total soybean imports into the EU. The countries representing collectively less than 1% of the total imports to the EU are indicated as "Other countries". The full list of countries exporting soybean to the EU, as collected by EuropaBio (source EUROSTAT 2019), is provided in Annex 1.

² Exporting country where 305423 x 40-3-2 soybean was cultivated in 2018 and/or 2019. 305423 soybean was not cultivated.

³ Quantity in tonnes of commodity crop (GM and non-GM soybean) imported during the reporting period (1st July 2018-30 June 2019) (rounded to nearest ton). Source: EUROSTAT 2019 (extracted October 2019) collected by EuropaBio (see Annex 1).

⁴ The authorisation holder is not an operator directly involved in the import of soybean oilseed into the EU for food/feed and processing. The approximate share of cultivation in the country of origin is provided, expressed as "NA" (not applicable, these GM soybeans were not cultivated in the country), "0-10%", "10-20%", "20-40%", "40-60%", "60-80%", or "80-100%".

⁵ 305423 x 40-3-2 soybeans (Plenish high oleic soybeans) have been cultivated and managed under identity preserved production to separate high oleic soybeans from commodity soybeans in order to maintain their identity in the context of a higher value, special use soybean oil. Although there were no exports to the EU of viable 305423 or 305423 x 40-3-2 soybeans for crushing into oil and while any potential import of 305423 or 305423 x 40-3-2 soybeans as commodity soybean would be negligible, general surveillance was conducted by operators in the same manner as for other GM products.

3.1.2 Commodity crop (GM and non-GM) imports into the Community by country of destination

Destination ¹	Quantity (tonnes) 2018-2019 ²
Austria	2 942
Belgium	587 966
Bulgaria	36
Croatia	-
Cyprus	-
Czech Republic	4 857
Denmark	9 208
Estonia	-
Finland	25 191
France	564 836
Germany	2 315 458
Greece	305 996
Hungary	25 953
Ireland	11 254
Italy	1 685 146
Latvia	-
Lithuania	1 291
Luxembourg	-
Malta	12
Netherlands	4 109 406
Poland	67 498
Portugal	1 070 678
Romania	169 841
Slovakia	46
Slovenia	-
Spain	3 392 808
Sweden	6 111
United Kingdom	701 871
EU Total	15 058 407

¹ EU Member States into which the commodity crop (GM and non-GM soybean) is imported.

² Quantity in tonnes of commodity crop (GM and non-GM soybean) imported during the reporting period (1st July 2018-30 June 2019) (rounded to nearest ton). Source: EUROSTAT 2019 (extracted October 2019), collected by EuropaBio (see details Annex 1).

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The soybean oilseed (GM and non-GM) import data from suppliers to the EU from outside the EU-28 (extra-EU) is presented in section 3.1.1 and 3.1.2, and is based on EUROSTAT data collected by the European Association of Bioindustries (EuropaBio) for the reporting period from July 2018 to June 2019. During this period, total extra-EU soybean imports represented approximately 15.058 million tonnes (Section 3.1.1). Extra-EU soybean imports vary from year to year depending on several factors (e.g. annual EU soybean harvest yields, the international currencies exchange rates, soybean oilseed price, transportation costs).

The largest suppliers of extra-EU soybean to the EU during the July 2018 - June 2019 period were the United States of America (USA), Brazil, Ukraine, Canada, Uruguay and Paraguay. Together, they accounted for approximately 98.95 % of total extra-EU soybean imports into the EU during the reporting period. The USA, by themselves, accounted for approximately 41.4 %, and Brazil (the second largest supplier) accounted for approximately 32.1 %. Section 3.1.1 also provides estimates for potential share for these GM soybeans based on data from the authorisation holder. It shall be mentioned that although there were no exports to the EU of viable 305423 or 305423 x 40-3-2 soybeans for crushing into oil and while any potential import of 305423 or 305423 x 40-3-2 soybean as commodity soybean would be negligible, if any, general surveillance was conducted by operators in the same manner as for other GM products.

Section 3.1.2 summarises the total soybean imports from outside the EU by destination. During the July 2018 - June 2019 period, the Netherlands, with a share of approximately 27.3%, was the main importer of extra-EU soybean in the EU. Other significant import markets for extra-EU soybean during the reporting period were Spain and Germany with a share of approximately 22.5 % and 15.4 %, respectively, followed by Italy and Portugal with a share of approximately 11.2 % and 7.11%, respectively.

Bulk shipments of soybean entering the EU are typically processed into compound animal feed, whereby the processed feed is unlikely to contain whole soybean seeds. The handling of the shipments is the same across Europe; upon arrival, shipments being unloaded into silos at the port of the importing Member State and transferred from there to feed processing plants adjacent to the port.

Regulation (EC) No 178/2002 regarding the general principles and requirements of food law and food safety procedures (EC, 2002), Regulation (EC) No 853/2004 on the hygiene of foodstuffs (EC, 2004), and Regulation (EC) No 1831/2003 regarding feed hygiene (EC, 2003) 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.

3.2 General surveillance

3.2.1 Description of General Surveillance

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

Pioneer is not involved in commodity trade with these GM soybeans. The monitoring methodology is, therefore, predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of these viable GM soybeans. These operators are exposed to these imported viable GM soybeans 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 post-market environmental monitoring (see below).

Since traders may co-mingle these GM soybeans with other commercial soybean, including other authorised GM soybeans, the authorisation holder works 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 on a general framework for monitoring of GMOs, including these GM soybeans, as follows:

⇒ The authorisation holder represented by EuropaBio shall:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed post-market environmental monitoring plan.
- Inform operators concerning the authorisation, safety and general characteristics of these GM soybeans and of the conditions as to general surveillance.
- Set up and maintain a website dedicated to operators including detailed information on these GM soybeans. The website, hosted on the EuropaBio website under <http://www.europabio.org/information-operators-product-information>, contains the following information:
 - An introduction to the purpose of the website
 - A table giving an overview of all currently approved GM plant products subject to general surveillance
 - A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU
 - A contact point at EuropaBio for information exchange on any of the GM plant products

The website will be regularly updated in order to further facilitate and ensure a transparent process for general surveillance and easy access to relevant information for operators.

- Contact the selected networks of operators annually reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).

⇒ The selected networks of operators (European trade associations) 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 GMOs and to routinely eradicate adventitious populations on their premises
 - to inform and remind their own member companies of this requirement
 - to report back any adverse effect reported to them to the European trade associations
- Report to the authorisation holders directly or via EuropaBio
 - at least annually, regardless 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. EuropaBio shall forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission.

The general surveillance information reported to and collected by the authorisation holder from the European trade associations or other sources shall be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and these GM soybeans can be established. If the investigation establishes that these GM soybeans were present when the adverse effect was identified, and confirms that these GM soybeans are the cause of the adverse effect, the authorisation holder shall immediately inform the European Commission. The authorisation holder, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

As described in the bullet points above, the authorisation holder shall submit an annual monitoring report, including results of the general surveillance, in accordance with the conditions of the authorisation. The report shall contain information on any unanticipated adverse effects, if any, that have arisen from handling and use of these viable GM soybeans.

The report shall include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of these GM soybeans and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

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

The authorisation holder, together with other members of the plant biotechnology industry and EuropaBio, implements general surveillance of viable GM soybeans, including these GM soybeans, 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 agro-supply. It represents the interests of the European collectors, traders, importers, exporters and port silo storekeepers of the above mentioned agricultural products. The main importers of cereals and feedstuffs into the EU are members of COCERAL.

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

⇒ Silo Operators

UNISTOCK is the European association representing professional storekeepers for 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/>

⇒ 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 oil producers/processors. Its members represent around 85% of the EU industry.

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 (EC, 2003b), 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 these viable GM soybeans, 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 monitoring plan for these GM soybeans (and the agreement with the network of operators, see Section 3.2.1) requires that the authorisation holder informs operators

of the introduction of these GM soybeans into the EU as well as on the safety and general characteristics of the product and of the conditions as to monitoring. Accordingly, the authorisation holder undertook to provide the necessary and relevant information concerning the placing on the market of these GM soybeans to the relevant stakeholders within the first year following the authorisation of these GM soybeans.

A summary of the information provided to the operators in accordance with the general surveillance system is provided under Section 3.2.1 of this report.

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 these GM soybeans placed on the market during the period from July 2018 to June 2019.

The trade associations implemented the monitoring in the framework of their routine surveillance of the commodities (GM and non-GM) they handle and use. As required in the monitoring plan, they reminded their members *“to monitor for potential unanticipated adverse effects; that, in the framework of their management or safety standards (ISO, HACCP, etc), procedures must be in place and implemented to limit losses and spillage of viable GMOs and to routinely eradicate adventitious populations on their premises – any such adventitious populations, resisting routine eradication procedures, shall be treated as potential adverse effects; to inform and remind their own member companies of this requirement; and to report back any adverse effect reported to them to the European trade associations”*.

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

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

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

3.2.5 Additional information

Pioneer point of contacts in the EU have been made available to operators and users as part of the information provided in the fact-sheets on these GM soybeans (published on the EuropaBio website). This allows operators and users to contact the authorisation holder directly for inquiries or to report any unusual effects observed in relation to the product, if any.

To date, no inquiries or reports of unusual effects observed in relation with these GM soybeans have been received.

3.2.6 Review of peer-reviewed publications

An updated systematic search and review of peer-reviewed literature, in line with the EFSA guidance on conducting a systematic review (EFSA, 2010) and taking into account the explanatory note on literature searching (EFSA, 2019), was conducted with the following review question “Do 305423 soybean or 305423 x 40-3-2 soybean and derived food/feed products, or the intended traits (the newly expressed proteins or their combination), have adverse effects on human and animal health and the environment in the scope of their authorisation?”, as described in Annex 4. The current systematic search complements the searches previously performed in the frame of the 2018 annual monitoring reports.

The review question and the search procedure took into account the product and scope of the authorisation (i.e., authorisation for import into the EU of food and feed containing, consisting of, or produced from 305423 or 305423 x 40-3-2 soybean) and the objectives of the studies (i.e., assessment of potential adverse effects on human and animal health and the environment of the genetically modified food and feed containing, consisting of or produced from 305423 or 305423 x 40-3-2 soybean). The systematic searches were performed according to the relevant parts of the EFSA guidance on the application of systematic review methodology to food and feed safety assessments (EFSA, 2010). The fundamental principles followed in this study were (1) methodological rigour and coherence in the retrieval and selection of studies; (2) transparency; and (3) reproducibility. Each search used a procedure that was developed *a priori*.

The systematic search and review of studies published in the scientific literature followed a tiered approach that included: (i) a systematic literature search, (ii) a screening of the retrieved records for relevance to the review question, and (iii) a thorough analysis of potential studies that were considered relevant.

The outcome of this systematic literature search and review showed that no new publications relevant for the review question were identified within the selected time-period (see Annex 4). No safety concerns have been identified for these GM maize by this literature search exercise.

3.3 Case-Specific Monitoring

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

The GMO Panel evaluated the environmental monitoring plan proposed by the authorisation holder for these GM soybeans and from its risk assessment considered that there was no requirement for a case-specific monitoring since no adverse effects were identified. The monitoring plans consisting of a general surveillance plan is in line with the intended uses for the GMO since the scope does not include cultivation.

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

The results of the monitoring plan of these GM soybeans indicate that no adverse effects on human and animal health or the environment have been observed for these GM soybeans import and use for food, feed and processing.

A post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003 is required for 305423 and 305423 x 40-3-2 soybean oil by article 5 of Commission Implementing Decision (EU) 2017/2448 (EC, 2017). As authorisation holder, Pioneer collaborates with third parties, such as farmers, crushers and all exporters involved in the production and trade of 305423 and 305423 x 40-3-2 soybean oil or 305423 and 305423 x 40-3-2 soybeans for crushing into oil, to collect, as required by the Commission Implementing decisions (EU) 2015/698 of 24 April 2015 and (EU) 2017/2448 of 21 December 2017, respectively, information on the quantities of 305423 and 305423 x 40-3-2 soybean oil and 305423 and 305423 x 40-3-2 soybeans for oil extraction, imported in the European Union for the placing on the market as or in products for food. On the basis of this information and as required by Commission Implementing decisions (EU) 2015/698 of 24 April 2015 and (EU) 2017/2448, respectively, we confirm that during the current Post-Market Monitoring (PMM) reporting period ending 30 June 2019, no 305423 or 305423 x 40-3-2 soybean oil or 305423 or 305423 x 40-3-2 soybeans for crushing into oil were exported to the EU for the placing on the market as or in products for food. This concludes our PMM reporting for 2019. Monitoring will continue as required and subsequent reports will be provided in 2020.

4 SUMMARY OF RESULTS AND CONCLUSIONS

Pioneer, as authorisation holder, has continued to implement the monitoring requirements in accordance with the relevant articles of the authorising decisions and as required under Articles 4 and 5 of Decision (EU) 2015/698 of 24 April 2015 (EC, 2015) and Articles 4 and 5 of Decision (EU) 2017/2448 (EC, 2017).

The general surveillance system put in place by the plant biotechnology industry and the European trade associations and utilised by the authorisation holder for these GM soybean imports, is functioning well. It provides for monitoring of potential unanticipated adverse effects that might arise from the presence of GMO material (including these GM soybeans) during import, handling and processing of crop commodities and ensures that any observed adverse effects are reported immediately to the authorisation holder. Furthermore, the trade associations provide annual reports to the authorisation holder via EuropaBio for the period from July to June, every year at the end of their business year.

The annual reports provided by the trade associations for the period from July 2018 to June 2019 revealed no adverse effects in the context of the placing on the market of these GM soybean imports (Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of these GM soybeans were reported to EuropaBio or the authorisation holder from July 2019 to date. Thus, no adverse effects have been reported by the trade associations from the date of authorisation of these GM soybeans for import and use as or in food, feed and processing to date. In addition, during the current Post-Market Monitoring (PMM) reporting period ending 30 June 2019, no 305423 or 305423 x 40-3-2 soybean oil or 305423 or 305423 x 40-3-2 soybeans for crushing into oil were exported to the EU for the placing on the market as or in products for food. This concludes our PMM reporting for 2019. Monitoring will continue as required and subsequent reports will be provided in 2020.

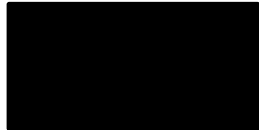
No articles or reports demonstrating adverse effects to human or animal health or the environment arising from these GM soybeans in the scope of these authorisations were published in peer-reviewed scientific publications during the current reporting period or before.

As a consequence, the results of the general surveillance of these GM soybeans carried out from July 2018 to June 2019 confirm no adverse effects on human and animal health or the environment have arisen from the import of these GM soybeans into the EU.

5 ADAPTATIONS OF MONITORING PLAN AND ASSOCIATED METHODOLOGY FOR FUTURE YEARS

In the light of the successful implementation of and results from current monitoring activities, which confirm the risk assessment and findings of the previous annual monitoring report, the authorisation holder consider that the general surveillance system in place for the monitoring of these GM soybean imports is fully appropriate and does not require amendment.

Signed:

A black rectangular box redacting the signature of the authorisation holder.

Date: 07.01.2020

REFERENCES

- EC, 2001. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Union 106, 1-38.
- EC, 2002. Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Union 31, 1-24.
- EC, 2003a. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Union 268, 1-23.
- EC, 2003b. Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Official Journal of the European Union 268, 1-5.
- EC, 2004. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. Official Journal of the European Union 226, 22-82.
- EC, 2005. Regulation (EC) No 1831/2003 laying down requirements for feed hygiene. In accordance with these Regulations, the principles of HACCP (Hazard Analysis and Critical Control Points) shall apply. Official Journal of the European Union 35, 1-22.
- EC, 2009. Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council. Official Journal of the European Union 275, 9-27.
- EC, 2015. Commission Implementing Decision (EU) 2015/698 of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union 112, 71-76.
- EC, 2017. Commission Implementing Decision (EU) 2017/2448 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 x 40-3-2 (DP-3Ø5423-11 x MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. Official Journal of the European Union 346, 6-11.
- EFSA, 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 8(6):1637. [90 pp.].
- EFSA, 2013. Scientific Opinion on application EFSA-GMO-NL-2007-45 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 for food and feed uses, import and processing under

Regulation (EC) No 1829/2003 from Pioneer. EFSA Journal 2013;11(12):3499, 35 pp. doi:10.2903/j.efsa.2013.3499.

EFSA, 2016 Scientific opinion on application by Pioneer (EFSA-GMO-NL-2007-47) for the placing on the market of the herbicide-tolerant, high oleic, genetically modified soybean 305423 x 40-3-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2016; 14(8):4566, 31pp. doi:10.2903/j.efsa.2016.4566

EFSA, 2019. Explanatory note on literature searching conducted in the context of GMO applications for (renewed) market authorisation and annual post-market environmental monitoring reports on GMOs authorised in the EU market. EFSA supporting publications 2019:EN-1614. [62 pp.].