Annual report on the implementation and the results of the monitoring activities for 4114 and 1507x59122xMON810xNK603 maize and its sub-combinations authorised by Commission Implementing Decisions (EU) 2019/1304 and (EU) 2018/1110, respectively

December 2020

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1 GENERAL INFORMATION

1.1 Crop/trait(s)

Maize / insect protection and herbicide tolerance traits

- 4114 maize
- 1507 x 59122 x MON 810 x NK603 maize and the following genetically modified maize combining two or three of the single events 1507, 59122, MON810 and NK603 (hereafter referred to as 'its sub-combinations covered by the authorisation'):

Maize	Unique identifier
1507 x 59122 x MON 810 x NK603	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6
Triple stack subcombinations	
1507 x 59122 x MON 810	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6
59122 x 1507 x NK603	DAS-59122-7 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6
1507 x MON 810 x NK603	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6
59122 x MON 810 x NK603	DAS-59122-7 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6
Double stack subcombinations	
1507 x 59122	DAS-Ø15Ø7-1 x DAS-59122-7
1507 x MON 810	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6
59122 x MON 810	DAS-59122-7 x MON-ØØ81Ø-6
59122 x NK603	DAS-59122-7 x MON-ØØ6Ø3-6

4114 maize and 1507 x 59122 x MON 810 x NK603 maize and its sub-combinations covered by the authorisation are hereafter collectively referred to as "these GM maize".

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

- 4114 maize : Commission Implementing Decision (EU) 2019/1304 of 26 July 2019[1] (EC, 2019)

[1] Article 5 (1) and (2) of Decision (EU) 2019/1304 requires the implementation and annual reporting on the results of the monitoring plan in accordance with Decision 2009/770/EC and Annex VII to Directive 2001/18/EC. The monitoring plan for 4114 maize is publicly available on the EU Register for Food and Feed:
https://webgate.ec.europa.eu/dyna/gm_register/maize4114_environmental_monitoring_plan.pdf.

- 1507 x 59122 x MON 810 x NK603 and its sub-combinations covered by the authorisation: Commission Implementing Decision (EU) 2018/1110 of 3 August 2018[2] (EC, 2018a, 2018b).

1.4 Unique identifier

- 4114 : DP-ØØ4114-3
- 1507 x 59122 x MON 810 x NK603 and its sub-combinations covered by the authorisation: See section 1.1 above

1.5 Reporting period from

July 2019 - June 2020[3]

1.6 Other monitoring reports have been submitted in respect of cultivation

Yes ☐ No ☒

[2] Article 5 (1) and (2) of Decision (EU) 2018/1110 requires the implementation and annual reporting on the results of the monitoring plan in accordance with Decision 2009/770/EC and Annex VII to Directive 2001/18/EC. The monitoring plan for 1507 x 59122 x MON 810 x NK603 maize and its sub-combinations is publicly available on the EU Register for Food and Feed: https://webgate.ec.europa.eu/dyna/gm_register/Monitoring%20plan%20AP92.pdf.

[3] 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

4114 maize and 1507 x 59122 × MON810 × NK603 maize have been developed by Pioneer Hi-Bred International, Inc. represented in the EU by Pioneer Overseas Corporation[4], hereafter referred to as Pioneer.

After the assessment made by the European Food Safety Authority (EFSA) (EFSA, 2018), 4114 maize received full European Union (EU) approval for import and use as or in food, feed and processing in July 2019 in accordance with:

> **Commission Implementing Decision (EU) 2019/1304** of 26 July 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 4114 (DP-ØØ4114-3), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (EC, 2019)

After the positive assessment made by EFSA of 1507 x 59122 × MON810 × NK603 maize and all its sub-combinations independently of their origin (EFSA, 2017), 1507 x 59122 × MON810 × NK603 maize and its sub-combinations covered by the authorisation (see section 1.1) received full EU approval for import and use as or in food, feed and processing in August 2018 in accordance with:

> **Commission Implementing Decision (EU) 2018/1110** authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 x 59122 x MON 810 x NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU (EC, 2018a).

Pioneer is the authorisation holder for the approval for placing on the market of 4114 maize and 1507 x 59122 × MON810 × NK603 maize and its sub-combinations covered by the authorisation 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) 2019/1304 (EC, 2019) and (EU) 2018/1110 (EC, 2018a).

The monitoring requirements outlined in decisions (EU) 2019/1304 (EC, 2019) and (EU) 2018/1110 (EC, 2018a) consist primarily of the implementation and reporting on the results of the monitoring plans in accordance with Annex VII to Directive 2001/18/EC (EC, 2001). No additional monitoring requirements apply for the use of these GM maize as or in food. Monitoring applies for the duration of the authorisation(s).

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

During this latest reporting period, monitoring activities for these GM maize, in particular general surveillance, were carried out in accordance with the monitoring plans and in line with the conditions laid out in the Decisions. 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 maize into the EU for this annual reporting period.** These findings concur with those of the previous annual monitoring report.

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) 2019-2020[6]	Estimated data of potential GM maize share in imports (where not possible approximate share of cultivation in the country of origin), for each specified product[7]
Ukraine	11 913 649	NA
Brazil[2]	**4 792 260**	**0-10%**
Serbia	1 225 186	NA
Moldova	326 029	NA
Canada[3]	298 489	**0-10%**
Argentina[4]	235 695	**0-10%**
Russian Federation	185 379	NA
United States of America[5]	**17 445**	**0-10%**
Other countries	38 590	NA
Total from countries cultivating these GM maize (GM and non-GM maize)	**5 343 889**	
Total from all countries (GM and non-GM maize)	**19 032 722**	

[1] Main countries exporting maize to the EU, which combined make up approximately 99% of total maize 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 maize to the EU, as collected by EuropaBio (source EUROSTAT 2020), is provided in Annex 1.

[2] Exporting country where 1507xMON810xNK603 and 1507xMON810 were cultivated in 2019 and/or 2020.

[3] Exporting country where 1507x59122xMON810xNK603 and 59122x1507xNK603 were cultivated in 2019.

[4] Exporting country where 1507xMON810xNK603 was cultivated in 2019 and/or 2020.

[5] Exporting country where 1507x59122xMON810xNK603, 59122x1507xNK603, 1507xMON810xNK603 were cultivated in 2019.

[6] Quantity in tonnes of commodity crop (GM and non-GM maize) imported during the reporting period (1st July 2019-30 June 2020) (rounded to nearest ton). Source: EUROSTAT 2020 (extracted August 2020) collected by EuropaBio (see Annex 1).

[7] The authorisation holder is not an operator directly involved in the import of maize grain into the EU for food/feed and processing. Therefore, it is not in a position to report directly on globally traded volumes of grain of the GM maize covered by these authorisations. However, in order to provide an estimate of the amount of these GM maize that could possibly be imported into the EU, the approximate share of cultivation in the country of origin is provided, for each specified GM maize product (see footnotes 2-5) expressed as "NA" (not applicable, GM maize covered by these authorisations were not cultivated in the country), "0-10%", 10-20%", "20-40%", "40-60%", "60-80%, or 80-100%". It must be kept in mind that these figures are estimates only, and that the potential amount of these GM maize that will be exported to the EU will only represent a portion of the cultivated amounts.

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

Destination[1]	Quantity (tonnes) 2019-2020[2]
Austria	113 997
Belgium	634 131
Bulgaria	1 414
Croatia	29 489
Cyprus	119 337
Czech Republic	165
Denmark	43 444
Estonia	2 306
Finland	11 040
France	10 900
Germany	744 625
Greece	133 632
Hungary	29 100
Ireland	946 985
Italy	1 659 499
Latvia	72 640
Lithuania	320 666
Luxembourg	-
Malta	6 604
Netherlands	3 989 721
Poland	46 480
Portugal	1 661 430
Romania	99 976
Slovakia	3 549
Slovenia	572 668
Spain	6 956 941
Sweden	20 349
United Kingdom	801 633
EU Total	**19 032 722**

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

[2] Quantity in tonnes of commodity crop (GM and non-GM maize) imported during the reporting period (1st July 2019-30 June 2020) (rounded to nearest ton). Source: EUROSTAT 2020 (extracted August2020), collected by EuropaBio (see details Annex 1).

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The maize grain (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 2019 to June 2020. During this period, total extra-EU maize imports represented approximately 19,033 million tonnes (Section 3.1.1). Extra-EU maize imports vary from year to year depending on several factors (e.g. annual EU maize harvest yields, the international currencies exchange rates, maize grain price, transportation costs).

The largest suppliers of extra-EU maize to the EU during the July 2019 to June 2020 period were Ukraine, Brazil, Serbia, Moldova, Canada, Argentina and the Russian Federation. Together, they accounted for approximately 99.7 % of total extra-EU maize imports into the EU during the reporting period. Ukraine, by itself, accounted for approximately 62.6 %, and Brazil (the second largest supplier) accounted for approximately 25.2 %. Section 3.1.1 also provides estimates for potential share for these GM maize based on data from the authorisation holder.

Section 3.1.2 summarises the total maize imports from outside the EU by destination. During the July 2019 to June 2020 period, Spain, with a share of approximately 36.5 %, was the main importer of extra-EU maize in the EU. Other significant import markets for extra-EU maize during the reporting period were the Netherlands with a share of approximately 21 %, Portugal and Italy both with a share of approximately 8.7 %, followed by Ireland and the UK with a share of approximately 5 % and 4.2 %, respectively.

Bulk shipments of maize entering the EU are typically processed into compound animal feed, whereby the processed feed is unlikely to contain whole maize kernels. 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 852/2004 on the hygiene of foodstuffs (EC, 2004), and Regulation (EC) No 183/2005 regarding feed hygiene (EC, 2005) contain operational rules and standards applicable to the handling of maize 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 maize commodity (listed in Section 3.2.2).

Pioneer is not involved in commodity trade with these GM maize. The monitoring methodology is, therefore, predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of these GM maize. These operators are exposed to these imported viable GM maize and therefore are 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 maize with other commercial maize, including other authorised GM maize, 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 maize, 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 maize and of the conditions as to general surveillance.
- Set up and maintain a website dedicated to operators including detailed information on these GM maize. 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, 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
  - 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 maize can be established. If the investigation establishes that these GM maize were present when the adverse effect was identified, and confirms that these GM maize 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 maize.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of these GM maize 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 maize, including these GM maize, with the help of the selected networks described below, according to the methodology outlined in the authorisation holder' 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 maize 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 maize, 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 maize (and the agreement with the network of operators, see Section 3.2.1) requires that the authorisation holder informs operators and users of the introduction of these GM maize 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 maize to the relevant stakeholders within the first year following the authorisation of these GM maize.

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 maize, placed on the market during the period from July 2019 to June 2020.

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 maize in the time period from July 2019 - June 2020 (see Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of these GM maize have been reported to EuropaBio or the authorisation holder since July 2020 to date.

3.2.5 Additional information

Contact points for Pioneer in Europe have been made available to operators and users as part of the information provided in the fact-sheet on these GM maize (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.
To date, no inquiries or reports of unusual effects observed in relation with these GM maize 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 for the authorised genetically modified (GM) maize, 4114 and 1507x59122xMON810xNK603 and its sub-combinations covered by the authorisation, with the following review question "Do the authorised GM maize 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 2019 annual monitoring report.

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 these GM maize) 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 these GM maize). 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, if any.

The outcome of this systematic literature search and review showed that two publications were identified as relevant for the review question (notably for 1507xMON810 maize and stacks with 1507) during the selected time-period (Annex 4). No safety concerns were 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 monitoring plan proposed by the authorisation holder and from its risk assessment considered that there was no requirement for a case-specific monitoring since no adverse effects were identified. The monitoring plan consisting of a general surveillance plan is in line with the intended uses for the GMOs since the scope does not include cultivation.

3.3.2 Processing (if applicable)

Not applicable.

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

Not applicable, see 3.3.1.

3.4 Concluding remarks

The results of the monitoring plan of these GM maize indicate that no adverse effects on human and animal health or the environment have been observed for these GM maize import and use for food, feed and processing. These findings concur with those of the previous annual monitoring report.

4 SUMMARY OF RESULTS AND CONCLUSIONS

Pioneer, as authorisation holder, has implemented the monitoring requirements in accordance with the relevant articles of the authorising decisions and as required in Commission Implementing decisions (EU) 2019/1304 (EC, 2019) and (EU) 2018/1110 (EC, 2018a).

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 maize 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 maize) 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 report provided by the trade associations for the period from July 2019 - June 2020 revealed no adverse effects in the context of the placing on the market of these GM maize imports (Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of these GM maize were reported to EuropaBio or the authorisation holder from July 2020 to date. Thus, no adverse effects have been reported by the trade associations from the date of authorisation of these GM maize for import and use as or in food, feed and processing to date.

No articles or reports demonstrating adverse effects to human or animal health or the environment arising from these GM maize in the scope of the 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 maize carried out from July 2019 - June 2020 confirm no adverse effects on human and animal health or the environment have arisen from the import of these GM maize into the EU for this annual reporting period. These findings concur with those of the previous annual monitoring report.

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, the authorisation holder considers that the general surveillance system in place for the monitoring of these GM maize imports is fully appropriate and does not require amendment.

Signed: 

Date: 21.12.2020

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