Annual report on the implementation and the results of the monitoring activities for 1507, 59122 and 1507xNK603 maize authorised by Commission Implementing decisions (EU) 2017/2452, 2018/1109 and 2019/1306, respectively

December 2021

TABLE OF CONTENTS

1 GENERAL INFORMATION

1.1 Crop/trait(s)

Maize / insect protection and herbicide tolerance traits

- 1507 maize – also referred to as Herculex® I Insect Protection [1] in the commercial context
- 59122 maize – also referred to as Herculex® RW Rootworm Protection [2] in the commercial context
- 1507xNK603 maize – also referred to as Herculex® I Insect Protection trait[1] stacked with the Roundup Ready® Corn 2 trait[3] (HX1xRR2) in the commercial context

1507, 59122 and 1507xNK603 maize 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

• 1507 maize	- Commission Implementing Decision (EU) 2017/2452 of 21 December 2017 (EC, 2017) amended by Commission implementing decision (EU) 2019/241 of 6 February 2019 as regards the representative of the authorisation holder (EC, 2019a) - Decisions originating from the EU/ 2017 No. 2452 amended by UK Statutory Instruments/ 2019 No. 705/PART 3
• 59122 maize	- Commission Implementing Decision (EU) 2018/1109 of 3 August 2018 (EC, 2018a) amended by Commission implementing decision (EU) 2019/241 of 6 February 2019 as regards the representative of the authorisation holder (EC, 2019a) - Decisions originating from the EU/ 2018 No. 1109 amended by UK Statutory Instruments/ 2019 No. 705/PART 3
• 1507xNK603 maize	- Commission Decision 2019/1306 of 26 July 2019 (EC, 2019b)

[1] Herculex I® Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred; Herculex® is a registered trademark of Dow AgroSciences LLC; Herculex® I Insect Protection is identified by the OECD unique identifier DAS-Ø15Ø7-1.
[2] Herculex® RW Rootworm Protection technology by Dow AgroSciences and Pioneer Hi-Bred International, Inc.; Herculex® is a registered trademark of Dow AgroSciences LLC.
[3] Roundup Ready® is a registered trademark of Monsanto Technology LLC. Roundup Ready® Corn 2 is identified by the OECD unique identifier MON-ØØ6Ø3-6. Note that maize is referred to as corn in the United States.

- Decisions originating from the EU/ 2019 No. 1306 amended by UK Statutory Instruments/2020 No. 1504/PART 3/Regulation 17

1.4 Unique identifier

- 1507 maize: DAS-Ø15Ø7-1
- 59122 maize: DAS-59122-7
- 1507xNK603 maize: DAS-Ø15Ø7-1xMON-ØØ6Ø3-6

1.5 Reporting period from

July 2020 - June 2021

1.6 Other monitoring reports have been submitted in respect of cultivation

Yes ☐ No ☒

2 EXECUTIVE SUMMARY

1507, 59122 and 1507 × NK603 maize have been developed by Pioneer Hi-Bred International, Inc. and Dow AgroSciences LLC[4,] hereafter referred to as Pioneer and Dow AgroSciences, respectively.

After the assessment made by the European Food Safety Authority (EFSA) (EFSA, 2004, 2005a, 2005b, 2009), **1507 maize** received full European Union (EU) approval for import and use as or in food, feed and processing in accordance with Commission Decisions 2005/772/EC (EC, 2005a) and the final consent of the Dutch Competent Authority issued on 16 March 2006, and Commission Decision 2006/197/EC of 3 March 2006 (EC, 2006), including a renewal of the authorisation to place on the market existing feed produced from 1507 maize in accordance with Commission Decision 2011/365/EU (EC, 2011). The food and feed safety of 1507 maize has also been substantiated by EFSA scientific opinions on the 1507 maize cultivation notification (EFSA, 2008, 2012). Following the positive opinion of the EFSA GMO Panel on the application for renewal of the authorisation of 1507 maize for food and feed use, import and processing in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 (EFSA, 2017b), the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 was **renewed** in accordance with **Commission Implementing Decision (EU) 2017/2452 of 21 December 2017** (EC, 2017). This decision has been fully transposed to the UK under Decisions originating from the EU/ 2017 No. 2452 (amended by UK Statutory Instruments/ 2019 No. 705/ PART3).

After the assessment made by the EFSA (EFSA, 2007), **59122 maize** received full EU approval for import and use as or in food, feed and processing in October 2007 in accordance with Commission Decision 2007/702/EC (EC). The safety of 59122 maize, notably the introduced Cry34Ab1/Cry35Ab1 and PAT proteins, has been further substantiated by an EFSA positive scientific opinion on the 59122 maize cultivation application (EFSA, 2013). Following the positive opinion of the EFSA GMO Panel of the application for renewal of the authorisation of 59122 maize for food and feed use, import and processing in accordance with Articles 11 and 23 of Regulation (EFSA, 2017a), the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified 59122 maize was **renewed** in accordance with **Commission Implementing Decision (EU) 2018/1109** (EC, 2018a, 2018b) as of 3 August 2018. This decision has been fully transposed to the UK under Decisions originating from the EU/ 2018 No. 1109 (amended by UK Statutory Instruments/ 2019 No. 705/ PART3).

After the assessment made by the EFSA (EFSA, 2006), **1507xNK603 maize** received full EU approval for import and use as or in food, feed and processing in October 2007 in accordance with Commission Decision 2007/703/EC (EC, 2007b). Following the positive

[4] represented in the EU by Pioneer Overseas Corporation and by Dow AgroSciences Distribution S.A.S, respectively, hereafter referred to as Pioneer and Dow AgroSciences, respectively. Pioneer and Dow AgroSciences are members of Corteva Agriscience group of companies. Dow AgroSciences LLC changed the name to Corteva Agriscience LLC as of 1st January 2021.

opinion by the EFSA GMO Panel (EFSA, 2018) on the application for renewal of the authorisation of 1507xNK603 maize for food and feed use, import and processing in accordance with Articles 11 and 23 of Regulation No 1829/2003, the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified 1507xNK603 maize was **renewed** in accordance with **Commission Implementing Decision (EU) 2019/1306 of 26 July 2019** (EC, 2019b). This decision has been fully transposed to the UK under Decisions originating from the EU/ 2019 No. 1306 (amended by UK Statutory Instruments/2020 No. 1504/PART 3/Regulation 17).

Pioneer and Dow AgroSciences are joint authorisation holders for the authorisations for placing on the market of 1507, 59122 and 1507xNK603 maize for import, food and feed uses. The purpose of this report is to provide information on the implementation and results of monitoring activities carried out by the authorisation holders 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) 2017/2452 (EC, 2017), (EU) 2018/1109 (EC, 2018a), (EU) 2019/1306 (EC, 2019b), (UK) Decisions originating from the EU/2017 No. 2452 (amended by UK Statutory Instruments 2019/No. 705/PART 3), (UK) Decisions originating from the EU/2018 No. 1109 (amended by UK Statutory Instruments 2019/No. 705/PART 3), and (UK) Decisions originating from the EU/2019 No. 1306 (amended by UK Statutory Instruments/ 2020 No. 1504/PART3/Regulation 17).

The monitoring requirements outlined in the above-mentioned decisions 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)[5]. No additional monitoring requirements apply for the use of 1507, 59122 and 1507xNK603 maize as or in food. Monitoring applies for the duration of the authorisations.

During this latest reporting period, monitoring activities for 1507, 59122 and 1507xNK603 maize, in particular general surveillance, were carried out in accordance with the monitoring plan 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 1507, 59122 and 1507xNK603 maize into the EU or Great Britain (GB) for this annual reporting period.** These findings concur with those of the previous annual reports on the implementation and results of monitoring activities for 1507, 59122 and 1507xNK603 maize.

[5] As per Article 5 of Commission Implementing Decisions (EU) 2017/2452 (EC, 2017), (EU) 2018/1109 (EC, 2018), and (EU) 2019/1306 (EC, 2019) respectively. The monitoring plan for 1507, 59122 and 1507xNK603 maize are publicly available on the EU Register for Food and Feed:
1507 : https://webgate.ec.europa.eu/dyna/gm_register/Monitoring%20plan%20maize%201507.pdf;
59122: https://webgate.ec.europa.eu/dyna/gm_register/environmental_monitoring_plan_maize_59122.pdf;
1507xNK603: http://ec.europa.eu/food/dyna/gm_register/maize_1507xNK603_environmental_monitoring_plan.pdf

3 USES OF GMOs OTHER THAN CULTIVATION

3.1 Commodity imports into the EU and the UK

3.1.1 Commodity crop (GM and non-GM) imports into the EU and the UK by country of origin for reporting period

Country of origin[1]	Quantity (EU imports in tons)[5]	Quantity (UK imports in tons)[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	6 534 236	834 228	NA
Brazil[2]	4 202 398	291 259	0-10%
Serbia	1 573 855	67 411	NA
Canada	1 006 085	319 125	0-10%
Russia	427 696	32 458	NA
South Africa	240 749	-	NA
Argentina[3]	148 022	204 621	0-10%
Turkey	-	19 322	NA
Other countries[4]	164 144	12 449	
Total from countries cultivating these GM maize (GM and non-GM maize)	4 355 062	507 142	
Total from all countries (GM and non-GM maize)	14 297 186	1 780 873	

[1] Data are provided for the main exporting countries, which combined make up approximately 99% of total maize imports from outside the EU and the UK. For the full list of exporting countries and detailed information on commodity types please refer to Annex 1.

[2] Exporting country where 1507 and 1507xNK603 were cultivated in 2020 and/or 2021.

[3] Exporting country where 1507xNK603 was cultivated in 2020 and/or 2021.

[4] It shall be noted that 1507 and 1507xNK603 were cultivated in Colombia which exported 0,4 ton to the EU[5] and 2,2 tons to the UK[6], 1507xNK603 was cultivated in Paraguay which exported 217 tons to the EU[5] and in the United States (USA) which exported 4425 tons to the EU[5] and 11262 tons to the UK[6].

[5] Source: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021). Data extracted October 2021, collected by CropLife Europe (see Annex 1).

[6] Source: HMRC/AHDB (2021) data for the UK covers Great Britain and Northern Ireland (July 2020 to June 2021) as it is not possible to extract the data for Great Britain separately. Data extracted October 2021, collected by CropLife Europe (see Annex 1).

[7] The authorisation holders are not operators directly involved in the import of maize grain into the EU or UK for food/feed and processing. Therefore, they are 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 or UK, the approximate share of cultivation in the country of origin is provided, for each specified GM maize product (see footnotes 2-4) 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 or UK will only represent a portion of the cultivated amounts.

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

Destination	Quantity (tonnes) 2020-2021[1]
Austria	88.007
Belgium	475.451
Bulgaria	33.148
Croatia	12.792
Cyprus	91.569
Czech Republic	339
Denmark	11.893
Estonia	2.104
Finland	7.868
France	5.486
Germany	287.441
Greece	184.352
Hungary	34.066
Ireland	1.016.083
Italy	1.387.352
Latvia	80.652
Lithuania	176.724
Luxembourg	-
Malta	18
Netherlands	2.681.280
Poland	56.014
Portugal	1.738.357
Romania	72.641
Slovakia	-
Slovenia	506.533
Spain	5.346.720
Sweden	295
United Kingdom	1.780.873

[1] Sources: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021). HMRC/AHDB (2021) data for the UK covers Great Britain and Northern Ireland (July 2020 to June 2021).

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The authorisation holders, via CropLife Europe[6] have collected data on maize grain imports (GM and non-GM) into the EU[7] and UK[8] for the reporting period from July 2020 to June 2021.

For the EU, according to this data, total imports of maize represented approximately 14.3 million tons and the main exporters of maize to the EU were Ukraine, Brazil, Serbia, Canada, Russian Federation, South Africa and Argentina which together accounted for approximately 98.8 % of total extra-EU maize imports (Table 3.1.1). Section 3.1.1 also provides estimates for potential share for these GM maize based on data from the authorisation holders.
During the July 2020 to June 2021 period, the main importer country for extra-EU maize in the EU were Spain, the Netherlands, Portugal, Italy and Ireland. Together, they accounted for approximately85% of the total extra-EU maize imports. Other significant import markets for extra-EU maize in the EU were Slovenia and Belgium (Table 3.1.2).

For the UK, according to the collected data, total imports of maize were approximately 1.78 million tons and the main exporters of maize to the UK were Ukraine, Canada, Brazil, Argentina, the Russian Federation, Serbia and Turkey which together accounted for approximately 99% of total maize imports (Table 3.1.1). Section 3.1.1 also provides estimates for potential share for these GM maize based on data from the authorisation holders.

Extra-EU and -UK maize imports vary from year to year depending on several factors (e.g. annual EU or UK maize harvest yields, the international currencies exchange rates, maize grain price, transportation costs).

Bulk shipments of maize entering the EU and the UK 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 country 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, 2005b) 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.

---

[6] As of January 1st, 2021, the authorisation holders ceased to be members of the European Association for Bio-industries (EuropaBio) and continue their post-market monitoring related activities under the umbrella of CropLife Europe.

[7] Source: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021).

[8] Source: HMRC/AHDB (2021) data for the UK covers Great Britain and Northern Ireland (July 2020 to June 2021) as it is not possible to extract the data for Great Britain separately.

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 CropLife Europe and has been endorsed by the operators involved in the trade of viable maize commodity (listed in Section 3.2.2).

The authorisation holders are 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 holders work together with other members of the plant biotechnology industry within CropLife Europe and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology.

The different parties agreed on a general framework for monitoring of GMOs, including these GM maize, as follows:

⇒ The authorisation holders represented by CropLife Europe 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 CropLife Europe website[9] under https://croplifeeurope.eu/product-information/, contains the following information:
  - An introduction to the purpose of the website
  - A table giving an overview of all currently approved GM plant products subject to general surveillance
  - A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU and GB
  - A contact point at CropLife Europe for information exchange on any of the GM plant products

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

[9] Hosted on the European Association for Bio-industries (EuropaBio) website until 31 December 2020

- 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 CropLife Europe
  - at least annually, regardless of whether an adverse effect was observed or not
  - immediately any adverse effects reported to them

Consequently, the European trade associations, COCERAL, UNISTOCK and FEDIOL, shall notify CropLife Europe of the results of the general surveillance on an annual basis. CropLife Europe shall forward this report to the respective authorisation holders for inclusion in their annual report to the European Commission and the Food Safety Agency (FSA).

The general surveillance information reported to and collected by the authorisation holders 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 holders 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 holders shall immediately inform the European Commission and the FSA. The authorisation holders, in collaboration with the European Commission and the FSA and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human 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 holders 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 holders, together with other members of the plant biotechnology industry and CropLife Europe, implement 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 holders' 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 EU28. 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 holders inform operators and users of the introduction of these GM maize into the EU and GB as well as on the safety and general characteristics of the product and of the conditions as to monitoring. Accordingly, the authorisation holders 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, CropLife Europe reminded the trade associations to provide their annual report on any occurrence of unanticipated adverse effects arising from the approved GM products, including these GM maize, placed on the market during the period from July 2020 to June 2021.

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

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

The trade associations informed CropLife Europe in a format that reiterates the terms of the agreement of the general surveillance system and reports on the outcome of the monitoring. The format allows the authorisation holders to comply with the requirement to give evidence to the Commission, the Competent Authorities and the FSA 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 2020 - June 2021 (see Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of these GM maize have been reported to CropLife Europe or the authorisation holders since July 2020 to date.

3.2.5 Additional information

Contact points for the authorisation holders 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 CropLife Europe website). This allows operators and users to contact the

authorisation holders 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, 2019b), was conducted for the authorised genetically modified (GM) maize, 1507, 59122 and 1507 × NK603, 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 2020 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 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 one publication was identified as relevant for the review question (notably for 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 holders 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

The authorisation holders have continued to implement the monitoring requirements in accordance with the relevant articles of the authorising decisions.

The general surveillance system put in place by the plant biotechnology industry and the European trade associations and utilised by the authorisation holders 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 holders. Furthermore, the trade associations provide annual reports to the authorisation holders via CropLife Europe for the period from July to June, every year at the end of their business year.

As in the previous year, the annual report provided by the trade associations for the period from July 2020 to June 2021 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 CropLife Europe or the authorisation holders from July 2020 to date. Thus, no adverse effects have been reported by the trade associations from the date of approvals 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 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 maize carried out from July 2020 to June 2021 confirm the findings of the previous annual reports on the implementation and results of monitoring activities for these GM maize. No adverse effects on human and animal health or the environment have arisen from the introduction of these GM maize into the EU and GB.

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 holders consider that the general surveillance system in place for the monitoring of these GM maize imports is fully appropriate and does not require amendment.

Signed: [redacted]

Date: 21.12.2021

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 852/2004 of the European Paliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. Official Journal of the European Union 226, 22-82.

EC, 2005a. 2005/772/EC: Commission Decision of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium. Official Journal of the European Union 291, 42-44.

EC, 2005b. Regulation (EC) No 183/2005 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 1-27.

EC, 2006. 2006/197/EC: Commission Decision of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union 70, 82-86.

EC, 2007a. 2007/702/EC: Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union 285, 42-46.

EC, 2007b. 2007/703/EC: Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union 285, 47-51.

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, 2011. 2011/365/EU: Commission Decision of 17 June 2011 amending Decision 2006/197/EC as regards the renewal of the authorisation to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council Official Journal of the European Union 163, 52-54.

EC, 2017. Commission Implementing Decision (EU) 2017/2452 of 21 December 2017 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC)

No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union 346, 25-30.

EC, 2018a. Commission Implementing Decision (EU) 2018/1109 of 3 August 2018 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council Official Journal of the European Union 203, 7-12.

EC, 2018b. Corrigendum to Commission Implementing Decision (EU) 2018/1109 of 1 August 2018 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council Official Journal of the European Union 221, 4.

EC, 2019a. Commission Implementing Decision (EU) 2019/241 of 6 February 2019 amending Decision 2007/703/EC and Implementing Decisions (EU) 2017/2452 and (EU) 2018/1109 as regards the representative of the authorisation holder. Official Journal of the European Union 39, 14-15.

EC, 2019b. Commission Implementing Decision (EU) 2019/1306 of 26 July 2019 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union 204, 75-80.

EC, 2019c. Commission Implementing Decision (EU) 2019/2086 of 28 November 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. Official Journal of the European Union 316, 87-93.

EC, 2019d. Commission Implementing Decision (EU) 2019/239 of 6 February 2019 amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449 and (EU) 2017/2450 as regards the representative or the authorisation holder. Official Journal of the European Union 39, 7-10.

EFSA, 2004. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/NL/00/10) for the placing on the market of insect-tolerant genetically modified maize 1507, for import and processing, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds (Question No EFSA-Q-2004-011). EFSA Journal 124, 1-18.

EFSA, 2005a. Opinion of the GMO Panel on an application (reference EFSA-GMO-NL-2004-02) for the placing on the market of insect-tolerant genetically modified maize 1507, for food use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International/Mycogen Seeds (Question No EFSA-Q-2004-087). EFSA Journal 182, 1-22.

EFSA, 2005b. Opinion of the GMO Panel related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds (Question No EFSA-Q-2004-072). EFSA Journal 181, 1-33.

EFSA, 2006. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2004-05) for the placing on the market of insect-protected and glufosinate and glyphosate-tolerant genetically modified maize 1507 x NK603, for food and feed uses, and import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred and Mycogen Seeds. EFSA Journal 4.

EFSA, 2007. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2005-12) for the placing on the market of insect-resistant

genetically modified maize 59122, for food and feed uses, import and processing under Regulation (EC) No 1829/2003, from Pioneer Hi-Bred International, Inc and Mycogen Seeds, c/o Dow AgroSciences LLC (Question No EFSA-Q-2005-045). EFSA Journal 470, 1-25.

EFSA, 2008. Request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507 - Scientific opinion of the Panel on Genetically Modified Organisms (Question No EFSA-Q-2008-679). EFSA Journal 851, 1-27.

EFSA, 2009. Application (EFSA-GMO-RX-1507) for renewal of authorisation for the continued marketing of existing products produced from maize 1507 for feed use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc./Mycogen Seeds. EFSA Journal 7.

EFSA, 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 8, 90.

EFSA, 2012. Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations on the genetically modified insect resistant maize 1507 for cultivation. EFSA Journal 10.

EFSA, 2013. Scientific Opinion on an application from Pioneer Hi-Bred International and Dow AgroSciences LLC (EFSA-GMO-NL-2005-23) for placing on the market of genetically modified maize 59122 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003. EFSA Journal 11, 104.

EFSA, 2017a. Scientific opinion on an application for renewal of authorisation for continued marketing of maize 59122 and derived food and feed submitted under articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. EFSA Journal 15.

EFSA, 2017b. Scientific opinion on an application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. EFSA Journal 15.

EFSA, 2018. Scientific Opinion on the assessment of genetically modified maize 1507 x NK603 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-008). EFSA Journal 16, 1-11.

EFSA, 2019a. Assessment of genetically modified maize MON89034x1507xMON88017x59122xDAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No1829/2003 (application EFSA-GMO-NL-2013-113). EFSA Journal 17, 30.

EFSA, 2019b. 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 16, 1614E-1614E.