

**Annual general surveillance report in 2018/2019 season for
genetically modified maize products* authorised in accordance with
Commission Decisions
2013/648/EU¹ and 2013/650/EU² amended by Commission Implementing
Decision (EU) 2019/240 as regards the representative of the authorisation
holders
by**

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¹ MON 89034 × 1507 × NK603

² MON 89034 × 1507 × MON 88017 × 59122, MON 89034 × 1507 × MON 88017, MON 89034 × 1507 × 59122, MON 89034 × MON 88017 × 59122, 1507 × MON 88017 × 59122, MON 89034 × 1507, MON 89034 × 59122, MON 1507 × MON 88017, MON 88017 × 59122

Data protection.

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

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1. General Information					
1.1 Crop/trait(s)¹	1.2 Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC	1.3 Decision authorisation number and date of authorisation under Regulation (EC) No 1829/2003	1.4 Unique identifier	1.5 Reporting period	1.6 Other monitoring reports have been submitted in respect of cultivation
Maize MON 89034 × 1507 × NK603	N/A	Commission Decision of 6 November 2013 (2013/648/EU) ²	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6	July 2018 – June 2019	No
Maize MON 89034 × 1507 × MON 88017 × 59122 and part of its sub-combinations ³	N/A	Commission Decision of 6 November 2013 (2013/650/EU) ²	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 and part of its sub-combinations ⁴	July 2018 – June 2019	No

¹ Hereafter, referenced as DAS and Bayer GM maize products.

² Amended by Commission Implementing Decision (EU) 2019/240 as regards the representative of the authorisation holders

³ MON 89034 × 1507 × MON 88017, MON 89034 × 1507 × 59122, MON 89034 × MON 88017 × 59122, 1507 × MON 88017 × 59122, MON 89034 × 1507, MON 89034 × 59122, 1507 × MON 88017, MON 88017 × 59122

⁴ MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON- 88Ø17-3, MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7, MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7, DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7, MON-89Ø34-3 × DAS- Ø15Ø7-1, MON-89Ø34-3 × DAS-59122-7, DAS- Ø15Ø7-1 × MON-88Ø17-3, MON-88Ø17-3 × DAS-59122-7

2. Executive Summary

In accordance with the product specific Commission Decisions, the authorisation holders Dow AgroSciences Distribution S.A.S. and Bayer Agriculture BVBA⁵, are accountable for general surveillance of the placing on the market of genetically modified (GM) whole-grain maize in the EU for the duration of the validity of the consents.

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

This annual general surveillance report for the 2018/2019 season presents the monitoring results of DAS and Bayer GM maize: MON 89034 × 1507 × NK603 and MON 89034 × 1507 × MON 88017 × 59122 and part of its sub-combinations³.

During the last year, taking into account our extensive commercial experience with these products; the lack of adverse findings from independent research, available through the public literature; and the fact that no reports of adverse effects of these products have been communicated; there is, to the best of our knowledge, no information available that questions the conclusion that any DAS and Bayer GM maize as referred to in this monitoring report does not pose any risk to health or the environment greater than conventional maize.

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

⁵ Hereafter, referenced as DAS and Bayer

3. Uses of GMOs Other Than Cultivation

3.1 Maize imports into the Community

3.1.1 Maize (GM + non-GM) imports into the Community by country of origin from countries where DAS and Bayer GM maize products are cultivated (2018/2019)

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

Maize products	Maize imports into the EU from where DAS and Bayer GM maize was cultivated and approximate share of cultivation in the country of origin					Total maize imports from the countries where DAS and Bayer GM maize was cultivated	Total maize imports from GM and non-GM maize cultivating countries
	Argentina	Brazil	Canada	Colombia	USA		
GM + non-GM imports into the EU*							
2018/2019 (Quantity 10 ³ tonnes)	401	4 030	2 037	9.7	281	6 749	24 183
Share of GM cultivation in 2018**							
MON 89034 × 1507 × NK603	0-20%	0-20%	0-20%	0-20%	0-20%	NA	NA
MON 89034 × 1507 × MON 88017 × 59122 ⁶	-	-	0-20%	-	0-20%		

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

** DAS and Bayer are not operators directly involved in the import of maize grain into the EU. Therefore, DAS and Bayer are not in a position to report directly on globally traded volumes of DAS and Bayer GM maize grain. However, in order to provide an idea of the amount of DAS and Bayer GM maize that could possibly be imported into the EU, the approximate share of cultivation in the country of origin is provided, expressed as “-“(no cultivation), 0-20%, 20-40%, 40-60%, 60-80% or 80-100%. It must be kept in mind that information on approximate share of cultivation are estimates only, and that the amount of DAS and Bayer GM maize that will be exported to the EU will only represent a portion of the cultivated amounts.

NA = Not applicable

⁶ None of the sub-combinations of MON 89034 × 1507 × MON 88017 × 59122 covered by Commission Decision of 6 November 2013 (2013/650/EU) is commercially cultivated

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

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

Country of destination	Quantity (10 ³ tonnes) in 2018/2019
Spain	7 131
Netherlands	4 851
Italy	2 203
United Kingdom	1 951
Portugal	1 756
Germany	1 661
Ireland	1 393
Belgium	690
Slovenia	457
Denmark	455
Lithuania	383
Poland	261
Austria	236
Greece	153
Latvia	144
Cyprus	127
France	120
Romania	46
Finland	43
Hungary	38
Sweden	36
Croatia	21
Estonia	10
Malta	6
Bulgaria	5
Slovakia	3
Czech Republic	2
Luxembourg	-
TOTAL	24 183

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

3.1.3 Analysis of data provided in Tables 3.1.1 and 3.1.2

The maize grain (GM and non-GM) import data from suppliers to the EU from outside the EU-28 (extra-EU) is presented in **Tables 3.1.1** and **3.1.2**.

Total extra-EU maize imports in 2018/2019 were approximately 24.2 million tonnes. Extra-EU maize imports vary from year to year depending on several factors (*e.g.* EU maize harvest, weather conditions, commodity price).

In 2018/2019, the largest suppliers of extra-EU maize to the EU were Ukraine, Brazil, Canada, Serbia, Argentina, Russia, Moldova, USA and South Africa⁷. Together, they accounted for over 99 % of total extra-EU maize imports into the EU in 2018/2019. Of these, Argentina, Brazil, Canada, Colombia and USA cultivated DAS and Bayer GM maize in 2018 (**Table 3.1.1**).

Table 3.1.2 summarizes the total maize imports into the EU by country of destination. These data indicate that Spain, the Netherlands, Italy, the United Kingdom, Portugal, Germany and Ireland are the main importers of extra-EU maize in the EU in 2018/2019, accounting for over 86 % of the total maize import volume.

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

Regulation (EC) No. 178/2002 regarding the general principles and requirements of food law and food safety procedures, Regulation (EC) No. 852/2004 on the hygiene of foodstuffs, and Regulation (EC) No. 1831/2003 regarding feed hygiene, 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 represents the consensus between all applicants/consent holders within European Association of Bioindustries (EuropaBio) and has been endorsed by the operators involved in the trade of viable maize commodity (listed in Section 3.2.2).

DAS and Bayer are not involved in commodity trade with GM maize. The monitoring methodology

⁷ According to EUROSTAT 2019 data, the suppliers of extra-EU maize to the EU in 2018/2019 were by decreasing order of importance: Ukraine, Brazil, Canada, Serbia, Argentina, Russia, Moldova, USA, South Africa, Mexico, North Macedonia, Bosnia and Herzegovina, Peru, Libya, Belarus, Australia, Turkey, India, China, Thailand, Japan, Ghana, Madagascar, Egypt, Switzerland, Kenya, Ecuador, Lebanon, Norway, Bolivia, Vietnam, Colombia, Cote d'Ivoire, Somalia, Mozambique, Sri Lanka, Philippines, Chile, Albania, Azerbaijan, Uzbekistan, Jordan, Guinea, South Korea, Nigeria, and Saudi Arabia. The EUROSTAT data showing all maize exporters into the EU are provided as Annex to this document.

hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable GM maize. They are exposed to the imported viable GM maize and therefore are the best placed to observe and report any unanticipated adverse effects in the framework of their routine surveillance of the commodities they handle and use. The routine surveillance is based on the HACCP principles as reflected on the website of the trade associations representing the operators involved in the PMEM (*see* below).

Since traders may commingle GM maize with other commercial maize, including authorised GM maize, DAS and Bayer are working together with other members of the plant biotechnology industry within the EuropaBio and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology.

The different parties agreed to collaborate on the following basis:

⇒ The consent holders represented by EuropaBio shall:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
- Inform the operators in a timely fashion of any newly approved GM plant products for import and processing under Regulation (EC) No 1829/2003 subject to general surveillance.
- Set up and maintain a website dedicated to operators that provides an overview and detailed information on approved GM plant products subject to general surveillance. The website⁸, contains the following information:
 - An introduction to the purpose of the website
 - A table giving an overview of all currently approved GM plant products subject to general surveillance
 - A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decisions(s) authorising the GM plant product in the EU
 - A contact point at EuropaBio for information exchange on any of the GM plant products

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

- Contact the selected networks of operators annually, providing them with an update on the approved GM plant products subject to general surveillance and reminding them of their agreement to report on any unanticipated adverse effects (or absence thereof).

⁸ EuropaBio - <http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information> - Accessed on 22 November 2019.

⇒ 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 maize and to routinely eradicate adventitious populations on their premises - any such adventitious populations, resisting routine eradication procedures, shall be treated as a potential adverse effect;
 - to inform and remind their own member companies of this requirement
 - to report back any adverse effect reported to them to the European trade associations
- Report to the consent holders directly or via EuropaBio
 - at least annually, regardless of whether an adverse effect was observed or not
 - immediately any adverse effects reported to them

Consequently, the European trade associations COCERAL, UNISTOCK and FEDIOL shall notify EuropaBio of the results of the general surveillance on an annual basis. The report shall cover all approved GM plant products subject to general surveillance. EuropaBio shall forward this report to the respective consent holders for inclusion in their annual report to the European Commission.

The general surveillance information reported to and collected by the consent 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 consent holders shall immediately investigate to determine and confirm whether a significant correlation between the effect and a specific GM maize can be established. If the investigation establishes that a specific GM maize is the cause of the adverse effect, the consent holders shall immediately inform the European Commission. The consent holders, 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 consent holders shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the consent. The report shall contain information on any unanticipated adverse effects that have arisen from handling and use of viable GM maize.

The report will include a scientific evaluation of the confirmed adverse effect, if any, a conclusion of

the safety of the 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

DAS and Bayer, together with other members of the plant biotechnology industry and EuropaBio, implement the general surveillance of viable GM maize, with the help of selected networks, according to the methodology outlined in DAS's and Bayer's general surveillance plan and as detailed in Section 3.2.1. The following networks are currently involved:

⇒ Importers / Traders

COCERAL is the European association of trade in cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agro-supply. It represents the interests of the European collectors, traders, importers, exporters and port silo storekeepers of the above mentioned agricultural products. The main importers of cereals and feedstuffs into the EU are members of COCERAL.

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

⇒ Silo Operators

UNISTOCK is the European association representing professional storekeepers for agribulk commodities in the EU. UNISTOCK full and extraordinary members are present in twelve countries and UNISTOCK is itself a full member of COCERAL. Commodity imports enter the EU by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.

Also see: <http://www.unistock.be> - Accessed on 22 November 2019.

⇒ Processors

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

Also see: <http://www.fediol.eu> - Accessed on 22 November 2019.

These associations represent the majority of European operators importing, handling and processing viable 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 1831/2003 and are therefore best placed to observe and report any unanticipated adverse effects.

Other networks consisting of operators further down the food and feed chain have not been selected for the general surveillance of viable GM 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.

Following the Commission Decisions regarding the placing of DAS and Bayer GM maize on the market under Regulation (EC) No 1829/2003, DAS and Bayer informed the operators in the Community who handle and process bulk mixtures of imported maize grains of the regulatory progress made in the EU. This notice also included a description of the establishment of a general surveillance plan.

Additionally, specific information concerning the safety, general characteristics and the general surveillance conditions for each of DAS and Bayer GM maize were uploaded on the website dedicated to trade associations representing the relevant operators that import, handle and process viable maize commodity in the EU, providing an overview and detailed information on approved GM plant products subject to general surveillance. The website⁸, hosted by EuropaBio, contains the following information for DAS and Bayer GM maize:

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

3.2.4 Results of General Surveillance

The reporting by the trade associations takes place at the end of their business year, *i.e.* end of June. Therefore, EuropaBio reminded the trade associations to provide their annual report on any occurrence of unanticipated adverse effects arising from the approved GM products, including MON 89034 × 1507 × NK603 maize, and MON 89034 × 1507 × MON 88017 × 59122 and part of its sub-combinations³, placed on the market during the period from July 2018 to June 2019.

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

companies of this requirement; and to report back any adverse effect reported to them to the European trade associations”.

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

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

The reports received from COCERAL, UNISTOCK and FEDIOL indicate that no adverse effects were reported from their members, thus implying that no adverse effects were linked to the presence of MON 89034 × 1507 × NK603 maize, or MON 89034 × 1507 × MON 88017 × 59122 and part of its sub-combinations⁹ in the time period from July 2018 to June 2019 (*see Appendix 1*). Furthermore, no incidents in relation to the placing on the market of MON 89034 × 1507 × NK603 maize, or MON 89034 × 1507 × MON 88017 × 59122 and part of its sub-combinations³ have been reported to EuropaBio or the authorisation holder since July 2018 to date.

3.2.5 Additional Information

Operators in the food and feed supply chain and/or any other person wishing to report a potential adverse effect associated with the import or use of DAS and Bayer GM maize in the EU, can refer to a contact point at EuropaBio website⁸. This contact will record any reports of potential adverse effects by means of a standardised adverse effect reporting form (**Appendix 2**). Reports of adverse effects are analysed in the annual general surveillance report.

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

3.2.6 Literature search

As part of the general surveillance requirements for maize DAS and Bayer GM maize, a literature search that complies with the recommendations outlined in the 2017 EFSA explanatory note on literature searching⁹ has been conducted on a monthly basis covering the time span June 2018 – May 2019 and is provided along with the literature search completeness checklist (Annex 2) in **Appendix 3**.

DAS and Bayer confirm that the literature search, conducted in accordance with the 2017 EFSA explanatory note on literature searching and within the context of the general surveillance for DAS and Bayer GM maize in the EU, identified no relevant publications that would invalidate the initial conclusions of the risk assessment for MON 89034 × 1507 × NK603 and MON 89034 × 1507 × MON 88017 × 59122 and part of its sub-combinations³.

Another important source of information supporting the safety of DAS and Bayer GM maize is the body of independent research performed on the parental lines as well as on sub-combinations covered by separate decisions. The relevant publications that specifically support the safety of those products can be found in the respective specific annual monitoring reports, submitted separately to-date.

3.3 Case-Specific Monitoring

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

The scientific evaluation of the characteristics of any DAS and Bayer GM maize in the environmental risk assessment (ERA) has shown that the risk for potential adverse effects on human and animal health or the environment is negligible in the context of the intended uses of DAS and Bayer GM maize. It is therefore considered that there is no need for case-specific monitoring.

3.3.2 Processing (if applicable)

Not applicable, *see* Section 3.3.1.

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

Not applicable, *see* Section 3.3.1.

3.4 Concluding remarks

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

⁹ EFSA - <https://www.efsa.europa.eu/en/supporting/pub/en-1207> - Accessed on 22 November 2019.

4. Summary of Results and Conclusions

In accordance with the Commission Decisions for the DAS and Bayer GM maize presented in Section 1, the consent holders for DAS and Bayer GM maize, Dow AgroSciences Distribution S.A.S. and Bayer Agriculture BVBA, are accountable for general surveillance of the placing on the market of these products in the EU for the duration of the validity of each consent.

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

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

5. Adaptation of the Monitoring Plan and Associated Methodology for future years

In view of the results given in this report, no revisions to the general surveillance plan are considered necessary for any DAS and Bayer GM maize

December 2019

EUROSTAT data showing all maize exporters into the EU

[illegible]