

**Annual general surveillance report in 2020/2021 season for  
genetically modified maize products\* authorised in accordance with**

**Commission Decision**

**2010/429/EU<sup>1</sup>,**

**Commission Implementing Decisions (EU)**

**2015/683<sup>2</sup>, 2015/684<sup>3</sup>, 2015/2279<sup>4</sup>, 2015/2281<sup>5</sup>, 2017/1207<sup>6</sup>, 2018/2045<sup>7</sup>,  
2018/2046<sup>8</sup>, 2019/1307<sup>9</sup>, 2019/1308<sup>10</sup>, 2021/60<sup>11</sup>, 2021/61<sup>12</sup>, 2021/63<sup>13</sup>,  
2021/65<sup>14</sup>, 2021/67<sup>15</sup>**

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\*<sup>1</sup>MON 88017 × MON 810, <sup>2</sup>MON 87460, <sup>3</sup>NK603, <sup>4</sup>NK603 × T25, <sup>5</sup>MON 87427, <sup>6</sup>MON 810, <sup>7</sup>NK603 × MON 810, <sup>8</sup>MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, MON 87427 × MON 89034 × 1507 × MON 88017, MON 87427 × MON 89034 × 1507 × 59122, MON 87427 × MON 89034 × MON 88017 × 59122, MON 87427 × 1507 × MON 88017 × 59122, MON 87427 × MON 89034 × 1507, MON 87427 × MON 89034 × MON 88017, MON 87427 × MON 89034 × 59122, MON 87427 × 1507 × MON 88017, MON 87427 × 1507 × 59122, MON 87427 × MON 88017 × 59122, MON 87427 × 1507, MON 87427 × MON 88017, MON 87427 × 59122, MON 89034 × MON 88017, <sup>9</sup>MON 87403, <sup>10</sup>MON 87411, <sup>11</sup>MON 87427 × MON 89034 × MIR162 × NK603, <sup>12</sup>MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603, <sup>13</sup>MON 89034, <sup>14</sup>MON 87427 × MON 89034 × MIR162 × MON 87411, <sup>15</sup>MON 88017

**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) <sup>1</sup>	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 <sup>2,3</sup>	1.4 Unique identifier	1.5 Reporting period	1.6 Other monitoring reports have been submitted in respect of cultivation
Maize MON 88017 × MON 810	N/A	Commission Decision of 28 July 2010 (2010/429/EU)	MON-88Ø17-3 × MON- ØØ81Ø-6	July 2020 – June 2021	No
Maize MON 87460	N/A	Commission Implementing Decision (EU) 2015/683 of 24 April 2015	MON 8746Ø-4	July 2020 – June 2021	No
Maize NK603	N/A	Commission Implementing Decision (EU) 2015/684 of 24 April 2015	MON-ØØ603-6	July 2020 – June 2021	No
Maize NK603 × T25	N/A	Commission Implementing Decision (EU) 2015/2279 of 4 December 2015	MON-ØØ6Ø3-6 × ACS-ZMØØ3-2	July 2020 – June 2021	No
Maize MON 87427	N/A	Commission Implementing Decision (EU) 2015/2281 of 4 December 2015	MON 87427-7	July 2020 – June 2021	No
Maize MON 810	N/A	Commission Implementing Decision (EU) 2017/1207 of 4 July 2017	MON-ØØ81Ø-6	July 2020 – June 2021	Yes

<sup>1</sup> Hereafter, referenced as Bayer GM maize products.

<sup>2</sup> EU: The decisions have been amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 and Commission Implementing Decision (EU) 2021/184 of 12 February 2021, as regards the representative of the authorisation holder.

<sup>3</sup> GB: Commission decisions adopted prior to 31 December 2020 have been transposed into GB legislation.

Maize NK603 × MON 810	N/A	Commission Implementing Decision (EU) 2018/2045 of 19 December 2018	MON-ØØ603-6 × MON-ØØ81Ø-6	July 2020 – June 2021	No
Maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 and part of its sub-combinations <sup>4</sup>	N/A	Commission Implementing Decision (EU) 2018/2046 of 19 December 2018	MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 and part of its sub-combinations <sup>5</sup>	July 2020 – June 2021	No
Maize MON 87403	N/A	Commission Implementing Decision (EU) 2019/1307 of 26 July 2019	MON-874Ø3-1	July 2020 – June 2021	No
Maize MON 87411	N/A	Commission Implementing Decision (EU) 2019/1308 of 26 July 2019	MON-87411-9	July 2020 – June 2021	No
Maize MON 87427 × MON 89034 × MIR162 × NK603 and part of its sub-combinations <sup>6</sup>	N/A	Commission Implementing Decision (EU) 2021/60 of 22 January 2021 <sup>7</sup>	MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 and part of its sub-combinations <sup>8</sup>	July 2020 – June 2021	No

<sup>4</sup> MON 87427 × MON 89034 × 1507 × MON 88017, MON 87427 × MON 89034 × 1507 × 59122, MON 87427 × MON 89034 × MON 88017 × 59122, MON 87427 × 1507 × MON 88017 × 59122, MON 87427 × MON 89034 × 1507, MON 87427 × MON 89034 × MON 88017, MON 87427 × MON 89034 × 59122, MON 87427 × 1507 × MON 88017, MON 87427 × 1507 × 59122, MON 87427 × MON 88017 × 59122, MON 87427 × 1507, MON 87427 × MON 88017, MON 87427 × 59122, MON 89034 × MON 88017

<sup>5</sup> MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3; MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7; MON-87427-7 × MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7; MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7; MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1; MON-87427-7 × MON-89Ø34-3 × MON-88Ø17-3; MON-87427-7 × MON-89Ø34-3 × DAS-59122-7; MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3; MON-87427-7 × DAS-Ø15Ø7-1 × DAS-59122-7; MON-87427-7 × MON-88Ø17-3 × DAS-59122-7; MON-87427-7 × DAS-Ø15Ø7-1; MON-87427-7 × MON-88Ø17-3; MON-87427-7 × DAS-59122-7; MON-89Ø34-3 × MON-88Ø17-3

<sup>6</sup> MON 87427 × MON 89034 × MIR162, MON 87427 × MON 89034 × NK603, MON 87427 × MIR162 × NK603, MON 89034 × MIR162 × NK603, MON 87427 × MON 89034, MON 87427 × NK603, MON 87427 × MIR162, MON 89034 × NK603, MON 89034 × MIR162, MIR162 × NK603

<sup>7</sup> GB application under review

<sup>8</sup> MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4, MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6, MON-87427-7 × SYN-IR162-4 × MON-ØØ6Ø3-6, MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6, MON-87427-7 × MON-89Ø34-3, MON-87427-7 × MON-ØØ6Ø3-6, MON-87427-7 × MIR162, MON-89Ø34-3 × MON-ØØ6Ø3-6, MON-89Ø34-3 × SYN-IR162-4, SYN-IR162-4 × MON-ØØ6Ø3-6

Maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and part of its sub-combinations <sup>9</sup>	N/A	Commission Implementing Decision (EU) 2021/61 of 22 January 2021 <sup>7</sup>	MON-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4 × MON-00603-6 and part of its sub-combinations <sup>10</sup>	July 2020 – June 2021	No
Maize MON 89034	N/A	Commission Decision of 30 October 2009 (2009/813/EC) <sup>7</sup>	MON-89034-3	July 2020 – June 2021	No
Maize MON 87427 × MON 89034 × MIR162 × MON 87411 and part of its sub-combinations <sup>11</sup>	N/A	Commission Implementing Decision (EU) 2021/65 of 22 January 2021 <sup>7</sup>	MON-87427-7 × MON-89034-3 × SYN-IR162-4 × MON-87411-9 and part of its sub-combinations <sup>12</sup>	July 2020 – June 2021	No
Maize MON 88017	N/A	Commission Decision of 30 October 2009 (2009/814/EC) <sup>7</sup>	MON-88017-3	July 2020 – June 2021	No

<sup>9</sup> MON 87427 × MON 87460 × MON 89034 × MIR162, MON 87427 × MON 87460 × MON 89034 × NK603, MON 87427 × MON 87460 × MIR162 × NK603, MON 87460 × MON 89034 × MIR162 × NK603, MON 87427 × MON 87460 × MON 89034, MON 87427 × MON 87460 × MIR162, MON 87427 × MON 87460 × NK603, MON 87460 × MIR162 × NK603, MON 87460 × MON 89034 × MIR162, MON 87460 × MON 89034 × NK603, MON 87427 × MON 87460, MON 87460 × MIR162, MON 87460 × NK603, MON 87460 × MON 89034

<sup>10</sup> MON-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4, MON-87427-7 × MON-87460-4 × MON-89034-3 × MON-00603-6, MON-87427-7 × MON-87460-4 × SYN-IR162-4 × MON-00603-6, MON-87460-4 × MON-89034-3 × SYN-IR162-4 × MON-00603-6, MON-87427-7 × MON-87460-4 × MON-89034-3, MON-87427-7 × MON-87460-4 × SYN-IR162-4, MON-87427-7 × MON-87460-4 × MON-00603-6, MON-87460-4 × SYN-IR162-4 × MON-00603-6, MON-87460-4 × MON-89034-3 × SYN-IR162-4, MON-87460-4 × MON-89034-3 × MON-00603-6, MON-87427-7 × MON-87460-4, MON-87460-4 × SYN-IR162-4, MON-87460-4 × MON-00603-6, MON-87460-4 × MON-89034-3

<sup>11</sup> MON 87427 × MON 89034 × MON 87411, MON 87427 × MIR162 × MON 87411, MON 89034 × MIR162 × MON 87411, MON 87427 × MON 87411, MON 89034 × MON 87411, MIR162 × MON 87411

<sup>12</sup> MON-87427-7 × MON-89034-3 × MON-87411-9, MON-87427-7 × SYN-IR162-4 × MON-87411-9, MON-89034-3 × SYN-IR162-4 × MON-87411-9, MON-87427-7 × MON-87411-9, MON-89034-3 × MON-87411-9, SYN-IR162-4 × MON-87411-9

## 2. Executive Summary

In accordance with Directive 2001/18/EC and the product specific Commission (Implementing) Decisions as mentioned in Section 1.3, the authorisation holder Bayer, is accountable for general surveillance of the placing on the market of genetically modified (GM) whole-grain maize in the EU and GB for the duration of the validity of the consents.

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

This annual general surveillance report for the 2020/2021 season presents the monitoring results of Bayer GM maize as listed in Section 1 of this report. During the last year, taking into account our extensive experience with these products; the lack of adverse findings from independent research, available through the public literature; and the fact that no reports of adverse effects of these products have been communicated; there is, to the best of our knowledge, no information available that questions the conclusion that any Bayer GM 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 Bayer GM maize in the EU and GB indicates that, to date, there have been no adverse health or environmental effects associated with the importation or use of any Bayer GM maize in the EU and GB.

### 3. Uses of GMOs Other Than Cultivation

#### 3.1 Maize imports into the EU and UK<sup>2</sup>

##### 3.1.1 Maize (GM + non-GM) imports into the EU and UK by country of origin from countries where Bayer GM maize is cultivated (2020/2021)

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

Maize products	Maize imports into the EU and UK from where Bayer GM maize was cultivated and approximate share of Bayer GM maize cultivation in the country of origin										Total maize imports from the countries where Bayer GM maize was cultivated	Total maize imports from GM and non-GM maize cultivating countries
	Brazil	Canada	Argentina	USA	Paraguay	Vietnam	Colombia	Uruguay	Philippines	Honduras		
<b>GM + non-GM imports into the EU<sup>1</sup>/UK<sup>2</sup></b>												
2020/2021 (Quantity 10 <sup>3</sup> tonnes)	4 202 / 291	1 006 / 319	148 / 205	4 / 11	0.22 / 0	0.02 / 0.05	0 / 0.002	0 / 0	0 / 0	0 / 0	5 213 / 826	14 297 / 1 781
<b>Share of GM cultivation in 2020<sup>3</sup></b>												
MON 88017 × MON 810											NA	NA
MON 87460												
NK603												
NK603 × T25												
MON 87427												
MON 810												
NK603 × MON 810												
MON 87427 × MON 89034 × 1507 × MON 88017 × 59122												
MON 89034 × MON 88017												
MON 87403												
MON 87411												
MON 87427 × MON 89034 × MIR162 × NK603												
MON 89034 × NK603												
MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603												
MON 87460 × MON 89034 × NK603												
MON 89034												

MON 87427 × MON 89034 × MIR162 × MON 87411			
MON 88017			

- <sup>1</sup> Source: EUROSTAT (2021) data covers 27 EU Member States (July 2020 to June 2021). Data are obtained through CropLife Europe (CLE) in October 2021 and show total maize imports into the EU in 2020/2021 from countries where Bayer GM maize was also cultivated in 2020. The EUROSTAT data showing all maize exporters into the EU are provided as an Annex to this document.
- <sup>2</sup> Source: HMRC/AHDB (2021) data for UK cover Great Britain and Northern Ireland (July 2020 to June 2021). Data are obtained through CLE in October 2021 and show total maize imports into the UK in 2020/2021 from countries where Bayer GM maize was also cultivated in 2020. The HMRC/AHDB data showing all maize exporters into the UK are provided as an Annex to this document.
- <sup>3</sup> Bayer is not an operator directly involved in the import of maize grain into the EU and UK. Therefore, Bayer is not in a position to report directly on globally traded volumes of GM maize grain. However, in order to provide an idea of the amount of GM maize that could possibly be imported into the EU and UK, the approximate share of cultivation in the country of origin is provided, expressed as “-“ (no cultivation), 0-20%, 20-40%, 40-60%, 60-80% or 80-100%. It must be kept in mind that information on approximate share of cultivation are estimates only, and that the amount of GM maize that will be exported to the EU and UK will only represent a portion of the cultivated amounts.

NA = Not applicable

### 3.1.2 Commodity Crop (GM + non-GM) imports into the EU and UK by country of destination (2020/2021)

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

Country of destination	Quantity (10 <sup>3</sup> tonnes) in 2020/2021
Spain	5 347
Netherlands	2 681
Portugal	1 738
Italy	1 387
Ireland	1 016
Slovenia	507
Belgium	475
Germany	287
Greece	184
Lithuania	177
Cyprus	92
Austria	88
Latvia	81
Romania	73
Poland	56
Hungary	34
Bulgaria	33
Croatia	13
Denmark	12
Finland	8
France	5
Estonia	2
Czech Republic	0
Sweden	0
Malta	0
Slovakia	0
Luxembourg	0
<b>TOTAL EU</b>	<b>14 297</b>
<b>TOTAL UK</b>	<b>1 781</b>

Sources: EUROSTAT (2021) data cover 27 EU Member States. HMRC/AHDB (2021) data for UK cover Great Britain and Northern Ireland. Period covers July 2020 to June 2021.

### 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 and GB from outside the EU and GB is presented in **Tables 3.1.1** and **3.1.2**.

Extra-EU/GB maize imports vary from year to year depending on several factors (*e.g.* EU maize harvest, weather conditions, commodity price).

For the **EU**, total extra-EU maize imports in 2020/2021 were approximately 14.3 million tonnes.

In 2020/2021, the suppliers of extra-EU maize to the EU were Ukraine, Brazil, Serbia, Canada, Russia, South Africa, Argentina and Moldova<sup>13</sup>. Of these, Brazil, Canada and Argentina cultivated Bayer GM maize in 2020 (**Table 3.1.1**).

**Table 3.1.2** summarises the total maize imports into the EU by country of destination. These data indicate that Spain, Netherlands, Portugal, Italy, Ireland, Slovenia, Belgium, and Germany are the main importers of extra-EU maize in the EU in 2020/2021, accounting for over 93 % of the total maize import volume.

For UK, total maize imports in 2020/2021 were approximately 1.8 million tonnes.

In 2020/2021, the suppliers of maize import into UK were Ukraine, Canada, Brazil, Argentina, Serbia, Russia, Turkey, and USA<sup>14</sup>. Of these, Canada, Brazil, Argentina, and USA cultivated Bayer GM maize in 2020 (**Table 3.1.1**).

**Table 3.1.2** summarises the total maize imports into UK.

Bulk shipments of maize entering the EU and UK 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 and UK; 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.

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<sup>13</sup> According to EUROSTAT 2021 data, the suppliers of extra-EU maize to the EU in 2020/2021 were by decreasing order of importance: Ukraine, Brazil, Serbia, Canada, Russia, South Africa, Argentina, Moldova, Belarus, Bosnia and Herzegovina, North Macedonia, Peru, USA, Ghana, Somalia, Turkey, Thailand, India, Paraguay, China, Kenya, Sri Lanka, Mexico, Madagascar, Japan, Switzerland, Vietnam, Lebanon, Ivory Coast, Guinea, Nigeria, Bolivia, Ecuador, Syria, Chile, South Korea, Cameroon, Antigua and Barbados, Jordan, Egypt, Malaysia, Senegal, United Arab Emirates, Australia, Trinidad and Tobago, Armenia, Costa Rica, Indonesia, Taiwan, Kazakhstan, Saudi Arabia, Uganda, Dominican Republic, Israel and Togo. The EUROSTAT data showing all maize exporters into the EU are provided as Annex to this document.

<sup>14</sup> According to HMRC/AHDB 2021 data, the suppliers of maize to UK in 2020/2021 were by decreasing order of importance: Ukraine, Canada, Brazil, Argentina, Serbia, Russia, Turkey, USA, South Africa, India, Vietnam, Mexico, Egypt, Peru, Ghana, Lebanon, Somalia, Sri Lanka, Pakistan, Thailand, China, Colombia, Ivory Coast, Philippines, Iran and Syria. The HMRC/AHDB data showing all maize exporters into GB are provided as Annex to this document.

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 183/2005 regarding feed hygiene, and their amendments, 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 CropLife Europe (CLE) and has been endorsed by the operators involved in the trade of viable maize commodity (listed in Section 3.2.2).

Bayer is not involved in commodity trade with GM maize. The monitoring methodology hence needs to be predominantly based on collaboration with third parties, such as operators involved in the import, handling and processing of viable GM 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 other authorised GM maize, Bayer is working 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 to collaborate on the following basis:

⇒ The consent holder represented by CropLife Europe shall:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
- Inform the operators in a timely fashion of any newly approved GM plant products for import and processing under Regulation (EC) No 1829/2003 or Directive 2001/18/EC subject to general surveillance.

- Set up and maintain a website dedicated to operators, that provides an overview and detailed information on approved GM plant products subject to general surveillance. The website<sup>15</sup> 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 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.

- 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<sup>15</sup> to report on any unanticipated adverse effects (or absence thereof).

⇒ The selected networks of operators (European trade associations) shall:

- Inform and remind their member organisations and companies on an annual basis
  - to monitor for potential unanticipated adverse effects
  - that, in the framework of their management or safety standards (ISO, HACCP, ...), procedures must be in place and implemented to limit losses and spillage of viable 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

<sup>15</sup> CropLife Europe - <https://croplifeeurope.eu/product-information/> - Accessed on 28 September 2021.

- Report to the consent 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. The report shall cover all approved GM plant products subject to general surveillance. CropLife Europe shall forward this report to the respective consent holders for inclusion in their annual report to the European Commission and to FSA.

The general surveillance information reported to and collected by the consent holder from the European trade associations or other sources shall be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the consent holder shall immediately investigate to determine and confirm whether a significant correlation between the effect and 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 holder shall immediately inform the European Commission and FSA. The consent holder, in collaboration with the European Commission and 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 consent holder shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the consent. The report shall contain information on any unanticipated adverse effects that have arisen from handling and use of the 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**

Bayer, together with other members of the plant biotechnology industry and CropLife Europe, implements the general surveillance of viable GM maize, with the help of selected networks, according to the methodology outlined in Bayer's general surveillance plan and as detailed in

Section 3.2.1. The following networks are currently involved:

⇒ *Importers / Traders*

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

Also see: <http://www.coceral.com> - Accessed on 28 September 2021.

⇒ *Silo Operators*

UNISTOCK is the European association representing professional storekeepers for agribulk commodities in the EU and GB. UNISTOCK full and extraordinary members are present in twelve countries and UNISTOCK is itself a full member of COCERAL. Commodity imports enter the EU and GB 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 28 September 2021.

⇒ *Processors*

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

Also see: <http://www.fediol.eu> - Accessed on 28 September 2021.

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 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 (Implementing) Decisions regarding the placing of Bayer GM maize on the market pursuant to Regulation (EC) No 1829/2003, Bayer informs the operators in the EU and GB who handle and process bulk mixtures of imported maize grains of the regulatory progress made in the EU and GB. 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 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 and GB, providing an overview and detailed information on approved GM plant products subject to general surveillance. The website<sup>15</sup>, hosted by CropLife Europe, contains the following information for each Bayer GM maize product:

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

### 3.2.4 Results of General Surveillance

The reporting by the trade associations takes place at the end of their business year, *i.e.* end of June. Therefore, 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 Bayer GM maize products as listed in Section 1 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 holder(s) to comply with the requirement to give evidence to the European Commission, FSA 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 Bayer GM maize products as listed in Section 1 in the time period from July 2020 to June 2021 (*see Appendix 1*). Furthermore, no incidents in relation to the placing on the market of Bayer GM maize products as listed in Section 1 have been reported to CropLife Europe or the authorisation holder since July 2020 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 Bayer GM maize in the EU and GB, can refer to a contact point at CropLife Europe website<sup>15</sup>. 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. Additionally, the Bayer Product Stewardship page offers a global contact point for

reporting any safety concern<sup>16</sup>.

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

### **3.2.6 Literature search**

As part of the general surveillance requirements for Bayer GM maize, a literature search that complies with the recommendations outlined in the 2019 EFSA explanatory note on literature searching<sup>17</sup> has been conducted on a quarterly basis covering the time span June 2020 – May 2021 and is provided along with the Appendix E – completeness checklist in **Appendix 3**.

Bayer confirms that the literature search, conducted in accordance with the 2019 EFSA explanatory note on literature searching and within the context of the general surveillance for the Bayer GM maize products in the EU and GB, identified no relevant publications that would invalidate the initial conclusions of the risk assessment for Bayer GM maize products as listed in Section 1.

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<sup>16</sup> Bayer - <https://www.bayer.com/en/product-stewardship.aspx> - Accessed on 28 September 2021.

<sup>17</sup> EFSA - <https://www.efsa.europa.eu/en/supporting/pub/en-1614> - Accessed on 28 September 2021.

### **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 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 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 any Bayer GM maize in the EU and GB indicates that there have been no adverse health or environmental effects associated with the importation or use of any Bayer GM maize.

## **4. Summary of results and conclusions**

In accordance with the Commission (Implementing) Decisions for the Bayer GM maize presented in Section 1, the consent holder, Bayer CropScience, is accountable for general surveillance of the placing on the market of these GM maize products in the EU and GB for the duration of the validity of each consent.

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

Therefore, the general surveillance accompanying the placing on the market of Bayer GM maize in the EU and GB 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 and

GB.

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

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

**October 2021**

**ANNEX. EUROSTAT and HMRC/AHDB data showing all maize exporters into the EU and UK, respectively**

## **EUROSTAT data showing all maize exporters into the EU**

July 2020 until June 2021 EU Corn Imports by Member State and by MAIN Exporter in tons (CN 10059000)

Reporter/Period	Austria	Belgium	Bulgaria	Croatia	Cyprus	Czechia	Denmark	Estonia
Ukraine	0,0	474.055,8	127,3	0,0	33.162,1	0,0	3.499,8	396,1
Brazil	0,0	20,8	0,0	0,0	0,0	0,0	0,0	0,0
Serbia	87.971,8	0,0	30.955,4	5.288,7	23.925,1	0,0	0,0	0,0
Canada	0,0	4,9	0,0	0,0	0,0	0,0	0,0	0,0
Russian Federation	0,0	0,0	745,0	0,0	17.369,6	0,0	5.269,9	0,0
South Africa	0,0	5,1	0,0	0,0	0,0	0,0	0,0	311,2
Argentina	20,3	390,6	1.089,5	390,0	181,1	323,0	3.050,6	
Moldova, Republic of		1,2			16.910,3			
Belarus								1.397,1
Bosnia and Herzegovina				7.113,0				
North Macedonia								
Peru		154,8						
United States	0,2	225,4	94,6		20,8		37,5	
Ghana								
Somalia								
Turkey	10,8	524,9	136,5				30,0	
Thailand								
India								
Paraguay								
China		3,4						
Kenya								
Sri Lanka		0,3						
Mexico		19,3					2,1	
Madagascar								
Japan								
Viet Nam						15,6	0,9	
Switzerland	3,4							
Lebanon		4,6			0,3			
Côte d'Ivoire		12,2						
Guinea		9,5						
Nigeria		8,6						
Bolivia								
Ecuador								
Syrian Arab Republic		5,9						
Chile								
Republic of South Korea								
Cameroon		2,5						
Antigua and Barbuda							2,4	
Jordan		0,7			0,1			
Egypt								
Malaysia								
Senegal								
United Arab Emirates								
Australia								
Trinidad and Tobago								
Armenia		0,3						
Costa Rica								
Indonesia								
Taiwan								
Kazakhstan								
Saudi Arabia								
Uganda								
Dominican Republic								
Israel		0,1						
Togo								
<b>Total</b>	<b>88.006,5</b>	<b>475.450,9</b>	<b>33.148,3</b>	<b>12.791,7</b>	<b>91.569,4</b>	<b>338,6</b>	<b>11.893,2</b>	<b>2.104,4</b>

Source: Eurostat, October 2021

Commodity Code: CN 10059000 Maize (excl. seed for sowing)



Netherland	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	Total
2.131.812,8	1.640,7	765.554,9	0,0	0,0	0,0	1.885.518,1	0,0	6.534.235,7
401.579,2	25,0	744.329,1	0,0	0,0	0,0	2.457.303,4	18,5	4.202.397,6
0,0	0,0	119.646,9	66.393,6	0,0	504.980,3	484.683,7	0,0	1.573.855,3
81.680,5	0,0	90.673,8	0,0	0,0	0,0	326.814,8	0,7	1.006.084,9
32.511,0	0,0	17.539,7	0,0	0,0	0,0	31.368,9	0,0	427.696,1
747,9	24,0	0,0	0,0	0,0	0,0	99.762,3	0,0	240.749,2
22.913,2	53.901,2	194,6	360,0			55.514,7	15,3	148.022,3
5.305,6			5.811,2					71.253,3
								59.294,6
					1.550,2		0,3	8.664,7
								5.178,5
68,9		55,1				4.640,3		5.082,0
729,9	415,2	0,5	76,3			1.099,7	221,3	4.424,5
								3.600,0
2.853,4							3,1	2.856,5
403,2					2,9		28,8	2.268,6
534,1								534,1
12,4		145,5						356,0
		216,5				0,4		216,9
15,2							0,2	62,4
53,5							0,3	53,8
49,2								49,5
3,3	8,0					5,0	0,2	47,3
							3,8	37,9
								32,3
0,5								21,6
								24,3
2,3								15,6
								12,3
								9,5
								8,8
						8,5		8,5
								6,0
								5,9
						0,1		4,2
1,0							1,3	2,7
								2,5
								2,4
0,4								1,2
								0,9
0,8								0,8
								0,8
								0,5
0,5								0,5
0,4								0,4
								0,3
0,3								0,3
							0,3	0,3
0,3								0,3
0,2								0,2
							0,2	0,2
							0,2	0,2
0,1								0,1
								0,1
								0,1
2.681.280,1	56.014,1	1.738.356,6	72.641,1	0,0	506.533,4	5.346.719,9	294,5	14.297.185,5

## **HMRC/AHDB data showing all maize exporters into the UK**

**July 2020 to June 2021 UK Maize Imports in tons (CN 10059000-10051018-10051090-10051019)**

Reporter/Period	United Kingdom
Ukraine	834.227,5
Canada	319.124,7
Brazil	291.258,5
Argentina	204.621,0
Serbia	67.410,9
Russia	32.458,2
Turkey	19.322,2
USA	11.262,0
South Africa	863,6
India	148,3
Vietnam	45,7
Mexico	32,3
Egypt	25,0
Peru	17,2
Ghana	12,9
Lebanon	10,9
Somalia	6,5
Sri Lanka	5,9
Pakistan	5,7
Thailand	4,5
China	2,6
Colombia	2,2
Ivory Coast	1,9
Philippines	1,4
Iran	0,5
Syria	0,4
<b>Total</b>	<b>1.780.872,5</b>

Source: HMRC, via the Agriculture and Horticulture Development Board  
<https://ahdb.org.uk/cereals-oilseeds/trade-data>

**Commodity Codes:**

10059000: Maize (excl. seed for sowing)

10051018: Hybrid maize seed for sowing (excl. three-cross and simple hybrid seed),

10051090: Maize seed for sowing (excl. hybrid)

10051019: Hybrid maize seed (excl. double, top cross, three-cross and simple hybrid maize seed)