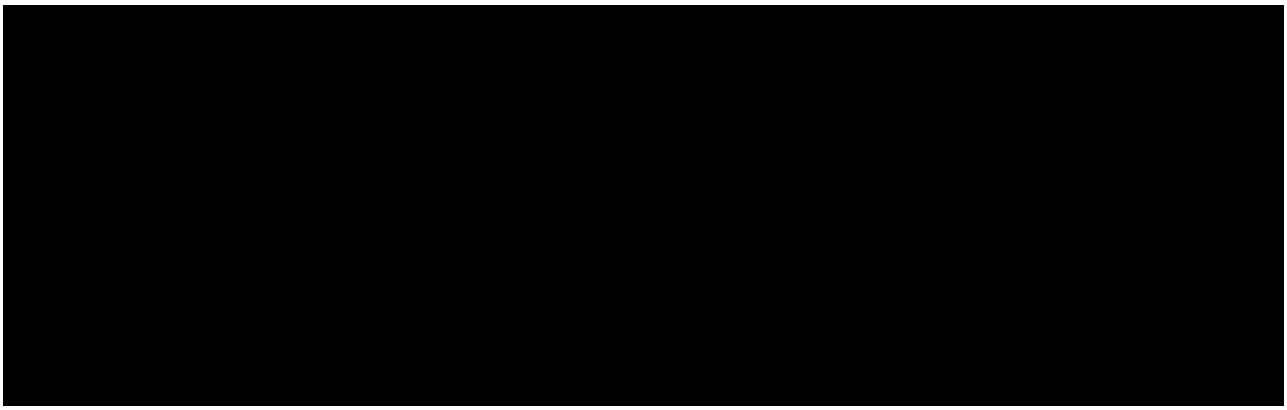
2021 Post-Market Environmental Monitoring (PMEM) Report for MIR162 Maize

This document is complete as of November 2021. It may be subject to later amendment or replacement. The information may also be supplemented with additional material requested by regulatory authorities. As such, it may only be considered properly with reference to those later amendments or supplementary materials and in the context of the dossier as a whole.



MONITORING REPORT FOR GMO USES OTHER THAN CULTIVATION

Format for presenting the monitoring results for GMO uses other than cultivation in accordance with: Articles 19(3), 20(1) and Annex VII to Directive 2001/18/EC and Articles 9(1) and 21(1) of Regulation (EC) No 1829/2003.

1. General information

1.1 Crop/trait(s): Maize / insect resistance

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 of authorisation under Regulation (EC) No 1829/2003: Commission Implementing Decision 2012/651/EU of 18 October 2012; Commission Implementing Decision (EU) 2019/60 of 11 January 2019

1.4 Unique identifier: SYN-IR162-4

1.5 Reporting period: July 2020 – June 2021

1.6 Other monitoring reports have been submitted in respect of:

cultivation: Yes ☐ **No** ☑

2. Executive summary

Taking into account the reports from the European trade associations (operators involved in the import, handling and processing of viable MIR162 maize), who are selected as the most appropriate participants in the general surveillance network, and the lack of adverse findings from independent research, available through the public literature, there is, to the best of our knowledge, no relevant information suggesting the occurrence of any adverse effects from MIR162 maize.

3. Uses of GMOs other than cultivation

Please note that this section relates to the monitoring of the environmental effects of GMO uses other than cultivation. Such uses include the use of Food and Feed containing or consisting of GMOs (living organisms).

3.1 Commodity imports into the Community

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

Country of origin[1]	Quantity of total maize imported (tons) July 2020 – June 2021		Estimated data of GMO share in imports (where not possible approximate share of cultivation in the country of origin)[2,3]
	EU[4]	UK[5]	MIR162
Ukraine	6,534,235.7	834,227.5	[redacted]
Brazil	4,202,397.6	291,258.5	
Serbia	1,573,855.3	67,410.9	
Canada	1,006,084.9	319,124.7	
Russia	427,696.1	32,458.2	
South Africa	240,749.2	863.6	
Argentina	148,022.3	204,621.0	
Moldova	71,253.3	< 0.1	
Belarus	59,294.6	< 0.1	
Bosnia and Herzegovina	8,664.7	< 0.1	
USA	4,424.5	11,262.0	
Turkey	2,268.6	19,322.2	
India	356.0	148.3	
Colombia	< 0.1	2.2	
Paraguay	216.9	< 0.1	
Philippines	< 0.1	1.4	
Uruguay	< 0.1	< 0.1	
Vietnam	21.6	45.7	
All other countries	17,644.2	126.3	
Total	**14,297,185.5**	**1,780,872.5**	

[1] Data are provided for (a) the top 10 (*i.e.* main) exporting countries for imports into the EU or UK (making up > 99% of total maize imports into the EU or UK); these countries are underlined, (b) countries where MIR162 maize is being cultivated, but that do not fall within the category of main exporting countries, and (c) all other remaining countries combined that export maize.

[2] Syngenta is not an operator directly involved in the import of maize into the EU or UK. Therefore, Syngenta is not in a position to report directly on globally traded volumes of MIR162 maize. However, in order to provide an idea of the amount of MIR162 maize that could possibly be imported into the EU or UK, the approximate share of cultivation of MIR162 maize in the country of origin is provided (rounded up figure). It must be kept in mind that these figures are estimates only, and that the amount of MIR162 maize that will be exported to the EU or UK will only represent a portion of the cultivated amounts. nc: GM maize in question not cultivated in the country.

[3] < 0.1%: indicates the threshold below which some insignificant amount of GM maize in question may be derived as a result of diverse minor sources such as field trials or Mendelian segregation of the harvested grain from a transformation stack hybrid (containing the GM maize in question) cultivated in that country during the same period.

[4] 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).

[5] Source: 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).

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

Country by destination[6]	Quantity of maize exported by all exporting countries (tons) July 2020 to June 2021[7]
Spain	5,346,719.9
Netherlands	2,681,280.1
Portugal	1,738,356.6
Italy	1,387,352.1
Ireland	1,016,083.3
Slovenia	506,533.4
Belgium	475,450.9
Germany	287,441.1
Greece	184,352.1
Lithuania	176,724.0
All other EU countries	496,892.0
EU total	**14,297,185.5**
United Kingdom	**1,780,872.5**

[6] Data are provided for the top 10 EU importing countries (making up approximately 96.5% of total maize imports in the EU) and for the UK.

[7] 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). See Annex 1.

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The maize (GM and non-GM) import data from suppliers to the EU and UK from outside the EU (extra-EU) and UK (extra-UK) are presented in **Tables 3.1.1** and **3.1.2**, and are based on the Eurostat and HMRC/AHDB data, respectively, collected by CropLife Europe for the reporting period July 2020 to June 2021.

Maize imports vary from year to year depending on EU and UK maize harvest and the demand of the feed industry. 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 the EU and UK; upon arrival, the shipments are unloaded into silos at the port of the importing Member State or UK and transferred from there to the feed processing plant present at the port.

The top 10 largest suppliers of extra-EU maize to the EU in the reporting period July 2020 to June 2021 are Ukraine, Brazil, Serbia, Canada, Russia, South Africa, Argentina, Moldova, Belarus and Bosnia and Herzegovina. Together, they accounted for approximately 99.8% of total extra-EU maize imports in the period July 2020 to June 2021. Of these countries, as can be seen in **Table 3.1.1**, only Brazil cultivated MIR162 maize. Annex 1 provides the EU maize imports by Member State and by exporting country in tons for the reporting period July 2020 to June 2021.

The top 10 largest suppliers of extra-UK maize to the UK in the reporting period July 2020 to June 2021 are Ukraine, Canada, Brazil, Argentina, Serbia, Russia, Turkey, USA, South Africa and India. Together, they accounted for over 99.9% of total extra-UK maize imports in the period July 2020 to June 2021. Of these countries, as can be seen in **Table 3.1.1**, only Brazil cultivated MIR162 maize. Annex 1 provides the UK maize imports by exporting country in tons for the reporting period July 2020 to June 2021.

Taking into account the estimated share of cultivation of MIR162 maize in the exporting countries and the relative weight of these countries among the import origins, it could be estimated that [redacted] of total imported maize into the EU and UK might contain the MIR162 maize event.

The top 10 largest EU importing countries of extra-EU maize in the reporting period July 2020 to June 2021 are Spain, Netherlands, Portugal, Italy, Ireland, Slovenia, Belgium, Germany, Greece and Lithuania, as provided in **Table 3.1.2**. Together, they accounted for approximately 96.5% of total maize imports into the EU in the reporting period July 2020 to June 2021.

The total maize import into the UK is also provided in **Table 3.1.2**.

3.2 General surveillance

3.2.1 Description of general surveillance

The current approach used for general surveillance represents the 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).

Syngenta is not involved in commodity trade with MIR162 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 MIR162 maize. They are exposed to the imported viable MIR162 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.

Since traders may commingle MIR162 maize with other commercial maize, including authorised GM maize, Syngenta 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 PMEM plan.
- Inform operators concerning the authorisation, safety and general characteristics of MIR162 maize and of the conditions as 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, hosted on the CropLife Europe website 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 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 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 maize 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
  - to report back any adverse effect reported to them to the European trade associations
- 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 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/authorisation holders for inclusion in their annual report to the European Commission and UK's Food Standards Agency.

The general surveillance information reported to and collected by Syngenta from the European trade associations or other sources shall be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, Syngenta will immediately investigate to determine and confirm whether a significant correlation between the effect and MIR162 maize can be established. If the investigation establishes that MIR162 maize was present when the adverse effect was identified, and confirms that MIR162 maize is the cause of the adverse effect, Syngenta shall immediately inform the European Commission and UK's Food Standards Agency. Syngenta, in collaboration with the European Commission and UK's Food Standards Agency, 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 confirmed effect.

As described in the bullet points above, Syngenta 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 that have arisen from handling and use of viable MIR162 maize.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MIR162 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

Syngenta, together with other members of the plant biotechnology industry and CropLife Europe, will implement general surveillance of viable GM maize, including MIR162 maize, with the help of the selected networks described below, according to the methodology outlined in the authorisation holder's general surveillance plan and as detailed in Section 3.2.1. The following networks are currently involved:

⇒ *Importers / Traders*

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

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

⇒ *Silo Operators*

UNISTOCK is the European association representing professional storekeepers for agribulk commodities. 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 UK 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 European Vegetable Oil and Proteinmeal Industry, represents the interests of the European crushers of oilseeds, meal producers and vegetable oil producers/processors. Its members represent around 85% of the European 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, 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 MIR162 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.

According to the general surveillance plan agreed with the operators, CropLife Europe acts as the focal point for exchanging information on MIR162 maize.

CropLife Europe maintain a website dedicated to operators that provides an overview and detailed information on approved GM plant products subject to general surveillance. The website, hosted on the CropLife Europe website 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 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

MIR162 maize information was introduced immediately after the publication of the Commission Decision.

The information on MIR162 maize contains:

- Trade Name, Company Development Code and Unique Identifier.
- A Factsheet with information on MIR162.
- The Opinion of the Scientific Panel on Genetically Modified Organisms on the application.
- The authorisations granted in the EU:
    - Community Register for GM Food and Feed Entry for MIR162 maize

In addition, following the publication of the Commission Decision, Syngenta informed directly to relevant stakeholders (including international maize traders, processing companies, North American maize growers and the general public) of the regulatory progress made in the EU and UK.

Syngenta keeps direct communication with operators through their industry associations in the exporting countries and in the EU and UK.

3.2.4 Result 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 MIR162 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 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 MIR162 maize in the time period from July 2020 to June 2021 (see Annexes 2 and 3). Furthermore, no incidents in relation to the placing on the market of MIR162 maize have been reported to CropLife Europe or the authorisation holder since July 2021 to date.

3.2.5 Additional information

No adverse effects associated with the import or use of Syngenta's MIR162 maize in any part of the world have been reported.

3.2.6 Review of peer-reviewed publications – Appendix

Syngenta has performed a review of all publications which have emerged during the reporting period including peer-reviewed publications and any additional studies or other sources of information relevant to the importation and processing and to food and/or feed use of the MIR162 maize. The literature search report is provided in Annex 4.

No indication of adverse effect of MIR162 maize in the context of the authorisation has been found.

3.3 Case-specific monitoring

3.3.1 Description and results of case-specific monitoring (if applicable)

Not applicable.

3.3.2 Processing (if applicable)

Not applicable.

EU Member State	Point of entry / site of cultivation	Point of processing	Distance from point of entry / site of cultivation	Transport used

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

Syngenta has informed operators about appropriate management measures to be taken in the event of accidental grain spillage. No further case-specific monitoring measures are required.

3.4 Concluding remarks

There have been no reports on adverse health or environmental effects associated with the use of MIR162 maize in any of the places where it is being planted and/or consumed.

4. Summary of results and conclusions

The top 10 largest suppliers of extra-EU maize to the EU in the reporting period July 2020 to June 2021 are Ukraine, Brazil, Serbia, Canada, Russia, South Africa, Argentina, Moldova, Belarus and Bosnia and Herzegovina. Together, they accounted for approximately 99.8% of total extra-EU maize imports in the period July 2020 to June 2021. Of these countries, as can be seen in **Table 3.1.1**, only Brazil cultivated MIR162 maize.

The top 10 largest suppliers of extra-UK maize to the UK in the reporting period July 2020 to June 2021 are Ukraine, Canada, Brazil, Argentina, Serbia, Russia, Turkey, USA, South Africa and India. Together, they accounted for over 99.9% of total extra-UK maize imports in the period July 2020 to June 2021. Of these countries, as can be seen in **Table 3.1.1**, only Brazil cultivated MIR162 maize.

Taking into account the estimated share of cultivation of MIR162 maize in the exporting countries and the relative weight of these countries among the import origins, it could be estimated that [redacted] of total imported maize into the EU and UK might contain the MIR162 maize event.

The reports received from COCERAL, UNISTOCK and FEDIOL show that no adverse effects linked to the presence of MIR162 maize were recorded in the time period from July 2020 to June 2021.

Syngenta has not received any adverse report or indication from operators handling MIR162 maize in the EU or UK.

There have been no reports on adverse health or environmental effects associated with the use of MIR162 maize in the countries where it is being commercialized.

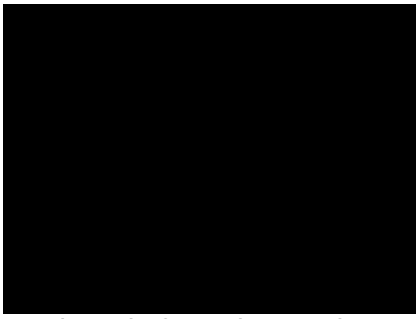
No indication of adverse effects of MIR162 maize in the context of the authorisation has been found in the literature search.

In summary, there is, to the best of our knowledge, no information available that questions the conclusion that MIR162 maize does pose any greater risk to health or the environment than conventional maize.

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 MIR162 maize.

Signed:



(Head of Seeds Regulatory EAME)

Date: November 25, 2021