2019 Annual Report on the General Surveillance of T25 Maize in the EU

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Represented by
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ANNUAL REPORT ON THE GENERAL SURVEILLANCE OF T25 MAIZE IN THE EU

1. General Information

1.1 Crop/trait(s): T25 Maize / Glufosinate-ammonium herbicide tolerance

1.2 Decision authorisation number pursuant to Directive 2001/18/EC and number and date of consent pursuant to Directive 2001/18/EC: NA[1]

1.3 Decision authorisation number and date of authorisation pursuant to Regulation (EC) No 1829/2003: Commission Implementing Decision (EU) 2015/697 of 24 April 2015

1.4 Unique identifier: ACS-ZMØØ3-2

1.5 Reporting Period from: July 2018 to June 2019

1.6 Other monitoring reports have been submitted in respect of Cultivation: No

2. Executive Summary

On 24 April 2015, the European Commission issued Commission Implementing Decision (EU) 2015/697[2] (as amended by Commission Implementing Decision (EU) 2019/1195[3] addressed to BASF SE) authorising the placing on the market of genetically modified maize T25 and renewing the existing maize T25 products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

This authorisation covers the following products:
a) foods and food ingredients containing, consisting of, or produced from T25 maize;
b) feed containing, consisting of, or produced from T25 maize;
c) products other than food and feed containing or consisting of T25 maize for the same uses as any other maize with the exception of cultivation.

In accordance with Directive 2001/18/EC and Article 4 of Commission Implementing Decision (EU) 2015/697, the authorisation holder for T25 maize, shall ensure that the monitoring plan, contained in the application and consisting of a general surveillance plan, is put in place and implemented. In addition, Article 4 of Commission Implementing Decision (EU) 2015/697 stipulates that the authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan.

[1] NA: not applicable.
[2] Commission Implementing Decision of 24th of April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize T25 (ACS-ZMØØ3-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council ((EU) 2015/697). *Official Journal of the European Union* L 112/66, 30.04.2015.
[3] Commission Implementing Decision (EU) 2019/1195 of 10 July 2019 amending Decisions 2008/730/EC, 2008/837/EC, 2009/184/EC, 2011/354/EU, Implementing Decisions 2012/81/EU, 2013/327/EU, (EU) 2015/690, (EU) 2015/697, (EU) 2015/699, (EU) 2016/1215, (EU) 2017/1208 and (EU) 2017/2451 as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean, cotton, oilseed rape and maize. *Official Journal of the European Union* L 187/43, 12.7.2019.

In view of the obligation to submit annual monitoring reports for T25 maize, the authorisation holder has undertaken a number of general surveillance activities accompanying the placing on the market of T25 maize in the EU. An updated status on these activities is given in this annual monitoring report.

To date, the general surveillance accompanying the placing on the market of T25 maize indicates that there have been no adverse health or environmental effects associated with the importation or use of T25 maize. Therefore, no revisions to the general surveillance plan are considered necessary for T25 maize.

3. Uses of GMOs Other Than Cultivation

3.1 Commodity imports into the Community

3.1.1 Commodity crop (GM + non-GM) imports into the Community by country of origin (actuals for the reporting period of July 2018 to June 2019)[4]

Country of origin[5]	**Quantity[6] (tons)**
Ukraine	15.658.048,0
Brazil*	4.029.556,2
Canada*	2.036.703,6
Serbia	829.269,0
Argentina*	401.039,8
Russia	327.066,1
Moldova	326.310,1
United States*	281.242,5
All Other Countries	293.507,4
TOTAL extra-EU	**24.182.742,7**

[4] Source: Eurostat (2019).
[5] Data are provided for the main exporting countries, which combined make up approximately 98% of total maize imports. Data for exporting countries where T25 maize is authorised for cultivation is marked with "*".
[6] The quantities are total EU-28 imports.

3.1.2 Commodity crop (GM + non-GM) imports into the Community by country of destination (actuals for reporting period of June 2018 to July 2019)[4]

Destination country	**Quantity[6] (tons)**
Spain	7.131.161,6
Netherlands	4.851.080,9
Italy	2.202.562,9
United Kingdom	1.951.371,1
Portugal	1.756.152,1
Germany	1.661.347,3
Ireland	1.392.727,2
Belgium (and Luxembourg)	689.775,4
Slovenia	456.572,8
Denmark	455.381,5
Lithuania	382.854,5
Poland	261.416,9
Austria	235.914,3
Greece	153.253,8
Latvia	143.577,2
Cyprus	127.176,4
France	120.207,4
Romania	46.053,0
Finland	42.810,2
Hungary	37.832,8
Sweden	36.465,8
Croatia	20.526,3
Estonia	10.189,4
Malta	6.124,4
Bulgaria	4.992,3
Slovakia	3.421,0
Czech Republic	1.794,2
TOTAL	**24.182.742,7**

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The authorisation holder, via EuropaBio, has collected EUROSTAT data on maize imports into the EU for the period of July 2018 to June 2019. According to this data, total extra-EU imports of maize were 24.182.742,7 tons and the main exporters of maize to the EU were Ukraine, Brazil, Canada, Serbia, Argentina, Russia and Moldova which together accounted for approximately 98% of total extra-EU maize imports.

For the period of July 2018 to June 2019, T25 maize was authorised for cultivation in Brazil, United States, Canada and Argentina. The total EU maize imports from Brazil, United States, Canada and Argentina were 4.029.556,2, 281.242,5, 2.036.703,6 and 401.039,8 tons, respectively. For the period of July 2018 to June 2019, Brazil, United States, Canada and Argentina maize exports to the EU accounted for around 28 % of total extra-EU maize imports (**Table 3.1.1**).

Table 3.1.2 summarizes the total maize imports from outside the EU-28 by destination. The main import countries for maize in the EU during the period of July 2018 to June 2019 were Spain, Netherlands, Italy and the United Kingdom. They are accounting together for approximately 67% of the total maize imports. Other main import markets of extra-EU maize grain were Portugal, Germany, Ireland and Belgium (and Luxembourg).

3.2 General Surveillance

3.2.1 Description of General Surveillance

The current approach used for general surveillance represents the consensus between all authorisation holders within EuropaBio and has been endorsed by the operators involved in the trade of viable maize commodity (listed in Section 3.2.2).

The authorisation holder is not involved in commodity trade with T25 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 T25 maize. They are exposed to the imported viable T25 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 T25 maize with other commercial maize, including authorised GM maize, the authorisation holder is working together with other members of the plant biotechnology industry within the European Association of Bioindustries (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 holder 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 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, hosted on the EuropaBio website under

  http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information, contains the following information:

  - An introduction to the purpose of the website
  - A table giving an overview of all currently approved GM plant products subject to general surveillance
  - A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission 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).

⇒ 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
  - 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 of 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 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 authorisation holders for inclusion in their annual report to the European Commission.

The general surveillance information reported to and collected by the authorisation holder from the European trade associations or other sources shall be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the authorisation holder will immediately investigate to determine and confirm whether a significant correlation between the effect and T25 maize can be established. If the investigation establishes that T25 maize was present when the adverse effect was identified, and confirms that T25 maize is the cause of the adverse effect, the authorisation holder shall immediately inform the European Commission. The authorisation holder in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial

action is proportionate to the significance of the observed effect.

As described in the bullet points above, the authorisation holder shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the authorisation. The report shall contain information on any unanticipated adverse effects that have arisen from handling and use of viable T25 maize.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of T25 maize and, as appropriate, the measures that were taken to ensure the safety of human and animal health or the environment.

3.2.2 Details of industry, environmental, food and/or feed related surveillance networks used during General Surveillance

The authorisation holder, together with other members of the plant biotechnology industry and EuropaBio, will implement general surveillance of viable GM maize, including T25 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 agrosupply. 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 within the EU. UNISTOCK full and extraordinary members are present in twelve countries and UNISTOCK is itself a full member of COCERAL. Commodity imports enter the EU by sea and transit through sea-port silos. The main storekeepers managing these silos are members of UNISTOCK.

Also see: http://www.unistock.be/

⇒ *Processors*

FEDIOL, the federation of the EU vegetable Oil and Protein Meal Industry, represents the interests of the European crushers of oilseeds, meal producers and vegetable oil producers/processors.

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 T25 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 authorisation holder directly informed the selected network of operators (i.e. COCERAL, UNISTOCK and FEDIOL) that T25 maize was authorised pursuant to Regulation (EC) No 1829/2003 by Commission Implementing Decision (EU) 2015/697 and that a website dedicated to operators that provides an overview and detailed information on the authorised T25 maize has been made available as described below.

Specific information concerning the safety, general characteristics and the general surveillance conditions for T25 maize was uploaded in a 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 website, hosted on the EuropaBio website under http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information , contains the following information:

-An introduction to the purpose of the website

-A table giving an overview of all currently approved GM plant products subject to general surveillance

-A profile for every approved GM plant product providing documentation on characteristics and safety, positive EFSA opinion(s) and Commission Decision(s) authorising the GM plant product in the EU. The document providing documentation on characteristics and safety for T25 maize is attached as Appendix 1 to this annual monitoring report.

-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.

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 T25 maize 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 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 T25 maize in the time period from July 2018 to June 2019 (see Appendix 2 and Appendix 3). Furthermore, no incidents in relation to the placing on the market of T25 maize have been reported to EuropaBio or the authorisation holder since July 2018 to date.

3.2.5 Additional Information

Not applicable since no adverse or unanticipated effects were reported.

3.2.6 Review of peer-reviewed publications

The authorisation holder actively monitors peer-reviewed scientific literature related to its products. In the light of the 2019 annual general surveillance report for T25 maize, a literature review was performed for the T25 maize and the newly expressed protein PAT/*pat*. A broad literature search was performed using a comprehensive collection of bibliographic databases, covering a database entry period from October 1, 2018 to September 30, 2019. Additional sources of information, such as web pages of food safety, agriculture, and biotechnology-related organizations were searched for the period of October 1, 2018 to September 30, 2019, along with the bibliographies of relevant reviews. The references identified were evaluated for potential relevance according to pre-defined criteria.

This literature search identified a total of 438 unique references. Out of these 438 references, 427 were considered obviously irrelevant and excluded, and 11 were eligible for detailed assessment. None of the remaining publications were relevant after detailed review.

No new publications constituted new data on molecular characterization of T25 maize and the newly expressed PAT/*pat* protein, nor did they suggest any potential adverse effects on human and animal health or on the environment.

Therefore, this literature search and review of the retrieved publications identified no relevant references that relate to the existing safety assessment of T25 maize or the newly expressed PAT/*pat* protein (Annex I_T25 Literature Review).

3.3 Case-Specific Monitoring

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

The scientific evaluation of the characteristics of T25 maize in the environmental risk assessment (e.r.a.) 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 T25 maize. It is therefore considered that there is no need for case-specific monitoring.

3.3.2 Processing (if applicable)

Not applicable.

3.3.3 Monitoring and reporting of adverse effects resulting from accidental spillage (Not applicable)

3.4 Concluding remarks

The information reported to and collected by the authorisation holder within the frame of the general surveillance accompanying the placing on the market of T25 maize in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of T25 maize. The reports received from COCERAL, UNISTOCK and FEDIOL show that no adverse effects linked to the presence of T25 maize were recorded and no adverse findings from independent research relating to T25 maize have been published.

4. Summary of Results and Conclusions

To date, the general surveillance accompanying the placing on the market of T25 maize in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of T25 maize.

Taking into account:

a) the favourable scientific evaluations by scientists and regulatory agencies around the world;
b) our experience with this product;
c) the reports from the European trade associations (operators involved in the import, handling and processing of viable T25 maize) who are selected as the most appropriate participants in the general surveillance network;
d) the lack of adverse findings from independent research, available through the public literature;
e) the fact that no adverse effects for T25 maize have been reported to the authorisation holder

there is, to the best of our knowledge, no information available that questions the conclusion that T25 maize does not 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 T25 maize.

Signed: **BASF**

Date: **19th December 2019**