

2020 Annual Report on the General Surveillance of T45 oilseed rape in the EU

BASF Agricultural Solutions Seed US LLC
Represented by
BASF SE

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ANNUAL REPORT ON THE GENERAL SURVEILLANCE OF T45 OILSEED RAPE IN THE EU

1. General Information

- 1.1 Crop/trait(s): T45 oilseed rape/ 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: NA¹
- 1.3 Decision authorisation number and date of authorisation pursuant to Regulation (EC) No 1829/2003: Commission Implementing Decision (EU) 2019/2081 of 28 November 2019
- 1.4 Unique identifier: ACS-BNØØ8-2
- 1.5 Reporting Period from: July 2019 to June 2020
- 1.6 Other monitoring reports have been submitted in respect of Cultivation: No

2. Executive Summary

On 10 March 2009, Commission Decision 2009/184/EC² (as amended by Commission Implementing Decision (EU) 2019/1195³ addressed to BASF SE) authorised the placing on the market of T45 oilseed rape pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. On 28 November 2019, Commission Implementing Decision (EU) 2019/2081⁴ renewed authorization of the said product. This authorisation covers the following products:

- a) foods and food ingredients containing or produced from oilseed rape T45;
- b) feed containing or produced from oilseed rape T45;
- c) products containing genetically modified oilseed rape T45 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

In accordance with Directive 2001/18/EC and Article 5(2) of Commission Implementing Decision (EU) 2019/2081, the authorisation holder for T45, shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC. In addition, Article 6(1) of Commission Implementing Decision (EU) 2019/2081 requires that the authorisation holder shall ensure that shipments of oilseed rape imported in the European Union from a third country in which oilseed rape T45 seeds were commercialised until 2005 are sampled and

¹ NA: not applicable.

² Commission Decision of 10 March 2009 authorising the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2) resulting from the commercialisation of this oilseed rape in third countries until 2005 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (2009/184/EC). *Official Journal of the European Union* L 68/28, 13.03.2009.

³ Commission Implementing Decision of 25 June 2013 authorising the placing on the market of food containing or consisting of genetically modified oilseed rape MS8, RF3 and MS8 × RF3, or food and feed produced from those genetically modified organisms pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. *Official Journal of the European Union* L175/57, 27.06.2015.

⁴ Commission Implementing Decision (EU) 2019/2081 of 28 November 2019 renewing the authorisation for the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2), resulting from the commercialisation of this oilseed rape in third countries until 2005, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. *Official Journal of the European Union* L 316/57, 6.12.2019.

tested for the presence of oilseed rape T45.

Annual reports on the implementation and the results of the general surveillance activities together with results of the monitoring activities for the presence of T45 oilseed rape need to be submitted to the Commission in line with Articles 5(2) and 6(3), respectively, of Commission Implementing Decision (EU) 2019/2081. In view of the obligation to submit annual monitoring reports for T45 oilseed rape, the authorisation holder, has undertaken a number of general surveillance activities accompanying the placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005. In accordance with Article 5(2) and 6(3) of Commission Implementing Decision (EU) 2019/2081 for T45 oilseed rape, an updated status on the general surveillance activities from July 2019 to June 2020 is given in this annual monitoring report.

To date, the general surveillance accompanying the placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005 indicates that there have been no adverse health or environmental effects associated with the importation or use of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005. Therefore, no revisions to the general surveillance plan are considered necessary for T45 oilseed rape.

In view of Article 6 of Commission Implementing Decision (EU) 2019/2081, the authorisation holder has been informed, through communication with the trade industry in Canada (Canadian Grain Commission), that there were commodity shipments of oilseed rape imported into the European Union between July 2019 and June 2020 from a third country in which T45 oilseed rape seeds were commercialised until 2005. Those shipments were sampled and tested for the presence of ACS-BN-ØØ8-2 oilseed rape (Appendix 6).

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 2019 to June 2020)⁵

Country of origin ⁶	Quantity ⁷ (tons)
Ukraine	3.027.736,4
Canada*	2.030.618,1
Australia*	994.352,0
United States*	0,0
All Other Countries	150.980,3
TOTAL extra-EU	6.203.686,8

⁵ Source: Eurostat (2020).

⁶ Data are provided for the main exporting countries, which combined make up approximately 98% of total oilseed rape imports. Data for exporting countries where T45 Oilseed rape is authorised for cultivation are marked with “*”.

⁷ 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 the reporting period of July 2019 to June 2020)⁵

Destination country	Quantity ⁷ (tons)
Netherlands	1.811.441,4
France	1.525.444,1
Germany	1.182.318,8
Belgium (and Luxembourg)	1.156.690,0
Portugal	169.363,4
Poland	154.741,2
United Kingdom	95.637,9
Romania	73.302,2
Bulgaria	10.484,6
Latvia	9.171,3
Hungary	6.816,7
Austria	3.127,7
Czech Republic	2.353,4
Croatia	1.833,3
Lithuania	916,8
Slovenia	23,6
Spain	20,4
TOTAL	6.203.686,8

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

T45 oilseed rape was first commercialized in Canada and the USA in 1998 with peak sales in 1999 of approximately 4% of the market share. Sales of T45 declined in subsequent seasons and the commercialisation was stopped in 2003 with the exception of a single distributor. Sales in the year 2004 and 2005 were limited to approximately 40.000 and 10.000 acres, respectively. Therefore, the final season of sales of T45 was approximately 0.1% of canola seeded acres. All parties with licenses for the production and sale of T45 certified the destruction of all existing stocks. A termination agreement was signed with all third parties that required quality assurance monitoring of seed production to ensure that the T45 event would not be present in future canola product lines. De-registration of the T45 derived varieties was initiated in 2003 and completed in 2004 with the exception of a single line that was still sold in limited quantities until 2005. No sales of T45 seed were made into 2006 season and all stocks have been destroyed. Currently, it is no longer legal to sell certified seeds of these de-registered varieties which contain T45 in Canada.

The authorisation holder, via EuropaBio, has collected EUROSTAT data on oilseed rape

imports into the EU for the period of July 2019 to June 2020. According to this data, total extra-EU imports of oilseed rape were 6.203.686,8 tons and the main exporters of oilseed rape to the EU were Ukraine, Canada and Australia which together accounted for approximately 98% of total extra-EU oilseed rape imports. (**Table 3.1.1**).

Table 3.1.2 summarizes the total oilseed rape imports from outside the EU-28 by destination. The main import countries for oilseed rape in the EU for the period of July 2019 to June 2020 were the Netherlands, France, Germany and Belgium (and Luxembourg). They are accounting together for about 91% of the total oilseed rape imports. Other significant import markets for extra-EU oilseed rape were Portugal, Poland and the United Kingdom.

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 oilseed rape commodity (listed in Section 3.2.2).

The authorisation holder is not involved in commodity trade with T45 oilseed rape. 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 T45 oilseed rape. They are exposed to the imported viable T45 oilseed rape 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 T45 oilseed rape with other commercial oilseed rape, including authorised GM oilseed rape, 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 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 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 T45 oilseed rape can be established. If the investigation establishes that T45 oilseed rape was present when the adverse effect was identified, and confirms that T45 oilseed rape 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 T45 oilseed rape.

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

the safety of T45 oilseed rape 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 oilseed rape, including T45 oilseed rape, 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 oilseed rape 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 T45 oilseed rape, 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 T45 oilseed rape was authorised pursuant to Regulation (EC) No 1829/2003 by Commission Implementing Decision (EU) 2019/2081 and that a website dedicated to operators that provides an overview and detailed information on the authorised T45 oilseed rape has been made available as described below.

Specific information concerning the safety, general characteristics and the general surveillance conditions for T45 oilseed rape was uploaded in a website dedicated to trade associations representing the relevant operators that import, handle and process viable oilseed rape 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 T45 oilseed rape is attached as Appendix 1 to this annual monitoring report. In line with the general surveillance requirements for T45 oilseed rape as described in Commission Implementing Decision (EU) 2019/2081, this document also informs operators about the possibility of and consequences arising from accidental spillage of T45 oilseed rape in the context of its intended uses and alerts the operators to the possibility that accidental spillage of imported oilseed rape grains in ports and crushing facilities may result in the germination and establishment of volunteer plants, including T45 oilseed rape.
- A contact point at EuropaBio for information exchange on any of the GM plant products
- In the specific case of T45 oilseed rape, operators in the food and feed supply chain, wishing to report a potential adverse effect associated with the import or use of T45 oilseed rape grain have also been provided with a list of national contact points. The list contains experts that can be directly contacted by phone (Appendix 2). The relevant phone numbers have been made available to the selected industry associations at the EuropaBio website dedicated to operators under <https://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information>. The national contact points record any reports of potential adverse effects. Reports of adverse effects would be analysed in the annual general surveillance report. To date no adverse effects have been reported via any of the national contact points.
- In line with the general surveillance requirements for T45 oilseed rape as described in Commission Implementing Decision (EU) 2019/2081, a document translating into practice the recommendations of the EU Commission as specified in Commission Implementing Decision (EU) 2019/2081 to assist the operators importing oilseed rape grain in the EU by providing them the appropriate technical advice to eradicate oilseed rape volunteers which

may include T45 (Appendix 3).

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 T45 oilseed rape placed on the market during the period from July 2019 to June 2020.

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 T45 oilseed rape in the time period from July 2019 to June 2020 (see Appendix 4 and Appendix 5). Furthermore, no incidents in relation to the placing on the market of T45 oilseed rape have been reported to EuropaBio or the authorisation holder since July 2020 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 2020 annual general surveillance report for T45 oilseed rape, a scoping review was performed for the T45 oilseed rape and its newly expressed protein, PAT/*pat*. The objective of this scoping review was to determine if there were studies about the molecular characterization of T45 oilseed rape, its effect on food and feed safety, or on environmental safety, that might require in-depth examination. A set of broad literature searches was performed using several bibliographic databases covering scientific literature from October 1, 2019 to September 30, 2020. Additional sources of information, such as web pages of food safety, agriculture, and biotechnology-related authorities were searched for the same time window, along with the bibliographies of relevant reviews. The references identified were evaluated for potential relevance to the scoping review questions according to pre-defined criteria.

These literature searches identified a total of 204 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 5 publications were progressed for detailed assessment. Three of the five were previously included in the 2019 Post-Market Environmental Monitoring literature review report and were excluded from further consideration in this report. Neither of the remaining two publications were relevant after detailed review.

No new publications were found that contained new data on the molecular characterization of the T45 oilseed rape and its newly expressed protein, PAT/*pat*. Similarly, no new publications were found that suggested any potential adverse effects of this event on human health, animal health, or the environment.

In summary, these literature searches and review of the retrieved publications identified no relevant publication that would contradict the existing safety assessment of the T45 oilseed rape or its newly expressed protein Pat/*pat*. (Annex I T45 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 T45 oilseed rape 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 T45 oilseed rape. It is therefore considered that there is no need for case-specific monitoring.

3.3.2 Processing (if applicable)

Typically, bulk imports of oilseed rape grain are unloaded at the port of importation into silos and processed in situ. Transport to inland crushing plants are not a viable economic option for processing imported oilseed rape, except under extreme circumstances. Crushing plants located at ports are the only facilities likely to process imports of oilseed rape. Operators are careful to minimise spills, as spills can result in fines and the revocation of operating licences, and they are obliged to clean up any spillages that occur at discharge. The handling entity transporting the product assumes responsibility for any spills and clean up.

The operational rules and standards applicable to the handling of oilseed rape imports are laid out in Regulation (EC) No 178/2002 laying down the general principles and requirements of

food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; Regulation (EC) No 852/2004 on the hygiene of foodstuffs; and, Regulation (EC) No 1831/2003 laying down requirements for feed hygiene. In accordance with these Regulations, the principles of HACCP (Hazard Analysis and Critical Control Points) apply.

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

The authorisation holder 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

The information reported to and collected by the authorisation holder within the frame of the general surveillance accompanying the placing on the market of T45 oilseed rape in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of T45 oilseed rape. The reports received from COCERAL, UNISTOCK and FEDIOL show that no adverse effects linked to the presence of T45 oilseed rape were recorded and no adverse findings from independent research relating to T45 oilseed rape have been published.

4. Summary of Results and Conclusions

To date, the general surveillance accompanying the placing on the market of products containing or produced from genetically modified oilseed rape T45 resulting from the commercialisation of this oilseed rape in third countries until 2005 indicates that there have been no adverse health or environmental effects associated with the importation or use of T45 oilseed rape.

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 T45 oilseed rape) 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 T45 oilseed rape have been reported to the authorisation holder

there is, to the best of our knowledge, no information available that questions the conclusion that T45 oilseed rape does not pose any greater risk to health or the environment than conventional oilseed rape.

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 T45 oilseed rape.
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Signed: **BASF**

Date: **11th December 2020**