

**Annual general surveillance report in 2018/2019 season for
MON 88302 × MS8 × RF3, MON 88302 × MS8 and MON 88302 × RF3
authorised in accordance with**

Commission Implementing Decision (EU) 2017/2453

by

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Appendix 1: Literature search for annual monitoring on the general surveillance of BASF and Bayer GM oilseed rape in the EU

1. General Information

1.1 Crop/trait(s)¹

Oilseed rapes / MON 88302 × MS8 × RF3, MON 88302 × MS8 and MON 88302 × RF3²

1.2 Decision authorisation number under Directive 2001/18/EC and number and date of consent under Directive 2001/18/EC

N/A

1.3 Decision authorisation number and date of authorisation under Regulation (EC) No 1829/2003

Commission Implementing Decision (EU) 2017/2453 of 21 December 2017

1.4 Unique identifier

MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6, MON-883Ø2-9 × ACSBNØØ5-8 and MON-883Ø2-9 × ACS-BNØØ3-6

1.5 Reporting Period

July 2018 – June 2019

1.6 Other monitoring reports have been submitted in respect of cultivation

No

¹ Hereafter, referenced as BASF and Bayer GM oilseed rapes.

² MON 88302 × MS8 × RF3 was not grown in 2018. None of the sub-combinations derived from MON 88302 × MS8 × RF3 and covered by European Commission Decision 2017/2453 are produced for commercial cultivation.

2. Executive Summary

In accordance with the product specific Commission Decision, the authorisation holders BASF Agricultural Solutions Seed US LLC and Bayer Agriculture BVBA³, are accountable for general surveillance of the placing on the market of genetically modified (GM) oilseed rape in the EU for the duration of the validity of the consent.

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

MON 88302 × MS8 × RF3 oilseed rape has received regulatory approvals for cultivation in Canada and the USA. In 2018, it was not grown commercially in any country. None of the sub-combinations derived from MON 88302 × MS8 × RF3, covered by European Commission Implementing Decision (EU) 2017/2453 are produced for commercial cultivation.

This annual general surveillance report for the 2018/2019 season presents the monitoring results of BASF and Bayer GM oilseed rape: MON 88302 × MS8 × RF3 and sub-combinations^{Error! Bookmark not defined.}.

During the last year, as MON 88302 × MS8 × RF3 was not commercially grown, this general surveillance focused on literature search. Based on this, there is, to the best of our knowledge, no information available that questions the conclusion that MON 88302 × MS8 × RF3, MON 88302 × MS8 and MON 88302 × RF3 do not pose any risk to health or the environment greater than conventional oilseed rape.

³ Hereafter, referenced as BASF and Bayer

3. Uses of GMOs Other Than Cultivation

3.1 Oilseed rape imports into the Community

3.1.1 Oilseed rape (GM + non-GM) imports into the Community by country of origin from countries where BASF and Bayer GM oilseed rape products are cultivated (2018/2019)

In 2018/2019, total import of oilseed rape into the EU was approximately 3.7 million tonnes. MON 88302 × MS8 × RF3 was not grown in any country in 2018. None of the sub-combinations derived from MON 88302 × MS8 × RF3 and covered by European Commission Decision 2017/2453 are produced for commercial cultivation.

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

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

Country of destination	Quantity (10 ³ tonnes) in 2018/2019
Germany	1 204
Belgium	1 167
France	793
Netherlands	202
Portugal	130
Poland	103
Romania	31
Latvia	25
Hungary	5.56
Austria	3.59
Lithuania	2.51
Czech Republic	1.82
Croatia	1.80
Italy	1.12
Slovenia	0.12
Sweden	0.12
Spain	0.09
Bulgaria	-
Cyprus	-
Denmark	-
Estonia	-
Finland	-
Greece	-
Ireland	-
Luxembourg	-
Malta	-
Slovakia	-
United Kingdom	-
TOTAL	3 705

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

3.1.3 Analysis of data provided

Not applicable. *See* Section 3.1.1

3.2 General Surveillance

3.2.1 Description of General Surveillance

The current approach used for general surveillance represents the consensus between all applicants/consent holders within European Association of Bioindustries (EuropaBio) and has been endorsed by the operators involved in the trade of viable oilseed rape commodity (listed in Section 3.2.2).

The consent holders are not involved in commodity trade with BASF and Bayer GM 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 BASF and Bayer GM oilseed rape. They are exposed to the imported viable BASF and Bayer GM 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 as reflected on the website of the trade associations representing the operators involved in the PMEM (*see* below).

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

The different parties agreed to collaborate on the following basis:

⇒ The consent holders represented by EuropaBio shall:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
- Inform the operators in a timely fashion of any newly approved GM plant products for import and processing under Regulation (EC) No 1829/2003 subject to general surveillance.
- Set up and maintain a website dedicated to operators that provides an overview and detailed information on approved GM plant products subject to general surveillance. The website⁴, contains the following information:
 - An introduction to the purpose of the website

⁴ EuropaBio - <http://www.europabio.org/agricultural-biotech/trade-and-approvals/operators-product-information> - Accessed on 22 November 2019.

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

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

The general surveillance information reported to and collected by the consent holders from the European trade associations or other sources shall be analysed for its relevance. Where information indicates the possibility of an unanticipated adverse effect, the consent holders shall immediately investigate to determine and confirm whether a significant correlation between the effect and BASF

and Bayer GM oilseed rape can be established. If the investigation establishes that BASF and Bayer GM oilseed rape is the cause of the adverse effect, the consent holders shall immediately inform the European Commission. The consent holders, in collaboration with the European Commission and based on a scientific evaluation of the potential consequences of the observed adverse effect, shall define and implement management measures to protect human and animal health or the environment, as necessary. It is important that the remedial action is proportionate to the significance of the observed effect.

As described in the bullet points above, the consent holders shall submit an annual monitoring report including results of the general surveillance in accordance with the conditions of the consent. The report shall contain information on any unanticipated adverse effects that have arisen from handling and use of viable BASF and Bayer GM oilseed rape.

The report includes a scientific evaluation of the confirmed adverse effect, if any, a conclusion of the safety of BASF and Bayer GM 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

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

⇒ Importers / Traders

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

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

⇒ Silo Operators

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

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

⇒ *Processors*

FEDIOL, the federation of the EU vegetable Oil and Protein Meal Industry, represents the interests of the European crushers of oilseed meal producers and vegetable oils producers/processors. Its members represent 85% of the EU industry and hold 150 oilseeds processing and vegetable oils and fats production facilities across Europe.

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

These associations represent the majority of European operators importing, handling and processing viable 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 BASF and Bayer GM 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.

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

Additionally, specific information concerning the safety, general characteristics and the general surveillance conditions for BASF and Bayer GM oilseed rape were uploaded on the 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 website⁴, hosted by EuropaBio, contains the following information for BASF and Bayer GM oilseed rape:

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

3.2.4 Results of General Surveillance

Not applicable. *See* Section 3.1.1.

3.2.5 Additional Information

Not applicable. *See* Section 3.1.1.

3.2.6 Literature search

As part of the general surveillance requirements for oilseed rape BASF and Bayer GM oilseed rape, a literature search that complies with the recommendations outlined in the 2017 EFSA explanatory note on literature searching⁵ has been conducted on a monthly basis covering the time span June 2018 – May 2019 and is provided along with the literature search completeness checklist (Annex 2) in **Appendix 1**.

BASF and Bayer confirm that the literature search, conducted in accordance with the 2017 EFSA explanatory note on literature searching and within the context of the general surveillance for BASF and Bayer GM oilseed rape in the EU, identified no relevant publications that would invalidate the initial conclusions of the risk assessment for BASF and Bayer GM oilseed rape.

3.3 Case-Specific Monitoring

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

The scientific evaluation of the characteristics of BASF and Bayer GM oilseed rape 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 BASF and Bayer GM oilseed rape. 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

In this 2018/2019 annual general surveillance report, the literature search did not bring any new information that questions the conclusion that MON 88302 × MS8 × RF3, MON 88302 × MS8 and MON 88302 × RF3 do not pose any risk to health or the environment greater than conventional oilseed rape.

⁵ EFSA - <https://www.efsa.europa.eu/en/supporting/pub/en-1207> - Accessed on 22 November 2019.

4. Summary of Results and Conclusions

In accordance with the Commission Decision for the BASF and Bayer GM oilseed rape presented in Section 1, the consent holders for BASF and Bayer GM oilseed rape, BASF Agricultural Solutions Seed US LLC and Bayer Agriculture BVBA, are accountable for general surveillance of the placing on the market of these products in the EU for the duration of the validity of the consent.

As MON 88302 × MS8 × RF3 was not commercially grown in 2018, this general surveillance focused on literature search. Based on this, there is, to the best of our knowledge, no information available that questions the conclusion that MON 88302 × MS8 × RF3, MON 88302 × MS8 and MON 88302 × RF3 do not pose any risk to health or the environment greater 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 any BASF and Bayer GM oilseed rape

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ANNEX

EUROSTAT data showing all oilseed rape exporters into the EU

July 2018 until June 2019 EU Rapeseed Imports by Member State and by MAIN Exporter in tons (CN 12051090)																													
REPORTER/PERIOD	AUSTRIA	BELGIUM (a)	BULGARIA	CROATIA	CYPRUS	CZECHIA	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY (a)	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM	TOTAL
UKRAINE	3593,9	630589,8				90				314880,7	620180,4															62,8			1785674,8
AUSTRALIA		438018,2					32702,8			188710	489104,1				1056		2464,4			191092,3	100819,8	110828,5		1108,5					1339627,4
CANADA		82844,7								277623,1	63567,3											19135					22,8		443192,9
MOLDOVA, REPUBLIC OF										11514,2	7731,3										1015,4			30342,9					50603,8
KAZAKHSTAN						21,5					60				66	22657,5				5999,1	694,3								29498,4
SERBIA				1046,6		1535,3					10118,4		5562,7												124				18387
RUSSIAN FEDERATION (RUSSIA)		1090,1				174					12978,9					2610,3	42			396,7	573,8								17865,8
URUGUAY		13701																											13701
ARGENTINA		725,6																		4316,5									5042,1
BOSNIA HERZEGOVINA				755,6																									755,6
NORWAY (incl.SJ excl.1995,1996)																											116,8		116,8
TURKEY																				40,7									40,7
TOTAL	3593,9	1166969,4		1802,2		1820,8	32702,8			792728	1203740,4		5562,7		1122	25267,8	2506,4			201845,3	103103,3	129963,5		31451,4		124	85,6	116,8	3704506,3
Source: Eurostat																													