2021 Annual Report on the General Surveillance of MS8, RF3 and MS8 x RF3 oilseed rape in the EU

BASF Agricultural Solutions Seed US LLC
Represented by
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ANNUAL REPORT ON THE GENERAL SURVEILLANCE OF MS8, RF3 AND MS8 X RF3 OILSEED RAPE IN THE EU

1. General information

1.1 Crop/trait(s): MS8, RF3 and MS8 x RF3 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: NA[1]

1.3 Decision authorisation number and date of authorisation pursuant to Regulation (EC) No 1829/2003: Commission Decision 2013/327/EU of 25 June 2013 and Commission Implementing Decision (EU) 2019/1301 of 10 July 2019

1.4 Unique identifier: ACS-BNØØ5-8 for MS8
ACS-BNØØ3-6 for RF3
ACS-BNØØ5-8 x ACS-BNØØ3-6 for MS8 x RF3

1.5 Reporting period from: July 2020 to June 2021

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

2. Executive summary

On 26 March 2007, the European Commission issued Commission Decision 2007/232/EC[2] approving the placing on the market of the genetically modified oilseed rape MS8, RF3 and MS8 x RF3 (ACS-BNØØ5-8 for MS8; ACS-BNØØ3-6 for RF3; ACS-BNØØ5-8xACS-BNØØ3-6 for MS8 x RF3) in accordance with Directive 2001/18/EC on the deliberate release of genetically modified organisms in the environment1. This approval under Directive 2001/18/EC resulted from the notification C/BE/96/01 that covers the import and use of MS8, RF3 and MS8 x RF3 oilseed rape as any other oilseed rape, with the exception of cultivation and uses as or in food. In accordance with the provisions of Article 18(2) of the Directive, the Belgian Lead Member State informed the notifier of the import approval decision on 25 May 2007.

On 25 June 2013, Commission Implementing Decision 2013/327/EU[3] (as amended by Commission Implementing Decision (EU) 2019/1195[4] addressed to BASF SE) authorised the

[1] NA: Not applicable.
[2] Commission Decision of 26 March 2007 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (*Brassica napus* L. lines MS8, RF3 and MS8 x RF3) genetically modified for tolerance to the herbicide glufosinate-ammonium (2007/232/EC). *Official Journal of the European Union* L 100/20, 17.4.2007.
[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 (2013/327/EU). *Official Journal of the European Union* L175/57, 27.06.2015.
[4] 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

placing on the market of food containing or consisting of genetically modified oilseed rapes MS8, RF3 and MS8 × RF3 and of food and feed produced from those genetically modified oilseed rapes.

On 30 November 2017, the applicant asked the Commission to merge into a single authorisation the uses of oilseed rapes MS8, RF3 and MS8 × RF3 covered by the renewal application and the uses of those oilseed rapes covered by Implementing Decision 2013/327/EU. By a letter dated 5 December 2017, the Commission informed the applicant that the merger would take effect through the extension of the scope of Implementing Decision 2013/327/EU to the products concerned by the renewal application of 20 May 2016. The applicant has therefore been made aware that, as a result of the merger, the products covered by the renewal application would be subject to the conditions of authorisation set out in Commission Implementing Decision 2013/327/EU. As a consequence, Commission Decision 2007/232/EC was repealed.

In accordance with Article 4 of Commission Implementing Decision 2013/327/EU (and consequently Commission Implementing Decision 2019/1301[5]) under the Regulation (EC) No 1829/2003, the authorisation holder, shall ensure that the monitoring plan, contained in the notification and consisting of a general surveillance plan is put in place and implemented throughout the period of validity of the consent.

In view of the obligation to submit annual monitoring reports for MS8, RF3 and MS8 x RF3 oilseed rape, the authorisation holder has undertaken a number of general surveillance activities accompanying the placing on the market of MS8, RF3 and MS8 x RF3 oilseed rape in the EU. In accordance with Article 4(3) and 4(5) of Commission Implementing Decision 2013/327/EU (and consequently Commission Implementing Decision (EU) 2019/1301) for MS8, RF3 and MS8 x RF3 oilseed rape, an updated status on the general surveillance activities from July 2020 to June 2021 is given in this annual monitoring report.

To date, the general surveillance accompanying the placing on the market of MS8, RF3 and MS8 x RF3 oilseed rape indicates that there have been no adverse health or environmental effects associated with the importation or use of MS8, RF3 and MS8 x RF3 oilseed rape. Therefore, no revisions to the general surveillance plan are considered necessary for MS8, RF3 and MS8 x RF3 oilseed rape.

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.

[5] Commission Implementing Decision (EU) 2019/1301 of 26 July 2019 amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. *Official Journal of the European Union* L 204/50, 2.8.2019.

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 EU and UK by country of origin

Country of origin[6]	Quantity[7] (EU import in tons)	Quantity[8] (UK import in tons)
Canada*	2.089.284,7	0
Ukraine	2.013.598,8	253.359,2
Australia*	1.377.219,5	148.224,1
Uruguay	25.302,6	84.999,8
United States*	0,3	0
All Other Countries	122.802,9	28,0
TOTAL	**5.628.208,8**	**486.611,1**

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

Destination country	Quantity[9] (tons) July 2020 - June 2021
France	1.562.676,0
Belgium	1.400.228,7
Germany	1.204.858,8
Netherlands	1.087.280,6
United Kingdom	486.611,1
Portugal	130.485,5
Poland	93.410,1
Romania	90.253,7
Denmark	30.000,0

[6] Data are provided for the main exporting countries, which combined make up approximately 97 % of total oilseed rape imports from outside the EU and nearly 100 % of total oilseed rape imports from outside the UK. Data for exporting countries where MS8, RF3 and MS8 x RF3 oilseed rape is authorised for cultivation are marked with "*". For the full list of exporting countries and detailed information on commodity types please refer to Annex 2 and Annex 3.

[7] Source: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021). Data extracted October 2021, collected by CropLife Europe (see Annex 2).

[8] Source: HMRC/AHDB (2021) data for 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 3).

[9] Sources: Eurostat (2021) data covers 27 EU Member States (July 2020 to June 2021). HMRC/AHDB (2021) data for UK covers Great Britain and Northern Ireland (July 2020 to June 2021).

Bulgaria	11.679,0
Czechia	8.713,3
Austria	5.193,5
Croatia	1.924,6
Hungary	1.018,8
Sweden	218,9
Lithuania	200,0
Spain	67,3

3.1.3 Analysis of data provided in tables 3.1.1 and 3.1.2

The authorisation holder, via CropLife Europe, has collected data on oilseed rape imports (GM and non-GM) into the EU and UK for the period of July 2020 to June 2021.

For the EU, according to this data, total imports of oilseed rape were 5.628.208,8 tons and the main exporters of oilseed rape to the EU were Canada, Ukraine and Australia which together accounted for approximately 97 % of total extra-EU oilseed rape imports (**Table 3.1.1)**.

MS8, RF3 and MS8 x RF3 oilseed rape was authorised for cultivation in Canada, Australia, and the United States. The total EU oilseed rape imports from Canada, Australia and the United States were 2.089.284,7, 1.377.219,5 and 0,3 tons respectively. Canada, Australia, and United States oilseed rape exports to the EU accounted for around 62 % of total extra-EU oilseed rape imports (**Table 3.1.1**).

The main import countries for oilseed rape in the EU were France, Belgium, Germany, and the Netherlands. They are accounting together for 93 % of the total oilseed rape imports. Other main import markets of extra-EU oilseed rape are Portugal, Poland, and Romania (**Table 3.1.2**).

For the UK, according to this data, total imports of oilseed rape were 486.611,1 tons and the main exporters of oilseed rape to the UK were Ukraine, Australia, and Uruguay which accounted for nearly 100 % of total extra-UK oilseed rape imports (**Table 3.1.1)**.

MS8, RF3 and MS8 x RF3 oilseed rape was authorised for cultivation in Australia. The total UK oilseed rape imports from Australia were 148.224,1 tons. Australia oilseed rape exports to the UK accounted for 30 % of total extra-UK oilseed rape imports (**Table 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 authorisation holders within CropLife Europe 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 MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 oilseed rape. They are exposed to the imported viable MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 oilseed rape with other commercial oilseed rape, including authorised GM oilseed rape, the authorisation holder is working together with other members of the industry within CropLife Europe and trade associations representing the relevant operators in order to implement a harmonised monitoring methodology.

The different parties agreed to collaborate on the following basis:

⇒ The consent holder represented by CropLife Europe shall:

- Agree with the operators before adding or amending activities that fall under their responsibility in accordance with the proposed monitoring plan.
- Inform the operators in a timely fashion of any newly approved GM plant products for import and processing under Regulation (EC) No 1829/2003 or Directive 2001/18/EC subject to general surveillance.
- Set up and maintain a website dedicated to operators that provides an overview and detailed information on approved GM plant products subject to general surveillance. The website, 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
  - 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 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 MS8, RF3 and MS8 x RF3 oilseed rape can be established. If the investigation establishes that MS8, RF3 and MS8 x RF3 oilseed rape was present when the adverse effect was identified and confirms that MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 oilseed rape.

The report will include a scientific evaluation of the confirmed adverse effect, a conclusion of the safety of MS8, RF3 and MS8 x RF3 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 industry and CropLife Europe, will implement general surveillance of viable GM oilseed rape, including MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 oilseed rape was authorised pursuant to Regulation (EC) No 1829/2003 by Commission Implementing Decision (EU) 2019/1301 and Commission Implementing Decision 2013/327/EU that a website dedicated to operators that provides an overview and detailed information on the authorised MS8, RF3 and MS8 x RF3 oilseed rape has been made available as described below.

Specific information concerning the safety, general characteristics and the general surveillance conditions for MS8, RF3 and MS8 x RF3 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 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 Decision(s) authorising the GM plant product in the EU. The document providing documentation on characteristics and safety for MS8, RF3 and MS8 x RF3 oilseed rape is attached as Appendix 1 to this annual monitoring report. In line with the general surveillance requirements for MS8, RF3 and MS8 x RF3 oilseed rape as described in Commission Implementing Decision (EU) 2019/1301 and Commission Implementing Decision 2013/327/EU, this document also informs operators about the possibility of and consequences arising from accidental spillage of MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 oilseed rape.

-A contact point at CropLife Europe for information exchange on any of the GM plant products

-In the specific case of MS8, RF3 and MS8 x RF3 oilseed rape, operators in the food and feed supply chain, wishing to report a potential adverse effect associated with the import or use of MS8, RF3 and MS8 x RF3 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 CropLife Europe website dedicated to operators under https://croplifeeurope.eu/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 MS8, RF3 and MS8 x RF3 oilseed rape as described in Commission Implementing Decision (EU) 2019/2081 and Commission Implementing Decision 2013/327/EU, a document translating into practice the recommendations of the EU Commission as specified in Commission Implementing Decision (EU) 2019/2081 and Commission Implementing Decision 2013/327/EU 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 MS8, RF3 and MS8 x RF3 (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, 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 MS8, RF3 and MS8 x RF3 oilseed rape 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 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 MS8, RF3 and MS8 x RF3 oilseed rape in the time period from July 2020 to June 2021 (see Appendix 4 and Appendix 5). Furthermore, no incidents in relation to the placing on the market of MS8, RF3 and MS8 x RF3 oilseed rape have been reported to CropLife Europe or the authorisation holder since July 2021 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 2021 annual general surveillance report for MS8, RF3 and MS8 x RF3 oilseed rape, a scoping review was performed for MS8, RF3 and MS8 x RF3 *B. napus* and their newly expressed proteins, PAT/*bar*, Barnase and Barstar. The objective of this scoping review was to determine if there were studies about the molecular characterization of MS8, RF3 or MS8 x RF3 *B. napus*, or their effect on food and feed safety or 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, 2020 to September 30, 2021. 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 876 unique publications, which were subject to rapid assessment to exclude obviously irrelevant publications. A total of 4 publications were progressed for detailed assessment.

One of the four publications were determined to be relevant after detailed review. The relevant article did not constitute new data on molecular characterization of MS8, RF3 and MS8 x RF3 *B. napus* or their newly expressed proteins, PAT/*bar*, Barnase and Barstar, nor did it suggest any potential adverse effects on human and animal health or on the environment. No evidence was identified that would warrant conducting a systematic review.

In summary, these literature searches and review of the retrieved articles identified one relevant publication that supports the existing safety assessment of MS8, RF3 and MS8 x RF3 *B. napus* and their newly expressed proteins Barstar, Barnase and PAT/*bar* (Annex 1_MS8 x RF3 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 MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 oilseed rape. 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 MS8, RF3 and MS8 x RF3 oilseed rape in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of MS8, RF3 and MS8 x RF3 oilseed rape. The reports received from COCERAL, UNISTOCK and FEDIOL show that no adverse effects linked to the presence of MS8, RF3 and MS8 x RF3 oilseed rape were recorded and no adverse findings from independent research relating to MS8, RF3 and MS8 x RF3 oilseed rape have been published.

4. Summary of Results and Conclusions

To date, the general surveillance accompanying the placing on the market of MS8, RF3 and MS8 x RF3 oilseed rape in the EU indicates that there have been no adverse health or environmental effects associated with the importation or use of MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 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 MS8, RF3 and MS8 x RF3 oilseed rape.

Signed: **BASF**

Date: **14th December 2021**