BASF Agricultural Solutions
Seed US LLC

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Fact-sheet

InVigor®
Hybrid oilseed rape MS8/RF3

Unique Identifier
ACS-BNØØ5-8, ACS-BNØØ3-6 and
ACS-BNØØ5-8xACS-BNØØ3-6

January 2021

Information, obligations and recommendations to operators handling and processing bulk mixtures of imported oilseed rape grains which may contain MS8, RF3 and MS8xRF3 oilseed rape (ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8xACS-BNØØ3-6)

The information set out in this document is principally directed to all operators handling and processing bulk mixtures of imported oilseed rape grains.

A. Authorisation

On 26 March 2007, the European Commission issued Commission Decision 2007/232/EC approving the placing on the market of the genetically modified oilseed rape products MS8, RF3 and MS8xRF3 in accordance with Directive 2001/18/EC on the deliberate release of genetically modified organisms in the environment.

This approval under Directive 2001/18/EC resulted from the notification C/BE/96/01, submitted by Bayer BioScience N.V. to the Competent Authority of Belgium in 1996, and covers the import and use of MS8, RF3 and MS8xRF3 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, Bayer BioScience N.V., of the import approval decision on 25 May 2007.

In addition, on 25 June 2013, Commission Decision 2013/327/EU authorised 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.

On 30 November 2017, the applicant Bayer CropScience 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

By letter dated 1 August 2018, Bayer CropScience AG requested the Commission the transfer of its rights and obligations for all authorisations to BASF Agricultural Solutions Seed US LLC. By letter dated 6 August 2018, BASF SE confirmed the agreement to this transfer on behalf of BASF Agricultural Solutions Seed US LLC. This transfer affects Decisions 2007/232/EC and 2013/327/EU.

The authorisation was amended pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by Commission Implementing Decision 2019/1301 of 26 July 2019.

For more information, please visit the Community Register of GM Food and Feed using the following link: https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm.

B. General Product Information

MS8xRF3 comprises a two component system for an efficient seed production of F1 hybrids. The first component is MS8 as female parent, containing a gene for male sterility. The second component

is RF3 as male parent, containing a gene for fertility restoration. As a result of hybrid vigour, cross-pollinated plants MS8xRF3 produce higher yield as compared to self-pollinated oilseed rape.

In addition to the genes encoding male sterility and restoration of fertility, both parents also have a gene encoding for the tolerance to glufosinate ammonium herbicides for better weed control.

C. Food, Feed and Environmental Safety

The Scientific Panel on Genetically Modified Organisms ("the GMO Panel") of the European Food Safety Authority (EFSA) has considered information related to 1) the molecular characterization and expression of the inserted DNA in MS8xRF3 oilseed rape, 2) the comparative assessment of MS8xRF3 oilseed rape and its non-transgenic comparator, 3) the safety of the newly expressed proteins in MS8xRF3 oilseed rape and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of MS8xRF3 oilseed rape.

The GMO Panel concluded that: "*MS8, RF3 and MS8xRF3 oilseed rape is as safe as conventional oilseed rape for humans and animals and, in the context of the proposed uses, for the environment*." Further information can be retrieved from EFSA website at:
http://www.efsa.europa.eu/en/efsajournal/pub/281

An event-specific quantitative detection method for MS8 and RF3 oilseed rape was validated by the Community Reference Laboratory (CRL) of the Joint Research Centre (JRC) and is publicly available on the JRC-CRL website:
http://gmo-crl.jrc.ec.europa.eu/summaries/Ms8_validated_Method_Corrected%20version%201.pdf

and

http://gmo-crl.jrc.ec.europa.eu/summaries/Rf3_validated_Method.pdf

Certified reference material of MS8 and RF3 oilseed rape is available from the American Oil Chemists Society (AOCS):
https://www.aocs.org/crm#canola

D. General obligations for operators

Each operator handling and processing bulk mixtures of imported GM oilseed rape shall comply with the requirements laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003, handling the labelling and traceability of genetically modified organisms and the conditions for labeling and traceability outlined in Commission Decision 2007/232/EC on MS8, RF3 and MS8xRF3 oilseed rape. The words "Not for cultivation" shall appear either on the label or in a document accompanying the product. The Unique Identifier Codes assigned to MS8, RF3 and MS8xRF3 oilseed rape are **ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8xACS-BNØØ3-6**, respectively.

In addition, the operators are requested to collaborate with the authorisation holder in the general surveillance to identify the occurrence of unanticipated adverse effects of the viable MS8, RF3 and MS8xRF3 oilseed rape or its use for human and animal health or the environment that were not predicted in the e.r.a. (see point F). In addition, these operators are requested to comply with all management measures in place to minimize spillage of viable oilseed rape and with respect to clean-up practices.

E. Contact points for Operators

As there are other technology providers for GM oilseed rape it is essential to develop an industry wide approach because the shipments entering the European harbours may be co-mingled.

CropLife Europe, plays an important role in this area and is the central communication point for GM plant technology providers. CropLife Europe is the primary address for reporting general surveillance activities or any unanticipated adverse effects, and is skilled to provide adequate response. In addition, CropLife Europe will transfer the messages to the relevant GMO industry partner if further action is required.

Operators are requested to report, if possible via their branch representative, any unanticipated adverse effect to CropLife Europe at: www.ecpa.eu/product-info

In addition, a complete list of national contact points for operators to directly address local questions or remarks is included in a separate document, named 'List of national contacts'.

If required, additional comments or questions relative to MS8, RF3 and MS8xRF3 oilseed rape can also be addressed at gent.info.operators@basf.com.

F. General surveillance

F1. Monitoring and General Surveillance

In the authorisation procedure for a GMO, an environmental risk assessment is included to identify and evaluate on a case by case basis potential adverse effects either direct or indirect, immediate or delayed of the GMO, on human health and the environment which the deliberate release or the placing on the market of GMOs may have.

To evaluate the conclusions reached in the environmental risk assessment, monitoring is required. The objective of the monitoring is:

1. To confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment is correct. This is referred to as case-specific monitoring, and;

2. To identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment. This is referred to as general surveillance.

In the case of MS8, RF3 and MS8xRF3 oilseed rape, the EFSA GMO panel concluded that "*no potential risks requiring the establishment of a case-specific monitoring plan were identified in the environmental risk assessment*."

However, and in order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the e.r.a., a general surveillance plan for MS8, RF3 and MS8xRF3 oilseed rape is in place. The EFSA GMO Panel concluded that: "*the general approaches and measures proposed by the applicant are appropriate*."

The general surveillance system for MS8, RF3 and MS8xRF3 oilseed rape will involve the authorisation holder and operators handling and using viable MS8, RF3 and MS8xRF3 oilseed rape. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect from handling and use of viable MS8, RF3 and MS8xRF3 oilseed rape.

The authorisation holder will report the results of the general surveillance for MS8, RF3 and MS8xRF3 oilseed rape to the Belgian competent authority and the European Commission on an annual basis.

F2. Awareness of accidental spillage

Accidental or unintentional loss and spillage of imported oilseed rape grains in ports and crushing facilities should be minimized. In the event that grain containing MS8, RF3 and/or MS8xRF3 oilseed rape is lost during handling this may result in the germination and possible establishment of volunteer plants, including MS8, RF3 and/or MS8xRF3 oilseed rape.
Volunteers are plants emerging from grain losses. The likelihood of spillage or loss of viable grain is highest in ports and crushing or processing facilities during storage and handling prior to processing into derived, non-viable products. It is essential that good practices are followed to manage the accidental spillage of viable grains at those locations.

However, and in the case of accidental spillage of imported oilseed rape grains, it is very unlikely it would establish a feral population or that it would outcross to commercial oilseed rape. Furthermore, unintended environmental effects due to the unintended release of MS8, RF3 and MS8xRF3 oilseed rape will be no different than that of other commercial oilseed rape.

In any case, environmental exposure from accidental spillage is highly unlikely to give rise to an adverse effect and can be easily controlled by clean up measures and the application of current practices used for the control of any adventitious oilseed rape plants, such as manual or mechanical removal and the application of herbicides (see Point F.3.).

F3. Eradication of volunteer MS8, RF3 and MS8xRF3 oilseed rape plants

In the event that volunteer plants include MS8, RF3 and/or MS8xRF3 oilseed rape, these plants should be eradicated to minimize the potential for unanticipated adverse effects arising from the GM plant. In that perspective it is essential that good practices are followed to control the establishment of volunteer plants. In order to assist operators importing oilseed rape grain in the EU, BASF Agricultural Solutions Seed US LLC in collaboration with Bayer Agriculture BVBA has made available appropriate technical advice on how to eradicate oilseed rape volunteers which may include T45 and/or MS8/RF3 and/or GT73 oilseed rape. Please refer to the Guideline for the Management of Oilseed Rape Volunteers.

In the event that herbicides are used to eliminate volunteer oilseed rape plants it is essential not to use products based on glyphosate or glufosinate-ammonium only but to apply other broad-leaf herbicides. In the case of doubt it is advised to seek technical advice and support with the local supplier of pesticides regarding the appropriate product to use in areas such as harbours and/or crushing facilities or other non-agricultural environments.