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Seed US LLC

Factsheet

InVigor®
Hybrid oilseed rape MS8/RF3
Unique Identifier
ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 x ACS-BNØØ3-6

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BASF Agricultural Solutions Seed US LLC

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

On 10 January 2019, Commission implementing Decision (EU) 2019/1195 amending Decision 2013/327/EU as regards the authorisation holder and the representative for the placing on the market of genetically modified cotton has adopted the transfer of authorisation from Bayer CropScience AG to BASF Agricultural Solutions Seed US LLC.

The authorisation was renewed pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, by Commission Implementing Decision (EU) 2024/389 of 26 January 2024.
The authorisation for placing on the market of the following products is renewed as regards:

a) foods and food ingredients containing, consisting of or produced from genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 x ACS-BNØØ3-6;
b) feed containing, consisting of or produced from genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 x ACS-BNØØ3-6;
c) products containing or consisting of genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 x ACS-BNØØ3-6, for uses other than those provided for in points (a) and (b), with the exception of cultivation.

For more information, please visit the Community Register of GM Food and Feed using the following link: GMO register (europa.eu)

B. General Product Information

MS8 x RF3 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 MS8 x RF3 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 MS8 x RF3 oilseed rape, 2) the comparative assessment of MS8 x RF3 oilseed rape and its non-transgenic comparator, 3) the safety of the newly expressed proteins in MS8 x RF3 oilseed rape and 4) the potential risk associated with any changes to the toxicological, allergic or nutritional properties of MS8 x RF3 oilseed rape.

The GMO Panel concluded that: "MS8, RF3 and MS8 x RF3 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: https://doi.org/10.2903/j.efsa.2005.281

Additionally, in delivering its scientific opinion on the renewal of MS8, RF3 and MS8 x RF3 oilseed rape, the GMO Panel of EFSA took into account application EFSA-GMO-RX-024, additional information provided by the applicant, scientific comments submitted by the EU Member States and relevant scientific publications. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatic analyses, and additional documents or studies performed by or on behalf of the applicant.

The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequences of the events in oilseed rape MS8, RF3 and MS8x RF3 considered for renewal are identical to the sequences of the originally assessed events, the GMO Panel concludes that there is no evidence in renewal application EFSA-

GMO-RX-024 for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on oilseed rape MS8, RF3 and MS8 x RF3

Further information regarding the Scientific Opinion of the Renewal can be retrieved from EFSA website at: https://doi.org/10.2903/j.efsa.2023.7934

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

https://gmo-crl.jrc.ec.europa.eu/summaries/CRLVL0704VP%20Corr1.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 labelling and traceability outlined in Commission Implementing Decision (EU) 2024/389.

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘oilseed rape’. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified MS8, RF3 and MS8 x RF3 oilseed rape, with the exception of foods and food ingredients.

The Unique Identifier Code assigned to MS8, RF3 and MS8 x RF3 oilseed rape is ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 x ACS-BNØØ3-6.

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 MS8 x RF3 oilseed rape for its use for human and animal health or the environment that were not predicted in the environmental risk assessment (ERA). 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 all 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: Product information - CropLife Europe

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

F. General surveillance

General surveillance is not based on a particular hypothesis, and it should be used to identify the occurrence of unanticipated adverse effects of the viable GMO or its use for human and animal health or the environment that were not predicted in the environmental risk assessment (ERA).

In order to safeguard against any adverse effects on human and animal health or the environment that were not anticipated in the ERA, a general surveillance plan for MS8, RF3 and MS8 x RF3 oilseed rape is in place. In the case of MS8, RF3 and MS8 x RF3 oilseed rape, EFSA concluded that: "*the general approaches and measures proposed by the applicant are appropriate*".

The general surveillance system for MS8, RF3 and MS8 x RF3 oilseed rape involves the authorisation holder and operators who are handling and using viable MS8, RF3 and MS8 x RF3 oilseed rape. The operators will be provided with guidance to facilitate reporting of any unanticipated adverse effect that may arise from the handling and use of viable MS8, RF3 and MS8 x RF3 oilseed rape. The authorisation holder will report the results of the general surveillance for MS8, RF3 and MS8 x RF3 oilseed rape to the European Commission on an annual basis.