Part III - Summary

Request for Renewal of the Authorization of the genetically modified herbicide tolerant canola

MS8, RF3 and MS8 x RF3

for food and feed uses, and import and processing, in accordance with articles 11 and 23 of Regulation (EC) N° 1829/2003

EFSA-GMO-RX024

Version CC3

Submitted on
15 October 2021

PART III – SUMMARY

EFSA-GMO-RX024 (MS8, RF3 AND MS8 X RF3)

1. GENERAL INFORMATION

1.1. Details of application

(a) Application number

EFSA-GMO-RX024

(b) Name of the product (commercial and any other names)

MS8, RF3 and MS8 x RF3 canola, unique identifier are ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 x ACS-BNØØ3-6, respectively. The commercial name of the planting seed product is InVigor™ canola.

(c) Date of acknowledgement of valid renewal application

Not available at the time of submission

1.2. Applicant

(a) Name of applicant

BASF Agricultural Solutions Seed US LLC

(b) Address of applicant

BASF Agricultural Solutions Seed US LLC
100 Park Avenue
Florham Park, NJ 07932
USA

(c) Name and address of the representative of the applicant established in the Union (if the applicant is not established in the Union)

Representative of the applicant established in the Union:
BASF SE
Carl-Bosh-Str. 38
D-67063 Ludwigshafen
Germany

BASF Belgian Coordination Center CommV is the contact for this submission and all correspondence should be directed to:

Belgian Coordination Center CommV,
Rue Marie de Bourgogne 58,
1000 Brussels
Belgium

1.3. Scope of the renewal application

(a) Genetically modified food

- ☑ Food containing or consisting of genetically modified plants
- ☑ Food produced from genetically modified plants or containing ingredients produced from genetically modified plants

(b) Genetically modified feed

- ☑ Feed containing or consisting of genetically modified plants
- ☑ Feed produced from genetically modified plants

(c) Genetically modified plants for food or feed uses

- ☑ Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation

1.4. Has the product been subject to an application and/or authorised in a third country either previously or simultaneously to this application?

Submission for authorisation of MS8, RF3 and MS8 x RF3 canola for food and feed uses has been made in Indonesia. MS8, RF3 and MS8 x RF3 canola is authorised for food and feed uses in USA, Australia & New Zealand, Canada, Japan, Korea, China, Colombia, Mexico, Taiwan, Vietnam, EU, India, Philippines, Singapore, South Africa, and Malaysia. Food use of the oil derived from MS8 x RF3 has been authorized in India. MS8, RF3 and MS8 x RF3 canola has been approved for cultivation in the USA, Canada and Australia.

More information on the regulatory status of the product in the EU and third countries can be retrieved from the EU Register of authorised GMOs[1] and the CropLife International database[2]

1.5. General description of the product

The recipient plant is canola. The genetically modified MS8, RF3 and MS8 x RF3 canola hybrids express the Barnase, Barstar and PAT/*bar* proteins. The developed breeding tool is used to produce canola glufosinate-ammonium tolerant hybrids. The hybrid technology comprises three components: a dominant gene for male sterility – the *barnase* gene (event MS8), a dominant gene for fertility restoration – the *barstar* gene (event RF3), and the *bar* gene (found in both MS8 and RF3) conferring tolerance to glufosinate-ammonium.

[1] https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm
[2] http://www.biotradestatus.com/#

2. Information Required Under Articles 11 and 23 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed

2.1 A copy of the authorisation for placing the food and feed on the market

A copy of the Commission Implementing Decision 2013/327/EU authorising placing on the market of food and food ingredients containing, consisting of genetically modified oilseed rapes MS8, RF3 and MS8 x RF3 and food and feed produced from MS8, RF3 and MS8 x RF3 oilseed rape pursuant to Regulation (EC) No 1829/2003 of the European Parliament and the Council; and the Commission Implementing Decision (EU) 2019/1301 amending Implementing Decision 2013/327/EU as regards of incorporation into its scope such products as the feed containing or consisting of genetically modified canola MS8, RF3 and MS8 x RF3, and other uses than food or feed, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council is provided in Annex 1 to Part II accompanying this request.

A copy of 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 canola MS8, RF3 and MS8 x RF3 is also provided in Annex 1 to Part II accompanying this request.

2.2 A report on the results of the monitoring, if so specified in the authorisation

In line with Article 4 of the Commission Decision 2013/327/EU, the authorisation holder ensured the implementation of the monitoring plan for environmental effects and submitted to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

The Annual Post Market Environmental Monitoring (PMEM) reports for the genetically modified canola MS8, RF3 and MS8 x RF3 covering the monitoring period from June 2013 until June 2020 are provided in Annex 2 to Part II accompanying this request. The PMEMs for a period from 2013 up to 2015 have already been provided to and evaluated by EFSA in frame of application EFSA-GMO-RX-004.

The general surveillance considering the placing on the market of MS8, RF3 and MS8 x RF3 canola in the EU indicates that there have been no adverse health or environmental effects associated with the import or use of MS8, RF3 and MS8 x RF3 canola.

2.3 Any other new information which has become available with regard to the evaluation of the safety in use of the food and feed and the risks of the food and feed to the consumer, animals or the environment

2.3.1 Systematic search and evaluation of literature

A scoping review for MS8, RF3 and MS8 x RF3 canola and its newly expressed proteins, Barnase, Barstar and PAT/*bar*, identified no literature changing the original risk assessment conclusions.

2.3.2 Update Bioinformatics

Following the requirement as laid out in the EFSA Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003, updated bioinformatics analyses were conducted.

The results of the updated bioinformatics analyses do not change the original risk assessment conclusion on MS8, RF3 and MS8 x RF3 canola.

2.3.3 Additional documents or studies performed by or on behalf of the applicant

None of the competent authorities has prohibited or revoked the authorisation for MS8, RF3 and MS8 x RF3 canola for neither import nor cultivation purposes.

The detailed review of unpublished studies produced, controlled or sponsored by the applicant did not identify any studies that would constitute any new data relevant for the risk assessment of MS8, RF3 and MS8 x RF3 canola for the scope of the application or the newly expressed proteins (Barnase, Barstar and PAT/*bar*) or which challenge or change in any way the conclusions of the original risk assessment.

2.4 Where appropriate, a proposal for amending or complementing the conditions of the original authorisation, inter alia the conditions concerning future monitoring

This application is for renewal of the authorisation of genetically modified herbicide tolerant MS8, RF3 and MS8 x RF3 canola for food and feed uses, import and processing. The application does not cover cultivation of MS8, RF3 and MS8 x RF3 canola in the EU.

The initial authorisation, which was issued on 25 June 2013, Commission Implementing Decision 2013/327/EU for placing on the market of MS8, RF3 and MS8 x RF3 canola pursuant to Regulation (EC) No 1829/2003 lays out conditions in Article 4 and point (h) of the Annex of the authorization decision. These lay down the need for general monitoring and do not impose specific conditions or restrictions on the placing on the market, use or handling of the products. Considering that the annual EU Post market environmental monitoring activities for the years 2013-2020 did not identify adverse effects and that there was no literature identified changing previous risk assessment conclusions, no revisions or changes to the general surveillance measures are considered necessary.

Based on the conclusions of the overall assessment of the here presented renewal application of MS8, RF3 and MS8 x RF3 canola for food and feed uses, the conditions of the original authorisation should not be amended or complemented and should therefore remain unchanged.