Application for modifying the terms of the authorisation regarding the placing on the market of isolated seed protein from GT73 oilseed rape for food in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

EFSA-GMO-RX-026/02 / EFSA-Q-2021-00283

Part III

Summary of Application

1. GENERAL INFORMATION

1.1. Details of application.

(a) Application number

EFSA-GMO-RX-026/02

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

GT73 oilseed rape was developed by Monsanto Company[1] and provides tolerance to glyphosate herbicides by the expression of GOXv247 and CP4 EPSPS proteins. It is associated with the trademark Roundup Ready®[2].

(c) Date of acknowledgement of valid renewal application

Not available at the time of submission.

1.2. Applicant

(a) Name of applicant

Bayer Agriculture BV *on behalf of* Bayer CropScience LP.

(b) Address of applicant

Bayer Agriculture BV Haven 627 Scheldelaan 460 B-2040 Antwerp; Belgium	Bayer CropScience LP 800 N. Lindbergh Boulevard St. Louis, Missouri 63167 USA

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

See above.

1.3. Scope of the application

Application for modifying the terms of the authorisation regarding the placing on the market of isolated seed protein from GT73 oilseed rape for food in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed[3].

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1 On August 1st, 2020, Monsanto Company converted its legal form and changed its name to Bayer CropScience LP.

2 Roundup Ready® is a registered trademark of Bayer CropScience LP

3 On the basis of the EFSA GMO Panel conclusion in its scientific opinion on Application EFSA-GMO-RX-002 adopted on July 2, 2020 (EFSA (2020). Assessment of genetically modified oilseed rape GT73 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-002). *EFSA Journal* 18(7):6199, 14pp.):"*Overall, the GMO Panel also concludes, based on a weight of evidence consideration of the 28-day toxicity study, molecular characterisation, enzymatic properties and likely degradation on ingestion, that GOXv247 expressed in oilseed rape GT73 will not cause any adverse effects in animals or humans consuming food and feed containing, consisting and produced from this crop.*"

1.4. General description of the product

(a) Name of the recipient or parental plant and the intended function of the genetic modification

GT73 was developed using the *Agrobacterium*-mediated transformation method. It expresses GOXv247 and CP4 EPSPS proteins which confer tolerance to glyphosate herbicides.

(b) Regulatory status

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[4] and the CropLife International database[5].

2. INFORMATION TO BE SUBMITTED ACCORDING TO ARTICLES 11 AND 23 OF REGULATION (EC) NO 1829/2003

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

Commission Implementing Decision 2015/701/EU of 24 April 2015[6] authorising the placing on the market of food containing or consisting of genetically modified oilseed rape GT73 (MON-ØØØ73-7), or food and feed produced from that genetically modified organism pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

Also note the Commission Implementing Decision (EU) 2021/1385 of 17 August 2021[7] renewing the authorisation for the placing on the market of feed and products other than food and feed containing or consisting of genetically modified oilseed rape GT73 (MON-ØØØ73-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council.

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

In accordance with Article 4 of Commission Implementing Decision 2015/701/EU[6], the authorisation holder for GT73, shall submit to the Commission annual reports on the implementation and the results of post-market environmental monitoring (PMEM) activities for the duration of the validity of the consent.

Taking into account the above and Commission Decision 2005/635/EC[8] of 31 August 2005, monitoring activities were performed and reported as from 2008. The results of those PMEM reports do not change in any way the conclusions of the previous risk assessments.

[4] https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-register_en; Accessed on 12 October 2021.
[5] http://www.biotradestatus.com/; Accessed on 12 October 2021.
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02015D0701-20210216; COMMISSION IMPLEMENTING DECISION (EU) 2015/701 of 24 April 2015.
[7] Renewal application (EFSA-GMO-RX-002): https://www.efsa.europa.eu/en/efsajournal/pub/6199; EFSA scientific opinion adopted on 2 July 2020 and https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021D1385; COMMISSION IMPLEMENTING DECISION (EU) 2021/1385 of 17 August 2021
[8] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32005D0635; COMMISSION DECISION of 31 August 2005.

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

The results of a review of the peer-reviewed scientific data on the GMO and derived food and feed relevant for the safety of the GM product for humans, animals and environment and updated bioinformatics analyses that have become available since Application EFSA-GMO-RX-002 was reviewed by EFSA do not change in any way the conclusions of the previous risk assessments.

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

Based on the above, the conditions of the original PMEM plan should not be amended or complemented and should therefore remain unchanged.