Application for renewal of the authorisation for products containing, consisting of, or produced from genetically modified soybean MON 87701 under Regulation (EC) No 1829/2003 on genetically modified food and feed (Commission Implementing Decision 2012/83/EU of 10 February 2012[1])

EFSA-GMO-RX-021 / EFSA-Q-2021-00061

Part III

Summary

[1] Amended by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019.

1. GENERAL INFORMATION

1.1. Details of application.

(a) Application number

Not available at the time of submission

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

MON 87701 soybean was developed by Monsanto Company[2] and provides protection against certain lepidopteran pests by the expression of Cry1Ac protein.

(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 renewal application

Application for renewal of the authorisation for products containing, consisting of, or produced from genetically modified soybean MON 87701 under the Regulation (EC) No 1829/2003 (Commission Implementing Decision 2012/83/EU of 10 February 2012[1]).

1.4. General description of the product

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

MON 87701 was developed using the *Agrobacterium*-mediated transformation method. It produces the Cry1Ac protein which confers insect protection.

(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[3] and the CropLife International database[4].

[2] On August 1st, 2020, Monsanto Company converted its legal form and changed its name to Bayer CropScience LP.
[3] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm; Accessed on 4 December 2020.
[4] http://www.biotradestatus.com/; Accessed on 4 December 2020.

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 2012/83/EU of 10 February 2012[1] authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 (MON-877Ø1-2) 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 Implementing Decision 2012/83/EU[1], the authorisation holder for MON 87701 shall submit to the Commission annual reports on the implementation and the results of post-market environmental monitoring (PMEM) activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

Taking into account the above, monitoring activities were performed and reported as from 2012. The results of those PMEM reports do not change in any way the conclusions of the initial risk assessment.

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 that have become available since the initial authorisation, updated bioinformatics analyses and studies performed by the applicant do not change in any way the conclusions of the initial 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

Based on the above, the conditions of the initial authorisation should not be amended or complemented and should therefore remain unchanged.