Application for renewal of the authorisation for foods and food ingredients/feed containing, consisting of, or produced from MON 89788 soybean and products other than food and feed containing or consisting of MON 89788 soybean under the Regulation (EC) No 1829/2003 (Commission Decision 2008/933/EC of 4 December 2008)

EFSA-GMO-RX-011

Summary of Application

1. GENERAL INFORMATION

1.1. Details of application.

(a) Member State of application

Not applicable

(b) Application number

EFSA-GMO-RX-011

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

Soybean MON 89788 was developed by Monsanto Campany and provides tolerance to glyphosate based herbicides, conferred by the expression of CP4 EPSPS protein. It is associated with the trademark Genuity® Roundup Ready 2 Yield®[1].

(d) Date of acknowledgement of valid renewal application

Not available at the time of submission.

1.2. Applicant

(a) Name of applicant

Monsanto Company, represented by Monsanto Europe S.A.

(b) Address of applicant

Monsanto Europe S.A.
Avenue de Tervueren 270-272
B-1150 Brussels
BELGIUM

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
US

(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 foods and food ingredients/feed containing, consisting of, or produced from MON 89788 soybean and products other than food and feed containing or consisting of MON 89788 soybean under the Regulation (EC) No 1829/2003 (Commission Decision 2008/933/EC of 4 December 2008).

1.4. General description of the product

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

MON 89788 was developed using the *Agrobacterium*-mediated transformation method. It produces CP4 EPSPS protein which confers tolerance to glyphosate.

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

[1] Genuity® and Roundup Ready 2 Yield® are registered trademarks of Monsanto Technology LLC.
[2] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm; Accessed on 12 March 2018.

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 Decision of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 89788 (MON-89788-1) 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 Directive 2001/18/EC and Article 4 of Commission Decision 2007/701/EC, the consent holder for MON 89788, Monsanto Europe S.A., is accountable for the submission of annual reports on the results of post-market environmental (PMEM) monitoring activities to the Commission and to the competent authorities of the Member States for the duration of the validity of the consent.

Taking into account the above, monitoring activities were performed and reported as from 2008. The results of those monitoring reports do not change in any way the conclusions of the original 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 original authorisation, updated bioinformatics analyses and studies performed by the applicant do not 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

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

[3] http://www.biotradestatus.com/; Accessed on 12 March 2018.