Application for renewal of the authorisation for foods and food ingredients/feed containing, consisting of, or produced from MON 88017 maize and products other than food and feed containing or consisting of MON 88017 maize under the Regulation (EC) No 1829/2003 (Commission Decision 2009/814/EC of 30 October 2009)

EFSA-GMO-RX-XXX

Summary of Application

1. GENERAL INFORMATION

1.1. Details of application.

(a) Member State of application

Not applicable

(b) Application number

Not available at the time of submission

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

MON 88017 maize was developed by Monsanto Company and provides protection against certain coleopteran pests and tolerance to glyphosate based herbicides by the expression of Cry3Bb1 and CP4 EPSPS proteins, respectively. It is associated with the trademark YieldGard VT Rootworm/RR2®[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 88017 maize and products other than food and feed containing or consisting of MON 88017 maize under the Regulation (EC) No 1829/2003 (Commission Decision 2009/814/EC of 30 October 2009).

1.4. General description of the product

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

MON 88017 was developed using the *Agrobacterium*-mediated transformation method. It produces Cry3Bb1 and CP4 EPSPS proteins which confer insect protection and tolerance to glyphosate, respectively.

[1] RR2® is a registered trademark of Monsanto Technology LLC.
[2] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm; Accessed on 27 June 2018.

(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].

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 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON 88Ø17-3) 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 2009/814/EC, the consent holder for MON 88017, 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 2010. 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 27 June 2018.