Application for renewal of the authorization for products containing, consisting of or produced from NK603 × MON 810 maize under the Regulation (EC) No 1829/2003 (Commission Decision 2007/701/EC of 24 October 2007)

EFSA-GMO-RX-007

Summary of Application

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Not applicable

(b) Application number

EFSA-GMO-RX-007

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

The Monsanto development code for this genetically modified maize is NK603 × MON 810. In countries where NK603 × MON 810 varieties are being cultivated, packages of hybrid seed of this maize are marketed under the name of the hybrid variety, in association with the trademarks Roundup Ready® Corn 2 with YieldGard® Corn Borer, indicating clearly to growers that the hybrid is tolerant to Roundup® herbicide and protected from specific lepidopteran insect pests.

(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./N.V.

(b) Address of applicant

Monsanto Europe S.A./N.V.
Avenue de Tervuren 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 authorization for products containing, consisting of, or produced from NK603 × MON 810 maize under the Regulation (EC) No 1829/2003 (Commission Decision 2007/701/EC of 24 October 2007).

1.4. General description of the product

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

NK603 × MON 810 is produced by crossing maize plants containing MON 810 and NK603 using traditional breeding methods.

- Like NK603, NK603 × MON 810 produces the two CP4 EPSPS proteins (CP4 EPSPS and CP4 EPSPS L214P) which provide tolerance to glyphosate.
- Like MON 810, NK603 × MON 810 produces the Cry1Ab protein which provides protection from feeding damage caused by certain lepidpteran insect pests.

® Roundup, Roundup Ready and YieldGard are registered trademarks of Monsanto Technology LLC.

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

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

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

Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × MON810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) 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 authorization

In accordance with Directive 2001/18/EC and Article 4 of Commission Decision 2007/701/EC, the consent holder for NK603 × MON 810, 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 authorization, 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 authorization, inter alia the conditions concerning future monitoring

Based on the above, a proposal for amending the conditions of the original authorization, inter alia the conditions concerning future monitoring, was provided in the renewal application.

[1] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm; Accessed on 18 January 2017.
[2] http://www.biotradestatus.com/; Accessed on 18 January 2017.