Application for renewal of the authorization for food and feed produced from genetically modified sugar beet H7-1 under Regulation (EC) No 1829/2003 (Commission Decision 2007/692/EC of 24 October 2007)

EFSA-GMO-RX-006

Summary of Application

1. GENERAL INFORMATION

1.1. Details of application

(a) Member State of application

Not applicable

(b) Application number

EFSA-GMO-RX-006

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

Sugar beet H7-1 was developed by KWS SAAT SE and Monsanto Company[1] and provides tolerance to glyphosate based herbicides, conferred by the expression of CP4 EPSPS protein. It is therefore associated with the trademark Roundup Ready®.

(d) Date of acknowledgement of valid renewal application

Not available at the time of submission.

1.2. Applicant

(a) Name of applicant

KWS SAAT SE and Monsanto Company, represented by Monsanto Europe S.A./N.V.

(b) Address of applicant

KWS SAAT SE
Grimsehlstrasse 31
D 37574 Einbeck
GERMANY

and

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 food and feed produced from genetically modified sugar beet H7-1 under Regulation (EC) No 1829/2003 (Commission Decision 2007/692/EC of 24 October 2007)

[1] KWS SAAT SE is the developer of the genetically modified sugar beet event H7-1, breeder and seed producer of sugar beet varieties. Monsanto is the developer of the *cp4 epsps* gene technology in Roundup Ready® crops, including sugar beet.

® Roundup Ready is a registered trademark of Monsanto Technology LLC.

1.4. General description of the product

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

H7-1 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].

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 food and feed produced from genetically modified sugar beet H7-1 (KM-ØØØH71-4) 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

NOT APPLICABLE as per Commission Decision 2007/692/EC of 24 October 2007.

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 applicants 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, the conditions of the original authorization should not be amended or complemented.

[2] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm; Accessed on 31 January 2017.
[3] http://www.biotradestatus.com/; Accessed on 31 January 2017.