

COMMISSION IMPLEMENTING DECISION (EU) 2018/1113**of 3 August 2018****renewing the authorisation for 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***(notified under document C(2018) 5029)***(Only the Dutch, French and German texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2007/692/EC ⁽²⁾ authorised the placing on the market of foods, food ingredients and feed produced from genetically modified sugar beet H7-1 (hereinafter 'sugar beet H7-1').
- (2) On 22 January 2018, KWS SAAT SE informed the Commission that it became, on 15 April 2015, the legal successor of the previous co-authorisation holder KWS SAAT AG. Therefore, the rights and obligations of KWS SAAT AG as co-authorisation holder were taken over by KWS SAAT SE.
- (3) On 20 October 2016, KWS SAAT SE and Monsanto Europe S.A./N.V. jointly submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (4) On 16 November 2017, the European Food Safety Authority ('EFSA') published a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded ⁽³⁾ that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment ⁽⁴⁾ on sugar beet H7-1.
- (5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) Taking into account those considerations, the authorisation for the placing on the market of foods, food ingredients and feed produced from genetically modified sugar beet H7-1 should be renewed.
- (7) A unique identifier has been assigned to sugar beet H7-1, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁵⁾, by Commission Decision 2007/702/EC ⁽⁶⁾. That unique identifier should continue to be used.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2007/692/EC 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 (OJ L 283, 27.10.2007, p. 69).

⁽³⁾ Assessment of genetically modified sugar beet H7-1 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-006). *EFSA Journal* 2017;15(11):5065

⁽⁴⁾ Opinion of the Scientific Panel on Genetically Modified Organisms on an application (reference EFSA GMO-UK-2004-08) for the placing on the market of products produced from glyphosate-tolerant genetically modified sugar beet H7-1, for food and feed uses, under Regulation (EC) No 1829/2003 from KWS SAAT and Monsanto. *EFSA Journal* 2006;4(12):431

⁽⁵⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽⁶⁾ Commission Decision 2007/702/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 42).

- (8) On the basis of the abovementioned EFSA opinion, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for the products covered by this Decision.
- (9) Similarly, the EFSA opinion does not justify the imposition of specific conditions or restrictions on the placing on the market or for use and handling, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (10) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Regulation (EC) No 1829/2003.
- (11) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified sugar beet (*Beta vulgaris subsp. vulgaris*) H7-1, as specified in point (b) of the Annex, is assigned the unique identifier KM-ØØØH71-4, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of authorisation

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients produced from KM-ØØØH71-4 sugar beet;
- (b) feed produced from KM-ØØØH71-4 sugar beet.

Article 3

Labelling

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'sugar beet'.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of sugar beet H7-1.

Article 5

Community register

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed referred to in Article 28 of Regulation (EC) No 1829/2003.

*Article 6***Authorisation holders**

1. The authorisation holders shall be:

- (a) KWS SAAT SE, Germany; and
- (b) Monsanto Company, United States of America, represented by Monsanto Europe S.A./N.V., Belgium.

2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

*Article 7***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8***Addressee**

This Decision is addressed to:

- (a) KWS SAAT SE, Grimsehlstrasse 31, 37574 Einbeck, Germany; and
- (b) Monsanto Europe S.A./N.V., Scheldelaan 460, Haven 627, 2040 Antwerp, Belgium.

Done at Brussels, 3 August 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicants and Authorisation holders:

Name: KWS SAAT SE

Address: Grimsehlstrasse 31, 37574 Einbeck, Germany

and

Name: Monsanto Company

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented by Monsanto Europe S.A./N.V., Scheldelaan 460, Haven 627, 2040 Antwerp, Belgium.

(b) Designation and specification of the products:

(1) Foods and food ingredients produced from KM-ØØØH71-4 sugar beet;

(2) Feed produced from KM-ØØØH71-4 sugar beet.

The genetically modified KM-ØØØH71-4 sugar beet, as described in the application, expresses the CP4 EPSPS protein after insertion of the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 into sugar beet (*Beta vulgaris* subsp. *vulgaris*).

The CP4 EPSPS protein confers tolerance to glyphosate containing herbicides.

(c) Labelling:

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'sugar beet'.

(d) Method for detection:

(1) Event specific realtime PCR-based method for the quantification of KM-ØØØH71-4 sugar beet.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

(3) Reference Material: ERM®-BF419 is accessible via the Joint Research Centre (JRC) of the European Commission, at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>

(e) Unique identifier:

KM-ØØØH71-4

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Not applicable.

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan for environmental effects:

Not applicable.

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.
