

COMMISSION IMPLEMENTING DECISION (EU) 2015/685**of 24 April 2015****authorising the placing on the market of genetically modified cotton MON 15985 (MON-15985-7) and renewing the authorisation for existing genetically modified cotton MON 15985 (MON-15985-7) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2015) 2755)***(Only the Dutch and French 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 7(3), 11(3), 19(3) and 23(3) thereof,

Whereas:

- (1) On 9 December 2004, Monsanto Europe S.A. submitted to the competent authority of the United Kingdom an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 for the placing on the market of food and feed produced from genetically modified cotton MON 15985.
- (2) Food additives, feed materials and feed additives produced from genetically modified cotton MON 15985 were placed on the market before the entry into force of Regulation (EC) No 1829/2003 and were notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation.
- (3) On 17 April 2007, Monsanto Europe S.A. submitted to the Commission an application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 for the renewal of the authorisation for existing food additives, feed materials and feed additives produced from genetically modified cotton MON 15985.
- (4) On 22 April 2008, Monsanto Europe S.A. submitted a new broader application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from genetically modified cotton MON 15985, including the existing products ('the application') and on 2 July 2008 withdrew its application submitted on 9 December 2004.
- (5) The application also covers the placing on the market of genetically modified cotton MON 15985 in products consisting of it or containing it for other uses than food and feed as any other cotton, with the exception of cultivation.
- (6) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003 the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to that Directive. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (7) On 29 July 2014, the European Food Safety Authority ('EFSA') gave an opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. It concluded that genetically modified cotton MON 15985, as described in the application, is as safe as its conventional counterpart and non-genetically modified cotton commercial varieties and is unlikely to have adverse effects on human and animal health and the environment, notwithstanding the incompleteness in the agronomic and phenotypic dataset. Considering the scope of these

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on applications (EFSA-GMO-UK-2008-57 and EFSA-GMO-RX-MON15985) for the placing on the market of insect-resistant genetically modified cotton MON 15985 for food and feed uses, import and processing, and for renewal of authorisation of existing products produced from cotton MON 15985, both under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2014;12(7):3770, 42 pp. doi:10.2903/j.efsa.2014.3770

applications and the poor ability of cotton to survive outside cultivated fields, EFSA concluded that the likelihood of any adverse environmental impacts due to the accidental release into the environment of viable seeds from cotton MON 15985 is very low.

- (8) EFSA concluded that the analysis of horizontal gene transfer from genetically modified cotton MON 15985 to bacteria did not indicate a risk to human or animal health or to the environment in the context of its intended uses, considering the expected low frequency of gene transfer from plant to bacteria compared with that between bacteria, and the very low exposure to DNA from genetically modified cotton MON 15985.
- (9) 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 Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (10) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.
- (11) Consequently, authorisation should be granted to the products containing, consisting of, or produced from genetically modified cotton MON 15985.
- (12) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (13) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from genetically modified cotton MON 15985. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing, consisting of, or produced from MON 15985 cotton, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (14) Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽²⁾ lays down labelling requirements for products containing or consisting of GMOs. Traceability requirements for those products are laid down in paragraphs 1 to 5 of Article 4 and traceability requirements for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (15) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ⁽³⁾. The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.
- (16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- (17) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁴⁾.
- (18) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

⁽¹⁾ 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).

⁽²⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽³⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁴⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.) MON 15985, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-15985-7, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from MON-15985-7 cotton;
- (b) feed containing, consisting of, or produced from MON-15985-7 cotton;
- (c) MON-15985-7 cotton in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-15985-7 cotton, with the exception of products referred to in point (a) of Article 2.

Article 4

Monitoring for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

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, as provided for in Article 28 of Regulation (EC) No 1829/2003.

Article 6

Authorisation holder

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

*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 Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels — Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States of America.

(b) **Designation and specification of the products**

1. Foods and food ingredients containing, consisting of, or produced from MON-15985-7 cotton.
2. Feed containing, consisting of, or produced from MON-15985-7 cotton.
3. MON-15985-7 cotton in products containing it or consisting of it for any other use than those provided in points 1 and 2, with the exception of cultivation.

The genetically modified MON-15985-7 cotton, as described in the application, expresses the Cry2Ab2 and Cry1Ac proteins which confer protection against certain lepidopteran pests and GUS protein which acts as selection marker. In addition, an *nptII* gene, conferring kanamycin and neomycin resistance, and *aadA* gene, conferring spectinomycin and streptomycin resistance, were used as selective markers in the genetic modification process.

(c) **Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-15985-7 cotton with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

1. Event specific real-time PCR based method for the quantification of MON-15985-7.
2. Validated on genomic DNA, extracted from seeds 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: AOCS 0804-D and AOCS 0804-A are accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

(e) **Unique identifier**

MON-15985-7

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

Biosafety Clearing-House, Record ID: see [to be completed when notified].

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

Not required.

(h) **Monitoring plan for environmental effects**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: plan published on the internet]

(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 Community register of genetically modified food and feed.
