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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)

(OJ L 112, 30.4.2015, p. 11)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2019/1579 of 18 September 2019	L 244	8	24.9.2019

▼B

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(notified under document C(2015) 2755)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

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.

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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.

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Article 6

Authorisation holder

The authorisation holder shall be Bayer Agriculture BVBA, Belgium, representing Monsanto Company, United States of America.

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Article 7

Validity

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

▼M1

Article 8

Addressee

This Decision is addressed to Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

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ANNEX

▼M1

(a) **Applicant and authorisation holder**

Name: Bayer Agriculture BVBA

Address: Scheldelaan 460, 2040 Antwerp, Belgium

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

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(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 *npt*II gene, conferring kanamycin and neomycin resistance, and *aad*A 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.

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(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.