

COMMISSION IMPLEMENTING DECISION (EU) 2015/695**of 24 April 2015**

renewing the authorisation for existing genetically modified cotton MON 531 x MON 1445 (MON-ØØ531-6 x MON-Ø1445-2) products and authorising the placing on the market of cottonseed oil produced from genetically modified cotton MON 531 x MON 1445 (MON-ØØ531-6 x MON-Ø1445-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2015) 2769)

(Only the French and Dutch 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 30 November 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 cottonseed oil and its constituents produced from genetically modified cotton MON 531 x MON 1445.
- (2) Food additives, feed materials and feed additives produced from genetically modified cotton MON 531 x MON 1445 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 531 x MON 1445 cotton.
- (4) The scope of the two applications, taken together, covers the full range of current commercial uses of food and feed produced from cotton as defined in Articles 3(1)(c) and 15(1)(c) of Regulation (EC) No 1829/2003.
- (5) On 28 March 2012, the European Food Safety Authority ('EFSA') gave a favourable opinion ⁽²⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that products derived from genetically modified cotton MON 531 x MON 1445 are as safe as products derived from the conventional counterpart, in the context of their intended uses.
- (6) EFSA concluded that the analysis of horizontal gene transfer from genetically modified cotton MON 531 x MON 1445 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 531 x MON 1445.
- (7) 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.
- (8) Consequently, authorisation should be granted for the products produced from genetically modified cotton MON 531 x MON 1445.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Scientific Opinion on applications EFSA-GMO-UK-2005-09 and EFSA-GMO-RX-MON531×MON1445 for the placing on the market of food and feed produced from or containing ingredients produced from insect-resistant and herbicide-tolerant genetically modified cotton MON 531 × MON 1445; and for the renewal of authorisation of existing products produced from cotton MON 531 × MON 1445, both under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal (2012);10(3):2608. doi:10.2903/j.efsa.2012.2608.

- (9) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (10) 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 produced from genetically modified cotton MON 531 x MON 1445.
- (11) 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.
- (12) 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 Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽²⁾.
- (13) 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,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.) MON 531 x MON 1445, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ531-6 x MON-Ø1445-2, 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) food produced from MON-ØØ531-6 x MON-Ø1445-2 cotton;
- (b) feed produced from MON-ØØ531-6 x MON-Ø1445-2 cotton.

Article 3

Labelling

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

Article 4

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.

⁽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 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).

*Article 5***Authorisation holder**

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

*Article 6***Validity**

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

*Article 7***Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, B-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, B-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. Food produced from MON-ØØ531-6 x MON-Ø1445-2 cotton.

2. Feed produced from MON-ØØ531-6 x MON-Ø1445-2 cotton.

The genetically modified MON-ØØ531-6 x MON-Ø1445-2 cotton, as described in the application, expresses the Cry1Ac protein which confers resistance to lepidopteran pests and the CP4 EPSPS protein which confers tolerance to glyphosate-containing herbicides. 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**

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

(d) **Method for detection**

1. Event specific real-time PCR based method for the quantification of MON-ØØ531-6 x MON-Ø1445-2 cotton

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/statusofdoss.htm>

3. Reference Material: AOCS 0804-B, AOCS 0804-C and AOCS 0804-A are accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

(e) **Unique identifier**

MON-ØØ531-6 x MON-Ø1445-2

(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 required.

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

Not required.
