

Commission Implementing Decision (EU) 2015/689 of 24 April 2015 renewing the authorisation for existing genetically modified cotton MON 531 (MON-ØØ531-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2015) 2761) (Only the French and Dutch texts are authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2015/689

of 24 April 2015

renewing the authorisation for existing genetically modified cotton MON 531 (MON-ØØ531-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2761)*

(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<sup>(1)</sup>, and in particular Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Food additives, feed materials and feed additives produced from genetically modified cotton MON 531 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.
- (2) 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 ('the application').
- (3) On 16 June 2011, Monsanto Europe S.A. requested an extension of the scope of the application to include food cottonseed oil produced from genetically modified cotton MON 531, which was previously notified as an existing product in accordance with Article 8(1)(a) of Regulation (EC) No 1829/2003.
- (4) The scope of the application as extended 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 16 September 2011, the European Food Safety Authority ('EFSA') gave a favourable opinion<sup>(2)</sup> in accordance with Articles 6 and 18 of Regulation (EC) No

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1829/2003. It concluded that products derived from genetically modified cotton MON 531, as described in the application, are as safe as products derived from its 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 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.
- (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 renewed for the products produced from genetically modified cotton MON 531.
- (9) A unique identifier should be assigned to each genetically modified organism as provided for in Commission Regulation (EC) No 65/2004<sup>(3)</sup>.
- (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.
- (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<sup>(4)</sup>.
- (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, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ531-6, as provided for in Regulation (EC) No 65/2004.

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## Article 2

### Renewal of authorisation

The authorisation for the placing on the market of the following products is renewed for the purposes of Articles 11 and 23 of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) food produced from MON-ØØ531-6 cotton;
- (b) feed produced from MON-ØØ531-6 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.

## <sup>F1</sup> Article 5

### Authorisation holder

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

#### Textual Amendments

- F1** Substituted by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union (notified under document C(2019) 6520) (Only the Dutch text is authentic) (Text with EEA relevance).

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## Article 6

### Validity

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

## <sup>F1</sup> Article 7

### Addressee

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

#### Textual Amendments

- F1** Substituted by [Commission Implementing Decision \(EU\) 2019/1579 of 18 September 2019 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, \(EU\) 2015/683, \(EU\) 2015/684, \(EU\) 2015/685, \(EU\) 2015/686, \(EU\) 2015/687, \(EU\) 2015/688, \(EU\) 2015/689, \(EU\) 2015/693, \(EU\) 2015/695, \(EU\) 2015/696, \(EU\) 2015/700, \(EU\) 2015/701, \(EU\) 2015/2279, \(EU\) 2015/2281, \(EU\) 2016/1216, \(EU\) 2016/1217, \(EU\) 2017/1207, \(EU\) 2018/1111, \(EU\) 2018/2045 and \(EU\) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union \(notified under document C\(2019\) 6520\) \(Only the Dutch text is authentic\) \(Text with EEA relevance\).](#)

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## ANNEX

### [<sup>F1</sup>(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.]

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

1. Food produced from MON-ØØ531-6 cotton.
2. Feed produced from MON-ØØ531-6 cotton.

The genetically modified MON-ØØ531-6 cotton, as described in the application, expresses the Cry1Ac protein which confers resistance to lepidopteran pests. An *npII* 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 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-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

### (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.

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- (1) [OJ L 268, 18.10.2003, p. 1.](#)
- (2) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on application EFSA-GMO-RX-MON531 for renewal of the authorisation for continued marketing of existing cottonseed oil, food additives, feed materials and feed additives produced from MON 531 cotton that were notified under Articles 8(1)(a), 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2011;9(9):2373. [1-30] doi:10.2903/j.efsa.2011.2373.
- (3) 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.](#))
- (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.](#))

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**Changes and effects yet to be applied to :**

- Art. 4 heading substituted by [S.I. 2019/705 reg. 238](#)
- Art. 4 word omitted by [S.I. 2019/705 reg. 239](#)