

COMMISSION IMPLEMENTING DECISION (EU) 2017/1211**of 4 July 2017**

authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (DAS-24236-5 × DAS-21023-5 × MON-88913-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2017) 4495)

(Only the English text is 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 12 March 2009, Dow AgroSciences Europe submitted to the competent authority of The Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from 281-24-236 × 3006-210-23 × MON 88913 cotton.
- (2) The application also covers the placing on the market of 281-24-236 × 3006-210-23 × MON 88913 cotton in products consisting of it or containing it for any other uses than food and feed as any other cotton, with the exception of cultivation.
- (3) In accordance with Article 5(5) and Article 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 Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (4) On 8 April 2016, the European Food Safety Authority ('EFSA') issued a favourable opinion ⁽³⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 is as safe and as nutritious as its conventional counterpart in the context of its intended uses.
- (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) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.
- (7) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913.
- (8) A unique identifier should be assigned to genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.

⁽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), 2016. Scientific Opinion on application EFSA-GMO-NL-2012-68 for the placing on the market of genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2016; 14(4):4430, 21 pp. doi:10.2903/j.efsa.2016.4430.

⁽⁴⁾ 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).

- (9) On the basis of the 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 foods, food ingredients and feed containing, consisting of, or produced from cotton 281-24-236 × 3006-210-23 × MON 88913. However, in order to ensure the use of the products containing or consisting of cotton 281-24-236 × 3006-210-23 × MON 88913 within the limits of the authorisation provided for by this Decision, the labelling of those products, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.
- (10) 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 ⁽¹⁾.
- (11) The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or of 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 Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (12) 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.
- (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.) 281-24-236 × 3006-210-23 × MON 88913, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-24236-5×DAS-21Ø23-5×MON-88913-8, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 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 DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (b) feed containing, consisting of, or produced from DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (c) DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽²⁾, the 'name of the organism' shall be 'cotton'.

⁽¹⁾ 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).

⁽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).

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton with the exception of the 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 the format set out in 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 referred to in Article 28 of Regulation (EC) No 1829/2003.

Article 6

Authorisation holder

The authorisation holder shall be Dow AgroSciences Europe, United Kingdom, representing Mycogen Seeds, United States.

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 Dow AgroSciences Europe, European Development Centre 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 4 July 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Dow AgroSciences Europe, representing Mycogen Seeds, United States.

Address: Dow AgroSciences Europe, European Development Centre 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of, or produced from DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (2) feed containing, consisting of, or produced from DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (3) DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton in products containing it or consisting of it for any other than (1) and (2), with the exception of cultivation.

The genetically modified DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton, as described in the application, expresses the phosphinothricin acetyl transferase (PAT) protein which confers tolerance to glufosinate-ammonium herbicides and the modified CP4 5-enolpyruvyl-shikimate-3-phosphate synthase (CP4EPSPS) protein which confers tolerance to glyphosate herbicides, Cry1F and Cry1Ac proteins, conferring protection against certain lepidopteran insect pests.

(c) Labelling:

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 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 documents accompanying products containing or consisting of DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton with the exception of products referred to in point (a) of Article 2.

(d) Method for detection:

- (1) Event specific real-time quantitative PCR based methods for DAS-24236-5, DAS-21Ø23-5 and MON-88913-8 cottons; the detection methods have been validated on genomic DNA extracted from seeds DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton and on genomic DNA extracted from seeds of the single-trait events and verified on genomic DNA extracted from seeds of DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (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®-BF422 for 281-24-236 × 3006-210-23 cotton is accessible via accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://crm.jrc.ec.europa.eu/> and
 - AOCS 0906-D and AOCS 0804-A for MON 88913 cotton is accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

(e) Unique identifier:

DAS-24236-5×DAS-21Ø23-5×MON-88913-8

(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.
