

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2017/2448

of 21 December 2017

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2 (DP-305423-1 × MON-04032-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

(notified under document C(2017) 9040)

(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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 20 September 2007, Pioneer Overseas Corporation submitted an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from 305423 × 40-3-2 soybean ('the application') to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of genetically modified soybean 305423 × 40-3-2 in products consisting of it or containing it for other uses than food and feed as any other soybean, with the exception of cultivation.
- (2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the data and information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to that Directive.
- (3) On 18 August 2016, the European Food Safety Authority ('EFSA') gave a favourable opinion ⁽³⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. EFSA concluded that genetically modified soybean 305423 × 40-3-2, as described in the application, is as safe as the non-genetically modified comparator and other non-genetically modified conventional soybean varieties as regards the potential effects on human and animal health and the environment in the context of the scope of the application.
- (4) 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.
- (5) In its opinion, 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.
- (6) In addition, EFSA recommended that a post-market monitoring plan should be implemented, focusing on the collection of consumption data for the population of the Union.

⁽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 an application by Pioneer (EFSA-GMO-NL-2007-47) for the placing on the market of the herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 × 40-3-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2016; 14(8):4566, 31 pp. doi:10.2903/j.efs.2016.4566.

- (7) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2.
- (8) A unique identifier should be assigned to each genetically modified organism ('GMO'), in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (9) Food, food ingredients and feed containing, consisting of, or produced from 305423 × 40-3-2 soybean should be labelled in accordance with the requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003.
- (10) On the basis of the EFSA opinion confirming that fatty acid composition of the seeds of 305423 × 40-3-2 soybean and derived oil has been changed in relation to the conventional counterpart, specific labelling should be included in accordance with Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003.
- (11) On the basis of the EFSA opinion, no specific labelling requirements, other than those laid down in Article 13(1) and in 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⁾, appear necessary for the products covered by this Decision. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO for which authorisation is requested, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.
- (12) 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 the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽³⁾.
- (13) The EFSA opinion does not justify either the imposition of specific conditions for the protection of particular ecosystems/environments or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (14) The authorisation holder should also submit annual reports on the implementation and the results of the activities set out in the post-market monitoring plan.
- (15) 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.
- (16) 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 ⁽⁴⁾.
- (17) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it 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 soybean (*Glycine max* (L.) Merr.) 305423 × 40-3-2, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DP-3Ø5423-1 × MON-Ø4Ø32-6, as provided for in Regulation (EC) No 65/2004.

⁽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).

*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 DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (b) feed containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (c) DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean 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 Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and Article 4(6) of Regulation (EC) No 1830/2003 the 'name of the organism' shall be 'soybean'.
2. For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.
3. The words 'not for cultivation' shall appear on the label of the product and in the documents accompanying products containing or consisting of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean, with the exception of products referred to in point (a) of Article 2.

*Article 4***Monitoring plan 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 annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

*Article 5***Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003**

1. The authorisation holder shall ensure that the post-market monitoring plan of the DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean oil, as set out in point (g) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the post-market monitoring plan to the Commission for the duration of the authorisation.

*Article 6***Community register**

The information set out in the Annex 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 7***Authorisation holder**

The authorisation holder shall be Pioneer Overseas Corporation, representing Pioneer Hi-Bred International, Inc., United States.

*Article 8***Validity**

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

*Article 9***Addressee**

This Decision is addressed to Pioneer Overseas Corporation, Avenue des Arts 44, B-1040 Brussels – Belgium.

Done at Brussels, 21 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, 1040 Brussels - Belgium

On behalf of Pioneer Hi-Bred International, Inc. – 7100 NW 62nd Avenue – P.O. Box 1014 – Johnston, IA 50131-1014 - United States of America.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (2) feed containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (3) DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean 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 DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean, as described in the application, has a reduced expression of the soybean enzyme omega-6 desaturase, which results in a high oleic acid and reduced linoleic acid profile, expresses an optimised *Glycine max-hra* gene, which confers tolerance to acetolactate synthase-inhibiting herbicides and expresses the CP4 EPSPS protein which confers tolerance to glyphosate herbicides.

(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 'soybean';
- (2) For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products;
- (3) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean 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 DP-3Ø5423-1 and MON-Ø4Ø32-6 soybeans; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (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-BF426 (for DP-3Ø5423-1) and ERM-BF410 (for MON-Ø4Ø32-6) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue>

(e) Unique identifier:

DP-3Ø5423-1 × MON-Ø4Ø32-6

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

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

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

Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003

(1) The authorisation holder shall collect the following information:

- (i) Quantities of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean oil and DP-3Ø5423-1 × MON-Ø4Ø32-6 soybeans for oil extraction, imported into the European Union for the placing on the market as or in products for food.
- (ii) In case of import of products mentioned under (i), results of database searches in the FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed.

(2) The authorisation holder shall, based on the information collected and reported, review the nutritional assessment conducted as part of the risk assessment.

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

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

[Link: *plan published in the Community register of genetically modified food and feed*]

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.
