

COMMISSION IMPLEMENTING DECISION (EU) 2017/2451**of 21 December 2017****authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127, 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) 9043)***(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) Regulation (EC) No 1829/2003 lays down authorisation procedures for genetically modified food and feed. On 10 December 2013, Bayer CropScience LP and M.S. Technologies, LLC submitted to the national competent authority of the Netherlands, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127. The application also covered the placing on the market of genetically modified soybean FG72 × A5547-127 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 environmental 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 conforming with Annex VII to Directive 2001/18/EC.
- (3) On 6 April 2017, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. EFSA concluded that genetically modified soybean FG72 × A5547-127, as described in the application, is as safe as the non-genetically modified comparator and non-genetically modified soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses ⁽³⁾. However, the EFSA GMO Panel could not conclude on the use of forage from genetically modified soybean FG72 × A5547-127 as or in feed, as no compositional data on forage was submitted by the applicants. That use should therefore be excluded from the scope of this authorisation. Since forage is usually used where the cultivation takes place, no import is expected thereof in the Union and the exclusion of forage from the scope of the authorisation does not need to be accompanied by further measures.
- (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 addition, EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicants, is in line with the intended uses of the products.

⁽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), 2017. Scientific opinion on application EFSA-GMO-NL-2013-120 for authorisation of genetically modified soybean FG72 × A5547-127 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Bayer CropScience LP and M.S. Technologies LLC. *EFSA Journal* 2017;15(4):4744, 23 pp. doi:10.2903/j.efsa.2017.4744

- (6) Taking into account those considerations, the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127 for the uses listed in the application, with the exception of the use of forage as or in feed, should be authorised.
- (7) A unique identifier should be assigned to genetically modified soybean FG72 × A5547-127 in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (8) On the basis of the EFSA opinion, no specific labelling requirements, other than those 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⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified soybean FG72 × A5547-127, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation.
- (9) 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⁾.
- (10) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environments and geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.
- (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 ⁽⁴⁾.
- (13) 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.) FG72 × A5547-127 (hereinafter 'soybean FG72 × A5547-127'), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MST-FGØ72-2 × ACS-GMØØ6-4, 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 soybean FG72 × A5547-127;

⁽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).

- (b) feed containing, consisting of, or produced from soybean FG72 × A5547-127 with the exception of forage;
- (c) soybean FG72 × A5547-127, 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. The words 'not for cultivation' shall appear on the label of the product and in the documents accompanying products containing or consisting of soybean FG72 × A5547-127, with the exception of foods and food ingredients.

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

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of soybean FG72 × A5547-127.

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 Bayer CropScience N.V., Belgium, representing Bayer CropScience LP, United States, and M.S. Technologies, LLC, 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 Bayer CropScience N.V., J.E. Mommaertslaan 14, 1831 Diegem, Belgium.

Done at Brussels, 21 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Bayer CropScience N.V.

Address: J.E. Mommaertslaan 14, 1831 Diegem, Belgium

On behalf of

Bayer CropScience LP, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, RTP - North Carolina 27709, USA

and

M.S. Technologies, LLC, 103 Avenue D, West Point, Iowa 52656, USA

(b) Designation and specification of the products:

(1) foods and food ingredients containing, consisting of, or produced from soybean FG72 × A5547-127;

(2) feed containing, consisting of, or produced from soybean FG72 × A5547-127, with the exception of forage;

(3) soybean FG72 × A5547-127 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.

Soybean FG72 × A5547-127, as described in the application, expresses the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides, the 2mEPSPS protein, which confers tolerance to glyphosate-based herbicides and the HPPD W336 protein, which confers tolerance to isoxaflutole.

(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) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting the soybeans specified in (e) with the exception of foods and food ingredients.

(d) Method for detection:

(1) A PCR detection method for soybean FG72 × A5547-127 has been developed. The detection method for soybean FG72 × A5547-127 is based on the validated detection methods that are available for genetically modified soybeans FG72 and A5547-127 (<http://gmo-crl.jrc.ec.europa.eu/gmomethods/>).

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/>.

(3) Reference Material: Certified reference material for genetically modified soybean FG72 and genetically modified soybean A5547-127 is available at the American Oil Chemists' Society (AOCS): <http://aocs.igx.rdn.net/crm#soybean>, with the respective product code 0610-A3 and 0707-C5.

(e) Unique identifier:

MST-FGØ72-2 × ACS-GMØØ6-4.

(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:

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 in the Community register of genetically modified food and feed*]

(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.
