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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)

(OJ L 346, 28.12.2017, p. 20)

Amended by:

<u>B</u>

Official Journal

No page date

►<u>M1</u> Commission Implementing Decision (EU) 2019/1195 of 10 July 2019 L 187 43 12.7.2019

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Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) FG72 \times A5547-127 (hereinafter 'soybean FG72 \times A5547-127'), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MST-FGØ72-2 \times 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;
- (b) feed containing, consisting of, or produced from soybean FG72 \times A5547-127 with the exception of forage;
- (c) soybean FG72 \times 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'.

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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 \times 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 $FG72 \times A5547-127$.

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.

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Article 7

Authorisation holders

The authorisation holders shall be

(a) BASF Agricultural Solutions Seed US LLC, United States, represented by BASF SE, Germany;

and

(b) BASF SE, Germany, representing M.S. Technologies, LLC, United States.

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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 $\blacktriangleright \underline{M1}$ BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany \blacktriangleleft .

ANNEX

▼ M1

(a) Applicants and authorisation holders:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States

of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen,

Germany;

and

Name: BASF SE Germany

Address: Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany

On behalf of M.S. Technologies LLC, 103, Avenue D, West Point, Iowa 52656, United States of America.

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(b) Designation and specification of the products:

- foods and food ingredients containing, consisting of, or produced from soybean FG72 × A5547-127;
- (2) feed containing, consisting of, or produced from soybean FG72 \times 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 \times 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.rd.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.