

authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3 (MON-88302-9 × ACSBNØØ5-8 × ACS-BNØØ3-6), MON 88302 × Ms8 (MON-88302-9 × ACSBNØØ5-8) and MON 88302 × Rf3 (MON-88302-9 × ACS-BNØØ3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

(Only the Dutch and French texts are authentic)

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COMMISSION IMPLEMENTING DECISION (EU) 2017/2453

of 21 December 2017

authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3 (MON-88302-9 × ACSBN005-8 × ACS-BN003-6), MON 88302 × Ms8 (MON-88302-9 × ACSBN005-8) and MON 88302 × Rf3 (MON-88302-9 × ACS-BN003-6) 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) 9045)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

Article 1

Genetically modified organism and unique identifier

1. The following unique identifiers for genetically modified organisms (GMOs) are assigned in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier MON-88302-9 × ACS-BN005-8 × ACS-BN003-6 for genetically modified oilseed rape (*Brassica napus* L.) MON 88302 × Ms8 × Rf3;
- (b) the unique identifier MON-88302-9 × ACS-BN005-8, for genetically modified oilseed rape (*Brassica napus* L.) MON 88302 × Ms8;
- (c) the unique identifier MON-88302-9 × ACS-BN003-6 for genetically modified oilseed rape (*Brassica napus* L.) MON 88302 × Rf3.

2. The genetically modified oilseed rapes referred to in paragraph 1 are specified in point (b) of the Annex.

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 the GMOs referred to in Article 1(1);

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- (b) feed containing, consisting of, or produced from the GMOs referred to in Article 1(1);
- (c) GMOs referred to in Article 1(1) in products containing them or consisting of them 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 in Article 4(6) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘oilseed rape’.

2. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying products containing or consisting of the GMOs referred to in Article 1(1), with the exception of foods and food ingredients.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of genetically modified oilseed rapes MON 88302 × Ms8 × Rf3, MON 88302 × Ms8 and MON 88302 × Rf3.

*Article 5***Monitoring for environmental effects**

1. The authorisation holders 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 holders shall submit joint 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 6***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.

▼B*Article 7***Authorisation holders**

1. The authorisation holders shall be:
 - (a) ►**M1** Bayer Agriculture BVBA, Belgium ◀, representing Monsanto Company, United States;
 - and
 - (b) ►**M1** BASF Agricultural Solutions Seed US LLC, represented by BASF SE, Germany. ◀
2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

*Article 8***Validity**

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

▼M1*Article 9***Addressees**

This Decision is addressed to:

- (a) Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium;
- and
- (b) BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.

▼B*ANNEX***▼M1****(a) Authorisation holders:**

(1) Name: Bayer Agriculture BVBA, Belgium

Address: Scheldelaan 460, 2040 Antwerp, Belgium.

On behalf of

Monsanto Company, 800 N. Lindbergh Boulevard, St Louis, Missouri, 63167, United States;

and

(2) 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.

▼B**(b) Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified oilseed rapes (*Brassica napus* L.) as specified in (e);
- (2) feed containing, consisting of, or produced from genetically modified oilseed rapes (*Brassica napus* L.) as specified in (e);
- (3) genetically modified oilseed rapes (*Brassica napus* L.) as specified in (e) in products containing them or consisting of them for any other use than those provided in points (1) and (2), with the exception of cultivation.

MON-88302-9 oilseed rape expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides;

ACS-BN005-8 oilseed rape expresses the barnase protein and the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides;

ACS-BN003-6 oilseed rape expresses the barstar protein and PAT protein, which confers tolerance to glufosinate ammonium-based herbicides.

The expression of barnase and barstar proteins from *Bacillus amyloliquefaciens* constitutes the basis of a male fertility control system, through the use of the barnase gene, which removes male fertility in order to promote hybridisation, and the barstar gene which restores male fertility with oilseed rape lines ACS-BN005-8 and ACS-BN003-6 for obtaining heterosis (hybrid vigour).

(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 'oilseed rape';

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- (2) The words ‘not for cultivation’ shall appear on the label of and in the accompanying documents of the products containing or consisting the oilseed rapes specified in (e), with the exception of foods and food ingredients.

(d) Method for detection:

- (1) Event specific real-time quantitative PCR based methods for MON-88302-9, ACSBN005-8 and ACS-BN003-6 oilseed rapes; the detection methods are validated on the single events and verified on genomic DNA extracted from seeds of MON-88302-9 × ACSBN005-8 × ACS-BN003-6 oilseed rape;
- (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: AOCS 1011-A (for MON-88302-9), AOCS 0306-F6 (for ACSBN005-8) and AOCS 0306-G5 (for ACS-BN003-6) accessible via the American Oil Chemists Society at <http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248>.

(e) Unique identifiers:

MON-88302-9 × ACSBN005-8 × ACS-BN003-6;

MON-88302-9 × ACSBN005-8;

MON-88302-9 × ACS-BN003-6.

(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 of 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.