

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)

COMMISSION IMPLEMENTING DECISION (EU) 2017/2453

of 21 December 2017

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(notified under document C(2017) 9045)

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

Whereas:

- (1) On 3 December 2013, Monsanto Europe S.A. and Bayer CropScience N.V. submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified oilseed rape MON 88302 × Ms8 × Rf3 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 oilseed rape MON 88302 × Ms8 × Rf3 in products consisting of it or containing it for other uses than food and feed as any other oilseed rape, with the exception of cultivation. The application covered, for those uses, all sub-combinations of the single genetic modification events constituting oilseed rape MON 88302 × Ms8 × Rf3.

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- (2) In accordance with Articles 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 10 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⁽³⁾. EFSA concluded that genetically modified oilseed rape MON 88302 × Ms8 × Rf3, as described in the application, is as safe and nutritious as its conventional counterpart and non-genetically modified reference varieties as respect to potential effects on human and animal health and the environment, and no safety concerns were identified for the sub-combinations covered by the scope of the application.
- (4) On 23 May 2017, Monsanto Europe S.A. and Bayer CropScience N.V. updated the scope of the application by excluding the sub-combination Ms8 × Rf3, which is already authorised by Commission Decision 2007/232/EC⁽⁴⁾ and Commission Implementing Decision 2013/327/EU⁽⁵⁾.
- (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 Articles 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) 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.
- (7) Taking into account those considerations, the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3, MON 88302 × Ms8 and MON 88302 × Rf3, for the uses listed in the application should be authorised.
- (8) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') in accordance with Commission Regulation (EC) No 65/2004⁽⁶⁾.
- (9) On the basis of the EFSA opinion, no specific labelling requirements, other than those laid down in Articles 13(1) and 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⁽⁷⁾, 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 oilseed rapes MON 88302 × Ms8 × Rf3, MON 88302 × Ms8 and MON 88302 × Rf3, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (10) The authorisation holders should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects.

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Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC⁽⁸⁾.

- (11) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) 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 as provided for in Regulation (EC) No 1829/2003.
- (13) 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 Articles 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council⁽⁹⁾.
- (14) 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

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);
- (b) feed containing, consisting of, or produced from the GMOs referred to in Article 1(1);

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- (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.

Article 7

Authorisation holders

- 1 The authorisation holders shall be:
- a ^[F1]Bayer Agriculture BVBA, Belgium], representing Monsanto Company, United States;

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and

b ^{F1} [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.

Textual Amendments

F1 Substituted by [Commission Implementing Decision \(EU\) 2019/1167 of 28 June 2019 amending Implementing Decision \(EU\) 2017/2453 as regards the authorisation holders and the representatives \(notified under document C\(2019\) 4610\) \(Only the Dutch and German texts are authentic\) \(Text with EEA relevance\)](#).

Article 8

Validity

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

^{F1}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.]

Textual Amendments

F1 Substituted by [Commission Implementing Decision \(EU\) 2019/1167 of 28 June 2019 amending Implementing Decision \(EU\) 2017/2453 as regards the authorisation holders and the representatives \(notified under document C\(2019\) 4610\) \(Only the Dutch and German texts are authentic\) \(Text with EEA relevance\)](#).

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ANNEX

[^{F1}(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) **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';
- (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:**

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- (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.

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- (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-2013-119 for authorisation of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MON 88302 × MS8 × RF3 and subcombinations independently of their origin, for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto Company and Bayer CropScience. *EFSA Journal* 2017;15(4):4767, 25 pp. doi:10.2903/j.efsa.2017.4767.
- (4) Commission Decision 2007/232/EC of 26 March 2007 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8 × Rf3) genetically modified for tolerance to the herbicide glufosinate-ammonium ([OJ L 100, 17.4.2007, p. 20.](#)).
- (5) Commission Implementing Decision 2013/327/EU of 25 June 2013 authorising the placing on the market of food containing or consisting of genetically modified oilseed rape Ms8, Rf3 and Ms8 × Rf3, or food and feed produced from those genetically modified organisms pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council ([OJ L 175, 27.6.2013, p. 57.](#)).
- (6) 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.](#)).
- (7) 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.](#)).
- (8) 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.](#)).
- (9) 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.](#)).

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Changes and effects yet to be applied to :

- Annex point (f) word omitted by [S.I. 2019/705 reg. 371\(a\)](#)
- Annex point (h) word omitted by [S.I. 2019/705 reg. 371\(b\)](#)
- Annex Note word omitted by [S.I. 2019/705 reg. 371\(c\)](#)
- Art. 5(2) words substituted by [S.I. 2019/705 reg. 368](#)
- Art. 6 heading substituted by [S.I. 2019/705 reg. 369](#)
- Art. 6 word omitted by [S.I. 2019/705 reg. 370](#)