



COMMISSION IMPLEMENTING DECISION (EU) 2024/389

of 26 January 2024

renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2024) 432)

(Only the German text is 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 ⁽¹⁾, and in particular Article 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2013/327/EU ⁽²⁾ authorised the placing on the market of food containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3, or food and feed produced from genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3.
- (2) Commission Implementing Decision (EU) 2019/1301 ⁽³⁾ amended Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3. The scope of that authorisation also covered the renewal of the placing on the market of products containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 for uses other than food and feed, with the exception of cultivation, previously authorised by Commission Decision 2007/232/EC ⁽⁴⁾.
- (3) On 8 February 2021, BASF SE, based in Germany, submitted on behalf of BASF Agricultural Solutions Seed US LLC, based in the United States, an application to the Commission for the renewal of that authorisation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Implementing Decision 2013/327/EU of 25 June 2013 authorising the placing on the market of food and feed containing, consisting of or produced from genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 175, 27.6.2013, p. 57).

⁽³⁾ Commission Implementing Decision (EU) 2019/1301 of 26 July 2019 amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 204, 2.8.2019, p. 50).

⁽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 Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium (OJ L 100, 17.4.2007, p. 20).

- (4) On 26 April 2023, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ⁽⁵⁾. It concluded that the renewal application did not contain evidence for any new hazards, modified exposure or scientific uncertainties that would change the original risk assessment on genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3, adopted by the Authority in 2012 ⁽⁶⁾.
- (5) In its scientific opinion, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) The Authority also concluded that the monitoring plan for the environmental effects, consisting of general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (7) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 and of products containing or consisting of them for uses other than food and feed, with the exception of cultivation, should be renewed.
- (8) Unique identifiers have been assigned to genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3, in accordance with Commission Regulation (EC) No 65/2004 ⁽⁷⁾, in the context of the initial authorisation by Implementing Decision 2013/327/EU.
- (9) For the products covered by this Decision, no specific labelling requirements, other than those provided for 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 ⁽⁸⁾, appear to be necessary. However, in order to ensure that the use of products containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 remain within the limits of the authorisation granted by this Decision, the labelling of such products, with the exception of food and food ingredients, should contain a clear indication that they are not intended for cultivation.
- (10) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ⁽⁹⁾.
- (11) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market for use and handling, including post-market monitoring requirements regarding the consumption of food and feed containing, consisting of or produced from genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3, or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5), point (e), and Article 18(5), point (e) of Regulation (EC) No 1829/2003.

⁽⁵⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2023. Scientific Opinion on the assessment of genetically modified oilseed rape MS8, RF3 and MS8 x RF3 for renewal authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-024). *EFSA Journal* 2023;21(4):7934, 14 pp. <https://doi.org/10.2903/j.efsa.2023.7934>

⁽⁶⁾ EFSA GMO Panel, 2012. Scientific Opinion on application (EFSA-GMO-BE-2010-81) for the placing on the market of genetically modified herbicide-tolerant oilseed rape Ms8, Rf3 and Ms8 × Rf3 for food containing or consisting of, and food produced from or containing ingredients produced from, oilseed rape Ms8, Rf3 and Ms8 × Rf3 (with the exception of processed oil) under Regulation (EC) No 1829/2003 from Bayer. *EFSA Journal* 2012;10(9):2875, 32 pp. <https://doi.org/10.2903/j.efsa.2012.2875>

⁽⁷⁾ 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).

⁽⁸⁾ 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).

⁽⁹⁾ 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).

- (12) All relevant information on the authorisation of the products covered by this Decision should be entered in the Community register of genetically modified food and feed referred to in Article 28(1) of 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 Article 9(1) and Article 15(2), point (c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽¹⁰⁾.
- (14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chair. 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 organisms and unique identifiers

Genetically modified oilseed rape (*Brassica napus* L.) Ms8, Rf3 and Ms8 × Rf3, as specified in point (b) of the Annex to this Decision, are assigned the unique identifiers ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6, respectively, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The authorisation for placing on the market of the following products is renewed as regards:

- (a) foods and food ingredients containing, consisting of or produced from genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6;
- (b) feed containing, consisting of or produced from genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6;
- (c) products containing or consisting of genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6, for uses other than those provided for 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 the products containing or consisting of genetically modified oilseed rapes as referred to in Article 1, with the exception of products referred to in Article 2, point (a).

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6.

⁽¹⁰⁾ 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 5***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 to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the format set out in Decision 2009/770/EC.

*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 referred to in Article 28(1) of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, United States, represented in the Union by BASF SE, Germany.

*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 BASF Agricultural Solutions Seed US LLC, 100 Park Avenue, Florham Park, New Jersey 07932, United States, represented in the Union by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.

Done at Brussels, 26 January 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: BASF Agricultural Solutions Seed US LLC

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

Represented in the Union 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 ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6;
- (2) feed containing, consisting of or produced from genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6;
- (3) products containing or consisting of genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

Genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 express the *phosphinothricin acetyl transferase (pat)* gene, which confers tolerance to glufosinate-ammonium-based herbicides and the *barnase* gene (ACS-BNØØ5-8) for male sterility and the *barstar* gene (ACS-BNØØ3-6) restoring fertility.

(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 documents accompanying the products containing or consisting of oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6, with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

- (1) Event specific real-time quantitative PCR based method for detection of the genetically modified oilseed rapes ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6;
- (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 0306-F, AOCS 0306-G and AOCS 0306-B (for the non-genetically modified counterpart) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm?SSO=True>.

(e) **Unique identifier:**

ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6.

(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:**

Not required.

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

Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council ⁽¹⁾.

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

(i) **Post-market monitoring plan:**

Not required.

Note: *links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.*

⁽¹⁾ 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).