

COMMISSION IMPLEMENTING DECISION (EU) 2023/416**of 22 February 2023****authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape MON 94100 (MON-94100-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2023) 1135)***(Only the Dutch 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 of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 29 October 2020, Bayer Agriculture BV, based in Belgium, submitted, on behalf of Bayer CropScience LP, based in the United States, an application to the national competent authority of the Netherlands ('the application') for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified oilseed rape MON 94100, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also concerned the placing on the market of products containing or consisting of genetically modified oilseed rape MON 94100 for uses other than food and feed, 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 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⁾. It also included the information required pursuant to Annexes III and IV to that Directive and a monitoring plan for environmental effects in accordance with Annex VII to that Directive.
- (3) On 22 July 2022, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion ⁽³⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. The Authority concluded that genetically modified oilseed rape MON 94100, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified oilseed rape reference varieties with respect to the potential effects on human and animal health and the environment. The Authority also concluded that the consumption of food and feed from genetically modified oilseed rape MON 94100 does not represent any nutritional concern for humans and animals.

⁽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), 2022. Scientific Opinion on assessment of genetically modified oilseed rape MON 94100 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2020-169). EFSA Journal 2022; 20(7):7411, 29 pp. <https://doi.org/10.2903/j.efsa.2022.7411>.

- (4) 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.
- (5) The Authority also concluded that the monitoring plan for environmental effects, submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products.
- (6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified oilseed rape MON 94100 should be authorised for the uses listed in the application.
- (7) A unique identifier should be assigned to genetically modified oilseed rape MON 94100 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.
- (8) 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 ⁽⁵⁾, appear to be necessary. However, in order to ensure that the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified oilseed rape MON 94100, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.
- (9) 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 ⁽⁶⁾.
- (10) The opinion of the Authority does not justify the imposition of other specific conditions or restrictions for the placing on the market, for the use and handling 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.
- (11) 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.
- (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), point (c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁷⁾.
- (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,

⁽⁴⁾ 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).

⁽⁵⁾ 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).

⁽⁶⁾ 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).

⁽⁷⁾ 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).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified oilseed rape (*Brassica napus* L.) MON 94100, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-941ØØ-2, 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 genetically modified oilseed rape MON-941ØØ-2;
- (b) feed containing, consisting of or produced from genetically modified oilseed rape MON-941ØØ-2;
- (c) products containing or consisting of genetically modified oilseed rape MON-941ØØ-2, for uses other than those provided for in points (a) and (b) of this Article, 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 rape MON-941ØØ-2, 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 genetically modified oilseed rape MON-941ØØ-2.

Article 5

Monitoring 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 Bayer CropScience LP, represented in the Union by Bayer Agriculture BV.

*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 LP, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States, represented in the Union by Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 22 February 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Bayer CropScience LP

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States.

Represented in the Union by: Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) Designation and specification of the products:

(1) foods and food ingredients containing, consisting of or produced from genetically modified oilseed rape MON-941ØØ-2;

(2) feed containing, consisting of or produced from genetically modified oilseed rape MON-941ØØ-2;

(3) products containing or consisting of genetically modified oilseed rape MON-941ØØ-2 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified oilseed rape MON-941ØØ-2 expresses the *dmo* gene, which confers tolerance to dicamba-based herbicides.

(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 rape MON-941ØØ-2, 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 rape MON-941ØØ-2;

(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 0421-A is accessible via the American Oil Chemists Society at <https://www.aocs.org/crm?SSO=True>

(e) Unique identifier:

MON-941ØØ-2

(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

[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.