COMMISSION IMPLEMENTING DECISION (EU) 2021/1391

of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified oilseed rapes Ms8 × Rf3 × GT73, Ms8 × GT73 and Rf3 × GT73 pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council

(notified under document C(2021)5998)

(Only the Dutch and German 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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 20 October 2009, Monsanto Europe S.A/N.V., based in Belgium, submitted, on behalf of Monsanto Company, based in the United States, and Bayer CropScience AG, based in Germany, an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified oilseed rape Ms8 × Rf3 × GT73, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'). The application also concerned the placing on the market of products containing or consisting of genetically modified oilseed rape Ms8 × Rf3 × GT73 for uses other than food and feed, with the exception of cultivation. In addition, the application concerned the placing on the market of products containing, consisting of or produced from all sub-combinations of the single transformation events constituting oilseed rape Ms8 × Rf3 × GT73.

(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 9 September 2013, Monsanto Europe S.A./N.V. and Bayer CropScience AG updated the contents of the application, in order to exclude from its scope the specific use of Ms8 × Rf3 × GT73 oilseed rape for the production of isolated seed protein for food.

(4) On 12 August 2015, Monsanto Europe S.A./N.V. and Bayer CropScience AG updated further the contents of the application, in order to exclude from its scope the sub-combination Ms8 × Rf3, which was already authorised by Commission Decision 2007/232/EC ([3]) and Commission Implementing Decision 2013/327/EU ([4]).

([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]) 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).

([4]) 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).

(5) This Decision concerns the remaining two sub-combinations, Ms8 × GT73 and Rf3 × GT73, and excludes the use, for food, of isolated seed protein products produced from oilseed rape Ms8 × Rf3 × GT73 and from the sub-combinations Ms8 × GT73 and Rf3 × GT73.

(6) On 20 May 2016, the European Food Safety Authority ('the Authority') issued an opinion, in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([5]). The Authority was not able to reach a conclusion on the safety of Ms8 × Rf3 × GT73 oilseed rape products rich in protein, such as rapeseed protein isolates, in feed, because of a lack of a 28-day toxicity study with the GOXv247 protein. As the risk assessment of the three-event stack oilseed rape could not be completed for products rich in protein, the Authority was not in a position to complete the food and feed safety assessment of the sub-combinations Ms8 × GT73 and Rf3 × GT73 within the scope of the application.

(7) By a letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfer its rights and obligations pertaining to all authorisations and pending applications for genetically modified products to BASF Agricultural Solutions Seed US LLC. By a letter dated 19 October 2018, BASF Agricultural Solutions Seed US LLC confirmed its agreement with this transfer and authorised BASF SE, based in Germany, to act as its representative in the Union.

(8) By a letter dated 27 August 2018, Monsanto Europe S.A./N.V. informed the Commission that, as of 23 August, it converted its legal form and changed its name to Bayer Agriculture BVBA.

(9) On 23 October 2018, the co-applicants provided a new 28-day toxicity study on the GOXv247 protein.

(10) By a letter dated 28 July 2020, Bayer Agriculture BVBA informed the Commission that, as of 1 August 2020, it changed its name to Bayer Agriculture BV.

(11) By a letter dated 28 July 2020, Bayer Agriculture BVBA representing Monsanto Company, informed the Commission that, as of 1 August 2020, Monsanto Company converted its legal form and changed its name to Bayer CropScience LP.

(12) On 30 July 2020, the Authority published a statement complementing its scientific opinion ([6]), taking into consideration the supplementary toxicity study. The Authority concluded that oilseed rape Ms8 × Rf3 × GT73 and its sub-combinations Ms8 × GT73 and Rf3 × GT73, as defined in the application and as assessed in the initial opinion and in the supplementary toxicity study, are as safe as its conventional counterpart for the requested uses.

(13) In its opinion of 20 May 2016, 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 Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(14) 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.

(15) Taking into account these conclusions, the placing on the market of products containing, consisting of or produced from genetically modified oilseed rapes Ms8 × Rf3 × GT73, Ms8 × GT73 and Rf3 × GT73 should be authorised for the uses listed in the application.

([5]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific Opinion on an application by Bayer CropScience and Monsanto (EFSA-GMO-NL-2009-75) for placing on the market of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MS8 × RF3 × GT73 and subcombinations, which have not been authorised previously (i.e. MS8 × GT73 and RF3 × GT73) independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food, under Regulation (EC) No 1829/2003; EFSA Journal 2016;14(5):4466; https://doi.org/10.2903/j.efsa.2016.4466.

([6]) EFSA GMO Panel, 2020. Scientific Opinion on the statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-NL-2009-75) for placing on the market of genetically modified oilseed rape Ms8 × Rf3 × GT73 and subcombinations, which have not been authorised previously (i.e. Ms8 × GT73 and Rf3 × GT73) independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food, under Regulation (EC) No 1829/2003), taking into consideration additional information; EFSA Journal 2020;18(7):6200; https://doi.org/10.2903/j.efsa.2020.6200.

(16) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004 ([7]).

(17) 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 those products remains within the limits of the authorisation granted by this Decision, the labelling of the products covered by it, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

(18) The authorisation holders should submit annual reports on the implementation and on the results of the activities set out in the monitoring plan for environment effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC ([9]).

(19) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market, for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, containing, consisting of or produced from genetically modified oilseed rapes Ms8 × Rf3 × GT73, Ms8 × GT73 and Rf3 × GT73, with the exception of isolated seed protein for food, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(20) 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.

(21) 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)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([10]).

(22) 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 rapes (*Brassica napus* L.), as specified in point (b) of the Annex to this Decision, are assigned the following unique identifiers, in accordance with Regulation (EC) No 65/2004:

(a) the unique identifier ACS-BNØØ5-8 × ACS-BNØØ3-6 × MON-ØØØ73-7 for genetically modified oilseed rape Ms8 × Rf3 × GT73;

([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).

([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).

(b) the unique identifier ACS-BNØØ5-8 × MON-ØØØ73-7 for genetically modified oilseed rape Ms8 × GT73;

(c) the unique identifier ACS-BNØØ3-6 × MON-ØØØ73-7 for genetically modified oilseed rape Rf3 × GT73.

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 rapes as referred to in Article 1, with the exception of isolated seed protein;

(b) feed containing, consisting of or produced from genetically modified oilseed rapes as referred to in Article 1;

(c) products containing or consisting of genetically modified oilseed rapes as referred to in Article 1 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 products containing or consisting of genetically modified oilseed rapes as referred to in Article 1, with the exception of products referred to in point (a) of Article 2.

Article 4

Method for detection

The methods set out in point (d) of the Annex shall apply for the detection of genetically modified oilseed rapes as referred to in Article 1.

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 to the Commission joint 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 holders

The authorisation holders shall be:

(a) Bayer CropScience LP represented in the Union by Bayer Agriculture BV

and

(b) BASF Agricultural Solutions Seed US LLC represented in the Union by BASF SE.

Article 8

Validity

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

Article 9

Addressees

This Decision is addressed to Bayer CropScience LP represented in the Union by Bayer Agriculture BV, Scheldelaan 460, BE-2040 Antwerp, Belgium and to BASF Agricultural Solutions Seed US LLC represented in the Union by BASF SE, Carl-Bosch-Str. 38, D-67063 Ludwigshafen, Germany.

Done at Brussels, 17 August 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) **Applicants and authorisation holders:**

(1) Name: Bayer CropScience LP

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

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

and

(2) 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, D-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 referred to in point (e), with the exception of isolated seed protein;

(2) feed containing, consisting of or produced from genetically modified oilseed rapes (*Brassica napus* L.) as referred to in point (e);

(3) products containing or consisting of genetically modified oilseed rapes (*Brassica napus* L.) as referred to in point (e) for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified ACS-BNØØ5-8 oilseed rape expresses the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides, and the *barnase* gene, which confers male sterility during anther development.

The genetically modified ACS-BNØØ3-6 oilseed rape expresses the *pat* gene, which confers tolerance to glufosinate-ammonium-based herbicides, and the *barstar* gene, which restores fertility after crossing with ACSBNØØ5-8.

The genetically modified oilseed rape MON-ØØØ73-7 expresses the *cp4 epsps* and *goxv247* genes, which confer tolerance to glyphosate-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 the oilseed rapes specified in point (e), with the exception of products referred to in point (b)(1).

(d) **Method for detection:**

(1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified oilseed rape events ACS-BNØØ5-8, ACS-BNØØ3-6 and MON-ØØØ73-7 and further verified on oilseed rape stack ACSBNØØ5-8 × ACS-BNØØ3-6 × MON-ØØØ73-7;

(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 (for ACSBNØØ5-8), AOCS 0306-G (for ACS-BNØØ3-6) and AOCS 0304-B (for MON-ØØØ73-7) are accessible via the American Oil Chemists Society at https://www.aocs.org/crm.

(e) **Unique identifiers:**

ACS-BNØØ5-8 × ACS-BNØØ3-6 × MON-ØØØ73-7;

ACS-BNØØ5-8 × MON-ØØØ73-7;

ACS-BNØØ3-6 × MON-ØØØ73-7.

(f) **Information required pursuant to 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 requirements for the use of the food for human consumption:**

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).