COMMISSION IMPLEMENTING DECISION (EU) 2022/531

of 31 March 2022

authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean GMB151 (BCS-GM151-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2022)1893)

(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 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 9 October 2018, BASF SE, based in Germany, submitted, on behalf of BASF Agricultural Solutions Seed US LLC, 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 soybean GMB151, 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 soybean GMB151 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 19 April 2021, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). The Authority concluded that genetically modified soybean GMB151, as described in the application, is as safe as its conventional counterpart and the tested non-genetically modified soybean reference varieties with respect to potential effects on human and animal health and the environment. The Authority updated an Annex of its scientific opinion on 4 November 2021 to include information missing from the previous version of this Annex due to a technical problem. The conclusions of the scientific opinion were not affected by this update.

(4) In its 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 consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

([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), 2021. Scientific Opinion on the assessment of genetically modified soybean GMB151, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2018-153). EFSA Journal 2021; 19(4):6424. https://doi.org/10.2903/j.efsa.2021.6424.

(6) Taking into account the Authority's conclusions, the placing on the market of products containing, consisting of or produced from genetically modified GMB151 should be authorised for the uses listed in the application.

(7) A unique identifier should be assigned to genetically modified soybean GMB151 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 covered by it, with the exception of food products, 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 environment 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 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 GMB151, or for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(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 of 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 ([7]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time 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 organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) GMB151, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GM151-6, in accordance with Regulation (EC) No 65/2004.

([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).

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 soybean as referred to in Article 1;

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

(c) products containing or consisting of genetically modified soybean 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 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified soybean 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 soybean as referred to in Article 1.

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 BASF 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

Addressee

This Decision is addressed to BASF Solutions Seed US LLC, 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.

Done at Brussels, 31 March 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: BASF 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 soybean BCS-GM151-6;

(2) feed containing, consisting of or produced from genetically modified soybean BCS-GM151-6;

(3) products containing or consisting of genetically modified soybean BCS-GM151-6 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean BCS-GM151-6 expresses the *cry14Ab-1.b* gene, which confers resistance to nematodes and the *hppdPf-4Pa* gene, which confers tolerance to 4-hydroxyphenylpyruvate dioxygenase (HPPD) inhibitor herbicides, such as isoxaflutole.

(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 'soybean';

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified soybean BCS-GM151-6, with the exception of the products referred to in point (b)(1).

(d) **Method for detection:**

(1) Event-specific method for the quantification of genetically modified soybean BCS-GM151-6 using real-time PCR

(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: ERM®-BF443 is accessible via the Joint Research Center (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/.

(e) **Unique identifier:**

BCS-GM151-6

(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.

[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.