COMMISSION IMPLEMENTING DECISION (EU) 2021/1386

of 17 August 2021

authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean DAS-81419-2 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2021) 5993)

(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 9 February 2012, Dow AgroSciences Ltd, based in United Kingdom, submitted, on behalf of Dow AgroSciences LLC, based in the United States of America, 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 soybean DAS-81419-2, in accordance with Article 5 and Article 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 soybean DAS-81419-2 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 5 December 2016, the European Food Safety Authority ('the Authority') issued a favourable scientific opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 ([3]). The Authority concluded that genetically modified soybean DAS-81419-2, as described in the application, is as safe as and as nutritious as its conventional counterpart and the tested non-genetically modified soybean reference varieties with respect to the potential effects on human and animal health and the environment.

(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 the environmental effects, submitted by the applicant, consisting of a general surveillance plan, 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), 2016. Scientific Opinion on an application by Dow AgroSciences (EFSA-GMO-NL-2013-116) for placing on the market of genetically modified insect-resistant soybean DAS-81419-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2016;14(12):4642[, 23 pp.; https://doi.org/10.2903/j.efsa.2016.4642

(6) By a letter dated 10 July 2017, Dow AgroSciences Ltd, requested the Commission not to proceed with the authorisation of genetically modified soybean DAS-81419-2 until the scientific opinion of the Authority on genetically modified soybean DAS-81419-2 x DAS-44406-6 is published.

(7) By a letter dated 13 September 2018, Dow AgroSciences Ltd informed the Commission that the new representative in the Union of Dow AgroSciences LLC, United States, is Dow AgroSciences Distribution SAS, based in France. By letters, respectively dated 7 September 2018 and 12 October 2018, Dow AgroSciences Distribution SAS and Dow AgroSciences LLC confirmed their agreement with the requested change.

(8) By a letter dated 25 January 2021, following the publication on 20 November 2020 of the Authority's positive scientific opinion on genetically modified soybean DAS-81419-2 x DAS-44406-6 ([4]), Dow AgroSciences Distribution SAS requested the Commission to proceed with the authorisation of genetically modified soybean DAS-81419-2.

(9) Taking into account the conclusions expressed in the Authority's opinion, the placing on the market of products containing, consisting of or produced from genetically modified soybean DAS-81419-2 should be authorised for the uses listed in the application.

(10) By a letter of 22 March 2021, Corteva Agriscience Belgium BV informed the Commission that Dow AgroSciences LLC changed the name to Corteva Agriscience LLC, based in the United States, as of 1 January 2021.

(11) By a letter of 22 March 2021, Corteva Agriscience LLC informed the Commission that its representative in the Union is Corteva Agriscience Belgium B.V., based in Belgium, as of 22 March 2021.

(12) A unique identifier should be assigned to genetically modified soybean DAS-81419-2 in accordance with Commission Regulation (EC) No 65/2004 ([5]).

(13) 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 ([6]), 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 soybean DAS-81419-2, with the exception of foods and food ingredients, should contain a clear indication that they are not intended for cultivation.

(14) 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 ([7]).

(15) 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 soybean DAS-81419-2, 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.

([4]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2020. Scientific Opinion on application EFSA-GMO-NL-2016-132 for authorisation of genetically modified of insect-resistant and herbicide-tolerant soybean DAS–81419–2 × DAS–44406–6 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Dow Agrosciences LCC. *EFSA Journal* 2020;18(11):6302, 37 pp.; https://doi.org/10.2903/j.efsa.2020.6302

([5]) 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).

([6]) 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).

([7]) 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).

(16) 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.

(17) 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 ([8]).

(18) 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

Genetically modified soybean (*Glycine max* (L.) Merr.) DAS-81419-2, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-81419-2, 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 soybean DAS-81419-2;

(b) feed containing, consisting of or produced from genetically modified soybean DAS-81419-2;

(c) products containing or consisting of genetically modified soybean DAS-81419-2 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 the products containing or consisting of genetically modified soybean DAS-81419-2 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 soybean DAS-81419-2.

([8]) 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 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 Corteva Agriscience LLC represented in the Union by Corteva Agriscience Belgium B.V.

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 Corteva Agriscience LLC, 9330 Zionsville Road Indianapolis, Indiana 46268-1054, United States of America, represented by Corteva Agriscience Belgium B.V., Bedrijvenlaan 9, 2800 Mechelen, Belgium.

Done at Brussels, 17 August 2021.

For the Commission,
Stella KYRIAKIDES
Member of the Commission

ANNEX

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

Name: Corteva Agriscience LLC

Address: 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States

Represented in the Union by: Corteva Agriscience Belgium B.V., Bedrijvenlaan 9, 2800 Mechelen, Belgium.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of or produced from genetically modified soybean DAS-81419-2;

(2) feed containing, consisting of or produced from genetically modified soybean DAS-81419-2;

(3) products containing or consisting of genetically modified soybean DAS-81419-2 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean DAS-81419-2 expresses the synthetic *cry1Fv3* gene and the synthetic *cry1Ac* gene, which confer protection against certain lepidopteran pests. In addition, the *pat* gene, conferring tolerance to glufosinate-ammonium-based herbicide, was used as a selection marker in the genetic modification process.

(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 soybean DAS-81419-2, 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 soybean DAS-81419-2;

(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: ERM®-BF437 is accessible via the Joint Research Centre (JRC) of the European Commission at https://ec.europa.eu/jrc/en/reference-materials/catalogue.

(e) **Unique identifier:**

DAS-81419-2

(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 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).