

COMMISSION IMPLEMENTING DECISION (EU) 2021/64**of 22 January 2021****authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean SYHT0H2 (SYN-ØØØH2-5), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2021) 266)***(Only the Dutch and French 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 to Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 8 August 2012, Syngenta Crop Protection AG submitted, through its affiliated company Syngenta Crop Protection NV/SA, an application to the national competent authority of Germany ('the application'), in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application covered the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified soybean (*Glycine max* (L.) Merr.) SYHT0H2. The application also covered the placing on the market of products containing or consisting of genetically modified soybean SYHT0H2 for uses other than food and feed, with the exception of cultivation.
- (2) In accordance with Articles 5(5) and 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 20 January 2020, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. It concluded that genetically modified soybean SYHT0H2, as described in the application, is as safe as and nutritionally equivalent to 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.
- (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 Articles 6(4) and 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.
- (6) Taking into account those conclusions, the placing on the market of products containing, consisting of or produced from genetically modified soybean SYHT0H2 should be authorised for the uses listed in the application.

⁽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), 2020. Scientific Opinion on the assessment of genetically modified soybean SYHT0H2 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2012-111). *EFSA Journal* 2020;18(1):5946.

- (7) A unique identifier should be assigned to genetically modified soybean SYHT0H2 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 Articles 13(1) and 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 soybean SYHT0H2, 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 food and feed containing, consisting of or produced from genetically modified soybean SYHT0H2, or for the protection of particular ecosystems/environment or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.
- (11) All relevant information on the authorisation of the products 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 Articles 9(1) and 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 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.) SYHT0H2, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-ØØØH2-5, 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 Articles 4(2) and 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 SYN-ØØØH2-5;
- (b) feed containing, consisting of or produced from genetically modified soybean SYN-ØØØH2-5;
- (c) products containing or consisting of genetically modified soybean SYN-ØØØH2-5 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 Articles 13(1) and 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 SYN-ØØØH2-5, with the exception of products referred to in point (a) of Article 2.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of genetically modified soybean SYN-ØØØH2-5.

*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 Syngenta Crop Protection AG, Switzerland, represented in the Union by Syngenta Crop Protection NV/SA, Belgium.

*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 Syngenta Crop Protection NV/SA, Avenue Louise, 489, 1050 Brussels, Belgium.

Done at Brussels, 22 January 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

(a) Applicant and authorisation holder

Name: Syngenta Crop Protection AG

Address: Rosentalstrasse 67, CH-4058 Basel, Switzerland

Represented in the Union by: Syngenta Crop Protection NV/SA, Avenue Louise, 489, 1050 Brussels, Belgium.

(b) Designation and specification of the products

- (1) foods and food ingredients containing, consisting of or produced from genetically modified soybean SYN-ØØØH2-5;
- (2) feed containing, consisting of or produced from genetically modified soybean SYN-ØØØH2-5;
- (3) products containing or consisting of genetically modified soybean SYN-ØØØH2-5 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean SYN-ØØØH2-5 expresses the *avhppd-03* gene, which confers tolerance to p-hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting herbicides, and the *pat* gene, which confers tolerance to glufosinate-ammonium based herbicides.

(c) Labelling

- (1) For the purposes of the labelling requirements laid down in Articles 13(1) and 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 SYN-ØØØH2-5, 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 SYN-ØØØH2-5.
- (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 0112-A is accessible via the American Oil Chemists Society (AOCS) at <https://www.aocs.org/crm>

(e) Unique identifier

SYN-ØØØH2-5

(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.

[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.
