

**COMMISSION IMPLEMENTING DECISION (EU) 2018/1112****of 3 August 2018****renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2018) 5020)***(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 <sup>(1)</sup>, and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

- (1) Commission Decision 2008/280/EC <sup>(2)</sup> authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified maize GA21 (hereinafter 'maize GA21'). The scope of that authorisation also covered products other than food and feed containing or consisting of maize GA21, for the same uses as any other maize with the exception of cultivation.
- (2) On 6 October 2016, Syngenta France SAS submitted to the Commission, on behalf of Syngenta Crop Protection AG, Switzerland, an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (3) On 24 October 2017, the European Food Safety Authority ('EFSA') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. Based on the data provided, it concluded <sup>(3)</sup> that there was no evidence in the renewal application for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment <sup>(4)</sup> on maize GA21.
- (4) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (5) EFSA also concluded that the environmental monitoring plan submitted by the applicant, consisting of a general surveillance plan, was in line with the intended uses of the products.
- (6) By a letter dated 27 February 2018, Syngenta France SAS asked the transfer of its rights and obligations as authorisation holder of Decision 2008/280/EC to Syngenta Crop Protection NV/SA, Belgium. By a letter dated 27 February 2018, Syngenta Crop Protection NV/SA, Belgium, confirmed its agreement to this transfer and indicated that it acts as representative in the Union of Syngenta Crop Protection AG, Switzerland.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Commission Decision 2008/280/EC of 28 March 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 87, 29.3.2008, p. 19).

<sup>(3)</sup> Scientific opinion on the assessment of genetically modified maize GA21 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-005). *EFSA Journal* 2017;15(10):5006.

<sup>(4)</sup> Opinion of the Scientific Panel on Genetically Modified Organisms on applications (references EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21) for the placing on the market of glyphosate-tolerant genetically modified maize GA21, for food and feed uses, import and processing and for renewal of the authorisation of maize GA21 as existing product, both under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG. *EFSA Journal* (2007) 541, 1-25.

- (7) Taking into account those considerations, the authorisation for the placing on the market of food and feed containing, consisting of, or produced from maize GA21 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.
- (8) A unique identifier has been assigned to maize GA21 by Decision 2008/280/EC, in accordance with Commission Regulation (EC) No 65/2004 <sup>(1)</sup>. That unique identifier should continue to be used.
- (9) On the basis of the EFSA opinion, 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 <sup>(2)</sup>, appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of products containing or consisting of maize GA21 remains within the limits of the authorisation granted by this Decision, the labelling of those products, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation.
- (10) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the environmental monitoring plan. These results should be presented in accordance with Commission Decision 2009/770/EC <sup>(3)</sup>.
- (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 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)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council <sup>(4)</sup>.
- (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 maize (*Zea mays* L.) GA21, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØØ21-9, in accordance with Regulation (EC) No 65/2004.

#### Article 2

### Renewal of the authorisation

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) food and food ingredients containing, consisting of or produced from maize GA21;

<sup>(1)</sup> 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).

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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) feed containing, consisting of or produced from maize GA21;
- (c) maize GA21 in products containing it or consisting of it for any other use 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 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of maize GA21, with the exception of food and food ingredients.

*Article 4*

**Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of maize GA21.

*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 Decision 2009/770/EC.

*Article 6*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed referred to in Article 28 of Regulation (EC) No 1829/2003.

*Article 7*

**Authorisation holder**

The authorisation holder shall be Syngenta Crop Protection AG, Switzerland, represented 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, 3 August 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX

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

Name: Syngenta Crop Protection AG

Address: Schwarzwaldallee 215, CH-4058 Basel, Switzerland

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

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

(1) food containing, consisting of, or produced from maize GA21;

(2) feed containing, consisting of, or produced from maize GA21;

(3) maize GA21 in products containing it or consisting of it for any other use than those provided for in points (1) and (2), with the exception of cultivation.

Maize GA21, as described in the application, expresses the mEPSPS protein which confers tolerance to glyphosate herbicide.

**(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 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of maize GA21, with the exception of food and food ingredients.

**(d) Method for detection:**

(1) Event-specific real-time quantitative PCR-based method for detection of the genetically modified maize MON-ØØØ21-9.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at [http://gmo-crl.jrc.ec.europa.eu/summaries/GA21Syngenta\\_validated\\_Method\\_correctedVersion1.pdf](http://gmo-crl.jrc.ec.europa.eu/summaries/GA21Syngenta_validated_Method_correctedVersion1.pdf)

(3) Reference Material: AOCS 0407-A and AOCS 0407-B are accessible via the American Oil Chemists Society (AOCS) at <https://www.aocs.org/crm>

**(e) Unique identifier:**

MON-ØØØ21-9

**(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 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 conforming with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup>.

[Link: *plan published in the register of genetically modified food and feed*]

<sup>(1)</sup> 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).

(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 the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.

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