

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2018/1109

of 1 August 2018

renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2018) 4978)

(Only the Dutch, English 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 Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2007/702/EC ⁽²⁾ authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified maize 59122 (hereinafter 'maize 59122'). The scope of that authorisation also covered products other than food and feed containing or consisting of maize 59122, for the same uses as any other maize with the exception of cultivation.
- (2) On 19 July 2016, Pioneer Overseas Corporation and Dow AgroSciences Ltd jointly submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (3) Pioneer Overseas Corporation and Dow AgroSciences Ltd had submitted another application on 12 October 2005 covering the same products as those concerned by the present Decision as well as the cultivation of maize 59122. Pioneer Overseas Corporation and Dow AgroSciences Ltd withdrew on 27 July 2017 all the other uses than cultivation from the scope of that application.
- (4) On 29 June 2017, the European Food Safety Authority ('EFSA') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded ⁽³⁾ that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment ⁽⁴⁾ on maize 59122.
- (5) 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2007/702/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 42).

⁽³⁾ Scientific opinion on an application for renewal of authorisation for continued marketing of maize 59122 and derived food and feed submitted under articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. The *EFSA Journal* (2017); 15(6):4861.

⁽⁴⁾ Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2005-12) for the placing on the market of insect-resistant genetically modified maize 59122, for food and feed uses, import and processing under Regulation (EC) No 1829/2003, from Pioneer Hi-Bred International, Inc. and Mycogen Seeds, c/o Dow Agrosciences LLC. The *EFSA Journal* 2007;470, 1-25.

- (6) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicants, is in line with the intended uses of the products.
- (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 59122 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 59122, in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾, by Decision 2007/702/EC. That unique identifier should continue to be used.
- (9) On the basis of the abovementioned 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 ⁽²⁾, 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 59122 remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of maize 59122, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation.
- (10) The authorisation holders should submit joint annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. These results should be presented in accordance with Commission Decision 2009/770/EC ⁽³⁾.
- (11) All relevant information on the authorisation of the products should be entered in the EU 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 ⁽⁴⁾.
- (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 measures provided for in this Decision are in accordance with the opinion of the appeal committee,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) line 59122, as specified in point (b) of the Annex, is assigned the unique identifier DAS-59122-7, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of 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 59122;

⁽¹⁾ 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).

⁽²⁾ 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).

⁽³⁾ 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).

⁽⁴⁾ 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 59122;
- (c) maize 59122 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 59122, 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 59122.

Article 5

Monitoring plan 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 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 holders

1. The authorisation holders shall be:
 - (a) Pioneer Overseas Corporation, Belgium, representing Pioneer Hi-Bred International, Inc., United States; and
 - (b) Dow AgroSciences Ltd, United Kingdom, representing Dow AgroSciences LLC, United States.
2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

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:

- (a) Pioneer Overseas Corporation, Avenue des Arts 44, 1040 Brussels, Belgium; and
- (b) Dow AgroSciences Europe Ltd, European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 1 August 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicants and Authorisation holders:

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, 1040 Brussels, Belgium

On behalf of Pioneer Hi-Bred International, Inc., 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, United States

and

Name: Dow AgroSciences Europe Ltd

Address: European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom

On behalf of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States

(b) Designation and specification of the products:

(1) food containing, consisting of, or produced from maize 59122;

(2) feed containing, consisting of, or produced from maize 59122;

(3) maize 59122 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 59122, as described in the application, expresses the Cry34Ab1 and Cry35Ab1 proteins, derived from *Bacillus thuringiensis*, which confer resistance to certain coleopteran pests, including Western corn rootworm, and the PAT protein, derived from *Streptomyces viridochromogenes*, which confers tolerance to glufosinate-ammonium based herbicides and was used as a selection marker.

(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 59122, 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 DAS-59122-7.

(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: ERM@-BF424 (for DAS-59122-7) 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-59122-7

(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 ⁽¹⁾.

[Link: *plan published in the 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 the time. Those modifications will be made available to the public via the updating of the 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).