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►**B** ►**C1** **COMMISSION IMPLEMENTING DECISION (EU) 2018/1109**

of 3 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)

(OJ L 203, 10.8.2018, p. 7)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2019/241 of 6 February 2019	L 39	14	11.2.2019

Corrected by:

►**C1** Corrigendum, OJ L 221, 31.8.2018, p. 4 (2018/1109)

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▼C1

COMMISSION IMPLEMENTING DECISION (EU) 2018/1109

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(Only the Dutch, English and French texts are authentic)

(Text with EEA relevance)

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;

(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.

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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) ►**M1** Dow AgroSciences Distribution S.A.S., France, 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) ►**M1** Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France ◄.

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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: ►M1 Dow AgroSciences Distribution S.A.S. ◄

Address: ►M1 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France ◄

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/

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(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).