Commission Implementing Decision (EU) 2017/1212 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council on genetically modified food and feed (notified under document C(2017) 4503) (Only the English text is authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2017/1212

of 4 July 2017

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council on genetically modified food and feed

(notified under document C(2017) 4503)

(Only the English 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 Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 11 November 2010, Dow AgroSciences Europe submitted an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from DAS-40278-9 maize ('the application') to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of genetically modified maize DAS-40278-9 in products consisting of it or containing it for other uses than food and feed as any other maize, with the exception of cultivation.

(2) In accordance with Articles 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)] and the data and information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to Directive 2001/18/EC.

(3) On 5 December 2016, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003[(3)]. EFSA concluded that genetically modified maize DAS-40278-9, as described in the

application, is as safe and as nutritious as its conventional counterpart and non-genetically modified commercial varieties as regards the potential effects on human health and the environment.

(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 Articles 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(5) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

(6) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified maize DAS-40278-9.

(7) A unique identifier should be assigned to the genetically modified organism (hereinafter 'GMO') in accordance with Commission Regulation (EC) No 65/2004[(4)].

(8) On the basis of the EFSA opinion, no specific labelling requirements, other than those 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 of the European Parliament and of the Council[(5)], appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of maize DAS-40278-9, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.

(9) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC[(6)].

(10) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) 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 as provided for 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 Articles 9(1) and Article 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 maize (*Zea mays* L.) DAS-40278-9, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-4Ø278-9, 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 the GMO referred to in Article 1;

(b) feed containing, consisting of, or produced from GMO referred to in Article 1;

(c) The GMO referred to in Article 1 in products containing it or consisting of it for any other use than those provided 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 products containing or consisting of the GMO referred to in Article 1, with the exception of products referred to in point (a) of Article 2.

Article 4

Monitoring for environmental effects

1 The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (g) of the Annex, is put in place and implemented.

2 The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

Article 5

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, as provided for in Article 28 of Regulation (EC) No 1829/2003.

[F1*Article 6*

Authorisation holder

The authorisation holder shall be Dow AgroSciences Distribution S.A.S., France.**]**

Textual Amendments

F1 Substituted by Commission Implementing Decision (EU) 2019/239 of 6 February 2019 amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449 and (EU) 2017/2450 as regards the representative or the authorisation holder (notified under document C(2019) 736) (Only the French and English texts are authentic) (Text with EEA relevance).

Article 7

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

[F1*Article 8*

Addressee

This Decision is addressed to Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.**]**

Textual Amendments

F1 Substituted by Commission Implementing Decision (EU) 2019/239 of 6 February 2019 amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449 and (EU) 2017/2450 as regards the representative or the authorisation holder (notified under document C(2019) 736) (Only the French and English texts are authentic) (Text with EEA relevance).

ANNEX

[F1(a)Authorisation holder:

Name : Dow AgroSciences Distribution S.A.S.
Address : 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.**]**

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

(1) foods and food ingredients containing, consisting of, or produced from maize DAS-40278-9;

(2) feed containing, consisting of, or produced from maize DAS-40278-9;

(3) Maize DAS-40278-9 in products containing it or consisting of it for any other use than those provided in points (1) and (2), with the exception of cultivation.

DAS4Ø278-9 maize expresses the AAD-1 protein which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides.

(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 the accompanying documents of the products containing or consisting of maize DAS-40278-9 with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based method for DAS-4Ø278-9 maize; the detection method is validated on the single-trait event using genomic DNA extracted from seeds of DAS-4Ø278-9 maize;

(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®-BF433 accessible via the Joint Research Centre (JRC) of the European Commission at https://crm.jrc.ec.europa.eu/.

(e) **Unique identifier:**

DAS-4Ø278-9;

(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 Community register of genetically modified food and feed when notified*].

(g) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

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

(h) **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 Community register of genetically modified food and feed.

(**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 LLC (EFSA-GMO-NL-2010-89) for placing on the market the genetically modified herbicide-tolerant maize DAS-40278-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2016;14(12):4633, 25 pp. doi: 10.2903/j.efsa.2016.4633.

(**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).

Changes to legislation:
There are outstanding changes not yet made to Commission Implementing Decision (EU) 2017/1212. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Annex point (a) substituted by S.S.I. 2023/59 reg. 11(4)
- Annex point (a) substituted by S.I. 2023/235 reg. 11(4)
- Annex point (a) substituted by S.I. 2023/379 reg. 11(4)
- Annex point (f) word omitted by S.I. 2019/705 reg. 340(a)
- Annex point (g) word omitted by S.I. 2019/705 reg. 340(b)
- Annex Note word omitted by S.I. 2019/705 reg. 340(c)
- Art. 4(2) words substituted by S.I. 2019/705 reg. 337
- Art. 5 heading substituted by S.I. 2019/705 reg. 338
- Art. 5 word omitted by S.I. 2019/705 reg. 339
- Art. 6 substituted by S.I. 2023/379 reg. 11(2)
- Art. 6 words substituted by S.S.I. 2023/59 reg. 11(2)
- Art. 6 words substituted by S.I. 2023/235 reg. 11(2)
- Art. 8 substituted by S.I. 2023/379 reg. 11(3)
- Art. 8 words substituted by S.S.I. 2023/59 reg. 11(3)
- Art. 8 words substituted by S.I. 2023/235 reg. 11(3)