Commission Implementing Decision (EU) 2018/2046 of 19 December 2018 authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU (notified under document C(2018) 8238) (Only the Dutch and French texts are authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2018/2046

of 19 December 2018

authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU

(notified under document C(2018) 8238)

(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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 26 November 2013, Monsanto Europe SA/NV submitted, on behalf of Monsanto Company, an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 ('the application') to the national competent authority of Belgium. The application also covered the placing on the market of products containing or consisting of genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 for uses other than food and feed, with the exception of cultivation.

(2) In addition, the application covered the placing on the market of products containing, consisting of or produced from 25 sub-combinations of the single transformation events constituting maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. Twelve of those sub-combinations are already authorised: 1507 × 59122, authorised by Commission Implementing Decision (EU) 2018/1110[(2)]; MON 89034 × MON 88017,

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authorised by Commission Decision 2011/366/EU[(3)]; MON 87427 × MON 89034 authorised by Commission Decision (EU) 2018/1111[(4)]; and MON 89034 × 1507 × MON 88017 × 59122, MON 89034 × 1507 × MON 88017, MON 89034 × 1507 × 59122, MON 89034 × MON 88017 × 59122, 1507 × MON 88017 × 59122, MON 89034 × 1507, MON 89034 × 59122, 1507 × MON 88017, MON 88017 × 59122, authorised by Commission Implementing Decision 2013/650/EU[(5)].

(3) Monsanto Europe SA/NV, the authorisation holder for one of those 12 sub-combinations already authorised, sub-combination MON 89034 × MON 88017, requested the Commission to repeal Decision 2011/366/EU and to incorporate that Decision in the scope of the present Decision.

(4) This Decision covers fourteen sub-combinations: four sub-combinations of four events (MON 87427 × MON 89034 × 1507 × MON 88017, MON 87427 × MON 89034 × 1507 × 59122, MON 87427 × MON 89034 × MON 88017 × 59122 and MON 87427 × 1507 × MON 88017 × 59122); six sub-combinations of three events (MON 87427 × MON 89034 × 1507, MON 87427 × MON 89034 × MON 88017, MON 87427 × MON 89034 × 59122, MON 87427 × 1507 × MON 88017, MON 87427 × 1507 × 59122 and MON 87427 × MON 88017 × 59122); and four sub-combinations of two events (MON 87427 × 1507, MON 87427 × MON 88017, MON 87427 × 59122 and MON 89034 × MON 88017).

(5) In accordance with Article 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[(6)] and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC.

(6) On 5 September 2017, the European Food Safety Authority ('the Authority') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003[(7)]. The Authority concluded that genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is as safe and nutritious as the non-genetically modified comparator and the tested non-genetically modified reference varieties in the context of the scope of the application. No new safety concerns were identified for the previously assessed sub-combinations and therefore previous conclusions on those sub-combinations remain valid. As regards the remaining sub-combinations, the Authority concluded that they are expected to be as safe as the single transformation events MON 87427, MON 89034, 1507, MON 88017 and 59122, the previously assessed sub-combinations and the five-event stack maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122.

(7) In its opinion, the Authority considered the 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.

(8) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, was in line with the intended uses of the products. However, the monitoring plan has been revised by

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the Commission, as recommended by the Authority, to cover also the sub-combinations governed by this Decision.

(9) Taking those considerations into account, the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and of the 14 sub-combinations indicated in recital 4 and listed in the application should be authorised.

(10) In the interest of simplification, Decision 2011/366/EU should be repealed.

(11) A unique identifier should be assigned to each genetically modified organism covered by this Decision, in accordance with Commission Regulation (EC) No 65/2004[(8)]. The unique identifier assigned by Decision 2011/366/EU should continue to be used.

(12) On the basis of the Authority's 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[(9)], appear to be necessary for the products covered by this Decision. 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 such products, with the exception of those intended for food uses, should contain a clear indication that they are not intended for cultivation.

(13) The authorisation holder must submit annual reports on the implementation and on 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[(10)].

(14) The opinion of the Authority does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements regarding the consumption of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(15) 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.

(16) 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[(11)].

(17) 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:

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Article 1

Genetically modified organisms and unique identifiers

The following unique identifiers are assigned to genetically modified maize as specified in point (b) of the Annex to this Decision, in accordance with Regulation (EC) No 65/2004:

(a) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 1507 × MON 88017 × 59122;

(b) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 1507 × MON 88017;

(c) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 1507 × 59122;

(d) the unique identifier MON-87427-7 × MON-89Ø34-3 × MON-88Ø17-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × MON 88017 × 59122;

(e) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × 1507 × MON 88017 × 59122;

(f) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 1507;

(g) the unique identifier MON-87427-7 × MON-89Ø34-3 × MON-88Ø17-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × MON 88017;

(h) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × 59122;

(i) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × MON-88Ø17-3 for genetically modified maize (*Zea mays* L.) MON 87427 × 1507 × MON 88017;

(j) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × 1507 × 59122;

(k) the unique identifier MON-87427-7 × MON-88Ø17-3 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 88017 × 59122;

(l) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) MON 87427 × 1507;

(m) the unique identifier MON-87427-7 × MON-88Ø17-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 88017;

(n) the unique identifier MON-87427-7 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) MON 87427 × 59122;

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(o) the unique identifier MON-89Ø34-3 × MON-88Ø17-3 for genetically modified maize (*Zea mays* L.) MON 89034 × MON 88017.

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 genetically modified maize referred to in Article 1;

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

(c) genetically modified maize referred to in Article 1 in products containing them or consisting of them, for uses other than those provided for in points (a) and (b) of this Article, 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 genetically modified maize referred to in Article 1, 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 the genetically modified maize referred to in Article 1.

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.