Commission Implementing Decision (EU) 2019/2083 of 28 November 2019 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2019) 7482) (Only the Dutch and French texts are authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/2083

of 28 November 2019

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(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 to Articles 11(3) and 23(3) thereof,

Whereas:

(1) Commission Decision 2008/933/EC[(2)] authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 89788. The scope of that authorisation also covers the placing on the market of products containing or consisting of genetically modified soybean MON 89788 for uses other than food and feed, with the exception of cultivation.

(2) On 20 November 2017, the authorisation holder, Monsanto Europe S.A./N.V., on behalf of Monsanto Company, submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.

(3) On 19 November 2018, the European Food Safety Authority ('the Authority') issued a favourable opinion[(3)] in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that the renewal application did not contain evidence for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment on soybean MON 89788, adopted by the Authority in 2008[(4)].

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Decision (EU) 2019/2083. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) In its opinion of 19 November 2018, the Authority considered all the questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(5) The Authority also concluded that the monitoring plan for the 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 conclusions, the authorisation for the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 89788 and of products containing or consisting of it for uses other than food and feed, with the exception of cultivation, should be renewed.

(7) By letter dated 27 August 2018, Monsanto Europe S.A./N.V. informed the Commission that it converted its legal form and changed its name to Bayer Agriculture BVBA, Belgium. Monsanto Company confirmed the change of representative.

(8) A unique identifier has been assigned to genetically modified soybean MON 89788, in accordance with Commission Regulation (EC) No 65/2004[(5)], in the context of its initial authorisation by Decision 2008/933/EC. That unique identifier should continue to be used.

(9) On the basis of the opinion of the Authority, no specific labelling requirements, other than those provided for 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[(6)] 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 the products containing or consisting of genetically modified soybean MON 89788, with the exception of food products, should contain a clear indication that they 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 monitoring plan for environmental effects. Those results should be presented in accordance with the requirements laid down in Commission Decision 2009/770/EC[(7)].

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

(12) 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.

(13) 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

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Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council[8].

(14) 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 soybean (*Glycine max* (L.) Merr.) MON 89788, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-89788-1, 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) foods and food ingredients containing, consisting of or produced from genetically modified soybean MON-89788-1;

(b) feed containing, consisting of or produced from genetically modified soybean MON-89788-1;

(c) products containing or consisting of genetically modified soybean MON-89788-1 for uses other 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 Articles 13(1) and 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 ‘soybean’.

2 The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified soybean MON-89788-1, with the exception of products referred to in point (a) of Article 2.

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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 genetically modified soybean MON-89788-1.

Article 5

Monitoring plan 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 the format set out in 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, as referred to in Article 28(1) of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Monsanto Company, United States, represented by Bayer Agriculture BVBA, 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 Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.