Commission Implementing Decision (EU) 2019/1302 of 26 July 2019 authorising the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × LLCotton25 × MON 15985 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2019) 5501) (Only the German text is authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/1302

of 26 July 2019

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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 7(3) and 19(3) thereof,

Whereas:

(1) On 11 February 2011, Bayer CropScience AG (‘the applicant’) submitted 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 cotton GHB614 × LLCotton25 × MON 15985 and the subcombination LLCotton25 × MON 15985 (‘the application’) to the national competent authority of the Netherlands. The application also covered the placing on the market of genetically modified cotton GHB614 × LLCotton25 × MON 15985 and the subcombination LLCotton25 × MON 15985 in products consisting of it or containing it for uses other than food and feed, with the exception of cultivation.

(2) By letter of 20 April 2011, the applicant was informed that, due to the reproductive characteristics of cotton GHB614 × LLCotton25 × MON 15985, the subcombination LLCotton25 × MON 15985 should be removed from the application in order to assess it separately. By letter of 15 June 2015, the applicant submitted an updated version of the application to the European Food Safety Authority (‘the Authority’), limiting the scope of the application to the placing on the market of foods, food ingredients and

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feed containing, consisting of or produced from cotton GHB614 × LLCotton25 × MON 15985.

(3) In accordance with Articles 5(5) and 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 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.

(4) On 20 April 2018, the Authority issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003[(3)]. The Authority concluded that genetically modified cotton GHB614 × LLCotton25 × MON 15985 is as safe as and is expected to have the same nutritional impact as its non-genetically modified comparator in the context of the scope of the application.

(5) In its opinion, the Authority 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.

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

(7) Taking those considerations into account, the placing on the market of products containing, consisting of or produced from genetically modified cotton GHB614 × LLCotton25 × MON 15985 should be authorised.

(8) By letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfer the rights and obligations of Bayer CropScience AG pertaining to all authorisations and pending applications for genetically modified products, to BASF Agricultural Solutions Seed US LLC. By letter dated 6 August 2018, BASF SE confirmed consent to this transfer on behalf of BASF Agricultural Solutions Seed US LLC.

(9) A unique identifier should be assigned to genetically modified cotton GHB614 × LLCotton25 × MON 15985 in accordance with Commission Regulation (EC) No 65/2004[(4)].

(10) On the basis of the Authority's opinion, 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[(5)], appear 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 products containing or consisting of genetically modified cotton GHB614 × LLCotton25 × MON 15985, with the exception of food products, should contain a clear indication that they are not intended for cultivation.

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(11) 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 standard reporting format requirements laid down in Commission Decision 2009/770/EC[(6)].

(12) 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 for the protection of particular ecosystems/ environment or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(13) 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.

(14) 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[(7)].

(15) 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 cotton (Gossypium hirsutum) GHB614 × LLCotton25 × MON 15985, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ2-5 × ACS-GHØØ1-3 × MON-15985-7, 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 GHB614 × LLCotton25 × MON 15985 cotton;

(b) feed containing, consisting of or produced from GHB614 × LLCotton25 × MON 15985 cotton;

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(c) products containing or consisting of GHB614 × LLCotton25 × MON 15985 cotton 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 ‘cotton’.

2 The words ‘not for cultivation’ shall appear on the label and in the documents accompanying products containing or consisting of genetically modified cotton 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 cotton referred to in Article 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 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 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 BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany.