Commission Implementing Decision (EU) 2019/2082 of 28 November 2019 renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified cotton LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2019) 7481) (Only the German text is authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/2082

of 28 November 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 11(3) and 23(3) thereof,

Whereas:

(1) Commission Decision 2008/837/EC[(2)] authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified cotton LLCotton25 (hereinafter 'LLCotton25'). The scope of that authorisation also covers the placing on the market of products, other than food and feed, containing or consisting of LLCotton25 for the same uses as any other cotton with the exception of cultivation.

(2) On 2 October 2017, the initial authorisation holder, Bayer CropScience AG 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 14 November 2018, the European Food Safety Authority ('the Authority') published 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 LLCotton25, adopted by the Authority in 2006[(4)].

(4) In its opinion of 14 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 Bayer CropScience AG, 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 LLCotton25 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.

(7) By letter dated 1 August 2018, Bayer CropScience AG requested that the Commission transfers their rights and obligations pertaining to all authorisations and pending applications for genetically modified products, to BASF Agricultural Solutions Seed US LLC. By letter dated 19 October 2018, BASF Agricultural Solutions Seed US LLC confirmed its agreement with this transfer and authorised BASF SE to act as its representative in the Union.

(8) A unique identifier has been assigned to LLCotton25, in accordance with Commission Regulation (EC) No 65/2004[(5)], in the context of its initial authorisation by Decision 2008/837/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 products containing or consisting LLCotton25 remains within the limits of the authorisation, the labelling of such products, 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. 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 containing, consisting of, or produced from genetically modified cotton LLCotton25, or for the protection of particular ecosystems/environment and/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 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:

(**1**) OJ L 268, 18.10.2003, p. 1.

(**2**) Commission Decision 2008/837/EC of 29 October 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 299, 8.11.2008, p. 36).

(**3**) EFSA GMO Panel 2018. Assessment of genetically modified LLCotton25 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA#GMO#RX#010), EFSA Journal 2018;16(11): 5473.

(**4**) Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMONL-2005-13) for the placing on the market of glufosinate-tolerant genetically modified LLCotton25, for food and feed uses, and import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience, The EFSA Journal (2006) 429, 1-19.

(**5**) 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).

(**6**) 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).

(**7**) 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).

(**8**) 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).