Commission Implementing Decision (EU) 2019/2081 of 28 November 2019 renewing the authorisation for the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2), resulting from the commercialisation of this oilseed rape in third countries until 2005, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2019) 7480) (Only the German text is authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/2081

of 28 November 2019

renewing the authorisation for the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2), resulting from the commercialisation of this oilseed rape in third countries until 2005, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2019) 7480)

(Only the German 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 to Articles 11(3) and 23(3) thereof,

Whereas:

(1) Commission Decision 2009/184/EC[(2)] authorised the placing on the market of food and feed containing or produced from genetically modified oilseed rape T45 (‘T45 oilseed rape’). The scope of that authorisation also covered the placing on the market of products, other than food and feed, containing T45 oilseed rape for the same uses as any other oilseed rape with the exception of cultivation.

(2) The applicant indicated in its applications and in communications to the Commission that the commercialisation of T45 oilseed rape seeds was stopped after the 2005 planting season.

(3) Therefore, the only purpose of these applications was to cover the presence of T45 oilseed rape resulting from its past cultivation in third countries.

(4) Following the monitoring requirements set in Decision 2009/184/EC, the applicant has shown that minute traces of T45 oilseed rape are still present in commodity rapeseed in third countries and being imported into the Union.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Decision (EU) 2019/2081. 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*

(5) As a result, on 9 January 2018, the 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.

(6) The applicant reconfirmed in its application that the purpose of the application was to cover the presence of T45 oilseed rape in food and feed, resulting from its cultivation in third countries until 2005.

(7) On 14 February 2019, the European Food Safety Authority ('the Authority') published a comprehensive favourable opinion[(3)] on T45 oilseed rape 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 T45 oilseed rape, adopted by the Authority in 2008[(4)].

(8) In its opinion of 14 February 2019, 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.

(9) 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.

(10) Taking into account those conclusions, the authorisation for the placing on the market of food and feed containing or produced from T45 oilseed rape and of products other than food and feed, containing T45 oilseed rape for the same uses as any other oilseed rape, with the exception of cultivation, should be renewed.

(11) On the basis of the opinion of the Authority, no specific labelling requirements appear to be necessary for the products covered by this Decision. Pursuant to Articles 12(2) and 24(2) of Regulation (EC) No 1829/2003 and to Article 4(7) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council[(5)], general traceability and labelling requirements do not apply to the adventitious or technically unavoidable presence of genetically modified food or feed in a proportion not exceeding 0,9 %.

(12) In order to continue monitoring the phasing out of T45 oilseed rape, its presence in imported products should continue to be regularly reported as provided in Decision 2009/184/EC.

(13) 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 this transfer and authorised BASF SE to act as its representative in the Union.

(14) On 17 May 2019, the applicant requested the Commission to restrict the scope of the Decision of renewal to allow the presence of T45 oilseed rape in food and feed in a proportion not exceeding 0,9 %. Following this request, the scope of this decision is restricted to a maximal level of 0,9 % of presence of T45 oilseed rape in food and feed.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Decision (EU) 2019/2081. 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*

(15) A unique identifier has been assigned to T45 oilseed rape, in accordance with Commission Regulation (EC) No 65/2004[(6)], in the context of its initial authorisation by Decision 2009/184/EC. That unique identifier should continue to be used.

(16) 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)].

(17) 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 or produced from genetically modified oilseed rape T45, 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.

(18) 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.

(19) 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)].

(20) 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 oilseed rape (*Brassica napus L*) T45, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-BNØØ8-2, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

1 The purpose of this Decision is to renew an authorisation covering, for the products referred to in paragraph 2, the presence of ACS-BNØØ8-2 oilseed rape resulting directly or indirectly from the commercialisation, until 2005, of ACS-BNØØ8-2 oilseed rape seeds in third countries.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Decision (EU) 2019/2081. 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*

2 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 or produced from genetically modified oilseed rape ACS-BNØØ8-2;

b feed containing or produced from genetically modified oilseed rape ACS-BNØØ8-2;

c products containing genetically modified oilseed rape ACS-BNØØ8-2 for uses other than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Maximum level

The presence of genetically modified oilseed rape ACS-BNØØ8-2 in products defined in Article 2 is authorised in a proportion not exceeding 0,9 %.

Article 4

Method for detection

The method set out in point (c) of the Annex shall apply for the detection of genetically modified oilseed rape ACS-BNØØ8-2.

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 (g) 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

Monitoring of the phasing out

1 The authorisation holder shall ensure that shipments of oilseed rape imported into the Union from a third country in which genetically modified oilseed rape seeds ACS-BNØØ8-2 were commercialised until 2005 are sampled and tested appropriately for the presence of genetically modified oilseed rape ACS-BNØØ8-2.

2 The method used for the sampling of oilseed rape ACS-BNØØ8-2 shall be internationally recognised. The testing shall be made in an accredited laboratory and in accordance with the validated method of detection as set out in the Annex.

3 The authorisation holder shall submit to the Commission, together with the reports referred to in Article 5(2), annual reports on the monitoring activities for the presence of genetically modified oilseed rape ACS-BNØØ8-2.