Commission Implementing Decision (EU) 2019/1301 of 26 July 2019 amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2019) 5499) (Only the German text is authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/1301

of 26 July 2019

amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2019) 5499)

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

Whereas:

(1) Commission Implementing Decision 2013/327/EU[(2)] authorised the placing on the market of food containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 and of food and feed produced from those genetically modified oilseed rapes.

(2) Previously, Commission Decision 2007/232/EC[(3)] authorised the placing on the market of feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3. The scope of that authorisation also covered products containing or consisting of oilseed rapes Ms8, Rf3 and Ms8 × Rf3, for other uses than food or feed, with the exception of cultivation.

(3) On 20 May 2016, Bayer CropScience AG submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation for the placing on the market of the products covered by Decision 2007/232/EC.

(4) On 28 November 2017, the European Food Safety Authority ('the Authority') issued a favourable opinion[(4)] 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 oilseed rapes Ms8, Rf3 and Ms8 × Rf3, adopted by EFSA in 2005[(5)].

(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 the environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

(7) Taking into account those considerations, the authorisation for the placing on the market of the products covered by Decision 2007/232/EC should be renewed.

(8) On 30 November 2017, the applicant Bayer CropScience asked the Commission to merge into a single authorisation the uses of oilseed rapes Ms8, Rf3 and Ms8 × Rf3 covered by the renewal application and the uses of those oilseed rapes covered by Implementing Decision 2013/327/EU. By a letter dated 5 December 2017, the Commission informed the applicant that the merger would take effect through the extension of the scope of Implementing Decision 2013/327/EU to the products concerned by the renewal application of 20 May 2016. The applicant has therefore been made aware that, as a result of the merger, the products covered by the renewal application would be subject to the conditions of authorisation set out in Implementing Decision 2013/327/EU.

(9) The Commission considers that the request of the applicant is justified, in the interest of simplification. Therefore, Implementing Decision 2013/327/EU should be amended to incorporate into its scope the products currently covered by Decision 2007/232/EC.

(10) By letter dated 1 August 2018, Bayer CropScience AG requested the Commission the transfer of its rights and obligations for all authorisations to BASF Agricultural Solutions Seed US LLC. By letter dated 6 August 2018, BASF SE confirmed the agreement to this transfer on behalf of BASF Agricultural Solutions Seed US LLC. This transfer affects Decision 2007/232/EC and Implementing Decision 2013/327/EU.

(11) A unique identifier has been assigned to oilseed rapes Ms8, Rf3 and Ms8 × Rf3, in accordance with Commission Regulation (EC) No 65/2004[(6)]. That unique identifier should continue to be used.

(12) On the basis of the opinion of the Authority, 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[(7)], 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 oilseed rapes Ms8, Rf3 and Ms8 × Rf3, with the exception

of food products, should contain a clear indication that the products in question are not intended for cultivation.

(13) The monitoring plan for environmental effects set out in Implementing Decision 2013/327/EU does not need to be amended as it is substantially identical to the one assessed by the Authority in the framework of the renewal application.

(14) 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.

(15) Decision 2007/232/EC should be repealed.

(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[8].

(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:

Article 1

Amendments

1 Implementing Decision 2013/327/EU is amended as follows:

(1) The title is replaced by the following:
Commission Implementing Decision 2013/327/EU of 25 June 2013 authorising the placing on the market of food and feed containing, consisting of or produced from genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(2) Article 2 is replaced by the following:

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 ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes;

(b) feed containing, consisting of or produced from ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rapes;