Commission Decision of 10 March 2009 authorising 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 number C(2009) 1541) (Only the German text is authentic) (Text with EEA relevance) (2009/184/EC)

COMMISSION DECISION

of 10 March 2009

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(Text with EEA relevance)

(2009/184/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 7(3) and 19(3) thereof,

Whereas:

(1) On 28 October 2005, Bayer CropScience AG submitted to the competent authority of the United Kingdom 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 or produced from T45 oilseed rape.

(2) The application also covers the placing on the market of other products containing T45 oilseed rape for the same uses as any other oilseed rape with the exception of cultivation. Therefore, in accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, it includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[(2)] and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC.

(3) On 17 April 2007, Bayer CropScience AG submitted to the Commission an application, in accordance with Articles 8(4) and 20(4) of Regulation (EC) No 1829/2003, for the authorisation of existing products produced from T45 oilseed rape (food additives and feed materials produced from T45 oilseed rape).

(4) 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.

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

(6) On 5 March 2008, the European Food Safety Authority ('EFSA') gave a single comprehensive favourable opinion for both applications in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 and concluded that it is unlikely that the placing on the market of the products containing or produced from T45 oilseed rape as described in the applications ('the products') will have any adverse effects on human or animal health or the environment in the context of their intended uses[(3)]. In its opinion, EFSA 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 Articles 6(4) and 18(4) of that Regulation.

(7) In particular, EFSA concluded that as no indication of biologically relevant compositional and agronomical changes was identified for seeds from T45 oilseed rape except the presence of the PAT protein, no further animal safety studies with the whole food/feed (e.g. a 90-day toxicity study in rats) are needed.

(8) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended use of the products. However, due to the physical characteristics of oilseed rape seeds and methods of transportation, EFSA recommended that appropriate management systems should be in place to minimise accidental loss and spillage of transgenic oilseed rape during transportation, storage, handling and processing. The monitoring plan submitted by the applicant has been modified to take into account this EFSA recommendation.

(9) In order to monitor the phasing out of T45 oilseed rape, its presence in imported products should be regularly reported.

(10) Taking into account those considerations, it is appropriate to grant an authorisation to cover the presence in products of T45 oilseed rape resulting from the commercialisation of T45 oilseed rape seeds in third countries until 2005.

(11) A unique identifier should be assigned to each GMO as provided for in 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[(4)].

(12) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, or produced from T45 oilseed rape. However, in order to ensure the use of the products within the limits of the

authorisation provided for by this Decision, the labelling of feed containing the GMO and other products than food and feed containing the GMO for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(13) Similarly, the EFSA opinion 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, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.

(14) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(15) Article 4(6) of 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[(5)], lays down labelling requirements for products consisting or containing GMOs.

(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 Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms[(6)].

(17) The applicant has been consulted on the measures provided for in this Decision.

(18) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman; the Commission has therefore submitted a proposal to the Council on 30 October 2008 in accordance with Article 5 of the Council Decision 1999/468/EC[(7)], the Council being required to act within three months.

(19) However, the Council has not acted within the required time limit; a Decision should now be adopted by the Commission,

HAS ADOPTED THIS DECISION:

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

(**2**) OJ L 106, 17.4.2001, p. 1.

(**3**) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question = EFSA-Q-2005-278

(**4**) OJ L 10, 16.1.2004, p. 5.

(**5**) OJ L 268, 18.10.2003, p. 24.

(**6**) OJ L 287, 5.11.2003, p. 1.

(**7**) OJ L 184, 17.7.1999, p. 23.

Changes to legislation:
There are outstanding changes not yet made to Commission Decision of 10 March 2009 authorising 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 number C(2009) 1541) (Only the German text is authentic) (Text with EEA relevance) (2009/184/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.