COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.10.2008
COM(2008) 678 final

Proposal for a

COUNCIL DECISION

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

The attached proposal for a Council Decision concerns food and feed containing or produced from genetically modified oilseed rape T45, for which a request for placing on the market was submitted by Bayer CropScience AG to the competent authority of the United Kingdom on 28 October 2005, under Regulation (EC) No 1829/2003 on genetically modified food and feed.

The attached proposal also concerns 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.

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

Therefore, the only purpose of the application is to cover the presence of T45 oilseed rape resulting from its past cultivation in third countries.

On 5 March 2008, the European Food Safety Authority gave a favourable opinion 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 application will have adverse effects on human or animal health or the environment.

Against this background, a draft Commission Decision authorising the placing on the Community market of products containing or produced from genetically modified oilseed rape T45 was submitted to the Standing Committee on the Food Chain and Animal Health, on 14 July 2008, for vote. The Committee delivered no opinion: ten Member States (146 votes) voted in favour, twelve Member States (167 votes) voted against and five Member States (32 votes) abstained.

Consequently, pursuant to Article 35, paragraph 2 of Regulation (EC) No 1829/2003 and in accordance with Article 5 of Council Decision 1999/468/EC modified by Council Decision 2006/512/EC, the Commission is required to submit to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by a qualified majority, and inform the Parliament.

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(Only the German text is authentic)
(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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,

Having regard to the proposal from the Commission,

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).

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1 OJ L 268, 18.10.2003, p 1.
2 OJ L 106, 17.4.2001, p. 1.

(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

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[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_1178620786239.htm

[4] OJ L 10, 16.1.2004, p. 5.

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,

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, as provided for in Regulation (EC) No 65/2004.

[5] OJ L 268, 18.10.2003, p. 24.
[6] OJ L 287, 5.11.2003, p. 1.

Article 2
Authorisation

1. The purpose of this Decision is to grant 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.

2. The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

   (a) foods and food ingredients containing or produced from ACS-BNØØ8-2 oilseed rape;

   (b) feed containing or produced from ACS-BNØØ8-2 oilseed rape;

   (c) products other than food and feed containing ACS-BNØØ8-2 oilseed rape for the same uses as any other oilseed rape with the exception of cultivation.

Article 3
Labelling

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 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 ’oilseed rape’.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing ACS-BNØØ8-2 oilseed rape referred to in Article 2.2(b) and (c).

Article 4
Monitoring 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 to the Commission annual reports on the implementation and the results of the activities set out in the monitoring activities.

Article 5
Monitoring of the phasing out

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

2. The method used for the sampling of oilseed rape shall be internationally recognised. The testing shall be made in a duly accredited laboratory and in accordance with the validated method of detection as set out in the Annex to this Decision.

3. The authorisation holder shall submit to the Commission, together with the reports referred to in Article 4(2), annual reports on the monitoring activities for the presence of ACS-BNØØ8-2 oilseed rape.

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 provided for in Article 28 of Regulation (EC) No 1829/2003.

Article 7
Authorisation holder

The authorisation holder shall be Bayer Cropscience AG.

Article 8
Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9
Addressee

This Decision is addressed to Bayer CropScience AG, Alfred-Nobel-Strasse 50, D - 40789 Monheim am Rhein - Germany.

Done at Brussels,

For the Council
The President

ANNEX

(a) Applicant and Authorisation holder:

Name: Bayer CropScience AG

Address: Alfred-Nobel-Strasse 50, D - 40789 Monheim am Rhein - Germany

(b) Designation and specification of the products:

(1) Foods and food ingredients containing or produced from ACS-BNØØ8-2 oilseed rape;

(2) Feed containing or produced from ACS-BNØØ8-2 oilseed rape;

(3) Products other than food and feed containing of ACS-BNØØ8-2 oilseed rape for the same uses as any other oilseed rape with the exception of cultivation.

The genetically modified ACS-BNØØ8-2 oilseed rape, as described in the application, expresses the PAT protein which confers tolerance to the glufosinate-ammonium herbicide.

(c) Labelling:

(1) For the purposes of the specific labelling requirements laid down in Articles 13(1) and 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 ’oilseed rape’.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing ACS-BNØØ8-2 oilseed rape referred to in Article 2.2(b) and (c) of this Decision.

(d) Method for detection:

– Event specific real-time PCR based method for the quantification of ACS-BNØØ8-2 oilseed rape

– Validated on seeds by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm

– Reference Material: AOCS 0208-A accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm/bayer_canola.cfm

(e) Unique identifier:

ACS-BNØØ8-2

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Biosafety Clearing-House, Record ID: see [*to be completed when notified*]

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC

[Link: *plan published on the internet*]

(i) Post market monitoring requirements for the use of the food for human consumption

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.