COMMISSION DECISION

of 8 September 2008

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document number C(2008) 4735)

(Only the German text is authentic)

(Text with EEA relevance)

(2008/730/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 1 July 2005, Bayer CropScience AG submitted to the competent authority of the Netherlands 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, consisting of, or produced from A2704-12 soybean ('the application').

(2) The application also covers the placing on the market of other products containing or consisting of A2704-12 soybean for the same uses as any other soybean with the exception of cultivation. Therefore, in accordance with the provisions of 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 10 August 2007, the European Food Safety Authority (EFSA) 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, consisting of, or produced from A2704-12 soybean as described in the application ('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.

(4) In particular, EFSA concluded that after considering all the data available in the application on the molecular characterisation, compositional analysis and agronomic performance, A2704-12 soybean is equivalent to its non-genetically modified counterpart and, as a consequence, that no further animal safety studies with the whole food/feed (e.g. a 90-day toxicity study in rats) are needed.

(5) 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.

(6) Taking into account those considerations, authorisation should be granted for the products.

(7) A unique identifier should be assigned to each genetically modified organism (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].

[1] OJ L 268, 18.10.2003, p 1.
[2] OJ L 106, 17.4.2001, p. 1.
[3] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_1178620785771.htm
[4] OJ L 10, 16.1.2004, p. 5.

(8) 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 the foods, food ingredients and feed containing, consisting of, or produced from A2704-12 soybean. However, in order to ensure the use of the products within the limits of the authorisation provided by this Decision, the labelling of feed containing or consisting of the GMO and other products than food and feed containing or consisting of 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.

(9) 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.

(10) 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.

(11) 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 [1], lays down labelling requirements for products consisting or containing GMOs.

(12) 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 [2].

(13) 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 28 April 2008 in accordance with Article 5 of the Council Decision 1999/468/EC [3], the Council being required to act within three months.

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

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max*) A2704-12, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-GMØØ5-3, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

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, consisting of, or produced from ACS-GMØØ5-3 soybean;

(b) feed containing, consisting of, or produced from ACS-GMØØ5-3 soybean;

(c) products other than food and feed containing or consisting of ACS-GMØØ5-3 soybean for the same uses as any other soybean 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 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of ACS-GMØØ5-3 soybean referred to in Article 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 the point (h) of the Annex, is put in place and implemented.

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 287, 5.11.2003, p. 1.
[3] OJ L 184, 17.7.1999, p 23.

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

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 6

Authorisation holder

The authorisation holder shall be Bayer CropScience AG.

Article 7

Validity

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

Article 8

Addressee

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

Done at Brussels, 8 September 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

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, consisting of, or produced from ACS-GMØØ5-3 soybean.
2. Feed containing, consisting of, or produced from ACS-GMØØ5-3 soybean.
3. Products other than food and feed containing or consisting of ACS-GMØØ5-3 soybean for the same uses as any other soybean with the exception of cultivation.

The genetically modified ACS-GMØØ5-3 soybean, 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 'soybean'.
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of ACS-GMØØ5-3 soybean referred to in Article 2(b) and (c) of this Decision.

(d) **Method for detection:**

— event specific real-time PCR-based method for the quantification of ACS-GMØØ5-3 soybean,

— validated on seeds by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.it/statusofdoss.htm

— reference material: AOCS 0707-A, AOCS 0707-B and AOCS 0707-C accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm/bayer_soy.cfm

(e) **Unique identifier:**

ACS-GMØØ5-3.

(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 time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.