COMMISSION IMPLEMENTING DECISION

of 25 June 2013

authorising the placing on the market of food containing or consisting of genetically modified oilseed rape Ms8, Rf3 and Ms8 × Rf3, or food and feed produced from those genetically modified organisms pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2013) 3873)

(Only the German text is authentic)

(Text with EEA relevance)

(2013/327/EU)

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 7(3), 11(3), 19(3) and 23(3) thereof,

Whereas:

(1) 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 renewal of the authorisation of existing food (processed oil) and feed produced from Ms8, Rf3 and Ms8 × Rf3 oilseed rape.

(2) On 22 September 2009, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that it is unlikely that the continued marketing of the food and feed produced from oilseed rape Ms8, Rf3 and Ms8 × Rf3 as described in the application will have any adverse effects on human or animal health or the environment in the context of their intended uses [2].

(3) On 4 June 2010, Bayer CropScience AG submitted to the competent authority of Belgium an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods and food ingredients containing, consisting of, or produced from oilseed rape Ms8, Rf3 and Ms8 × Rf3 with the exception of processed oil.

(4) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, that application 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 [3] 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. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(5) On 26 September 2012, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that oilseed rape Ms8, Rf3 and Ms8 × Rf3, as described in the application, is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore, it concluded that it is unlikely that the placing on the market of the foods and food ingredients containing, consisting of, or produced from oilseed rape Ms8, Rf3 and Ms8 × Rf3 as described in the application will have any adverse effects on human or animal health or the environment in the context of their intended uses [4].

(6) 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 uses of the products.

(7) In both opinions, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultations of the national competent authorities as provided for in Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(8) The use of feed containing or consisting of Ms8, Rf3, Ms8 × Rf3 oilseed-rape and products other than food and feed containing it or consisting of it with the exception of cultivation, have already been authorised by Commission Decision 2007/232/EC [5].

(9) Taking into account those considerations, authorisation should be granted to the foods and food ingredients containing, consisting of Ms8, Rf3, Ms8 × Rf3 oilseed rape and food and feed produced from Ms8, Rf3, Ms8 × Rf3 oilseed rape.

[1] OJ L 268, 18.10.2003, p. 1.
[2] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00748
[3] OJ L 106, 17.4.2001, p. 1.
[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00794
[5] OJ L 100, 17.4.2007, p. 20.

(10) A unique identifier should be assigned to each genetically modified organism (hereinafter '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 ([1]).

(11) On the basis of the two EFSA opinions, 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 containing or consisting of, and food and feed produced from oilseed rape Ms8, Rf3 and Ms8 × Rf3.

(12) 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 ([2]), lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 of that Regulation and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(13) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council ([3]). The EFSA opinions do 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 for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and in Article 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) 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 point (c) of Article 15(2) 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 ([4]).

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

(17) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act 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 identifiers

Genetically modified oilseed rape (*Brassica napus* L.) Ms8, Rf3 and Ms8 × Rf3, as specified in point (b) of the Annex to this Decision, are assigned the unique identifiers ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 respectively, 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-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rape;

(b) feed produced from ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rape.

Article 3

Labelling

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'.

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.

([1]) OJ L 10, 16.1.2004, p. 5.
([2]) OJ L 268, 18.10.2003, p. 24.
([3]) OJ L 275, 21.10.2009, p. 9.
([4]) OJ L 287, 5.11.2003, p. 1.

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 Decision 2009/770/EC.

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, 40789 Monheim am Rhein, Germany,

Done at Brussels, 25 June 2013.

For the Commission

Tonio BORG

Member of the Commission

ANNEX

(a) **Applicant and Authorisation holder**

Name: Bayer CropScience AG

Address: Alfred-Nobel-Straße 50, 40789 Monheim am Rhein — Germany

(b) **Designation and specification of the products**

(1) foods and food ingredients containing, consisting of, or produced from ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rape;

(2) feed produced from ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rape.

The genetically modified ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rape, as described in the applications, express the phosphinothricin acetyl transferase (PAT) protein which confers tolerance to the herbicidal active ingredient glufosinate-ammonium and *barnase* (ACS-BNØØ5-8) and *barstar* (ACS-BNØØ3-6) proteins for male sterility and restorer of fertility.

(c) **Labelling**

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'.

(d) **Method for detection**

— Event specific real-time PCR based method for the quantification of ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6 oilseed rape;

— Validated on seeds by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm

— Reference Material: AOCS 0306-B, AOCS 0306-F and AOCS 0306-G are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifiers**

ACS-BNØØ5-8, ACS-BNØØ3-6 and ACS-BNØØ5-8 × ACS-BNØØ3-6

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

Biosafety Clearing-House [*to be entered in the Community register of genetically modified food and feed 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 [*to be entered in the Community register of genetically modified food and feed when notified*].

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

Not required.