DECISIONS

COMMISSION IMPLEMENTING DECISION

of 18 October 2012

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR162 (SYN-IR162-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2012) 7198)

(Only the French text is authentic)

(Text with EEA relevance)

(2012/651/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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 2 July 2010, Syngenta Seeds SAS submitted to the competent authority of Germany 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 MIR162 maize (the application).

(2) The application also covers the placing on the market of MIR162 maize in products consisting of it or containing it for any other uses than food and feed as any other maize, with the exception of cultivation.

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

(4) On 21 June 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 MIR162 maize, 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 products containing, consisting of, or produced from MIR162 maize 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].

(5) 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 Article 6(4) and Article 18(4) of that Regulation.

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

(8) 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 [4].

[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-2010-00972
[4] OJ L 10, 16.1.2004, p. 5.

(9) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from MIR162 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO with the exception of food products for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(10) 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 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 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(11) 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 [2]. 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 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 Article 18(5) of Regulation (EC) No 1829/2003.

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

(13) 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 of 15 July 2003 on transboundary movements of genetically modified organisms [3].

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

(15) 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 identifier

Genetically modified maize (*Zea mays* L.) MIR162, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-IR162-4, as provided for in Regulation (EC) No 65/2004.

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 SYN-IR162-4 maize;

(b) feed containing, consisting of, or produced from SYN-IR162-4 maize;

(c) SYN-IR162-4 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down 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, the 'name of the organism' shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-IR162-4 maize with the exception of products referred to in point (a) of Article 2.

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 268, 18.10.2003, p. 24.
[2] OJ L 275, 21.10.2009, p. 9.
[3] 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

EU register

The information set out in the Annex to this Decision shall be entered in the EU 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 Syngenta Seeds SAS, France, representing Syngenta Crop Protection AG, Switzerland.

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 Syngenta Seeds SAS, 12, Chemin de l'Hobit, 31790 Saint-Sauveur, France.

Done at Brussels, 18 October 2012.

For the Commission

Maroš ŠEFČOVIČ

Vice-President

ANNEX

(a) **Applicant and Authorisation holder**

Name: Syngenta Seed SAS

Address: 12, Chemin de l'Hobit, 31790 Saint-Sauveur, France

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-4058 Basel, Switzerland.

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

(1) Foods and food ingredients containing, consisting of, or produced from SYN-IR162-4 maize;

(2) feed containing, consisting of, or produced from SYN-IR162-4 maize;

(3) SYN-IR162-4 maize in products containing it or consisting of it for any other use than (1) and (2), with the exception of cultivation.

The genetically modified SYN-IR162-4 maize, as described in the application, expresses the Vip3Aa20 protein which confers protection against certain lepidopteran pests and PMI protein which was used as a selectable marker.

(c) **Labelling**

(1) For the purposes of the specific labelling requirements laid down 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, the 'name of the organism' shall be 'maize';

(2) the words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-IR162-4 maize with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— Event specific real-time PCR-based method for the quantification of SYN-IR162-4 maize;

— 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 1208-A and AOCS 0407-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

SYN-IR162-4

(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.