COMMISSION DECISION

of 28 July 2010

renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC

(notified under document C(2010) 5129)

(Only the French text is authentic)

(Text with EEA relevance)

(2010/419/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, Syngenta Seeds SAS on behalf of Syngenta Crop Protection AG, submitted to the Commission an application, in accordance with Articles 5, 11, 17 and 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation for continued marketing of existing foods and food ingredients produced from Bt11 maize (including food additives), and renewal of the authorisation for continued marketing of existing feed containing, consisting of or produced from Bt11 maize (including feed additives and feed materials) and products other than food and feed containing and consisting of Bt11 maize with the exception of cultivation (the application) which were previously notified in accordance with Article 8(1)(a)(b) and Article 20(1)(a)(b) of that Regulation. The application also covers the renewal of the authorisation for the placing on the market of foods and food ingredients which are authorised under Commission Decision 2004/657/EC of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council [2]. Within its application, Syngenta Seeds SAS also requested the authorisation of foods and food ingredients containing or consisting of Bt11 field maize which were never authorised in the Union.

(2) On 17 February 2009, the European Food Safety Authority (EFSA) gave a favourable opinion [3] in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 and concluded that the new information provided in the application and the review of the literature that has been published since the previous scientific opinion on Bt11 maize [4] by EFSA does not require changes and confirmed the previous conclusion that Bt11 maize is as safe as its non-genetically modified counterpart and that it is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses which also applies to the products which are subject of the application.

(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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(4) 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.

(5) Taking into account these considerations, the fact that the company Syngenta Crop Protection AG Switzerland which absorbed Syngenta Seeds AG, addressee of Decision 2004/657/EC is the same legal entity, on behalf of which the applicant asked for the renewal of authorisation, that it confirmed that the scope of its application also covers the request for authorisation of foods and food ingredients containing or consisting of Bt11 field maize and that it intended to ask for a renewal of products covered by Decision 2004/657/EC prior to

[1] OJ L 268, 18.10.2003, p. 1.
[2] OJ L 300, 25.9.2004, p. 48.
[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question = EFSA-Q-2007-146
[4] EFSA opinion published on 19 May 2005, for the placing on the market of Bt11 for cultivation, feed and industrial processing — http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question = EFSA-Q-2004-012

the expiration of the authorisation mentioned in that Decision so that a single Decision covering these products may be adopted which will take effect on the same date, renewal of the authorisation for continued marketing of the existing products, renewal of the authorisation of foods and food ingredients containing, consisting of or produced from Bt11 sweet maize (sweet maize fresh or canned) and authorisation of food and foods ingredients containing or consisting of Bt11 field maize should be granted. Consequently, Decision 2004/657/EC should be repealed.

(6) 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 ([1]).

(7) 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 Bt11 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 feed containing or consisting of the GMO and products other than food and feed containing or consisting of the GMO for which renewal of the authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(8) 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]).

(9) 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 Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.

(10) All relevant information on the authorisation or the renewal 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 ([3]), lays down labelling requirements for products consisting of, 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 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 ([4]).

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

(14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman.

(15) At its meeting on 29 June 2010, the Council was unable to reach a decision by qualified majority either for or against the proposal. The Council indicated that its proceedings on this file were concluded. It is accordingly for the Commission to adopt the measures,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize Bt11 (*Zea mays* L.), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-BTØ11-1, as provided for in Regulation (EC) No 65/2004.

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

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-BTØ11-1 maize;

(b) feed containing, consisting of, or produced from SYN-BTØ11-1 maize;

(c) products other than food and feed containing or consisting of SYN-BTØ11-1 maize for the same uses as any other maize 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-BTØ11-1 maize 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 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 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 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

Repeal

Decision 2004/657/EC is repealed.

Article 9

Addressee

This Decision is addressed to Syngenta Seeds SAS, Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France, representing Syngenta Crop Protection AG, Switzerland.

Done at Brussels, 28 July 2010.

For the Commission
John DALLI
Member of the Commission

ANNEX

(a) **Applicant and authorisation holder:**

Name: Syngenta Seeds SAS

Address: Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France

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

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

1. foods and food ingredients containing, consisting of, or produced from SYN-BTØ11-1 maize;
2. feed containing, consisting of, or produced from SYN-BTØ11-1 maize;
3. products other than food and feed containing or consisting of SYN-BTØ11-1 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-BTØ11-1 maize, as described in the application, expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and 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 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-BTØ11-1 maize referred to in Article 2(b) and (c).

(d) **Method for detection:**

— event specific real-time PCR-based method for the quantification of SYN-BTØ11-1 maize

— validated 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: ERM®-BF412 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at https://irmm.jrc.ec.europa.eu/rmcatalogue

(e) **Unique identifier:**

SYN-BTØ11-1

(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.