EUROPEAN COMMISSION

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2011/0265 (NLE)

Proposal for a

COUNCIL DECISION

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604xGA21 (SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Only the French text is authentic)

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

The attached proposal for a Council Decision concerns food and feed containing, consisting of or produced from genetically modified maize Bt11xMIR604xGA21 (SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9), for which a request for placing on the market was submitted by Syngenta Seeds S.A.S. to the competent authority of the United Kingdom on 31 May 2008, under Regulation (EC) No 1829/2003 on genetically modified food and feed.

The attached proposal also concerns the placing on the market of products other than food and feed containing and consisting of Bt11xMIR604xGA21maize for the same uses as any other maize with the exception of cultivation.

On 15 June 2010, the European Food Safety Authority gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It considered that Bt11xMIR604xGA21 maize 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 Bt11xMIR604xGA21 maize 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.

Against this background, a draft Commission Decision authorising the placing on the Union market of products containing, consisting of or produced from genetically modified Bt11xMIR604xGA21 maize was submitted to the Standing Committee on the Food Chain and Animal Health, on 9 February 2011, for vote. The Committee delivered no opinion: 13 Member States (180 votes) voted in favour, 12 Member States (109 votes) voted against and 2 Member States (56 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 French text is authentic)

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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,

Having regard to the proposal from the European Commission,

Whereas:

(1) On 31 March 2008, Syngenta Seeds S.A.S. submitted to the competent authority of the United Kingdom an application, in accordance with Article 5 and Article 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 Bt11xMIR604xGA21 maize ('the application').

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of Bt11xMIR604xGA21 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with Article 5(5) and Article 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. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

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1 OJ L 268, 18.10.2003, p. 1.

2 OJ L 106, 17.4.2001, p. 1.

(3) On 15 June 2010, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003. It considered that maize Bt11xMIR604xGA21 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 Bt11xMIR604xGA21 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]. 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.

(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 those considerations, authorisation should be granted for the products.

(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[4].

(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 Bt11xMIR604xGA21 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 authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(8) 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 in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraph (1) to (5) of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(9) 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

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3 http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-00834

4 OJ L 10, 16.1.2004, p. 5.

5 OJ L 268, 18.10.2003, p. 24.

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[6]. 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.

(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) 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[7].

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

(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,

HAS ADOPTED THIS DECISION:

Article 1
Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) Bt11xMIR604xGA21, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9, 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-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize;

(b) feed containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize;

[6] OJ L 275, 21.10.2009, p. 9.
[7] OJ L 287, 5.11.2003, p. 1.

(c) products other than food and feed containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 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-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 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 the Commission 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 S.A.S. 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 S.A.S., Chemin de l'Hobit 12, BP 27 – F-31790 Saint-Sauveur - France.

Done at Brussels,

For the Council,
The President

ANNEX

(a) Applicant and Authorisation holder:

Name: Syngenta Seeds S.A.S.

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

On behalf of Syngenta Crop Protection AG - Schwarzwaldallee 215 - CH 4058 Basle - Switzerland

(b) Designation and specification of the products:

(1) foods and food ingredients containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize;

(2) feed containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize;

(3) products other than food and feed containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9maize, as described in the application, is produced by crosses between maize containing SYN-BTØ11-1, SYN-IR6Ø4-5 and MON-ØØØ21-9 events and expresses the Cry1Ab protein which confers protection against certain lepidopteran pests, the PAT protein which confers tolerance to glufosinate-ammonium herbicides, the Cry3A protein which provides protection against certain coleopteran pests and the mEPSPS protein which confers tolerance to glyphosate herbicide. A *pmi* gene, which allows transformed maize cells to utilize mannose as a sole carbon source, was used as a selectable marker in the genetic modification process for SYN-IR6Ø4-5 event.

(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-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9 maize referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection:

– Event specific real-time quantitative PCR based methods for genetically modified maize SYN-BTØ11-1, SYN-IR6Ø4-5 and MON-ØØØ21-9 maize validated on SYN-BTØ11-1xSYN-IR6Ø4-5 xMON-ØØØ21-9 maize;

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

– Reference Material: ERM®-BF412 (for SYN-BTØ11-1) and ERM®-BF423 (for SYN-IR6Ø4-5) 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 and AOCS 0407-A, AOCS 0407-B (for MON-ØØØ21-9) accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm.

(e) Unique identifier:

SYN-BTØ11-1xSYN-IR6Ø4-5xMON-ØØØ21-9.

(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.