Commission Decision of 28 March 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2008) 1112) (Only the French text is authentic) (2008/280/EC)

COMMISSION DECISION

of 28 March 2008

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document number C(2008) 1112)

(Only the French text is authentic)

(2008/280/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 Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 29 July 2005, Syngenta Seeds S.A.S., on behalf of Syngenta Crop Protection AG, submitted to the competent authorities of the United Kingdom 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 GA21 maize.

(2) That application also covers the placing on the market of other products containing or consisting of GA21 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with the provision 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 17 April 2007, Syngenta Seeds S.A.S., on behalf of Syngenta Crop Protection AG, submitted to the Commission an application, in accordance with Articles 8(4) and 20(4) of Regulation (EC) No 1829/2003, for the authorisation of existing products produced

from GA21 maize (food additives, feed materials and feed additives produced from GA21 maize).

(4) On 2 October 2007, the European Food Safety Authority (EFSA) gave a single comprehensive favourable opinion for both applications 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 GA21 maize as described in the applications (the products) will have adverse effects on human or animal health or the environment[3]. In its opinion, EFSA considered all specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities provided for by Articles 6(4) and 18(4) of that Regulation.

(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 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].

(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 GA21 maize. However, in order to ensure the use of the products within the limits of 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[5], 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[6].

(13) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion within the time limit laid down by its Chairman. The Commission therefore submitted to the Council a proposal relating to these measures.

(14) At its meeting on 18 February 2008, 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 and that the Commission could finalise the decision-making process. It is accordingly for the Commission to adopt the measures,

HAS ADOPTED THIS DECISION:

Article 1 U.K.

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) GA21, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØØ21-9, as provided for in Regulation (EC) No 65/2004.

Article 2 U.K.

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 MON-ØØØ21-9 maize;

(b) feed containing, consisting of, or produced from MON-ØØØ21-9 maize;

(c) products, other than food and feed, containing or consisting of MON-ØØØ21-9 maize for the same uses as any other maize with the exception of cultivation.

Article 3 U.K.

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 ‘maize’.

2 The words ‘not for cultivation’ shall appear on the label of and in documents accompanying products containing or consisting of MON-ØØØ21-9 maize referred to in Article 2(b) and (c).

Article 4 U.K.

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.

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.

Article 5 U.K.

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 U.K.

Authorisation holder

The authorisation holder shall be Syngenta Seeds S.A.S., France, representing Syngenta Crop Protection AG, Switzerland.

Article 7 U.K.

Validity

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

Article 8 U.K.

Addressee

This Decision is addressed to Syngenta Seeds S.A.S., Chemin de l’Hobit 12, BP 27, F-31790 Saint-Sauveur, France.

Done in Brussels, 28 March 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX U.K.

(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: U.K.

(1) Foods and food ingredients containing, consisting of, or produced from MON-ØØØ21-9 maize;

(2) Feed containing, consisting of, or produced from MON-ØØØ21-9 maize;

(3) Products other than food and feed containing or consisting of MON-ØØØ21-9 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified maize MON-ØØØ21-9, as described in the application, expresses the mEPSPS protein which confers tolerance to herbicide glyphosate

(c) Labelling: U.K.

(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 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-ØØØ21-9 maize referred to in Article 2(b) and (c).

(d) Method for detection: U.K.

— Event specific real-time quantitative PCR based methods for genetically modified maize MON-ØØØ21-9,

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

— Reference Material: AOCS 0407-A and AOCS 0407-B accessible via the American Oil Chemists Society (AOCS) at http://www.aocs.org

(e) Unique identifier: U.K.

MON-ØØØ21-9

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity: U.K.

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: U.K.

Not required.

(h) Monitoring plan U.K.

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 U.K.

Not required.

Note: links to relevant documents may need to be modified overtime. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

(**1**) OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).

(**2**) OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

(**3**) http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_1178620785956.htm

(**4**) OJ L 10, 16.1.2004, p. 5.

(**5**) OJ L 268, 18.10.2003, p. 24.

(**6**) OJ L 287, 5.11.2003, p. 1.

Changes to legislation:
There are outstanding changes not yet made to Commission Decision of 28 March 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2008) 1112) (Only the French text is authentic) (2008/280/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Annex Note word omitted by S.I. 2019/705 reg. 94
- Art. 4(2) words substituted by S.I. 2019/705 reg. 91
- Art. 5 heading substituted by S.I. 2019/705 reg. 92
- Art. 5 word omitted by S.I. 2019/705 reg. 93