COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.12.2007
COM(2007) 814 final

Proposal for a

COUNCIL DECISION

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON863xNK603 (MON-ØØ863-5xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(Only the French and Dutch texts are authentic)

(presented by the Commission)

EXPLANATORY MEMORANDUM

The attached proposal for a Council Decision concerns food and feed containing, consisting of, or produced from genetically modified maize MON863xNK603, for which a request for placing on the market was submitted by Monsanto Europe S.A. to the competent authorities of The United Kingdom on 22 October 2004, under Regulation (EC) No 1829/2003 on genetically modified food and feed.

The attached proposal also concerns the placing on the market of other products containing or consisting of maize MON863xNK603 for the same uses as any other maize with the exception of cultivation.

On 31 Mars 2006, the European Food Safety Authority ('EFSA') gave a favourable opinion 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 maize MON863xNK603 as described in the application will have adverse effects on human or animal health or the environment[1].

In October 2006, EFSA published detailed clarifications on how the comments of the competent authorities of the Member States had been taken into account in its opinion.

On 13 April 2007, EFSA reconfirmed that the use of the *nptII* gene as a selectable marker in GM plants does not pose a risk to human or animal health or the environment.
On 28 June 2007, following a scientific publication regarding a re-analysis of the MON 863 90-day rat study and questioning the safety of MON 863, EFSA confirmed its earlier favourable safety assessment on MON 863 maize.

Against this background, a draft Commission Decision authorising the placing on the Community market of products containing, consisting of, or produced from genetically modified maize MON863xNK603 was submitted to the Standing Committee on the Food Chain and Animal Health, on 10 October 2007, for vote. The Committee delivered no opinion: twelve Member States (149 votes) voted in favour, eleven Member States (119 votes) voted against and four Member States (77 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.

[1] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_1178620784791.htm

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(Only the French and Dutch texts are authentic)

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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[2], and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 22 October 2004, Monsanto Europe S.A., 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 MON863xNK603 maize ('the application').

(2) The application also covers the placing on the market of other products containing or consisting of MON863xNK603 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[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.

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2 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).

3 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) On 31 March 2006, the European Food Safety Authority ('EFSA') gave a favourable opinion 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 MON863xNK603 maize as described in the application ('the products') will have adverse effects on human or animal health or the environment[4]. In its opinion, EFSA concluded that it was acceptable to use the data for the single events in support of the safety of the products and 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.

(4) In October 2006, upon request of the Commission, EFSA published detailed clarifications on how the comments of the competent authorities of the Member States had been taken into account in its opinion and also published further information on the different elements considered by the Scientific Panel on Genetically Modified Organisms of EFSA.

(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) On 25 January 2007, following comments from the public and a report published by the World Health Organisation listing kanamycin and neomycin as 'critically important antibacterial agents for human medicine and for risk management strategies of non-human use', the Commission consulted the European Medicines Agency (EMEA) regarding the therapeutic relevance in human and veterinary medicine of antibiotics for which *nptII* gene allows resistance. Upon reception of the answer of EMEA, the Commission consulted EFSA regarding the safety assessments of *nptII* gene and GM plants comprising the *nptII* gene. On 13 April 2007, EFSA confirmed its earlier safety assessments of GM plants comprising the *nptII* gene concluding that the presence of the *nptII* gene in GM plants for food and feed uses does not pose a risk to human or animal health or to the environment.

(7) On 15 March 2007, following a scientific publication regarding a re-analysis of the MON 863 90-day rat study and questioning the safety of MON 863 maize, the Commission consulted EFSA on what impact this analysis study might have on its earlier opinion on MON 863 maize. On 28 June 2007, EFSA indicated that the publication does not raise new issues which are toxicologically relevant and confirmed its earlier favourable safety assessment on MON 863 maize.

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

(9) 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[5].

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4 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_1178620784791.htm

5 OJ L 10, 16.1.2004, p. 5.

(10) 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 MON863xNK603 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.

(11) 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. 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.

(12) 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[6], lays down labelling requirements for products consisting of or containing GMOs.

(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[7].

(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 and the measures provided for in this Decision must therefore be adopted by the Council,

HAS ADOPTED THIS DECISION:

Article 1
Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON863xNK603 produced by crosses between maize containing MON-ØØ863-5 and MON-ØØ6Ø3-6 events, as specified in point (b) of the Annex to this Decision is assigned the unique identifier MON-ØØ863-5xMON-ØØ6Ø3-6, as provided for in Regulation (EC) No 65/2004.

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6 OJ L 268, 18.10.2003, p. 24.
7 OJ L 287, 5.11.2003, p. 1.

Article 2
Authorisation and placing on the market

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003, according with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-ØØ863-5xMON-ØØ6Ø3-6 maize;

(b) feed containing, consisting of, or produced from MON-ØØ863-5xMON-ØØ6Ø3-6 maize;

(c) products, other than food and feed, containing or consisting of MON-ØØ863-5xMON-ØØ6Ø3-6 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 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-ØØ863-5xMON-ØØ6Ø3-6 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 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
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 Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

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 Monsanto Europe S.A., Scheldelaan 460, Haven 627 – B 2040 Antwerp - Belgium.

Done at Brussels,

For the Council
The President

ANNEX

(a) Applicant and Authorisation holder:

Name: Monsanto Europe S.A.

Address: Scheldelaan 460, Haven 627 – B 2040 Antwerp – Belgium

On behalf of Monsanto Company - 800 N. Lindbergh Boulevard – St. Louis, Missouri 63167 - United States of America

(b) Designation and specification of the products:

(1) Foods and food ingredients containing, consisting of, or produced from MON-ØØ863-5xMON-ØØ6Ø3-6 maize;

(2) Feed containing, consisting of, or produced from MON-ØØ863-5xMON-ØØ6Ø3-6 maize;

(3) Products other than food and feed containing or consisting of MON-ØØ863-5xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified maize MON-ØØ863-5xMON-ØØ6Ø3-6, as described in the application, is produced by crosses between maize containing MON-ØØ863-5 and MON-ØØ6Ø3-6 events and expresses the CryBb1 protein which confers protection against certain coleopteran insect pests (*Diabrotica* spp.) and the CP4 EPSPS protein which confers tolerance to herbicide glyphosate. An *nptII* gene, conferring kanamycin resistance, was used as a selectable marker in the genetic modification process.

(c) 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-ØØ863-5xMON-ØØ6Ø3-6 maize referred to in Article 2(b) and (c).

(d) Method for detection:

– Event specific real-time quantitative PCR based methods for genetically modified maize MON-ØØ863-5 and MON-ØØ6Ø3-6 validated on MON-ØØ863-5xMON-ØØ6Ø3-6 maize.

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

– Reference Material: ERM®-BF416 (for MON-ØØ863-5) and ERM®-BF415 (for MON-ØØ6Ø3-6) accessible via the Joint Research Centre (JRC) of the

European Commission, the Institute of Reference Materials and Measurements (IRMM) at
http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

(e) Unique identifier:

MON-ØØ863-5xMON-ØØ6Ø3-6

(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.