



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.7.2005
COM(2005)346 final

Proposal for a

COUNCIL DECISION

authorising the placing on the market of foods and food ingredients produced from genetically modified Roundup Ready maize line GA21 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

(presented by the Commission)

EXPLANATORY MEMORANDUM

The attached draft Council Decision concerns foods and food ingredients produced from genetically modified maize line GA21, for which a request for placing on the market was submitted by Monsanto to the competent authorities of the Netherlands on 24 July 1998, under Regulation (EC) No 258/97.

Following the initial assessment report from the Netherlands, who considered GA21 maize as safe as conventional maize, reasoned objections were raised by some Member States. These objections were referred to the Scientific Committee on Foods which delivered the opinion, on 27 February 2002, that GA21 maize is as safe as conventional maize. The detection method was validated and published by the Joint Research Centre (JRC) on 17 January 2005.

The original application of Monsanto concerned food and food ingredients derived from genetically modified organisms. On 24 April 2002, Monsanto asked to limit the request to food and food ingredients produced from genetically modified organisms.

Regulation (EC) No 1829/2003 on GM food and feed is applicable from 18 April 2004. In the light of Article 46(1) of this Regulation, requests submitted under Regulation (EC) No 258/97 before 18 April 2004 and for which an additional assessment report has been transmitted to the Commission before that date, shall be processed under Regulation (EC) No 258/97.

Against this background, a draft Commission Decision to place food and food ingredients produced from modified maize line GA21 on the Community market was submitted to the Standing Committee on Food Chain and Animal Health, on 27 April 2005, for vote. Nine Member States voted in favour, five Member States voted against and eight Member States abstained. Three Member States were not present.

The Committee delivered no opinion. Consequently, pursuant to Article 13, paragraph 4 b) of Regulation (EC) No 258/97 and in accordance with Article 5 of Council Decision 1999/468/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. The European Parliament was informed on 28 April 2005.

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(Only the French and Dutch texts are authentic)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients¹, and in particular Article 7 thereof,

Having regard to the proposal of the Commission,

Whereas:

- (1) On 24 July 1998, Monsanto submitted to the competent authorities of the Netherlands a request, in accordance with Article 4 of Regulation (EC) No 258/97, for placing on the market foods and food ingredients derived from genetically modified maize line GA21 as novel foods or novel food ingredients.
- (2) In its initial assessment report of 21 December 1999, the Netherlands' competent food assessment body came to the conclusion that GA21 maize and foodstuffs and food ingredients made from it are as safe to eat as maize and maize products that have not been genetically modified.
- (3) The Commission forwarded the initial assessment report to all Member States on 18 February 2000. Within the 60-day period laid down in Article 6 (4) of Regulation (EC) No 258/97, reasoned objections to the marketing of the product were raised in accordance with that provision.
- (4) On 18 May 2000, the Commission requested an opinion from the Scientific Committee on Foods (SCF) in accordance with Article 11 of Regulation (EC) No 258/97. On 27 February 2002 the SCF delivered its opinion that from the point of view of consumer health, GA21 maize and derived products are as safe as grain and derived products from conventional maize lines. In delivering its opinion the SCF considered all specific questions and concerns raised by the Member States.

¹ OJ L 43, 14.2.1997, p. 1

- (5) On 24 April 2002, Monsanto asked to limit the request to food and food ingredients produced from genetically modified organisms.
- (6) With respect to the use of the product as or in feed, Monsanto submitted, on 12 December 1997, a notification under Part C of Directive 90/220/EEC². The opinion adopted on 22 September 2000 by the Scientific Committee on Plants concluded that there is no evidence to indicate that the placing on the market of GA21 maize for this use is likely to cause any adverse effects on human health and the environment. However, the application was withdrawn for commercial reasons.
- (7) Article 46(1) of Regulation (EC) No 1829/2003 on genetically modified food and feed³ provides that requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation shall be processed under the provisions of Regulation (EC) No 258/97, notwithstanding Article 38 of Regulation (EC) No 1829/2003, in cases where the additional assessment report required in accordance with Article 6(3) or 6(4) of Regulation (EC) No 258/97 has been transmitted to the Commission before the date of application of Regulation (EC) No 1829/2003.
- (8) The Joint Research Centre of the European Commission (JRC) in collaboration with the European Network of GMO Laboratories (ENGL), has validated a method for detection of GA21 maize. The JRC has carried out a full validation study (ring-trial) following internationally accepted guidelines to test the performance of a quantitative event-specific method to detect and quantify the GA21 transformation event in maize. The materials needed in the study had been provided by Monsanto. The JRC has considered that the method performance was appropriate for its aimed purpose, taken into account the performance criteria proposed by the ENGL for methods submitted for regulatory compliance as well as the current scientific understanding about satisfactory method performance. Both the method and the results of the validation have been published by the JRC.
- (9) Reference material for GA21 maize has been produced by the JRC.
- (10) Food and food ingredients from GA21 maize should be labelled in accordance with the provisions of Regulation (EC) No 1829/2003 and should be subject to the traceability requirements laid down in Regulation (EC) No 1830/2003 of the European Parliament and 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/EC⁴.
- (11) In accordance with Commission Regulation (EC) No 65/2004⁵, a unique identifier has been assigned to the product for the purposes of Regulation (EC) No 1830/2003.
- (12) Information, contained in the Annex, on the identification of foods and food ingredients produced from GA21 maize, including the validated detection method and

2 OJ L 117, 08.5.1990, p. 15-27

3 OJ L268, 18.10.2003, p. 1

4 OJ L268, 18.10.2003, p. 24

5 OJ L10, 16.1.2004, p. 5

the reference material, should be retrievable from the Register referred to in Article 28 of Regulation (EC) No 1829/2003.

- (13) The Standing Committee on the Food Chain and Animal Health has not given an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Foods and food ingredients produced from genetically modified maize line GA21 (hereinafter referred to as “the products”), as designated and specified in the Annex, may be placed on the Community market as novel foods or novel food ingredients.

Article 2

The products shall be labelled as “genetically modified maize” or “produced from genetically modified maize” in accordance with the labelling requirements laid down in Article 13 of Regulation (EC) No 1829/2003.

Article 3

The products and the information included in the Annex shall be entered in the Community Register of genetically modified food and feed.

Article 4

This Decision is addressed to Monsanto Europe S.A., Belgium, representing Monsanto Company, U.S.A. It shall be valid for a period of 10 years.

Done at Brussels,

For the Council
The President

ANNEX

INFORMATION TO BE ENTERED IN THE COMMUNITY REGISTER OF GENETICALLY MODIFIED FOOD AND FEED

(1) Applicant and authorisation holder:

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, B-1150 Brussels, Belgium

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard St. Louis, Missouri 63167, U.S.A.

(2) Designation and specification of the products

Foods and food ingredients produced from genetically modified maize (*Zea mays* L.) line GA21 with increased tolerance to the herbicide glyphosate and from all its crosses with traditionally bred maize lines. GA21 maize contains the modified 5-enolpyruvylshikimate-3-phosphate synthase (mEPSPS) coding sequence under the regulation of the rice actin 1 promoter (r-act) and an optimised transit peptide (OPT) sequence based on chloroplast transit peptide sequences from *Helianthus annuus* and the RuBisCo gene from *Zea mays* L.

(3) Labelling:

“Genetically modified maize” or “produced from genetically modified maize”

(4) Method for detection:

- Event specific real-time quantitative PCR based method for genetically modified maize line GA21.
- Validated by the Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), published at <http://gmo-crl.jrc.it/statusofdoss.htm>.
- Reference Material: IRMM-414 produced by the Joint Research Centre (JRC) of the European Commission.

(5) Unique identifier:

MON- 00021-9

(6) Information required under Annex II to the Cartagena Protocol:

Not applicable

(7) Conditions or restrictions for the placing on the market of the product:

Not applicable

(8) Post market monitoring requirements:

Not applicable