



**COUNCIL OF
THE EUROPEAN UNION**

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(OR. fr)**

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PROPOSAL

from: European Commission

dated: 28 June 2004

Subject: Proposal for a Council Decision authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mrs Patricia BUGNOT, Director, to Mr Javier SOLANA, Secretary-General/High Representative.

Encl.: COM(2004) 439 final



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.6.2004
COM(2004) 439 final

Proposal for a

COUNCIL DECISION

authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 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

On 24 April 2001, Monsanto submitted, under Article 4 of the Novel Food Regulation (EC) N° 258/97, a request to the competent authorities of the Netherlands for the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or as novel food ingredients.

The initial assessment report from the Netherlands concluded that foods and food ingredients derived from genetically modified maize line NK 603 were as safe as foods and food ingredients derived from conventional maize and may be used in the same manner but other Member States raised reasoned objections to their placing on the market. Therefore an authorisation Decision via comitology procedure was required in accordance with Article 7 (1) of Regulation (EC) No 258/97. In view of the Member States' objections, the Commission requested an opinion from the European Food Safety Authority, which was delivered on 25 November 2003 and concluded that NK 603 maize is as safe as conventional maize and therefore its placing on the market for food or feed or processing is unlikely to have an adverse effect on human and animal health and, in that context, the environment¹.

Against this background, a draft Commission Decision to place food and food ingredients derived from genetically modified maize line NK 603 on the Community market was submitted to the Standing Committee on Food Chain and Animal Health, on 30 April 2004, for vote. The result of the vote was as follows:

50 votes in favour: (BE, FR, IE, IT, NL, FI, SE, UK)

19 votes against: (DK, EL, LU, AT, PT)

18 votes through abstention: (DE, ES)

The Committee failed to deliver, by qualified majority, an opinion on the draft submitted by the Commission. 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 must without delay 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 European Parliament, which may consider appropriate to take a position in accordance with Article 8 of the above Decision.

In accordance with Article 46 of Regulation (EC) No 1829/2003 on genetically modified food and feed, the authorisation in case must be granted under the provisions of Regulation (EC) No 258/97. However, in order take into account the new legislative framework for the authorisation of genetically modified food and feed, the Commission proposal includes also the particulars required by Article 6, paragraph 5 and Article 7, paragraph 2 of Regulation (EC) No 1829/2003.

¹ The EFSA Journal (2003) 9, 1-14.

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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 ingredients² (hereinafter referred to as the Regulation), and in particular Article 7 thereof,

Having regard to the proposal of the Commission,

Whereas:

- (1) On 24 April 2001, Monsanto submitted to the competent authorities of the Netherlands a request, in accordance with Article 4 of the Regulation, for placing on the market foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or as novel food ingredients.
- (2) In their initial assessment report of 5 November 2002, the Netherlands' competent food assessment body came to the conclusion that foods and food ingredients derived from maize NK603 are as safe as foods and food ingredients derived from conventional maize and may be used in the same manner.
- (3) The Commission forwarded the initial assessment report to all Member States on 6 January 2003. Within the 60 days period laid down in Article 6 (4) of the Regulation, reasoned objections to the marketing of the product were raised in accordance with that provision.
- (4) On 27 August 2003, the Commission requested an opinion from the European Food Safety Authority (EFSA), in accordance with Article 11 of the Regulation. On 25 November 2003, EFSA delivered its opinion that NK 603 maize is as safe as conventional maize and therefore the placing on the market of NK603 maize for food or feed or processing is unlikely to have an adverse effect on human and animal health and, in that context, the environment³. In delivering its opinion, the EFSA considered all specific questions and concerns raised by the Member States.

² OJ L 43, 14.2.1997, p. 1.

³ The EFSA Journal (2003) 9, 1-14.

- (5) Article 46(1) of Regulation (EC) No 1829/2003 on genetically modified food and feed⁴ 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) of Regulation (EC) No 258/97 has been transmitted to the Commission before the date of application of Regulation (EC) No 1829/2003.
- (6) 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 the NK603 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 NK603 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 made publicly available.
- (7) Reference material for maize from genetically modified maize line NK603 has been produced by the Joint Research Centre (JRC) of the European Commission.
- (8) Food and food ingredients from genetically modified maize line NK 603 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 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/EC⁵.
- (9) In accordance with Commission Regulation (EC) No 65/2004, a unique identifier has been assigned to the product for the purposes of Regulation (EC) No 1830/2003.
- (10) Information, contained in the Annex, on the identification of foods and food ingredients derived from genetically modified maize line NK603, including the validated detection method and the reference material, should be retrievable from the Register referred to in Article 28 of Regulation (EC) No 1829/2003.
- (11) The Standing Committee on the Food Chain and Animal Health has not given a favourable opinion.

⁴ OJ L 268, 18.10.2003, p. 1.

⁵ OJ L 268, 18.10.2003, p. 24.

HAS ADOPTED THIS DECISION:

Article 1

Foods and food ingredients derived from genetically modified maize line NK603 (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) N° 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, Avenue de Tervuren 270-272, B-1150 Brussels, 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

(a) 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.

(b) Designation and specification of the products:

Foods and food ingredients derived from genetically modified maize (*Zea mays* L.) line NK603 with increased tolerance to the herbicide glyphosate and from all its crosses with traditionally bred maize lines. Maize line NK 603 contains the following DNA sequences in two intact cassettes:

- A 5-enolpyruvylshikimate-3-phosphate synthase (*epsps*) gene derived from *Agrobacterium spec.* strain CP (CP4 EPSPS), which imparts tolerance to glyphosate, under the regulation of the rice actin 1 gene promoter, terminator sequence from *Agrobacterium tumefaciens* and the chloroplast transit peptide sequence from the *epsps* gene of *Arabidopsis thaliana*.
- A 5-enolpyruvylshikimate-3-phosphate synthase (*epsps*) gene derived from *Agrobacterium spec.* strain CP (CP4 EPSPS), which imparts tolerance to glyphosate, under the regulation of an enhanced 35S promoter derived from cauliflower mosaic virus, terminator sequence from *Agrobacterium tumefaciens* and the chloroplast transit peptide sequence from the *epsps* gene of *Arabidopsis thaliana*.

(c) Labelling: “Genetically modified maize” or “produced from genetically modified maize”

(d) Method for detection:

- Event specific real-time quantitative PCR based method for genetically modified NK 603 maize.
- Validated by the Joint Research Centre (JRC) of the European Commission, in collaboration with the European Network of GMO Laboratories (ENGL), to be published at <http://engl.jrc.it/crl/oj/nk603.pdf>.
- Reference Material: IRMM-415 produced by the Joint Research Centre (JRC) of the European Commission.

(e) Unique identifier: MON-00603-6

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

Not applicable

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

Not applicable

(h) Post market monitoring requirements

Not appropriate