

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 3 March 2005

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

(notified under document number C(2005) 580)

(Only the French and Dutch texts are authentic)

(2005/448/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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 ingredients ⁽¹⁾, (hereinafter referred to as the Regulation), and in particular Article 7 thereof,

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 NK 603 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 NK 603 maize for food or feed or processing is unlikely to have an adverse effect on human and animal health and, in that context, the environment ⁽²⁾. In delivering its opinion, the EFSA considered all specific questions and concerns raised by the Member States.

(5) Article 46(1) of Regulation (EC) No 1829/2003 on genetically modified food and feed ⁽³⁾ 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.

⁽¹⁾ OJ L 43, 14. 2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ The EFSA Journal (2003) 9, 1-14.

⁽³⁾ OJ L 268, 18.10.2003, p. 1.

- (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 NK 603 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 NK 603 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 NK 603 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/EC⁽¹⁾.
- (9) In accordance with Commission Regulation (EC) No 65/2004⁽²⁾, 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 NK 603, 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 an opinion; the Commission has therefore submitted a proposal to the Council on 4 February 2004 pursuant to Article 13(b) of Regulation (EC) No 258/97 and in accordance with Article 5(4) of the Council Decision 1999/468/EC⁽³⁾, the Council being required to act within three months.
- (12) However, the Council has not acted within the required time-limit; a Decision should now be adopted by the Commission.

HAS ADOPTED THIS DECISION:

Article 1

Foods and food ingredients derived from genetically modified maize line NK 603 (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 SA, Avenue de Tervuren 270-272, B-1150 Brussels, Belgium, representing the Monsanto Company, United States of America. It shall be valid for a period of 10 years.

Done at Brussels, 3 March 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 10, 16.1.2004, p. 5.

⁽³⁾ OJ L 184, 17.7.1999, p. 23.

ANNEX

INFORMATION TO BE ENTERED IN THE COMMUNITY REGISTER OF GENETICALLY MODIFIED FOOD AND FEED**(a) Authorisation holder:**

Name: Monsanto Europe SA

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

Foods and food ingredients derived from genetically modified maize (*Zea mays* L.) line NK 603 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://gmo-crl.jrc.it/statusofdoss.htm>.
- 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.
