



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.7.2005  
COM(2005) 338 final

Proposal for a

**COUNCIL DECISION**

**authorising the placing on the market of foods and food ingredients derived from  
genetically modified maize line MON 863 as novel foods or novel food ingredients under  
Regulation (EC) No 258/97 of the European Parliament and of the Council**

## **EXPLANATORY MEMORANDUM**

The attached draft Council Decision concerns foods and food ingredients derived from genetically modified maize line MON 863, for which a request for placing on the market was submitted by Monsanto to the competent authorities of Germany on 15 July 2002, under Regulation (EC) No 258/97.

Following the initial assessment report from Germany, who came to the conclusion that an additional assessment was required because of the presence of an antibiotic resistance marker gene (*nptII*) used in the product concerned, reasoned objections were raised by some Member States. These objections were referred to the European Food Safety Authority which delivered the opinion, on 2 April 2004, that MON 863 maize is as safe as conventional maize. The detection method was validated by the Joint Research Centre (JRC).

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 MON 863 on the Community market was submitted to the Standing Committee on Food Chain and Animal Health, on 19 May 2005, for vote. Ten Member States voted in favour, eight Member States voted against and six Member States abstained. One Member State was 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, and inform the Parliament.

Proposal for a

## COUNCIL DECISION

**authorising the placing on the market of foods and food ingredients derived from genetically modified maize line MON 863 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council**

**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 ingredients<sup>1</sup>, and in particular Article 7 thereof,

Having regard to the proposal of the Commission,

Whereas:

- (1) On 15 July 2002, Monsanto submitted to the competent authorities of Germany 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 MON 863 (hereinafter referred to as MON 863 maize) as novel foods or novel food ingredients, in accordance with Regulation (EC) No 258/97.
- (2) In its initial assessment report of 8 April 2003, Germany's competent food assessment body came to the conclusion that an additional assessment was required because of the presence of an antibiotic resistance marker gene (*nptII*) used in the product concerned.
- (3) The Commission forwarded the initial assessment report to all Member States on 3 June 2003 with additional comments raised by the Member States.
- (4) On 9 December 2003 the Commission requested a scientific opinion from the European Food Safety Authority (EFSA) in accordance with Article 11 of the Regulation. On 2 April 2004 the EFSA delivered its opinion that from the point of view of consumer health, MON 863 maize and derived products are as safe as grain and derived products from conventional maize lines. In delivering its opinion the EFSA addressed all specific questions and concerns raised by the Member States.
- (5) Article 46(1) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed<sup>2</sup> provides that

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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 OJ L 268, 18.10.2003, p. 1.

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.

- (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 MON 863 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 MON 863 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 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 MON 863 maize has been produced by the JRC.
- (8) Food and food ingredients from MON 863 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 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<sup>3</sup>.
- (9) In accordance with Commission Regulation (EC) No 65/2004<sup>4</sup>, 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 MON 863 maize, 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) On the basis of the information available, it is established that MON 863 maize complies with criteria laid down in Regulation (EC) No 258/97.
- (12) The Standing Committee on the Food Chain and Animal Health has not given an opinion,

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3 OJ L 268, 18.10.2003, p. 24.

4 OJ L 10, 16.01.2004, p. 5.

HAS ADOPTED THIS DECISION:

*Article 1*

Foods and food ingredients derived from genetically modified maize line MON 863 (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 derived from genetically modified maize (*Zea mays* L.) line MON 863 with increased protection to insects and from all its crosses with traditionally bred maize lines. MON 863 maize contains two cassettes:

(a) Cassette 1:

A modified *cry3Bb1* gene derived from *Bacillus thuringiensis* subsp. *kumamotoensis*, which confers resistance to the corn rootworm *Diabrotica spp.*, under the regulation of the 4AS1 promoter derived from *Cauliflower Mosaic Virus*, the wtCAB translation enhancer from wheat (*Triticum aestivum*), the transcription enhancer *ract1* intron from the actin 1 gene of rice (*Oryza sativa*) and terminator sequences tahsp 17 3' from wheat.

(b) Cassette 2:

The *nptII* gene from *E. coli*, which confers resistance to aminoglycosides comprising kanamycin and neomycin, under the regulation of the 35S *Cauliflower Mosaic Virus* promoter, and the NOS 3' terminator sequences from *Agrobacterium tumefaciens* as well as the non-functional, truncated *ble* gene from *E. coli*.

**(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 MON 863.
- 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-416 produced by the Joint Research Centre (JRC) of the European Commission.

**(5) Unique identifier:**

MON- 00863-5

**(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