



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.11.2005
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Proposal for a

COUNCIL DECISION

concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., hybrid MON 863 x MON 810) genetically modified for resistance to corn rootworm and certain lepidopteran pests of maize

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. In accordance with Article 13 of Directive 2001/18/EC, the German authorities received a notification (Reference C/DE/02/9) concerning the placing on the market of a maize product (*Zea mays* L., hybrid MON 863 x MON 810), genetically modified for resistance to corn rootworm and certain lepidopteran pests of maize.
2. The notification originally covered importation and use as for any other maize grains including feed, with the exception of food use and cultivation. In July 2005 Monsanto Europe S.A. agreed to limit the scope of the notification to import and processing, given that the placing on the market of feed products containing, consisting of, or produced from MON 863 x MON 810 maize was covered in its application under Regulation (EC) No 1829/2003.
3. In accordance with Article 14 of the Directive, the German competent authority forwarded to the Commission its assessment report of the notification, which concluded that no reasons have emerged on the basis of which consent for the placing on the market of the *Zea mays* L. hybrid MON 863 x MON 810 should be withheld, provided that specific conditions are fulfilled.
4. The Commission forwarded the assessment report to all other Member States, some of which raised and maintained objections to the report in terms of molecular characterisation, allergenicity, toxicity, inadequate monitoring plan, accidental spillage, presence of an antibiotic resistance marker gene and detection of the product; whereby the Commission in accordance with Article 18 of Directive 2001/18/EC is required to take a decision in accordance with the procedure laid down in Article 30(2) of the Directive to which Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard the provisions of Article 8 thereof.
5. A draft of the measures to be taken was submitted, in accordance with Article 5(2) of Decision 1999/468/EC, for opinion, to the Committee set up under Article 30 of Directive 2001/18/EC.
6. The Committee has not delivered an opinion, which requires that the Commission, in accordance with Article 5(4) of Decision 1999/468/EC, must, without delay, submit to the Council a proposal relating to the measures to be taken and inform the European Parliament (informed on 22 September 2005), which may consider appropriate to take a position in accordance with Article 8 of the above Decision.
7. Article 5(6) of Decision 1999/468/EC provides that the Council may, where appropriate in view of any such position, act by qualified majority within a period set at three months in accordance with Article 30(2) of Directive 2001/18/EC. If within that three-month period, the Council has indicated by qualified majority that it opposes the proposal, the Commission shall re-examine it; whereas if, on expiry of that period, the Council has neither adopted the proposed implementing act nor indicated its opposition, then the proposed implementing act shall be adopted by the Commission.

Proposal for a

COUNCIL DECISION

concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., hybrid MON 863 x MON 810) genetically modified for resistance to corn rootworm and certain lepidopteran pests of maize

(Only the German text is authentic)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard 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 and repealing Council Directive 90/220/EEC¹, and in particular the first subparagraph of Article 18(1) thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority of a Member State, in accordance with the procedure laid down in that Directive.
- (2) A notification concerning the placing on the market of two genetically modified maize products (*Zea mays* L., line MON 863 and hybrid MON 863 x MON 810) was submitted by Monsanto Europe S.A. to the competent authority of Germany (Reference C/DE/02/9). A unique identifier (MON-ØØ863-5xMON-ØØ81Ø-6) has been assigned to the MON 863 x MON 810 maize for the purposes 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/EC² and Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms³.

¹ 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).

² OJ L 268, 18.10.2003, p.24.

³ OJ L 10, 16.01.2004, p. 5.

- (3) The notification originally covers importation and use as for any other maize grains including feed, with the exception of food use and cultivation in the Community of varieties derived from the MON 863 transformation event and of the MON 863 x MON 810 hybrid.
- (4) In accordance with the procedure provided for in Article 14 of Directive 2001/18/EC, the competent authority of Germany prepared an assessment report, which was submitted on 7 February 2003 to the Commission and the competent authorities of the other Member States. That assessment report concludes that no reasons have emerged on the basis of which consent for the placing on the market of MON 863 as well as MON 863 x MON 810 should be withheld, if specific conditions are fulfilled.
- (5) The competent authorities of other Member States raised objections to the placing on the market of MON 863 as well as MON 863 x MON 810.
- (6) The placing on the market of MON 810 maize is authorised in accordance with Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC⁴. The placing on the market of MON 863 is authorised in accordance with Commission Decision of 8 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line MON 863) genetically modified for resistance to corn rootworm⁵.
- (7) On 2 April 2004, the European Food Safety Authority considered that it is scientifically valid to use the data from the single lines MON 863 and MON 810 to support the safety assessment of MON 863 x MON 810, but decided, with regard to the need for confirmatory data for the safety assessment of the hybrid itself, to request a 90-day sub-chronic rat study with the maize hybrid in order to complete its safety assessment.
- (8) The opinion adopted on 8 June 2005 by the European Food Safety Authority, in accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁶, concluded, from all evidence provided, that MON 863 x MON 810 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed use. The European Food Safety Authority also found that the scope of the monitoring plan provided by the consent holder is in line with the intended uses of MON 863 x MON 810.
- (9) On 8 July 2005, Monsanto Europe S.A. agreed to limit the scope of the present Decision to import and processing. An application for the placing on the market of food and feed containing, consisting of, or produced from MON 863 x MON 810 has been made by Monsanto Europe S.A. under Regulation (EC) No 1829/2003.

⁴ OJ L 131/33, 05.05.98, p. 32.

⁵ OJ L 207, 10.08.2005, p 17.

⁶ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

- (10) An examination of the information submitted in the notification, the objections maintained by Member States in the framework of Directive 2001/18/EC, and the opinion of the European Food Safety Authority, discloses no reason to believe that the placing on the market of MON 863 x MON 810 will adversely affect human or animal health or the environment.
- (11) Adventitious or technically unavoidable traces of genetically modified organisms in products are exempted from labelling and traceability requirements in accordance with thresholds established under Directive 2001/18/EC and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁷.
- (12) In the light of the opinion of the European Food Safety Authority, it is not necessary to establish specific conditions for the intended uses with regard to the handling or packaging of the product and the protection of particular ecosystems, environments or geographical areas.
- (13) Prior to the placing on the market of the product, the necessary measures to ensure its labelling and traceability at all stages of its placing on the market, including verification by appropriate validated detection methodology, should be applicable.
- (14) The Committee established under Article 30 of Directive 2001/18/EC has not delivered an opinion on the measures laid down in a draft Commission Decision, following its consultation, on 19 September 2005, in accordance with the procedure laid down in Article 30(2) of that Directive,

HAS ADOPTED THIS DECISION:

Article 1
Consent

Without prejudice to other Community legislation, in particular Regulation (EC) No 258/97 and Regulation (EC) No 1829/2003, written consent shall be granted by the competent authority of Germany to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified by Monsanto Europe S.A. (Reference C/DE/02/9).

The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, which are set out in Articles 3 and 4.

Article 2
Product

The genetically modified organisms to be placed on the market as or in products, hereinafter 'the product', are grains of maize (*Zea mays* L. MON 863 x MON 810), obtained by conventional breeding of MON 863 and MON 810. Descriptions of the MON 810 and MON 863 maizes are provided for in Commission Decisions 1998/294/EC and 2005/608/EC respectively.

⁷ OJ L 268, 18.10.2003, p.1.

Article 3
Conditions for placing on the market

The product may be put to the same uses as any other maize, with the exception of cultivation and uses as or in food and feed, and may be placed on the market subject to the following conditions:

- (a) the period of validity of the consent shall be 10 years starting from the date on which the consent is issued;
- (b) the unique identifier of the product shall be MON-ØØ863-5xMON-ØØ81Ø-6;
- (c) without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall, whenever requested to do so, make positive and negative control samples of the product, or its genetic material, or reference materials available to the competent authorities and inspection services of Member States as well as to the Community control laboratories;
- (d) without prejudice to specific labelling requirements provided by Regulation (EC) No 1829/2003 the words ‘This product contains genetically modified maize’ or ‘This product contains genetically modified MON 863 x MON 810’ shall appear either on a label or in a document accompanying the product, except where other Community legislation sets a threshold below which such information is not required;
- (e) as long as the product has not been authorised for the placing on the market for the purpose of cultivation, the words ‘not for cultivation’ shall appear either on a label or in a document accompanying the product.

Article 4
Monitoring

1. Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan, contained in the notification and consisting of a general surveillance plan, the objective of which is to check for any adverse effects on human and animal health or the environment arising from handling or use of the product, is put in place and implemented.
2. The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the product and of the conditions as to monitoring, including the appropriate management measures to be taken in case of accidental grain spillage.
3. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of the monitoring activities.
4. Without prejudice to Article 20 of Directive 2001/18/EC the monitoring plan as notified shall, where appropriate and subject to the agreement of the Commission and the competent authority of the Member State which received the original notification, be revised by the consent holder and/or by the competent authority of the Member State which received the original notification, in the light of the results of the

monitoring activities. Proposals for a revised monitoring plan shall be submitted to the competent authorities of the Member States.

5. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:
 - (a) that the monitoring networks as specified in the monitoring plan contained in the notification collect the information relevant for the monitoring of the product and
 - (b) that the members of these networks have agreed to make available that information to the consent holder before the date of the submission of the monitoring reports to the Commission and competent authorities of the Member States in accordance with paragraph 3.

*Article 5
Applicability*

This Decision shall apply from the date on which a Community Decision authorising the placing on the market of the product referred to in Article 1 for uses as or in food and feed within the meaning of Regulation (EC) No 178/2002 and including a method, validated by the Community reference laboratory, for detection of the product is applicable.

*Article 6
Addressee*

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels,

*For the Council
The President*