COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26.04.2005
COM(2005)163 final

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. line MON 863) genetically modified for resistance to corn rootworm

(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/02/09) concerning the placing on the market of maize product (*Zea mays* L. line MON 863 and hybrid MON 863 x MON 810), genetically modified for resistance to different insects.

2. The notification covers importation and use as for any other maize grains including feed but not food use, with the exception of the cultivation in the Community of varieties derived from the MON 863 transformation event as well as with the exception of the cultivation in the Community of MON 863 x MON 810 hybrids.

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 MON 863 maize as well as MON 863 x MON 810 maize should be withheld, if 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 said report in terms of molecular characterisation, agronomic equivalence, sampling methods, antibiotic resistance marker gene, allergenicity, toxicity and monitoring of the product.

5. Since objections were maintained, the Commission decided to consult the European Food Safety Authority (EFSA). The EFSA concluded, in an opinion adopted on 2 April 2004, that from all evidence provided, the *Zea mays* L. line MON 863 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed use. The EFSA also found that the scope of the monitoring plan provided by the applicant is in line with the intended uses of MON 863.

6. Concerning hybrid MON 863 x MON 810, the EFSA 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 hybrid MON 863 x MON 810, but decided regarding 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. Thus, only the safety assessment of the maize line MON 863 has been finalised.

7. Under such circumstances, Article 18 of Directive 2001/18/EC requires the Commission 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 to the provisions of Article 8 thereof.

8. Since both the German authorities and the EFSA gave a positive assessment concerning the placing on the market of MON 863 maize, the Commission prepared a draft Decision authorising the use of this product, with the exception of cultivation and uses as or in food, and its placing on the market subject to specific conditions. Regarding hybrid MON 863 x MON 810, the Commission decided not to propose any decision pending the availability and assessment of the scientific information requested by EFSA.

9. The draft Decision 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.

10. The Committee has not delivered an opinion on 29 November 2004, which requires that, the Commission, in accordance with Article 5(4) of Decision 1999/468/EC, shall, without delay, submit to the Council a proposal relating to the measures to be taken and shall inform the European Parliament.

11. 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. line MON 863) genetically modified for resistance to corn rootworm

Text with EEA relevance)
(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/EEC[1], 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).

(3) The notification covers importation and use as for any other maize grains including feed but not food use, with the exception of the cultivation in the Community of varieties derived from the MON 863 transformation event as well as with the exception of the cultivation in the Community of MON 863 x MON 810 hybrids.

(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 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

[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)

which consent for the placing on the market of MON 863 maize as well as MON 863 x MON 810 maize 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 the product.

(6) The opinion adopted on 2 April 2004 by the European Food Safety Authority, concluded, from all evidence provided, that *Zea mays* L. line MON 863 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 applicant is in line with the intended uses of MON 863.

(7) Concerning hybrid MON 863 x MON 810, 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 hybrid MON 863 x MON 810, but decided regarding 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. Thus, only the safety assessment of the maize line MON 863 has been finalised.

(8) An examination of each of the objections in the light of Directive 2001/18/EC, of the information submitted in the notification and of the opinion of the European Food Safety Authority, discloses no reason to believe that the placing on the market of *Zea mays* L. line MON 863 will adversely affect human or animal health or the environment.

(9) A unique identifier should be assigned to the MON 863 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/EC[2] 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 organisms[3].

(10) 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 feed[4].

(11) 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.

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2 OJ L 268, 18.10.2003, p.24
3 OJ L 10, 16.01.2004, p. 5-10
4 OJ L 268, 18.10.2003, p.1

(12) 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.

(13) 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 29 November 2004, 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

1. The genetically modified organisms to be placed on the market as or in products, hereinafter 'the product', are grains of maize (*Zea mays* L.), with resistance to the corn rootworm (*Diabrotica spp.*), derived from the *Zea mays* cell culture line AT824 (initiated from immature embryos of an inbred maize line AT), which has been transformed using particle acceleration technology with a *Mlu*I DNA restriction fragment isolated from plasmid PV-ZMIR13.

   The product contains the following DNA in 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*.

2. The consent shall cover grains from progeny derived from crosses of maize line MON 863 with any traditionally bred maize as or in products.

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 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-ØØ863-5;

(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 organisms' or 'This product contains genetically modified MON 863 maize' 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, 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, users, national agencies for animal nutrition and feed research as well as veterinary services of the introduction of MON 863 maize into the Community as well as on the safety and general characteristics of the product and of the conditions as to monitoring.

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.

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 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