COMMISSION DECISION

of 3 November 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 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium

(notified under document number C(2005) 4192)

(Only the Dutch text is authentic)

(2005/772/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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,

After consulting the European Food Safety Authority,

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 a genetically modified maize product (*Zea mays* L., line 1507) was submitted by Pioneer Hi-Bred International, INC and Mycogen Seeds to the competent authority of the Netherlands (ref C/NL/00/10).

(3) The notification covers importation and use as for any other maize grains including feed, with the exception of cultivation and uses as or in food, in the Community, of varieties derived from the 1507 transformation event.

(4) In accordance with the procedure provided for in Article 14 of Directive 2001/18/EC, the competent authority of the Netherlands prepared an assessment report, which was submitted to the Commission and the competent authorities of the other Member States; whereby the assessment report concluded that no reasons have emerged on the basis of which consent for the placing on the market of *Zea mays* L. line 1507 should be withheld, provided that 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 24 September 2004 by the European Food Safety Authority, concluded that *Zea mays* L. line 1507 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 deemed that the monitoring plan provided by the applicant was in line with the intended uses of 1507 maize.

(7) 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 1507 will adversely affect human or animal health or the environment.

(8) A unique identifier should be assigned to the 1507 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].

(9) 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].

[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, 16.1.2004, p. 5.

[4] OJ L 268, 18.10.2003, p. 1.

(10) In view 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.

(11) 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.

(12) The measures provided for in this Decision are not in accordance with the opinion of the Committee established under Article 30 of Directive 2001/18/EC and the Commission therefore submitted to the Council a proposal relating to these measures. Since on the expiry of the period laid down in Article 30(2) of Directive 2001/18/EC the Council had neither adopted the proposed measures nor indicated its opposition to them in accordance with Article 5(6) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1] the measures should be adopted by the Commission;

HAS ADOPTED THIS DECISION:

Article 1

Consent

Without prejudice to other Community legislation, in particular Regulation (EC) No 258/97 of the European Parliament and of the Council [2] and Regulation (EC) No 1829/2003, written consent shall be granted by the competent authority of the Netherlands to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified by Pioneer Hi-Bred International, Inc. and Mycogen Seeds (Reference C/NL/00/10).

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 European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests and with tolerance to the herbicide glufosinate-ammonium, derived from *Zea mays* line 1507, which has been transformed using particle acceleration technology with the linear DNA fragment PHI8999A containing the following DNA in two cassettes:

(a) cassette 1:

a synthetic version of the truncated *cry*1F gene derived from *Bacillus thuringiensis* subsp. *aizawai*, which confers resistance to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests such as the pink borer (*Sesamia* spp.), fall armyworm (*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*) and southwestern corn borer (*Diatraea grandiosella*), under the regulation of the ubiquitin promoter *ubi*ZM1(2) derived from *Zea mays* and the ORF25PolyA terminator from *Agrobacterium tumefaciens* pTi15955;

(b) cassette 2:

a synthetic version of the *pat* gene derived from *Streptomyces viridochromogenes* strain Tü494, which confers tolerance to the herbicide glufosinate-ammonium, under the regulation of the 35S *Cauliflower Mosaic Virus* promoter and terminator sequences.

2. The consent shall cover grains from progeny derived from crosses of maize line 1507 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 DAS-Ø15Ø7-1;

(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;

[1] OJ L 184, 17.7.1999, p. 23.
[2] OJ L 43, 14.2.1997, p. 1.

(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 1507 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, and consisting of a general surveillance plan, 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 1507 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. 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 within the meaning of Regulation (EC) No 178/2002 of the European Parliament and of the Council [1] 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 Kingdom of the Netherlands.

Done at Brussels, 3 November 2005.

For the Commission
Stavros DIMAS
Member of the Commission

[1] OJ L 31, 1.2.2002, p. 1.