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► **M1** COMMISSION DECISION

of 3 March 2006

authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) and renewing the authorisation to place on the market feed produced from such maize, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council ◀

(2006/197/EC)

(OJ L 70, 9.3.2006, p. 82)

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(2006/197/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽¹⁾, and in particular Article 7(3) thereof,

Whereas:

- (1) On 15 February 2001, Pioneer Overseas Corporation and Dow AgroSciences Europe jointly submitted to the competent authorities of the Netherlands a request, in accordance with Article 4 of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽²⁾, for the placing on the market of foods and food ingredients derived from genetically modified maize line 1507 as novel foods or as novel food ingredients (the products).
- (2) In their initial assessment report of 4 November 2003, the Netherlands competent food assessment body concluded that the products are just as safe as foods and food ingredients derived from conventional maize lines and may be used in the same manner.
- (3) The Commission forwarded the initial assessment report to all Member States on 10 November 2003. Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97, reasoned objections to the placing on the market of the products were raised in accordance with that provision. As a consequence, an additional assessment report was required.
- (4) Article 46(1) of Regulation (EC) No 1829/2003 (hereinafter referred to as the Regulation) provides that requests submitted pursuant to Article 4 of Regulation (EC) No 258/97 before the date of application of the Regulation, i.e. 18 April 2004, shall be transformed into applications pursuant to Chapter II, Section 1 of the Regulation in cases where an additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ 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).

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- (5) The scope of Regulation (EC) No 258/97 is limited to the placing on the market, within the Community, of novel foods or novel food ingredients. Consequently the present decision does not cover the placing on the market of feed containing, consisting of or produced from maize line 1507.
- (6) In particular, the placing on the market of genetically modified maize line 1507 as or in some products including feed containing or consisting of this maize is subject to Commission Decision 2005/772/EC 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 ⁽¹⁾.
- (7) Feed produced from maize line 1507 has been placed on the market before the date of application of the Regulation, i.e. 18 April 2004. As a consequence, it is subject to the requirements provided for in Article 20 of the Regulation and may be placed on the market and used in accordance with the conditions laid down in the Community Register of genetically modified food and feed.
- (8) On 3 March 2005, the European Food Safety Authority (Authority) gave its opinion in accordance with Article 6 of the Regulation that there is no evidence to indicate that the placing on the market of the products is likely to cause adverse effects on human or animal health or the environment ⁽²⁾. In giving its opinion, the Authority considered all specific questions and concerns raised by the Member States.
- (9) Accordingly, the Authority advised that no specific labelling requirements other than those provided for in Article 13(1) of the Regulation are necessary. The Authority also advised that no specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements, and no specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) of the Regulation, are required.
- (10) In its opinion, the Authority concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended use of the products.
- (11) In the light of the above considerations, authorisation should be granted.
- (12) A unique identifier should be assigned to maize line 1507 as provided for in 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⁾.

⁽¹⁾ OJ L 291, 5.11.2005, p. 42.

⁽²⁾ http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/503/op_gm_07_ej182_1507_opinion_nl_doc2_en1.pdf

⁽³⁾ OJ L 10, 16.1.2004, p. 5.

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- (13) All information contained in the Annex to this Decision on the authorisation of the products should be entered in the Community Register of genetically modified food and feed as provided for in the Regulation.
- (14) In accordance with Article 4(2) of the Regulation, the conditions for authorisation of the product bind all persons placing it on the market.
- (15) This Decision should be notified through the Biosafety Clearing House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and to point 2(c) of Article 15 of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms ⁽¹⁾.
- (16) No opinion was delivered by the Standing Committee on the Food Chain and Animal Health; the Commission has therefore submitted a proposal to the Council on 5 October 2005 in accordance with Article 5(4) of Council Decision 1999/468/EC ⁽²⁾, the Council being required to act within three months.
- (17) However, the Council has not acted within the required time limit; a Decision should now be adopted by the Commission,

HAS DECIDED AS FOLLOWS:

▼M1*Article 1***Products**

This Decision covers foods and food ingredients containing and consisting of, or produced from genetically modified maize (*Zea mays* L.) line 1507 and feed produced from such maize (the products).

Genetically modified maize (*Zea mays* L.) line 1507 as further specified in the Annex to this Decision is assigned the unique identifier DAS-Ø15Ø7-1, as provided for in Regulation (EC) No 65/2004.

*Article 2***Placing on the market**

The placing on the market of the products, according to the conditions specified in this Decision and its Annex, is authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003.

⁽¹⁾ OJ L 287, 5.11.2003, p. 1.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

▼ M1*Article 3***Labelling**

For the purposes of the specific labelling requirements provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'maize'.

▼ B*Article 4***Monitoring for environmental effects**

1. Authorisation holders shall ensure that the monitoring plan for environmental effects, as specified in the Annex to this Decision, is put in place and implemented.

2. Authorisation holders shall submit to the Commission annual reports on the implementation and the results of the monitoring activities.

The reports shall clearly state those parts of the reports which are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003.

Confidential parts of such reports shall be submitted in separate documents.

*Article 5***Community Register**

The information in the Annex to this Decision shall be entered in the Community Register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6***Authorisation holders**

The authorisation holders are:

- (a) Pioneer Overseas Corporation, Belgium, representing Pioneer Hi-Bred International, United States of America; and
- (b) Dow AgroSciences Europe, United Kingdom, representing Mycogen Seeds, United States of America;

both of which are responsible for fulfilling the duties of authorisation holders provided for in this Decision and in Regulation (EC) No 1829/2003.

*Article 7***Validity**

This Decision shall be valid for a period of 10 years from the date of its adoption.

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ANNEX

a) **Applicants and authorisation holders:**

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, B-1040 Brussels.

On behalf of Pioneer Hi-Bred International, Inc., 400 Locus Street, Suite 800, Des Moines, IA50309, United States of America

and

Name: Dow AgroSciences Europe Ltd

Address: European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

On behalf of Mycogen Seeds c/o Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States of America.

▼M1b) **Designation and specification of the products:**

(i) foods and food ingredients containing, consisting of, or produced from DAS-Ø15Ø7-1 maize;

(ii) feed produced from DAS-Ø15Ø7-1 maize.

The genetically modified DAS-Ø15Ø7-1 maize, as described in the application, is resistant to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests and is tolerant to the herbicide glufosinate-ammonium. The genetically modified DAS-Ø15Ø7-1 maize contains the following DNA sequences in two cassettes:

— cassette 1:

A synthetic version of the truncated *cry1F* gene from *Bacillus thuringiensis* subsp. *aizawai*, which confers resistance to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests, under the regulation of the ubiquitin promoter *ubiZM1(2)* from *Zea mays* L. and the ORF25PolyA terminator from *Agrobacterium tumefaciens* pTi15955,

— cassette 2:

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

c) **Labelling:**

No specific requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003.

For the purpose of Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, the 'name of organism' shall be 'maize'.

▼B(d) **Method for detection:**

— Event specific real-time quantitative PCR based method for genetically modified maize DAS-Ø15Ø7-1.

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— Validated by the Community reference laboratory established pursuant to Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.it/detectionmethods/TC1507-WEB-Protocol-Validation.pdf>

— Reference Material: ERM®-BF418 accessible via the Joint Research Centre (JRC) of the European Commission, the Institute of Reference Materials and Measurements (IRMM) at http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

(e) **Unique identifier:**

DAS-Ø15Ø7-1

(f) **Information required in accordance with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Biosafety Clearing House, Record ID: see Decision 2006/197/EC.

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC

(Link: <http://gmo-crl.jrc.it/detectionmethods/TC1507-WEB-Protocol-Validation.pdf>)

(i) **Post market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community Register of genetically modified food and feed.