



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 5.10.2005
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Proposal for a

COUNCIL DECISION

authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) under Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(presented by the Commission)

EXPLANATORY MEMORANDUM

The attached draft proposal for a Council Decision concerns food containing, consisting of, or produced from genetically modified maize line 1507, for which a request for placing on the market was submitted by Pioneer Overseas Corporation and Dow AgroSciences Europe to the competent authorities of The Netherlands on 15 February 2001, under Regulation (EC) No 258/97 concerning novel foods and novel food ingredients.

Following the initial assessment report from the Netherlands, who considered 1507 maize as safe as conventional maize, reasoned objections were raised by some Member States. As a consequence, an additional assessment was required.

Regulation (EC) No 1829/2003 on GM food and feed is applicable from 18 April 2004. According to 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 was required and has not been transmitted to the Commission before that date, must be transformed into applications under Regulation (EC) No 1829/2003.

On 3 March 2005, the European Food Safety Authority gave its opinion that there is no evidence to indicate that the placing on the market of the food products presented in the application is likely to cause adverse effects on human or animal health or the environment.

Against this background, a draft Commission Decision authorising the placing on the Community market of food containing, consisting of, or produced from genetically modified maize line 1507 was submitted to the Standing Committee on the Food Chain and Animal Health, on 3 June 2005, for vote. Eight Member States (111 votes) voted in favour, nine Member States (69 votes) voted against and eight Member States (141 votes) abstained.

The Committee delivered no opinion. Consequently, pursuant to Article 35, paragraph 2 of Regulation (EC) No 1829/2003 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.

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THE COUNCIL OF THE EUROPEAN UNION,

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 feed¹, 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 ingredients², 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 under 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 under Chapter II, Section 1 of the Regulation in cases

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).

where an additional assessment report is required in accordance with Article 6(3) or 6(4) of Regulation (EC) No 258/97.

- (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) A notification for the placing on the market of feed containing or consisting of genetically modified maize line 1507 has been submitted under Part C of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms³. This notification should continue to be processed under this Directive in accordance with Article 46(3) of the Regulation.
- (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 environment⁴. 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, the 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 establishing a system for the development and assignment of unique identifiers for genetically modified organisms⁵.

³ OJ L 106, 17.4.2001, p. 1.

⁴ http://www.efsa.eu.int/science/gmo/gm_ff_applications/more_info/503/op_gm07_ej182_1507_opinion_nl_doc2_en1.pdf

⁵ OJ L 10, 16.1.2004, p. 5.

- (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 15(2), c), of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms⁶.
- (16) No opinion was delivered by the Standing Committee on the Food Chain and Animal Health,

HAS DECIDED AS FOLLOWS:

Article 1
Products

This Decision covers foods and food ingredients containing, consisting of, or produced from the genetically modified maize (*Zea mays* L.) line 1507 further specified in the Annex to this Decision ('the products') and 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 Article 4(2) of Regulation (EC) No 1829/2003.

Article 3
Labelling

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

Article 4
Monitoring for environmental effects

1. The 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.

⁶ OJ L 287, 5.11.2003, p. 1.

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

Those reports shall clearly state which parts of the reports 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, and
- (b) Dow AgroSciences Europe, United Kingdom, representing Mycogen Seeds, United States,

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.

Done at Brussels,

For the Council
The President

ANNEX

(a) Applicants and Authorisation holders:

Name: Pioneer Overseas Corporation

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

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

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.

(b) Designation and specification of the products:

Foods and food ingredients containing, consisting of, or produced from genetically modified maize (*Zea mays* L.) line 1507 as described in the application, unique identifier DAS-Ø15Ø7-1, with resistance to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests and with tolerance to the herbicide glufosinate-ammonium. The genetically modified maize DAS-Ø15Ø7-1 contains the following DNA sequences in two cassettes:

(a) 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.

(b) 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 other specific requirements than those provided under Article 13(1) of Regulation (EC) No 1829/2003.

For the purpose of Article 13(1) of Regulation (EC) No 1829/2003, the ‘name of the organism’ shall be ‘maize’.

d) Method for detection:

- Event specific real-time quantitative PCR based method for genetically modified maize DAS-Ø15Ø7-1.
- Validated by the Community reference laboratory established under 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 under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Biosafety Clearing House, Record ID: see [*to be completed when notified, before publication in the OJ*]

(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: plan published on the internet]

(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 the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.