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EUROPEAN COMMISSION

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2011/0016 (NLE)

Proposal for a

**COUNCIL DECISION**

**amending Commission Decision 2006/197/EC as regards the renewal of the authorization to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

**(Only the French, Dutch and English texts are authentic)**  
**(Text with EEA relevance)**

## **EXPLANATORY MEMORANDUM**

The attached proposal for a Council Decision concerns the renewal of the authorization for continued marketing of existing feed produced from genetically modified maize 1507 (DAS-Ø15Ø7-1), for which a request was jointly submitted by Pioneer Overseas Corporation on behalf of Pioneer Hi-bred International and Dow AgroSciences on behalf of Mycogen Seeds, on 12 April 2007, in accordance with Article 23 of the Regulation (EC) No 1829/2003 on genetically modified food and feed.

This proposal amends Commission Decision 2006/197/EC authorizing the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507, by extending its scope to the continued marketing of existing feed materials and feed additives produced from genetically modified maize 1507.

On 11 June 2009, the European Food Safety Authority gave a favourable opinion in accordance with Article 18 of Regulation (EC) No 1829/2003. It considered that the new information provided in the application and the review of the scientific literature published since the previous scientific opinions of the EFSA GMO Panel on 1507 maize, do not require changes of the previous scientific opinions on 1507 maize. Therefore it reiterated its previous conclusions that 1507 maize is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses.

Against this background, a draft Commission Decision amending Commission Decision 2006/197/EC as regards the renewal of the authorization for placing on the market existing feed produced from genetically modified 1507 maize (DAS-Ø15Ø7-1) was submitted to the Standing Committee on the Food Chain and Animal Health on 15 November 2010, for vote. The Committee delivered no opinion: 13 Member States (183 votes) voted in favour, 7 Member States (73 votes) voted against, 7 Member States (89 votes) abstained.

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 modified by Council Decision 2006/512/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.

Proposal for a

**COUNCIL DECISION**

**amending Commission Decision 2006/197/EC as regard the renewal of the authorization to place on the market existing feed produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

**(Only the French, Dutch and English texts are authentic)  
(Text with EEA relevance)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

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<sup>1</sup>, and in particular Article 7(3) and Article 19(3) thereof,

Having regard to the proposal of the European Commission,

Whereas:

- (1) Commission Decision 2006/197/EC 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) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council<sup>2</sup> does not cover the placing on the market of feed produced from maize line 1507 (DAS-Ø15Ø7-1) (hereafter 'maize line 1507').
- (2) Feed produced from maize line 1507 has been placed on the market before the date of application of Regulation (EC) 1829/2003 and notified in accordance with Article 20(1)(b) of that Regulation.
- (3) On 12 April 2007 Pioneer Overseas Corporation on behalf of Pioneer Hi-bred International and Dow AgroSciences on behalf of Mycogen Seeds jointly submitted to the Commission an application, in accordance with Article 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation for continued marketing of existing feed produced from maize line 1507.
- (4) On 11 June 2009, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Article 18 of Regulation (EC) No 1829/2003 and concluded that the new information provided in the application and the review of the scientific literature that has been published since the previous scientific opinions of the

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<sup>1</sup> OJ L 268, 18.10.2003, p. 1.

<sup>2</sup> OJ L 70, 9.3.2006, p. 82.

EFSA GMO Panel on maize line 1507<sup>3</sup> do not require changes of the previous scientific opinions on maize line 1507. Furthermore, EFSA reiterated the previous conclusions that 1507 maize is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses. This includes the use of feed produced from maize line 1507<sup>4</sup>.

- (5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 18(4) of that Regulation.
- (6) By letter of 21 January 2010, the applicant confirmed that he is aware of the fact that renewing the authorisation of existing feed produced from maize line 1507 by extending the scope of Commission Decision 2006/197/EC so as to include such product, would imply this category of products to be subject to the legal provisions of that Decision.
- (7) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 25(2) of Regulation (EC) No 1829/2003 appear to be necessary for feed produced from maize line 1507.
- (8) The EFSA opinion does not justify the imposition of 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 for the use of the feed, as provided for in point (e) of Article 18(5) of Regulation (EC) No 1829/2003.
- (9) For the sake of transparency, the applicant has been consulted on the measures provided for in this Decision.
- (10) Taking into account these considerations, renewal of the authorisation to place on the market existing feed produced from maize line 1507 should be granted.
- (11) Since it is general practice to authorise the placing on the market of food and feed in the same decision, the renewal of the authorisation to place on the market feed produced from maize line 1507 should be included in Decision 2006/197/EC. Decision 2006/197/EC should therefore be amended accordingly.
- (12) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman,

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<sup>3</sup> EFSA opinions published on:  
- 24 September 2004 for the placing on the market of maize 1507 for import and processing;  
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2004-011>  
- 19 January 2005 for the placing on the market of maize 1507 for import, feed and industrial processing and cultivation;  
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2004-072>  
- 19 January 2005 for the placing on the market of maize 1507 for food use  
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2004-087>

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-144>

HAS ADOPTED THIS DECISION:

*Article 1*  
*Amendments*

Decision 2006/197/EC is amended as follows:

- (1) The title is replaced by the following:

"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"

- (2) Articles 1, 2 and 3 of Decision 2006/197/EC are replaced by the following:

*"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 Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003.

*Article 3*  
*Labelling*

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

- (3) The Annex is amended as follows:

- (a) Section (b) is replaced by the following:

"(b) 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*."

- (b) Section (c) is replaced by the following:

"(c) Labelling:

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

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

*Article 2*  
*Addressees*

This Decision is addressed to:

- (a) Pioneer Overseas Corporation, Avenue des Arts 44, B-1040 Brussels, Belgium; and  
(b) Dow AgroSciences Europe, European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels,

*For the Council*  
*The President*