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COMMISSION DECISION

of 24 October 2007

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 (DAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document number C(2007) 5142)

(Only the French, Dutch and English texts are authentic)

(Text with EEA relevance)

(2007/703/EC)

(OJ L 285, 31.10.2007, p. 47)

Amended by:

Official Journal

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Article 1

Genetically modified organism and unique identifier

Genetically modified maize (Zea mays L.) 1507xNK603 produced by crosses between maize containing DAS-Ø15Ø7-1 and MON-ØØ6Ø3-6 events, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003, in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize;
- (b) feed containing, consisting of, or produced from DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize;
- (c) products, other than food and feed, containing or consisting of DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation.

Article 3

Labelling

- 1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
- 2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize referred to in Article 2(b) and (c).

Article 4

Monitoring for environmental effects

- 1. The authorisation holders shall ensure that the monitoring plan for environmental effects, as set out in the point (h) of the Annex, is put in place and implemented.
- 2. The authorisation holders shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan.

Article 5

Community register

The information set out 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

- 1. The authorisation holders shall be:
- (a) Pioneer Overseas Corporation, Belgium, representing Pioneer Hi-Bred International, United States;

and

- (b) ►<u>M1</u> Dow AgroSciences Distribution S.A.S., France, representing Mycogen Seeds, United States. ◀
- 2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

Article 7

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 8

Addressees

This Decision is addressed to:

(a) Pioneer Overseas Corporation, Avenue des Arts 44, B-1040 Brussels, Belgium;

and

(b) ►<u>M1</u> Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France ◀.

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., 7250 NW 62nd Avenue,

P. O. Box 552, Johnston, IA 50131-0552, United States

and

Name: ►M1 Dow AgroSciences Distribution S.A.S. ◀

Address: ▶M1 6, rue Jean Pierre Timbaud, 78180 Montigny-le-

Bretonneux, France ◀.

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 DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize;
- Feed containing, consisting of, or produced from DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize;
- Products, other than food and feed, containing or consisting of DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified maize DAS-Ø15Ø7-1xMON-ØØ6Ø3-6, as described in the application, is produced by crosses between maize containing DAS-Ø15Ø7-1 and MON-ØØ6Ø3-6 events and expresses the Cry1F protein which confers protection against certain lepidopteran pests such as the European corn borer (*Ostrinia nubilalis*) and species belonging to the genus *Sesamia*, the PAT protein which confers tolerance to the glufosinate-ammonium herbicide, and the CP4 EPSPS protein which confers tolerance to the glyphosate herbicide.

(c) Labelling:

- For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
- 2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize referred to in Article 2(b) and (c).

(d) Method for detection:

- Event specific real-time quantitative PCR based methods for genetically modified maize DAS-Ø15Ø7-1 and MON-ØØ6Ø3-6 maize validated on DAS-Ø15Ø7-1xMON-ØØ6Ø3-6 maize,
- Validated by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.it/ statusofdoss.htm
- Reference Material: ERM®-BF418 (for DAS-Ø15Ø7-1) and ERM®-BF415 (for MON-ØØ6Ø3-6) 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

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(e) Unique identifier:

DAS-Ø15Ø7-1xMON-ØØ6Ø3-6

(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]

(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]

 $(i) \quad \mbox{Post market monitoring requirements for the use of the food for human consumption} \\$

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.