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COMMISSION DECISION

of 30 November 2009

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604 (SYN-IR604-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2009) 9399)

(Only the French text is authentic)

(Text with EEA relevance)

(2009/866/EC)

(OJ L 314, 1.12.2009, p. 102)

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*Article 1***Genetically modified organism and unique identifier**

Genetically modified maize (*Zea mays* L.) MIR604, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-IR604-5, 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 SYN-IR604-5 maize;
- (b) feed containing, consisting of, or produced from SYN-IR604-5 maize;
- (c) products other than food and feed containing or consisting of SYN-IR604-5 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 SYN-IR604-5 maize referred to in Article 2(b) and (c).

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

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder 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 holder**

The authorisation holder shall be ►**M1** Syngenta Crop Protection NV/SA, Belgium ◀, representing Syngenta Crop Protection AG, Switzerland.

*Article 7***Validity**

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

*Article 8***Addressee**

This Decision is addressed to ►**M1** Syngenta Crop Protection NV/SA, Avenue Louise 489, 1050 Brussels, Belgium ◀.

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ANNEX

(a) Applicant and Authorisation holder:

Name: ► **M1** Syngenta Crop Protection NV/SA ◀

Address: ► **M1** Avenue Louise 489, 1050 Brussels, Belgium ◀

On behalf of Syngenta Crop Protection AG — Schwarzwaldallee 215 — CH 4058 Basle — Switzerland.

(b) Designation and specification of the products:

(1) Foods and food ingredients containing, consisting of, or produced from SYN-IR604-5 maize;

(2) Feed containing, consisting of, or produced from SYN-IR604-5 maize;

(3) Products other than food and feed containing or consisting of SYN-IR604-5 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-IR604-5 maize, as described in the application, expresses a modified Cry3A protein which provides protection to certain coleopteran pests (*Diabrotica* spp.). A *pmi* gene, allowing transformed maize cells to utilise mannose as a sole carbon source, was used as a selectable marker in the genetic modification process.

(c) Labelling:

(1) For the purposes of the specific 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 SYN-IR604-5 maize referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection:

— Event specific real-time PCR based method for the quantification of SYN-IR604-5 maize,

— Validated on seeds by the Community Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>,

— Reference Material: ERM®-BF423 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:

SYN-IR604-5.

(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].

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- (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.