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COMMISSION IMPLEMENTING DECISION

of 6 November 2013

authorising the placing on the market of pollen produced from maize MON 810 (MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2013) 4743)

(Only the Dutch and French texts are authentic)

(Text with EEA relevance)

(2013/649/EU) (OJ L 302, 13.11.2013, p. 44)

Amended by:

<u>B</u>

Official Journal

		No	page	date
<u>M1</u>	Commission Implementing Decision (EU) 2019/1579 of 18 September 2019	L 244	8	24.9.2019

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(2013/649/EU)

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON 810, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ81Ø-6, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

Pollen produced from maize MON 810, as or in foods and food ingredients, is authorised for the purposes of Article 4(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision.

Article 3

Labelling

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

Article 4

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.

▼<u>M1</u>

Article 5

Authorisation holder

The authorisation holder shall be Bayer Agriculture BVBA, Belgium, representing Monsanto Company, United States of America.

▼<u>B</u>

Article 6

Validity

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

▼<u>M1</u>

Article 7

Addressee

This Decision is addressed to Bayer Agriculture BVBA, Scheldelaan 460, 2040 Antwerp, Belgium.

▼<u>B</u>

ANNEX

▼ M1

(a) Applicant and Authorisation holder

Name: Bayer Agriculture BVBA

Address: Scheldelaan 460, 2040 Antwerp, Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States of America.

▼B

(b) Designation and specification of the products

Pollen produced from MON-ØØ81Ø-6 maize, as or in foods and food ingredients.

The genetically modified MON-ØØ81Ø-6 maize, as described in the application, expresses the Cry1Ab protein which confers protection against certain lepidopteran pests.

(c) Labelling

For the purposes of the specific labelling requirements laid down in 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 PCR based method for the quantification of MON-ØØ81Ø-6 maize.
- Validated on ground maize seeds (certified reference materials [CRM IRMM-413]), containing mixtures of genetically modified MON 810 and conventional maize, by the Federal Institute for Risk Assessment (BfR) in collaboration with the American Association of Cereal Chemists (AACC), Joint Research Centre (JRC) of the European Commission (EC) (Institute for Reference Material and Measurement (IRMM), Institute for Health and Consumer Protection (IHCP)), and GeneScan, Berlin, published at

http://gmo-crl.jrc.ec.europa.eu/summaries/Mon810_validation_report.pdf

Reference Material: ERM-BF413k accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at

http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

(e) Unique identifier

MON-ØØ81Ø-6

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Not required.

▼<u>B</u>

 $\left(g\right)$ Conditions or restrictions on the placing on the market, use or handling of the products

Not required.

(h) Monitoring plan

Not required.

 $\hspace{1.5cm} \hbox{(i)} \hspace{0.3cm} \hbox{ Post market monitoring requirements for the use of the food for human} \\ \hspace{0.3cm} \hbox{consumption}$

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.