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*Changes to legislation: There are outstanding changes not yet made to 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). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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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)

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)

THE EUROPEAN COMMISSION,

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) thereof,

Whereas:

- (1) On 12 March 2012, Monsanto Europe S.A submitted to the competent authority of The Netherlands an application, in accordance with Article 5 of Regulation (EC) No 1829/2003, for the placing on the market of pollen produced from maize MON 810, as or in foods and food ingredients ('the application').
- (2) On 19 December 2012, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Article 6 of Regulation (EC) No 1829/2003. It concluded that the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen were to replace pollen from non-GM maize in or as food.
- (3) 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.
- (4) Taking into account those considerations, authorisation should be granted to pollen produced from maize MON 810, as or in foods and food ingredients.
- (5) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 of

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14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms<sup>(2)</sup>.

- (6) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Article 13(1) of Regulation (EC) No 1829/2003, appear to be necessary for foods and food ingredients produced from maize MON 810 pollen.
- (7) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC<sup>(3)</sup>, lays down in Article 5 traceability requirements for products for foods produced from GMOs. All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- (8) The applicant has been consulted on the measures provided for in this Decision.
- (9) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

#### *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'.

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#### 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.

#### <sup>F1</sup>Article 5

### Authorisation holder

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

#### Textual Amendments

- F1** Substituted by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically modified food and feed in the Union (notified under document C(2019) 6520) (Only the Dutch text is authentic) (Text with EEA relevance).

#### Article 6

### Validity

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

#### <sup>F1</sup>Article 7

### Addressee

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

#### Textual Amendments

- F1** Substituted by Commission Implementing Decision (EU) 2019/1579 of 18 September 2019 amending Decisions 2008/933/EC, 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045 and (EU) 2018/2046 as regards the representative of the authorisation holder for placing on the market certain genetically

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modified food and feed in the Union (notified under document C(2019) 6520) (Only the Dutch text is authentic) (Text with EEA relevance).

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## ANNEX

**[<sup>F1</sup>(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) 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](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](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.

**(g) Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

**(h) Monitoring plan**

Not required.

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(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.

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- (1) OJ L 268, 18.10.2003, p. 1.
- (2) OJ L 10, 16.1.2004, p. 5.
- (3) OJ L 268, 18.10.2003, p. 24.

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**Changes and effects yet to be applied to :**

- Annex Note word omitted by [S.I. 2019/705 reg. 200](#)
- Art. 4 heading substituted by [S.I. 2019/705 reg. 198](#)
- Art. 4 word omitted by [S.I. 2019/705 reg. 199](#)