This text is meant purely as a documentation tool and has no legal effect. The Union's institutions do not assume any liability for its contents. The authentic versions of the relevant acts, including their preambles, are those published in the Official Journal of the European Union and available in EUR-Lex. Those official texts are directly accessible through the links embedded in this document

►**B**

COMMISSION IMPLEMENTING DECISION (EU) 2015/683

of 24 April 2015

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87460 (MON 8746Ø-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2015) 2749)

(Only the French and Dutch texts are authentic)

(Text with EEA relevance)

(OJ L 112, 30.4.2015, p. 1)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2019/1579 of 18 September 2019	L 244	8	24.9.2019

▼B

COMMISSION IMPLEMENTING DECISION (EU) 2015/683

of 24 April 2015

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87460 (MON 8746Ø-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2015) 2749)

(Only the French and Dutch texts are authentic)

(Text with EEA relevance)

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) MON 87460, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON 8746Ø-4, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 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 MON 8746Ø-4 maize;

(b) feed containing, consisting of, or produced from MON 8746Ø-4 maize;

(c) MON 8746Ø-4 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 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 MON 8746Ø-4 maize with the exception of products referred to in point (a) of Article 2.

▼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 in accordance with Decision 2009/770/EC.

Article 5

EU register

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

▼M1

Article 6

Authorisation holder

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

▼B

Article 7

Validity

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

▼M1

Article 8

Addressee

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

▼B

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**

1. foods and food ingredients containing, consisting of, or produced from MON 8746Ø-4 maize;

2. feed containing, consisting of, or produced from MON 8746Ø-4 maize;

3. MON 8746Ø-4 maize in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified MON 8746Ø-4 maize, as described in the application, expresses the cold shock protein B (CspB) which aims to reduce yield loss caused by drought stress. An *nptII* gene, conferring kanamycine and neomycine resistance, was used as a selective marker in the genetic modification process.

(c) **Labelling**

1. For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 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 MON 8746Ø-4 maize with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— Event-specific real-time PCR based method for the quantification of MON 8746Ø-4 maize.

— Validated on genomic DNA, extracted from seeds, by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

— Reference Material: AOCS 0709-A and AOCS 0406-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON 8746Ø-4

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

Biosafety Clearing-House (to be entered in the EU register of genetically modified food and feed when notified).

▼B

(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 [to be entered in the EU register of genetically modified food and feed when notified).

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.