Document Generated: 2023-10-29

Changes to legislation: There are outstanding changes not yet made to Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xMON810 (MON-ØØ603-6xMON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2007) 5140) (Only the French and Dutch texts are authentic) (Text with EEA relevance) (2007/701/EC). 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

ANNEX

(a) Applicant and Authorisation holder:

Name : Monsanto Europe S.A.

Address : Scheldelaan 460, Haven 627 — B 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:
- Foods and food ingredients containing, consisting of, or produced from MON-ØØ6Ø3-6xMON-ØØ81Ø-6 maize;
- (2) Feed containing, consisting of, or produced from MON-ØØ6Ø3-6xMON-ØØ81Ø-6 maize;
- Products other than food and feed containing or consisting of MON-ØØ6Ø3-6xMON-ØØ81Ø-6 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified maize MON-ØØ6Ø3-6xMON-ØØ81Ø-6, as described in the application, is produced by crosses between maize containing MON-ØØ6Ø3-6 and MON-ØØ81Ø-6 events and expresses the CP4 EPSPS protein which confers tolerance to glyphosate herbicides and the Cry1Ab protein which confers protection against certain lepidopteran insect pests (Ostrinia nubilalis, Sesamia spp.).

- (c) 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'.
- The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-ØØ6Ø3-6xMON-ØØ81Ø-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 MON-ØØ6Ø3-6 and MON-ØØ81Ø-6 maize validated on MON-ØØ6Ø3-6xMON-ØØ81Ø-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®-BF413 (for MON-ØØ81Ø-6) 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
- (e) Unique identifier:

MON-ØØ6Ø3-6xMON-ØØ81Ø-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:

Document Generated: 2023-10-29

Changes to legislation: There are outstanding changes not yet made to Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xMON810 (MON-ØØ603-6xMON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2007) 5140) (Only the French and Dutch texts are authentic) (Text with EEA relevance) (2007/701/EC). 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

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.

Changes to legislation:

There are outstanding changes not yet made to Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xMON810 (MON-ØØ6Ø3-6xMON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document number C(2007) 5140) (Only the French and Dutch texts are authentic) (Text with EEA relevance) (2007/701/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

View outstanding changes

Changes and effects yet to be applied to:

- Annex Note word omitted by S.I. 2019/705 reg. 79
- Art. 4(2) words substituted by S.I. 2019/705 reg. 76
- Art. 5 heading substituted by S.I. 2019/705 reg. 77
- Art. 5 word omitted by S.I. 2019/705 reg. 78