
Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 22 December 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11xMIR604 (SYN-BTØ11-1xSYN-IR6Ø4-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2011) 9535) (Only the French text is authentic) (Text with EEA relevance) (2011/893/EU). (See end of Document for details)

ANNEX

(a) Applicant and Authorisation holder

Name : Syngenta Seeds SAS
Address : Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-4058 Basel, Switzerland

(b) Designation and specification of the products

- (1) Foods and food ingredients containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5 maize;
- (2) feed containing, consisting of, or produced from SYN-BTØ11-1xSYN-IR6Ø4-5 maize;
- (3) products other than food and feed containing or consisting of SYN-BTØ11-1xSYN-IR6Ø4-5 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-BTØ11-1xSYN-IR6Ø4-5 maize, as described in the application, is produced by crosses between maize containing SYN-BTØ11-1 and SYN-IR6Ø4-5 events and expresses the Cry1Ab protein which confers protection against certain lepidopteran pests, the PAT protein which confers tolerance to glufosinate-ammonium herbicides and the Cry3A protein which provides protection against certain coleopteran pests. A *pmi* gene, which allows transformed maize cells to utilize mannose as a sole carbon source, was used as a selectable marker in the genetic modification process for SYN-IR6Ø4-5 event.

(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 SYN-BTØ11-1xSYN-IR6Ø4-5 maize referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection

- Event specific real-time quantitative PCR based methods for genetically modified maize SYN-BTØ11-1 and SYN-IR6Ø4-5 maize validated on SYN-BTØ11-1xSYN-IR6Ø4-5 maize.
- Validated on seeds by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- Reference Material: ERM®-BF412 (for SYN-BTØ11-1) and ERM®-BF423 (for SYN-IR6Ø4-5) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/rmcatalogue>

(e) Unique identifier

SYN-BTØ11-1xSYN-IR6Ø4-5.

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

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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**

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.

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