

**Changes to legislation:** There are outstanding changes not yet made to Commission Decision of 28 July 2010 renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC (notified under document C(2010) 5129) (Only the French text is authentic) (Text with EEA relevance) (2010/419/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

## ANNEX

**(a) Applicant and authorisation holder:**

Name : [F<sup>1</sup>Syngenta Crop Protection NV/SA]  
Address : [F<sup>1</sup>Avenue Louise 489, 1050 Brussels, Belgium]

**Textual Amendments**

**F1** Substituted by Commission Implementing Decision (EU) 2019/60 of 11 January 2019 amending Decision 2009/866/EC, Decision 2010/419/EU, Implementing Decision 2012/651/EU and Implementing Decision (EU) 2016/1685 as regards the representative of the authorisation holder (notified under document C(2019) 15) (Only the Dutch and French texts are authentic) (Text with EEA relevance).

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

**(b) Designation and specification of the products:**

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

The genetically modified SYN-BTØ11-1 maize, as described in the application, expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and the PAT protein which confers tolerance to the glufosinate-ammonium herbicide.

**(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-BTØ11-1 maize referred to in Article 2(b) and (c).

**(d) Method for detection:**

- event specific real-time PCR-based method for the quantification of SYN-BTØ11-1 maize
- validated by the Community Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- reference material: ERM®-BF412 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-BTØ11-1

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

- Decision revoked by [S.S.I. 2022/137 reg. 4\(d\)](#)
- Decision revoked by [S.I. 2022/486 reg. 4\(d\)](#)
- Decision revoked by [S.I. 2022/472 reg. 4\(d\)](#)
- Annex Note word omitted by [S.I. 2019/705 reg. 136](#)