

**ANNEX**

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

Name: Syngenta Crop Protection AG

Address: Rosentalstrasse 67, CH-4058 Basel, Switzerland

Represented in the Union by: Syngenta Crop Protection NV/SA, Avenue Louise, 489, 1050 Brussels, Belgium.

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

- (1) foods and food ingredients containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;
- (2) feed containing, consisting of or produced from genetically modified maize SYN-BTØ11-1;
- (3) products containing or consisting of genetically modified maize SYN-BTØ11-1 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

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

**(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’.
- (2) The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize SYN-BTØ11-1, with the exception of products referred to in point (b)(1).

**(d) Method for detection:**

- (1) Event specific real-time PCR based method for the detection of genetically modified maize SYN-BTØ11-1.
- (2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>.
- (3) Reference material: ERM®-BF412 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://crm.jrc.ec.europa.eu/>

- (e) **Unique identifier:**  
SYN-BTØ11-1
- (f) **Information required pursuant to Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**  
[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].
- (g) **Conditions or restrictions on the placing on the market, use or handling of the products:**  
Not required.
- (h) **Monitoring plan for environmental effects:**  
Monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council<sup>1</sup>.  
[Link: *plan published in the Community register of genetically modified food and feed*]
- (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 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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<sup>1</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).