



Brussels, **XXX**
SANTE/10285/2016 ANNEX CIS
(POOL/E3/2016/10285/10285-EN
ANNEX CIS.doc)
[...](2016) **XXX** draft

ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING DECISION

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maizes combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/893/EU, 2011/892/EU and 2011/894/EU

ANNEX

(a) Applicant and Authorisation holder:

Name: Syngenta France SAS

Address: 12, Chemin de l'Hobit, 31790 Saint-Sauveur, France

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

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (2) feed containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (3) genetically modified maizes (*Zea mays* L.) as specified in (e) in products containing them or consisting of them for any other use than those provided in points (1) and (2), with the exception of cultivation.

SYN-BTØ11-1 maize expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and a PAT protein which confers tolerance to glufosinate-ammonium herbicides.

SYN-IR162-4 maize expresses the Vip3Aa20 protein which confers protection against certain lepidopteran pests and PMI protein which was used as a selectable marker.

SYN-IR6Ø4-5 maize expresses the Cry3A protein which provides protection against certain coleopteran pests and PMI protein which was used as a selectable marker.

MON-ØØØ21-9 maize expresses the Cry1Ab protein which confers protection against certain lepidopteran pests, the mEPSPS protein which confers tolerance to glyphosate herbicides.

(c) 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 the accompanying documents of the products containing or consisting the maizes specified in (e) with the exception of products referred to in point (a) of Article 2.

(d) Method for detection:

- (1) Event specific real-time quantitative PCR based methods for SYN-BTØ11-1, SYN-IR162-4, SYN-IR6Ø4-5 and MON-ØØØ21-9 maizes; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9 maize;
- (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 (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> and AOCS 1208-A and AOCS 0407-A (for SYN-IR162-4), AOCS 0407-A and AOCS 0407-B (for MON-ØØØ21-9) accessible via the American Oil Chemists Society at <http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248>.

(e) Unique identifier:

SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5;

SYN-BTØ11-1 × SYN-IR162-4 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR162-4;

SYN-BTØ11-1 × SYN-IR6Ø4-5;

SYN-BTØ11-1 × MON-ØØØ21-9;

SYN-IR162-4 × SYN-IR6Ø4-5;

SYN-IR162-4 × MON-ØØØ21-9;

SYN-IR6Ø4-5 × MON-ØØØ21-9.

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

[Biosafety Clearing-House, Record ID number: *published in the Community 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:

Specific conditions in accordance with Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003

(1) The authorisation holder shall inform the Commission if the sub-combinations SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5, SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9, SYN-BTØ11-1 × SYN-IR162-4, SYN-IR162-4 × SYN-IR6Ø4-5 and/or SYN-IR162-4 × MON-ØØØ21-9 were to be created via targeted breeding approaches and commercialised.

(2) If it is the case, the authorisation holder shall collate information on the expression levels of the newly expressed proteins.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[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 the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.