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ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING DECISION

**concerning the placing on the market for cultivation of genetically modified maize Bt11
(SYN-BTØ11-1) seeds**

ANNEX

1. Method for detection:

- Event-specific real-time PCR-based method for the quantification of maize Bt11.
- Validated on genomic DNA extracted from seeds of SYN-BTØ11-1 maize by the Community Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>
- Reference material: ERM®-BF412 shall be 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>

2. Conditions or restrictions on the placing on the market, use or handling of the products:

2.1 Geographical scope of the authorisation for cultivation

The cultivation of maize Bt11 shall be prohibited in the following territories:

- Wallonia (Belgium);
- Bulgaria;
- Denmark;
- Germany (except for research purposes);
- Greece;
- France;
- Croatia;
- Italy;
- Cyprus;
- Latvia;
- Lithuania;
- Luxembourg;
- Hungary;
- Malta;
- The Netherlands;
- Austria;
- Poland;
- Slovenia;
- Northern Ireland (United Kingdom);
- Scotland (United Kingdom);
- Wales (United Kingdom).

2.2 Management measures

(a) *Planting of refuge areas to delay the development of resistance and limit exposure of non-target Lepidoptera species to Bt pollen*

In the following cases, the cultivation of maize Bt11 shall be accompanied by the planting of refuge areas consisting of non-Bt maize equivalent to at least 20% of the surface planted with Bt maize, including maize Bt11:

- (i) In the case of a single field in which the surface planted with Bt maize is greater than 5 hectares;
- (ii) In the case of a cluster of fields in which the aggregate surface planted with Bt maize is greater than 5 hectares, irrespective of individual field and farm size.

Refuge areas shall be planted as border rows along field margins where such margins are present.

(b) *Isolation distances from protected habitats*

Isolation distances of at least 5 metres shall be applied between a maize Bt11 field and a protected habitat as defined in Article 2(3) of Directive 2004/35/EC.

3. Leaflet

The leaflet referred to in Article 5(3) shall contain the following:

- General description of the product, including general characteristics of and safety requirements for varieties derived from maize Bt11, and the unique identifier assigned to the GMO;
- The requirement that all operators keep records of the transactions of Bt11 seeds, and that written information regarding the product must be provided as established by Article 4 of Regulation (EC) No 1830/2003;
- Design and management of the planting, including guidance to the operators to design refuges;
- The need for imposition of an isolation distance of at least 5 metres between a maize Bt11 field and a protected habitat as defined in Article 2(3) of Directive 2004/35/EC;
- Reference to the applicable national legislation on the cultivation of GMOs, including legislation on co-existence between GM maize crops and non-GM maize crops where applicable and its detailed provisions as regards treatment of equipment and product material, notification requirements if applicable, distances or refuge areas where relevant and reminder of the basic obligations for the cultivation and use of the product at national and Union level;
- Monitoring requirements and reference to the farmer questionnaire referred to in the monitoring plan for environmental effects.

4. Monitoring plan for environmental effects

Link: *[plan published on the internet]*