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ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION

**renewing the authorisation for the placing on the market for cultivation of genetically
modified maize MON 810 (MON-00810-6) seeds**

ANNEX

1. **Applicant and Authorisation holder:**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, B-1150 Brussels – Belgium

On behalf of Monsanto Company - 800 N. Lindbergh Boulevard - St. Louis, Missouri 63167 - United States.

2. **Designation and specification of the products:**

(a) Seeds for cultivation of maize MON 810.

(b) Seeds from genetically modified progeny derived from crosses of maize MON 810 with any conventional maize.

The genetically modified MON 810 maize as described in the application expresses the Cry1Ab protein, derived from *Bacillus thuringiensis* subsp. *kurstaki*, which confers protection against certain lepidopteran insect pests, including the European Corn Borer (ECB) (*Ostrinia nubilalis*) and pink borers (*Sesamia spp*).

3. **Labelling:**

(a) For the purposes of the labelling requirements laid down in 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 MON 810'.

(b) It shall be indicated on the label of each bag of seeds, or, for non-pre-packaged products, in an accompanying document, that 'the product protects itself against the European Corn Borer (*Ostrinia nubilalis*) and pink borers (*Sesamia spp*)'.

4. **Method for detection:**

- Event specific real-time PCR based method for the quantification of MON810 maize;
- Validated by the Federal Institute for Risk assessment (BfR) in collaboration with the Joint Research Centre of the European Commission and other parties, and verified by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from maize seeds, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;
- Reference Material: ERM-BF413 and ERM-AD413 shall be accessible via the Institute for Reference Materials and Measurements (IRMM) of the Joint Research Centre (JRC) of the European Commission at <https://irmm.jrc.ec.europa.eu/rmcatalogue>.

5. **Unique identifier:**

MON-ØØ81Ø-6

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

6.1 Geographical scope of the authorisation for cultivation

The cultivation of maize MON 810 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).

6.2 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 MON 810 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 MON 810:

- (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 meters shall be applied between a maize MON 810 field and a protected habitat as defined in Article 2(3) of Directive 2004/35/EC.

7. Monitoring plan for environmental effects

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

[Link: plan published on the internet]

8. Leaflet

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

- General description of the product, including general characteristics of the safety requirements for varieties derived from maize MON 810, and the unique identifier assigned to the GMO;
- The requirement that all operators keep records of transactions of maize MON 810 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 MON 810 field and a protected habitat as defined under 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, and 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.