

EN
ANNEX

(a) Applicant and authorisation holder:

Name: Bayer CropScience LP

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented in the Union by: Bayer Agriculture BV, Scheldelaan 460, 2040 Antwerp, Belgium.

(b) Designation and specification of the products:

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

The genetically modified maize MON-87427-7 expresses the CP4 *epsps* gene, which confers tolerance to glyphosate-based herbicides.

The genetically modified maize MON-87460-4 expresses a *Bacillus subtilis* modified *CspB* gene, which aims to reduce yield loss caused by drought stress. In addition, the *nptII* gene, conferring kanamycin and neomycin resistance, was used as a selection marker in the genetic modification process.

The genetically modified maize MON-89034-3 expresses the *cryIA.105* and *cry2Ab2* genes, which confer protection against certain lepidopteran pests.

The genetically modified maize SYN-IR162-4 expresses a modified *vip3Aa20* gene, which provides protection against certain lepidopteran pests. In addition, the *pmi* gene, coding for the PMI protein, was used as a selection marker in the genetic modification process.

The genetically modified maize MON-00603-6 expresses the CP4 *epsps* and the CP4 *epsps* L214P genes, which confers tolerance to glyphosate-based 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 documents accompanying the products containing or consisting of the genetically modified maize specified in point (e), with the exception of products referred to in point (b)(1).

(d) Method for detection:

- (1) The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events MON-87427-7, MON-87460-4, MON-89034-3, SYN-IR162-4 and MON-00603-6 and further verified on maize MON-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4 × MON-00603-6.
- (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: AOCS 0512 (for MON-87427-7), AOCS 0709 (for MON-87460-4) AOCS 0906 (for MON-89034-3) and AOCS 1208 (for SYN-IR162-4) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm#maize>, and ERM[®]-BF415 (for MON-00603-6) is accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue>.

(e) Unique identifiers:

MON-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4 × MON-00603-6;
MON-87427-7 × MON-87460-4 × MON-89034-3 × SYN-IR162-4;
MON-87427-7 × MON-87460-4 × MON-89034-3 × MON-00603-6;
MON-87427-7 × MON-87460-4 × SYN-IR162-4 × MON-00603-6;
MON-87460-4 × MON-89034-3 × SYN-IR162-4 × MON-00603-6;
MON-87427-7 × MON-87460-4 × MON-89034-3;
MON-87427-7 × MON-87460-4 × SYN-IR162-4;
MON-87427-7 × MON-87460-4 × MON-00603-6;
MON-87460-4 × SYN-IR162-4 × MON-00603-6;
MON-87460-4 × MON-89034-3 × SYN-IR162-4;
MON-87460-4 × MON-89034-3 × MON-00603-6;
MON-87427-7 × MON-87460-4;
MON-87460-4 × MON-89034-3.
MON-87460-4 × SYN-IR162-4;
MON-87460-4 × MON-00603-6;

(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 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:

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 Council¹.

[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.

¹ 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).