

ANNEX

(a) Applicant and authorisation holder:

Name: Bayer CropScience LP;

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

Represented in the Union by: Bayer Agriculture BV, Haven 627, Scheldelaan 460, B-2040 Antwerp, Belgium.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of or produced from genetically modified soybean as referred to in point (e);
- (2) feed containing, consisting of or produced from genetically modified soybean as referred to in point (e);
- (3) products containing or consisting of genetically modified soybean 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 soybean MON-87705-6 × MON-87708-9 × MON-89788-1, as described in the application, is produced by crosses between soybean containing MON-87705-6, MON-87708-9 and MON-89788-1 events. MON-87705-6 produces dsRNAs which downregulate endogenous fatty acid Δ 12-desaturase (FAD2) and palmitoyl acyl carrier protein thioesterase (FATB) enzymes; MON-87708-9 expresses the DMO protein and MON-89788-1 expresses the CP4 EPSPS protein. This combination confers an altered fatty acid profile (increased oleic acid and reduced linoleic acid content), and tolerance to herbicides containing glyphosate and to herbicides containing dicamba.

(c) Labelling:

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘soybean’;
- (2) For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words ‘with increased monounsaturated fat and reduced polyunsaturated fat’ shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products;
- (3) The words ‘not for cultivation’ shall appear on the label of and in documents accompanying the products containing or consisting of the genetically modified soybean referred to in point (e), with the exception of the 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 soybean MON-87705-6, MON-87708-9 and MON-89788-1 and further verified on soybean stack MON-87705-6 × MON-87708-9 × MON-89788-1.
- (2) Validated by the EU reference laboratory established under Regulation (EC) No1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>.
- (3) Reference Material: AOCS 0210-A (for MON87705), AOCS 0311-A (for MON87708) and AOCS 0906-B (for MON 89788) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>.

(e) Unique identifier:

MON-87705-6 × MON-87708-9 × MON-89788-1.

(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:

Not required.

(h) Monitoring plan for environmental effects:

Monitoring plan for environmental effects in accordance 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 plan:

1. The authorisation holder shall collect the following information:

- (i) quantities of genetically modified soybean MON-87705-6 × MON-87708-9 × MON-89788-1 for oil extraction, imported into the European Union for the placing on the market as or in products for food;
- (ii) In case of import of products mentioned under (i), results of database searches in the FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed.

2. The authorisation holder shall, based on the information collected and reported:

- (i) review the predicted consumption data of genetically modified soybean MON-87705-6 × MON-87708-9 × MON-89788-1;
- (ii) verify that the conditions of use of genetically modified soybean MON-87705-6 × MON-87708-9 × MON-89788-1 are those considered during the pre-market risk assessment.

Note: links to relevant documents may need to be modified over time. Those modifications will be made available to the public through the update of the Community register of genetically modified food and feed.