

ANNEX

(a) Applicant and authorisation holder:

Name: Bayer CropScience LLC

Address: 800 N. Lindbergh Boulevard, St Louis, Missouri, 63167, United States
represented in the Union by Bayer Agriculture B.V., 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 soybean MON-87705-6;
- (2) feed containing, consisting of or produced from genetically modified soybean MON-87705-6;
- (3) products containing or consisting of genetically modified soybean MON-87705-6, for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-87705-6 has a reduced expression of fatty acid Δ 12-desaturase (FAD2) and palmitoyl acyl carrier protein thioesterase (FATB) enzymes, which results in an increased oleic acid and a reduced linoleic acid profile and expresses the CP4 EPSPS protein, 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), points (a) and (b), of Regulation (EC) No 1829/2003, and in Article 4(6) 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 the documents accompanying the products containing or consisting of the genetically modified soybean MON-87705-6, with the exception of the products referred to in point (b)(1).

(d) Method for detection:

- (1) Event specific real-time PCR based method for the quantification of genetically modified soybean MON-87705-6;

- (2) validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <https://gmo-crl.jrc.ec.europa.eu/method-validations>;
- (3) reference material: AOCS 0210-A2 (for MON-877Ø5-6) and AOCS 0906-A (for the non-GM counterpart) are accessible through the American Oil Chemists Society (AOCS), at <https://www.aocs.org/>

(e) Unique identifier:

MON-877Ø5-6

(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:

Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003

1. The authorisation holder shall collect the following information:

- (i) quantities of MON-877Ø5-6 soybean oil and MON-877Ø5-6 soybeans 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, review the nutritional assessment conducted as part of the risk assessment.

(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 Council*.

*[Link: *plan published in the Community register of genetically modified food and feed*]

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

* 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, ELI: <http://data.europa.eu/eli/dir/2001/18/oj>).