

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-87769-7;
- (2) feed containing, consisting of or produced from genetically modified soybean MON-87769-7;
- (3) products containing or consisting of genetically modified soybean MON-87769-7, for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-87769-7 expresses the *Nc.Fad3* gene, which results in conversion of linoleic acid to α -linolenic acid, and the *Pj.D6D* gene which results in conversion of α -linolenic acid to stearidonic acid (SDA). SDA is a normal intermediate in the formation of long-chain omega-3 polyunsaturated fatty acids.

(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 stearidonic acid' 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 MON-87769-7, with the exception of the products referred to in point (b)(1).

(d) Method for detection:

- (1) event-specific method for the quantification of genetically modified soybean MON-87769-7 using real-time PCR;
- (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 0809-B (for MON-87769-7) and AOCS 0906-A (for the non-genetically modified counterpart) are accessible via the American Oil Chemists Society (AOCS) at <https://www.aocs.org/crm>.

(e) Unique identifier:

MON-87769-7

(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-87769-7 soybean oil and MON-87769-7 soybeans for oil extraction, imported into the Union for the placing on the market as or in products for food;
- (ii) in case of import of products referred to in point (i), results of 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;
- (iii) in case of import of products referred to in point (i), data on the different categories of food uses of MON-87769-7 soybean oil in the Union.

(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 Council¹.

[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.

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