

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 (*Glycine max* L.) MON-94637-8;
- (2) feed containing, consisting of or produced from genetically modified soybean (*Glycine max* L.) MON-94637-8;
- (3) products containing or consisting of genetically modified soybean (*Glycine max* L.) MON-94637-8 for uses other than those provided for in points (1) and (2), with the exception of cultivation.

The genetically modified soybean MON-94637-8 expresses the *cryIA.2* and *cryIB.2* genes, which confer protection against certain lepidopteran pests.

(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 ‘soybean’.
- (2) The words ‘not for cultivation’ shall appear on the label of and in documents accompanying the products containing or consisting of genetically modified soybean MON-94637-8, with the exception of 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-94637-8;
- (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 1023-A (for MON-94637-8) and AOCS 0906-A (for its non-GM counterpart), are accessible via the American Oil Chemists Society (AOCS), at <https://www.aocs.org/crm?SSO=True>.

(e) Unique identifier:

MON-94637-8

(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 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 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 through the updating of the Community register of genetically modified food and feed.