

**COMMISSION IMPLEMENTING DECISION (EU) 2017/2449****of 21 December 2017****authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed***(notified under document C(2017) 9041)***(Only the English text is authentic)****(Text with EEA relevance)***Article 1***Genetically modified organism and unique identifier**

Genetically modified soybean (*Glycine max* (L.) Merr.) DAS-68416-4, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-68416-4, in accordance with Regulation (EC) No 65/2004.

*Article 2***Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from soybean DAS-68416-4;
- (b) feed containing, consisting of, or produced from soybean DAS-68416-4;
- (c) soybean DAS-68416-4 in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation.

*Article 3***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 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 the product and in the documents accompanying products containing or consisting of genetically modified soybean DAS-68416-4, with the exception of products referred to in Article 2(a).

▼ B*Article 4***Monitoring plan for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

*Article 5***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of soybean DAS-68416-4.

*Article 6***Community register**

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

▼ M1*Article 7***Authorisation holder**

The authorisation holder shall be Dow AgroSciences Distribution S.A.S., France, on behalf of Dow AgroSciences LLC.

▼ B*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

▼ M1*Article 9***Addressee**

This Decision is addressed to Dow AgroSciences Distribution S.A.S., 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France.

▼ B*ANNEX***(a) Authorisation holder:**

Name: ► **M1** Dow AgroSciences Distribution S.A.S. ◀

Address: ► **M1** 6, rue Jean Pierre Timbaud, 78180 Montigny-le-Bretonneux, France ◀.

On behalf of

Dow AgroSciences LLC, 9330 Zionsville Road Indianapolis, Indiana 46268-1054, USA

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of, or produced from soybean DAS-68416-4;
- (2) feed containing, consisting of, or produced from soybean DAS-68416-4;
- (3) soybean DAS-68416-4 in products containing it or consisting of it for any other use than those provided in points (1) and (2), with the exception of cultivation.

DAS-68416-4 soybean expresses the AAD-12 protein, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, and the PAT protein, which confers tolerance to glufosinate ammonium-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 'soybean';
- (2) The words 'not for cultivation' shall appear on the label of the products and in the accompanying documents of the products containing or consisting of soybean DAS-68416-4 with the exception of products referred to in point (a) of Article 2.

(d) Method for detection:

- (1) Event specific real-time quantitative PCR based method for DAS-68416-4 soybean; the detection method is validated on the single-trait event using genomic DNA extracted from seeds of DAS-68416-4 soybean;
- (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: ERM®-BF432 accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/>.

(e) Unique identifier:

DAS-68416-4;

▼B**(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 conforming 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 the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.