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COMMISSION DECISION

of 10 March 2009

authorising the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2) resulting from the commercialisation of this oilseed rape in third countries until 2005 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document number C(2009) 1541)

(Only the German text is authentic)

(Text with EEA relevance)

(2009/184/EC)

(OJ L 68, 13.3.2009, p. 28)

Amended by:

Official Journal

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| <u>M1</u> | Commission Implementing Decision (EU) 2019/1195 of 10 July 2019 | L 187 | 43 | 12.7.2019 |

COMMISSION DECISION

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(Text with EEA relevance)

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Article 1

Genetically modified organism and unique identifier

Genetically modified oilseed rape (*Brassica napus* L.) T45, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-BNØØ8-2, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

- 1. The purpose of this Decision is to grant an authorisation covering, for the products referred to in paragraph 2, the presence of ACS-BNØØ8-2 oilseed rape resulting directly or indirectly from the commercialisation, until 2005, of ACS-BNØØ8-2 oilseed rape seeds in third countries.
- 2. The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:
- (a) foods and food ingredients containing or produced from ACS-BNØØ8-2 oilseed rape;
- (b) feed containing or produced from ACS-BNØØ8-2 oilseed rape;
- (c) products other than food and feed containing ACS-BNØØ8-2 oilseed rape for the same uses as any other oilseed rape with the exception of cultivation.

Article 3

Labelling

- 1. For the purposes of the labelling requirements laid down in Articles 13(1) and 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 'oilseed rape'.
- 2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing ACS-BNØØ8-2 oilseed rape referred to in Article 2(2)(b) and (c).

Article 4

Monitoring 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 to the Commission annual reports on the implementation and the results of the activities set out in the monitoring activities.

Article 5

Monitoring of the phasing out

- 1. The authorisation holder shall ensure that shipments of oilseed rape imported in the European Union from a third country in which ACS-BNØØ8-2 oilseed rape seeds were commercialised until 2005 are sampled and tested for the presence of ACS-BNØØ8-2 oilseed rape.
- 2. The method used for the sampling of oilseed rape shall be internationally recognised. The testing shall be made in a duly accredited laboratory and in accordance with the validated method of detection as set out in the Annex to this Decision.
- 3. The authorisation holder shall submit to the Commission, together with the reports referred to in Article 4(2), annual reports on the monitoring activities for the presence of ACS-BNØØ8-2 oilseed rape.

Article 6

Community register

The information set out in the Annex to this Decision 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.

Article 7

Authorisation holder

The authorisation holder shall be $ightharpoonup^{}\underline{M1}$ BASF Agricultural Solutions Seed US LLC, USA, represented by \overline{BASF} SE, Germany \blacktriangleleft .

Article 8

Validity

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

Article 9

Addressee

This Decision is addressed to $\blacktriangleright \underline{M1}$ BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen \blacktriangleleft , Germany.

ANNEX

▼ M1

(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States

of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.

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(b) Designation and specification of the products:

- 1. Foods and food ingredients containing or produced from ACS-BN $\emptyset\emptyset$ 8-2 oilseed rape.
- 2. Feed containing or produced from ACS-BNØØ8-2 oilseed rape.
- 3. Products other than food and feed containing ACS-BNØØ8-2 oilseed rape for the same uses as any other oilseed rape with the exception of cultivation.

The genetically modified ACS-BNØØ8-2 oilseed rape, as described in the application, expresses the PAT protein which confers tolerance to the glufosinate-ammonium herbicide.

(c) Labelling:

- 1. For the purposes of the specific labelling requirements laid down in Articles 13(1) and 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 'oilseed rape'.
- 2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing ACS-BNØØ8-2 oilseed rape referred to in Article 2(2)(b) and (c) of this Decision.

(d) Method for detection:

- Event specific real-time PCR-based method for the quantification of ACS-BNØØ8-2 oilseed rape.
- Validated on seeds by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec. europa.eu/statusofdoss.htm

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 Reference material: AOCS 0208-A accessible via the American Oil Chemists Society at https://www.aocs.org/crm

▼<u>B</u>

(e) Unique identifier:

ACS-BNØØ8-2

▼<u>B</u>

(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:

Biosafety Clearing-House, Record ID: see (to be completed when notified)

(g) Conditions or restrictions on the placing on the market, use or handling of the products:

Not required.

(h) Monitoring plan:

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC

(Link: plan published on the Internet)

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