Commission Decision of 2 March 2010 authorising the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2010) 1196) (Only the German text is authentic) (Text with EEA relevance) (2010/136/EU)

COMMISSION DECISION

of 2 March 2010

authorising the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2010) 1196)

(Only the German text is authentic)

(Text with EEA relevance)

(2010/136/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(1)], and in particular Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 28 February 2005, BASF Plant Science GmbH, submitted to the competent authorities of the United Kingdom an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of genetically modified potato EH92-527-1 for food and feed uses, food and feed containing, consisting, or produced from potato EH92-527-1, with the exception of cultivation.

(2) It follows from the application that feed produced from genetically modified potato EH92-527-1 is, as for any conventional starch potato, a by-product of the starch processing and is the only intended use in the food and feed chains.

(3) On 10 November 2006, the European Food Safety Authority (EFSA) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 and concluded that it is unlikely that the placing on the market of the products containing, consisting, or produced from potato EH92-527-1[(2)] as described in the application (the products) will have adverse effects on human or animal health or the environment. In its opinion, EFSA considered all the specific questions and concerns raised by the

Member States in the context of the consultation of the national competent authorities, as provided for by Articles 6(4) and 18(4) of that Regulation.

(4) Accordingly, EFSA advised that no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 are necessary. EFSA also considered that no specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements, and no specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Articles 6(5) and 18(5) of the Regulation, had to be applied.

(5) In its opinion, EFSA concluded that the environmental monitoring plan submitted by the applicant is in line with the intended uses of the products. This environmental monitoring will be carried out for the purpose of Commission Decision 2010/135/EU of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (*Solanum tuberosum* L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch[(3)].

(6) On 26 February 2007, in the light of a report published by the World Health Organisation listing kanamycin and neomycin as 'critically important antibacterial agents for human medicine and for risk management strategies of non-human use', the European Medicines Agency issued a statement highlighting the therapeutic relevance of both antibiotics in human and veterinary medicine. On 13 April 2007, taking into account this statement, EFSA indicated that the therapeutic effect of the antibiotics at stake will not be compromised by the presence of the *nptII* gene in GM plants. This is due to the extremely low probability of gene transfer from plants to bacteria and its subsequent expression and to the fact that this antibiotic resistant gene in bacteria is already widespread in the environment. It thus confirmed its previous assessment of the safe use of the antibiotic resistance marker gene *nptII* in genetically modified organisms and their derived products for food and feed uses.

(7) On 14 May 2008, the Commission sent a mandate to EFSA, with a request: (i) to prepare a consolidated scientific opinion taking into account the previous opinion and the statement on the use of ARM genes in GM plants intended or already authorised to be placed on the market and their possible uses for import and processing and for cultivation; (ii) to indicate the possible consequences of this consolidated opinion on the previous EFSA assessments on individual GMOs containing ARM genes. The mandate brought to the attention of EFSA, inter alia, letters by the Commission from Denmark and Greenpeace.

(8) On 11 June 2009, EFSA published a statement on the use of ARM genes in GM plants which concludes that the previous assessment of EFSA on genetically modified potato EH92-527-1 is in line with the risk assessment strategy described in the statement, and that no new evidence has become available that would prompt EFSA to change its previous opinion.

(9) In the light of the above considerations, authorisation should be granted.

(10) The authorisation for the cultivation and industrial use of potato EH92-527-1 is provided by Decision 2010/135/EU that is providing for conditions for use and handling that aim to avoid any co-mingling with material derived from conventional potatoes intended for food or feed.

(11) Despite the application of these measures, it can not be excluded that the genetically modified potato and some products of the starch processing may be present in food or feed. Such a presence should be considered adventitious or technically unavoidable and can be accepted provided it is in a proportion no higher than 0,9 %.

(12) A unique identifier should be assigned to each GMO as provided for in Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms[(4)].

(13) All information contained in the Annex to this Decision on the authorisation of the products should be entered in the Community register of genetically modified food and feed as provided for in the Regulation.

(14) In accordance with Articles 4(2) and 16(2) of the Regulation, the conditions for authorisation of the products bind all persons placing them on the market.

(15) This Decision should be notified through the Biosafety Clearing House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms[(5)].

(16) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman.

(17) At its meeting on 18 February 2008, the Council was unable to reach a decision by qualified majority either for or against the proposal. It is accordingly for the Commission to adopt the measures,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified potato (*Solanum tuberosum* L.) EH92-527-1, as specified in point (b) of the Annex, is assigned the unique identifier BPS-25271-9, as provided for in 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, according to the conditions specified in this Decision:

(a) feed produced from BPS-25271-9 potato;

(b) foods containing, consisting of, or produced from BPS-25271-9 potato resulting from the adventitious or technically unavoidable presence of this GMO in a proportion no higher than 0,9 % of the food ingredients considered individually or food consisting of a single ingredient;

(c) feed containing or consisting of BPS-25271-9 potato resulting from the adventitious or technically unavoidable presence of this GMO in a proportion no higher than 0,9 % of the feed and of each feed of which it is composed.

Article 3

Labelling

For the purposes of the labelling requirements laid down in Article 25(2) of Regulation (EC) No 1829/2003, the ‘name of the organism’ shall be ‘amylopectin starch potato’.

Article 4

Monitoring for environmental effects

1 The monitoring plan for environmental effects provided for in Article 4 of Decision 2010/135/EU shall be considered as also applicable for the purpose of this Decision.

2 The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the monitoring activities.

Those reports shall clearly state which parts of the reports are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003.

Confidential parts of such reports shall be submitted in separate documents.

Article 5

Community register

The information 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 6

Authorisation holder

The authorisation holder shall be BASF Plant Science GmbH, Germany.

Article 7

Validity

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

Article 8

Addressee

This Decision is addressed to BASF Plant Science GmbH, Carl-Bosch-Straße 38, 67056 Ludwigshafen, Germany.

Done at Brussels, 2 March 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a)**Applicant and Authorisation holder:**

Name : BASF Plant Science GmbH
Address : Carl-Bosch-Straße 38, 67056 Ludwigshafen, Germany

(b) **Designation and specification of the products:**

1. feed produced from BPS-25271-9 potato;

2. foods containing, consisting of, or produced from BPS-25271-9 potato resulting from the adventitious or technically unavoidable presence of this GMO in a proportion no higher than 0,9 % of the food ingredients considered individually or food consisting of a single ingredient;

3. feed containing or consisting of BPS-25271-9 potato resulting from the adventitious or technically unavoidable presence of this GMO in a proportion no higher than 0,9 % of the feed and of each feed of which it is composed.

The genetically modified potato BPS-25271-9, as described in the application, has an altered starch composition (higher amylopectin/amylose ratio). The modification implies inhibition of the expression of granule bound starch synthase protein (GBSS) responsible for amylose biosynthesis. As a result, the starch produced has little or no amylose and consists of amylopectin which modifies the physical properties of the starch. An *nptII* gene, conferring kanamycin resistance, was used as a selectable marker in the genetic modification process.

(c) **Labelling:**

For the purposes of the labelling requirements laid down in Article 25(2) of Regulation (EC) No 1829/2003, the ‘name of the organism’ shall be ‘amylopectin starch potato’.

(d) **Method for detection:**

— Event specific real-time quantitative PCR based method for genetically modified potato BPS-25271-9.

— Validated by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.it/statusofdoss.htm

— Reference Material: ERM®-BF421 accessible via the Joint Research Centre (JRC) of the European Commission, the Institute of Reference Materials and Measurements (IRMM) at http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

(e) **Unique identifier:**

BPS-25271-9

(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 provided for in Article 4 of Decision 2010/135/EU.

(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.

(**1**) OJ L 268, 18.10.2003, p. 1.

(**2**) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-070

(**3**) See page 11 of this Official Journal.

(**4**) OJ L 10, 16.1.2004, p. 5.

(**5**) OJ L 287, 5.11.2003, p. 1.

Status:
Point in time view as at 02/03/2010.

Changes to legislation:
There are currently no known outstanding effects for the Commission Decision of 2 March 2010 authorising the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2010) 1196) (Only the German text is authentic) (Text with EEA relevance) (2010/136/EU).