COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Draft

COMMISSION DECISION

of

authorising the placing on the market of food and feed containing, consisting of, or produced from the genetically modified potato line EH92-527-1 (BPS-25271-9) under Regulation (EC) No 1829/2003 of the European Parliament and of the Council

DOES NOT NECESSARILY REPRESENT THE POSITION OF THE COMMISSION

STILL UNDER INTERSERVICE CONSULTATION

Draft

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 Article 7(3) thereof,

Whereas:

(1) On 28 February 2005, BASF Plant Science, 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) 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 ('Authority') gave a favourable opinion in accordance with Articles 6 and 18 of the 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.

(4) Accordingly, the Authority advised that no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of the Regulation (EC) No 1829/2003 are necessary. The Authority 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

1 OJ L 268, 18.10.2003, p 1.

2 http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications/more_info/909.html

provided for in point (e) of Articles 6(5) and 18(5) of the Regulation, had to be applied.

(5) In its opinion, the Authority 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 …[3] 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.

(6) On 25 January 2007, following comments from the public and 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 Commission consulted the European Medicines Agency (EMEA) regarding the therapeutic relevance in human and veterinary medicine of antibiotics for which *nptII* gene allows resistance. Upon reception of the answer of EMEA, the Commission requested EFSA to review its earlier safety assessments of *nptII* gene and GM plants comprising the *nptII* gene in the light of this response. On 13 April 2007, EFSA confirmed its earlier safety assessments of GM plants comprising the *nptII* gene concluding that the presence of the *nptII* gene in GM plants for food and feed uses does not pose a risk to human or animal health or to the environment.

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

(8) The authorisation for the cultivation and industrial use of potato EH92-527-1 is provided by Commission Decision *…[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]* 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.

(9) Despite 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. In this case the presence of EH92-527-1 potato or products produced from EH92-527-1 potato in food and feed should be considered adventitious or technically unavoidable and should be in a proportion no higher than 0.9 per cent.

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

(11) 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.

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[3] OJ references to be completed

[4] OJ L 10, 16.1.2004, p. 5.

(12) 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.

(13) 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 Articles 9(1) and 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].

(14) This Decision is in agreement with the opinion of the Standing Committee on the Food Chain and Animal Health that was delivered on …;

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 1829/2003, according to the conditions specified in this Decision and its Annex:

(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 per cent 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 per cent 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’.

[5] OJ L 287, 5.11.2003, p. 1.

Article 4
Monitoring for environmental effects

1. The monitoring plan for environmental effects provided for in Article 4 of Decision […] [*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*] 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 Annexes 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. Other modifications of the Community register shall be made accordingly.

Article 6
Authorisation holder

The authorisation holder is BASF Plant Science, Germany.

Article 7
Applicability and Validity

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

Article 8
Addressee

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

Done at Brussels, […]

For the Commission

[…]

ANNEX I

(a) Applicant and Authorisation holder:

Name: BASF Plant Science

Address: Carl-Bosch-Str.38, D-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 per cent 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 per cent 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. A *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 and in Article 4(6) of Regulation (EC) n° 1830/2003, 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 […] 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.

(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.