COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.12.2007
COM(2007) 813 final

Proposal for a

COUNCIL DECISION

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

(Only the German text is authentic)

(presented by the Commission)

EXPLANATORY MEMORANDUM

The attached proposal for a Council Decision concerns feed produced from the genetically modified potato EH92-527-1 and the adventitious or technically unavoidable presence of the potato in food and other feed products, for which a request for placing on the market was submitted by BASF Plant Science GmbH to the competent authorities of The United Kingdom on 28 February 2005, under Regulation (EC) No 1829/2003 on genetically modified food and feed.

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 of, or produced from potato EH92-527-1 as described in the application will have adverse effects on human or animal health or the environment[1].

On 13 April 2007, EFSA reconfirmed that the use of the *nptII* gene as a selectable marker in GM plants does not pose a risk to human or animal health or the environment.

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]*

Against this background, a draft Commission Decision authorising the placing on the Community market of feed produced from the genetically modified potato EH92-527-1 and the adventitious or technically unavoidable presence of the potato in food and other feed products was submitted to the Standing Committee on the Food Chain and Animal Health, on 10 October 2007, for vote. The Committee delivered no opinion: ten Member States (123 votes) voted in favour, twelve Member States (133 votes) voted against and five Member States (89 votes) abstained.

Consequently, pursuant to Article 35, paragraph 2 of Regulation (EC) No 1829/2003 and in accordance with Article 5 of Council Decision 1999/468/EC modified by Council Decision 2006/512/EC, the Commission is required to submit to the Council a proposal relating to the measures to be taken, the Council having three months in which to act by a qualified majority, and inform the Parliament.

[1] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_1178620785504.htm

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(Only the German text is authentic)

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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[2], 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 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[3] 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.

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2 OJ L 268, 18.10.2003, p 1. Regulation as amended by Commission Regulation EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).

3 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753816_1178620785504.htm

(4) Accordingly, EFSA 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. 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 … 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. [4]

(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 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 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[5].

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[4] OJ references to be completed.

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

(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.

(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[6].

(14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman and the measures provided for in this Decision must therefore be adopted by the Council,

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 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.

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

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 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*] 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-Str.38, D-67056 Ludwigshafen, Germany.

Done at Brussels,

For the Council
The President

ANNEX

(a) Applicant and Authorisation holder:

Name: BASF Plant Science GmbH

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. 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 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.

(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.