COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.6.2007
COM(2007) 336 final

Proposal for a

COUNCIL 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

(Only the Swedish text is authentic)

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. In accordance with Article 13 of Directive 2001/18/EC, the Swedish authorities received from BASF Plant Science a notification (Reference C/SE/96/35-01) concerning the placing on the market of a potato (*Solanum tuberosum* L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch.

2. The notification originally covered cultivation and processing into industrial starch, as well as use in feed in the Community.

3. In accordance with Article 14 of the Directive, the Swedish competent authority forwarded to the Commission its assessment report of the notification, which concluded that genetically modified potato should be placed on the market for its intended uses.

4. On 9 December 2005, BASF Plant Science informed the Swedish competent authority of its intention to exclude feed uses from the notification under Directive 2001/18/EC, limiting its scope to cultivation and production of starch for industrial uses.

5. The Commission forwarded the assessment report to all other Member States, some of which raised and maintained objections to the placing on the market of the products in terms of molecular characterisation, allergenicity, toxicity, an inadequate monitoring plan and the detection method of the product.

6. In light of these objections, and in accordance with Article 28(1) of Directive 2001/18/EC and Article 22(5)(c) of Regulation(EC) No 178/2002[1], the Commission consulted with the European Food Safety Authority (EFSA), which delivered its opinion on 24 February 2006 concluding that, from all evidence provided, the genetically modified potato (*Solanum tuberosum* L. line EH92-527-1) is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses.

7. Whereby in accordance with Article 18(1) of Directive 2001/18/EC the Commission is required to take a decision in accordance with the procedure laid down in Article 30(2) of Directive 2001/18/EC to which Articles 5 and 7 of Council Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

8. A draft of the measures to be taken was submitted, in accordance with Article 5(2) of Decision 1999/468/EC, for opinion, to the Committee set up in accordance with Article 30 of Directive 2001/18/EC.

9. The Committee which was consulted on 4 December 2006 has not delivered an opinion. Therefore, and in accordance with Article 5(4) of Decision 1999/468/EC, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken and inform the European Parliament; the European Parliament

[1] OJ L 31, 1.2.2002, p.1

was informed on 8 December 2006. The European Parliament may consider appropriate to take a position in accordance with Article 8 of the above Decision.

10. 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 23 March 2007, taking into account this statement, EFSA confirmed its previous assessment of the safe use of the antibiotic resistance marker gene *npt*II in genetically modified organisms and their derived products for food and feed uses.

11. Article 5(6) of Decision 1999/468/EC provides that the Council may, where appropriate in view of any such position, act by qualified majority on the proposal within a period set at three months in accordance with Article 30(2) of Directive 2001/18/EC. If within that three-month period the Council has indicated by qualified majority that it opposes the proposal, the Commission shall re-examine it; whereas if, on expiry of that period, the Council has neither adopted the proposed implementing act nor indicated its opposition, then the proposed implementing act shall be adopted by the Commission.

Proposal for a

COUNCIL 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

(Only the Swedish 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 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[2], and in particular the first subparagraph of Article 18(1) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority of the Member State that received the notification for the placing on the market of that product, in accordance with the procedure laid down in that Directive.

(2) A notification (Reference C/SE/96/3501) concerning the placing on the market of a genetically modified potato product (*Solanum tuberosum* L. line EH92-527-1) was submitted by BASF Plant Science (formerly Amylogen HB) to the competent authority of Sweden.

(3) The notification originally covered the placing on the market of *Solanum tuberosum* L. line EH92-527-1 for cultivation and processing into industrial starch, as well as use in feed in the Community.

(4) In accordance with the procedure established by Article 14 of Directive 2001/18/EC, the competent authority of Sweden prepared an assessment report , which concluded that there is no scientific evidence to indicate that the placing on the market of the

[2] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p.24).

Solanum tuberosum L. line EH92-527-1 poses any risk to human and animal health or the environment for the requested uses.

(5) The assessment report was submitted to the Commission and the competent authorities of the other Member States, which raised and maintained objections to the placing on the market of the product.

(6) On 9 December 2005, BASF Plant Science informed the Swedish competent authority of its intention to exclude feed uses from the notification under Directive 2001/18/EC, limiting its scope to cultivation of the *Solanum tuberosum* L. line EH92-527-1 and production of starch for industrial uses.

(7) An application for the placing on the market of feed and food containing, consisting of, or produced from *Solanum tuberosum* L. line EH92-527-1 was submitted, on 25 April 2005, by BASF Plant Science under Regulation (EC) No 1829/2003[3].

(8) The opinions of the European Food Safety Authority concerning the placing on the market of *Solanum tuberosum* L. line EH92-527-1 for cultivation and industrial starch production under Directive 2001/18/EC and feed and food under Regulation (EC) No 1829/2003, published on 24 February 2006, concluded that the product is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses.

(9) An examination of each of the objections maintained by the Member States in the light of Directive 2001/18/EC, of the information submitted in the notification and of the opinion of the European Food Safety Authority, discloses no evidence to believe that the placing on the market of *Solanum tuberosum* L. line EH92-527-1 is likely to cause adverse effects on human and animal health or the environment in the context of its proposed uses.

(10) 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 23 March 2007, taking into account this statement, EFSA confirmed its previous assessment of the safe use of the antibiotic resistance marker gene *npt*II in genetically modified organisms and their derived products for food and feed uses.

(11) A unique identifier should be assigned to the *Solanum tuberosum* L. line EH92-527-1 for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[4] and Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a

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[3] OJ L 268, 18.10.2003, p. 1

[4] OJ L 268, 18.10.2003, p. 24

system for the development and assignment of unique identifiers for genetically modified organisms[5].

(12) The proposed labelling, on a label or in an accompanying document, of products containing or consisting of *Solanum tuberosum* L. line EH92-527-1 should include wording to inform operators and final users that such material cannot be used for human or animal consumption.

(13) Until a Community Decision under Regulation (EC) No 1829/2003 authorising the placing on the market of the *Solanum tuberosum* L. line EH92-527-1 for uses as or in feed and food enters into force, potato tubers should be cultivated, handled, transported and processed to prevent the genetically modified potato product or the by-products resulting from the industrial starch production process from entering the food and feed chains; whereby such material should be exclusively used for industrial purposes or destroyed.

(14) Member States should utilise the registers established, in accordance with Article 31(3)(b) of Directive 2001/18/EC, for recording the location of GMOs grown under Part C of the Directive, inter alia to facilitate monitoring and general surveillance and for the purpose of inspection and control.

(15) In view of the opinion of the European Food Safety Authority, it is not necessary to establish specific conditions for the intended uses with regard to the handling or packaging of the product and the protection of particular ecosystems, environments or geographical areas.

(16) In order to complement existing field studies carried out in northern Europe, which indicated that the cultivation of *Solanum tuberosum* L. line EH92-527-1 is unlikely to have adverse effects on the environment, additional measures to monitor potato-feeding organisms in the fields and their vicinity where *Solanum tuberosum* L. line EH92-527-1 is commercially cultivated should be put in place as part of the monitoring programme.

(17) Prior to the placing on the market of the *Solanum tuberosum* L. line EH92-527-1, the necessary measures to ensure its labelling and traceability at all stages of its placing on the market, including verification by appropriate validated detection methodology, should be applicable.

(18) A detection method for the *Solanum tuberosum* L. line EH92-527-1 has been validated by the Community Reference Laboratory as referred to in Article 32 of Regulation (EC) No 1829/2003, in accordance with Commission Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003[6].

(19) The measures provided for in this Decision are in accordance with the opinion of the Committee set up under Article 30(1) of Directive 2001/18/EC;

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[5] OJ L 10, 16.01.2004, p. 5-10

[6] OJ L 102, 07.04.2004, p.14.

HAS ADOPTED THIS DECISION:

Article 1
Consent

Without prejudice to other Community legislation, in particular Regulation (EC) No 1829/2003, written consent shall be granted by the competent authority of Sweden to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified (Reference C/SE/96/3501) by BASF Plant Science.

The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, which are set out in Articles 3 and 4.

Article 2
Product

1. The genetically modified organism to be placed on the market as or in products, hereinafter 'the product' is potato (*Solanum tuberosum* L.) modified for enhanced content of the amylopectin component of starch, which has been transformed with Agrobacterium tumefaciens, using the vector pHoxwG, resulting in line EH92-527-1. The product contains the following DNA in two cassettes:

   (a) Cassette 1:

   An nptII-type kanamycin resistance gene originating from Tn5, under the regulation of a nopaline-synthase promoter for expression in plant tissue and terminated by a polyadenylation sequence from the Agrobacterium tumefaciens nopaline-synthase gene.

   (b) Cassette 2:

   A segment of the potato gbss gene encoding for granule bound starch synthase protein inserted in reversed orientation under the control of the gbss-promoter isolated from potato, and terminated by a polyadenylation sequence from the Agrobacterium tumefaciens nopaline-synthase gene.

2. The consent shall cover genetically modified *Solanum tuberosum* L. line EH92-527-1 as or in products.

Article 3
Conditions for placing on the market

The product may be placed on the market for cultivation and industrial use subject to the following conditions:

(a) In accordance with Article 15(4) of Directive 2001/18/EC, the period of validity of the consent shall be 10 years starting from the date at which the consent for *Solanum tuberosum* L. line EH92-527-1 is issued;

(b) The unique identifier of the products shall be BPS-25271-9;

(c) Without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall make available positive and negative control samples of the product and its genetic materials and reference materials to the competent authorities and to inspection services of Member States as well as to the Community control laboratories on request;

(d) A detection method specific to *Solanum tuberosum* L. line EH92-527-1, validated by the Community Reference Laboratory as referred to in the Annex of Regulation (EC) No 1829/2003 is available for the purpose of inspection and control;

(e) Without prejudice to specific labelling requirements provided by Regulation (EC) No 1829/2003, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified EH92-527-1 potato' and the words 'not for human consumption' shall appear either on a label or in a document accompanying the product. Pending Community approval of the product for use as or in feed, the words 'not for animal consumption' shall also appear on this label or in the document accompanying the product.

(f) It shall also be indicated on the label, or in an accompanying document, that the product contains an altered starch composition;

(g) Throughout the validity of the consent, the consent holder when placing *Solanum tuberosum* L. line EH92-527-1 on the market in a Member State shall directly inform operators and users on the safety and general characteristics of the product, of the legal requirements for the placing on the market of material harvested from crops containing this line;

(h) In view that this decision covers only cultivation and industrial use, the consent holder shall ensure that potato tubers of *Solanum tuberosum* L. line EH92-527-1 are;

(i) physically separated from potatoes for food and feed uses during planting, cultivation, harvest, transport, storage and handling in the environment;

(ii) delivered exclusively to designated starch processing plants, notified to the relevant national competent authority, for processing into industrial starch within a closed system, either by time or space separation, to avoid any co-mingling with material derived from potatoes intended for food or feed;

(iii) only processed into industrial starch on the basis that, pending Community approval of the product for use as or in feed, the by-product material from this process is used exclusively for industrial purposes or destroyed.

Article 4
Monitoring

1. Throughout the period of validity of the consent;

(a) The consent holder shall ensure that the monitoring plan, to monitor for any adverse effects on human and animal health or the environment arising from

handling or use of the product, is put in place and implemented. This monitoring plan includes case-specific monitoring, general surveillance and an Identity Preservation System (IPS), as contained in the notification and may be subject to further modifications as laid down in this Article.

(b) The consent holder shall ensure that monitoring includes data as to the area of land cultivated with *Solanum tuberosum* L. line EH92-527-1 and the quantity of harvested material.

(c) Pending Community approval of the product for use as or in feed, the consent holder shall ensure that information as to the disposal of the by-products is made available.

(d) The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

(i) that the existing monitoring networks, as specified in the monitoring plan contained in the notification, gathers the information relevant for the monitoring of the products; and

(ii) that these existing monitoring networks have agreed to make available that information to the consent holder before the date of submission of the monitoring reports to the Commission and competent authorities of the Member States in accordance with paragraph 3.

(e) The consent holder shall extend the existing monitoring networks, to include all growers of *Solanum tuberosum* L. line EH92-527-1, on the basis of the questionnaire and reporting system detailed in the notification.

(f) The consent holder shall carry out specific field studies to monitor potential adverse effects on potato-feeding organisms in the fields and their vicinity where *Solanum tuberosum* L. line EH92-527-1 is cultivated in accordance with the requirements laid down in Annex I.

2. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of all monitoring activities, the first time being one year after final consent is granted.

3. Without prejudice to Article 20 of Directive 2001/18/EC the monitoring plan as notified shall be revised by the consent holder, where appropriate and subject to the agreement of the Commission and the competent authority of the Member State which received the original notification, and/or by the competent authority of the Member State which received the original notification, subject to the agreement of the Commission, in the light of the results of the monitoring activities. Proposals for a revised monitoring plan shall be submitted to the competent authorities of the Member States.

Article 5
Addressee

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels,

For the Council
The President

ANNEX I

Monitoring of potato-feeding organisms in the fields where *Solanum tuberosum* L. line EH92-527-1 is cultivated and in their vicinity.

1. The consent holder shall undertake field studies to monitor the potential adverse effects on potato-feeding organisms in the fields where *Solanum tuberosum* L. line EH92-527-1 is cultivated and in their vicinity.

2. The monitoring study shall focus on model potato-feeding organisms in the potato fields and in their vicinity, representative of key ecological functions in the agricultural environment.

3. The monitoring study shall take into account the latest scientific findings and use state-of-the-art protocols including statistical analysis of the data in accordance with standard methods.

4. The results of these studies shall be evaluated in view of the risk assessment contained in the notification and reported as provided for in Article 4(2).

5. Where appropriate, the results of these studies shall be used to review and modify the monitoring plan proposed in the notification as provided for in Article 4(3).