Commission Decision 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 (notified under document C(2010) 1193) (Only the Swedish text is authentic) (Text with EEA relevance) (2010/135/EU)

COMMISSION DECISION

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

(notified under document C(2010) 1193)

(Only the Swedish text is authentic)

(Text with EEA relevance)

(2010/135/EU)

THE EUROPEAN COMMISSION,

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

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[1], and in particular the first subparagraph of Article 18(1) thereof,

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 *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 of the European Parliament and of the Council[(2)].

(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 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.

(11) 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.

(12) 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 *Solanum tuberosum* L. line 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.

(13) 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[(3)] and 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)].

(14) 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.

(15) Feed produced from *Solanum tuberosum* L. line EH92-527-1 as well as the adventitious or technically unavoidable presence of the potato in food and other feed products have been authorised under Commission Decision 2010/136/EU[(5)] under Regulation (EC) No 1829/2003.

(16) 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.

(17) In view of the opinion of EFSA, 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.

(18) 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.

(19) 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.

(20) 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 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation[(6)].

(21) The Committee established under Article 30(1) of Directive 2001/18/EC has not delivered an opinion within the time-limit laid down by its Chairman.

(22) At its meeting on 16 July 2007, 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

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 to 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;

(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, and 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.

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 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 2;

d 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;

e 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.

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, 2 March 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX

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).

(**1**) OJ L 106, 17.4.2001, p. 1.

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

(**3**) OJ L 268, 18.10.2003, p. 24.

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

(**5**) See page 15 of this Official Journal.

(**6**) OJ L 102, 7.4.2004, p. 14.

Changes to legislation:
There are currently no known outstanding effects for the Commission Decision 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 (notified under document C(2010) 1193) (Only the Swedish text is authentic) (Text with EEA relevance) (2010/135/EU).