

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)

#### *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.

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### 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:

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- 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.

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Done at Brussels, 2 March 2010.

*For the Commission*

John DALLI

*Member of the Commission*

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