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Contents

[1] Text with EEA relevance

(Continued overleaf)

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EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

EN

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 182/2010

of 3 March 2010

entering a name in the register of traditional specialities guaranteed (Belokranjska pogača (TSG))

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed [1], and in particular the first subparagraph of Article 9(4) thereof,

Whereas:

(1) In accordance with the first subparagraph of Article 8(2) of Regulation (EC) No 509/2006, and pursuant to Article 19(3) of the same Regulation, the application submitted by Slovenia to register the name 'Belokranjska pogača' was published in the *Official Journal of the European Union* [2].

(2) As no objection pursuant to Article 9 of Regulation (EC) No 509/2006 has been received by the Commission, this name should be entered in the register.

(3) The application also requested protection pursuant to Article 13(2) of Regulation (EC) No 509/2006. That protection should be granted to the name 'Belokranjska pogača' in so far as, in the absence of objections, it could not be demonstrated that the name is used in a lawful, renowned and economically significant manner for similar agricultural products or foodstuffs,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

Protection as referred to in Article 13(2) of Regulation (EC) No 509/2006 shall apply.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 93, 31.3.2006, p. 1.
[2] OJ C 137, 17.6.2009, p. 19.

ANNEX

Foodstuffs referred to in Annex I to Regulation (EC) No 509/2006:

Class 2.3. Confectionery, bread, pastry, cakes, biscuits and other baker's wares

SLOVENIA

Belokranjska pogača (TSG)

The use of the name is reserved.

COMMISSION REGULATION (EU) No 183/2010

of 3 March 2010

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [2], and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 4 March 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2010.

For the Commission,
On behalf of the President,
Jean-Luc DEMARTY
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 350, 31.12.2007, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	JO	67,6
	MA	114,4
	TN	135,3
	TR	129,4
	ZZ	111,7
0707 00 05	EG	211,5
	JO	145,3
	MK	147,9
	TR	154,5
	ZZ	164,8
0709 90 70	MA	135,4
	TR	90,4
	ZZ	112,9
0709 90 80	EG	40,8
	ZZ	40,8
0805 10 20	CL	52,4
	EG	44,1
	IL	56,9
	MA	47,1
	TN	55,1
	TR	46,3
	ZZ	50,3
0805 50 10	EG	76,3
	IL	76,3
	MA	59,9
	TR	74,0
	ZZ	71,6
0808 10 80	CA	76,4
	CN	69,3
	MK	24,7
	US	98,2
	ZZ	67,2
0808 20 50	AR	82,2
	CL	188,1
	CN	54,8
	US	95,6
	ZA	90,3
	ZZ	102,2

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION REGULATION (EU) No 184/2010

of 3 March 2010

amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EC) No 877/2009 for the 2009/10 marketing year

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (single CMO Regulation) [1],

Having regard to Commission Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector [2], and in particular Article 36(2), second subparagraph, second sentence thereof,

Whereas:

(1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2009/10 marketing year are fixed by Commission Regulation (EC) No 877/2009 [3]. These prices and duties have been last amended by Commission Regulation (EU) No 180/2010 [4].

(2) The data currently available to the Commission indicate that those amounts should be amended in accordance with the rules and procedures laid down in Regulation (EC) No 951/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Regulation (EC) No 877/2009 for the 2009/10, marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 4 March 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2010.

For the Commission,
On behalf of the President,
Jean-Luc DEMARTY
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 178, 1.7.2006, p. 24.
[3] OJ L 253, 25.9.2009, p. 3.
[4] OJ L 52, 3.3.2010, p. 46.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 4 March 2010

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 11 10 (1)	40,51	0,00
1701 11 90 (1)	40,51	2,75
1701 12 10 (1)	40,51	0,00
1701 12 90 (1)	40,51	2,45
1701 91 00 (2)	45,67	3,77
1701 99 10 (2)	45,67	0,64
1701 99 90 (2)	45,67	0,64
1702 90 95 (3)	0,46	0,24

(1) For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.
(2) For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.
(3) Per 1 % sucrose content.

DIRECTIVES

COMMISSION DIRECTIVE 2010/14/EU

of 3 March 2010

amending Council Directive 91/414/EEC to include heptamaloxyloglucan as active substance

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC France received on 9 May 2006 an application from Elicityl SA for the inclusion of the active substance heptamaloxyloglucan in Annex I to Directive 91/414/EEC. Commission Decision 2007/560/EC [2] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) For that active substance, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 26 July 2007.

(3) The assessment report was peer reviewed by the Member States and the EFSA and presented to the Commission in the format of the EFSA Scientific Report for heptamaloxyloglucan on 17 July 2009 [3]. This report was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 27 November 2009 in the format of the Commission review report for heptamaloxyloglucan.

(4) It has appeared from the various examinations made that plant protection products containing heptamaloxyloglucan may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include heptamaloxyloglucan in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.

(5) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing provisional authorisations of plant protection products containing heptamaloxyloglucan to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should transform existing provisional authorisations into full authorisations, amend them or withdraw them in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 213, 15.8.2007, p. 29.
[3] *EFSA Scientific Report* (2009) 334, 1-52, Conclusion regarding the peer review of the pesticide risk assessment of the active substance heptamaloxyloglucan (finalised: 17 July 2009).

(6) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(7) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 November 2010 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 December 2010.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing heptamaloxyloglucan as active substance by 30 November 2010. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to heptamaloxyloglucan are met, with the exception of those identified in part B of the entry concerning the active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13(2) of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing heptamaloxyloglucan as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 May 2010 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning heptamaloxyloglucan. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

(a) in the case of a product containing heptamaloxyloglucan as the only active substance, where necessary, amend or withdraw the authorisation by 30 November 2011 at the latest; or

(b) in the case of a product containing heptamaloxyloglucan as one of several active substances, where necessary, amend or withdraw the authorisation by 30 November 2011 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 June 2010.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 3 March 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 91/414/EEC, the following entry is added at the end of the table:

No	Common name, Identification numbers	IUPAC name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
'304	Heptamaloxyloglucan CAS No 870721-81-6 CIPAC No Not available	Full IUPAC name in footnote (*) Xyl p: xylopyranosyl Glc p: glucopyranosyl Fuc p: fucopyranosyl Gal p: galactopyranosyl Glc-ol: glucitol	≥ 780 g/kg The impurity Patulin must not exceed 50 µg/kg in the technical material.	1 June 2010	31 May 2020	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on heptamaloxyloglucan, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 November 2009 shall be taken into account.

(*) $\{[\alpha - D - Xyl\,p - (1\text{-}6)] - \beta - D - Glc\,p - (1\text{-}4)\}\{[\alpha - L - Fuc\,p - (1\text{-}2) - \beta - D - Gal\,p - (1\text{-}2) - \alpha - D - Xyl\,p - (1\text{-}6)] - \beta - D - Glc\,p - (1\text{-}4)\} - D - Glc\text{-}ol$'

(1) Further details on identity and specification of active substances are provided in the review report.

DECISIONS

COMMISSION DECISION

of 1 March 2010

amending Decision 2006/473/EC as regards the recognition of continental Australia as being free from *Xanthomonas campestris* (all strains pathogenic to Citrus)

(notified under document C(2010) 1063)

(2010/134/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community [1], and in particular point 16.2 of Section I of Part A of Annex IV thereof,

Whereas:

(1) By Commission Decision 2006/473/EC of 5 July 2006 recognising certain third countries and certain areas of third countries as being free from *Xanthomonas campestris* (all strains pathogenic to Citrus), *Cercospora angolensis* Carv. et Mendes and *Guignardia citricarpa* Kiely (all strains pathogenic to Citrus) [2] New South Wales, South Australia and Victoria in Australia are recognised as being free from *Xanthomonas campestris* (all strains pathogenic to Citrus).

(2) Australia has submitted detailed technical information, based on results of the disease management and eradication programmes and of multiannual official surveys, showing that an outbreak of *Xanthomonas campestris* in Queensland was successfully eradicated and that the Northern Territory and Western Australia were free from *Xanthomonas campestris*. The freedom from that harmful organism should therefore be recognised for all citrus-growing areas of continental Australia.

(3) Decision 2006/473/EC should therefore be amended accordingly.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DECISION:

Article 1

In Article 1(2) of Decision 2006/473/EC, point (a) is replaced by the following:

'(a) Australia: New South Wales, the Northern Territory, Queensland, South Australia, Victoria and Western Australia;'.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 1 March 2010.

For the Commission

John DALLI

Member of the Commission

[1] OJ L 169, 10.7.2000, p. 1.
[2] OJ L 187, 8.7.2006, p. 35.

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

[1] OJ L 106, 17.4.2001, p. 1.

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

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 [1] 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 [2].

(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 [3] 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 [4].

(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,

[1] OJ L 268, 18.10.2003, p. 24.
[2] OJ L 10, 16.1.2004, p. 5.
[3] See page 15 of this Official Journal.
[4] OJ L 102, 7.4.2004, 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 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).

COMMISSION DECISION

of 2 March 2010

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

(notified under document C(2010) 1196)

(Only the German text is authentic)

(Text with EEA relevance)

(2010/136/EU)

THE EUROPEAN COMMISSION,

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

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 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 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. 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.

(4) Accordingly, EFSA advised that no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of 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 2010/135/EU 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 [3].

(6) 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.

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

[2] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2005-070

[3] See page 11 of this Official Journal.

(7) 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.

(8) 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 genetically modified potato 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.

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

(10) The authorisation for the cultivation and industrial use of potato EH92-527-1 is provided by Decision 2010/135/EU 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.

(11) 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 %.

(12) A unique identifier should be assigned to each GMO as provided for in 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 [1].

(13) 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.

(14) 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.

(15) 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 Article 9(1) and Article 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 [2].

(16) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman.

(17) At its meeting on 18 February 2008, 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

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 % 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 % 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'.

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

[2] 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 2010/135/EU 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-Straße 38, 67056 Ludwigshafen, Germany.

Done at Brussels, 2 March 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) **Applicant and Authorisation holder:**

Name: BASF Plant Science GmbH

Address: Carl-Bosch-Straße 38, 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 % 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 % 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 Decision 2010/135/EU.

(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.

III

(Other acts)

EUROPEAN ECONOMIC AREA

DECISION OF THE STANDING COMMITTEE OF THE EFTA STATES

No 1/2010/SC

of 28 January 2010

establishing an EEA Financial Mechanism Interim Committee 2009-2014

THE STANDING COMMITTEE OF THE EFTA STATES,

Having regard to the Agreement on the European Economic Area, as adjusted by the Protocol Adjusting the Agreement on the European Economic Area, hereinafter referred to as the EEA Agreement,

Having regard to the agreement to be concluded establishing a new EEA Financial Mechanism for the period 2009-2014,

Considering the agreement between the Kingdom of Norway and the European Community to establish a Norwegian Financial Mechanism for the period 2009-2014,

HAS DECIDED AS FOLLOWS:

Article 1

1. An EEA Financial Mechanism Interim Committee 2009-2014, hereinafter referred to as the Interim Committee, which should be operative as soon as possible, is hereby established.

2. The Interim Committee shall assist the EFTA States in preparing for the implementation of the EEA Financial Mechanism for 2009-2014.

3. The Interim Committee shall report to the Standing Committee.

4. The Interim Committee may be assisted by the Missions of the EEA EFTA States to the EU.

5. The Interim Committee shall on the day of entering into force or on the day of provisional application of the legal act establishing the EEA Financial Mechanism 2009-2014 be replaced by an EEA Financial Mechanism Committee 2009-2014.

6. The Interim Committee shall discuss and assess possible coordination between the EEA Financial Mechanism and the Norwegian Financial Mechanism.

7. The Interim Committee shall agree upon a Chairman who shall be confirmed by the Standing Committee.

Article 2

This Decision shall take immediate effect.

Article 3

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 28 January 2010.

For the Standing Committee

The Chairman	*The Secretary-General*
H.S.H Prinz Nikolaus von LIECHTENSTEIN	Kåre BRYN

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