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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 675/2010

of 28 July 2010

entering a name in the register of traditional specialities guaranteed (Traditionally Farmed Gloucestershire Old Spots Pork (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) Pursuant to the first subparagraph of Article 8(2) of Regulation (EC) No 509/2006 and Article 19(3) thereof, the United Kingdom's application to register the name 'Traditionally Farmed Gloucestershire Old Spots Pork' was published in the *Official Journal of the European Union* ⁽²⁾.

(2) As no objection under 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 under Article 13(2) of Regulation (EC) No 509/2006. That protection should be granted to the name 'Traditionally Farmed Gloucestershire Old Spots Pork' 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, 28 July 2010.

*For the Commission**The President*

José Manuel BARROSO

⁽¹⁾ OJ L 93, 31.3.2006, p. 1.⁽²⁾ OJ C 238, 3.10.2009, p. 8.

ANNEX

Products intended for human consumption listed in Annex I to the Treaty:

Class 1.1. Fresh meat (and offal)

UNITED KINGDOM

Traditionally Farmed Gloucestershire Old Spots Pork (TSG)

The use of the name is reserved.

COMMISSION REGULATION (EU) No 676/2010**of 28 July 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 29 July 2010.

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

Done at Brussels, 28 July 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	MK	31,8
	TR	105,8
	ZZ	68,8
0707 00 05	TR	105,8
	ZZ	105,8
0709 90 70	TR	106,3
	ZZ	106,3
0805 50 10	AR	92,4
	UY	83,6
	ZA	102,8
	ZZ	92,9
0806 10 10	AR	137,6
	CL	75,2
	EG	142,7
	IL	126,4
	MA	161,7
	TR	151,2
	ZA	90,0
	ZZ	126,4
0808 10 80	AR	160,0
	BR	80,4
	CA	98,9
	CL	100,8
	CN	81,7
	MA	54,2
	NZ	111,8
	US	108,8
	UY	111,6
	ZA	93,6
	ZZ	100,2
0808 20 50	AR	70,4
	CL	157,1
	NZ	130,0
	ZA	103,2
	ZZ	115,2
0809 10 00	TR	186,4
	ZZ	186,4
0809 20 95	TR	220,4
	US	520,8
	ZZ	370,6
0809 30	TR	176,9
	ZZ	176,9
0809 40 05	BA	62,2
	IL	162,2
	TR	126,3
	XS	74,4
	ZZ	106,3

⁽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 677/2010**of 28 July 2010****on the issue of import licences for applications lodged for the period 1 July 2010 to 30 June 2011
under the tariff quota opened by Regulation (EC) No 748/2008 for frozen thin skirt of bovine
animals**

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 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences ⁽²⁾, and in particular Article 7(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 748/2008 of 30 July 2008 on the opening and administration of an import tariff quota for frozen thin skirt of bovine animals falling

within CN code 0206 29 91 ⁽³⁾ opens an import tariff quota for beef and veal products.

- (2) The applications for import licences lodged for the period 1 July 2010 to 30 June 2011 relate to quantities exceeding those available. The extent to which import licences may be issued should therefore be determined and an allocation coefficient laid down to be applied to the quantities applied for,

HAS ADOPTED THIS REGULATION:

Article 1

The quantities for which import licence applications covered by the quota with the order number 09.4020 have been lodged for the period 1 July 2010 to 30 June 2011 under Regulation (EC) No 748/2008 shall be multiplied by an allocation coefficient of 53,747872 %.

Article 2

This Regulation shall enter into force on 29 July 2010.

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

Done at Brussels, 28 July 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 238, 1.9.2006, p. 13.

⁽³⁾ OJ L 202, 31.7.2008, p. 28.

COMMISSION REGULATION (EU) No 678/2010
of 28 July 2010
amending Regulation (EU) No 626/2010 fixing the import duties in the cereals sector applicable
from 16 July 2010

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 (EU) No 642/2010 of 20 July 2010 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of import duties in the cereals sector ⁽²⁾, and in particular Article 2(1) thereof,

Whereas:

- (1) The import duties in the cereals sector applicable from 16 July 2010 were fixed by Commission Regulation (EU) No 626/2010 ⁽³⁾.

- (2) As the average of the import duties calculated differs by more than EUR 5/tonne from that fixed, a corresponding adjustment must be made to the import duties fixed by Regulation (EU) No 626/2010.

- (3) Regulation (EU) No 626/2010 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and II to Regulation (EU) No 626/2010 are hereby replaced by the text in the Annex to this Regulation.

Article 2

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

It shall apply from 29 July 2010.

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

Done at Brussels, 28 July 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 187, 21.7.2010, p. 5.

⁽³⁾ OJ L 182, 16.7.2010, p. 9.

ANNEX I

Import duties on the products referred to in Article 136(1) of Regulation (EC) No 1234/2007 applicable from 29 July 2010

CN code	Description	Import duties ⁽¹⁾ (EUR/t)
1001 10 00	Durum wheat, high quality	0,00
	medium quality	0,00
	low quality	0,00
1001 90 91	Common wheat seed	0,00
ex 1001 90 99	High quality common wheat, other than for sowing	0,00
1002 00 00	Rye	31,78
1005 10 90	Maize seed other than hybrid	8,66
1005 90 00	Maize, other than seed ⁽²⁾	8,66
1007 00 90	Grain sorghum other than hybrids for sowing	31,78

⁽¹⁾ For goods arriving in the Union via the Atlantic Ocean or via the Suez Canal the importer may benefit, under Article 2(4) of Regulation (EU) No 642/2010, from a reduction in the duty of:

- 3 EUR/t, where the port of unloading is on the Mediterranean Sea, or on the Black Sea,
- 2 EUR/t, where the port of unloading is in Denmark, Estonia, Ireland, Latvia, Lithuania, Poland, Finland, Sweden, the United Kingdom or the Atlantic coast of the Iberian peninsula.

⁽²⁾ The importer may benefit from a flatrate reduction of EUR 24 per tonne where the conditions laid down in Article 3 of Regulation (EU) No 642/2010 are met.

ANNEX II

Factors for calculating the duties laid down in Annex I

15.7.2010-27.7.2010

1. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

(EUR/t)

	Common wheat ⁽¹⁾	Maize	Durum wheat, high quality	Durum wheat, medium quality ⁽²⁾	Durum wheat, low quality ⁽³⁾	Barley
Exchange	Minneapolis	Chicago	—	—	—	—
Quotation	176,76	115,21	—	—	—	—
Fob price USA	—	—	139,42	129,42	109,42	72,45
Gulf of Mexico premium	—	12,67	—	—	—	—
Great Lakes premium	22,79	—	—	—	—	—

⁽¹⁾ Premium of 14 EUR/t incorporated (Article 5(3) of Regulation (EU) No 642/2010).⁽²⁾ Discount of 10 EUR/t (Article 5(3) of Regulation (EU) No 642/2010).⁽³⁾ Discount of 30 EUR/t (Article 5(3) of Regulation (EU) No 642/2010).

2. Averages over the reference period referred to in Article 2(2) of Regulation (EU) No 642/2010:

Freight costs: Gulf of Mexico–Rotterdam: 20,50 EUR/t

Freight costs: Great Lakes–Rotterdam: 50,14 EUR/t

DECISIONS

COMMISSION DECISION

of 17 June 2010

establishing the Union's financial contribution towards the expenditure incurred in the context of the emergency measures taken to combat bluetongue in Spain in 2004 and 2005

(notified under document C(2010) 3804)

(Only the Spanish text is authentic)

(2010/418/EU)

THE EUROPEAN COMMISSION,

be fixed through a Commission decision to be adopted in accordance with the procedure of Article 40 of Decision 2009/470/EC.

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

Having regard to Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field ⁽¹⁾, and in particular Article 3(4) thereof,

(6) The results of the inspections carried out by the Commission in compliance with Article 7 of Decision 2005/650/EC and the conditions for granting Union's financial contributions mean the entire amount of the expenditure submitted cannot be recognised as eligible.

Whereas:

(7) The Commission's observations, method of calculating the eligible expenditure and final conclusions were communicated to Spain in a letter dated 1 July 2009.

(1) Outbreaks of bluetongue occurred in Spain in 2004 and 2005. The emergence of that disease presented a serious risk to the Union's livestock population.

(8) In view of the above considerations, the total amount of the Union's financial contribution to the eligible expenditure incurred associated with the eradication and surveillance of bluetongue in Spain in 2004 and 2005 should now be fixed.

(2) Commission Decision 2005/650/EC of 13 September 2005 concerning a financial contribution by the Community in the context of the emergency measures taken to combat bluetongue in Spain in 2004 and 2005 ⁽²⁾ granted a financial contribution from the Community to Spain towards the expenditure incurred under the emergency measures to combat bluetongue in 2004 and 2005.

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

(3) That Decision provided for a first instalment of EUR 2 500 000 subject to the results of the Commission *in situ* inspections.

HAS ADOPTED THIS DECISION:

Article 1

Financial contribution from the Union to Spain

The total Union financial contribution towards the expenditure associated with eradicating bluetongue in Spain in 2004 and 2005 pursuant to Decision 2005/650/EC is fixed at EUR 2 850 183,00.

(4) Pursuant to Article 6(2) of that Decision, the balance of the Union financial contribution is to be paid on the basis of the application submitted within 60 days of that Decision. Spain submitted that application on 11 November 2005.

Article 2

Payment arrangements

The balance of the Union's financial contribution is fixed at EUR 350 183,00.

(5) Pursuant to Article 4(2) of Decision 2005/650/EC, the balance of the Union financial contribution should now

⁽¹⁾ OJ L 155, 18.6.2009, p. 30.

⁽²⁾ OJ L 238, 15.9.2005, p. 19.

*Article 3***Addressee**

This Decision is addressed to the Kingdom of Spain.

Done at Brussels, 17 June 2010.

For the Commission

John DALLI

Member of the Commission

COMMISSION DECISION

of 28 July 2010

renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC

*(notified under document C(2010) 5129)***(Only the French text is authentic)****(Text with EEA relevance)**

(2010/419/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), 11(3), 19(3) and 23(3) thereof,

Whereas:

(1) On 17 April 2007, Syngenta Seeds SAS on behalf of Syngenta Crop Protection AG, submitted to the Commission an application, in accordance with Articles 5, 11, 17 and 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation for continued marketing of existing foods and food ingredients produced from Bt11 maize (including food additives), and renewal of the authorisation for continued marketing of existing feed containing, consisting of or produced from Bt11 maize (including feed additives and feed materials) and products other than food and feed containing and consisting of Bt11 maize with the exception of cultivation (the application) which were previously notified in accordance with Article 8(1)(a)(b) and Article 20(1)(a)(b) of that Regulation. The application also covers the renewal of the authorisation for the placing on the market of foods and food ingredients which are authorised under Commission Decision 2004/657/EC of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council⁽²⁾. Within its application, Syngenta Seeds SAS also requested the authorisation of foods and food ingredients containing or consisting of Bt11 field maize which were never authorised in the Union.

(2) On 17 February 2009, the European Food Safety Authority (EFSA) gave a favourable opinion⁽³⁾ in accordance with Article 6 and Article 18 of Regulation (EC) No 1829/2003 and concluded that the new information provided in the application and the review of the literature that has been published since the previous scientific opinion on Bt11 maize⁽⁴⁾ by EFSA does not require changes and confirmed the previous conclusion that Bt11 maize is as safe as its non-genetically modified counterpart and that it is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed uses which also applies to the products which are subject of the application.

(3) 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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(4) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended use of the products.

(5) Taking into account these considerations, the fact that the company Syngenta Crop Protection AG Switzerland which absorbed Syngenta Seeds AG, addressee of Decision 2004/657/EC is the same legal entity, on behalf of which the applicant asked for the renewal of authorisation, that it confirmed that the scope of its application also covers the request for authorisation of foods and food ingredients containing or consisting of Bt11 field maize and that it intended to ask for a renewal of products covered by Decision 2004/657/EC prior to

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 300, 25.9.2004, p. 48.

⁽³⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-146>

⁽⁴⁾ EFSA opinion published on 19 May 2005, for the placing on the market of Bt11 for cultivation, feed and industrial processing — <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2004-012>

the expiration of the authorisation mentioned in that Decision so that a single Decision covering these products may be adopted which will take effect on the same date, renewal of the authorisation for continued marketing of the existing products, renewal of the authorisation of foods and food ingredients containing, consisting of or produced from Bt11 sweet maize (sweet maize fresh or canned) and authorisation of food and food ingredients containing or consisting of Bt11 field maize should be granted. Consequently, Decision 2004/657/EC should be repealed.

- (6) 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⁾.
- (7) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from Bt11 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of feed containing or consisting of the GMO and products other than food and feed containing or consisting of the GMO for which renewal of the authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.
- (8) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾.
- (9) The EFSA opinion does not justify the imposition of 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 for the use of the food and feed, or of specific conditions for the protection of particular

ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.

- (10) All relevant information on the authorisation or the renewal of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- (11) Article 4(6) 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⁾, lays down labelling requirements for products consisting of, or containing GMOs.
- (12) This Decision is to 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 ⁽⁴⁾.
- (13) The applicant has been consulted on the measures provided for in this Decision.
- (14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman.
- (15) At its meeting on 29 June 2010, the Council was unable to reach a decision by qualified majority either for or against the proposal. The Council indicated that its proceedings on this file were concluded. It is accordingly for the Commission to adopt the measures,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize Bt11 (*Zea mays* L.), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier SYN-BTØ11-1, as provided for in Regulation (EC) No 65/2004.

⁽¹⁾ OJ L 10, 16.1.2004, p. 5.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 268, 18.10.2003, p. 24.

⁽⁴⁾ OJ L 287, 5.11.2003, p. 1.

*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 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from SYN-BTØ11-1 maize;
- (b) feed containing, consisting of, or produced from SYN-BTØ11-1 maize;
- (c) products other than food and feed containing or consisting of SYN-BTØ11-1 maize for the same uses as any other maize with the exception of cultivation.

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-BTØ11-1 maize referred to in Article 2(b) and (c).

*Article 4***Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5***Community register**

The information set out 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 Syngenta Seeds SAS, France, representing Syngenta Crop Protection AG, Switzerland.

*Article 7***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8***Repeal**

Decision 2004/657/EC is repealed.

*Article 9***Addressee**

This Decision is addressed to Syngenta Seeds SAS, Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France, representing Syngenta Crop Protection AG, Switzerland.

Done at Brussels, 28 July 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX

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

Name: Syngenta Seeds SAS

Address: Chemin de l'Hobit 12, BP 27, 31790 Saint-Sauveur, France

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, 4058 Basel, Switzerland

(b) **Designation and specification of the products:**

1. foods and food ingredients containing, consisting of, or produced from SYN-BTØ11-1 maize;
2. feed containing, consisting of, or produced from SYN-BTØ11-1 maize;
3. products other than food and feed containing or consisting of SYN-BTØ11-1 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified SYN-BTØ11-1 maize, as described in the application, expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and the PAT protein which confers tolerance to the glufosinate-ammonium herbicide.

(c) **Labelling:**

1. for the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';
2. the words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of SYN-BTØ11-1 maize referred to in Article 2(b) and (c).

(d) **Method for detection:**

- event specific real-time PCR-based method for the quantification of SYN-BTØ11-1 maize
- validated by the Community Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofloss.htm>
- reference material: ERM®-BF412 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/rmcatalogue>

(e) **Unique identifier:**

SYN-BTØ11-1

(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 conforming with Annex VII to Directive 2001/18/EC

[Link: plan published on the Internet]

(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.

COMMISSION DECISION

of 28 July 2010

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON89034xNK603 (MON-89034-3xMON-00603-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2010) 5133)***(Only the French and Dutch texts are authentic)****(Text with EEA relevance)**

(2010/420/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 24 January 2007, Monsanto Europe S.A. submitted to the competent authority of the Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MON89034xNK603 maize ('the application').

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of MON89034xNK603 maize for the same uses as any other maize with the exception of cultivation. Therefore, in accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, it includes the data and information required by Annexes III and IV 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 information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(3) On 29 September 2009, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It considered that maize

MON89034xNK603 is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment. Therefore it concluded that it is unlikely that the placing on the market of the products containing, consisting of, or produced from MON89034xNK603 maize as described in the application ('the products') will have any adverse effects on human or animal health or the environment in the context of their intended uses⁽³⁾. 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) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended use of the products.

(5) Taking into account those considerations, authorisation should be granted for the products.

(6) 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⁽⁴⁾.

(7) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients, and feed containing, consisting of, or produced from MON89034xNK603 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of feed containing or consisting of the GMO and products other than food and feed containing or consisting of the GMO for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 106, 17.4.2001, p. 1.

⁽³⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00759>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

- (8) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council ⁽¹⁾.
- (9) The EFSA opinion does not justify the imposition of 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 for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.
- (10) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- (11) Article 4(6) 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 ⁽²⁾, lays down labelling requirements for products containing or consisting of GMOs.
- (12) This Decision is to 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 ⁽³⁾.
- (13) The applicant has been consulted on the measures provided for in this Decision.
- (14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman.
- (15) At its meeting on 29 June 2010, the Council was unable to reach a decision by qualified majority either for or against the proposal. The Council indicated that its proceedings on this file were concluded. It is accordingly for the Commission to adopt the measures,
- HAS ADOPTED THIS DECISION:
- Article 1*
- Genetically modified organism and unique identifier**
- Genetically modified maize (*Zea mays* L.) MON89034xNK603, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-89034-3xMON-00603-6, as provided for in Regulation (EC) No 65/2004.
- Article 2*
- Authorisation**
- The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:
- (a) foods and food ingredients containing, consisting of, or produced from MON-89034-3xMON-00603-6 maize;
- (b) feed containing, consisting of, or produced from MON-89034-3xMON-00603-6 maize;
- (c) products other than food and feed containing or consisting of MON-89034-3xMON-00603-6 maize for the same uses as any other maize with the exception of cultivation.
- Article 3*
- Labelling**
1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-89034-3xMON-00603-6 maize referred to in Article 2(b) and (c).
- Article 4*
- Monitoring for environmental effects**
1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

⁽¹⁾ OJ L 275, 21.10.2009, p. 9.

⁽²⁾ OJ L 268, 18.10.2003, p. 24.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with the Decision 2009/770/EC.

Article 5

Community register

The information set out 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 Monsanto Europe S.A., Belgium, representing Monsanto Company, United States.

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 Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, BELGIUM.

Done at Brussels, 28 July 2010.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels, BELGIUM

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, UNITED STATES.

(b) Designation and specification of the products:

1. foods and food ingredients containing, consisting of, or produced from MON-89Ø34-3xMON-ØØ6Ø3-6 maize;
2. feed containing, consisting of, or produced from MON-89Ø34-3xMON-ØØ6Ø3-6 maize;
3. products other than food and feed containing or consisting of MON-89Ø34-3xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified MON-89Ø34-3xMON-ØØ6Ø3-6 maize, as described in the application, is produced by crosses between maize containing MON-89Ø34-3 and MON-ØØ6Ø3-6 events and expresses the Cry1A.105 and Cry2Ab2 proteins which confer protection against certain lepidopteran pests and the CP4 EPSPS protein which confers tolerance to glyphosate herbicides.

(c) Labelling:

1. for the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';
2. the words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-89Ø34-3xMON-ØØ6Ø3-6 maize referred to in Article 2(b) and (c) of this Decision.

(d) Method for detection:

- event specific real-time quantitative PCR based methods for genetically modified maize MON-89Ø34-3 and MON-ØØ6Ø3-6 maize validated on MON-89Ø34-3xMON-ØØ6Ø3-6 maize,
- validated on seeds by the Community Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- Reference Material: AOCS 0906-E and AOCS 0406-A (for MON-89Ø34-3) accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm> and ERM®-BF415 (for MON-ØØ6Ø3-6) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://irmm.jrc.ec.europa.eu/rmcatalogue>

(e) Unique identifier:

MON-89Ø34-3xMON-ØØ6Ø3-6

(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 conforming with Annex VII to Directive 2001/18/EC.

[Link: plan published on the Internet]

(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.

CORRIGENDA**Corrigendum to Council Decision of 26 July 2010 concerning restrictive measures against Iran and repealing Common Position 2007/140/CFSP**

(Official Journal of the European Union L 195 of 27 July 2010)

In the title of the Decision in the content on the cover page:

for: '2010/413/CFSP

Council Decision of 26 July 2010 concerning restrictive measures against Iran and repealing Common Position 2007/140/CFSP',

read: 'Council Decision 2010/413/CFSP of 26 July 2010 concerning restrictive measures against Iran and repealing Common Position 2007/140/CFSP';

on page 39

for: 'COUNCIL DECISION of 26 July 2010 concerning restrictive measures against Iran and repealing Common Position 2007/140/CFSP',

read: 'COUNCIL DECISION 2010/413/CFSP of 26 July 2010 concerning restrictive measures against Iran and repealing Common Position 2007/140/CFSP'.

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