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Contents

I Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory

REGULATIONS

Commission Regulation (EC) No 1042/2009 of 4 November 2009 establishing the standard import values for determining the entry price of certain fruit and vegetables 1

Commission Regulation (EC) No 1043/2009 of 4 November 2009 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 3

★ **Commission Regulation (EC) No 1044/2009 of 4 November 2009 amending Regulation (EC) No 274/2009 fixing the quantitative limit for the exports of out-of-quota sugar and isoglucose until the end of the 2009/2010 marketing year** 5

Commission Regulation (EC) No 1045/2009 of 4 November 2009 amending Regulation (EC) No 958/2009 fixing an acceptance percentage for the issuing of export licences, rejecting export licence applications and suspending the lodging of export licence applications for out-of-quota sugar 6

★ **Commission Regulation (EC) No 1046/2009 of 3 November 2009 establishing a prohibition of fishing for spurdog/dogfish in EC waters of ICES zone IIIa by vessels flying the flag of Denmark** 7

Price: EUR 3

(Continued overleaf)

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.

II Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory

DECISIONS

Commission

2009/810/EC:

- ★ **Commission Decision of 22 September 2008 drawing up the standard reporting form referred to in Article 17 of Regulation (EC) No 561/2006 of the European Parliament and of the Council (notified under document C(2008) 5123) ⁽¹⁾** 9

2009/811/EC:

- ★ **Commission Decision of 2 October 2009 on the Community financial contribution to national programmes of certain Member States in 2009 for the collection, management and use of data in the fisheries sector (notified under document C(2009) 7424)** 16

2009/812/EC:

- ★ **Commission Decision of 26 October 2009 granting a derogation requested by France pursuant to Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices (notified under document C(2009) 8041)** 19

2009/813/EC:

- ★ **Commission Decision of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2009) 8383) ⁽¹⁾** 21

2009/814/EC:

- ★ **Commission Decision of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON-88Ø17-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2009) 8384) ⁽¹⁾** 25

2009/815/EC:

- ★ **Commission Decision of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122xNK603 (DAS-59122-7xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2009) 8386) ⁽¹⁾** 29



⁽¹⁾ Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 1042/2009

of 4 November 2009

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 5 November 2009.

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

Done at Brussels, 4 November 2009.

For the Commission

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	MA	46,4
	MK	24,1
	TR	52,0
	ZZ	40,8
0707 00 05	EG	114,7
	JO	161,3
	TR	127,6
	ZZ	134,5
0709 90 70	MA	69,0
	TR	107,3
	ZZ	88,2
0805 20 10	MA	103,9
	ZZ	103,9
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	AR	49,8
	HR	64,9
	TR	84,7
	UY	49,8
	ZZ	62,3
0805 50 10	AR	77,2
	TR	80,5
	ZA	75,5
	ZZ	77,7
0806 10 10	BR	224,2
	EG	85,0
	TR	123,2
	US	245,6
	ZZ	169,5
0808 10 80	AU	227,7
	CA	70,7
	MK	20,3
	NZ	95,2
	US	116,0
	ZA	79,1
0808 20 50	ZZ	101,5
	CN	45,3
	ZZ	45,3

⁽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 (EC) No 1043/2009**of 4 November 2009****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 COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 (EC) No 1017/2009 ⁽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 5 November 2009.

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

Done at Brussels, 4 November 2009.

For the Commission

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 281, 28.10.2009, p. 3.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 5 November 2009

(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⁾	37,63	0,00
1701 11 90 ⁽¹⁾	37,63	3,62
1701 12 10 ⁽¹⁾	37,63	0,00
1701 12 90 ⁽¹⁾	37,63	3,32
1701 91 00 ⁽²⁾	40,49	5,32
1701 99 10 ⁽²⁾	40,49	2,19
1701 99 90 ⁽²⁾	40,49	2,19
1702 90 95 ⁽³⁾	0,40	0,28

⁽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.

COMMISSION REGULATION (EC) No 1044/2009**of 4 November 2009****amending Regulation (EC) No 274/2009 fixing the quantitative limit for the exports of out-of-quota sugar and isoglucose until the end of the 2009/2010 marketing year**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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⁾, and in particular Article 61, first subparagraph, point (d), in conjunction with Article 4 thereof,

Whereas:

- (1) According to Article 61, first subparagraph, point (d) of Regulation (EC) No 1234/2007, the sugar produced during a marketing year in excess of the quota referred to in Article 56 of that Regulation may be exported only within the quantitative limit to be fixed.
- (2) Detailed implementing rules for out-of-quota exports, in particular concerning the issue of export licences, are laid down by 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⁾. However, the quantitative limit should be fixed per marketing year in view of the possible opportunities on the export markets.
- (3) Commission Regulation (EC) No 274/2009 ⁽³⁾ has fixed the quantitative limit for the exports of out-of-quota sugar at 650 000 tonnes in respect of marketing year 2009/2010. However, according to the most recent forecasts issued at the beginning of the 2009/2010 sugar beet harvest it is certain that due to exceptionally favourable weather conditions a very important amount

of out-of-quota beet sugar would be produced in the Community. The amount of out-of-quota sugar to be produced in 2009/2010 is initially estimated at around 3-4 million tonnes, which would lead to serious storage problems and provoking large quantity of sugar to be carried forward as quota sugar for marketing year 2010/2011. It is therefore necessary to increase the quantitative limit for out-of-quota sugar exports to 1 350 000 t in respect of marketing year 2009/2010.

- (4) Regulation (EC) No 274/2009 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 1 of Regulation (EC) No 274/2009, paragraph 1 is replaced by the following:

‘1. For the 2009/2010 marketing year, running from 1 October 2009 to 30 September 2010, the quantitative limit referred to in Article 61, first subparagraph, point (d) of Regulation (EC) No 1234/2007 shall be 1 350 000 tonnes for exports without refund of out-of-quota white sugar falling within CN code 1701 99.’

Article 2

This Regulation shall enter into force on the third 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, 4 November 2009.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 178, 1.7.2006, p. 24.

⁽³⁾ OJ L 91, 3.4.2009, p. 16.

COMMISSION REGULATION (EC) No 1045/2009**of 4 November 2009****amending Regulation (EC) No 958/2009 fixing an acceptance percentage for the issuing of export licences, rejecting export licence applications and suspending the lodging of export licence applications for out-of-quota sugar**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 7e in conjunction with Article 9(1) thereof,

Whereas:

- (1) According to Article 61, first subparagraph, point (d) of Regulation (EC) No 1234/2007, the sugar produced during a marketing year in excess of the quota referred to in Article 56 of that Regulation may be exported only within the quantitative limit to be fixed.
- (2) Commission Regulation (EC) No 274/2009 of 2 April 2009 fixing the quantitative limit for the exports of out-of-quota sugar and isoglucose until the end of the 2009/2010 marketing year ⁽³⁾ has fixed the quantitative limit at 650 000 tonnes.

(3) The quantities of sugar covered by applications for export licences exceeded that quantitative limit. Therefore Commission Regulation (EC) No 958/2009 ⁽⁴⁾ suspended the lodging of applications for out-of-quota sugar export licences for the period 19 October 2009 to 30 September 2010.

(4) By amendment of Regulation (EC) No 274/2009, introduced by Commission Regulation (EC) No 1044/2009 ⁽⁵⁾, the quantitative limit for the exports of out-of-quota sugar in respect of marketing year 2009/2010 was increased by 700 000 tonnes.

(5) As the quantitative limit in respect of marketing year 2009/2010 is increased the lodging of applications should once again be possible.

(6) Regulation (EC) No 958/2009 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 1 of Regulation (EC) No 958/2009, paragraph 3 is deleted.

Article 2

This Regulation shall enter into force on the third 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, 4 November 2009.

For the Commission

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 91, 3.4.2009, p. 16.

⁽⁴⁾ OJ L 270, 15.10.2009, p. 5.

⁽⁵⁾ See page 5 of this Official Journal.

COMMISSION REGULATION (EC) No 1046/2009**of 3 November 2009****establishing a prohibition of fishing for spurdog/dogfish in EC waters of ICES zone IIIa by vessels flying the flag of Denmark**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2371/2002 of 20 December 2002 on the conservation and sustainable exploitation of fisheries resources under the Common Fisheries Policy ⁽¹⁾, and in particular Article 26(4) thereof,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to common fisheries policy ⁽²⁾, and in particular Article 21(3) thereof,

Whereas:

- (1) Council Regulation (EC) No 43/2009 of 16 January 2009 fixing for 2009 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks applicable in Community waters and for Community vessels, in waters where catch limitations are required ⁽³⁾, lays down quotas for 2009.
- (2) According to the information received by the Commission, catches of the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein have exhausted the quota allocated for 2009.

- (3) It is therefore necessary to prohibit fishing for that stock and its retention on board, transhipment and landing,

HAS ADOPTED THIS REGULATION:

*Article 1***Quota exhaustion**

The fishing quota allocated to the Member State referred to in the Annex to this Regulation for the stock referred to therein for 2009 shall be deemed to be exhausted from the date set out in that Annex.

*Article 2***Prohibitions**

Fishing for the stock referred to in the Annex to this Regulation by vessels flying the flag of or registered in the Member State referred to therein shall be prohibited from the date set out in that Annex. It shall be prohibited to retain on board, tranship or land such stock caught by those vessels after that date.

*Article 3***Entry into force**

This Regulation shall enter into force on the day following that of 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 November 2009.

For the Commission

Fokion FOTIADIS

Director-General for Maritime Affairs and Fisheries

⁽¹⁾ OJ L 358, 31.12.2002, p. 59.

⁽²⁾ OJ L 261, 20.10.1993, p. 1.

⁽³⁾ OJ L 22, 26.1.2009, p. 1.

ANNEX

No	E2/DK/NS/001
Member State	Denmark
Stock	DGS/03A-C.
Species	Spurdog/dogfish (<i>Squalus acanthias</i>)
Zone	EC waters of IIIa
Date	17.10.2009

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 22 September 2008

drawing up the standard reporting form referred to in Article 17 of Regulation (EC) No 561/2006 of the European Parliament and of the Council

(notified under document C(2008) 5123)

(Text with EEA relevance)

(2009/810/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85 ⁽¹⁾, and in particular Article 25(2) thereof,

Having regard to the opinion of the Committee established by Article 18(1) of Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport ⁽²⁾,

Whereas:

(1) The standard form referred to in Article 17(1) of Regulation (EC) No 561/2006 should be used as the medium through which the Member States communicate to the Commission, every 2 years, the necessary information for the preparation of a report on the implementation of that Regulation, of Regulation (EEC) No 3821/85 and on developments in the fields in question.

(2) The standard form previously established by Commission Decision 93/173/EEC ⁽³⁾ should now be updated in order to take account, inter alia, of developments in the Community rules on driving times and rest periods.

(3) The new reporting requirements established by Regulation (EC) No 561/2006 and Directive 2006/22/EC of the European Parliament and of the Council ⁽⁴⁾ which lays down minimum conditions for its implementation cover in particular information on national exceptions granted by Member States under Article 13(1) of Regulation (EC) No 561/2006 and more precise details of checks undertaken on vehicles.

(4) Directive 2002/15/EC of the European Parliament and of the Council of 11 March 2002 on the organisation of the working time of persons performing mobile road transport activities ⁽⁵⁾ complements the provisions on driving time, breaks and rest periods laid down in Regulation (EC) No 561/2006.

(5) In accordance with Article 13(1) of Directive 2002/15/EC, a report on the implementation of that Directive should be made by the Member States every 2 years. This 2-year period coincides with that laid down in Article 17(1) of Regulation (EC) No 561/2006.

⁽¹⁾ OJ L 102, 11.4.2006, p. 1.

⁽²⁾ OJ L 370, 31.12.1985, p. 8.

⁽³⁾ OJ L 72, 25.3.1993, p. 33.

⁽⁴⁾ OJ L 102, 11.4.2006, p. 35.

⁽⁵⁾ OJ L 80, 23.2.2002, p. 35.

- (6) It is accordingly appropriate for reasons of administrative convenience and effective monitoring of the impact of the Community rules in this field to make provision for the inclusion of this information on the standard form,

References to the repealed Decision shall be construed as references to this Decision.

Article 3

HAS ADOPTED THIS DECISION:

This Decision is addressed to the Member States.

Article 1

The standard form referred to in Article 17(1) of Regulation (EC) No 561/2006 shall be drawn up in accordance with the specimen in the Annex to this Decision.

Done at Brussels, 22 September 2008.

Article 2

Decision 93/173/EEC is hereby repealed.

For the Commission

Antonio TAJANI

Vice-President

ANNEX

Standard form for reporting on the implementation by Member States of Regulation (EC) No 561/2006, Regulation (EEC) No 3821/85 and Directive 2002/15/EC in accordance with Article 17 of Regulation (EC) No 561/2006 and Article 13 of Directive 2002/15/EC

1. MEMBER STATE

2. REFERENCE PERIOD

(Article 17 of Regulation (EC) No 561/2006)

From (date):

To (date):

3. CALCULATION OF MINIMUM CHECKS TO BE CARRIED OUT

(Article 2 of Directive 2006/22/EC)

(a) Number of days worked per driver during the reference period:

(b) Total number of vehicles subject to Regulation (EC) No 561/2006:

(c) Total number of days worked [(a) $\times$ (b)]:

(d) Minimum checks [2 % of (c) from 1 January 2008, 3 % from January 2010]:

4. CHECKS AT THE ROADSIDE

4.1. Number of drivers checked at the roadside by country of registration and main type of carriage

Main type of carriage	EU/EEA/Switzerland		Third Countries
	Nationals	Non-nationals	
Carriage of passengers			
Carriage of goods			
Total			

4.2. Number of vehicles stopped for roadside check by type of road and country of registration

Type of road	A	B	BG	CY	CZ	D	DK	E	EST	F	FIN	GB	GR	H	I	IRL	L
Motorway																	
National road																	
Secondary road																	
Type of road	LT	LV	M	NL	P	PL	RO	S	SK	SLO	FL	IS	N	CH	Other	Total	
Motorway																	
National road																	
Secondary road																	

4.3. Number of vehicles stopped for roadside check by type of tachograph

Type of tachograph	EU/EEA/Switzerland		Third Countries
	Nationals	Non-nationals	
Analogue			
Digital			
Total			

If national statistics allow, please fill in also the table below giving the exact figures concerning vehicles fitted with digital tachograph:

(a) Number of vehicles fitted with digital tachograph	
(b) Share of vehicles fitted with digital tachograph in a total fleet of vehicles subject to Regulations	

4.4. Number of working days checked at the roadside by main type of carriage and country of registration

Main type of carriage	EU/EEA/Switzerland		Third Countries
	Nationals	Non-nationals	
Carriage of passengers			
Carriage of goods			
Total			

4.5. Offences — number and type of offences detected at the roadside

(R — offence against Regulation (EC) No 561/2006, D — offence against Directive 2006/22/EC)

Article	Type of offence	Carriage of passengers			Carriage of goods		
		EU/EEA/Switzerland		Third Countries	EU/EEA/Switzerland		Third Countries
		Nationals	Non-nationals		Nationals	Non-nationals	
R 6	Driving time: — daily limit — weekly limit — fortnightly limit						
R 6	Lack of records for other work and/or availability						
R 7	Breaks in driving time (driving more than 4,5 hours without break or break too short)						
R 8	Rest periods: — daily minimum — weekly minimum						

Article	Type of offence	Carriage of passengers			Carriage of goods		
		EU/EEA/Switzerland		Third Countries	EU/EEA/Switzerland		Third Countries
		Nationals	Non-nationals		Nationals	Non-nationals	
R 10 & 26	Driving time records: — 1 year for keeping data — record sheets for the preceding 28 days Working Time records:						
D Annex I A	Recording equipment: — incorrect functioning — misuse or manipulation of the recording equipment						

5. CHECKS AT THE PREMISES OF UNDERTAKING

5.1. Number of drivers checked and number of working days checked at the premises of undertaking

Type of carriage	Number of drivers checked	Number of working days checked
I. Typology		
Carriage of passengers		
Carriage of goods		
II. Typology		
Carriage for hire or reward		
Carriage on own account		

5.2. Offences — number and type of offences detected at the premises

(R — offence against Regulation (EC) No 561/2006, D — offence against Directive 2006/22/EC)

Article	Type of offence	Carriage of passengers	Carriage of goods
R 6	Driving time: — daily limit — weekly limit — fortnightly limit		
R 6	Lack of records for other work and/or availability		
R 7	Breaks in driving time (driving more than 4,5 hours without break or break too short)		
R 8	Rest periods: — daily minimum — weekly minimum		

Article	Type of offence	Carriage of passengers	Carriage of goods
R 10 & 26	Driving time records: — 1 year for keeping data — record sheets for the 28 preceding days		
D Annex I	Recording equipment: — incorrect functioning — misuse or manipulation of the recording equipment		

5.3. *Number of undertakings and drivers checked at the premises by size of fleet of the undertaking*

Size of fleet	Number of undertakings checked	Number of drivers checked	Number of offences detected
1			
2-5			
6-10			
11-20			
21-50			
51-200			
201-500			
Over 500			

6. NATIONAL ENFORCEMENT CAPACITY

- (a) Number of control officers involved in checks at the roadside and at the premises:
- (b) Number of control officers trained to be able to analyse data from digital tachographs at both the roadside or at company premises:
- (c) Number of units of equipment provided to control officers to be able to download, read and analyse data from digital tachographs at the roadside and company premises:

7. NATIONAL AND INTERNATIONAL INITIATIVES

7.1. *National*

- (a) Regulatory (including the update on what use has been made of exceptions under Article 13(1))
- (b) Administrative
- (c) Other

7.2. *International*

- (a) Concerted checks: number in each year, countries collaborating
- (b) Exchange of experience, data, staff: number of initiatives, people, subjects of exchange, countries collaborating

8. PENALTIES

8.1. Scales in the reference year

8.2. Changes

(a) Date and nature of most recent changes (based on reference year)

(b) Administrative or legal references

9. CONCLUSIONS AND COMMENTS, INCLUDING ANY DEVELOPMENTS IN THE FIELDS IN QUESTION

10. REPORT ON IMPLEMENTATION OF WORKING TIME DIRECTIVE 2002/15/EC

This section should in general include information on:

- how the report has been produced, what stakeholders have been consulted,
- implementation [*legal situation, how the transposition changed the previous legal situation regarding working time, any specific difficulties encountered at the application of the Directive, measures taken in response to those difficulties, any flanking measures to facilitate the practical implementation of the legislation*],
- monitoring of implementation [*bodies responsible for monitoring compliance with the rules, methods used for monitoring, problems encountered and solutions applied*],
- judicial interpretation [*indicate whether there have been court decisions at national level interpreting or applying the Directive on any significant issues, what were the key legal points on the issue*],
- assessment of effectiveness [*data used to assess the effectiveness of transposing measures, positive and negative aspects of practical implementation of the legislation*],
- outlook [*any priorities in the subject area, suggest adaptations or amendments to the Directive stating the reason, indicate any changes which are considered necessary to technical progress, suggest any flanking measures at EU level*].

11. PERSON RESPONSIBLE FOR THE COMPILATION OF THIS REPORT

Name:

Position:

Organisation:

Administrative address:

Tel./fax

E-mail:

Date:

COMMISSION DECISION

of 2 October 2009

**on the Community financial contribution to national programmes of certain Member States in 2009
for the collection, management and use of data in the fisheries sector**

(notified under document C(2009) 7424)

(2009/811/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 861/2006 of 22 May 2006 establishing Community financial measures for the implementation of the common fisheries policy and in the area of the Law of the Sea ⁽¹⁾, and in particular Article 24(1) thereof,

Whereas:

- (1) Regulation (EC) No 861/2006 lays down the conditions whereby Member States may receive a contribution from the Community for expenditure incurred in their national programmes of collection and management of data.
- (2) Those programmes are to be drawn up in accordance with Council Regulation (EC) No 199/2008 of 25 February 2008 concerning the establishment of a Community framework for the collection, management and use of data in the fisheries sector and support for scientific advice regarding the Common Fisheries Policy ⁽²⁾ and Commission Regulation (EC) No 665/2008 of 14 July 2008 laying down detailed rules for the application of Council Regulation (EC) No 199/2008 ⁽³⁾.
- (3) Belgium, Bulgaria, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Cyprus, Latvia, Lithuania, Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Finland, Sweden and the United Kingdom have submitted national programmes for 2009 and 2010 as provided for in Articles 4(4) and 4(5) of Council Regulation (EC) No 199/2008. These programmes were approved in accordance with Article 6(3) of Regulation (EC) No 199/2008.
- (4) Those Member States have submitted annual budget forecasts covering the period 2009-2010 according to Article 2 of Commission Regulation (EC) No 1078/2008 of 3 November 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 861/2006 as regards the expenditure incurred by Member States for the collection and management of the basic fisheries data ⁽⁴⁾. The Commission has

evaluated Member States' annual budget forecasts, as laid down in Article 4 of Regulation (EC) No 1078/2008, by taking into account the national programmes approved in accordance with Article 6(3) of Regulation (EC) No 199/2008.

- (5) Article 5 of Regulation (EC) No 1078/2008 establishes that the Commission is to approve the annual budget forecast and is to decide on the annual Community financial contribution to each national programme in accordance with the procedure laid down in Article 24 of Regulation (EC) No 861/2006 and on the basis of the outcome of the evaluation of the annual budget forecasts as referred to in Article 4 of Regulation (EC) No 1078/2008.
- (6) Article 24(3)(b) of Regulation (EC) No 861/2006 establishes that a Commission Decision is to fix the rate of the financial contribution. Article 16 of that Regulation provides that Community financial measures in the area of basic data collection is not to exceed 50 % of the costs incurred by Member States in carrying out the programme of collection, management and use of data in the fisheries sector. Article 24(2) stipulates that priority shall be given to the actions which are most appropriate in order to improve the collection of data necessary for the CFP.
- (7) This Decision is to constitute the financing decision within the meaning of Article 75(2) of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ⁽⁵⁾.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS DECISION:

Article 1

The maximum global amount of the financial Community contribution to be granted to each Member State for the collection, management and use of data in the fisheries sector for 2009, and the rate of the Community financial contribution, are established in the Annex.

⁽¹⁾ OJ L 160, 14.6.2006, p. 1.

⁽²⁾ OJ L 60, 5.3.2008, p. 1.

⁽³⁾ OJ L 186, 15.7.2008, p. 3.

⁽⁴⁾ OJ L 295, 4.11.2008, p. 24.

⁽⁵⁾ OJ L 248, 16.9.2002, p. 1.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 2 October 2009.

For the Commission

Joe BORG

Member of the Commission

ANNEX

NATIONAL PROGRAMMES 2009-2010

ELIGIBLE EXPENDITURE AND MAXIMUM COMMUNITY CONTRIBUTION FOR 2009

(EUR)

Member State	Eligible expenditure	Maximum Community contribution (Rate of 50 %)
BELGIUM	1 416 944,00	708 472,00
BULGARIA	369 615,00	184 807,50
DENMARK	5 978 374,00	2 989 187,00
GERMANY	5 779 328,00	2 889 664,00
ESTONIA	580 285,00	290 142,50
IRELAND	6 103 290,00	3 051 645,00
GREECE	4 437 307,00	2 218 653,50
SPAIN	12 864 496,00	6 432 248,00
FRANCE	12 138 570,00	6 069 285,00
ITALY	6 362 897,00	3 181 448,50
CYPRUS	462 877,00	231 438,50
LATVIA	443 750,00	221 875,00
LITHUANIA	380 632,00	190 316,00
MALTA	602 884,00	301 442,00
NETHERLANDS	3 875 926,00	1 937 963,00
POLAND	1 030 137,00	515 068,50
PORTUGAL	2 962 407,00	1 481 203,50
ROMANIA	572 686,00	286 343,00
SLOVENIA	194 614,00	97 307,00
FINLAND	1 652 991,00	826 495,50
SWEDEN	5 121 508,00	2 560 754,00
UNITED KINGDOM	9 339 135,00	4 669 567,50
TOTAL	82 670 653,00	41 335 326,50

COMMISSION DECISION

of 26 October 2009

granting a derogation requested by France pursuant to Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices

*(notified under document C(2009) 8041)***(Only the French text is authentic)**

(2009/812/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision) ⁽¹⁾, and in particular Article 4(5) thereof,

Having regard to Commission Decision 2006/771/EC of 9 November 2006 on harmonisation of the radio spectrum for use by short-range devices ⁽²⁾, and in particular Article 3(2) thereof,

Having regard to the request made by France on 29 June 2009,

Whereas:

(1) Decision 2006/771/EC, as amended by Commission Decision 2009/381/EC ⁽³⁾, provides that Member States must designate the frequency band 2 400-2 483,5 MHz for wideband data transmission systems and radio determination applications and make it available on a non-exclusive, non-interference and non-protected basis, subject to specific conditions, by 1 November 2009.

(2) Article 3(2) of Decision 2006/771/EC states that, by way of derogation, Member States may request transitional periods and/or radio spectrum-sharing arrangements, pursuant to Article 4(5) of Decision No 676/2002/EC.

(3) France has informed the Commission that the 2 454-2 483,5 MHz sub-band is currently used by military systems, and that it cannot therefore meet the requirements laid down in Decision 2006/771/EC in time.

(4) France has indicated that the Ministry of Defence has started implementing a plan to replace the equipment used at present. From 1 July 2012, the frequency band 2 400-2 483,5 MHz will be made available entirely for wideband data transmission systems and radio determination applications, in accordance with Decision 2006/771/EC.

(5) By letter of 29 June 2009, France officially asked the Commission for a transitional period during which wideband data transmission systems and radio determination applications could be used in the 2 454-2 483,5 MHz sub-band on its territory solely subject to the following conditions. Outside buildings, these devices may only be used with a power limited to 10 mW. However, inside buildings, they may be used with the maximum power authorised by Decision 2006/771/EC, as amended by Decision 2009/381/EC, that is to say 100 mW e.i.r.p. for wideband data transmission systems and 25 mW e.i.r.p. for radio determination applications. Wideband data transmission systems and radio determination applications may be used in the 2 400-2 454 MHz sub-band subject to the conditions laid down in Decision 2006/771/EC.

(6) In support of its request, France has provided sufficient information and technical justifications demonstrating that there is a risk of interference with military equipment.

(7) A report on the development of the situation in France would be beneficial for the smooth progress of the transitional period.

(8) The members of the Radio Spectrum Committee indicated at their meeting on 8 July 2009 that they did not object to this transitional derogation.

(9) The derogation requested would not unduly delay implementation of Commission Decision 2006/771/EC, as amended by Decision 2009/381/EC, or create disproportionate differences between Member States in terms of competition or regulation. There is sufficient justification for this derogation in view of the special situation in France, and full implementation of Decision 2006/771/EC should be facilitated there,

⁽¹⁾ OJ L 108, 24.4.2002, p. 1.

⁽²⁾ OJ L 312, 11.11.2006, p. 66.

⁽³⁾ OJ L 119, 14.5.2009, p. 32.

HAS ADOPTED THIS DECISION:

Article 1

France is hereby authorised to derogate from its obligations under Commission Decision 2006/771/EC, subject to the conditions laid down in this Decision.

Article 2

Until 30 June 2012, France is hereby authorised to limit the power of wideband data transmission systems and radio determination applications in the 2 454-2 483,5 MHz sub-band in metropolitan France to 10 mW e.i.r.p. where the devices in question are used outside buildings, including places assimilated thereto such as an aircraft, in which the shielding will typically provide the necessary attenuation to facilitate sharing with other services.

Article 3

By 31 December 2010, France shall submit a report to the Commission on the implementation of this Decision.

Article 4

This Decision is addressed to the French Republic.

Done at Brussels, 26 October 2009.

For the Commission

Viviane REDING

Member of the Commission

COMMISSION DECISION

of 30 October 2009

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2009) 8383)***(Only the French and Dutch texts are authentic)****(Text with EEA relevance)**

(2009/813/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 14 December 2006, Monsanto Europe SA 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 MON 89034 maize (the application).

(2) The application also covers the placing on the market of other products containing or consisting of MON 89034 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 18 December 2008, 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 of, or produced from MON 89034 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 MON 89034 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 other products 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-2007-042>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

- (8) Similarly, 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 point (e) of Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.
- (9) 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.
- (10) 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 ⁽¹⁾, lays down labelling requirements for products consisting of, or containing GMOs.
- (11) 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 Articles 9(1) and 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⁾.
- (12) The applicant has been consulted on the measures provided for in this Decision.
- (13) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman.
- (14) At its meeting on 19 October 2009, 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.) MON 89034, as specified in point (b) of the Annex to this Decision, is

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 287, 5.11.2003, p. 1.

assigned the unique identifier MON-89Ø34-3, 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-89Ø34-3 maize;
- (b) feed containing, consisting of, or produced from MON-89Ø34-3 maize;
- (c) products other than food and feed containing or consisting of MON-89Ø34-3 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-89Ø34-3 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.

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 SA, Belgium, representing Monsanto Company, United States of America.

*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 SA, Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 30 October 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

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

Name: Monsanto Europe SA

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

On behalf of Monsanto Company – 800 N. Lindbergh Boulevard – St. Louis, Missouri 63167 – United States of America.

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

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

The genetically modified MON-89Ø34-3 maize, as described in the application, expresses the Cry1A.105 and Cry2Ab2 proteins which confer protection to certain lepidopteran pests.

(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-89Ø34-3 maize referred to in Article 2(b) and (c) of this Decision.

(d) **Method for detection:**

- Event specific real-time PCR based method for the quantification of MON-89Ø34-3 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 accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm/corn.cfm>

(e) **Unique identifier:**

MON-89Ø34-3

(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.

NB: 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 30 October 2009

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON-88Ø17-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2009) 8384)***(Only the French and Dutch texts are authentic)****(Text with EEA relevance)**

(2009/814/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 4 October 2005, Monsanto Europe SA submitted to the competent authority of the Czech Republic 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 MON 88017 maize (the application).

(2) The application also covers the placing on the market of other products containing or consisting of MON 88017 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 6 May 2009, 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 of, or produced from MON 88017 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 MON 88017 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 other products 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-2005-280>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

- (8) Similarly, 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 point (e) of Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.
- (9) 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.
- (10) 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⁽¹⁾, lays down labelling requirements for products consisting of, or containing GMOs.
- (11) 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 Articles 9(1) and 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⁾.
- (12) The applicant has been consulted on the measures provided for in this Decision.
- (13) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman.
- (14) At its meeting on 19 October 2009, 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.) MON 88017, as specified in point (b) of the Annex to this Decision, is

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 287, 5.11.2003, p. 1.

assigned the unique identifier MON-88Ø17-3, 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-88Ø17-3 maize;
- (b) feed containing, consisting of, or produced from MON-88Ø17-3 maize;
- (c) products other than food and feed containing or consisting of MON-88Ø17-3 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-88Ø17-3 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.

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 SA, Belgium, representing Monsanto Company, United States of America.

*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 SA, Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 30 October 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

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

Name: Monsanto Europe SA

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

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.

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

1. Foods and food ingredients containing, consisting of, or produced from MON-88Ø17-3 maize;
2. feed containing, consisting of, or produced from MON-88Ø17-3 maize;
3. products other than food and feed containing or consisting of MON-88Ø17-3 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified MON-88Ø17-3 maize, as described in the application, expresses a modified Cry3Bb1 protein which provides protection to certain coleopteran pests and the CP4 EPSPS protein which confer 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-88Ø17-3 maize referred to in Article 2(b) and (c) of this Decision.

(d) **Method for detection:**

- Event specific real-time PCR based method for the quantification of MON-88Ø17-3 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 0406-D accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm/corn.cfm>

(e) **Unique identifier:**

MON-88Ø17-3

(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.

NB: 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 30 October 2009

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122xNK603 (DAS-59122-7xMON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2009) 8386)***(Only the French and Dutch texts are authentic)****(Text with EEA relevance)**

(2009/815/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 26 August 2005, Pioneer Overseas Corporation submitted to the competent authority 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 foods, food ingredients, and feed containing, consisting of, or produced from 59122xNK603 maize (the application).

(2) The application also covers the placing on the market of other products containing or consisting of 59122xNK603 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 25 November 2008, 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 of, or produced from 59122xNK603 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 59122xNK603 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 other products 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-2005-247>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

- (8) Similarly, 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 point (e) of Articles 6(5) and 18(5) of Regulation (EC) No 1829/2003.
- (9) 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.
- (10) 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⁽¹⁾, lays down labelling requirements for products consisting of, or containing GMOs.
- (11) 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 Articles 9(1) and 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⁾.
- (12) The applicant has been consulted on the measures provided for in this Decision.
- (13) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman.
- (14) At its meeting on 19 October 2009, 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.) 59122xNK603, as specified in point (b) of the Annex to this Decision, is

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 287, 5.11.2003, p. 1.

assigned the unique identifier DAS-59122-7xMON-ØØ6Ø3-6, 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:

- foods and food ingredients containing, consisting of, or produced from DAS-59122-7xMON-ØØ6Ø3-6 maize;
- feed containing, consisting of, or produced from DAS-59122-7xMON-ØØ6Ø3-6 maize;
- products other than food and feed containing or consisting of DAS-59122-7xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation.

Article 3

Labelling

- 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'.
- The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DAS-59122-7xMON-ØØ6Ø3-6 maize referred to in Article 2(b) and (c).

Article 4

Monitoring for environmental effects

- 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.
- 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.

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 Pioneer Overseas Corporation, Belgium, representing Pioneer Hi-Bred International Inc., United States of America.

*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 Pioneer Overseas Corporation, Avenue des Arts 44, 1040 Brussels, Belgium.

Done at Brussels, 30 October 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

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

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, 1040 Brussels, Belgium

On behalf of Pioneer Hi-Bred International Inc., 7100 NW 62nd Avenue, PO Box 1014, Johnston, IA 50131-1014, United States of America.

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

1. Foods and food ingredients containing, consisting of, or produced from DAS-59122-7xMON-ØØ6Ø3-6 maize;
2. feed containing, consisting of, or produced from DAS-59122-7xMON-ØØ6Ø3-6 maize;
3. products other than food and feed containing or consisting of DAS-59122-7xMON-ØØ6Ø3-6 maize for the same uses as any other maize with the exception of cultivation.

The genetically modified DAS-59122-7xMON-ØØ6Ø3-6 maize, as described in the application, is produced by crosses between maize containing DAS-59122-7 and MON-ØØ6Ø3-6 events and expresses the Cry34Ab1 and Cry35Ab1 proteins which confer tolerance to certain coleopterans pests, the PAT protein, used as a selectable marker, which confers tolerance to the glufosinate-ammonium herbicide and the CP4 EPSPS protein which confers tolerance to glyphosate herbicide.

(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 DAS-59122-7xMON-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 DAS-59122-7 and MONØØ6Ø3-6 maize validated on DAS-59122-7xMON-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: ERM®-BF424 (for DAS-59122-7) and ERM®-BF415 (for MON-ØØ6Ø3-6) 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:**

DAS-59122-7xMON-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.

NB: Links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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