

Official Journal

of the European Union

L 40



English edition

Legislation

Volume 55

14 February 2012

Contents

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

- ★ **Information concerning the entry into force of the Agreement renewing the Agreement for scientific and technological cooperation between the European Community and Ukraine** 1

REGULATIONS

- ★ **Commission Implementing Regulation (EU) No 122/2012 of 13 February 2012 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance methylprednisolone ⁽¹⁾** 2

- ★ **Commission Implementing Regulation (EU) No 123/2012 of 13 February 2012 amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance monepantel ⁽¹⁾** 4

Commission Implementing Regulation (EU) No 124/2012 of 13 February 2012 establishing the standard import values for determining the entry price of certain fruit and vegetables 6

Price: EUR 3

(Continued overleaf)

⁽¹⁾ Text with EEA relevance

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.

DECISIONS

2012/79/EU:

- ★ **Council Decision of 10 February 2012 appointing an Austrian member of the Committee of the Regions** 8

2012/80/EU:

- ★ **Council Decision of 10 February 2012 appointing four Czech members and four Czech alternate members of the Committee of the Regions** 9

2012/81/EU:

- ★ **Commission Implementing Decision of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council** (*notified under document C(2012) 691*) ⁽¹⁾..... 10

2012/82/EU:

- ★ **Commission Implementing Decision of 10 February 2012 as regards the renewal of the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified soybean 40-3-2 (MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council** (*notified under document C(2012) 700*) ⁽¹⁾..... 14

2012/83/EU:

- ★ **Commission Implementing Decision of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 (MON-877Ø1-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council** (*notified under document C(2012) 701*) ⁽¹⁾..... 18

2012/84/EU:

- ★ **Commission Implementing Decision of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 356043 (DP-356Ø43-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council** (*notified under document C(2012) 702*) ⁽¹⁾..... 22



⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information concerning the entry into force of the Agreement renewing the Agreement for scientific and technological cooperation between the European Community and Ukraine

The Agreement renewing the Agreement for scientific and technological cooperation between the European Community and Ukraine, signed on 4 July 2002 ⁽¹⁾ and renewed on 7 October 2003 ⁽²⁾ and 9 March 2011 ⁽³⁾, has, in accordance with Article 12 thereof, entered into force on 21 December 2011.

⁽¹⁾ OJ L 36, 12.2.2003, p. 32.

⁽²⁾ OJ L 267, 17.10.2003, p. 25.

⁽³⁾ OJ L 79, 25.3.2011, p. 3.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 122/2012

of 13 February 2012

amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance methylprednisolone

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin ⁽²⁾).

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

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ⁽¹⁾, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (3) Methylprednisolone is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for bovine species, applicable to muscle, fat, liver, kidney and milk. The provisional maximum residue limits (hereinafter 'MRLs') for that substance set out for bovine milk expired on 1 July 2011.
- (4) Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend that the provisional MRLs for methylprednisolone for bovine milk should be set as definitive.
- (5) The entry for methylprednisolone in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

- (1) The maximum residue limit for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry should be established in accordance with Regulation (EC) No 470/2009.

- (2) Pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2009 on

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

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

⁽¹⁾ OJ L 152, 16.6.2009, p. 11.

⁽²⁾ OJ L 15, 20.1.2010, p. 1.

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

Done at Brussels, 13 February 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX

The entry for methylprednisolone in Table 1 of the Annex to Regulation (EU) No 37/2010 is replaced by the following:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic classification
Methylprednisolone	Methylprednisolone	Bovine	10 µg/kg 10 µg/kg 10 µg/kg 10 µg/kg 2 µg/kg	Muscle Fat Liver Kidney Milk		Corticoides/ Glucocorticoides

COMMISSION IMPLEMENTING REGULATION (EU) No 123/2012**of 13 February 2012****amending the Annex to Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as regards the substance monepantel****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council⁽¹⁾, and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

- (1) The maximum residue limit (MRL) for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry should be established in accordance with Regulation (EC) No 470/2009.
- (2) Pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin are set out in the Annex to Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin⁽²⁾.

(3) Monepantel is currently included in Table 1 of the Annex to Regulation (EU) No 37/2010 as an allowed substance, for ovine and caprine species, applicable to muscle, fat, liver, and kidney, excluding animals producing milk for human consumption. The provisional maximum residue limits for that substance set out for caprine species expired on 1 January 2012.

(4) Additional data were provided and assessed leading the Committee for Medicinal Products for Veterinary Use to recommend that the provisional MRLs for monepantel for caprine species should be set as definitive.

(5) The entry for monepantel in Table 1 of the Annex to Regulation (EU) No 37/2010 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

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, 13 February 2012.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 152, 16.6.2009, p. 11.

⁽²⁾ OJ L 15, 20.1.2010, p. 1.

ANNEX

The entry monepantel in Table 1 of the Annex to Regulation (EU) No 37/2010 is replaced by the following:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
Monepantel	Monepantel-sulfone	Ovine, caprine	700 µg/kg 7 000 µg/kg 5 000 µg/kg 2 000 µg/kg	Muscle Fat Liver Kidney	Not for use in animals producing milk for human consumption.	Antiparasitic agents/Agents acting against endoparasites'

COMMISSION IMPLEMENTING REGULATION (EU) No 124/2012**of 13 February 2012****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 Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral 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 XVI, Part A thereto.

- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed 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*.

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

Done at Brussels, 13 February 2012.

*For the Commission,
On behalf of the President,
José Manuel SILVA RODRÍGUEZ
Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 157, 15.6.2011, 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	54,6
	TN	85,2
	TR	93,7
	ZZ	77,8
0707 00 05	EG	229,9
	JO	134,1
	TR	168,6
	US	57,6
	ZZ	147,6
0709 91 00	EG	330,9
	ZZ	330,9
0709 93 10	MA	84,3
	TR	149,7
	ZZ	117,0
0805 10 20	EG	47,7
	IL	74,0
	MA	51,9
	TN	51,6
	TR	72,7
	ZZ	59,6
0805 20 10	IL	163,3
	MA	106,7
	ZZ	135,0
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	CN	60,1
	EG	95,0
	IL	107,5
	MA	111,8
	TR	71,6
	ZZ	89,2
0805 50 10	EG	58,2
	TR	51,1
	ZZ	54,7
0808 10 80	CA	124,7
	CL	98,4
	CN	111,0
	MK	26,7
	US	151,3
	ZZ	102,4
0808 30 90	CL	178,7
	CN	80,5
	US	122,2
	ZA	112,3
	ZZ	123,4

⁽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'.

DECISIONS

COUNCIL DECISION

of 10 February 2012

appointing an Austrian member of the Committee of the Regions

(2012/79/EU)

THE COUNCIL OF THE EUROPEAN UNION,

HAS ADOPTED THIS DECISION:

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal from the Austrian Government,

Whereas:

(1) On 22 December 2009 and 18 January 2010, the Council adopted Decisions 2009/1014/EU ⁽¹⁾ and 2010/29/EU ⁽²⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2010 to 25 January 2015. On 26 April 2010, Mr Markus WALLNER was appointed as member until 25 January 2015 by Council Decision 2010/242/EU ⁽³⁾, following the end of the term of office of Mr Herbert SAUSGRUBER.

(2) A member's seat on the Committee of the Regions has become vacant following the end of the electoral mandate on the basis of which Mr Markus WALLNER was appointed,

Article 1

The following is hereby reappointed to the Committee of the Regions as member for the remainder of the current term of office, which runs until 25 January 2015:

— Mr Markus WALLNER, *Landeshauptmann von Vorarlberg* (change of mandate).

Article 2

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 10 February 2012.

For the Council
The President
C. ANTORINI

⁽¹⁾ OJ L 348, 29.12.2009, p. 22.

⁽²⁾ OJ L 12, 19.1.2010, p. 11.

⁽³⁾ OJ L 107, 29.4.2010, p. 20.

COUNCIL DECISION
of 10 February 2012
appointing four Czech members and four Czech alternate members of the Committee of the Regions
(2012/80/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Czech Government,

Whereas:

(1) On 22 December 2009 and on 18 January 2010, the Council adopted Decisions 2009/1014/EU ⁽¹⁾ and 2010/29/EU ⁽²⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2010 to 25 January 2015.

(2) Four members' seats on the Committee of the Regions have become vacant following the end of the terms of office of Mr Jiří BYTEL, Mr Jan KUBATA, Ms Helena LANGŠÁDLOVÁ and Mr Juraj THOMA. Four alternate members' seats on the Committee of the Regions have become vacant following the end of the terms of office of Ms Ivana ČERVINKOVÁ, Mr Tomáš CHALUPA, Ms Sylva KOVÁČIKOVÁ and Mr Tomáš ÚLEHLA,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2015:

(a) as members:

— Mr Ondřej BENEŠÍK, starosta obce Strání,

— Ms Štěpánka FRAŇKOVÁ, primátorka statutárního města Pardubic,

— Mr Dan JIRÁNEK, primátor statutárního města Kladna,

— Mr Juraj THOMA, primátor statutárního města Českých Budějovic (change of mandate);

and

(b) as alternate members:

— Mr Pavel BRANDA, místostarosta obce Rádlo,

— Ms Sylva KOVÁČIKOVÁ, zastupitelka města Bílovec (change of mandate),

— Mr Jan MAREŠ, primátor statutárního města Chomutova,

— Mr Robert ZEMAN, místostarosta města Prachatic.

Article 2

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 10 February 2012.

For the Council
The President
C. ANTORINI

⁽¹⁾ OJ L 348, 29.12.2009, p. 22.

⁽²⁾ OJ L 12, 19.1.2010, p. 11.

COMMISSION IMPLEMENTING DECISION

of 10 February 2012

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2012) 691)***(Only the German text is authentic)****(Text with EEA relevance)**

(2012/81/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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 31 March 2008, Bayer CropScience AG 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 A5547-127 soybean ('the application').
- (2) The application also covers the placing on the market of products other than food and feed containing or consisting of A5547-127 soybean for the same uses as any other soybean 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 10 May 2011, the European Food Safety Authority (EFSA) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that soybean A5547-127, as described in the

application, is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment ⁽³⁾.

- (4) 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.
- (5) In particular, EFSA concluded that soybean A5547-127 is compositionally and agronomically not different from its non-genetically modified counterpart and equivalent to commercial varieties, except for the introduced trait and as a consequence, that animal safety studies with the whole food/feed (e.g. a 90-day toxicity study in rats) are not needed.
- (6) 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.
- (7) Taking into account those considerations, authorisation should be granted for the products containing, consisting of, or produced from A5547-127 soybean as described in the application ('the products').
- (8) 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⁾.
- (9) 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 A5547-127 soybean. 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

⁽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-2011-00292>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

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.

- (10) 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 in Article 4(6) labelling requirements for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (11) 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⁾. 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 Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.
- (12) 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.
- (13) 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 point (c) of Article 15(2) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on trans-boundary movements of genetically modified organisms⁽³⁾.
- (14) The applicant has been consulted on the measures provided for in this Decision.
- (15) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was

deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean A5547-127, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-GMØØ6-4, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from ACS-GMØØ6-4 soybean;
- (b) feed containing, consisting of, or produced from ACS-GMØØ6-4 soybean;
- (c) products other than food and feed containing or consisting of ACS-GMØØ6-4 soybean for the same uses as any other soybean 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 'soybean'.
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of ACS-GMØØ6-4 soybean referred to in points (b) and (c) of Article 2.

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 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

*Article 6***Authorisation holder**

The authorisation holder shall be Bayer CropScience AG.

*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 Bayer CropScience AG, Alfred-Nobel-Strasse 50, 40789 Monheim am Rhein, GERMANY.

Done at Brussels, 10 February 2012.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) **Applicant and authorisation holder**

Name: Bayer CropScience AG

Address: Alfred-Nobel-Strasse 50, 40789 Monheim am Rhein, GERMANY

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

(1) Foods and food ingredients containing, consisting of, or produced from ACS-GMØØ6-4 soybean.

(2) Feed containing, consisting of, or produced from ACS-GMØØ6-4 soybean.

(3) Products other than food and feed containing or consisting of ACS-GMØØ6-4 soybean for the same uses as any other soybean with the exception of cultivation.

The genetically modified ACS-GMØØ6-4 soybean, as described in the application, expresses 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 'soybean'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of ACS-GMØØ6-4 soybean 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 ACS-GMØØ6-4 soybean,

— validated by the European Union Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>

— reference material: AOCS 0707-C3 and 0707-A2 accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

(e) **Unique identifier**

ACS-GMØØ6-4

(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 time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION

of 10 February 2012

as regards the renewal of the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified soybean 40-3-2 (MON-Ø4Ø32-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2012) 700)***(Only the Dutch and the French texts are authentic)****(Text with EEA relevance)**

(2012/82/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) By Commission Decision 96/281/EC of 3 April 1996 concerning the placing on the market of genetically modified soya beans (*Glycine max* L.) with increased tolerance to the herbicide glyphosate, pursuant to Council Directive 90/220/EEC⁽²⁾ the United Kingdom gave its consent for placing on the market genetically modified soybean 40-3-2.
- (2) Food produced from genetically modified soybean 40-3-2, including food additives, feed materials and feed additives produced from genetically modified soybean 40-3-2 were placed on the market before the entry into force of Regulation (EC) No 1829/2003.
- (3) Articles 8(1) and 20(1) of Regulation (EC) No 1829/2003 allow the products which have been lawfully placed on the market before the date of application of that Regulation to continue to be placed on the market, provided that a notification is made to the Commission.
- (4) Articles 8(4) and 20(4) of Regulation (EC) No 1829/2003 require the operators responsible for placing on the market those products to submit an application for renewal of authorisation within certain time limits.

- (5) On 16 April 2007, Monsanto Europe SA submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 for renewal of the authorisation for continued marketing of existing food additives, feed materials and feed additives produced from 40-3-2 soybean which were previously notified according to Articles 8(1)(b) and 20(1)(b) of that Regulation.
- (6) On 18 April 2007, Monsanto Europe SA submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation of food containing, consisting of, or produced from 40-3-2 soybean, feed containing or consisting of 40-3-2 soybean and products other than food and feed containing or consisting of 40-3-2 soybean with the exception of cultivation which were previously notified according to Articles 8(1)(a) and 20(1)(a) of that Regulation.
- (7) On 1 December 2010, the European Food Safety Authority (EFSA) gave two favourable opinions in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 and concluded that the new information provided in the applications and the review of the literature published since the previous scientific assessment of 40-3-2 soybean⁽³⁾ do not require changes of the previous scientific opinions on 40-3-2 soybean and reiterated the previous conclusions that 40-3-2 soybean 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 40-3-2 soybean as described in the applications ('the products') will have any adverse effects on human or animal health or the environment in the context of its proposed uses⁽⁴⁾.

⁽³⁾ Safety assessment of 40-3-2 soybean performed by the Advisory Committee on Novel Foods and Processes in the UK — http://www.foodstandards.gov.uk/multimedia/webpage/acnfp_report_1994

⁽⁴⁾ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-01260>
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-01259>

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ OJ L 107, 30.4.1996, p. 10.

- (8) In its opinions, 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 Regulation (EC) No 1829/2003.
- (9) In its opinions, 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.
- (10) Taking into account those considerations, renewal of the authorisation should be granted for the products.
- (11) 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⁾.
- (12) On the basis of the EFSA opinions, 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 and feed containing, consisting of, or produced from 40-3-2 soybean. 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.
- (13) 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 in Article 4(6) labelling requirements for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (14) 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 ⁽³⁾. The EFSA opinions do 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 Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.
- (15) All relevant information on the renewal of 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.
- (16) In the interest of clarity and consistency, Decision 96/281/EC should be repealed and replaced by this Decision.
- (17) 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 point (c) of Article 15(2) 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⁾.
- (18) The applicant has been consulted on the measures provided for in this Decision.
- (19) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,
- HAS ADOPTED THIS DECISION:
- Article 1*
- Genetically modified organism and unique identifier**
- Genetically modified soybean 40-3-2, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-Ø4Ø32-6, 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:

⁽¹⁾ OJ L 10, 16.1.2004, p. 5.

⁽²⁾ OJ L 268, 18.10.2003, p. 24.

⁽³⁾ OJ L 275, 21.10.2009, p. 9.

⁽⁴⁾ OJ L 287, 5.11.2003, p. 1.

- (a) foods and food ingredients containing, consisting of, or produced from MON-Ø4Ø32-6 soybean;
- (b) feed containing, consisting of, or produced from MON-Ø4Ø32-6 soybean;
- (c) products other than food and feed containing or consisting of MON-Ø4Ø32-6 soybean for the same uses as any other soybean 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 'soybean'.
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-Ø4Ø32-6 soybean 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 the requirements set in 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 SA, Belgium, representing Monsanto Company, United States.

Article 7

Repeal

Decision 96/281/EC shall be repealed from 13 February 2012.

Article 8

Validity

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

Article 9

Addressee

This Decision is addressed to Monsanto Europe SA, Avenue de Tervuren/Tervurenlaan 270-272, 1150 Bruxelles/Brussel, BELGIQUE/BELGIË.

Done at Brussels, 10 February 2012.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) Applicant and authorisation holder

Name: Monsanto Europe SA

Address: Avenue de Tervuren/Tervurenlaan 270-272, 1150 Bruxelles/Brussel, BELGIQUE/BELGIË

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-Ø4Ø32-6 soybean.
- (2) Feed containing, consisting of, or produced from MON-Ø4Ø32-6 soybean.
- (3) Products other than food and feed containing or consisting of MON-Ø4Ø32-6 soybean for the same uses as any other soybean with the exception of cultivation.

The genetically modified MON-Ø4Ø32-6 soybean, as described in the applications, expresses the CP4 EPSPS protein which confers tolerance to the 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 'soybean'.
- (2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-Ø4Ø32-6 soybean referred to in Article 2(b) and (c).

(d) Method for detection

- Event-specific real-time PCR-based method for the quantification of MON-Ø4Ø32-6 soybean,
- validated 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®-BF410 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-Ø4Ø32-6

(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 of the European Parliament and of the Council ⁽¹⁾

[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 time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

⁽¹⁾ OJ L 106, 17.4.2001, p. 1.

COMMISSION IMPLEMENTING DECISION

of 10 February 2012

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 (MON-877Ø1-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2012) 701)***(Only the Dutch and French texts are authentic)****(Text with EEA relevance)**

(2012/83/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 6 May 2010, Monsanto Europe SA submitted to the competent authority of Belgium 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 87701 soybean ('the application').

(2) The application also covers the placing on the market of products other than food and feed containing or consisting of MON 87701 soybean for the same uses as any other soybean 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 26 July 2011, the European Food Safety Authority (EFSA) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that soybean MON 87701, as described in the

application, is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment⁽³⁾.

(4) 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.

(5) 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.

(6) Taking into account those considerations, authorisation should be granted for the products containing, consisting of, or produced from MON 87701 soybean as described in the application ('the products').

(7) A unique identifier should be assigned to each genetically modified organism (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⁾.

(8) 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 87701 soybean. 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-2011-00857>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

- (9) 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 in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.
- (10) 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⁾. 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 Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.
- (11) All relevant information on the authorisation of the products should be entered in the EU register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- (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. An implementing act was deemed to be necessary and the chair submitted the

draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean MON 87701, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-877Ø1-2, 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-877Ø1-2 soybean;
- (b) feed containing, consisting of, or produced from MON-877Ø1-2 soybean;
- (c) products other than food and feed containing or consisting of MON-877Ø1-2 soybean for the same uses as any other soybean 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 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-877Ø1-2 soybean 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

*Article 5***EU register**

The information set out in the Annex to this Decision shall be entered in the EU 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.

*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, 10 February 2012.

For the Commission

John DALLI

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-877Ø1-2 soybean.

(2) Feed containing, consisting of, or produced from MON-877Ø1-2 soybean.

(3) Products other than food and feed containing or consisting of MON-877Ø1-2 soybean for the same uses as any other soybean with the exception of cultivation.

The genetically modified MON-877Ø1-2 soybean, as described in the application, expresses the Cry1Ac protein which confers protection against certain lepidopteran pests.

(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 'soybean'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-877Ø1-2 soybean 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-877Ø1-2 soybean,

— validated on grains by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>

— reference material: AOCS 0809-A and AOCS 0906-A accessible via the American Oil Chemists Society at <http://www.aocs.org/tech/crm>

(e) Unique identifier

MON-877Ø1-2

(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 EU register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION

of 10 February 2012

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 356043 (DP-356043-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2012) 702)***(Only the Dutch, English and French texts are authentic)****(Text with EEA relevance)**

(2012/84/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁽¹⁾, and in particular Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 28 February 2007, 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 356043 soybean ('the application').
- (2) The application also covers the placing on the market of products other than food and feed containing or consisting of 356043 soybean for the same uses as any other soybean 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 26 July 2011, the European Food Safety Authority (EFSA) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that soybean 356043, as described in the

application, is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment⁽³⁾.

- (4) 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.
- (5) 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.
- (6) Taking into account those considerations, authorisation should be granted for the products containing, consisting of, or produced from 356043 soybean as described in the application ('the products').
- (7) A unique identifier should be assigned to each genetically modified organism (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⁾.
- (8) 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 356043 soybean. 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.
- (9) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically

⁽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-2011-00856>

⁽⁴⁾ OJ L 10, 16.1.2004, p. 5.

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 in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(10) 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⁾. 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 Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products should be entered in the EU register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(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. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the Appeal Committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean 356043, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DP-356043-5, 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 DP-356043-5 soybean;
- (b) feed containing, consisting of, or produced from DP-356043-5 soybean;
- (c) products other than food and feed containing or consisting of DP-356043-5 soybean for the same uses as any other soybean 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 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DP-356043-5 soybean 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

EU register

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 24.

⁽²⁾ OJ L 275, 21.10.2009, p. 9.

⁽³⁾ OJ L 287, 5.11.2003, p. 1.

*Article 6***Authorisation holder**

The authorisation holder shall be Pioneer Overseas Corporation, Belgium, representing Pioneer Hi-Bred International, Inc., 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 Pioneer Overseas Corporation, Avenue des Arts/Kunstlaan 44, 1040 Bruxelles/Brussel, BELGIQUE/BELGIË.

Done at Brussels, 10 February 2012.

For the Commission

John DALLI

Member of the Commission

ANNEX

(a) Applicant and Authorisation holder

Name: Pioneer Overseas Corporation

Address: Avenue des Arts/Kunstlaan 44, 1040 Bruxelles/Brussel, BELGIQUE/BELGIË

On behalf of Pioneer Hi-Bred International, Inc., 7100 NW 62nd Avenue, P.O. 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 DP-356Ø43-5 soybean.
- (2) Feed containing, consisting of, or produced from DP-356Ø43-5 soybean.
- (3) Products other than food and feed containing or consisting of DP-356Ø43-5 soybean for the same uses as any other soybean with the exception of cultivation.

The genetically modified DP-356Ø43-5 soybean, as described in the application, expresses the GAT protein which confers tolerance to glyphosate herbicides and GM-HRA protein which confers tolerance to ALS-inhibiting 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 'soybean'.
- (2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DP-356Ø43-5 soybean 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 DP-356Ø43-5 soybean,
- validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm>
- reference material: ERM®-AD425 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

DP-356Ø43-5.

(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 time. Those modifications will be made available to the public via the updating of the EU register of genetically modified food and feed.

2012 SUBSCRIPTION PRICES (excluding VAT, including normal transport charges)

EU Official Journal, L + C series, paper edition only	22 official EU languages	EUR 1 200 per year
EU Official Journal, L + C series, paper + annual DVD	22 official EU languages	EUR 1 310 per year
EU Official Journal, L series, paper edition only	22 official EU languages	EUR 840 per year
EU Official Journal, L + C series, monthly DVD (cumulative)	22 official EU languages	EUR 100 per year
Supplement to the Official Journal (S series), tendering procedures for public contracts, DVD, one edition per week	multilingual: 23 official EU languages	EUR 200 per year
EU Official Journal, C series — recruitment competitions	Language(s) according to competition(s)	EUR 50 per year

Subscriptions to the *Official Journal of the European Union*, which is published in the official languages of the European Union, are available for 22 language versions. The Official Journal comprises two series, L (Legislation) and C (Information and Notices).

A separate subscription must be taken out for each language version.

In accordance with Council Regulation (EC) No 920/2005, published in Official Journal L 156 of 18 June 2005, the institutions of the European Union are temporarily not bound by the obligation to draft all acts in Irish and publish them in that language. Irish editions of the Official Journal are therefore sold separately.

Subscriptions to the Supplement to the Official Journal (S Series — tendering procedures for public contracts) cover all 23 official language versions on a single multilingual DVD.

On request, subscribers to the *Official Journal of the European Union* can receive the various Annexes to the Official Journal. Subscribers are informed of the publication of Annexes by notices inserted in the *Official Journal of the European Union*.

Sales and subscriptions

Subscriptions to various priced periodicals, such as the subscription to the *Official Journal of the European Union*, are available from our sales agents. The list of sales agents is available at:

http://publications.europa.eu/others/agents/index_en.htm

EUR-Lex (<http://eur-lex.europa.eu>) offers direct access to European Union legislation free of charge. The *Official Journal of the European Union* can be consulted on this website, as can the Treaties, legislation, case-law and preparatory acts.

For further information on the European Union, see: <http://europa.eu>



Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN