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Price: EUR 3

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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.

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II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 18 June 2012

on the position to be taken by the European Union within the relevant Committees of the United Nations Economic Commission for Europe regarding the adaptation to technical progress of Regulations Nos 11, 13H, 30, 44, 49, 54, 64, 101, 106 and 121 and regarding the adaptation to technical progress of Global Technical Regulation No 1 concerning door locks and retention components of the United Nations Economic Commission for Europe

(2012/348/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) In accordance with Council Decision 97/836/EC ⁽¹⁾, the Community acceded to the Agreement of the United Nations Economic Commission for Europe ('UNECE') concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement').
- (2) In accordance with Council Decision 2000/125/EC ⁽²⁾, the Union acceded to the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ('Parallel Agreement').
- (3) Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) ⁽³⁾ replaced the Member States' approval systems with a Union approval procedure, establishing

a harmonised framework containing the administrative provisions and general technical requirements for all new vehicles, systems, components and separate technical units. That Directive incorporated UNECE Regulations in the EU vehicle type-approval system, either as requirements for type-approval or as alternatives to Union legislation. Since the adoption of Directive 2007/46/EC, UNECE Regulations have increasingly replaced Union legislation in the framework of EU vehicle type-approval.

- (4) In the light of experience and technical developments, the requirements relating to certain elements or features covered by UNECE Regulations Nos 11, 13H, 30, 44, 49, 54, 64, 101, 106 and 121 and Global Technical Regulation No 1 of the UNECE need to be adapted.
- (5) It is appropriate to establish the position to be adopted on the Union's behalf in the Administrative Committee of the Revised 1958 Agreement and in the Executive Committee of the 1998 Agreement concerning the amendments to be made to the aforementioned UNECE acts.
- (6) The measures laid down in this Decision are in accordance with the view of the Technical Committee — Motor Vehicles,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken by the European Union within the Administrative Committee of the Revised 1958 Agreement and the Executive Committee of the 1998 Agreement on 25 to 29 June 2012 shall be to vote in favour of the proposed amendments listed in the Annex.

⁽¹⁾ OJ L 346, 17.12.1997, p. 78.

⁽²⁾ OJ L 35, 10.2.2000, p. 12.

⁽³⁾ OJ L 263, 9.10.2007, p. 1.

Article 2

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

Done at Luxembourg, 18 June 2012.

For the Council
The President
M. GJERSKOV

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REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 582/2012

of 2 July 2012

approving the active substance bifenthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 13(2) and Article 78(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(c) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply to active substances for which completeness has been established in accordance with Article 16 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ⁽³⁾, with respect to the procedure and the conditions for approval. Bifenthrin is an active substance for which completeness has been established in accordance with that Regulation.
- (2) Commission Regulations (EC) No 451/2000 ⁽⁴⁾ and (EC) No 1490/2002 ⁽⁵⁾ lay down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included bifenthrin. By Commission Decision 2009/887/EC ⁽⁶⁾ it was decided not to include bifenthrin in Annex I to Directive 91/414/EEC.
- (3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a

new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Regulation (EC) No 33/2008.

- (4) The application was submitted to France, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2009/887/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.
- (5) France evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 6 August 2010. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on bifenthrin to the Commission on 11 May 2011 ⁽⁷⁾. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 1 June 2012 in the format of the Commission review report for bifenthrin.
- (6) The additional report by the rapporteur Member State and the new conclusion by the Authority concentrate on the concerns that led to the non-inclusion. Those concerns were in particular the potential contamination of groundwater by a major soil degradation product (TFP acid), a possible underestimation of the risk to consumers, due to the limited number of residue data made available and the lack of investigation on the metabolism pattern of the two isomers constituting bifenthrin. As regards ecotoxicology, the risk for

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 230, 19.8.1991, p. 1.

⁽³⁾ OJ L 15, 18.1.2008, p. 5.

⁽⁴⁾ OJ L 55, 29.2.2000, p. 25.

⁽⁵⁾ OJ L 224, 21.8.2002, p. 23.

⁽⁶⁾ OJ L 318, 4.12.2009, p. 41.

⁽⁷⁾ European Food Safety Authority; 'Conclusion on the peer review of the pesticide risk assessment of the active substance bifenthrin'. *EFSA Journal* 2011;9(5):2159. 0;8(11): [101 pp.] doi:10.2903/j.efsa.2011.2159. Available online: www.efsa.europa.eu/efsajournal.htm

mammals, aquatic organisms, earthworms, non-target arthropods, non-target plants and non-target soil macro-organisms had not been sufficiently addressed.

- (7) The new information submitted by the applicant shows that the potential contamination of groundwater by bifenthrin and its metabolites, including TFP acid, is low. Adequate residue data and information as regards the metabolism of the isomers have been submitted and confirm an acceptable risk for consumers. As regards ecotoxicology, the refined risk assessment for mammals, aquatic organisms, earthworms, non-target arthropods, non-target macro-organisms and non-target plants permitted to identify acceptable risk scenarios for the concerned species.
- (8) Consequently, the additional information provided by the applicant permits to eliminate the specific concerns that led to the non-inclusion. No other open scientific questions have arisen.
- (9) It has appeared from the various examinations made that plant protection products containing bifenthrin may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular as regards the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve bifenthrin in accordance with Regulation (EC) No 1107/2009.
- (10) The acceptable risk scenarios as regards ecotoxicology notwithstanding, the risk assessment revealed that bifenthrin has a potential to show bioaccumulation effects. The approval period should therefore be seven years rather than the possible maximum of 10 years.
- (11) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions.

- (12) Without prejudice to the conclusion that bifenthrin should be approved, it is, in particular, appropriate to require further confirmatory information.

- (13) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances ⁽¹⁾ should be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance bifenthrin, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth 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, 2 July 2012.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 153, 11.6.2011, p. 1.

ANNEX I

Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Bifenthrin CAS No 82657-04-3 CIPAC No 415	2-methylbiphenyl-3-ylmethyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate or 2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	≥ 930 g/kg Impurities: Toluene: not more than 5 g/kg	1 August 2012	31 July 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the persistency in the environment; (b) the risk for bioaccumulation and biomagnification; (c) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (d) the risk to aquatic organisms, in particular fish and invertebrates, non-target arthropods and bees, ensuring that conditions of authorisation include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the residual toxicity for non-target arthropods and the potential for recolonisation; (2) the fate and behaviour of soil metabolite 4'-OH bifenthrin; (3) the degradation in soil of the isomers which constitute bifenthrin, 4'-OH bifenthrin and TFP acid. The applicant shall submit to the Commission, the Member States and the Authority the information set out in points 1, 2 and 3 by 31 July 2014. The applicant shall present to the Commission, the Member States and the Authority a monitoring programme to assess the potential for bioaccumulation and biomagnification in the aquatic and terrestrial environment by 31 July 2013. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State, the Commission and the Authority by 31 July 2015.

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

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) 540/2011, the following entry is added:

No	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
23	Bifenthrin CAS No 82657-04-3 CIPAC No 415	2-methylbiphenyl-3-ylmethyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate or 2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	≥ 930 g/kg Impurities: Toluene: not more than 5 g/kg	1 August 2012	31 July 2019	PART A Only uses as insecticide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bifenthrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the persistency in the environment; (b) the risk for bioaccumulation and biomagnification; (c) the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, where appropriate; (d) the risk to aquatic organisms, in particular fish and invertebrates, non-target arthropods and bees, ensuring that conditions of authorisation include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: (1) the residual toxicity for non-target arthropods and the potential for recolonisation; (2) the fate and behaviour of soil metabolite 4'-OH bifenthrin; (3) the degradation in soil of the isomers which constitute bifenthrin, 4'-OH bifenthrin and TFP acid.

No	Common name, identification numbers	IUPAC name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit to the Commission, the Member States and the Authority the information set out in points 1, 2 and 3 by 31 July 2014. The applicant shall present to the Commission, the Member States and the Authority a monitoring programme to assess the potential for bioaccumulation and biomagnification in the aquatic and terrestrial environment by 31 July 2013. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State, the Commission and the Authority by 31 July 2015.'

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

COMMISSION REGULATION (EU) No 583/2012**of 2 July 2012****amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polysorbates (E 432-436) in coconut milk****(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) and Article 30(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) That list may be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾.
- (3) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.
- (4) An application for authorisation of the use of polyoxyethylene sorbitan monooleate (polysorbate 80, E 433) as an emulsifier in coconut milk was submitted and has been made available to the Member States.
- (5) Coconut milk, which is a fruit preparation made of the internal layer below the peel of coconut together with water via homogenisation, cannot remain in the form of an emulsion without the use of an emulsifier. Polyoxyethylene sorbitan monooleate (polysorbate 80, E 433) and polysorbates (E 432-436) in general have been approved as the most effective emulsifiers used for this purpose in third countries.
- (6) To the group of polysorbates (E 432-436) an acceptable daily intake (ADI) value was allocated at a level of 10 mg/kg bw/day by the Scientific Committee on Food

in its opinion of 8 July 1983 ⁽³⁾. The Report from the Commission on Dietary Food Additive Intake in the European Union ⁽⁴⁾ concluded that polysorbates (E 432-436) may require a more realistic intake assessment based on actual use levels of the food additives. The European Food Safety Authority ('the Authority') is expected to carry out that intake assessment during the re-evaluation of polysorbates (E 432-436) by the end of 2016 as foreseen by Commission Regulation (EU) No 257/2010 ⁽⁵⁾. Until then, only insignificant contributors to the total intake of those substances should be examined for a potential extension of use. The expected intake of polysorbates (E 432-436) via its use in coconut milk as assessed on the basis of total market distribution data of coconut milk provided by the applicant remains far below the ADI and thus will not lead to a significant additional exposure. Coconut milk is a non-widely consumed product, which is mainly used for the preparation of Asian food and desserts. The assessed intake is negligible and much less than 1 % of ADI, which is not considered to be a significant contributor. Therefore, that particular extension of use is not considered to be of safety concern.

- (7) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the Authority in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health. Since the authorisation of use of polysorbates (E 432-436) as emulsifiers in coconut milk constitutes an update of that list which is not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.
- (8) In Annex II to Regulation (EC) No 1333/2008 polysorbates (E 432-436) are authorised as a group, as they belong to the same chemical group of substances defined as mixtures of the partial esters of sorbitol and its mono- and dianhydrides with fatty acids. It is therefore appropriate to allow the use of all polysorbates (E 432-436) in coconut milk and not only the use of the food additive polyoxyethylene sorbitan monooleate (polysorbate 80, E 433).
- (9) Pursuant to the transitional provisions of Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Report of the Scientific Committee for Food concerning emulsifiers, stabilisers, thickeners and gelling agents (15th series, 1985).

⁽⁴⁾ COM(2001) 542 final.

⁽⁵⁾ OJ L 80, 26.3.2010, p. 19.

of the European Parliament and of the Council by establishing a Union list of food additives ⁽¹⁾, Annex II establishing the Union list of food additives approved for use in foods and conditions of use applies from 1 June 2013. In order to allow the use of polysorbates (E 432-436) in coconut milk before that date, it is necessary to specify an earlier date of application with regard to that food additive.

- (10) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing

Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth 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, 2 July 2012.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 295, 12.11.2011, p. 1.

ANNEX

In Part E of Annex II to Regulation (EC) No 1333/2008 the following entry is inserted in the food category 04.2.4.1 'Fruit and vegetable preparations excluding compote' after the entry for E 405:

	'E 432-436	Polysorbates	500	(1)	only coconut milk	Period of application: From 23 July 2012'
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COMMISSION IMPLEMENTING REGULATION (EU) No 584/2012**of 2 July 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, 2 July 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	TR	54,8
	ZZ	54,8
0707 00 05	TR	103,2
	ZZ	103,2
0709 93 10	TR	111,2
	ZZ	111,2
0805 50 10	AR	85,3
	TR	54,0
	UY	86,2
	ZA	95,4
	ZZ	80,2
0808 10 80	AR	109,0
	BR	94,5
	CL	109,5
	NZ	136,6
	US	167,0
	UY	58,9
	ZA	107,4
	ZZ	111,8
0809 10 00	TR	191,9
	ZZ	191,9
0809 29 00	TR	382,5
	ZZ	382,5

⁽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

COMMISSION IMPLEMENTING DECISION

of 27 June 2012

concerning a financial contribution by the Union to Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom for studies on Schmallerberg virus

*(notified under document C(2012) 4203)***(Only the Dutch, English, French, German, Italian and Spanish texts are authentic)**

(2012/349/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field ⁽¹⁾, and in particular Article 23 thereof,

Whereas:

(1) In accordance with Article 75 of the Financial Regulation and Article 90(1) of the Implementing Rules, the commitment of expenditure from the budget of the European Union shall be preceded by a financing decision setting out the essential elements of the action involving expenditure and adopted by the institution or the authorities to which powers have been delegated by the institution.

(2) Schmallerberg virus is an emerging contagious pathogen of ruminants putatively included in the Simbu serogroup of the *Bunyaviridae* family, genus *Orthobunyavirus*. Very little information is known on this emerging pathogen, most assumptions are extrapolated from scientific information available on other viruses of the Simbu serogroup.

(3) Only some *Orthobunyavirus* had been isolated in the Union (Tahyna virus from the California serogroup) but never from the Simbu serogroup. Schmallerberg virus was first detected in November 2011 in Germany in samples collected in the summer and autumn 2011 from diseased animals. In December 2011, congenital malformations were reported in newborn lambs in the Netherlands, linked to the presence of the virus. Subsequently up to March 2012, Belgium, Germany,

United Kingdom, France, Luxembourg, Italy and Spain have reported stillbirth and congenital malformations. Schmallerberg virus presence was confirmed through the Polymerase Chain Reaction (PCR) tests.

(4) As this is the first time that this virus is isolated in the Union, there are no harmonised rules as regards control or notification of Schmallerberg virus.

(5) No efficient diagnostic tools are available to assess the actual spread of Schmallerberg virus and its impact on animal health.

(6) Several trading partners have taken temporary protective measures including trade restrictions and requested for additional guarantees for certain commodities awaiting for further scientific knowledge before resuming trade.

(7) On 23 January 2012, the Agriculture Council requested the Commission to take actions with respect to this emerging disease.

(8) In a meeting organised on 14 February 2012, the Commission in close collaboration with the Member States identified the priorities and areas for which additional information should be gathered prior to considering the development of veterinary legislation addressing this new infection. These are in particular, the mechanism by which the disease is caused (pathogenesis), the epidemiology, notably focusing on transmission pathways, the host range, the role of vectors and reservoirs; and the confirmation of the non-zoonotic potential of this virus and the methods to diagnose the disease in animal samples and their validation.

(9) Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom have drawn up scientific studies intended to gain knowledge on Schmallerberg virus in the areas identified above and submitted them to the Commission on 5 March 2012, requesting EU financial support.

⁽¹⁾ OJ L 155, 18.6.2009, p. 30.

- (10) Some of the scientific studies have been presented by several Member States in the form of a consortium, in these cases and for the purpose of clarity, one of the partners has been identified as coordinator of the consortium and responsible for communication with the Commission and transmission of technical reports.
- (11) Pursuant to Article 22 of Decision 2009/470/EC, the Union may undertake, or assist the Member States or international organisations in undertaking, the technical and scientific measures necessary for the development of EU veterinary legislation and for the development of veterinary education or training.
- (12) A financial contribution should be granted to the studies on Schmallenberg virus implemented by Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom as the outcomes may lead to new insights on the subject mentioned above.
- (13) The Commission has evaluated all the proposals and selected those that matched with the agreed priorities. Considering the resources needed to develop the studies and the need to start as soon as possible the activities in order to get the results, it is appropriate to start financing them as from 1 April 2012.
- (14) Under Council Regulation (EC) No 1290/2005 of 21 June 2005 on the financing of the common agricultural policy⁽¹⁾, veterinary measures are to be financed under the European Agricultural Guarantee Fund. For financial control purposes, Articles 9, 36 and 37 of that Regulation are to apply.
- (15) The payment of the financial contribution shall be subject to the condition that the studies planned have actually been carried out and that the authorities supply all the necessary information to the Commission.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,
- for the studies listed in Annex I and in accordance with the budgets listed in Annex II, for the period 1 April 2012 to 31 December 2013;
- (b) shall not exceed the following:
- (i) EUR 438 615 for Belgium;
 - (ii) EUR 595 883 for Germany;
 - (iii) EUR 146 590 for Spain;
 - (iv) EUR 589 380 for France;
 - (v) EUR 124 120 for Italy;
 - (vi) EUR 639 342 for the Netherlands;
 - (vii) EUR 371 811 for the United Kingdom;
- (c) Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom, or in cases when the scientific studies are carried out by more than one Member State in a consortium, the coordinator Member State as listed in Annex I, shall submit to the Commission:
- no later than 31 March 2013 an intermediate technical report per project,
 - no later than 31 March 2014 a final technical report per project;
- (d) Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom shall submit to the Commission:
- no later than 31 March 2014 a paper version and an electronic version of their financial report drawn up in accordance with Annex IV. The supporting documents, evidencing all the expenditure referred to in the application for reimbursement, shall be sent to the Commission on request;
- (e) the outcome of the studies must be made available to the Commission, all Member States and EFSA and presented at the Standing Committee on the Food Chain and Animal Health.

HAS ADOPTED THIS DECISION:

Article 1

1. The Union shall grant Belgium, Germany, Spain, France, Italy, the Netherlands and the United Kingdom financial assistance for their scientific studies on Schmallenberg virus, as summarised in Annex I. The present decision constitutes a financing decision in the meaning of Article 75 of the Financial Regulation.

2. The financial contribution by the Union

- (a) shall be at the rate of 50 % of the eligible costs to be incurred by each Member State referred to in paragraph 1

Article 2

1. The maximum overall contribution authorised by this Decision for the costs incurred for the work referred to in Article 1(1) is set at EUR 2 905 741 to be financed from the following budgetary line of the general budget of the European Union for 2012:

— budgetary line No 17 04 02 01.

2. Expenditure relating to staff dedicated to the projects, consumables, animal studies, travel costs linked to meetings and overheads shall be eligible within the limits set out in Article 1 and in accordance with the eligibility rules set out in Annex III.

3. The Union's financial assistance shall be paid following presentation and approval of the reports and supporting documents referred to Article 1(2)(c) and (d).

⁽¹⁾ OJ L 209, 11.8.2005, p. 1.

Article 3

This Decision is addressed to the Kingdom of Belgium, the Federal Republic of Germany, the Kingdom of Spain, the French Republic, the Italian Republic, the Kingdom of the Netherlands and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 27 June 2012.

For the Commission

John DALLI

Member of the Commission

ANNEX I

Description of the technical and scientific studies on Schmallenberg virus (SBV), referred to in Article 1(1)**Area 1 — Pathogenesis***Project 1.1*

To determine the pathogenicity and dynamics of the virus in foetuses at different gestation stages by experimental infection in pregnant ewes, goats and cattle.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinator: Germany

Project 1.2

To identify the primary (and possibly secondary) replication sites and virus virulence in non-pregnant animals by experimental infection studies in young animals of cattle, sheep and goats.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinators: Sheep — the Netherlands, Goats — France

Project 1.3

To study the development of immunity to SBV by experimental infection studies in sero-positive as well as sero-negative animals of the different species.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinator: United Kingdom

Outcome for projects 1.1, 1.2 and 1.3:

Data on pathogenesis, viremia duration, incubation time, virus distribution, virus shedding and possible persistence of Schmallenberg virus to be used for tests on live animals, generation of vaccines as well as collection of reference materials for tests' validation.

Project 1.4

To test available serological samples (cattle and sheep) for SBV. A case-control study will be undertaken to investigate the clinical impact of the disease and the risk factors for introduction, transmission and clinical symptoms at the herd level.

Outcome:

Description of the current spread of SBV disease in the bovine and ovine population, the clinical consequences of SBV infection and the risk factors for introduction, transmission and morbidity in holdings and animals.

— Member States involved: Belgium

Project 1.5

Collection of SBV case data, baseline data on abortion, stillbirth and malformations and results of epidemiological studies (case/control study in cattle, sheep and goats; source identification study, seroprevalence study, sentinel study) to be provided to for meta-analyses of study results.

Outcome:

Joint epidemiological analysis with EFSA of data on SBV in Germany and other affected EU Member States including assessment of the impact of SBV on population dynamics, breeding management, and economy. Determination of the within-herd prevalence and between-herd prevalence as well as the spatial distribution of SBV infections in different susceptible species. Analysis of the route of entry, transmission pathways, the source of the epidemic and its temporal development in Germany. Analysis of potential coincidence with animal density, herd/flock density, climate, and weather conditions, geography and ecological parameters.

— Member State involved: Germany

Project 1.6

To identify clinical symptoms following SBV infection as well as potential risk factors for introduction and spread of SBV in dairy cattle herds and sheep.

Outcome:

1. Analysis of the impact of the SBV infection on health and productivity of dairy cattle and their offspring, the possibility of vertical transmission. Determination of how long infected calves stay viraemic. Guidance for potential control measures (e.g. grazing management).
2. Description and quantification of clinical signs in adult infected sheep after a primary infection with SBV. Determination of mortality rates in newborn lambs, relation between seroprevalence and clinical manifestations in herds. Identification of potential risk factors for introduction and spread of SBV in sheep flocks. The study will obtain baseline information on impact of SBV on sheep health and production, and risk factors associated with introduction, spread and impact of SBV.

— Member State involved: the Netherlands

Area 2 — Epidemiology

Project 2.1

To clarify or exclude horizontal transmission by trying to provoke infection with most virulent virus (preferably not cell cultured).

Outcome:

Determine if there are transmission routes without vector.

— Member States involved: Belgium, Germany, the Netherlands and the United Kingdom.

Coordinator: United Kingdom

Project 2.2a

To investigate which species are potential vectors for SBV by prospective and retrospective investigations.

Outcome:

To confirm status of a series of suspected SBV vectors from affected countries and their ability to effectively transmit the virus.

— Member States involved: Belgium, Germany, the Netherlands.

Coordinator: the Netherlands

Project 2.2b

To perform an experimental assessment of the rates of infection, dissemination and probable transmission in each vector group.

Outcome:

Epidemiological role played by the most common midge and mosquito species in transmitting SBV and assessment of the rates of infection, dissemination and probable transmission in each vector group.

— Member States involved: Spain, France, Italy and the United Kingdom.

Coordinator: Spain

Project 2.3

To investigate if bulls may excrete SBV in semen and to investigate risk of transmission via embryos by using frozen semen and *in vitro* fertilisation procedures with non-infected ovaries.

Outcome:

Reliable information on the risk of transmission of SBV via semen and embryos.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinator: the Netherlands

Project 2.4

Determination of the role of other species (pigs, rabbits, mice or birds (chicken)) in the epidemiology of SBV.

Outcome:

Identification of other species susceptible to SBV.

— Member States involved: Belgium, Germany, the Netherlands and the United Kingdom.

Coordinator: Belgium

Project 2.5

Determination of the role of wildlife (deer, wild boar, etc.) in the epidemiology of SBV.

Outcome:

Clarify if the virus infects wildlife and if wildlife could play a role in the epidemiology of the virus.

— Member States involved: Germany, the Netherlands and the United Kingdom.

Coordinator: United Kingdom

Area 3 — Diagnostics*Project 3.1*

To develop SBV specific monoclonal antibodies for the development and evaluation of a competitive or blocking enzyme-linked immunosorbent assay (ELISA) to detect SBV specific antibodies in sera.

Outcome:

Development of diagnostic assays to detect SBV specific antibodies.

— Member States involved: France and the United Kingdom.

Coordinator: United Kingdom

Project 3.2

To harmonise the validation of the different RT-PCR methods for the detection of SBV

Outcome:

Common protocol and minimum criteria for the validation of molecular and serological diagnostic tools with the involvement of the private sector.

— Member States involved: Belgium, Germany, France, the Netherlands and the United Kingdom.

Coordinator: Germany

ANNEX II

Budget per project (in EUR)**Area 1 — Pathogenesis***Projects 1.1, 1.2 and 1.3*

Item	Heading	Belgium	Germany	France	Netherlands	United Kingdom	Total
1	Staff	70 000	235 200	119 012	111 010	105 356	640 578
2	Consumables	40 000	78 800	104 300	19 000	50 007	292 107
3	Animal studies	140 000	98 000	112 000	127 147	86 708	563 855
4	Travel costs linked to meetings	0	3 000	8 200	0	7 076	18 276
5	Overheads (7 %)	17 500	29 050	24 046	18 001	17 440	106 037
	Total	267 500	444 050	367 558	275 158	266 587	1 620 853

Project 1.4

Item	Heading	Belgium
1	Staff	125 347
2	Consumables	90 000
3	Animal studies	0
4	Travel cost linked to meetings	0
5	Overheads (7 %)	15 074
	Total	230 421

Project 1.5

Item	Heading	Germany
1	Staff	121 950
2	Consumables	100 850
3	Animal studies	
4	Travel costs linked to meetings	6 000
5	Overheads (7 %)	16 016
	Total	244 816

Project 1.6

Item	Heading	Netherlands
1	Staff	279 005
2	Consumables	77 500
3	Animal studies	180 212
4	Travel costs linked to meetings	28 500
5	Overheads (7 %)	39 565
	Total	604 782

Area 2 — Epidemiology*Project 2.1, 2.2a, 2.3, 2.4 and 2.5*

Item	Heading	Belgium (excl. 2.5)	Germany	France (excl. 2.2a, 2.4 and 2.5)	Netherlands	United Kingdom (excl. 2.2a)	Total
1	Staff	139 937	255 150	30 000	250 865	127 807	803 759
2	Consumables	173 200	160 850	120 000	33 108	41 653	528 811
3	Animal studies	14 576	18 000	0	49 520	6 746	88 843
4	Travel costs linked to meetings	0	6 000	0	8 900	9 435	24 335
5	Overheads (7 %)	22 940	30 800	10 500	23 968	12 955	101 202
	Total	350 653	470 800	160 500	366 361	198 636	1 546 950

Project 2.2b

Item	Heading	Spain	France	Italy	United Kingdom	Total
1	Staff	175 000	373 220	170 000	72 305	790 525
2	Consumables	93 000	115 000	56 000	36 000	300 000
3	Animal studies	0	0	0	0	0
4	Travel costs linked to meetings	6 000	16 500	6 000	4 800	33 300
5	Overheads (7 %)	19 180	35 330	16 240	7 917	78 667
	Total	293 180	540 050	248 240	121 022	1 202 492

Area 3 — Diagnostics*Project 3.1 and 3.2*

Item	Heading	Belgium (excl. 3.1)	Germany (excl. 3.1)	France	Netherlands (excl. 3.1)	United Kingdom	Total
1	Staff	17 281	12 800	68 413	8 575	114 398	221 467
2	Consumables	9 000	16 200	30 000	6 150	28 224	89 574
3	Animal studies				3 040		3 040
4	Travel costs linked to meetings	500	1 000	5 000		4 459	10 959
5	Overheads (7 %)	1 875	2 100	7 239	1 244	10 296	22 754
	Total	28 656	32 100	110 652	19 009	157 377	347 794

Coordination

Item	Heading	Netherlands
1	Staff	10 000
2	Travel costs linked to meetings	2 500
5	Overheads (7 %)	875
	Total	13 375

ANNEX III

Eligibility rules**1. Staff**

Staff costs shall be limited to actual attributable labour costs (remuneration, wages, social charges and retirement costs) accrued in implementation of the study. To this end monthly time sheets have to be maintained.

Daily rate will be calculated on a 220 working days/year.

2. Consumables

Reimbursement is to be based on actual costs incurred for laboratory tests:

- the purchase of test kits, reagents and all consumables identifiable and especially used to carry out the laboratory test.

3. Animal studies

Reimbursement is to be based on actual costs incurred for the

- purchase of animals at market value,
- transport to facilities and housing and feeding,
- rendering of animals used in the experiments.

All other expenditure on administration and secretarial services is considered to be covered by 'overheads'.

4. Meetings (travel costs)

Travel and hotel costs incurred by the staff for the participation to meetings related to the studies are eligible in accordance with the rules laid down in Annex IV to Commission Implementing Regulation (EU) No 926/2011 ⁽¹⁾.

5. Overheads

A flat rate contribution of 7 % of actual eligible costs, calculated on the basis of all direct costs listed in items 1 to 4, may be claimed.

6. The expenditure submitted by the Member States for a financial contribution by the Union shall be expressed in euro and shall exclude value added tax (VAT) and all other taxes.
7. Member States may adjust the estimated budgets listed in Annex II by transfer between headings of eligible costs, provided that this adjustment of expenditure does not affect the implementation of the study, and without exceeding the total eligible cost per project. The Member States shall submit a written request to the Commission for its prior approval to increase the budget for one of the headings by more than 20 %.

⁽¹⁾ OJ L 241, 17.9.2011, p. 2.

ANNEX IV

Financial report

Member State:

Project number and title:

Total expenditure for the project (real costs, VAT excl.)

Item	Staff category	No of days	Daily rate	Total
1	Staff			
2	Consumables			
3	Animal studies			
4	Travel costs linked to meetings			
5	Overheads (max. 7 % of total costs)			
TOTAL				

Certification by the beneficiary

We certify that:

- the expenditure listed above was incurred in connection with the tasks defined,
- the expenditure was actually incurred, accurately accounted for and eligible under the provisions of Commission Implementing Decision 2012/349/EU ⁽¹⁾,
- all supporting documents relating to the expenditure are available for inspection,
- no other Union contribution was requested for the projects listed in this Decision.

Date:

Name and signature of the financial officer responsible:

⁽¹⁾ OJ L 173, 3.7.2012, p. 12.

COMMISSION IMPLEMENTING DECISION

of 2 July 2012

establishing the financial contribution by the Union to the expenditure incurred in the context of the emergency measures taken to combat avian influenza in Poland in 2007

(Only the Polish text is authentic)

(2012/350/EU)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) In accordance with Article 75 of the Financial Regulation and Article 90(1) of the Implementing Rules, the commitment of expenditure from the Union budget shall be preceded by a financing decision setting out the essential elements of the action involving expenditure and adopted by the institution or the authorities to which powers have been delegated by the institution.
- (2) Decision 2009/470/EC lays down the procedures governing the financial contribution from the Union towards specific veterinary measures, including emergency measures. With a view to helping to eradicate avian influenza as rapidly as possible the Union should contribute financially to eligible expenditure borne by the Member States. Article 4(3) first and second indents of that Decision lays down rules on the percentage that must be applied to the costs incurred by the Member States.
- (3) Article 3 of Commission Regulation (EC) No 349/2005 of 28 February 2005 laying down rules on the Community financing of emergency measures and of the campaign to combat certain animal diseases under Council Decision 90/424/EEC ⁽²⁾ sets rules on the expenditure eligible for Union financial support.
- (4) Commission Decision 2008/557/EC of 27 June 2008 on a financial contribution from the Community towards emergency measures to combat avian influenza in Poland in 2007 ⁽³⁾ granted a financial contribution by the Union towards emergency measures to combat avian influenza in Poland in 2007. An official request for reimbursement was submitted by Poland on 13 March 2008, as set out in Article 7(1) and 7(2) of Regulation (EC) No 349/2005.
- (5) The payment of the financial contribution from the Union is to be subject to the condition that the

planned activities were actually implemented and that the authorities provided all the necessary information within the set deadlines. Decision 2008/557/EC provided that a first tranche of EUR 845 000,00 be paid as part of the Union's financial contribution. Commission Implementing Decision 2011/799/EU ⁽⁴⁾ provided that a second tranche of EUR 750 000,00 be paid as part of the Union's financial contribution.

- (6) Poland has in accordance with Article 3(4) of Decision 2009/470/EC without delay informed the Commission and the other Member States of the measures applied in accordance with Union legislation on notification and eradication and the results thereof. The request for reimbursement was, as required in Article 7 of Regulation (EC) No 349/2005, accompanied by a financial report, supporting documents, an epidemiological report on each holding where the animals have been slaughtered or destroyed and the results of respective audits.
- (7) An audit according to Article 10 of Regulation (EC) No 349/2005 was carried out by the Commission's services. The Commission's observations, method of calculating the eligible expenditure and final conclusions were communicated to Poland on 23 December 2011. Poland agreed by letter dated 3 April 2012.
- (8) Consequently the total amount of the financial support from the Union to the eligible expenditure incurred in connection with the eradication of avian influenza in Poland in 2007 can now be fixed.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The financial contribution from the Union towards the expenditure associated with eradicating avian influenza in Poland in 2007 is fixed at EUR 1 648 571,50.

Article 2

The balance of the financial contribution is fixed at EUR 53 571,50.

⁽¹⁾ OJ L 155, 18.6.2009, p. 30.

⁽²⁾ OJ L 55, 1.3.2005, p. 12.

⁽³⁾ OJ L 180, 9.7.2008, p. 15.

⁽⁴⁾ OJ L 320, 3.12.2011, p. 47.

Article 3

This Decision constituting a financing decision in the meaning of Article 75 of the Financial Regulation is addressed to the Republic of Poland.

Done at Brussels, 2 July 2012.

For the Commission
John DALLI
Member of the Commission

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 42/2012 OF THE JOINT COMMITTEE ESTABLISHED UNDER THE AGREEMENT ON MUTUAL RECOGNITION BETWEEN THE EUROPEAN COMMUNITY AND THE UNITED STATES OF AMERICA

of 20 June 2012

**related to the listing of a Conformity Assessment Body under the Sectoral Annex on
Electromagnetic Compatibility**

(2012/351/EU)

THE JOINT COMMITTEE,

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America and in particular Articles 7 and 14;

Whereas the Joint Committee is to take a decision to list a Conformity Assessment Body or Bodies under a Sectoral Annex;

HAS DECIDED AS FOLLOWS:

1. The Conformity Assessment Body in Attachment A is added to the list of Conformity Assessment Bodies under column 'EC access to the US market' in Section V of the Sectoral Annex on Electromagnetic Compatibility.
2. The specific scope of listing, in terms of products and conformity assessment procedures, of the Conformity Assessment Body indicated in Attachment A has been agreed by the Parties and will be maintained by them.

This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who are authorised to act on behalf of the Parties for purposes of amending the Agreement. This Decision shall be effective from the date of the later of these signatures.

On behalf of the United States of America

James SANFORD

Signed in Washington DC,
on 12 June 2012

On behalf of the European Union

Fernando PERREAU DE PINNINCK

Signed in Brussels,
on 20 June 2012

Attachment A

EC Conformity Assessment Body added to the list of Conformity Assessment Bodies under column 'EC access to the US market' in Section V of the Sectoral Annex on Electromagnetic Compatibility

DELTA Dansk Elektronik, Lys & Akustik Venlighedsvej 4 2970 Hørsholm Denmark
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CORRIGENDA**Corrigendum to Council Implementing Regulation 2012/544/CFSP of 25 June 2012 implementing Article 32(1) of Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria**

(Official Journal of the European Union L 165 of 26 June 2012)

In the table of contents and on page 20, the title:

for: 'Council Implementing Regulation 2012/544/CFSP of 25 June 2012 implementing Article 32(1) of Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria',

read: 'Council Implementing Regulation (EU) No 544/2012 of 25 June 2012 implementing Article 32(1) of Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria'.

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