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Price: EUR 3

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⁽¹⁾ Text with EEA relevance

EN

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 143/2014

of 14 February 2014

approving the active substance pyridalyl, 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 Articles 13(2) and 78(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For pyridalyl the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2007/669/EC ⁽³⁾.
- (2) In accordance with Article 6(2) of Directive 91/414/EEC Austria received on 9 October 2006 an application from Sumitomo Chemical Agro Europe S.A.S. for the inclusion of the active substance pyridalyl in Annex I to Directive 91/414/EEC. Decision 2007/669/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽³⁾ Commission Decision 2007/669/EC of 15 October 2007 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of *Adoxophyes orana granulovirus*, amisulbrom, emamectin, pyridalil and *Spodoptera littoralis nucleopolyhedrovirus* in Annex I to Council Directive 91/414/EEC (OJ L 274, 18.10.2007, p. 15).

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 8 January 2009.

(4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance pyridalyl ⁽⁴⁾ on 24 May 2013. The draft assessment 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 13 December 2013 in the format of the Commission review report for pyridalyl.

(5) It has appeared from the various examinations made that plant protection products containing pyridalyl may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the use which was examined and detailed in the Commission review report. It is therefore appropriate to approve pyridalyl.

(6) 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. It is, in particular, appropriate to require further confirmatory information.

⁽⁴⁾ EFSA Journal 2013;11(6):3240. Available online: www.efsa.europa.eu

- (7) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.
- (8) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing pyridalyl. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- (9) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 ⁽¹⁾ has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.
- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽²⁾ 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,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

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

⁽¹⁾ Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10).

⁽²⁾ 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 (OJ L 153, 11.6.2011, p. 1).

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing pyridalyl as an active substance by 31 December 2014.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in Part B of the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing pyridalyl as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 June 2014 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account Part B of the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing pyridalyl as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2015 at the latest; or
- (b) in the case of a product containing pyridalyl as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

Article 3

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 4***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*.

It shall apply from 1 July 2014.

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

Done at Brussels, 14 February 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Pyridalyl CAS No 179101-81-6 CIPAC No 792	2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether	≥ 910 g/kg	1 July 2014	30 June 2024	<p>PART A</p> <p>Only uses in greenhouses with permanent structure may be authorised.</p> <p>PART B</p> <p>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 pyridalyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to re-entry workers;</p> <p>(b) the risk to groundwater when the substance is applied in regions with vulnerable soils and/or climatic conditions;</p> <p>(c) the risk to birds, mammals and aquatic organisms.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the toxicological and ecotoxicological information to address the relevance of impurities 4, 13, 16, 22 and 23;</p> <p>(2) the relevance of the metabolite HTFP and, concerning that metabolite, the groundwater risk assessment for all uses on crops in greenhouse;</p> <p>(3) the risk to aquatic invertebrates.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information as regards point (1) by 31 December 2014 and information as regards point (2) and (3) by 30 June 2016.</p> <p>The applicant shall present to the Commission, the Member States and the Authority a monitoring programme to assess the potential groundwater contamination from the metabolite HTFP in vulnerable zones, by 30 June 2016. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State, the Commission and the Authority by 30 June 2018.</p>

⁽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) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'64	Pyridalyl CAS No 179101-81-6 CIPAC No 792	2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl 3-[5-(trifluoromethyl)-2-pyridyloxy]propyl ether	≥ 910 g/kg	1 July 2014	30 June 2024	<p>PART A</p> <p>Only uses in greenhouses with permanent structure may be authorised.</p> <p>PART B</p> <p>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 pyridalyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>(a) the risk to re-entry workers;</p> <p>(b) the risk to groundwater when the substance is applied in regions with vulnerable soils and/or climatic conditions;</p> <p>(c) the risk to birds, mammals and aquatic organisms.</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards:</p> <p>(1) the toxicological and ecotoxicological information to address the relevance of impurities 4, 13, 16, 22 and 23;</p> <p>(2) the relevance of the metabolite HTFP and, concerning that metabolite, the groundwater risk assessment for all uses on crops in greenhouse;</p> <p>(3) the risk to aquatic invertebrates.</p>

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
						<p>The applicant shall submit to the Commission, the Member States and the Authority the relevant information as regards point (1) by 31 December 2014 and information as regards point (2) and (3) by 30 June 2016.</p> <p>The applicant shall present to the Commission, the Member States and the Authority a monitoring programme to assess the potential groundwater contamination from the metabolite HTEP in vulnerable zones by 30 June 2016. The results of that monitoring programme shall be submitted as a monitoring report to the rapporteur Member State, the Commission and the Authority by 30 June 2018.'</p>

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

COMMISSION IMPLEMENTING REGULATION (EU) No 144/2014

of 14 February 2014

approving the active substance valifenalate, 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)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For valifenalate the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2006/586/EC ⁽³⁾.
- (2) In accordance with Article 6(2) of Directive 91/414/EEC Hungary received on 2 September 2005 an application from Isagro S.p.A. ⁽⁴⁾ for the inclusion of the active substance valifenalate in Annex I to Directive 91/414/EEC. Decision 2006/586/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the

applicant. The designated rapporteur Member State submitted a draft assessment report on 19 February 2008. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ⁽⁵⁾ additional information was requested from the applicant on 18 July 2011. The evaluation of the additional data by Hungary was submitted in the format of an updated draft assessment report in April 2012.

- (4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance valifenalate ⁽⁶⁾ on 31 May 2013. The draft assessment 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 13 December 2013 in the format of the Commission review report for valifenalate.
- (5) It has appeared from the various examinations made that plant protection products containing valifenalate may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve valifenalate.
- (6) 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. It is, in particular, appropriate to require further confirmatory information.
- (7) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽³⁾ Commission Decision 2006/586/EC of 25 August 2006 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of chromafenozide, halosulfuron, tembotrione, valiphenal and Zucchini yellow mosaic virus — weak strain in Annex I to Council Directive 91/414/EEC (OJ L 236, 31.8.2006, p. 31).

⁽⁴⁾ On 17 June 2013, Isagro S.p.A. informed the Commission that the ownership of the active substance was transferred to Belchim Crop Protection SA/NV.

⁽⁵⁾ Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).

⁽⁶⁾ EFSA Journal 2013; 11(6):3253. Available online: www.efsa.europa.eu

- (8) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing valifenalate. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- (9) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 ⁽¹⁾ has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.
- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽²⁾ 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,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

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

⁽¹⁾ Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10).

⁽²⁾ 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 (OJ L 153, 11.6.2011, p. 1).

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing valifenalate as an active substance by 31 December 2014.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing valifenalate as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 June 2014 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing valifenalate as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2015 at the latest; or
- (b) in the case of a product containing valifenalate as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

Article 3

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 4***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*.

It shall apply from 1 July 2014.

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

Done at Brussels, 14 February 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Valifenalate CAS No 283159-90-0 CIPAC No 857	Methyl N-(isopropoxycarbonyl)-L-valyl- (3RS)-3-(4-chlorophenyl)-β-alaninate	≥ 980 g/kg	1 July 2014	30 June 2024	<p>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 valifenalate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the potential of metabolite S5 to contaminate groundwater.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016.</p>

⁽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) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'70	Valifenalate CAS No 283159-90-0 CIPAC No 857	Methyl <i>N</i> -(isopropoxycarbonyl)- <i>L</i> -valyl-(3 <i>RS</i>)-3-(4-chlorophenyl)- β -alaninate	≥ 980 g/kg	1 July 2014	30 June 2024	<p>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 valifenalate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the potential of metabolite S5 to contaminate groundwater.</p> <p>The notifier shall submit to the Commission, the Member States and the Authority the relevant information by 30 June 2016.'</p>

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

COMMISSION IMPLEMENTING REGULATION (EU) No 145/2014

of 14 February 2014

approving the active substance thien carbazon, 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)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For thien carbazon the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2008/566/EC ⁽³⁾.
- (2) In accordance with Article 6(2) of Directive 91/414/EEC the United Kingdom received on 13 April 2007 an application from Bayer CropScience AG for the inclusion of the active substance thien carbazon in Annex I to Directive 91/414/EEC. Decision 2008/566/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State

submitted a draft assessment report on 17 December 2008. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ⁽⁴⁾ additional information was requested from the applicant on 7 July 2011. The evaluation of the additional data by the United Kingdom was submitted in the format of an updated draft assessment report in April 2012.

- (4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance thien carbazon ⁽⁵⁾ on 17 June 2013. The draft assessment 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 13 December 2013 in the format of the Commission review report for thien carbazon.
- (5) It has appeared from the various examinations made that plant protection products containing thien carbazon may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve thien carbazon.
- (6) 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. It is, in particular, appropriate to require further confirmatory information.
- (7) A reasonable period should be allowed to elapse before approval in order to permit Member States and the interested parties to prepare themselves to meet the new requirements resulting from the approval.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽³⁾ Commission Decision 2008/566/EC of 1 July 2008 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of phosphane and thien carbazon in Annex I to Council Directive 91/414/EEC (OJ L 181, 10.7.2008, p. 52).

⁽⁴⁾ Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).

⁽⁵⁾ EFSA Journal 2013; 11(7):3270. Available online: www.efsa.europa.eu

- (8) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing thien-carbazone. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- (9) The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 ⁽¹⁾ has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.
- (10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽²⁾ 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,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

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

⁽¹⁾ Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10).

⁽²⁾ 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 (OJ L 153, 11.6.2011, p. 1).

Article 2

Re-evaluation of plant protection products

1. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing thien-carbazone as an active substance by 31 December 2014.

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing thien-carbazone as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 30 June 2014 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing thien-carbazone as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2015 at the latest; or
- (b) in the case of a product containing thien-carbazone as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2015 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

Article 3

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 4***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*.

It shall apply from 1 July 2014.

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

Done at Brussels, 14 February 2014.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Thien carbazole CAS No 317815-83-1 CIPAC No 797	Methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate	≥ 950 g/kg	1 July 2014	30 June 2024	<p>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 thien carbazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to</p> <p>(a) the risk to groundwater if the substance is applied under vulnerable geographical or climatic conditions;</p> <p>(b) the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the potential of thien carbazole for long-range atmospheric transport and the related environmental impacts.</p> <p>That confirmatory information shall consist of the results of a monitoring programme to assess the potential of thien carbazole for long-range atmospheric transport and the related environmental impacts. The applicant shall submit to the Commission, the Member States and the Authority this monitoring programme by 30 June 2016 and the results in form of a monitoring report by 30 June 2018.</p>

⁽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) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
'71	Thiencarbazone CAS No 317815-83-1 CIPAC No 797	Methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate	≥ 950 g/kg	1 July 2014	30 June 2024	<p>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 thiencarbazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 December 2013 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to</p> <p>(a) the risk to groundwater if the substance is applied under vulnerable geographical or climatic conditions;</p> <p>(b) the risk to aquatic organisms.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit confirmatory information as regards the potential of thiencarbazone for long-range atmospheric transport and the related environmental impacts.</p> <p>That confirmatory information shall consist of the results of a monitoring programme to assess the potential of thiencarbazone for long-range atmospheric transport and the related environmental impacts. The applicant shall submit to the Commission, the Member States and the Authority this monitoring programme by 30 June 2016 and the results in form of a monitoring report by 30 June 2018.'</p>

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

COMMISSION IMPLEMENTING REGULATION (EU) No 146/2014**of 14 February 2014****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 multilateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex 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, 14 February 2014.

*For the Commission,
On behalf of the President,*

Jerzy PLEWA
*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	IL	107,2
	MA	59,8
	TN	63,9
	TR	111,3
	ZZ	85,6
0707 00 05	EG	182,1
	JO	206,0
	MA	168,6
	TR	153,3
	ZZ	177,5
0709 91 00	EG	97,7
	ZZ	97,7
0709 93 10	MA	38,2
	TR	145,8
	ZZ	92,0
0805 10 20	EG	44,0
	IL	67,6
	MA	55,0
	TN	52,5
	TR	73,3
	ZZ	58,5
0805 20 10	IL	122,3
	MA	81,6
	ZZ	102,0
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	121,1
	JM	112,4
	KR	142,4
	MA	127,8
	TR	76,1
	ZZ	116,0
0805 50 10	AL	39,1
	MA	71,7
	TR	60,9
	ZZ	57,2
0808 10 80	CN	95,7
	MK	30,8
	US	168,8
	ZZ	98,4
0808 30 90	AR	193,7
	CL	174,0
	CN	71,8
	TR	122,2
	US	128,6
	ZA	97,9
ZZ	131,4	

⁽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'.

COMMISSION IMPLEMENTING REGULATION (EU) No 147/2014
of 14 February 2014
fixing the import duties in the cereals sector applicable from 16 February 2014

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

(1) Article 136(1) of Regulation (EC) No 1234/2007 states that the import duty on products covered by CN codes 1001 19 00, 1001 11 00, ex 1001 91 20 (common wheat seed), ex 1001 99 00 (high quality common wheat other than for sowing), 1002 10 00, 1002 90 00, 1005 10 90, 1005 90 00, 1007 10 90 and 1007 90 00 is to be equal to the intervention price valid for such products on importation and increased by 55 %, minus the cif import price applicable to the consignment in question. However, that duty may not exceed the rate of duty in the Common Customs Tariff.

(2) Article 136(2) of Regulation (EC) No 1234/2007 lays down that, in order to calculate the import duty

referred to in paragraph 1 of that Article, representative cif import prices are to be established on a regular basis for the products in question.

(3) Under Article 2(2) of Regulation (EU) No 642/2010, the price to be used for the calculation of the import duty on products covered by CN codes 1001 19 00, 1001 11 00, ex 1001 91 20 (common wheat seed), ex 1001 99 00 (high quality common wheat other than for sowing), 1002 10 00, 1002 90 00, 1005 10 90, 1005 90 00, 1007 10 90 and 1007 90 00 is the daily cif representative import price determined as specified in Article 5 of that Regulation.

(4) Import duties should be fixed for the period from 16 February 2014 and should apply until new import duties are fixed and enter into force.

(5) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

From 16 February 2014, the import duties in the cereals sector referred to in Article 136(1) of Regulation (EC) No 1234/2007 shall be those fixed in Annex I to this Regulation on the basis of the information contained in Annex II.

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, 14 February 2014.

*For the Commission,
On behalf of the President,*

Jerzy PLEWA
*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 187, 21.7.2010, p. 5.

ANNEX I

Import duties on the products referred to in Article 136(1) of Regulation (EC) No 1234/2007 applicable from 16 February 2014

CN code	Description	Import duties ⁽¹⁾ (EUR/t)
1001 19 00	Durum wheat, high quality	0,00
1001 11 00	medium quality	0,00
	low quality	0,00
ex 1001 91 20	Common wheat seed	0,00
ex 1001 99 00	High quality common wheat other than for sowing	0,00
1002 10 00	Rye	0,00
1002 90 00		
1005 10 90	Maize seed other than hybrid	0,00
1005 90 00	Maize other than seed ⁽²⁾	0,00
1007 10 90	Grain sorghum other than hybrids for sowing	0,00
1007 90 00		

⁽¹⁾ The importer may benefit, under Article 2(4) of Regulation (EU) No 642/2010, from a reduction in the duty of:

- EUR 3/t, where the port of unloading is located on the Mediterranean Sea (beyond the Strait of Gibraltar) or on the Black Sea, for goods arriving in the Union via the Atlantic Ocean or the Suez Canal,
- EUR 2/t, where the port of unloading is located in Denmark, Estonia, Ireland, Latvia, Lithuania, Poland, Finland, Sweden, the United Kingdom or on the Atlantic coast of the Iberian Peninsula, for goods arriving in the Union via the Atlantic Ocean.

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

ANNEX II

Factors for calculating the duties laid down in Annex I

31.1.2014-14.2.2014

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

(EUR/t)

	Common wheat ⁽¹⁾	Maize	Durum wheat, high quality	Durum wheat, medium quality ⁽²⁾	Durum wheat, low quality ⁽³⁾
Exchange	Minnéapolis	Chicago	—	—	—
Quotation	186,59	127,85	—	—	—
Fob price USA	—	—	269,23	259,23	239,23
Gulf of Mexico premium	126,47	26,28	—	—	—
Great Lakes premium	—	—	—	—	—

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

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

Freight costs: Gulf of Mexico-Rotterdam: 17,35 EUR/t

Freight costs: Great Lakes-Rotterdam: — EUR/t

DECISIONS

COMMISSION DECISION

of 13 February 2014

concerning the placing on the market for essential use of biocidal products containing copper*(notified under document C(2014) 718)***(Only the Dutch, English, Polish and Spanish texts are authentic)**

(2014/85/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market ⁽¹⁾, and in particular Article 5(3) thereof,

Whereas:

(1) Pursuant to Article 4 of Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products ⁽²⁾, copper was notified for use, inter alia, in product-types 2, 5 and 11, as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽³⁾.

(2) No complete dossier was submitted in support of the inclusion of copper in Annex I, IA or IB to Directive 98/8/EC within any of the relevant deadlines. Pursuant to Commission Decision 2012/78/EU of 9 February 2012 concerning the non-inclusion of certain substances in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market ⁽⁴⁾ read in combination with Article 4(2) of Regulation (EC) No 1451/2007, copper shall no longer be placed on the market for use in product-types 2, 5 or 11 as of 1 February 2013.

(3) Pursuant to Article 5 of Regulation (EC) No 1451/2007, the United Kingdom, Spain, the Netherlands and Poland have submitted separate applications to the Commission for permission to allow the placing on the market of biocidal products containing copper for the uses indicated by 'Yes' in the Annex to this Decision.

(4) The Commission made the applications publicly available by electronic means. Comments were received and were made publicly available.

(5) It follows from the applications that transmission of Legionella has been associated, in particular, with use of water such as drinking water, bathing water, showering water and water in cooling towers. Furthermore, it follows that Legionella can be fatal, especially in vulnerable groups such as hospital patients. According to the applications, selection of a suitable system for Legionella control is complex and depends on a number of parameters such as system design, age, complexity and water chemistry.

(6) It also follows from some of the applications, that biocidal products containing copper are used to prevent growth of organisms in the main water inlet for offshore oil and gas platforms, where that use is essential to avoid blocking the inlet of water used for, inter alia, processing, drinking water and bathing water production, and fire-fighting, since blocking that inlet could be fatal for the health and safety of the staff at the installation.

(7) Some comments received during the public consultation have pointed to the existence of alternative methods for water system disinfection. However, the Member States having submitted the applications have argued that, in their territories, it is necessary to have an adequate range of technical and economic feasible alternatives available to control Legionella, and, where relevant, to reduce the risk of blocking the main water inlet for offshore installations. This has been confirmed in some of the public consultations by users of the products in question, such as hospitals.

⁽¹⁾ OJ L 325, 11.12.2007, p. 3.

⁽²⁾ OJ L 228, 8.9.2000, p. 6.

⁽³⁾ OJ L 123, 24.4.1998, p. 1.

⁽⁴⁾ OJ L 38, 11.2.2012, p. 48.

- (8) It therefore appears likely that not allowing use for Legionella control, or where relevant for preventing growth of organisms in the water inlet for offshore oil and gas platforms, in those Member States would currently pose a serious risk for public health. The requested derogations for essential use are therefore currently necessary.
- (9) However, unless a complete application for approval of copper for use in the relevant product-types is submitted without undue delay, users of biocidal products containing copper should implement alternative methods for Legionella control or organism growth prevention. It is therefore appropriate to require that, in such a case, users in those Member States are actively informed in due time to allow them to ensure that those alternative methods are effective before the biocidal products containing copper have to be withdrawn from the market,

HAS ADOPTED THIS DECISION:

Article 1

1. Subject to the conditions provided for by Article 5(3) of Regulation (EC) No 1451/2007, the United Kingdom, Spain, the Netherlands and Poland may allow the placing on the market of biocidal products containing copper (EC No 231-159-6; CAS No 7440-50-8) for the uses indicated in the Annex to this Decision.

2. If dossiers for the approval of copper for the product-types relevant to those uses have been submitted and validated as complete by the evaluating Member State by 31 December 2014 at the latest, the United Kingdom, Spain, the Netherlands and Poland may continue allowing that placing on the market until the deadlines provided for in Article 89 of Regulation (EU) No 528/2012 for cases where a substance is or is not approved.

3. In other cases than those provided for in paragraph 2, the United Kingdom, Spain, the Netherlands and Poland may continue allowing that placing on the market until 31 December 2017 provided that those Member States ensure, as of 1 January 2015, that users are actively informed about the immediate need to effectively implement alternative methods for the relevant purposes.

Article 2

This Decision is addressed to the Kingdom of Spain, the Kingdom of the Netherlands, the Republic of Poland and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 13 February 2014.

For the Commission

Janez POTOČNIK

Member of the Commission

ANNEX

Uses which the Member States listed hereunder may allow, subject to compliance with the conditions of Article 1

	United Kingdom	Spain	Netherlands	Poland
Product-type 2: for control of Legionella in water for human use, such as bathing and showering water	Yes	Yes		Yes
Product-type 5: for control of Legionella in drinking water	Yes	Yes	Yes	
Product-type 11: for control of Legionella in cooling tower water		Yes	Yes	Yes
Product-type 11: for the prevention of growth of organisms in the water inlet for offshore oil and gas platforms			Yes	

COMMISSION IMPLEMENTING DECISION

of 13 February 2014

amending Decision 93/195/EEC as regards animal health and veterinary certification conditions for the re-entry of registered horses for racing, competition and cultural events after temporary export to Mexico and amending Annex I to Decision 2004/211/EC as regards the entry for Mexico in the list of third countries and parts thereof from which imports into the Union of live equidae and semen, ova and embryos of the equine species are authorised

(notified under document C(2014) 692)

(Text with EEA relevance)

(2014/86/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC⁽¹⁾, and in particular Article 17(3)(a) thereof,

Having regard to Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae⁽²⁾, and in particular Article 12(1) and (4), and the introductory phrase and points (a) and (b) of Article 19 thereof,

Whereas:

- (1) Directive 2009/156/EC lays down animal health conditions for the importation into the Union of live equidae. In accordance with Article 13(1)(a) one of the conditions for the authorisation of imports of equidae into the Union is that the third country has been free from Venezuelan equine encephalomyelitis for a period of two years.
- (2) Commission Decision 93/195/EEC⁽³⁾ provides models of health certificates for the re-entry of registered horses after temporary export to participate in racing, competition or cultural events.
- (3) Commission Decision 2004/211/EC⁽⁴⁾ establishes a list of third countries, or parts thereof where regionalisation applies, from which Member States are to authorise the

importation of live equidae and semen, ova and embryos thereof. That list is set out in Annex I to that Decision.

- (4) Commission Implementing Decision 2013/167/EU⁽⁵⁾ amending the list in Annex I to Decision 2004/211/EC provides that temporary admission of registered horses, re-entry after temporary export of registered horses for racing, competition and cultural events, imports of registered equidae and equidae for breeding and production, and imports of semen, ova and embryos of the equine species from Mexico are currently not authorised.
- (5) The Commission has received a risk assessment carried out by the French competent authorities relating to the re-entry of horses scheduled for temporary export to Mexico-City (Mexico). That assessment contains comprehensive details of the biosecurity measures applied by the Théâtre équestre Zingaro for the protection of the health status of their horses during their residence in Mexico-City as well as the quarantine measures imposed by the French competent authorities on those horses upon their return.
- (6) Given the degree of veterinary supervision, the agreed routine health checks and the separation from equidae of lower health status, it is possible to lay down specific animal health and the veterinary certification conditions for the re-entry of these horses after their temporary export for a period of less than 90 days to participate in specific equestrian cultural events in Mexico-City.
- (7) Decision 93/195/EEC should therefore be amended accordingly.
- (8) Since the measures provided for in this Decision concern only a region of high altitude and during dry and tempered winter season with a reduced risk of vector born transmission of vesicular stomatitis or certain subtypes of Venezuelan equine encephalitis, the re-entry of registered horses for racing, competition and cultural events after temporary export for a period of less than

⁽¹⁾ OJ L 268, 14.9.1992, p. 54.

⁽²⁾ OJ L 192, 23.7.2010, p. 1.

⁽³⁾ Commission Decision 93/195/EEC of 2 February 1993 on animal health conditions and veterinary certification for the re-entry of registered horses for racing, competition and cultural events after temporary export (OJ L 86, 6.4.1993, p. 1).

⁽⁴⁾ Commission Decision 2004/211/EC of 6 January 2004 establishing the list of third countries and parts of territory thereof from which Member States authorise imports of live equidae and semen, ova and embryos of the equine species, and amending Decisions 93/195/EEC and 94/63/EC (OJ L 73, 11.3.2004, p. 1).

⁽⁵⁾ Commission Implementing Decision 2013/167/EU of 3 April 2013 amending Annex I to Decision 2004/211/EC as regards the entry for Mexico in the list of third countries and parts thereof from which imports into the Union of live equidae and semen, ova and embryos of the equine species are authorised (OJ L 95, 5.4.2013, p. 19).

90 days to the Metropolitan area of Mexico-City, a region in which Venezuelan equine encephalomyelitis has not been reported for more than 2 years, should be authorised.

- (9) The entry for that third country in Annex I to Decision 2004/211/EC should therefore be amended.
- (10) Decision 2004/211/EC should therefore be amended accordingly.
- (11) 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

Decision 93/195/EEC is amended as follows:

- (1) in Article 1, the following indent is added:

— have taken part in specific cultural events in the Metropolitan area of Mexico-City and meet the requirements

laid down in a health certificate drawn up in accordance with the model health certificate set out in Annex X to this Decision.;

- (2) a new Annex X is added as set out in Annex I to this Decision.

Article 2

Annex I to Decision 2004/211/EC is amended in accordance with Annex II to this Decision.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 13 February 2014.

For the Commission

Tonio BORG

Member of the Commission

ANNEX I

ANNEX X

HEALTH CERTIFICATE

for re-entry into the Union of registered horses after temporary export to Mexico for less than 90 days to participate in specific cultural events in the Metropolitan area of Mexico-City

Certificate No:

Specific event:

Presentations by the Théâtre équestre Zingaro in the Metropolitan area of Mexico-City, Mexico, in 2014

Third country of dispatch: Mexico

Responsible ministry: (insert name of Ministry)

I. Identification of the horse

(a) No of identification document:

(b) Validated by: (name of competent authority)

II. Origin of the horse

The horse is to be sent from: (place of consignment)

to: (place of destination)

by air: (flight number)

Name and address of consignor:

Name and address of consignee:

III. Health information

I, the undersigned, certify that the horse described above meets the following requirements:

- (a) it comes from a country where the following diseases are compulsorily notifiable: African horse sickness, dourine, glanders, equine encephalomyelitis (of all types including Venezuelan equine encephalomyelitis), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;
(b) it has been examined today and shows no clinical signs of disease (1);
(c) it is not intended for slaughter under a national programme of infectious or contagious disease eradication;
(d) since its entry into the country of dispatch, it has been resident on holdings under veterinary supervision situated in the country or, in the case of official regionalisation according to Union legislation, in the part of the territory of the country listed in Annex I to Commission Decision 2004/211/EC (2), and was accommodated in separated stables without coming into contact with equidae of lower health status;
(e) it comes from the territory or, in the case of official regionalisation according to Union legislation, from a part of the territory of a third country in which:
(i) Venezuelan equine encephalomyelitis has not occurred during the last two years;
(ii) dourine has not occurred during the last six months;
(iii) glanders has not occurred during the last six months;
(f) it does not come from the territory or from a part of the territory of a third country considered, in accordance with Union legislation, as infected with African horse sickness;
(g) it does not come from a holding which was subject to a prohibition order for animal health reasons nor had contact with equidae from a holding which was subject to prohibition order for animal health reasons which laid down the following conditions:

- (j) if not all animals of species susceptible to one or more of the diseases referred to hereinafter were removed from the holding, the prohibition lasted for:
- six months in the case of equine encephalomyelitis, beginning on the date on which the equidae suffering from the disease are slaughtered or removed from the premises,
 - a period required to carry out two Coggins tests three months apart giving negative results on samples taken from the animals remaining after infected animals have been slaughtered, in the case of equine infectious anaemia,
 - one month from the last recorded case, in the case of rabies,
 - 15 days from the last recorded case, in the case of anthrax;
- (ii) if all the animals of species susceptible to the disease have been slaughtered or removed from the holding, the period of prohibition shall be 30 days, or 15 days in the case of anthrax, beginning on the day on which the premises were cleaned and disinfected following the destruction or removal of the animals;
- (h) it comes from a holding which
- (i) either was not subject to a prohibition order for vesicular stomatitis and the animal had no contact with equidae from a holding which was subject to such prohibition order during the past six months⁽³⁾; or
- (ii) was free of vesicular stomatitis during the 30 days prior to dispatch and on which the animal was protected from vector insects during the 30 days prior to dispatch and where it underwent one of the following health tests carried out on a blood sample taken not earlier than 21 days after the commencement of the vector protection period:
- a virus neutralisation test giving a negative result at a serum dilution of 1 in 12⁽²⁾,
 - a serological test carried out and giving a negative result in accordance with point B(2) of Chapter 2.1.19 of the Manual for Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE)⁽³⁾;
- (i) to the best of my knowledge, it has not been in contact with equidae suffering from an infectious or contagious disease in the 15 days prior to this declaration.

IV. Residence and quarantine information:

- (a) The horse entered the territory of Mexico on (*insert date*).
- (b) The horse arrived in the country of dispatch from a Member State of the European Union.
- (c) As far as can be ascertained, the horse has not been continuously outside the European Union for 90 days or more, including the date of scheduled return in accordance with this certificate, and has not been outside the country referred to in point (a) above.

V. The horse will be sent in a vehicle cleaned and disinfected in advance with a disinfectant officially recognised in the country of dispatch and designed in a way that droppings, litter or fodder cannot escape during transportation.

VI. The certificate is valid for 10 days and until 15 April 2014.

Date	Place	Stamp and signature of the official veterinarian ⁽¹⁾

Name in block capitals and capacity.

⁽¹⁾ The colour of the stamp and the signature must be different from that of the printing.

⁽¹⁾ This certificate must be issued on the day of loading of the animal for dispatch to the European Union or on the last working day before embarkation.

⁽²⁾ Commission Decision 2004/211/EC of 6 January 2004 establishing the list of third countries and parts of territory thereof from which Member States authorise imports of live equidae and semen, ova and embryos of the equine species, and amending Decisions 93/195/EEC and 94/63/EC (OJ L 73, 11.3.2004, p. 1).

⁽³⁾ Delete as appropriate.

ANNEX II

In Annex I to Decision 2004/211/EC the entry for Mexico is replaced by the following:

MX	Mexico	MX-0	Whole country	D	—	—	—	—	—	—	—	—	—	
		MX-1	Metropolitan area of Mexico-City	D	—	X	—	—	—	—	—	—	—	Valid until 15 April 2014'

COMMISSION IMPLEMENTING DECISION

of 13 February 2014

as regards measures to prevent the spread within the Union of *Xylella fastidiosa* (Well and Raju)

(notified under document C(2014) 726)

(2014/87/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community⁽¹⁾, and in particular the third sentence of Article 16(3) thereof,

Whereas:

- (1) *Xylella fastidiosa* (Well and Raju) (hereinafter 'the specified organism') is listed in Section I of Part A of Annex I to Directive 2000/29/EC as a harmful organism not known to occur in the Union, the introduction of which into, and spread within, all Member States is prohibited.
- (2) On 21 October 2013 Italy informed the other Member States and the Commission of the presence of the specified organism in its territory, in two separate areas of the province Lecce, in the region of Apulia. Subsequently two further separate outbreaks have been identified in the same province. The presence of the specified organism was confirmed in respect of several plants species, including *Olea europaea* L., *Prunus amygdalus* Batsch, *Nerium oleander* L. and *Quercus* sp. L. showing leaf scorching and rapid decline symptoms. This is the first time the presence of the specified organism in the territory of the Union is confirmed. For several other plants species checks concerning its presence have not yet been concluded. The identification of the vector of the specified organism in Apulia is pending.
- (3) On 29 October 2013 the region Apulia took emergency measures for the prevention and eradication of the specified organism⁽²⁾ in accordance with Article 16(1) of Directive 2000/29/EC.

- (4) Italy reported that the inspections it had carried out showed no presence of the specified organism in the neighbouring provinces of Brindisi and Taranto.
- (5) In response to a request by the Commission, the European Food Safety Authority, 'the Authority', adopted a statement on 25 November 2013⁽³⁾ which contains the following conclusions. The specified organism has probably a very broad range of host plants, including many cultivated and spontaneous plants common in Europe.
- (6) The main entry pathway for the specified organism is the movement of plants for planting, excluding seeds. The pathway of infective vectors of the specified organism transported on plant consignments is also of concern. Fruit and wood are minor pathways with negligible likelihood of introduction. Seeds, cut flowers and ornamental foliage are minor pathways with low likelihood of introduction. The movement of infected plants for planting is the most efficient way for long-distance dispersal of the specified organism.
- (7) In view of the nature of the specified organism, it is likely to spread rapidly and widely. In order to ensure that the specified organism does not spread to the rest of the Union, it is necessary to take measures immediately. Until more specific information becomes available concerning host range, vectors, pathways and risk reduction options, it is appropriate to prohibit movement out of areas possibly containing infected plants.
- (8) Taking into consideration the locations of the presence of the specified organism, the particular geographical situation of the administrative province of Lecce and the uncertainties concerning the criteria for demarcation, that entire province should be the subject of that prohibition, in order to apply that prohibition rapidly and effectively.

⁽¹⁾ OJ L 169, 10.7.2000, p. 1.

⁽²⁾ Deliberazione della Giunta Regionale, Regione Puglia, N.2023 del 29.10.2013 (Misure di emergenza per la prevenzione, il controllo e la eradicazione del batterio da quarantena *Xylella fastidiosa* associato al 'Complesso del disseccamento rapido dell'olivo').

⁽³⁾ Statement of EFSA on host plants, entry and spread pathways and risk reduction options for *Xylella fastidiosa* Wells et al. EFSA Journal 2013; 11(11):3468, 50 pp. doi:10.2903/j.efsa.2013.3468.

- (9) That prohibition should concern plants for planting, other than seeds, as those plants are the main pathway for the specified organism. However, extensive sampling and testing in the province of Lecce have found that plants for planting belonging to certain genera and species, and originating in infected parts of Lecce, are not infected by the specified organism. Based on that evidence the prohibition should not concern lots of plants for planting of those genera and species that have been sampled and tested concerning the presence of the specified organism. Moreover, it would be appropriate to also exempt from that prohibition plants for planting which have been grown in sites with complete physical protection against the introduction of the specified organism and which belong to genera and species subject to a certification scheme requiring them to be subject to official testing concerning the specified organism and found free from that organism.
- (10) In view of the limited information on the possible presence of the specified organism in the rest of the Union, Member States should conduct annual surveys concerning the presence of that organism in their territories. In view of the broad range of potential host plants, those surveys should be adapted to the specificities of each area, host plant and plant products, and the characteristics of the potential vectors.
- (11) In order to gather as much information as possible on the specified organism and its presence, Member States should ensure that relevant information is communicated to them.
- (12) Member States should immediately inform the Commission of the measures they have taken to comply with this Decision, to ensure an effective overview of the implementation of this Decision.
- (13) It is appropriate that the measures be reviewed by 30 April 2014, at the latest, in order to take into account more precise scientific and technical information that will become available, as well as the results of the ongoing inspections and tests carried out by the Italian authorities.
- (14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DECISION:

Article 1

Movement of plants for planting

The movement, out of the province of Lecce, region of Apulia, Italy, of plants for planting shall be prohibited.

That prohibition shall not apply to:

- (a) seeds;
- (b) lots of plants for planting of the genera and species listed in Annex I that have been sampled and tested concerning the presence of *Xylella fastidiosa* (Well and Raju) (hereinafter: 'the specified organism') and have been found free from that organism;
- (c) plants for planting of the genera and species listed in Annex II, which have been grown in sites with complete physical protection against the introduction of the specified organism and which are officially certified under a certification scheme requiring them to be subject to official testing concerning the presence of the specified organism, and found free from that organism.

Article 2

Surveys

1. Member States shall conduct official annual surveys for the presence of the specified organism on plants and plant products in their territory. Those surveys shall be carried out, as appropriate, taking into account the biology, growing conditions and growing periods of the plants subject to the survey, the climatic conditions, the biology of the specified organism and the characteristics of the potential vectors.

2. The results of the surveys referred to in paragraph 1 shall be notified to the Commission and to the other Member States by 31 October of each year and shall cover a one-year period ending on 30 September of the same year. The results of the first survey shall be notified by 31 October 2014 and shall cover the period from 1 February to 30 September 2014.

Article 3

Notification of presence

1. Member States shall ensure that where anyone becomes aware of the presence of the specified organism or has reason to suspect such a presence, that person shall notify the competent authority within ten calendar days.

2. Member States shall ensure that, if so requested by the competent authority, the person referred to in paragraph 1 shall provide that authority with the information, which is in the possession of that person, concerning that presence.

Article 4

Compliance

Member States shall immediately inform the Commission of the measures they have taken to comply with this Decision.

Article 5

Review

This Decision shall be reviewed by 30 April 2014.

Article 6

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 13 February 2014.

For the Commission

Tonio BORG

Member of the Commission

ANNEX I

List of genera and species referred to in point (b) of the second subparagraph of Article 1

Abelia R. Br.
Acacia dealbata Link
Acca sellowiana (O. Berg) Burret
Arbutus unedo L.
Begonia L.
Boronia crenulata Sm.
Brachychiton discolor F. Muell.
Buxus sempervirens L.
Callistemon citrinus (Curtis) Skeels
Camellia L.
Ceratonia siliqua L.
Cercis siliquastrum L.
Chamelaucium uncinatum Schauer
Cinnamomum camphora (L.) J.Presl.
Citrus L.
Crataegus Tourn. ex L.
Cyclamen L.
Diosma L.
Eriobotrya japonica (Thunb.) Lindl.
Euphorbia pulcherrima Willd. ex Klotzsch
Ficus L.
Grevillea R.Br. ex Knight
Ilex aquifolium L.
Jasminum L.
Laurus nobilis L.
Lavandula angustifolia Mill.
Ligustrum vulgare L.
Magnolia grandiflora L.
Mandevilla sanderi (Hemsl.) Woodson
Metrosideros Banks ex Gaertn.
Morus alba L.
Myrtus communis L.
Nandina domestica Thunb.

Polygala myrtifolia L.

Punica granatum L.

Rosa L.

Salvia officinalis L.

Schinus molle L.

Trachelospermum jasminoides (Lindl.) Lem.

Viburnum tinus L.

Viola L.

Vitis L.

Weigela florida (Bunge) A. DC.

ANNEX II

List of genera and species referred to in point (c) of the second subparagraph of Article 1

Apium graveolens L.

Brassica L.

Capsicum annuum L.

Citrullus lanatus (Thunb.) Matsum. & Nakai

Cucumis melo L.

Cucurbita pepo L.

Foeniculum vulgare Mill.

Lactuca L.

Petroselinum Hill

Solanum lycopersicum L.

Solanum melongena L.

COMMISSION IMPLEMENTING DECISION

of 13 February 2014

suspending temporarily imports from Bangladesh of foodstuffs containing or consisting of betel leaves ('Piper betle')

(notified under document C(2014) 794)

(Text with EEA relevance)

(2014/88/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽¹⁾, and in particular Article 53(1)(b)(i) thereof,

Whereas:

- (1) Regulation (EC) No 178/2002 lays down the general principles governing food in general, and food safety in particular, at Union and national level. It provides for emergency measures to be taken by the Commission where there is evidence that food imported from a third country is likely to constitute a serious risk to human health.
- (2) Since October 2011, 142 notifications have been issued to the Rapid Alert System for Food and Feed due to the presence of a wide range of pathogenic salmonella strains in foodstuffs containing or consisting of betel leaves ('Piper betle', commonly known as 'Paan leaf' or 'Betel quid') originating in or consigned from Bangladesh.
- (3) Bangladesh has informed the Commission that from November 2012 there has been a ban on all betel leaves exports, pending the introduction of a programme for the export of pathogen-free betel leaves.
- (4) The Food and Veterinary Office (FVO) of the Directorate-General for Health and Consumers of the Commission carried out an audit in Bangladesh from 30 January to 7 February 2013 in order to assess the system of official controls for the export of plants to the Union. It found that the programme for the export of pathogen-free betel leaves was still being developed. The audit concluded that weaknesses were present in each stage of the export system, and in particular the pre-export inspection

stage. Pre-export inspection is essential in order to ensure that only betel leaves which comply with that programme are exported to the Union.

- (5) Despite the measures introduced by Bangladesh and action taken by it against non-compliant exporters, betel leaves continue to be exported to the Union from Bangladesh and there are still a high number of rapid alerts.
- (6) That high level of contamination presents a serious risk for human health. It is therefore appropriate to suspend imports into the Union of foodstuffs containing or consisting of betel leaves from that third country, pending the receipt of sufficient guarantees from it.
- (7) In order to allow the time necessary for Bangladesh to provide feedback and to consider the appropriate risk management measures the temporary suspension of imports of betel leaves should be in force at least until 31 July 2014.
- (8) 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

This Decision shall apply to all foodstuffs containing or consisting of betel leaves ('Piper betle') including, but not limited to, those declared under CN codes 1404 90 00, originating in or consigned from Bangladesh.

Article 2

Member States shall prohibit the importation into the Union of the foodstuffs referred to in Article 1.

Article 3

All expenditure incurred in the application of this Decision shall be charged to the consignee or his agent.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

Article 4

This Decision shall apply until 31 July 2014.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 13 February 2014.

For the Commission
Tonio BORG
Member of the Commission

COMMISSION IMPLEMENTING DECISION

of 14 February 2014

on a pilot project to implement the administrative cooperation obligations set out in Directive 2007/59/EC of the European Parliament and of the Council by means of the Internal Market Information System

(Text with EEA relevance)

(2014/89/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1024/2012 of the European Parliament and of the Council of 25 October 2012 on administrative cooperation through the Internal Market Information System and repealing Commission Decision 2008/49/EC (‘the IMI Regulation’) ⁽¹⁾, and in particular Article 4(1) thereof,

Whereas:

- (1) The Internal Market Information System (‘IMI’), formally established by the IMI Regulation, is a software application accessible via internet, developed by the Commission in cooperation with the Member States, to assist Member States in the practical implementation of information exchange requirements laid down in Union law pertaining to the internal market by providing a centralised communication mechanism to facilitate the cross-border exchange of information and mutual assistance.
- (2) Directive 2007/59/EC of the European Parliament and of the Council ⁽²⁾ sets out certain common rules for the certification of train drivers in order to overcome national differences thus contributing to the aims of Union policies on the freedom of movement of workers, freedom of establishment and freedom to provide services in the context of the common transport policy, in order to make it easier for train drivers to move from one Member State to another. This includes, in particular, the interconnection of national registries of train drivers’ licences and certificates.
- (3) The European Railway Agency (ERA) established by Regulation (EC) No 881/2004 of the European Parliament and the Council ⁽³⁾ was set up to support the Commission in ensuring an harmonised approach to rail interoperability and safety in the Union.

- (4) A ‘Feasibility Study of Interoperable Registers of Train Driving Licences and Complementary Certificates’ by the ERA and adopted on 2 April 2013, deemed that IMI was a suitable tool to implement an information exchange between national licence registers and recommended that a pilot project be organised
- (5) Commission Decision 2010/17/EC ⁽⁴⁾ sets out that the European Railway Agency is responsible for monitoring and reporting on the functioning of the pilot. The IMI Regulation requires the Commission to evaluate the outcome of the pilot.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Internal Market Information System Committee,

HAS ADOPTED THIS DECISION:

*Article 1***Scope and objectives of the pilot project**

In order to test the effectiveness of the Internal Market Information System (‘IMI’) for implementing the provisions listed in Articles 4 and 5 below, the Commission shall carry out a pilot project.

*Article 2***Competent authorities**

For the purposes of this Decision, the authorities of the Member States shall be those referred to in Article 16 of Directive 2004/49/EC of the European Parliament and of the Council ⁽⁵⁾ (hereinafter referred to as ‘competent authorities’).

⁽¹⁾ OJ L 316, 14.11.2012, p. 1.

⁽²⁾ Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community (OJ L 315, 3.12.2007, p. 51).

⁽³⁾ Regulation (EC) No 881/2004 of the European Parliament and the Council of 29 April 2004 establishing a European Railway Agency (Agency Regulation) (OJ L 164, 30.4.2004, p. 1).

⁽⁴⁾ Commission Decision 2010/17/EC of 29 October 2009 on the adoption of basic parameters for registers of train driving licences and complementary certificates provided for under Directive 2007/59/EC of the European Parliament and of the Council (OJ L 8, 13.1.2010, p. 17).

⁽⁵⁾ Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community’s railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (OJ L 164, 30.4.2004, p. 44).

*Article 3***Monitoring and reporting**

In order for the European Railway Agency to fulfil monitoring and reporting tasks provided for in Article 3(2) of Decision 2010/17/EC, the Commission will provide the Agency with statistics and information about the usage of IMI.

*Article 4***Administrative cooperation between competent authorities**

1. For the purposes of the pilot project, IMI shall be used between the competent authorities for the exchange of information set out in the following provisions:

- (a) point (b) of Article 22(1) of Directive 2007/59/EC, in conjunction with points 4 and 5 of Annex I to Decision 2010/17/EC;
- (b) Article 29(2) of Directive 2007/59/EC;
- (c) Article 29(3) of Directive 2007/59/EC;
- (d) point (b) of Article 29(4) of Directive 2007/59/EC, for requests for further inspection or suspension.

2. Administrative cooperation pursuant to paragraph 1 shall be implemented following the procedure set out in Annex I.

*Article 5***Administrative cooperation between competent authorities and the Commission**

1. For the purposes of the pilot project, IMI shall be used among the competent authorities and between those competent authorities and the Commission for the exchange of information set out in the following provisions:

- (a) point (b) of Article 29(4) of Directive 2007/59/EC for information to the Commission and other competent authorities;
- (b) point (c) of Article 29(4) of Directive 2007/59/EC for information to the Commission and other competent authorities;
- (c) the second subparagraph of Article 29(4) of Directive 2007/59/EC for information to the Commission and other competent authorities;

(d) Article 29(5) of Directive 2007/59/EC, for referral to the Commission.

2. Administrative cooperation pursuant to paragraph 1 shall be implemented following the procedure set out in Annex II

*Article 6***Evaluation**

1. The Commission will carry out an evaluation of the pilot project to assess whether the objective set out in Article 1 has been achieved and will submit a report to the European Parliament and the Council no later than three years after its start taking into account the following criteria:

- (a) data protection issues;
- (b) cost-effectiveness;
- (c) effective translation functionalities;
- (d) user-friendliness;
- (e) overall user's satisfaction.

2. The evaluation of the pilot project shall be based on statistical information retrieved from IMI and on feedback from participants, including at least one on-line user survey addressed to the competent authorities.

*Article 7***Entry into force**

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 14 February 2014.

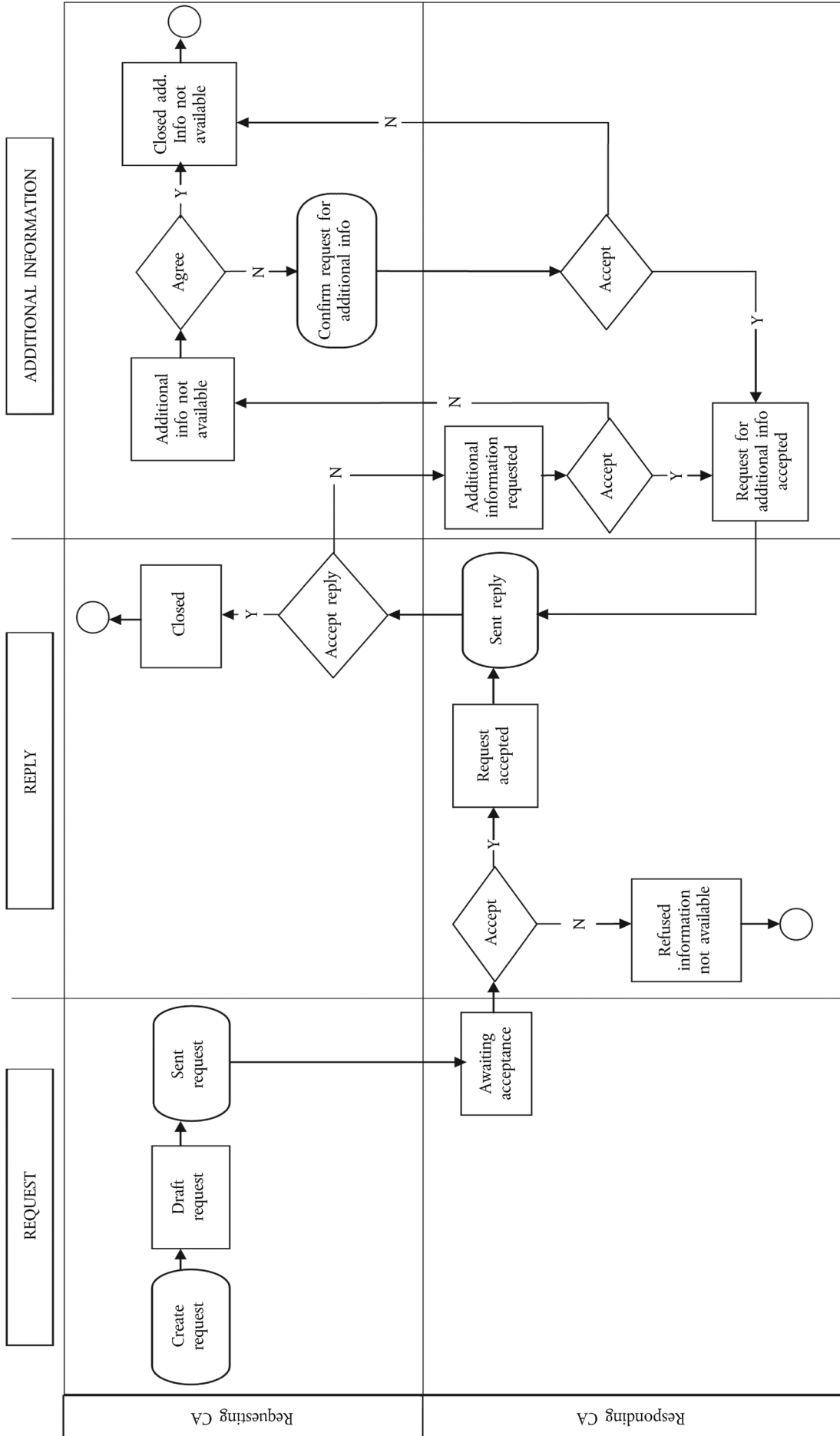
For the Commission

The President

José Manuel BARROSO

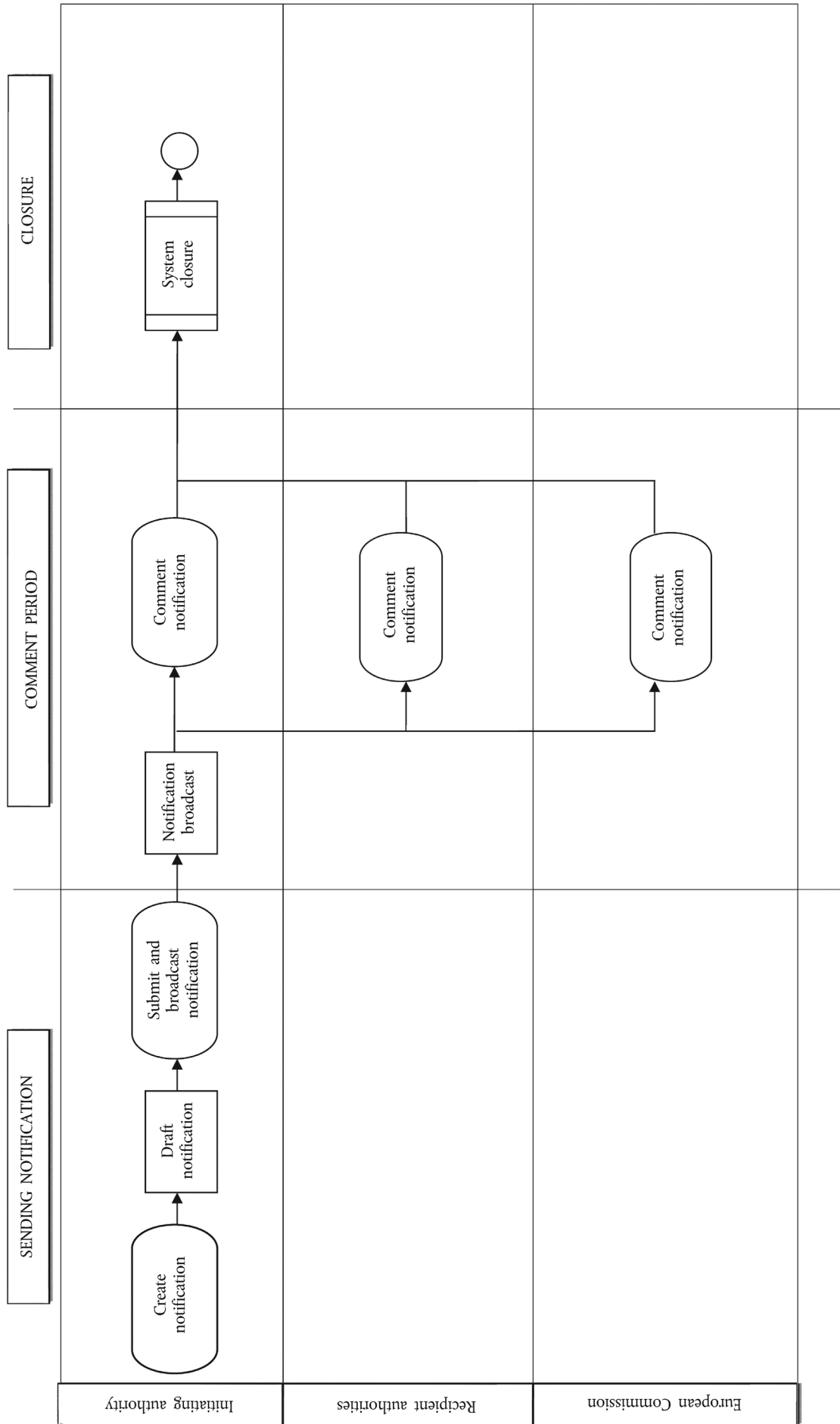
ANNEX I

INFORMATION REQUEST PROCEDURE



ANNEX II

NOTIFICATION PROCEDURE



CORRIGENDA**Corrigendum to Council Decision 2013/685/CFSP of 26 November 2013 amending Decision 2010/413/CFSP concerning restrictive measures against Iran**

(Official Journal of the European Union L 316 of 27 November 2013, p. 46)

Annex, page 48, entry 10 (Khazar Shipping Lines (Bandar Anzali)), third column (Reasons)

For: 'Marble Shipping Limited (Malta) is owned by IRISL.'

Read: 'Khazar Shipping Lines is owned by IRISL.';

Annex, page 48, entry 11 (Marble Shipping Limited (Malta)), third column (Reasons)

For: 'Entity owned by IRISL.'

Read: 'Marble Shipping Limited (Malta) is owned by IRISL.'

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