ISSN 1725-2555

Official Journal of the European Union

L 243

English edition

Legislation

Volume 54

21 September 2011

Contents

Price: EUR 3

(Continued overleaf)

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

DIRECTIVES

DECISIONS

RECOMMENDATIONS

EN

[1] Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION

of 12 July 2011

on the signing, on behalf of the Union, of the Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs

(2011/620/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with Article 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Commission has negotiated, on behalf of the Union, an Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs (the 'Agreement').

(2) The Agreement will enable the reciprocal protection of the geographical indications of the respective Parties and will contribute to the approximation of legislation among the EU neighbouring countries.

(3) The Agreement should be signed,

HAS ADOPTED THIS DECISION:

Article 1

The signing of the Agreement between the European Union and Georgia on protection of geographical indications of agricultural products and foodstuffs is hereby authorised on behalf of the Union, subject to the conclusion of the said Agreement [1].

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Union.

Article 3

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

Done at Brussels, 12 July 2011.

For the Council

The President

J. VINCENT-ROSTOWSKI

[1] The text of the Agreement will be published together with the decision on its conclusion.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 934/2011

of 20 September 2011

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:

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,

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 hereto.

Article 2

This Regulation shall enter into force on 21 September 2011.

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

Done at Brussels, 20 September 2011.

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	EC	23,1
	MK	31,3
	XS	31,8
	ZZ	28,7
0707 00 05	TR	106,2
	ZZ	106,2
0709 90 70	TR	103,0
	ZZ	103,0
0805 50 10	AR	69,0
	CL	80,1
	UY	66,0
	ZA	81,5
	ZZ	74,2
0806 10 10	CL	79,6
	EG	116,3
	MK	85,4
	TR	109,4
	US	271,3
	ZA	63,5
	ZZ	120,9
0808 10 80	AR	148,7
	CL	154,0
	CN	82,6
	NZ	118,4
	US	123,7
	ZA	108,7
	ZZ	122,7
0808 20 50	AR	217,1
	CN	81,9
	TR	116,8
	ZA	162,6
	ZZ	144,6
0809 30	TR	147,1
	ZZ	147,1

(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 935/2011

of 20 September 2011

on the issue of import licences for applications submitted in the first seven days of September 2011 under the tariff quota for high-quality beef administered by Regulation (EC) No 620/2009

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences [2], and in particular Article 7(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 620/2009 of 13 July 2009 providing for the administration of an import tariff quota for high-quality beef [3] sets out detailed rules for the submission and issue of import licences.

(2) Article 7(2) of Regulation (EC) No 1301/2006 provides that in cases where quantities covered by licence applications exceed the quantities available for the quota period, allocation coefficients should be fixed for the quantities covered by each licence application. The applications for import licences submitted pursuant to Article 3 of Regulation (EC) No 620/2009 between 1 and 7 September 2011 exceed the quantities available. Therefore, the extent to which import licences may be issued and the allocation coefficient should be determined,

HAS ADOPTED THIS REGULATION:

Article 1

Import licence applications covered by the quota with order number 09.4449 and submitted between 1 and 7 September 2011 in accordance with Article 3 of Regulation (EC) No 620/2009, shall be multiplied by an allocation coefficient of 0,465148 %.

Article 2

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

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

Done at Brussels, 20 September 2011.

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 238, 1.9.2006, p. 13.
[3] OJ L 182, 15.7.2009, p. 25.

COMMISSION IMPLEMENTING REGULATION (EU) No 936/2011

of 20 September 2011

fixing the allocation coefficient for the issuing of import licences applied for from 1 to 7 September 2011 for sugar products under certain tariff quotas and suspending submission of applications for such licences

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences ([2]), and in particular Article 7(2) thereof,

Having regard to Commission Regulation (EC) No 891/2009 of 25 September 2009 opening and providing for the administration of certain Community tariff quotas in the sugar sector ([3]), and in particular Article 5(2) thereof,

Whereas:

(1) Quantities covered by applications for import licences submitted to the competent authorities from 1 to 7 September 2011 in accordance with Regulation (EC) No 891/2009, exceed the quantity available under order number 09.4380.

(2) In these circumstances, an allocation coefficient for licences to be issued regarding order number 09.4380 should be fixed in accordance with Regulation (EC) No 1301/2006. Submission of further applications for licences for that order number should be suspended until the end of the marketing year, in accordance with Regulation (EC) No 891/2009,

HAS ADOPTED THIS REGULATION:

Article 1

1. The quantities for which import licence applications have been lodged under Regulation (EC) No 891/2009 from 1 to 7 September 2011 shall be multiplied by the allocation coefficients set out in the Annex to this Regulation.

2. Submission of further applications for licences, which correspond to the order numbers indicated in the Annex, shall be suspended until the end of the marketing year 2010/11.

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, 20 September 2011.

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 238, 1.9.2006, p. 13.
([3]) OJ L 254, 26.9.2009, p. 82.

ANNEX

CXL Concessions Sugar

2010/2011 marketing year

Applications lodged from 1.9.2011 to 7.9.2011

Order No	Country	Allocation coefficient (%)	Further applications
09.4317	Australia	—	Suspended
09.4318	Brazil	—	
09.4319	Cuba	—	Suspended
09.4320	Any third countries	—	Suspended
09.4321	India	—	Suspended

— Not applicable: no licence application has been sent to the Commission.

Balkans Sugar

2010/2011 marketing year

Applications lodged from 1.9.2011 to 7.9.2011

Order No	Country	Allocation coefficient (%)	Further applications
09.4324	Albania	—	
09.4325	Bosnia and Herzegovina	—	Suspended
09.4326	Serbia	—	
09.4327	Former Yugoslav Republic of Macedonia	—	
09.4328	Croatia	—	

— Not applicable: no licence application has been sent to the Commission.

Exceptional import sugar and industrial import sugar

2010/2011 marketing year

Applications lodged from 1.9.2011 to 7.9.2011

Order No	Type	Allocation coefficient (%)	Further applications
09.4380	Exceptional	20,0133	Suspended
09.4390	Industrial	—	

— Not applicable: no licence application has been sent to the Commission.

DIRECTIVES

COMMISSION DIRECTIVE 2011/78/EU

of 20 September 2011

amending Directive 98/8/EC of the European Parliament and of the Council to include *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard 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 [1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) 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 [2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes *Bacillus thuringiensis* subsp. *israelensis* Serotype H14.

(2) Pursuant to Regulation (EC) No 1451/2007, Strain AM65-52 of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive. Strain SA3A of *Bacillus thuringiensis* subsp. *israelensis* Serotype H14 is still under evaluation for use in that product-type.

(3) Italy was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 11 July 2008 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 6 May 2011, in an assessment report.

(5) It appears from the evaluations that biocidal products used as insecticides, acaricides and products to control other arthropods and containing *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52, may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 in Annex I to that Directive.

(6) Not all potential uses have been evaluated at Union level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.

(7) In the light of the potential risks identified for professional use without personal protective equipment, it is appropriate to require that product authorisations for professional use are granted only for use with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by others means.

(8) In the light of the possible indirect human exposure via consumption of food as a result of those uses represented in the assessment, it is appropriate to require, where relevant, verification of the need to set new or to amend existing maximum residue levels according to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.

down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]) or Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ([2]). Measures should be adopted ensuring that the applicable maximum residue levels are not exceeded.

(9) The provisions of this Directive should be applied at the same time in all Member States in order to ensure equal treatment on the Union market of biocidal products containing the active substance *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 and also to facilitate the proper operation of the market for biocidal products in general.

(10) A reasonable period should be allowed to elapse before an active substance is included in Annex I to Directive 98/8/EC, in order to permit Member States and interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(11) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.

(12) Directive 98/8/EC should therefore be amended accordingly.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 30 September 2012 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 September 2011.

For the Commission
The President
José Manuel BARROSO

([1]) OJ L 152, 16.6.2009, p. 11.
([2]) OJ L 70, 16.3.2005, p. 1.

ANNEX

In Annex I to Directive 98/8/EC, the following entry is added:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product-type	Specific provisions (*)
'46	*Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52	Not applicable	No relevant impurities	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means. For products containing *Bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

COMMISSION DIRECTIVE 2011/79/EU

of 20 September 2011

amending Directive 98/8/EC of the European Parliament and of the Council to include fipronil as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard 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 [1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) 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 [2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes fipronil for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to the Directive.

(2) Pursuant to Regulation (EC) No 1451/2007, fipronil has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18.

(3) France was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007 on 6 February 2009.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 6 May 2011, in an assessment report.

(5) It appears from the evaluations that biocidal products used as insecticides and containing fipronil may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include fipronil in Annex I to that Directive.

(6) Not all potential uses have been evaluated in the Union level assessment, which only addressed professional use indoors by application in locations normally inaccessible to man and domestic animals after application. It is therefore appropriate to require that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.

(7) The provisions of this Directive should be applied at the same time in all Member States in order to ensure equal treatment on the Union market of biocidal products containing the active substance fipronil, and also to facilitate the proper operation of the biocidal products market in general.

(8) A reasonable period should be allowed to elapse before an active substance is included in Annex I to Directive 98/8/EC in order to permit Member States and interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(9) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.

(10) Directive 98/8/EC should therefore be amended accordingly.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.

Article 2

1. Member States shall adopt and publish, by 30 September 2012 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 September 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following entry is added:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product-type	Specific provisions (*)
'47	fipronil	(±)-5-amino-1-(2,6-dichloro-α,α,α,-trifluoro-p-tolyl)-4-trifluoromethylsulfinylpyrazole-3-carbonitrile (1:1) EC No: 424-610-5 CAS No: 120068-37-3	950 g/kg	1 October 2013	30 September 2015	30 September 2023	18	Only professional use indoors by application in locations normally inaccessible after application to man and domestic animals has been addressed in the Union level risk assessment. When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

COMMISSION DIRECTIVE 2011/80/EU

of 20 September 2011

amending Directive 98/8/EC of the European Parliament and of the Council to include lambda-cyhalothrin as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard 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 [1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) 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 [2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes lambda-cyhalothrin.

(2) Pursuant to Regulation (EC) No 1451/2007, lambda-cyhalothrin has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive.

(3) Sweden was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 8 September 2008 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 6 May 2011, in an assessment report.

(5) It appears from the evaluations that biocidal products used as insecticides, acaricides and products to control other arthropods and containing lambda-cyhalothrin may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include lambda-cyhalothrin in Annex I to that Directive.

(6) Not all potential uses have been evaluated at Union level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.

(7) In the light of the risks identified for the aquatic and terrestrial ecosystems when products were emitted to a sewage treatment plant, it is appropriate to require that products are not authorised for such uses, unless data are submitted demonstrating that the product will meet the requirements of both Article 5 of and Annex VI to Directive 98/8/EC, if necessary by the application of appropriate risk mitigation measures.

(8) In the light of the risks identified for professional use without personal protective equipment, it is appropriate to require that product authorisations for professional use are granted only for use with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by others means.

(9) In the light of the possible indirect human exposure via consumption of food as a result of those uses represented in the assessment, it is appropriate to require, where relevant, verification of the need to set new or to amend existing maximum residue levels according to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council [3] or Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC [4]. Measures should be adopted ensuring that the applicable maximum residue levels are not exceeded.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.
[3] OJ L 152, 16.6.2009, p. 11.
[4] OJ L 70, 16.3.2005, p. 1.

(10) The provisions of this Directive should be applied at the same time in all Member States in order to ensure equal treatment on the Union market of biocidal products containing the active substance lambda-cyhalothrin and also to facilitate the proper operation of the biocidal products market in general.

(11) A reasonable period should be allowed to elapse before an active substance is included in Annex I to Directive 98/8/EC, in order to permit Member States and interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(12) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.

(13) Directive 98/8/EC should therefore be amended accordingly.

(14) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 30 September 2012 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 September 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following entry is added:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
'48	lambda-cyhalothrin	Reaction mass of (R)-α-cyano-3-phenoxybenzyl (1S,3S)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-[(Z)-2-chloro-3,3,3-trifluoropropenyl]-2,2-dimethylcyclopropanecarboxylate (1:1) CAS-No: 91465-08-6 EC No: 415-130-7	900 g/kg	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products applied in such a way that emission to a sewage treatment plant cannot be prevented shall not be authorised, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means. For products containing lambda-cyhalothrin that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

COMMISSION DIRECTIVE 2011/81/EU

of 20 September 2011

amending Directive 98/8/EC of the European Parliament and of the Council to include deltamethrin as an active substance in Annex I thereto

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard 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 [1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) 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 [2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes deltamethrin.

(2) Pursuant to Regulation (EC) No 1451/2007, deltamethrin has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to that Directive.

(3) Sweden was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 27 June 2008 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 6 May 2011, in an assessment report.

(5) It appears from the evaluations that biocidal products used as insecticides, acaricides and products to control other arthropods and containing deltamethrin may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include deltamethrin in Annex I to that Directive.

(6) Not all potential uses have been evaluated at Union level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to reduce the identified risks to acceptable levels.

(7) In the light of the risks identified for the aquatic ecosystem when products were used for indoor barrier treatment, resulting in emissions of a certain scale to a sewage treatment plant, it is appropriate to require that products are not authorised for uses resulting in such emissions, unless data are submitted demonstrating that the product will meet the requirements of both Article 5 of and Annex VI to Directive 98/8/EC, if necessary by the application of appropriate risk mitigation measures.

(8) The provisions of this Directive should be applied at the same time in all Member States in order to ensure equal treatment on the Union market of biocidal products containing the active substance deltamethrin and also to facilitate the proper operation of the biocidal products market in general.

(9) A reasonable period should be allowed to elapse before an active substance is included in Annex I to Directive 98/8/EC, in order to permit Member States and interested parties to prepare themselves to meet the new requirements entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(10) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.

(11) Directive 98/8/EC should therefore be amended accordingly.

(12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 30 September 2012 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 2013.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 September 2011.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following entry is added:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
'49	deltamethrin	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate CAS-No: 52918-63-5 EC No: 258-256-6	985 g/kg	1 October 2013	30 September 2015	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products shall not be authorised for indoor treatments resulting in sewage treatment plant emissions of the scale for which the Union level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.'

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

DECISIONS

COUNCIL DECISION 2011/621/CFSP

of 21 September 2011

extending the mandate of the European Union Special Representative to the African Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 28, Article 31(2) and Article 33 thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 6 December 2007, the Council adopted Joint Action 2007/805/CFSP [1] appointing Mr Koen VERVAEKE as European Union Special Representative ("EUSR") to the African Union ("AU"). His mandate expired on 31 August 2011.

(2) Therefore, the mandate of the EUSR should be extended from 1 September 2011 until 30 June 2012.

(3) The EUSR will implement his mandate in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

European Union Special Representative

The mandate of Mr Koen VERVAEKE as EUSR to the AU is hereby extended until 30 June 2012. The mandate of the EUSR may be terminated earlier, if the Council so decides, on a proposal of the High Representative ("HR").

Article 2

Policy objectives

The mandate of the EUSR shall be based on the EU's comprehensive policy objectives in support of African efforts to build a peaceful, democratic and prosperous future as set out in the Joint Africa-EU Strategy. These objectives include:

(a) enhancing the EU's political dialogue and broader relationship with the AU;

(b) strengthening the EU-AU partnership in all areas outlined in the Joint Africa-EU Strategy, contributing to the development and implementation of the Joint Africa-EU Strategy in partnership with the AU, respecting the principle of African ownership and working more closely with African representatives in multilateral fora in coordination with multilateral partners;

(c) working with, and providing support to the AU by supporting institutional development and strengthening the relationship between EU and AU Institutions, including through development assistance, to promote:

— peace and security: predict, prevent, manage, mediate and resolve conflict, support efforts to promote peace and stability, support post-conflict reconstruction,

— human rights and governance: promote and protect human rights; promote fundamental freedoms and respect for the rule of law; support, through political dialogue and financial and technical assistance, African efforts to monitor and improve governance; support growth of participatory democracy and accountability; support the fight against corruption and organised crime and further promote efforts to address the issue of children and armed conflict in all its aspects,

— sustainable growth, regional integration and trade: support efforts towards interconnectivity and facilitate people's access to water and sanitation, energy and information technology; promote a stable, efficient and harmonised legal business framework; assist to integrate Africa into the world trade system, assist African countries to comply with EU rules and standards; support Africa in countering the effects of climate change,

[1] OJ L 323, 8.12.2007, p. 45.

— investment in people: support efforts in the fields of gender, health, food security and education, promote exchange programmes, networks of universities and centres of excellence, address the root causes of migration.

Furthermore, the EUSR will play a key role in implementing the Joint Africa-EU Strategy intended to further develop and consolidate the strategic partnership between Africa and the EU.

Article 3

Mandate

In order to achieve the Common Foreign and Security Policy (CFSP)/Common Security and Defence Policy (CSDP) aspects of the objectives referred to in Article 2, the mandate of the EUSR shall be to:

(a) strengthen the overall EU influence in, and coordination of, the Addis Ababa-based dialogue with the AU and its Commission, on the whole range of CFSP/ESDP issues covered by the EU-AU relationship, in particular the Peace and Security Partnership and support to the operationalisation of the African Peace and Security Architecture;

(b) ensure an appropriate level of political representation, reflecting the importance of the EU as a political, financial and institutional partner of the AU, and the step change in that partnership necessitated by the growing political profile of the AU on the world stage;

(c) represent, should the Council so decide, EU positions and policies, when the AU plays a major role in a crisis situation for which no EUSR has been appointed;

(d) help achieve better coherence, consistency and coordination of EU policies and actions towards the AU, and contribute to enhance coordination of the broader partner group and its relation with the AU;

(e) contribute to the implementation of the EU human rights policy relevant to the AU, including the EU Guidelines on human rights, in particular the EU Guidelines on Children and Armed Conflict as well as on violence against women and girls and combating all forms of discrimination against them, and the EU policy on Women, Peace and Security;

(f) follow closely, and report on, all relevant developments at AU level;

(g) maintain close contact with the AU Commission, other AU organs, missions of African Sub-regional organisations to the AU and the missions of the AU Member States to the AU;

(h) facilitate the relations and cooperation between the AU and African Sub-regional organisations, especially in those areas where the EU is providing support;

(i) offer advice and provide support to the AU upon request in the areas outlined in the Joint Africa-EU Strategy;

(j) offer advice and provide support upon request to the building up of the AU's crisis management capabilities;

(k) on the basis of a clear division of tasks, coordinate with, and support, the actions of EUSRs with mandates in AU Member States/Regions; and

(l) maintain close contacts and promote coordination with key international partners of the AU present in Addis Ababa, especially the United Nations, but also with non-State actors on the whole range of the CFSP/CSDP issues covered by the EU-AU partnership.

Article 4

Implementation of the mandate

1. The EUSR shall be responsible for the implementation of the mandate acting under the authority of the HR.

2. The Political and Security Committee ("PSC") shall maintain a privileged link with the EUSR and shall be the EUSR's primary point of contact with the Council. The PSC shall provide the EUSR with strategic guidance and political direction within the framework of the mandate, without prejudice to the powers of the HR.

3. The EUSR shall work in close coordination with the European External Action Service ("EEAS").

Article 5

Financing

1. The financial reference amount intended to cover the expenditure related to the mandate of the EUSR in the period from 1 September 2011 to 30 June 2012 shall be EUR 715 000.

2. The expenditure shall be managed in accordance with the procedures and rules applicable to the general budget of the Union.

3. The management of the expenditure shall be subject to a contract between the EUSR and the Commission. The EUSR shall be accountable to the Commission for all expenditure.

Article 6

Constitution and composition of the team

1. Within the limits of his mandate and the corresponding financial means made available, the EUSR shall be responsible for constituting his team. The team shall include the expertise on specific policy issues as required by the mandate. The EUSR shall keep the Council and the Commission promptly informed of the composition of his team.

2. Member States, institutions of the Union and the EEAS may propose the secondment of staff to work with the EUSR. The salary of such seconded personnel shall be covered by the EU Member State, the institution of the Union concerned or the EEAS, respectively. Experts seconded by Member States to the institutions of the Union or the EEAS may also be posted to the EUSR. International contracted staff shall have the nationality of a Member State.

3. All seconded personnel shall remain under the administrative authority of the sending Member State, institution of the Union or the EEAS and shall carry out their duties and act in the interest of the mandate of the EUSR.

Article 7

Privileges and immunities of the EUSR and his staff

The privileges, immunities and further guarantees necessary for the completion and smooth functioning of the mission of the EUSR and the members of his staff shall be agreed with the host party/parties, as appropriate. Member States and the Commission shall grant all necessary support to such effect.

Article 8

Security of EU classified information

The EUSR and the members of his team shall respect the security principles and minimum standards established by Council Decision 2011/292/EU of 31 March 2011 on the security rules for protecting EU classified information ([1]).

Article 9

Access to information and logistical support

1. Member States, the Commission and the General Secretariat of the Council shall ensure that the EUSR is given access to any relevant information.

2. The Union's delegations and/or Member States, as appropriate, shall provide logistical support in the region.

Article 10

Security

In accordance with the Union's policy on the security of personnel deployed outside the Union in an operational capacity under Title V of the Treaty, the EUSR shall take all reasonably practicable measures, in conformity with his mandate and on the basis of the security situation in his geographical area of responsibility, for the security of all personnel under his direct authority, notably by:

(a) establishing a mission-specific security plan, providing for mission-specific physical, organisational and procedural security measures, governing the management of the secure movement of personnel to, and within, the mission area, and the management of security incidents, and providing for a contingency plan and a mission evacuation plan;

(b) ensuring that all personnel deployed outside the Union are covered by high risk insurance as required by the conditions in the mission area;

(c) ensuring that all members of his team to be deployed outside the Union, including locally contracted personnel, have received appropriate security training before or upon arriving in the mission area, based on the risk ratings assigned to the mission area;

(d) ensuring that all agreed recommendations made following regular security assessments are implemented and providing the Council, the Commission and the HR with written reports on their implementation and on other security issues within the framework of the mid-term and mandate implementation reports.

Article 11

Reporting

The EUSR shall regularly provide the HR and the PSC with oral and written reports. The EUSR shall also report as necessary to Council working parties. Regular written reports shall be circulated through the COREU network. Upon recommendation of the HR or the PSC, the EUSR may provide the Foreign Affairs Council with reports.

Article 12

Coordination

1. The EUSR shall promote overall Union political coordination. He shall help ensure that all Union instruments in the field are engaged coherently to attain the Union's policy objectives. The activities of the EUSR shall be coordinated with those of the Commission, as well as those of other EUSRs active in the region as appropriate. The EUSR shall provide regular briefings to Member States' missions and the Union's delegations.

([1]) OJ L 141, 27.5.2011, p. 17.

2. In the field, close liaison shall be maintained with the Heads of the Union delegations and Member States' Heads of Mission who shall make best efforts to assist the EUSR in the implementation of the mandate. The EUSR shall also liaise with other international and regional actors in the field.

Article 13

Review

The implementation of this Decision and its consistency with other contributions from the Union to the region shall be kept under regular review. The EUSR shall present the Council, the Commission and the HR with a progress report at the end of January 2012 and a comprehensive mandate implementation report at the end of the mandate.

Article 14

Entry into force

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

It shall apply from 1 September 2011.

Done at Brussels, 21 September 2011.

For the Council
The President
M. SAWICKI

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 20 September 2011

on the procedure demonstrating the level of compliance of existing railway lines with the basic parameters of the technical specifications for interoperability

(Text with EEA relevance)

(2011/622/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

According to Section 7.3.4 of the Annex to Commission Decision 2011/275/EU of 26 April 2011 concerning a technical specification for interoperability relating to the 'infrastructure' subsystem of the trans-European conventional rail system [1], existing lines that are not subject to a renewal or upgrading project may allow the circulation of TSI-conform vehicles whilst meeting the essential requirements of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community [2]. The infrastructure manager should be able in this case, on a voluntary basis, to complete the register of infrastructure in accordance with Annex D to Decision 2011/275/EU. A common procedure to be used for the demonstration of the level of compliance with the basic parameters of the TSI laid down in Decision 2011/275/EU should be recommended,

RECOMMENDS that

the procedure set out in the Annex be applied for demonstrating the level of compliance of existing fixed installations with the basic parameters of technical specifications for interoperability.

Done at Brussels, 20 September 2011.

For the Commission
Siim KALLAS
Vice-President

[1] OJ L 126, 14.5.2011, p. 53.
[2] OJ L 191, 18.7.2008, p. 1.

ANNEX

Procedure for demonstrating the level of compliance of existing railway lines with the basic parameters of the technical specifications for interoperability

1. **Introduction**

1.1. *Technical Scope*

This procedure concerns the following subsystems of the Union rail system:

(a) the infrastructure structural subsystem; and

(b) the energy structural subsystem.

These subsystems are included in the list of subsystems in Annex II (1) to Directive 2008/57/EC.

1.2. *Geographical Scope*

The geographical scope of this procedure is the Union rail system as determined by Directive 2008/57/EC.

1.3. *Definitions*

For the purpose of this procedure:

(a) 'EI' means existing infrastructure (fixed installations) placed in service before the entry into force of Directive 2008/57/EC or lines placed in service after the entry into force of Directive 2008/57/EC without being subject to the EC verification procedure;

(b) 'EI demonstration of compliance' means the verification whether basic parameters of a subsystem or/and an element of existing lines comply with requirements of the relevant TSIs;

(c) 'EI certificate of demonstration' means the document issued by an independent assessor as a result of the EI demonstration of compliance;

(d) 'EI declaration of demonstration' means the document issued by an applicant after receiving EI certificate of demonstration.

2. **Procedure demonstrating compliance with Technical Specifications for Interoperability for existing lines**

2.1. *Purpose*

According to Decision 2011/275/EU concerning a technical specification for interoperability relating to the 'infrastructure' subsystem of the trans-European conventional rail system, existing lines that are not subject to a renewal or upgrading project may allow the circulation of TSI-conform vehicles whilst meeting the essential requirements of Directive 2008/57/EC.

Therefore, the following procedure may be applied for demonstrating compliance of existing fixed installations with the relevant TSIs without being subject to a new authorisation for putting into service.

It is not mandatory, but may be used on a voluntary basis.

2.2. *Procedure for demonstration of the level of compliance with the basic parameters of the TSI*

1. Procedure for demonstration of the level of compliance with the basic parameters of the TSI is the EI demonstration of compliance procedure whereby the applicant fulfils the obligations laid down in points 2,3,5.2 and 5.4, and ensures and declares on his sole responsibility that the subsystem concerned, which has been subject to the provisions of point 4, satisfies the requirements of the relevant TSI(s).

2. The applicant lodges an application for the EI demonstration of compliance of the subsystem with an independent assessor of his choice.

The application includes:

(a) name and address of the applicant and, if the application is lodged by the authorised representative, his name and address as well;

(b) the technical documentation.

3. Technical documentation

3.1. The applicant establishes the technical documentation and makes it available to the independent assessor referred to in point 4. The documentation should make it possible to demonstrate the level of compliance of the existing subsystem's with the basic parameters of the relevant TSI(s).

3.2. The technical documentation contains, wherever applicable, the following elements:

(a) general description of the existing subsystem;

(b) the documents necessary for the compilation of the technical file;

(c) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union* and/or national technical specifications which are notified under Article 17(3) of Directive 2008/57/EC, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the relevant TSI(s) where those harmonised or national standards have not been applied. In the event of partly applied harmonised or national standards, the technical documentation specifies the parts which have been applied;

(d) conditions for use of the subsystem (restrictions of running time or distance, wear limits, etc.);

(e) descriptions and explanations necessary for the understanding of the operation and maintenance of the subsystem;

(f) conditions for maintenance and technical documentation regarding the maintenance of the subsystem;

(g) any technical requirement specified in the relevant TSI(s) that have to be taken into account during maintenance or operation of the subsystem;

(h) other appropriate technical evidences, which demonstrate that previous checking or tests have been successfully performed, under comparable conditions, by competent bodies.

3.3. The applicant keeps the technical documentation at the disposal of the relevant national authorities throughout the service life of the subsystem.

4. Procedure for demonstration of the level of compliance with the basic parameters of the TSI.

4.1. The independent assessor chosen by the applicant takes into account evidence of examinations, checks or tests that have been performed by other bodies or by the applicant.

4.2. The evidences gathered by the independent assessor should be suitable and sufficient to demonstrate the level of compliance with the requirement of the relevant TSI(s) and that all required and appropriate checks and tests have been carried out.

4.3. Where the existing subsystem meets the requirements of the relevant TSI(s), the independent assessor issues an EI certificate of demonstration.

5. EI declaration of demonstration

5.1. The applicant draws up a written EI declaration of demonstration for the subsystem and keeps it throughout the service life of the subsystem. The EI declaration of demonstration identifies the subsystem for which it has been drawn up.

5.2. The EI declaration of demonstration and the accompanying documents is written in accordance with Chapter 2.5.

5.3. A copy of the EI declaration of demonstration is made available to the relevant authorities upon request.

6. Technical file

6.1. The independent assessor is responsible for compiling the technical file that accompanies the EI declaration of demonstration.

6.2. The technical file accompanying the EI declaration of demonstration is lodged with the applicant.

6.3. The applicant keeps a copy of the technical file throughout the service life of the subsystem; it is sent to any other Member State which so requests.

2.3. *Characteristics to be assessed*

The characteristics to be assessed when applying the procedure for demonstration of the level of compliance with the basic parameters of the TSI are set out in:

— Table 1 for the conventional rail infrastructure subsystem,

— Table 2 for the conventional rail energy subsystem,

— Table 3 for the high speed rail infrastructure subsystem, and

— Table 4 for the high speed rail energy subsystem.

Table 1

Assessment of the conventional rail infrastructure subsystem for the EI demonstration of compliance

Characteristics to be assessed (CR INF TSI)	Existing line not subject to any EC verification	Particular assessment procedures (CR INF TSI)
	1	2
Structure gauge (4.2.4.1)	X	6.2.4.1
Distance between track centres (4.2.4.2)	X	6.2.4.2
Maximum gradients (4.2.4.3)	X	
Minimum radius of horizontal curve (4.2.4.4)	X	
Minimum radius of vertical curve (4.2.4.5)	X	
Nominal track gauge (4.2.5.1)	X	
Cant (4.2.5.2)	X	
Rate of change of cant (4.2.5.3)	X	
Cant deficiency (4.2.5.4)	X	6.2.4.3
Equivalent conicity (4.2.5.5.1) — design	n.a.	
Equivalent conicity (4.2.5.5.2) — in-service	Open point	6.2.4.5
Railhead profile for plain line (4.2.5.6)	n.a.	
Rail inclination (4.2.5.7)	X	
Track stiffness (4.2.5.8)	n.a.	
Means of locking (4.2.6.1)	X	
In service geometry of switches and crossings (4.2.6.2)	n.a.	

Characteristics to be assessed (CR INF TSI)	Existing line not subject to any EC verification	Particular assessment procedures (CR INF TSI)
	1	2
Maximum unguided length of fixed obtuse crossings (4.2.6.3)	X	6.2.4.7
Track resistance to vertical loads (4.2.7.1)	X	6.2.5
Longitudinal track resistance (4.2.7.2)	X	6.2.5
Lateral track resistance (4.2.7.3)	X	6.2.5
Resistance of new bridges to traffic loads (4.2.8.1)	n.a.	
Equivalent vertical loading for new earthworks and earth pressure effects (4.2.8.2)	n.a.	
Resistance of new structures over or adjacent to tracks (4.2.8.3)	n.a.	
Resistance of existing bridges and earthworks to traffic loads (4.2.8.4)	X	6.2.4.9
Determination of immediate action, intervention and alert limits (4.2.9.1)	n.a.	
The immediate action limit for track twist (4.2.9.2)	n.a.	
The immediate action limit for variation of track gauge (4.2.9.3)	n.a.	
The immediate action limit for cant (4.2.9.4)	n.a.	
Usable length of platforms (4.2.10.1)	X	
Width and edge of platforms (4.2.10.2)	X	
End of platforms (4.2.10.3)	X	
Height of platforms (4.2.10.4)	X	
Offset of platforms (4.2.10.5)	X	
Maximum pressure variation in tunnels (4.2.11.1)	X	6.2.4.6
Noise and vibration limits and mitigation measures (4.2.11.2)	Open point	
Protection against electric shock (4.2.11.3)	See ENE	
Safety in railway tunnels (4.2.11.4)	See SRT	
Effect of crosswinds (4.2.11.5)	Open point	
Distance markers (4.2.12.1)	X	
Toilet discharge (4.2.13.2)	X	6.2.4.10
Train external cleaning facilities (4.2.13.3)	X	6.2.4.10
Water restocking (4.2.13.4)	X	6.2.4.10
Refuelling (4.2.13.5)	X	6.2.4.10
Electric shore supply (4.2.13.6)	X	6.2.4.10

Table 2

Assessment of the conventional rail energy subsystem for the EI demonstration of compliance

Characteristics to be assessed (CR ENE TSI)	Existing line not subject to any EC verification	Particular assessment procedures (CR ENE TSI)
	1	2
Voltage and frequency (4.2.3)	X	
Parameters relating to system performance (4.2.4)	X	6.2.4.1
Continuity of power supply in case of disturbances in tunnels (4.2.5)	X	
Current capacity, DC systems, trains at standstill (4.2.6)	X	
Regenerative braking (4.2.7)	X	6.2.4.2
Electrical protection coordination arrangements (4.2.8)	X	6.2.4.3
Harmonics and dynamic effects for AC systems (4.2.9)	X	6.2.4.4
Geometry of the overhead contact line: contact wire height (4.2.13.1)	X	
Geometry of the overhead contact line: Variation in contact wire height (4.2.13.2)	X	
Geometry of the overhead contact line: Lateral deviation (4.2.13.3)	X	
Pantograph gauge (4.2.14)	X	
Mean contact force (4.2.15)	X	
Dynamic behaviour and quality of current collection (4.2.16)	X	6.1.4.1, 6.2.4.5
Pantograph spacing (4.2.17)	X	
Contact wire material (4.2.18)	X	
Phase separation sections (4.2.19)	X	
System separation sections (4.2.20)	X	
Management of power supply in case of danger (4.4.2.3)	X	
Maintenance rules (4.5)	X	6.2.4.6
Protection against electric shock (4.7.2, 4.7.3, 4.7.4)	X	

Table 3

Assessment of the high speed rail infrastructure subsystem for the EI demonstration of compliance

Characteristics to be assessed (HS INF TSI)	Existing line not subject to any EC verification	Particular assessment procedures (HS INF TSI)
	1	2
Nominal track gauge (4.2.2)	X	
Minimum structure gauge (4.2.3)	X	6.2.6.1
Distance between track centres (4.2.4)	X	
Maximum rising and falling gradients (4.2.5)	X	

Characteristics to be assessed (HS INF TSI)	Existing line not subject to any EC verification	Particular assessment procedures (HS INF TSI)
	1	2
Minimum radius of curvature (4.2.6)	X	
Track cant (4.2.7)	X	
Cant deficiency (4.2.8)	X	
Equivalent conicity (design value) (4.2.9.2)	n.a.	
Minimum value of mean track gauge (4.2.9.3.1)	n.a.	
Track Geometrical Quality and limits on isolated defects (4.2.10)	n.a.	
Rail inclination (4.2.11)	X	6.2.6.4
Means of locking (4.2.12.1)	X	
Use of swing nose (4.2.12.2)	X	
Geometrical characteristics (4.2.12.3)	n.a	
Track resistance (4.2.13)	X	
Traffic load on structures (4.2.14)	X	
Global track stiffness (4.2.15)	Open point	6.2.6.3
Maximum pressure variations in tunnels (4.2.16)	X	6.2.6.5
Effect of crosswinds (4.2.17)	X	
Electrical characteristics (4.2.18)	X	
Noise and vibrations (4.2.19)	n.a.	
Access to platforms (4.2.20.1)	X	
Usable length of platform (4.2.20.2)	X	
Platform height and distance from the centre of the track (4.2.20.4-5)	X	
Track layout along the platforms (4.2.20.6)	X	
Prevention of electric shock (4.2.20.7)	See HS ENE	
Access for people with reduced mobility (4.2.20.8)	See PRM	
Fire safety and safety in railway tunnels (4.2.21)	See SRT	
Access to or intrusion into line installations (4.2.22)	X	
Lateral space for passengers in the event of detrainment outside of a station (4.2.23)	X	
Length of stabling track (4.2.25.1)	X	
Gradient of stabling track (4.2.25.2)	X	
Radius of curvature (4.2.25.3)	X	
Fixed installations for servicing trains (4.2.26)	X	

Table 4

Assessment of the high speed energy subsystem for the EI demonstration of compliance

Characteristics to be assessed (HS ENE TSI)	Existing line not subject to any EC verification	Particular assessment procedures (HS ENE TSI)
	1	2
Voltage and frequency (4.2.2)	X	
System performance and installed power (4.2.3)	X	
Regenerative braking (4.2.4)	X	
Continuity of power supply (4.2.7)	n.a.	
Overhead contact line overall design, geometry (4.2.9)	X	
Compliance of the overhead contact line system with infrastructure gauge (4.2.10)	X	
Contact wire material (4.2.11)	X	
Contact wire wave propagation speed (4.2.12)	n.a.	
Static contact force (4.2.14)	n.a.	
Mean contact force (4.2.15)	X	
Quality of current collection with mean contact force (4.2.16)	X	4.2.16.2.1, 4.2.16.2.3
Vertical movement of the contact point (4.2.17)	X	
Current capacity of overhead contact line (4.2.18)	X	
Current at standstill (4.2.20)	X	
Phase separation sections (4.2.21)	X	
System separation sections (4.2.22)	X	
Electrical protection coordination arrangements (4.2.23)	X	
Harmonics and dynamic effects (4.2.25)	n.a.	
Power supply in case of danger (4.4.1)	X	
Maintenance — Manufacturer's responsibilities (4.5.1)	n.a.	
Maintenance — Infrastructure Manager's responsibilities (4.5.2)	n.a.	
Protection against electric shock (4.7.1, 4.7.2, 4.7.3)	X	

2.4. *Requirements for independent assessor*

1. An independent assessor selected by the applicant carries out the EI demonstration of compliance of the existing lines. An independent assessor may be an external entity or an internal part of the Infrastructure Manager.

2. With respect to railway infrastructure, the independent assessor possesses:

(a) proper technical training;

(b) a satisfactory knowledge of the requirements relating to the assessment that he carries out and sufficient practice in those checks; and

(c) the ability to draw up EI certificates of demonstration and technical documentations which constitute the formal record of the assessments conducted.

3. An independent assessor as an internal part of the Infrastructure Manager meets the following requirements:

(a) the assessor and its personnel is organisationally identifiable and has reporting methods which ensure their impartiality;

(b) neither the assessor nor its personnel is responsible for the operation or maintenance of the products they assess nor do they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities;

(c) the assessor supplies its services exclusively to the undertaking of which it forms a part.

2.5. *Declaration of demonstration*

1. The EI declaration of demonstration and accompanying documents are dated and signed.

2. That declaration is written in the same language as the technical file and contains the following:

(a) the references to the Procedure demonstrating compliance with Technical Specifications for Interoperability for existing lines;

(b) name and address of the applicant or its authorised representative established within the EU (give trade name and full address; in case of representative, also give the trade name of applicant);

(c) a brief description of the subsystem;

(d) name and address of independent assessor which conducted the EI demonstration of compliance;

(e) the references of the documents contained in the technical file;

(f) all the relevant temporary or definitive provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions;

(g) if temporary, duration of validity of the EI declaration of demonstration;

(h) identity of the signatory.

2011 SUBSCRIPTION PRICES (excluding VAT, including normal transport charges)

EU Official Journal, L + C series, paper edition only	22 official EU languages	EUR 1 100 per year
EU Official Journal, L + C series, paper + annual DVD	22 official EU languages	EUR 1 200 per year
EU Official Journal, L series, paper edition only	22 official EU languages	EUR 770 per year
EU Official Journal, L + C series, monthly DVD (cumulative)	22 official EU languages	EUR 400 per year
Supplement to the Official Journal (S series), tendering procedures for public contracts, DVD, one edition per week	multilingual: 23 official EU languages	EUR 300 per year
EU Official Journal, C series — recruitment competitions	Language(s) according to competition(s)	EUR 50 per year

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

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

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

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

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

Sales and subscriptions

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

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

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

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

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN