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Price: EUR 3

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⁽¹⁾ Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information on the date of signature of the Protocol setting out the fishing opportunities and the financial contribution provided for by the Fisheries Partnership Agreement between the European Community and the Republic of Kiribati

On 9 November 2012 and 15 January 2013 respectively, the European Union and the Government of the Republic of Kiribati signed the Protocol setting out the fishing opportunities and the financial contribution provided for by the Fisheries Partnership Agreement.

The Protocol accordingly applies provisionally from 16 September 2012 pursuant to Article 15 thereof.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 129/2013

of 14 February 2013

amending Regulation (EC) No 1121/2009 as regards the transitional national aid to be granted to the farmers in 2013 and Regulation (EC) No 1122/2009 as regards the reduction related to the voluntary adjustment of direct payments in 2013

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003⁽¹⁾, and in particular points (c) and (e) of Article 142 thereof,

Whereas:

- (1) In accordance with Article 133a of Regulation (EC) No 73/2009 as inserted by Regulation (EU) No 671/2012 of the European Parliament and of the Council⁽²⁾, certain new Member States may grant a transitional national aid in 2013 under the conditions applicable for the complementary national direct payments. For that reason, Chapter 2 of Title III of Commission Regulation (EC) No 1121/2009 of 29 October 2009 laying down detailed rules for the application of Council Regulation (EC) No 73/2009 as regards the support schemes for farmers provided for in Titles IV and V thereof⁽³⁾ containing implementing rules for complementary national direct payments should be amended in order to take into account this transitional aid.
- (2) Article 10b of Regulation (EC) No 73/2009 as inserted by Regulation (EU) No 671/2012 provides for a voluntary adjustment mechanism of direct payments in respect of 2013. It is therefore appropriate to adapt Article 79(1) of Commission Regulation (EC) No 1122/2009 of 30 November 2009 laying down detailed rules for the implementation of Council Regulation (EC) No 73/2009 as regards cross-compliance, modulation and the integrated administration and control system, under the direct support schemes for farmers provided for that Regulation, as well as for the implementation of Council Regulation (EC) No 1234/2007 as regards cross-compliance under the support scheme provided for the wine sector⁽⁴⁾ accordingly.

- (3) Regulations (EC) No 1121/2009 and (EC) No 1122/2009 should therefore be amended accordingly.

- (4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Direct Payments,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment of Regulation (EC) No 1121/2009

Regulation (EC) No 1121/2009 is amended as follows:

- (1) in Title III, the title of Chapter 2 is replaced by the following:

‘Complementary national direct payments and transitional national aid’;

- (2) Article 91 is replaced by the following:

‘Article 91

Coefficient of reduction

Where in a given sector the complementary national direct payments or the transitional national aid would exceed the maximum level authorised by the Commission in accordance with Article 132(7) or 133a(5) of Regulation (EC) No 73/2009, the rate of complementary national direct payments or transitional national aid of the concerned sector shall be reduced proportionally by application of a coefficient of reduction.’;

- (3) Articles 93, 94 and 95 are replaced by the following:

‘Article 93

Controls

New Member States shall apply appropriate control measures in order to ensure that the conditions for the granting of the complementary national direct payments and the transitional national aid, as set out by the Commission authorisation granted in accordance with Article 132(7) or 133a(5) of Regulation (EC) No 73/2009, are complied with.

⁽¹⁾ OJ L 30, 31.1.2009, p. 16.

⁽²⁾ OJ L 204, 31.7.2012, p. 11.

⁽³⁾ OJ L 316, 2.12.2009, p. 27.

⁽⁴⁾ OJ L 316, 2.12.2009, p. 65.

*Article 94***Annual report**

New Member States shall submit a report providing information on the measures for the implementation of the complementary national direct payments and the transitional national aid before 30 June of the year following their implementation. The report shall cover at least the following:

- (a) any changes in the situation affecting those payments;
- (b) for each of those payments, the numbers of beneficiaries, the total amount of national aid granted, the hectares, the number of animals or other units of payment paid and the rate of the payment where relevant;
- (c) a report on control measures applied in accordance with Article 93.

*Article 95***State aid**

Complementary national direct payments and transitional national aid paid not in conformity with the authorisation granted by the Commission in accordance with Articles 132(7) and 133a(5) of Regulation (EC) No 73/2009 shall be considered as unlawful State aid within the meaning of Council Regulation (EC) No 659/1999 (*).

(*) OJ L 83, 27.3.1999, p. 1.

*Article 2***Amendment of Regulation (EC) No 1122/2009**

In Article 79 of Regulation (EC) No 1122/2009, paragraph 1 is replaced by the following:

‘1. Reductions due to the modulation provided for in Articles 7 and 10 of Regulation (EC) No 73/2009 and, as the case may be, in Article 1 of Council Regulation (EC) No 378/2007 (*), and, for 2013, to the voluntary adjustment provided for in Article 10b of Regulation (EC) No 73/2009 as well as the reduction due to the financial discipline provided for in Article 11 of Regulation (EC) No 73/2009 and the reduction provided for in Article 8(1) of that Regulation, shall be applied to the sum of the payments from the different support schemes listed in Annex I to Regulation (EC) No 73/2009 to which each farmer is entitled to, in accordance with the procedure provided for in Article 78 of this Regulation.

(*) OJ L 95, 5.4.2007, p. 1.

*Article 3***Entry into force**

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

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

Done at Brussels, 14 February 2013.

For the Commission

The President

José Manuel BARROSO

COMMISSION IMPLEMENTING REGULATION (EU) No 130/2013**of 14 February 2013****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multi-lateral trade negotiations, the criteria whereby the

Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 14 February 2013.

*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	IL	88,5
	MA	51,7
	TN	92,5
	TR	105,5
	ZZ	84,6
0707 00 05	EG	158,2
	MA	176,1
	TR	176,7
	ZZ	170,3
0709 91 00	EG	91,5
	ZZ	91,5
0709 93 10	MA	51,2
	TR	125,6
	ZZ	88,4
0805 10 20	EG	51,8
	IL	65,4
	MA	62,1
	TN	51,5
	TR	62,8
	ZZ	58,7
0805 20 10	IL	129,5
	MA	104,7
	ZZ	117,1
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	130,8
	KR	135,8
	MA	119,3
	TR	76,0
	ZA	148,7
	ZZ	122,1
0805 50 10	EG	83,9
	MA	60,5
	TR	75,6
	ZZ	73,3
0808 10 80	CN	83,9
	MK	28,7
	US	189,2
	ZZ	100,6
0808 30 90	AR	150,6
	CL	153,9
	CN	36,6
	TR	172,1
	US	140,7
	ZA	110,5
	ZZ	127,4

⁽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'.

DIRECTIVES

COMMISSION DIRECTIVE 2013/3/EU

of 14 February 2013

amending Directive 98/8/EC of the European Parliament and of the Council to extend the inclusion in Annex I thereto of the active substance thiamethoxam to product-type 18

(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 thiamethoxam.
- (2) Commission Directive 2008/77/EC of 25 July 2008 amending Directive 98/8/EC of the European Parliament and of the Council to include thiamethoxam as an active substance in Annex I thereto⁽³⁾ included thiamethoxam as an active substance in Annex I to Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to Directive 98/8/EC.
- (3) Pursuant to Regulation (EC) No 1451/2007, thiamethoxam has now 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.
- (4) Spain was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 2 March 2009 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

- (5) 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 21 September 2012, in an assessment report.
- (6) It appears from the evaluations that biocidal products used as insecticides, acaricides and products to control other arthropods and containing thiamethoxam may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to extend the inclusion of thiamethoxam in Annex I to that Directive to product-type 18.
- (7) Not all potential uses have been evaluated at Union level. For example, neither outdoor use, nor use by non-professional users were assessed. 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.
- (8) In the light of the unacceptable risks identified for professional users in the brushing application scenario, 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.
- (9) In the light of the risks identified for the aquatic and terrestrial ecosystems when products were emitted via a sewage treatment plant or directly to surface water, 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.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

⁽³⁾ OJ L 198, 26.7.2008, p. 41.

- (10) In the light of the risks identified in several scenarios of use without personal protective equipment, it is appropriate to require that products authorised for professional use be used with such 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.
- (11) In the light of the possible indirect human exposure via consumption of food as a result of those uses presented in the assessment report, it is appropriate to require, where relevant, verification of the need to set new or to amend existing maximum residue levels in accordance with 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⁽¹⁾ or with 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.
- (12) In view of the risks identified for the environment, it is appropriate to require that product authorisations are subject to appropriate risk mitigation measures for the protection of honey bees.
- (13) The provisions of this Directive should be applied simultaneously in all Member States in order to ensure equal treatment on the Union market of biocidal products containing the active substance thiamethoxam and also to facilitate the proper operation of the biocidal products market in general.
- (14) 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.
- (15) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.
- (16) Directive 98/8/EC should therefore be amended accordingly.
- (17) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents⁽³⁾, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.
- (18) 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 31 January 2014 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.
- They shall apply those provisions from 1 February 2015.
- 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 twentieth day following that of its publication in the *Official Journal of the European Union*.
- Article 4*
- This Directive is addressed to the Member States.
- Done at Brussels, 14 February 2013.
- 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.

⁽³⁾ OJ C 369, 17.12.2011, p. 14.

ANNEX

In Annex I to Directive 98/8/EC, the following is added to entry No 14:

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
			'980 g/kg	1 February 2015	31 January 2017	31 January 2025	18	The Union level risk assessment did not address all potential uses; certain uses, such as outdoor application and use by non-professionals, were excluded. 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 application by brushing, 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 products containing thiamethoxam 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) in accordance with 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. Products applied in such a way that emission via a sewage treatment plant or directly to surface water 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.

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
								Member States shall ensure that authorisations are subject to the following conditions: (1) 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. (2) Where appropriate, measures shall be taken to protect honey bees.'

(*) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.

(**) For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 4(1) within 60 days of the granting of the first authorisation, the deadline for compliance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to 30 days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(4).

(***) 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 2013/4/EU**of 14 February 2013****amending Directive 98/8/EC of the European Parliament and of the Council to include Didecyldimethylammonium Chloride 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 Didecyldimethylammonium Chloride.
- (2) Pursuant to Regulation (EC) No 1451/2007, Didecyldimethylammonium Chloride has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product type 8, wood preservatives, as defined in Annex V to that Directive.
- (3) Italy was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 14 August 2007 in accordance with Article 10(5) and (7) 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 21 September 2012, in an assessment report.
- (5) It appears from the evaluations that biocidal products used as wood preservatives and containing Didecyldimethylammonium Chloride may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include Didecyldimethylammonium Chloride for use in product type 8 in Annex I to that Directive.

- (6) Not all potential uses and exposure scenarios have been evaluated at Union level. For example, neither use by non-professionals, nor exposure of food or feeding stuff was assessed. 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) In view of the risks identified for human health, it is appropriate to require that safe operational procedures are established, that products are used with appropriate personal protective equipment, and that products are not applied on wood with which children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.
- (8) In view of the risks identified for the environment, it is appropriate to require that industrial or professional application is conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber is stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of products used as wood preservatives and containing Didecyldimethylammonium Chloride are collected for reuse or disposal.
- (9) Unacceptable risks for the environment were identified for situations where wood treated with Didecyldimethylammonium Chloride was continually exposed to the weather or subject to frequent wetting (use class 3 as defined by OECD ⁽³⁾), was used for outdoor constructions near or above water (the 'bridge' scenario in use class 3, as defined by OECD ⁽⁴⁾) or was in contact with fresh water (use class 4b as defined by OECD ⁽⁵⁾). It is therefore appropriate to require that products are not authorised for the treatment of wood intended for those uses, unless data is 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.
- (10) The provisions of this Directive should be applied simultaneously in all Member States in order to ensure equal treatment on the Union market of biocidal products of

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.

⁽²⁾ OJ L 325, 11.12.2007, p. 3.

⁽³⁾ OECD series on emission scenario documents, Number 2, Emission Scenario Document for Wood Preservatives, part 2, p. 64.

⁽⁴⁾ Ibid.

⁽⁵⁾ Ibid.

product type 8 containing the active substance Didecyldimethylammonium Chloride 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)(iii) 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) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents⁽⁶⁾, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.
- (15) 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 31 January 2014 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2015.

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 twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 February 2013.

For the Commission

The President

José Manuel BARROSO

⁽⁶⁾ OJ C 369, 17.12.2011, p. 14.

ANNEX

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

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
'61	Didecyl-dimethylammonium Chloride; DDAC	N,N-Didecyl-N,N-dimethylammonium Chloride EC No: 230-525-2 CAS No: 7173-51-5	Dry weight: 870 g/kg	1 February 2015	31 January 2017	31 January 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. 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. Member States shall ensure that authorisations are subject to the following conditions: (1) For industrial or professional users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means. (2) Products shall not be used for treatment of wood with which children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level. (3) Labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
								(4) Products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, continually exposed to the weather or subject to frequent wetting, unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate mitigation measures.'

(*) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.

(**) For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 4(1) within 60 days of the granting of the first authorisation, the deadline for compliance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to 30 days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(4).

(***) 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 2013/5/EU**of 14 February 2013****amending Directive 98/8/EC of the European Parliament and of the Council to include pyriproxyfen 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 pyriproxyfen.
- (2) Pursuant to Regulation (EC) No 1451/2007, pyriproxyfen 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) The Netherlands were designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 2 October 2009 in accordance with Article 10(5) and (7) 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 21 September 2012, 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 pyriproxyfen may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include pyriproxyfen for use in product type 18 in Annex I to that Directive.

(6) Not all potential uses and exposure scenarios have been evaluated at Union level, which, in particular, included only professional use. 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) In the light of the findings in the assessment report that there is a 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 in accordance with 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 with 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.

(8) In view of the assumptions made during the risk assessment, it is appropriate to require that products authorised for professionals are used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to workers and operators can be reduced to an acceptable level.

(9) In view of the risks identified for the environment, it is appropriate to require that products are not authorised for direct use on surface water, unless it can be demonstrated in the application for product authorisation that risks to the aquatic and terrestrial ecosystems and groundwater can be reduced to an acceptable level, and that any authorisation of products intended to be used in waste treatment facilities is subject to appropriate risk mitigation measures to avoid contamination of the area outside the waste treatment site.

⁽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 simultaneously in all Member States in order to ensure equal treatment on the Union market of biocidal products of product-type 18 containing the active substance pyriproxyfen 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) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents⁽¹⁾, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.
- (15) 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 31 January 2014 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2015.

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 twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 February 2013.

For the Commission
The President

José Manuel BARROSO

⁽¹⁾ OJ C 369, 17.12.2011, p. 14.

ANNEX

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

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
'62	pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether EC No: 429-800-1 CAS No: 95737-68-1	970 g/kg	1 February 2015	31 January 2017	31 January 2025	18	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals, were excluded. 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 products containing pyriproxyfen 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) in accordance with 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. Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for professionals shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means. (2) Products shall not be authorised for direct use on surface water, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
								(3) Products intended to be used in waste treatment facilities shall be subject to appropriate risk mitigation measures to avoid contamination of the area outside the waste treatment site.'

(*) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.

(**) For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 4(1) within 60 days of the granting of the first authorisation, the deadline for compliance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to 30 days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(4).

(***) 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

COMMISSION IMPLEMENTING DECISION

of 13 February 2013

on the approval by the Commission of national plans for the implementation of the validation systems in accordance with Article 109(8) of Council Regulation (EC) No 1224/2009

(notified under document C(2013) 651)

(Only the Bulgarian, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Slovenian, Spanish and Swedish texts are authentic)

(2013/82/EU)

THE EUROPEAN COMMISSION,

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

Having regard to the Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Community control system for ensuring compliance with the rules of the common fisheries policy, amending Regulations (EC) No 847/96, (EC) No 2371/2002, (EC) No 811/2004, (EC) No 768/2005, (EC) No 2115/2005, (EC) No 2166/2005, (EC) No 388/2006, (EC) No 509/2007, (EC) No 676/2007, (EC) No 1098/2007, (EC) No 1300/2008, (EC) No 1342/2008 and repealing Regulations (EEC) No 2847/93, (EC) No 1627/94 and (EC) No 1966/2006 ⁽¹⁾, and in particular Article 109(8) thereof,

Having regard to the submission of national plans for the implementation of the validation systems by Member States,

Whereas:

- (1) Pursuant to Article 109(8) of Regulation (EC) No 1224/2009 Member States shall establish a national plan for the implementation of the validation system, allowing Member States to make priorities for the validation and cross-checks and subsequent follow up on inconsistencies based on risk management.
- (2) National plans of the Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Republic of Finland, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland have been submitted to the Commission for approval. They are in line with Article 109 of Regulation (EC) No 1224/2009 and Articles 143 to 145 of Commission

Implementing Regulation (EU) No 404/2011 of 8 April 2011 laying down detailed rules for the implementation of Council Regulation (EC) No 1224/2009 establishing a Community control system for ensuring compliance with the rules of the Common Fisheries Policy ⁽²⁾. They should therefore be approved.

- (3) This Decision constitutes the approval decision within the meaning of Article 109(8) of Regulation (EC) No 1224/2009.
- (4) The Commission will monitor the application of the national plans with respect to their effective operation. If, on the basis of the findings of the verifications, inspections and audits carried out by the Commission within the framework of Title X of Regulation (EC) No 1224/2009, amendments to the national validation plans will be deemed necessary, the Member States should amend the plan accordingly,

HAS ADOPTED THIS DECISION:

Article 1

1. The national plans according to Article 109(8) of Regulation (EC) No 1224/2009 of the Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Republic of Finland, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland for the implementation of the validation system are approved.

2. If, on the basis of the findings of the verifications, inspections and audits carried out within the framework of Title X of Regulation (EC) No 1224/2009, the Commission considers that the validation plans approved in accordance with paragraph 1 do not ensure effective implementation by

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

⁽²⁾ OJ L 112, 30.4.2011, p. 1.

Member States of the obligations laid down in Article 109 of Regulation (EC) No 1224/2009, it may, after having consulted the Member States concerned, request the amendment of the plans.

3. Member States shall amend their validation plans in accordance with the request of the Commission pursuant to paragraph 2.

Article 2

This Decision is addressed to the Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the Federal Republic of Germany, the Republic of Estonia, Ireland, the Kingdom of Spain, the French Republic, the Italian Republic, the Republic of Cyprus, the Republic of Latvia, the Republic of

Lithuania, the Republic of Malta, the Kingdom of the Netherlands, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Republic of Finland, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 13 February 2013.

For the Commission
Maria DAMANAKI
Member of the Commission

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