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Subject:	Commission Directive ../.../EU of XXX 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

Delegations will find attached Commission document D022401/02.

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EUROPEAN COMMISSION

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COMMISSION DIRECTIVE ../…/EU

of XXX

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)

COMMISSION DIRECTIVE ../…/EU

of XXX

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.

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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.

(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.

(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[4] 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

[4] OJ L 152, 16.6.2009, p. 11.

plant and animal origin and amending Council Directive 91/414/EEC[5]. 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 Member States and the Commission on explanatory documents of 28 September 2011[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.

(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.

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5 OJ L 70, 16.3.2005, p. 1.
6 OJ C 369, 17.12.2011, p. 14.

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,

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following is added to entry n° 14:

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 (*)
			"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.

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 (*)
								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. Member States shall ensure that authorisations are subject to the following conditions:

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 (*)
								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."

(*) 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