



**COUNCIL OF
THE EUROPEAN UNION**

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Subject: Commission Directive ../.../EU of XXX amending Directive 98/8/EC of the European Parliament and of the Council to include hydrogen cyanide as an active substance in Annex I thereto

Delegations will find attached Commission document D020516/02.

Encl.: D020516/02



EUROPEAN COMMISSION

Brussels, **XXX**
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[...] (2012) **XXX** draft

COMMISSION DIRECTIVE/.../EU

of **XXX**

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

(Text with EEA relevance)

COMMISSION DIRECTIVE ../.../EU

of **XXX**

amending Directive 98/8/EC of the European Parliament and of the Council to include hydrogen cyanide 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 market¹, 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 market² 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 hydrogen cyanide.
- (2) Pursuant to Regulation (EC) No 1451/2007, hydrogen cyanide has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in the following product types, as defined in Annex V to that Directive: product-type 8, wood preservatives, product-type 14, rodenticides, and product type 18, insecticides, acaricides and products to control other arthropods.
- (3) The Czech Republic was designated as Rapporteur Member State and submitted three competent authority reports, including recommendations, to the Commission on 24 January 2008 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.
- (4) The competent authority reports were 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 25 May 2012, in three assessment reports.

¹ OJ L 123, 24.4.1998, p. 1.

² OJ L 325, 11.12.2007, p. 3.

- (5) It appears from the evaluations that biocidal products used as wood preservatives, rodenticides, insecticides, acaricides and products to control other arthropods and containing hydrogen cyanide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include hydrogen cyanide in Annex I to that Directive.
- (6) Not all potential uses have been evaluated at Union level. 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 highly toxic and flammable properties of the active substance and the assumptions made during the risk assessment, it is appropriate to require that products are only authorised for use by professionals adequately trained to use them and that safe operational procedures during fumigation and venting are established for operators and bystanders, including the following requirements: Products shall be used with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing; re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and by-standers by ventilation; exposure during and after ventilation shall be prevented from exceeding safe levels for operators and by-standers by the establishment of a supervised exclusion zone; prior to fumigation, any food and any porous material with a potential to absorb the active substance, except wood intended to be treated, shall either be removed from the space to be fumigated or protected from absorption by adequate means, and the space to be fumigated shall be protected against accidental ignition.
- (8) 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-types 8, 14 and 18 containing the active substance hydrogen cyanide 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) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011³, Member States have

³ OJ C 369, 17.12.2011, p. 14.

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.

- (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 2013 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 October 2014.

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 entry is added:

No	Comm on 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 (*)
"(**) [OPOCE: please insert substance number]	hydrogen cyanide	hydrogen cyanide EC No: 200-821-6 CAS No: 74-90-8	976 g/kg	1 October 2014	30 September 2016	30 September 2024	8, 14 and 18	<p>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</p> <p>Member States shall ensure that authorisations of products for use as a fumigant are subject to the following conditions:</p> <p>(1) product shall only be supplied to and used by professionals adequately trained to use them;</p>

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								<p>(2) safe operational procedures during fumigation and venting shall be established for operators and bystanders,</p> <p>(3) products shall be used with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing;</p> <p>(4) re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and by-standers by ventilation;</p> <p>(5) exposure during and after ventilation shall be prevented from exceeding safe levels for operators and by-standers by the establishment of a supervised exclusion zone;</p>

No	Comm on Name	IUPAC Name Identificat ion 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 (*)
								(6) prior to fumigation, any food and any porous material with a potential to absorb the active substance, except wood intended to be treated, shall either be removed from the space to be fumigated or protected from absorption by adequate means, and the space to be fumigated shall be protected against accidental ignition."

(*) 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>