

## COMMISSION DIRECTIVE 2010/9/EU

of 9 February 2010

**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 aluminium phosphide releasing phosphine to product type 18 as defined in Annex V 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 <sup>(1)</sup>, 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 <sup>(2)</sup> 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 aluminium phosphide.
- (2) Commission Directive 2009/95/EC of 31 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include aluminium phosphide releasing phosphine as an active substance in Annex I thereto <sup>(3)</sup> included aluminium phosphide as an active substance in Annex I to Directive 98/8/EC for use in product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.
- (3) Pursuant to Regulation (EC) No 1451/2007, aluminium phosphide has now been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, as defined in Annex V to that Directive.
- (4) Germany was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 26 October 2007 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 17 September 2009, in an assessment report.

- (6) It appears from the examinations made that biocidal products used as insecticides and containing aluminium phosphide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include aluminium phosphide in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as insecticides and containing aluminium phosphide can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.
- (7) Not all potential uses have been evaluated at the Union level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to the compartments and populations 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. In particular, where relevant, Member States should assess outdoor use, which has not been addressed in the Union level risk assessment.
- (8) In the light of the conclusions of the assessment report, it is appropriate to require that products containing aluminium phosphide and used as insecticides be authorised only for use by trained professionals in accordance with Article 10(2)(i)(e) of Directive 98/8/EC, and that specific risk mitigation measures are applied at product authorisation level to such products. Such measures should be aimed at limiting the risk of exposure of users to aluminium phosphide to an acceptable level.
- (9) 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 <sup>(4)</sup> establishes maximum limits for aluminium phosphide residues which are present in or on food and feed. Pursuant to Article 3(2)(c) of Regulation (EC) No 396/2005, the maximum residue limits apply to any pesticide residues, including those which may arise as a result of use as a biocide. Member

<sup>(1)</sup> OJ L 123, 24.4.1998, p. 1.

<sup>(2)</sup> OJ L 325, 11.12.2007, p. 3.

<sup>(3)</sup> OJ L 201, 1.8.2009, p. 54.

<sup>(4)</sup> OJ L 70, 16.3.2005, p. 1.

States should ensure that adequate residue trials are provided at product authorisation to allow consumer risk assessment. Furthermore, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005.

- (10) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance aluminium phosphide 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 in order to permit Member States and the 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, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 18 containing aluminium phosphide to ensure that they comply with 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 31 January 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2012.

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, 9 February 2010.

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX

The following is added to entry 'No 20' in Annex I to Directive 98/8/EC:

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 (*)
			'830 g/kg	1 February 2012	31 January 2014	31 January 2022	18	<p>When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the Union level risk assessment. In particular, where relevant, Member States shall assess outdoor use.</p> <p>When granting product authorisation, Member States shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks.</p> <p>Member States shall ensure that authorisations are subject to the following conditions:</p> <ol style="list-style-type: none"> <li>1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products.</li> <li>2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas.</li> </ol>

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 (*)
								3. For products containing aluminium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Article 18 of Regulation (EC) No 396/2005 of the European Parliament and of the Council (OJ L 70, 16.3.2005, p. 1).'

(\*) 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>