# COMMISSION DIRECTIVE 2011/67/EU

## of 1 July 2011

## amending Directive 98/8/EC of the European Parliament and of the Council to include abamectin 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 abamectin.

(2) Pursuant to Regulation (EC) No 1451/2007, abamectin 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 was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 19 June 2009 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 18 February 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 abamectin may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include abamectin 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 sediment when products are used with a certain application rate and 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 findings of the assessment report, it is appropriate to require that risk mitigation measures are applied at product authorisation level. In particular, in the light of the possible risks for infants and children, appropriate risk mitigation measures should be taken to minimise the potential exposure of infants and children.

(9) It is important that the provisions of this Directive be applied simultaneously in all Member States in order to ensure equal treatment of biocidal products on the market containing the active substance abamectin and also to facilitate the proper operation of the biocidal products market 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.

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

(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*

**Transposition**

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

They shall apply those provisions from 1 July 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, 1 July 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 (*) |
|---|---|---|---|---|---|---|---|---|
| '43 | Abamectin | Abamectin is a mixture of avermectin $B_{1a}$ and avermectin $B_{1b}$<br><br>*Abamectin:*<br><br>IUPAC name: n.a.<br><br>EC No: n.a.<br><br>CAS No: 71751-41-2<br><br>*Avermectin $B_{1a}$:*<br><br>IUPAC name: (10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-6'-[(S)-secbutyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.$1^{4,8}$.$0^{20,24}$]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabinohex-opyranoside<br><br>EC No: 265-610-3<br><br>CAS No: 65195-55-3<br><br>*Avermectin $B_{1b}$:*<br><br>IUPAC name: (10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatet-racyclo[15.6.1.$1^{4,8}$.$0^{20,24}$]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl | The active substance shall comply with all the following purities:<br><br>*Abamectin:*<br><br>minimum 900 g/kg<br><br>*Avermectin $B_{1a}$:*<br><br>minimum 830 g/kg<br><br>*Avermectin $B_{1b}$:*<br><br>maximum 80 g/kg | 1 July 2013 | 30 June 2015 | 30 June 2023 | 18 | 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 human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.<br><br>Products applied in such a way that emission to a sewage treatment plant cannot be prevented shall not be authorised for those application rates 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.<br><br>Authorisations shall be subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children.' |

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|---|---|---|---|---|---|---|---|---|
| | | 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabinohexopyranoside<br><br>EC No: 265-611-9<br><br>CAS No: 65195-56-4 | | | | | | |

(*) 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