COMMISSION DIRECTIVE 2011/79/EU

of 20 September 2011

amending Directive 98/8/EC of the European Parliament and of the Council to include fipronil 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 fipronil for use in product-type 18, insecticides, acaricides and products to control other arthropods, as defined in Annex V to the Directive.

(2) Pursuant to Regulation (EC) No 1451/2007, fipronil has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18.

(3) France was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007 on 6 February 2009.

(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 6 May 2011, in an assessment report.

(5) It appears from the evaluations that biocidal products used as insecticides and containing fipronil may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include fipronil in Annex I to that Directive.

(6) Not all potential uses have been evaluated in the Union level assessment, which only addressed professional use indoors by application in locations normally inaccessible to man and domestic animals after application. 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) The provisions of this Directive should be applied at the same time in all Member States in order to ensure equal treatment on the Union market of biocidal products containing the active substance fipronil, and also to facilitate the proper operation of the biocidal products market in general.

(8) 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.

(9) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC.

(10) Directive 98/8/EC should therefore be amended accordingly.

(11) 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.

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

Article 2

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

They shall apply those provisions from 1 October 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, 20 September 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 (*)
'47	fipronil	(±)-5-amino-1-(2,6-dichloro-α,α,α,-trifluoro-p-tolyl)-4-trifluoromethylsulfinylpyrazole-3-carbonitrile (1:1) EC No: 424-610-5 CAS No: 120068-37-3	950 g/kg	1 October 2013	30 September 2015	30 September 2023	18	Only professional use indoors by application in locations normally inaccessible after application to man and domestic animals has been addressed in the Union level risk assessment. 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 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