DIRECTIVES

COMMISSION DIRECTIVE 2012/20/EU

of 6 July 2012

amending Directive 98/8/EC of the European Parliament and of the Council to include flufenoxuron as an active substance for product-type 8 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 flufenoxuron.

(2) Pursuant to Regulation (EC) No 1451/2007, flufenoxuron has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to that Directive.

(3) France was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 17 March 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 22 September 2011, in an assessment report.

(5) It appears from the evaluations that biocidal products used as wood preservatives and containing flufenoxuron may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. Therefore, and notwithstanding the fact that flufenoxuron has not been approved in certain other areas for which the use specific risk assessments gave a different result [3], it is appropriate to include flufenoxuron for use in product-type 8 in Annex I to that Directive.

(6) In view of its characteristics, which render it persistent, liable to bioaccumulate and toxic (PBT), as well as very persistent and very liable to bioaccumulate (vPvB), in accordance with the criteria laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [4], flufenoxuron should be included in Annex I for three years only and should be made subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in Annex I is renewed.

(7) The Union level risk assessment of flufenoxuron used in wood preservatives only addressed treatment of wood intended to be used indoors (use classes 1 and 2 as defined by OECD [5]) or outdoors not covered and not in contact with the ground and continually exposed to the weather, protected from the weather but subject to frequent wetting or in contact with fresh water (use class

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.
[3] Commission Implementing Regulation (EU) No 942/2011 of 22 September 2011 concerning the non-approval of the active substance flufenoxuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Decision 2008/934/EC (OJ L 246, 23.9.2011, p. 13); Commission Decision 2012/77/EU of 9 February 2012 concerning the non-inclusion of flufenoxuron for product type 18 in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 38, 11.2.2012, p. 47).
[4] OJ L 396, 30.12.2006, p. 1.
[5] OECD series on emission scenario documents, Number 2, Emission Scenario Document for Wood Preservatives, part 2, p. 64.

3 as defined by OECD [6]), which will not be used in animal housing or come into contact with food or feed. Unacceptable risks for the environment were identified for the *in situ* treatment of wood outdoors, as well as in various scenarios for outdoor use of treated wood. In view of the characteristics of flufenoxuron, it is appropriate to authorise only those uses and exposure scenarios that have been representatively addressed in the Union level risk assessment, and for which no unacceptable risk was found.

(8) In view of the risks identified for human health for industrial and professional use it is appropriate to require that safe operational procedures be established for products authorised for such use, and that those products be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means.

(9) In view of the risks identified for the aquatic and terrestrial compartments, it is appropriate to require that appropriate risk mitigation measures be taken to protect those compartments, in particular that freshly treated timber be stored after treatment under shelter or on impermeable hard standing, or both, and that any losses from the application of products used as wood preservatives and containing flufenoxuron be collected for reuse or disposal.

(10) 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 of product-type 8 containing the active substance flufenoxuron 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 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.

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

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

(14) The Committee established by Article 28(1) of Directive 98/8/EC has not delivered an opinion on the measures provided for in this Directive, and the Commission therefore submitted to the Council a proposal relating to the measures and forwarded it to the European Parliament. The Council did not act within the two-month period provided for by Article 5a of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [7]), and the Commission therefore submitted the proposal to the European Parliament without delay. The European Parliament did not oppose the measure within four months from the abovementioned forwarding,

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

They shall apply those provisions from 1 February 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, 6 July 2012.

For the Commission

The President

José Manuel BARROSO

[6]) Ibid.

[7]) OJ L 184, 17.7.1999, p. 23.

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 (*)
'57	flufenoxuron	1-[4-(2-chloro-alpha,alpha, alpha-trifluoro-para-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea EC No: 417-680-3 CAS No: 101463-69-8	960 g/kg	1 February 2014	31 January 2016	31 January 2017	8	Flufenoxuron shall be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. The Union level risk assessment addressed treatment of wood which will not be used in animal housing or come into contact with food or feed. Products shall not be authorised for uses or exposure scenarios that have not been representatively addressed in the Union level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: (1) Products shall only be used for treatment of wood intended for indoor use. (2) For products authorised for industrial or professional use safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means.

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) Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of authorised products shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.'

(*) 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