

DIRECTIVES

COMMISSION DIRECTIVE 2013/6/EU

of 20 February 2013

amending Directive 98/8/EC of the European Parliament and of the Council to include diflubenzuron 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 N-[[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide, which is a synonym for diflubenzuron.
- (2) Pursuant to Regulation (EC) No 1451/2007, diflubenzuron 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) Sweden was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 19 November 2007 in accordance with Article 10(5) and (7) of Commission Regulation (EC) No 2032/2003 of 4 November 2003 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, and amending Regulation (EC) No 1896/2000⁽³⁾.
- (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 21 September 2012, 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 diflubenzuron may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include diflubenzuron for use in product-type 18 in Annex I to that Directive.
- (6) Not all potential uses and exposure scenarios have been evaluated at Union level. For example, outdoor use, use by non-professionals, and exposure of livestock were not assessed. 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 the light of the findings in the assessment report that there is a possible indirect human exposure via consumption of food as a result of those uses represented in the assessment, it is appropriate to require, where relevant, verification of the need to set new or to amend existing maximum residue levels in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council⁽⁴⁾ or with 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⁽⁵⁾. Special consideration should be given to the *in vivo* genotoxic metabolite PCA. Measures should be adopted ensuring that the applicable maximum residue levels are not exceeded.

⁽¹⁾ OJ L 123, 24.4.1998, p. 1.⁽²⁾ OJ L 325, 11.12.2007, p. 3.⁽³⁾ OJ L 307, 24.11.2003, p. 1.⁽⁴⁾ OJ L 152, 16.6.2009, p. 11.⁽⁵⁾ OJ L 70, 16.3.2005, p. 1.

- (8) In view of the assumptions made during the risk assessment, it is appropriate to require that professional users of products containing diflubenzuron wear appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to workers and operators can be reduced to an acceptable level.
- (9) In view of the risks identified for the environment, it is appropriate to require, unless it can be demonstrated in the application for product authorisation that risks to the aquatic and terrestrial ecosystems can be reduced to an acceptable level, that products are not authorised in water systems, and that products authorised for use on manure are only used on dry manure, which has to undergo complete aerobic composting prior to application of the manure on arable land.
- (10) 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-type 18 containing the active substance diflubenzuron 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) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents⁽¹⁾, Member States have 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.

- (15) 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 2014 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 February 2015.

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, 20 February 2013.

For the Commission
The President

José Manuel BARROSO

⁽¹⁾ OJ C 369, 17.12.2011, p. 14.

ANNEX

In Annex I to Directive 98/8/EC, the following entry is added:

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
'63	diflubenzuron	1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea EC No: 252-529-3 CAS No: 35367-38-5	960 g/kg	1 February 2015	31 January 2017	31 January 2025	18	<p>The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use, use by non-professionals, and exposure of livestock were excluded. 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>For products containing diflubenzuron that may lead to residues in food or feed, Member States shall verify the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, with special consideration to the <i>in vivo</i> genotoxic metabolite PCA, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.</p> <p>Member States shall ensure that authorisations are subject to the following conditions unless it can be demonstrated in the application for product authorisation that the risks can be reduced to an acceptable level:</p> <p>(1) Professional users shall wear appropriate personal protective equipment.</p>

No	Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (*)	Date of inclusion	Deadline for compliance with Article 16(3), unless one of the exceptions indicated in the footnote to this heading applies (**)	Expiry date of inclusion	Product type	Specific provisions (***)
								<p>(2) Product information shall include the requirement that products shall only be used on dry manure, and that the manure must undergo complete aerobic composting by professionals prior to application on arable land.</p> <p>(3) Products shall not be used in water systems.'</p>

(*) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 11. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated substance.

(**) For products containing more than one active substance covered by Article 16(2), the deadline for compliance with Article 16(3) is that of the last of its active substances to be included in this Annex. For products for which the first authorisation has been granted later than 120 days before the deadline for compliance with Article 16(3) and a complete application has been submitted for mutual recognition in accordance with Article 4(1) within 60 days of the granting of the first authorisation, the deadline for compliance with Article 16(3) in relation to that application is extended to 120 days after the date of reception of the complete application for mutual recognition. For products for which a Member State has proposed to derogate from mutual recognition in accordance with Article 4(4), the deadline for compliance with Article 16(3) is extended to 30 days after the date of the Commission Decision adopted in accordance with the second subparagraph of Article 4(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>