COMMISSION DIRECTIVE 2011/69/EU

of 1 July 2011

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

(2) Pursuant to Regulation (EC) No 1451/2007, imidacloprid 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) Germany was designated as rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 15 September 2008 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 16 December 2010, 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 imidacloprid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include imidacloprid 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 view of the risks identified for the aquatic compartment, it is appropriate to require that products are not authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented, unless data is 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 risk for non-professionals, appropriate risk mitigation measures should be taken to minimise the potential exposure of infants and children.

(9) In the light of the findings relating to possible indirect human exposure via consumption of food, it is appropriate to require, where relevant, verification of the need to set new or amended existing maximum residue levels (MRLs) according to 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 [3] or 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 [4]. Measures should be adopted ensuring that the applicable MRLs are not exceeded.

[1] OJ L 123, 24.4.1998, p. 1.
[2] OJ L 325, 11.12.2007, p. 3.
[3] OJ L 152, 16.6.2009, p. 11.
[4] OJ L 70, 16.3.2005, p. 1.

(10) 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 imidacloprid 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 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 (*)
'42	imidacloprid	(2E)-1-[(6-chloropyridin-3-yl) methyl]-N-nitroimidazolidin-2-imine EC No: 428-040-8 CAS No: 138261-41-3	970 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. Products shall not be authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented, unless data is 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. 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. For products containing imidacloprid that may lead to residues in food or feed, Member States shall verify the need to set new or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.'

(*) 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