COMMISSION DIRECTIVE 2010/72/EU

of 4 November 2010

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

(2) Pursuant to Regulation (EC) No 1451/2007, spinosad 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 were designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 1 April 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 27 May 2010, in an assessment report.

(5) It appears from the examinations made that biocidal products used as insecticides, acaricides or to control other arthropods and containing spinosad may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include spinosad in Annex I to that Directive.

(6) Not all potential uses have been evaluated at EU level. It is therefore appropriate that Member States assess those uses or exposure scenarios and those risks to the compartments and populations that have not been representatively addressed in the EU 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 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 identified adverse health effects for the unprotected professional user during application by spraying of biocidal products containing spinosad, it is appropriate to require at product authorisation level that products intended for professional use by spraying be used with appropriate personal protective equipment, unless it can be demonstrated that risks for industrial or professional users can be reduced by other means. Furthermore, 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) and adoption of measures ensuring that the applicable MRLs are not exceeded.

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

(9) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the 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.

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

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

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

(12) 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 31 October 2011 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive.

They shall apply those provisions from 1 November 2012.

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, 4 November 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex I to Directive 98/8/EC, the following entry for the substance spinosad 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 (*)
'37	Spinosad	EC No: 434-300-1 CAS No: 168316-95-8 Spinosad is a mixture of 50-95 % spinosyn A and 5-50 % spinosyn D. **Spinosyn A** (2R,3aS,5aR,5bS,9S,13S,14R,16aS,-16bR)-2-[(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,1-6a,16b-tetradecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclo-dodecin-7,15-dione CAS No: 131929-60-7 **Spinosyn D** (2S,3aR,5aS,5bS,9S,13S,14R,16aS,-16bS)-2-[(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,1-6a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione CAS No: 131929-63-0	850 g/kg	1 November 2012	31 October 2014	31 October 2022	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 compartments and populations that have not been representatively addressed in the EU level risk assessment. Member States shall ensure that authorisations are subject to the following conditions: — Authorisations shall be subject to appropriate risk mitigation measures. In particular, products authorised for professional use by spraying shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by others means. — For products containing spinosad that may lead to residues in food or feed, Member States shall verify the need to set new and/or amended existing maximum residue levels (MRLs) according to Regulation (EC) No 470/2009 and/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