DIRECTIVES

COMMISSION DIRECTIVE 2013/44/EU

of 30 July 2013

amending Directive 98/8/EC of the European Parliament and of the Council to include powdered corn cob as an active substance in Annexes I and IA 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 powdered corn cob.

(2) Pursuant to Regulation (EC) No 1451/2007, powdered corn cob has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 14, rodenticides, as defined in Annex V to that Directive.

(3) Greece was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 22 October 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 with the involvement of the applicant. 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) The assessment report concludes that biocidal products used as rodenticides and containing powdered corn cob may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, and therefore recommends the inclusion of powdered corn cob for use in product type 14 in Annex I to that Directive. It is appropriate to follow that recommendation.

(6) The assessment report also concludes that biocidal products used as rodenticides and containing powdered corn cob may be expected to present only low risk to humans, non-target animals and the environment, in particular with regard to the use which was examined and detailed in the assessment report, that is, when used in the form of pellets in dry locations. The report therefore recommends the inclusion of powdered corn cob for that use in Annex IA to Directive 98/8/EC. It is appropriate to follow that recommendation.

(7) In accordance with current practice, and in compliance with Article 10(1) of Directive 98/8/EC, it is appropriate to limit the duration of the inclusion to 10 years.

(8) Not all potential uses and exposure scenarios have been evaluated at Union level. 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.

(9) The provisions adopted pursuant to 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 14 containing the active substance powdered corn cob and also to facilitate the proper operation of the biocidal products market in general.

(10) A reasonable period should be allowed to elapse before an active substance is included in Annex I and Annex IA 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.

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

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

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

(13) 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.

(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 [2], 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

Annexes I and IA to Directive 98/8/EC are 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 forthwith communicate to the Commission the text of those provisions.

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, 30 July 2013.

For the Commission
The President
José Manuel BARROSO

[1] OJ C 369, 17.12.2011, p. 14.
[2] OJ L 184, 17.7.1999, p. 23.

ANNEX

(1) 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 (***)
'67	Powdered corn cob	Not allocated	1 000 g/kg	1 February 2015	31 January 2017	31 January 2025	14	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.'

(*) 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

(2) In Annex IA 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 (*)
'3	Powdered corn cob	Not allocated	1 000 g/kg	1 February 2015	31 January 2017	31 January 2025	14	Member States shall ensure that registrations are subject to the following condition: — Only for use in the form of pellets in dry locations.'

(*) 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