

COMMISSION DIRECTIVE 2009/160/EU

of 17 December 2009

amending Council Directive 91/414/EEC to include 2-phenylphenol as active substance

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 1112/2002 ⁽²⁾ and (EC) No 2229/2004 ⁽³⁾ lay down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes 2-phenylphenol.

(2) For 2-phenylphenol the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 1112/2002 and (EC) No 2229/2004 for a range of uses proposed by the notifier. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 22 of Regulation (EC) No 2229/2004. For 2-phenylphenol the rapporteur Member State was Spain and all relevant information was submitted on 11 February 2008.

(3) The assessment report has been peer reviewed by the Member States and the EFSA and presented to the Commission on 19 December 2008 in the format of the EFSA Scientific Report for 2-phenylphenol ⁽⁴⁾. This report has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 27 November 2009 in the format of the Commission review report for 2-phenylphenol.

(4) It has appeared from the various examinations made that plant protection products containing 2-phenylphenol

may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include 2-phenylphenol in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

(5) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that the inclusion of a substance in Annex I may be subject to conditions. Therefore it is appropriate to require that the notifier submit further information on the potential for skin depigmentation for workers and consumers due to possible exposure to the metabolite 2-phenylhydroquinone (PHQ) on citrus peel. In addition, the notifier should submit further information to confirm that the analytical method applied in residue trials correctly quantifies the residues of 2-phenylphenol, PHQ and their conjugates.

(6) 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 which will result from the inclusion. Since authorisations granted in accordance with the first subparagraph of Article 8(2) of Directive 91/414/EEC for plant protection products containing 2-phenylphenol expire on 31 December 2009 at the latest, this Directive should enter into force no later than 1 January 2010 to avoid a gap with respect to such plant protection products.

(7) Until MRLs have been set in accordance 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⁾, European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners ⁽⁶⁾ continues to apply to 2-phenylphenol. For the sake of clarity and to avoid an overlap, it is therefore necessary that the date of application of this Directive is such that the same date may be set for the application of the MRLs adopted for 2-phenylphenol, pursuant to Regulation (EC) No 396/2005.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 168, 27.6.2002, p. 14.

⁽³⁾ OJ L 379, 24.12.2004, p. 13.

⁽⁴⁾ EFSA Scientific Report (2008) 217, Conclusion regarding the peer review of the pesticide risk assessment of the active substance 2-phenylphenol (finalised 19 December 2008).

⁽⁵⁾ OJ L 70, 16.3.2005, p. 1.

⁽⁶⁾ OJ L 61, 18.3.1995, p. 1.

- (8) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed an appropriate period after inclusion to review existing authorisations of plant protection products containing 2-phenylphenol to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (9) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market⁽¹⁾ has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.
- (10) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 31 December 2010 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

and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 January 2011.

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.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing 2-phenylphenol as active substances by 31 December 2010.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to 2-phenylphenol are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holders of the authorisations have, or have access to, dossiers satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing 2-phenylphenol as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 December 2009 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning 2-phenylphenol. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

- (a) in the case of a product containing 2-phenylphenol as the only active substance, where necessary, amend or withdraw the authorisation by 31 December 2014 at the latest; or
- (b) in the case of a product containing 2-phenylphenol as one of several active substances, where necessary, amend or withdraw the authorisation by 31 December 2014 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 January 2010.

⁽¹⁾ OJ L 366, 15.12.1992, p. 10.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2009.

For the Commission
The President
José Manuel BARROSO

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
305	2-phenylphenol (including its salts such as the sodium salt) CAS No 90-43-7 CIPAC No 246	<i>biphenyl-2-ol</i>	≥ 998 g/kg	1 January 2010	31 December 2019	<p>PART A</p> <p>Only uses as a post-harvest fungicide for indoor use in closed drench chambers may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on 2-phenylphenol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 November 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to put in place appropriate waste management practices to handle the waste solution remaining after application, including the cleaning water of the drenching system. Member States permitting the release of waste water into the sewage system shall ensure that a local risk assessment is carried out.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information on the potential for skin depigmentation for workers and consumers due to possible exposure to the metabolite 2-phenylhydroquinone (PHQ) on citrus peel.</p> <p>They shall ensure that the notifier provides such information to the Commission by 31 December 2011.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information to confirm that the analytical method applied in residue trials correctly quantifies the residues of 2-phenylphenol, PHQ and their conjugates.</p> <p>They shall ensure that the notifier provides such information to the Commission by 31 December 2011.</p>

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.