

**COMMISSION DIRECTIVE 2003/39/EC**  
**of 15 May 2003**  
**amending Council Directive 91/414/EEC to include propineb and propyzamide as active substances**  
**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant-protection products on the market <sup>(1)</sup>, as last amended by Commission Directive 2003/31/EC <sup>(2)</sup>, and in particular Article 6(1) thereof,

Whereas:

- (1) 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 <sup>(3)</sup>, as last amended by Regulation (EC) No 2266/2000 <sup>(4)</sup>, establishes 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 propineb and propyzamide.
- (2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifiers. In accordance with Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant-protection products and designating the rapporteur Member State for the implementation of Commission Regulation (EEC) No 3600/92 <sup>(5)</sup>, as last amended by Regulation (EC) No 2230/95 <sup>(6)</sup>, the following rapporteur Member States were designated, which in turn submitted the relevant assessment reports and recommendations to the Commission in accordance with Article 7(1)(c) of Regulation (EEC) No 3600/92: for propineb: rapporteur Member State Italy, all relevant information was submitted on 17 July 1996; for propyzamide: rapporteur Member State Sweden, all relevant information was submitted on 19 May 1998.
- (3) Those assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health.
- (4) In accordance with Article 6(4) of Directive 91/414/EEC and in view of a possible unfavourable decision for propineb, the Commission organised a tripartite meeting with the main data submitter and the rapporteur

Member State on 4 December 1997. The main data submitter provided further data in order to meet the initial concerns.

- (5) The reviews of all active substances were finalised on 26 February 2003 in the format of the Commission review reports for propineb and propyzamide.
- (6) The review of propyzamide did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.
- (7) The report on propineb and further information were also submitted to the Scientific Committee for Plants for separate consultation. The Scientific Committee was asked to comment on the long-term exposure assessment for birds and on the appropriate animal model to be used for derivation of the acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL). In its opinion <sup>(7)</sup> the Committee identified a number of respects in which the risks from propineb to birds and from propineb and the metabolite PTU to wild mammals have not been adequately addressed and also indicated ways to improve the risk assessment. Additionally, the Committee emphasised the necessity of a clear expression and justification of all end points, data, assumptions and rationales used for risk assessment. The Committee considered that the rat is the appropriate species for the derivation of ADI and AOEL. The recommendations of the Scientific Committee were taken into account during the further review and in this Directive and in the review report. After the missing information was subsequently delivered by the main notifier and evaluated by the rapporteur Member State, the Member States within the Standing Committee concluded that the risk for birds and wild mammals would be acceptable if appropriate risk-mitigation measures are applied.
- (8) It has appeared from the various examinations made that plant-protection products containing propineb or propyzamide may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) 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 these active substances 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.

<sup>(1)</sup> OJ L 230, 19.8.1991, p. 1.

<sup>(2)</sup> OJ L 101, 23.4.2003, p. 3.

<sup>(3)</sup> OJ L 366, 15.12.1992, p. 10.

<sup>(4)</sup> OJ L 259, 13.10.2000, p. 27.

<sup>(5)</sup> OJ L 107, 28.4.1994, p. 8.

<sup>(6)</sup> OJ L 225, 22.9.1995, p. 1.

<sup>(7)</sup> Opinion of the Scientific Committee on Plants on specific questions from the Commission regarding the evaluation of propineb in the context of Council Directive 91/414/EEC (SCP/PROPINEB/002 final adopted 8 November 2001).

- (9) The Commission review report is required for the proper implementation by the Member States, of several sections of the uniform principles laid down in Directive 91/414/EEC. It is, therefore, appropriate to provide that the finalised review report, except for confidential information, should be kept available or made available by the Member States for consultation by any interested parties.
- (10) 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.
- (11) After inclusion, Member States should be allowed a reasonable period within which to implement the provisions of Directive 91/414/EEC as regards plant-protection products containing propineb or propyzamide, and in particular, to review existing authorisations to ensure that the conditions regarding those active substances set out in Annex I to Directive 91/414/EEC are satisfied. A longer period should be provided for the submission and assessment of the complete dossier of each plant-protection product in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (12) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (13) 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 30 September 2004 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 October 2004.

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 review the authorisation for each plant-protection product containing propineb or propyzamide to ensure that the conditions relating to those active substances set out in Annex I to Directive 91/414/EEC are complied with. Where necessary and by 30 September 2004 at the latest, they shall amend or withdraw the authorisation.

2. Member States shall, for each authorised plant-protection product containing propineb or propyzamide 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 March 2004 at the latest, 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. 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. Where necessary and by 31 March 2008 at the latest, they shall amend or withdraw the authorisation.

*Article 4*

This Directive shall enter into force on 1 April 2004.

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 15 May 2003.

*For the Commission*

David BYRNE

*Member of the Commission*

## ANNEX

The following entries shall be added at the end of the table in Annex I to Directive 91/414/EC

No	Common name, identification Nos	IUPAC name	Purity <sup>(1)</sup>	Entry into force	Expiration of inclusion	Specific provisions
54	Propineb CAS No: 12071-83-9 (monomer), 9016-72-2 (homopolymer) CIPAC No: 177	Polymeric zinc 1,2-propylenebis(dithiocarbamate)	The technical active substance should comply with the FAO specification	1 April 2004	31 March 2014	<p>Only uses as fungicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propineb, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2003 shall be taken into account. In this overall assessment:</p> <ul style="list-style-type: none"> <li>— Member States should pay particular attention to the potential for ground water contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions</li> <li>— Member States should pay particular attention to the protection of small mammals, aquatic organisms and non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate</li> <li>— Member States should observe the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels</li> </ul>
55	Propyzamide CAS No: 23950-58-5 CIPAC No: 315	3,5-dichloro-N-(1,1-dimethylprop-2-ynyl)benzamide	920 g/kg	1 April 2004	31 March 2014	<p>Only uses as herbicide may be authorised</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propyzamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health 26 February 2003 shall be taken into account. In this overall assessment, Member States:</p> <ul style="list-style-type: none"> <li>— must pay particular attention to the protection of operators and must ensure that conditions of authorisation include risk mitigation measures, where appropriate</li> <li>— must pay particular attention to the protection of birds and wild mammals in particular if the substance is applied during the breeding season. Conditions of authorisation should include risk mitigation measures, where appropriate</li> </ul>

<sup>(1)</sup> Further details on identity and specification of active substance are provided in the review report.'