

**COMMISSION DIRECTIVE 2003/81/EC**  
**of 5 September 2003**  
**amending Council Directive 91/414/EEC to include molinate, thiram and ziram 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 2003/79/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 molinate, thiram and ziram.
- (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. By 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 molinate the rapporteur Member State was Portugal, and all relevant information was submitted on 30 November 1998. For thiram the Rapporteur Member State was Belgium, and the relevant information was submitted on 15 January 1998. For ziram the rapporteur Member State was Belgium and the relevant information was submitted on 9 June 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) The reviews of all active substances were finalised on 4 July 2003 in the format of the Commission review reports for molinate, thiram and ziram.
- (5) The reviews of molinate, thiram and ziram did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee on Plants.
- (6) It has appeared from the various examinations made that plant protection products containing molinate, thiram or ziram 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 these active substances in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.
- (7) 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.
- (8) 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 molinate, thiram or ziram, 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.
- (9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (10) 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.

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

<sup>(2)</sup> OJ L 205, 14.8.2003, p. 16.

<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.

*Article 2*

Member States shall adopt and publish by 31 January 2005 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 February 2005.

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 molinate, thiram or ziram 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 31 January 2005 at the latest, they shall amend or withdraw the authorisation.

2. Member States shall, for each authorised plant protection product containing molinate, thiram or ziram 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

July 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 July 2008 at the latest, they shall amend or withdraw the authorisation.

*Article 4*

This Directive shall enter into force on 1 August 2004.

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 5 September 2003.

*For the Commission*

David BYRNE

*Member of the Commission*

## The following entries 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 <sup>(1)</sup>	Entry into force	Expiration of inclusion	Specific provisions
72	Molinate CAS No 2212-67-1 CIPAC No 235	S-ethyl azepane-1-carbothioate; S-ethyl perhydroazepine-1-carbothioate; S-ethyl perhydroazepine-1-thiocarboxilate	950 g/kg	1 August 2004	31 July 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 molinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 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 groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation should include risk mitigation measures, where appropriate,</li> <li>— Member States should pay particular attention to the possibility of short-range transport of the active substance in air.</li> </ul>
73	Thiram CAS No 137-26-8 CIPAC No 24	tetramethylthiuram disulfide; bis (dimethylthiocarbamoyl)-disulfide	960 g/kg	1 August 2004	31 July 2014	<p>Only uses as fungicide or as repellent may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on thiram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 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 protection of aquatic organisms. Risk mitigation measures should be applied, where appropriate,</li> <li>— Member States should pay particular attention to the protection of small mammals and birds when the substance is used as a seed treatment in spring uses. Risk mitigation measures should be applied, where appropriate.</li> </ul>
74	Ziram CAS No 137-30-4 CIPAC No 31	Zinc bis (dimethyl-dithiocarbamate)	950 g/kg (FAO-specification) Arsenic: maximum 250 mg/kg Water: maximum 1,5 %	1 August 2004	31 July 2014	<p>Only uses as fungicide or as repellent may be authorised.</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on ziram, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 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 protection of non-target arthropods and aquatic organisms. Risk mitigation measures should be applied, 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>

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