

## DIRECTIVES

## COUNCIL DIRECTIVE 2009/116/EC

of 25 June 2009

**amending Directive 91/414/EEC to include paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 as active substances**

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

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>, and in particular Article 6(1) thereof,

Whereas:

- (1) Article 8(2) of Directive 91/414/EEC provides that a Member State may, during a period of 12 years following the notification of that Directive, authorise the placing on the market of plant protection products containing active substances not listed in Annex I to that Directive that are already on the market 2 years after the date of notification, while those substances are gradually being examined within the framework of a programme of work.
- (2) Commission Regulations (EC) No 1112/2002 <sup>(2)</sup> and (EC) No 2229/2004 <sup>(3)</sup> 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 paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3.
- (3) For paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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 10(1) of Regulation (EC) No 2229/2004. For paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 the rapporteur Member State was Greece and all relevant information was submitted on 6 May 2008.

- (4) 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 paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3. 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 12 April 2009 in the format of the Commission review report for paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3.
- (5) During the evaluation of these active substances, a number of concerns have been identified. In particular, the evidence produced during this evaluation was not sufficient to demonstrate a safe use with respect to operators, workers, bystanders and consumers. Consequently, it was not possible to conclude, on the basis of the information made available at that stage, that paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 met the criteria for inclusion in Annex I to Directive 91/414/EEC.
- (6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substances. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forward by the notifier, the Commission initially found that the concerns identified could not be completely eliminated.

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

<sup>(2)</sup> OJ L 168, 27.6.2002, p. 14.

<sup>(3)</sup> OJ L 379, 24.12.2004, p. 13.

- (7) However, in the light of the information before the Council it appears that the concerns are related to the lack of specifications and should be solved when the purity of the substances is demonstrated. In particular, as stated in the EFSA scientific report if it can be demonstrated that paraffin oils are of high purity (i.e. 100 %) no toxicological concern should be raised. For paraffins, specifications are set by the European Pharmacopoeia. It may be expected that, under the proposed conditions of use, plant protection products containing paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular where they meet such technical specifications. It is therefore appropriate to include paraffin oils in Annex I subject to the submission from the notifiers of confirmatory data to demonstrate the compliance of the substances with such specifications.
- (8) Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate as regards paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 to require that the notifier submits further information on technical specifications of the active substances.
- (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 which will result from the inclusion.
- (10) 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 a period of 6 months after inclusion to review existing authorisations of plant protection products containing paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 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.
- (11) 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 <sup>(1)</sup> 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.

- (12) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (13) In the absence of an opinion of the Standing Committee on the Food Chain and Animal Health, the Commission has been unable to adopt the provisions it envisaged under the procedure laid down in Article 19 of Directive 91/414/EEC.
- (14) In accordance with point 34 of the Interinstitutional agreement on better law-making <sup>(2)</sup>, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures, and to make them public.

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 June 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.

They shall apply those provisions from 1 July 2010.

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.

<sup>(1)</sup> OJ L 366, 15.12.1992, p. 10.

<sup>(2)</sup> OJ C 321, 31.12.2003, p. 1.

*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 paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 as active substances by 30 June 2010.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 are met, with the exception of those identified in part B of the entry concerning those active substances, and that the holder of the authorisation has, or has access to, a dossier 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 paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 either as the only active substances or together with 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 paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in points (b), (c), (d) and (e) of Article 4(1) of Directive 91/414/EEC.

Following that determination Member States shall:

- (a) in the case of a product containing paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 as the only active substances, where necessary, amend or withdraw the authorisation by 30 June 2014 at the latest; or
- (b) in the case of a product containing paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3 together with several active substances, where necessary, amend or withdraw the authorisation by 30 June 2014 or by the date fixed for such an amendment or withdrawal in the 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.

*Article 5*

This Directive is addressed to the Member States.

Done at Luxembourg, 25 June 2009.

*For the Council*  
*The President*  
L. MIKO

## 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 <sup>(1)</sup>	Entry into force	Expiration of inclusion	Specific provisions
	Paraffin oils CAS No 64742-46-7 CAS No 72623-86-0 CAS No 97862-82-3 CIPAC No n.a.	<i>paraffin oil</i>	European Pharmacopoeia 6.0	1 January 2010	31 December 2019	<p>PART A</p> <p>Only uses as insecticide and acaricide 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 paraffin oils CAS No 64742-46-7, CAS No 72623-86-0 and CAS No 97862-82-3, and in particular Appendices I and II thereto shall be taken into account.</p> <p>Conditions of use shall include, where appropriate, risk mitigation measures.</p> <p>The Member States concerned shall request:</p> <ul style="list-style-type: none"> <li>— the submission of the specification of the technical material as commercially manufactured to verify the compliance with purity criteria of European Pharmacopoeia. 6.0.</li> </ul> <p>They shall ensure that the notifiers provides such information to the Commission by 30 June 2010.'</p>

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