

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)

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⁽¹⁾, 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⁽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 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

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

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.
- (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

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

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⁽⁴⁾ 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⁽⁵⁾, 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:

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (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) OJ L 366, 15.12.1992, p. 10.
- (5) OJ C 321, 31.12.2003, p. 1.