

Commission Directive 2009/70/EC of 25 June 2009 amending Council Directive 91/414/EEC to include difenacoum, didecyldimethylammonium chloride and sulphur as active substances (Text with EEA relevance)

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(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⁽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 difenacoum, didecyldimethylammonium chloride and sulphur.
- (2) For those active substances 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 notifiers. 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 difenacoum the rapporteur Member State was Finland and all relevant information was submitted on 16 July 2007. For didecyldimethylammonium chloride the rapporteur Member State was the Netherlands and all relevant information was submitted on 28 November 2007. For sulphur the rapporteur Member State was France and all relevant information was submitted on 18 October 2007.
- (3) The assessment reports have 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 difenacoum⁽⁴⁾, for didecyldimethylammonium chloride⁽⁵⁾ and for sulphur⁽⁶⁾. These reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 26 February 2009 in the format of the Commission review reports for difenacoum, and on 12 March 2009 for didecyldimethylammonium chloride and sulphur.

- (4) It has appeared from the various examinations made that plant protection products containing difenacoum, didecyldimethylammonium chloride and sulphur 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 reports. 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.
- (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 inclusion of a substance in Annex I may be subject to conditions. Therefore, for difenacoum, it is appropriate to require that the notifier submit further information on methods for the determination of residues in body fluids and on the specification of the active substance as manufactured. Moreover, for didecyldimethylammonium chloride it is appropriate to require that the notifier submit further information on the chemical specification and on the risk assessment for aquatic organisms. Finally, it is appropriate for the sulphur to require that the notifier submit further information to confirm the risk assessment for non-target organisms, in particular birds, mammals, sediment-dwelling organisms and non-target arthropods.
- (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.
- (7) 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 six months after inclusion to review existing authorisations of plant protection products containing difenacoum, didecyldimethylammonium chloride and sulphur 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.
- (8) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 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.
- (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.

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 and a correlation table between those provisions and this Directive.

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.

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 difenacoum, didecyldimethylammonium chloride and sulphur 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 difenacoum, didecyldimethylammonium chloride and sulphur 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 difenacoum, didecyldimethylammonium chloride and sulphur 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 difenacoum, didecyldimethylammonium chloride and sulphur. 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 difenacoum, didecyldimethylammonium chloride and sulphur as the only active substance, where necessary, amend or withdraw the authorisation by 30 June 2014 at the latest; or
- b in the case of a product containing difenacoum, didecyldimethylammonium chloride and sulphur as one of 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 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.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 25 June 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

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 ^a	Entry into force	Expiration of inclusion	Specific provisions
'295	Difenacoum CAS No 56073-07-5 CIPAC No 514	3-[(1RS,3RS;1RS,3SR)-3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	≥ 905 g/kg	1 January 2010	30 December 2019	<div><div>PART A Only uses as rodenticide in the form of pre-prepared baits placed in specially constructed, tamper resistant and secured bait boxes are authorised.</div><div>The nominal concentration of the active substance in the products shall not exceed 50 mg/kg. Authorisations shall be limited to professional users.</div><div>PART B For the implementation</div></div>

^a Further details on identity and specification of active substance are provided in the review report.

Status: This is the original version (as it was originally adopted).

						of the uniform principles of Annex VI, the conclusions of the review report on difenacoum, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States shall
a	Further details on identity and specification of active substance are provided in the review report.					

						<div>pay particular attention to the protection of birds and non-target mammals from primary and secondary poisoning. Risk mitigation measures shall be applied where appropriate.</div> <div>The Member States concerned shall ensure that the notifier submits to the Commission further information on methods for the determination of residues of difenacoum in body fluids. They shall ensure that the notifier provides such information to the</div>
a	Further details on identity and specification of active substance are provided in the review report.					

						Commission by 30 November 2011. The Member States concerned shall ensure that the notifier submits to the Commission further information on the specification of the active substance as manufactured. They shall ensure that the notifier provides such information to the Commission by 31 December 2009.
296	Didecyl dimethyl chloride CAS: not allocated CIPAC: not allocated	Didecyl dimethyl chloride is a mixture of alkyl-quaternary ammonium salts with typical alkyl chain lengths of C8, C10 and C12, with more than 90 % of C10	70 % (Technical concentrate)	1 January 2010	31 December 2019	PART A Only indoor uses for ornamental plants as bactericide, fungicide, herbicide and algaecide may be authorised.

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

						<p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on didecyldimethylammonium chloride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2009 shall be taken into account.</p> <p>In this overall assessment</p>
a	Further details on identity and specification of active substance are provided in the review report.					

						<p>Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of the operator and worker safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of aquatic organisms. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned</p>
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a Further details on identity and specification of active substance are provided in the review report.

						shall ensure that the notifier submits to the Commission further information on the specification of the active substance as manufactured by 1 January 2010 and on the risk to aquatic organisms by 31 December 2011.
297	sulphur CAS No 7704-34-9 CIPAC No 18	sulphur	≥ 990 g/kg	1 January 2010	31 December 2019	<div>PART A Only uses as fungicide and acaricide may be authorised.</div> <div>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on</div>

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

Status: This is the original version (as it was originally adopted).

						<p>sulphur, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2009 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to: — the protection of birds, mammals, aquatic organisms and non- target arthropods. Conditions of</p>
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a Further details on identity and specification of active substance are provided in the review report.

						<p>authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submit to the Commission further information to confirm the risk assessment for birds, mammals, sediment dwelling organisms and non-target arthropods. They shall ensure that the notifier at whose request sulphur has been included in this Annex provide such data to the Commission at latest by 30 June 2011.'</p>
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a Further details on identity and specification of active substance are provided in the review report.

- (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) 218*, Conclusion regarding the peer review of the pesticide risk assessment of the active substance difenacoum (finalised 19 December 2008).
- (5) *EFSA Scientific Report (2008) 214*, Conclusion regarding the peer review of the pesticide risk assessment of the active substance didecyldimethylammonium chloride (finalised 19 December 2008).
- (6) *EFSA Scientific Report (2008) 221*, Conclusion regarding the peer review of the pesticide risk assessment of the active substance sulfur (finalised 19 December 2008).