

Commission Directive 2008/125/EC of 19 December 2008 amending Council Directive 91/414/EEC to include aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol as active substances (Text with EEA relevance) (repealed)

COMMISSION DIRECTIVE 2008/125/EC

of 19 December 2008

amending Council Directive 91/414/EEC to include aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol as active substances

(Text with EEA relevance) (repealed)

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 451/2000⁽²⁾ and (EC) No 1490/2002⁽³⁾ lay down the detailed rules for the implementation of the third 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 aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol.
- (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 451/2000 and (EC) No 1490/2002 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 10(1) of Regulation (EC) No 1490/2002. For aluminium phosphide, calcium phosphide, magnesium phosphide, 2,5-dichlorobenzoic acid methylester and sulcotrione the rapporteur Member State was Germany and all relevant information was submitted on 19 June 2007 for aluminium phosphide, calcium phosphide, magnesium phosphide and 2,5-dichlorobenzoic acid methylester and on 9 August 2006 for sulcotrione. For metamitron, and triadimenol the rapporteur Member State was the United Kingdom and all relevant information was submitted on 22 August 2007 and 29 May 2006 respectively. For cymoxanil, the rapporteur Member State was Austria and all relevant information was submitted

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on 15 June 2007. For dodemorph, the rapporteur Member State was the Netherlands and all relevant information was submitted on 9 February 2007. For tebuconazole the rapporteur Member State was Denmark and all relevant information was submitted on 5 March 2007.

- (3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 29 September 2008 for aluminium phosphide, calcium phosphide and metamitron, on 30 September 2008 for magnesium phosphide, on 17 September 2008 for cymoxanil and dodemorph, on 26 September 2008 for 2,5-dichlorobenzoic acid methylester, on 31 July 2008 for sulcotrione and on 25 September 2008 for tebuconazole and triadimenol in the format of the EFSA Scientific Reports⁽⁴⁾. 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 28 October 2008 in the format of the Commission review reports for aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol.
- (4) It has appeared from the various examinations made that plant protection products containing aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole or triadimenol 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, it is appropriate for metamitron to require the notifier to submit further information as regards the impact of soil metabolite M3 on groundwater, on residues in rotational crops, on the long term risk to insectivorous birds and on the specific risk to birds and mammals that may be contaminated by the intake of water in field. Furthermore, for sulcotrione it is appropriate to require the notifier to submit further information as regards the degradation in soil and water of the cyclohexadione moiety and the long term risk to insectivorous birds. In addition, it is appropriate to require that tebuconazole should be subjected to further testing for the confirmation of the risk assessment for birds and mammals and such information should be presented by the notifier. Moreover, it is appropriate to require that tebuconazole and triadimenol be subjected to further testing of their potential endocrine disrupting properties, as soon as OECD test guidelines on endocrine disruption, or, alternatively, Community agreed test guidelines exist. Finally, it is appropriate to require that triadimenol should be subjected to further testing for confirmation of the chemical specification and the long risk to birds and mammals and that such information should be presented by the notifier.

- (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 aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol 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 way of 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 28 February 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 March 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 aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol as active substances by 28 February 2010.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol are met, with the exception of those identified in part B of the entry concerning that active substance, 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 aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol 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 August 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 aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol respectively. 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 aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole or triadimenol as the only active substance, where necessary, amend or withdraw the authorisation by 28 February 2014 at the latest; or
- b in the case of a product containing aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole or triadimenol as one of several active substances, where necessary, amend or withdraw the authorisation by 28 February 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 September 2009.

Article 5

This Directive is addressed to the Member States.

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/ECC:

No	Common Name, Identification Numbers	IUPAC Name	Purity ^a	Entry into force	Expiration of inclusion	Specific provisions
'266	Aluminium phosphide CAS No 20859-73-8 CIPAC No 227	<i>Aluminium phosphide</i>	≥ 830 g/kg	1 September 2009	31 August 2019	<p>PART A [^{F1}Only uses as insecticide, rodenticide, talpicide and leporicide in the form of ready-to-use aluminium phosphide containing products may be authorised.</p> <p>As rodenticide, talpicide and leporicide only outdoor uses may be authorised.] Authorisations should be limited to professional users.</p> <p>PART B For the implementation of the</p>

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

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uniform principles of Annex VI, the conclusions of the review report on aluminium phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

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

							the protection of consumers and ensure that the spent ready-to-use aluminium phosphide containing products are removed from the food commodity in uses against storage pests and subsequently an adequate additional withholding period is applied; the operator and worker safety and ensure that conditions of use prescribe the application of adequate
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							personal and respiratory protective equipment; the protection of operators and workers during fumigation for indoor uses; the protection of workers at re-entry (after fumigation period) for indoor uses; the protection of bystanders against leaking of gas for indoor uses; the protection of birds and mammals. Conditions of authorisation should include risk
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						mitigation measures, such as the closure of the burrows and the achievement of complete incorporation of granules in the soil, where appropriate; the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones between treated areas and surface water bodies, where appropriate.
267	Calcium phosphide	<i>Calcium phosphide</i>	≥ 160 g/kg	1 September 2009	31 August 2019	PART A [F1 Only outdoor uses

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						<p>finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none">— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment;— the protection
a	Further details on identity and specification of active substance are provided in the review report.					

						and surface water bodies, where appropriate.
268	Magnesium phosphide CAS No 12057-74-8 CIPAC No 228	<i>Magnesium phosphide</i>	≥ 880 g/kg	1 September 2009	31 August 2019	<p>PART A [F¹Only uses as insecticide, rodenticide, talpicide and leporicide in the form of ready-to-use magnesium phosphide containing products may be authorised.</p> <p>As rodenticide, talpicide and leporicide only outdoor uses may be authorised.] Authorisations should be limited to professional users.</p> <p>PART B For the implementation of the uniform principles</p>

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of Annex VI, the conclusions of the review report on magnesium phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.

In this overall assessment Member States must pay particular attention to: — the protection

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						as the closure of the burrows and the achievement of complete incorporation of granules in the soil, where appropriate; the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones between treated areas and surface water bodies, where appropriate.
269	Cymoxanil CAS No 57966-95-7 CIPAC No 419	<i>1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea</i>	≥ 970 g/kg	1 September 2009	31 August 2019	PART A Only uses as fungicide may

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be authorised.

PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on cymoxanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.

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

						<p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none">— the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;— the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;— the protection of aquatic organisms
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						and must ensure that the conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate.
270	Dodemorph CAS No 1593-77-7 CIPAC No 300	<i>cis/trans</i> -[4-cyclododecyl]-2,6-dimethylmorpholine	≥ 950 g/kg	1 September 2009	31 August 2019	<p>PART A Only uses as fungicide on ornamentals in glasshouse may be authorised.</p> <p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dodemorph, and in particular</p>

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						<p>Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal</p>
a	Further details on identity and specification of active substance are provided in the review report.					

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						<p>protective equipment where appropriate; the protection of the groundwater, when the active substance is applied in regions with vulnerable soil conditions;</p> <p>Conditions of authorisation should include risk mitigation measures, where appropriate.</p>
271	2,5-Dichlorobenzodichlorobenzoate acid methylester CAS No 2905-69-3 CIPAC No 686	<i>methyl-2,5-dichlorobenzoate</i>	≥ 995 g/kg	1 September 2009	31 August 2019	<p>PART A Only indoor uses as plant growth regulator and fungicide for grafting of grapevines may be authorised.</p> <p>PART B For the implementation of</p>

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						the uniform principles of Annex VI, the conclusions of the review report on 2,5-Dichlorobenzoic acid methylester, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.
272	Metamitron CAS No 41394-05-2	4- <i>amino-4,5- dihydro-3- methyl-6-</i>	≥ 960 g/kg	1 September 2009	31 August 2019	PART A Only uses as herbicide

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CIPAC No 381	<i>phenyl-1,2,4-triazin-5-one</i>				<p>may be authorised.</p> <p>PART B In assessing applications to authorise plant protection products containing metamitron for uses other than on root crops, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted.</p>
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						<p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metamitron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none">— the operator safety and ensure that conditions of use prescribe the application of personal
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						<p>protective equipment where appropriate; the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;</p> <p>—</p> <p>the risk to birds and mammals, and non-target terrestrial plants.</p> <p>—</p> <p>Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information</p>
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a Further details on identity and specification of active substance are provided in the review report.

						on the impact of soil metabolite M3 on groundwater, on residues in rotational crops, on the long-term risk to insectivorous birds and the specific risk to birds and mammals that may be contaminated by the intake of water in field. They shall ensure that the notifiers at whose request metamitron has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.
273	Sulcotrione CAS No 99105-77-8 CIPAC No 723	2-(2-chloro-4-mesyloxybenzoyl)cyclohexanone	≥ 950 g/kg Impurities: not more than 80	1 September 2009	31 August 2019	PART A Only uses as herbicide may be authorised.

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		—	mg/ kg toluene: not more than 4 g/ kg		<p>PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sulcotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member</p>
<p>a Further details on identity and specification of active substance are provided in the review report.</p>					

						<p>States must pay particular attention to:</p> <ul style="list-style-type: none">— the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate;— the risk to insectivorous birds, aquatic and terrestrial non-target plants, and non-target arthropods. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall</p>
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						request the submission of further information on the degradation in soil and water of the cyclohexadione moiety and the long-term risk to insectivorous birds. They shall ensure that the notifier at whose request sulcotrione has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.
274	Tebuconazole CAS No 107534-96-3 CIPAC No 494	(<i>RS</i>)-1- <i>p</i> -chlorophenyl-4,4-dimethyl-3-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)-pentan-3-ol	≥ 905 g/kg	1 September 2009	31 August 2019	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the

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						<p>conclusions of the review report on tebuconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to: — the operator and worker safety and ensure</p>
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						that conditions of use prescribe the application of adequate personal protective equipment;
						the dietary exposure of consumers to the tebuconazole (triazole) metabolites;
						the protection of granivorous birds and mammals and herbivorous mammals and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.
						the protection of aquatic organisms and

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						concerned shall ensure that the notifier submits to the Commission further information addressing the potential endocrine disrupting properties of tebuconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.
275	Triadimenol CAS No 55219-65-3 CIPAC No 398	(<i>1RS,2RS;1RS,2SR</i>) (4-chlorophenoxy)dimethyl-1-(<i>1H-1,2,4-triazol-1-yl</i>)butan-2-ol	200 g/kg isomer A (<i>1RS,2SR</i>), isomer B (<i>1RS,2RS</i>) Diastereomer A, <i>RS + SR</i> , range: 70 to 85 % Diastereomer B, <i>RR + SS</i> , range: 15 to 30 %	1 September 2009	31 August 2019	PART A Only uses as fungicide may be authorised. PART B For the implementation of the uniform principles of Annex VI,

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the conclusions of the review report on triadimenol, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October shall be taken into account.

In this overall assessment Member States must pay particular attention to: — the presence of N-methylpyrrolidone in formulated

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						<p>products as regards operator, worker and bystander exposure; the protection of birds and mammals. In relation to these identified risks risk mitigation measures, such as buffer zones, should be applied where appropriate</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission</p> <p>— further information on the specification;</p> <p>— information to further address the</p>
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					disrupting properties of triadimenol within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.’
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Textual Amendments

- F1** Substituted by [Commission Directive 2009/146/EC of 26 November 2009 correcting Directive 2008/125/EC amending Council Directive 91/414/EEC to include aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol as active substances \(Text with EEA relevance\).](#)

- (1) [OJ L 230, 19.8.1991, p. 1.](#)
- (2) [OJ L 55, 29.2.2000, p. 25.](#)
- (3) [OJ L 224, 21.8.2002, p. 23.](#)
- (4) *EFSA Scientific Report (2008) 182, Conclusion regarding the peer review of the pesticide risk assessment of the active substance aluminium phosphide (finalised 29 September 2008).*
EFSA Scientific Report (2008) 183, Conclusion regarding the peer review of the pesticide risk assessment of the active substance calcium phosphide (finalised 29 September 2008).
EFSA Scientific Report (2008) 190, Conclusion regarding the peer review of the pesticide risk assessment of the active substance magnesium phosphide (finalised 30 September 2008).
EFSA Scientific Report (2008) 167, Conclusion regarding the peer review of the pesticide risk assessment of the active substance cymoxanil (finalised 17 September 2008).
EFSA Scientific Report (2008) 170, Conclusion regarding the peer review of the pesticide risk assessment of the active substance dodemorph (finalised 17 September 2008).
EFSA Scientific Report (2008) 180, Conclusion regarding the peer review of the pesticide risk assessment of the active substance 2,5-dichlorobenzoic acid methylester (finalised 26 September 2008).
EFSA Scientific Report (2008) 185, Conclusion regarding the peer review of the pesticide risk assessment of the active substance metamitron (finalised 29 September 2008).
EFSA Scientific Report (2008) 150, Conclusion regarding the peer review of the pesticide risk assessment of the active substance sulcotrione (finalised 31 July 2008).
EFSA Scientific Report (2008) 176, Conclusion regarding the peer review of the pesticide risk assessment of the active substance tebuconazole (finalised 25 September 2008).
EFSA Scientific Report (2008) 177, Conclusion regarding the peer review of the pesticide risk assessment of the active substance triadimenol (25 September 2008).