Commission Directive 2007/25/EC of 23 April 2007 amending Council Directive 91/414/EEC to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2007/25/EC

of 23 April 2007

amending Council Directive 91/414/EEC to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb 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[(1)], and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 451/2000[(2)] and (EC) No 703/2001[(3)] lay down the detailed rules for the implementation of the second 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 dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb.

(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 703/2001 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 8(1) of Regulation (EC) No 451/2000. For dimethoate, the rapporteur Member State was the United Kingdom and all relevant information was submitted on 4 August 2004. For dimethomorph and metribuzin, the rapporteur Member State was Germany and all relevant information was submitted on 11 June 2004 and 23 august 2004 respectively. For glufosinate, the rapporteur Member State was Sweden and all relevant information was submitted on 3 January 2003. For phosmet, the rapporteur Member State was Spain and all relevant information was submitted on 23 August 2004. For propamocarb, the rapporteur Member State was Ireland and all relevant information was submitted on 5 October 2004.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 14 March 2005 for glufosinate, on 12 May 2006 for phosmet and propamocarb, on 23 June 2006 for dimethoate and dimethomorph, and on 28 July 2006 for metribuzin, 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 24 November 2006 in the format of the Commission review reports for dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb.

(4) It has appeared from the various examinations made that plant protection products containing dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb 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 concerning dimethoate, glufosinate, metribuzin and phosmet. 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 to require that dimethoate, glufosinate, metribuzin and phosmet should be subjected to further testing for confirmation of the risk assessment for some issues and that such studies should be presented by the notifiers.

(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 dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb 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 Commission Regulation (EEC) No 3600/92[(5)] 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 31 March 2008 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 April 2008.

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 dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances by 31 March 2008.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb 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 dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb 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 30 September 2007 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 dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb 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 dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as the only active substance, where necessary, amend or withdraw the authorisation by 30 September 2011 at the latest; or

b in the case of a product containing dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as one of several active substances, where necessary, amend or withdraw the authorisation by 30 September 2011 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 October 2007.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 23 April 2007.

For the Commission

Markos KYPRIANOU

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	
‘155	Dimethoate CAS No 60-51-5 CIPAC No 59	*O,O*-Dimethyl-*S*-(*N*-methylcarbamoylmethyl) phosphorodithioate; 2-Dimethoxy-phosphinothioylthio-*N*-methylacetamide	≥ 950 g/kg Impurities: — omethoate: not more than 2 g/kg — isodimethoate: not more than 3 g/kg	1 October 2007	30 September 2017	Part A	Only uses as insecticide may be authorised.
						Part B	For the implementation of the uniform principles of Annex VI, the conclusions of the review report on dimethoate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food

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

						Chain and Animal Health on 24 November 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals, aquatic organisms and other non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones and reduction of

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						run-off and drainage inputs to surface water; — must pay particular attention to the dietary exposure of consumers; — must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment. The Member States concerned shall request the submission of further studies to confirm the risk assessment

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						for birds, mammals and non-target arthropods, as well as to confirm the toxicological assessment on metabolites potentially present in crops. They shall ensure that the notifier at whose request dimethoate has been included in this Annex provides such studies to the Commission within two years from the entry into force of this Directive.	
156	Dimethomorph CAS No 110488-70-5 CIPAC No 483	*(E,Z)* 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl]morpholine	≥ 965 g/kg	1 October 2007	30 September 2017	Part A	Only uses as fungicide may be authorised.
						Part B	For the implementation of the uniform principles of

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						Annex VI, the conclusions of the review report on dimethomorph, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators and workers

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						safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — to the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.
157	Glufosinate CAS No 77182-82-2 CIPAC No 437.007	ammonium(DL)-homoalanin-4-yl(methyl)phosphinate	915 g/kg	1 October 2007	30 September 2017	Part A Only uses as herbicide may be authorised. Part B In assessing applications to authorise plant protection products containing glufosinate for

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						uses other than in apple orchards, notably as regards the operator and consumer exposure, 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. For the implementation of the uniform principles of Annex VI, the conclusions

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						of the review report on glufosinate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators, workers and bystanders safety. Conditions of authorisation should include protective measures, where appropriate; — the potential for groundwater contamination, when the

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						active substance is applied in regions with vulnerable soil and/ or climatic conditions; — the protection of mammals, non-target arthropods and non-target plants. Conditions of authorisation should include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further studies to confirm the risk assessment for mammals and non-target arthropods in apple orchards.

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						They shall ensure that the notifier at whose request glufosinate has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.	
158	Metribuzin CAS No 21087-64-9 CIPAC No 283	4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4H)-one	≥ 910 g/kg	1 October 2007	30 September 2017	Part A	Only uses as herbicide may be authorised.
						Part B	In assessing applications to authorise plant protection products containing metribuzin for uses other than in post-emergence selective herbicide in potatoes Member States

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						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. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on metribuzin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal

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						Health on 24 November 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of algae, aquatic plants, non-target plants outside the treated field and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures. — must pay particular attention to the operator safety

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						and ensure that conditions of use prescribe the application of adequate personal protective equipment. The Member States concerned shall request the submission of further data to confirm the risk assessment for groundwater. They shall ensure that the notifiers at whose request metribuzin has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
159	Phosmet CAS No 732-11-6	O,O-dimethyl S-phthalimidomethyl	≥ 950 g/kg Impurities:	1 October 2007	30 September 2017	Part A Only uses as

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	CIPAC No 318	phosphorodithioate; N-(dimethoxyphosphinothioylthiomethyl)phatalimide	—	phosmet oxon: not more than 0,8 g/kg iso phosmet: not more than 0,4 g/kg			insecticide and acaricide may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on phosmet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be

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						taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and other non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones and reduction of run-off and drainage inputs to surface water,

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						— must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds (acute risk) and herbivorous mammals (long term risk). They shall ensure that the notifier at whose request phosmet has been included in this Annex

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						provides such studies to the Commission within two years from the entry into force of this Directive.	
160	Propamocarb CAS No 24579-73-5 CIPAC No 399	Propyl 3-(dimethylamino)propylcarbamate	≥ 920 g/kg	1 October 2007	30 September 2017	Part A	Only uses as fungicide may be authorised.
						Part B	In assessing applications to authorise plant protection products containing propamocarb for uses other than foliar applications, Member States shall pay particular attention to the criteria in Article 4(1)(b), as regards worker

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						exposure and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on propamocarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account. In this overall assessment

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						Member States must pay particular attention to: — the operators and workers safety. Conditions of authorisation should include protective measures, where appropriate; — the transfer of soil residues for rotating or succeeding crops; — the protection of surface and groundwater in vulnerable zones; — the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk

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						mitigation measures, where appropriate.’

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(**1**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/21/EC (OJ L 97, 12.4.2007, p. 42).

(**2**) OJ L 55, 29.2.2000, p. 25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p. 32).

(**3**) OJ L 98, 7.4.2001, p. 6.

(**4**) EFSA Scientific Report (2005) 27, 1-81, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance glufosinate (finalised: 14 March 2005).
EFSA Scientific Report (2006) 75, 1-72, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance phosmet (finalised: 12 May 2006).
EFSA Scientific Report (2006) 78, 1-72, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance propamocarb (finalised: 12 May 2006).
EFSA Scientific Report (2006) 84, 1-102, Conclusions on the peer review of the pesticide risk assessment of the active substance dimethoate (finalised: 23 June 2006).
EFSA Scientific Report (2006) 82, 1-69, Conclusions on the peer review of the pesticide risk assessment of the active substance dimethomorph (finalised: 23 June 2006).
EFSA Scientific Report (2006) 88, 1-74, Conclusions on the peer review of the pesticide risk assessment of the active substance metribuzin (finalised: 28 July 2006).

(**5**) OJ L 366, 15.12.1992, p. 10. Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).