Commission Directive 2007/5/EC of 7 February 2007 amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb as active substances (Text with EEA relevance)

COMMISSION DIRECTIVE 2007/5/EC

of 7 February 2007

amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb 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 captan, folpet, formetanate and methiocarb.

(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 captan, folpet and formetanate, the rapporteur Member State was Italy and all relevant information was submitted on 20 October 2003 for captan and folpet and on 13 July 2004 for formetanate. For methiocarb the rapporteur Member State was United Kingdom and all relevant information was submitted on 4 March 2004.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the Commission on 24 April 2006 for captan, folpet and formetanate and on 12 May 2006 for methiocarb 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 29 September 2006 in the format of the Commission review reports for captan, folpet, formetanate and methiocarb.

(4) It has appeared from the various examinations made that plant protection products containing captan, folpet, formetanate and methiocarb may be expected to satisfy, in

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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 captan, folpet, formetanate and methiocarb. Article 6(1) of Directive 91/414/EC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore it is appropriate to require that captan, folpet, formetanate and methiocarb 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 captan, folpet, formetanate and methiocarb 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:

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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 captan, folpet, formetanate and methiocarb 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 captan, folpet, formetanate and methiocarb 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 captan, folpet, formetanate and methiocarb 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 captan, folpet, formetanate and methiocarb 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 captan, folpet, formetanate and methiocarb 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 captan, folpet, formetanate and methiocarb 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.

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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
‘151	Captan CAS No 133-06-02 CIPAC No 40	N-(trichloromethylthio)cyclohex-4-ene-1,2-dicarboximide	≥ 910 g/kg Impurities: Perchloromethylmercaptan (R005406): not more than 5 g/kg Folpet: not more than 10 g/kg [F1Carbon tetrachloride not more than 0,1 g/kg]	1 October 2007	30 September 2017	PART A Only uses as fungicide can be authorised. PART B In assessing applications to authorise plant protection products containing captan for uses other than tomatoes Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data

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						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 captan, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operators and

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						workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures

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						and monitoring programmes should be initiated in vulnerable zones, where appropriate; — the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures. The Member States concerned shall request the submission of further studies to confirm the long term risk assessment for birds and mammals, as well as the toxicological assessment on metabolites potentially present in groundwater

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						under vulnerable conditions. They shall ensure that the notifiers at whose request captan has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
152	Folpet CAS No 133-07-3 CIPAC No 75	N-(trichloromethylthio)phthalimide	≥ 940 g/kg Hydrolysable chloride: not more than 3,5 g/kg Carbon tetrachloride not more than 4 g/kg	1 October 2007 Perchloromethylmercaptan (R005406): not more than 3,5 g/kg	30 September 2017	PART A Only uses as fungicide can be authorised. PART B In assessing applications to authorise plant protection products containing folpet for uses other than winter wheat Member States shall pay

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						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 folpet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29

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						September 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of birds, mammals, aquatic and soil

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						organisms. Conditions of authorisation should include risk mitigation measures. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and earthworms. They shall ensure that the notifiers at whose request folpet has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
153	Formetanate CAS No 23422-53-9 CIPAC No 697	3-dimethylaminomethylenea methylcarbamate	≥ 910 g/kg	1 October 2007	30 September 2017	PART A Only uses as insecticide and acaricide

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							may be authorised.
						PART B	In assessing applications to authorise plant protection products containing formetanate for uses other than in field tomatoes and ornamental shrubs 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

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						is granted. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on formetanate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals, non-target arthropods and

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						bees and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures; — must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — must pay particular attention to the dietary exposure of consumers in view of future revisions

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						of Maximum Residue Levels. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and non-target arthropods. They shall ensure that the notifier at whose request formetanate has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.
154	Methiocarb CAS No 2032-65-7 CIPAC No 165	4-methylthio-3,5-xylyl methylcarbamate	≥ 980 g/kg	1 October 2007	30 September 2017	PART A Only uses as repellent in seed treatment, insecticide and molluscicide

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							may be authorised.
						PART B	In assessing applications to authorise plant protection products containing methiocarb for uses other than seed treatment in maize 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.

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						For the implementation of the uniform principles of Annex VI, the conclusions of the review report on methiocarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of birds, mammals and non-target arthropods and must

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						ensure that the conditions of authorisation include, where appropriate, risk mitigation measures; — must pay particular attention to the operator and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment; — must pay particular attention to the dietary exposure of consumers in view of future revisions of

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						Maximum Residue Levels. The Member States concerned shall request the submission of further studies to confirm the risk assessment 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 methiocarb has been included in this Annex provide such studies to the Commission within two years from the entry into force of this Directive.’

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Textual Amendments

F1 Substituted by Commission Decision of 7 October 2008 correcting Directive 2007/5/EC amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb as active substances (notified under document number C(2008) 5583) (Text with EEA relevance) (2008/782/EC).

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(**1**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2006/136/EC (OJ L 349, 12.12.2006, 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 (2006) 71, 1-89, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance captan (finalised: 24 April 2006)
EFSA Scientific Report (2006) 70, 1-78, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance folpet (finalised: 24 April 2006)
EFSA Scientific Report (2006) 69, 1-78, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance formetanate (finalised: 24 April 2006)
EFSA Scientific Report (2006) 79, 1-82, Conclusions on the peer review of methiocarb (finalised: 12 May 2006).