COMMISSION DIRECTIVE 2008/44/EC

of 4 April 2008

amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole 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) In accordance with Article 6(2) of Directive 91/414/EEC Belgium received on 19 April 2002 an application from Kumiai Chemicals Industry Co. Ltd for the inclusion of the active substance benthiavalicarb in Annex I to Directive 91/414/EEC. Commission Decision 2003/35/EC [2] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) In accordance with Article 6(2) of Directive 91/414/EEC Germany received on 26 April 2001 an application from BASF AG for the inclusion of the active substance boscalid in Annex I to Directive 91/414/EEC. Commission Decision 2002/268/EC [3] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(3) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands received on 26 March 1997 an application from Luxan B.V. for the inclusion of the active substance carvone in Annex I to Directive 91/414/EEC. Commission Decision 1999/610/EC [4] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(4) In accordance with Article 6(2) of Directive 91/414/EEC United Kingdom received on 25 March 2002 an application from Bayer AG for the inclusion of the active substance fluoxastrobin in Annex I to Directive 91/414/EEC. Decision 2003/35/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(5) In accordance with Article 6(2) of Directive 91/414/EEC Belgium received on 15 September 2002 an application from Prophyta for the inclusion of the active substance *Paecilomyces lilacinus* strain 251 (hereafter *Paecilomyces lilacinus*) in Annex I to Directive 91/414/EEC. Commission Decision 2003/305/EC [5] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(6) In accordance with Article 6(2) of Directive 91/414/EEC United Kingdom received on 25 March 2002 an application from Bayer CropScience for the inclusion of the active substance prothioconazole in Annex I to Directive 91/414/EEC. Decision 2003/35/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(7) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The designated rapporteur Member States submitted draft assessment report on 13 April 2004 (benthiavalicarb), 22 November 2002 (boscalid), 16 October 2000 (carvone), 2 September 2003 (fluoxastrobin), 3 November 2004 (*Paecilomyces lilacinus*) and 18 October 2004 (prothioconazole).

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2008/41/EC (OJ L 89, 1.4.2008, p. 12).
[2] OJ L 11, 16.1.2003, p. 52.
[3] OJ L 92, 9.4.2002, p. 34.
[4] OJ L 242, 14.9.1999, p. 29.
[5] OJ L 112, 6.5.2003, p. 10.

(8) The assessment reports were peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission in the format of the EFSA Scientific Reports on 15 June 2007 for fluoxastrobin [1] and *Paecilomyces lilacinus* [2] and on 12 July for benthiavalicarb [3] and prothioconazole [4]. These reports and the draft assessment reports for boscalid and carvone were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and the review was finalised on 22 January 2008 in the format of the Commission review reports for benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole.

(9) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1) (a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole in Annex I to that Directive, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances may be granted in accordance with the provisions of that Directive.

(10) Without prejudice to the above conclusion, for fluoxastrobin and prothioconazole 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 to require that fluoxastrobin should be subjected to further testing for confirmation of the risk assessment for surface water and for non-rat metabolites and that prothioconazole should be subjected to further testing for confirmation of the risk assessment as regards the triazole metabolite derivatives and the risk to granivorous birds and mammals and that such studies should be presented by the notifiers.

(11) 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 provisional authorisations of plant protection products containing benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole 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 transform existing provisional authorisations into full authorisations, amend them or withdraw them 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.

(12) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(13) 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

1. Member States shall adopt and publish by 31 January 2009 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 February 2009.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

[1] *EFSA Scientific Report* (2007) 102, 1-84, Conclusion regarding the peer review of the pesticide risk assessment of the active substance fluoxastrobin (finalised: 13 June 2007).

[2] *EFSA Scientific Report* (2007) 103, 1-35, Conclusion regarding the peer review of the pesticide risk assessment of the active substance *Paecilomyces lilacinus* strain 251 (finalised: 13 June 2007).

[3] *EFSA Scientific Report* (2007) 107, 1-81, Conclusion regarding the peer review of the pesticide risk assessment of the active substance benthiavalicarb (finalised: 12 July 2007).

[4] *EFSA Scientific Report* (2007) 106, 1-98, Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole (finalised: 12 July 2007).

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 benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole as active substance by 31 January 2009. By that date, they shall in particular verify that the conditions in Annex I to that Directive relating to benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole, respectively, are met, with the exception of those identified in part B of the entry concerning the 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(2) of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole 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 July 2008 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 benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole. 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 benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole as the only active substance, where necessary, amend or withdraw the authorisation by 31 January 2010 at the latest; or

(b) in the case of a product containing benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* or prothioconazole as one of several active substances, where necessary, amend or withdraw the authorisation by 31 January 2010 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 August 2008.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 4 April 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

In Annex I to Directive 91/414/EEC, the following rows are added at the end of the table:

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
'169	Benthiavalicarb CAS No 413615-35-7 CIPAC No 744	[(S)-1-{[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl) ethyl]carbamoyl}-2-methylpropyl] carbamic acid	≥ 910 g/kg The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material: 6,6′-difluoro-2,2′-dibenzothiazole: < 3,5 mg/kg bis(2-amino-5-fluorophenyl) disulfide: < 14 mg/kg	1 August 2008	31 July 2018	Part A Only uses as fungicide may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on benthiavalicarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety, — the protection of non-target arthropods. Conditions of use shall include adequate risk mitigation measures, where appropriate. In assessing applications to authorise plant protection products containing benthiavalicarb for uses other than in glasshouses, 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. The Member States shall inform the Commission in accordance with Article 13(5) on the specification of the technical material as commercially manufactured.

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
170	Boscalid CAS No 188425-85-6 CIPAC No 673	2-Chloro-*N*-(4′-chlorobiphenyl-2-yl)nicotinamide	≥ 960 g/kg	1 August 2008	31 July 2018	Part A Only uses as fungicide may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on boscalid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention — to the operator safety, — to the long term risk to birds and soil organisms, — to the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include adequate risk mitigation measures, where appropriate.
171	Carvone CAS No 99-49-0 (d/l mixture) CIPAC No 602	5-isopropenyl-2-methylcyclohex-2-en-1-one	≥ 930 g/kg with a d/l ratio of at least 100:1	1 August 2008	31 July 2018	Part A Only uses as plant growth regulator may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on carvone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to the operator safety. Conditions of use shall include risk mitigation measures, where appropriate.

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
172	Fluoxastrobin CAS No 361377-29-9 CIPAC No 746	(*E*)-{2-[6-(2-chlorophenoxy)-5-fluoropyrimidin-4-yloxy]phenyl}(5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methyloxime	≥ 940 g/kg	1 August 2008	31 July 2018	Part A Only uses as fungicide may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fluoxastrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety, in particular when handling the undiluted concentrate. Conditions of use shall include adequate protective measures, such as wearing a face shield, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the levels of residues of the metabolites of fluoxastrobin, when straw from treated areas is used as animal feeding stuff. Conditions of use shall include restrictions for feeding to animals, where appropriate, — the risk of accumulation in the soil surface, if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — data to allow a comprehensive aquatic risk assessment to be made taking into account spray drift, run-off, drainage and the effectiveness of potential risk mitigation measures, — data on toxicity of non-rat metabolites if straw from treated areas is to be used as feedstuff. They shall ensure that the notifier at whose request fluoxastrobin has been included in this Annex provide such studies to the Commission within two years from the entry into force of the Directive of inclusion.

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
173	*Paecilomyces lilacinus* (Thom) Samson 1974 strain 251 (AGAL: No 89/030550) CIPAC No 753	Not applicable		1 August 2008	31 July 2018	Part A Only uses as nematicide may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on *Paecilomyces lilacinus*, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety (although there was no need to set an AOEL, as a general rule, microorganisms should be considered as potential sensitisers), — the protection of leaf dwelling non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate.
174	Prothioconazole CAS No 178928-70-6 CIPAC No 745	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione	≥ 970 g/kg The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material: — Toluene: < 5 g/kg — Prothioconazole-desthio (2-(1-chlorocyclopropyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): < 0,5 g/kg (LOD)	1 August 2008	31 July 2018	Part A Only uses as fungicide may be authorised. Part B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prothioconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety in spray applications. Conditions of use shall include adequate protective measures, — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of birds and small mammals. Risk mitigation measures shall be applied, where appropriate.

No	Common name, identification numbers	IUPAC name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
						Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: — information to allow the assessment of consumer exposure to triazole metabolite derivatives in primary crops, rotational crops, and products of animal origin, — a comparison of the mode of action of prothioconazole and the triazole metabolite derivatives to allow the assessment of the toxicity resulting from the combined exposure to these compounds, — information to further address the long-term risk to granivorous birds and mammals arising from the use of prothioconazole as a seed treatment. They shall ensure that the notifier at whose request prothioconazole has been included in this Annex provide such studies to the Commission within two years from the entry into force of the Directive of inclusion.'

(*) Further details on identity and specification of active substances are provided in the review report.