COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
COM(2007) XXX

Draft

COMMISSION DECISION

of […]

concerning the non-inclusion of certain substances in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

EN

Draft

COMMISSION DECISION

of […]

concerning the non-inclusion of certain substances in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No XXXX/2007 of XX November 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market[2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC.

(2) For a number of substance/product type combinations included in that list, either all participants have discontinued their participation from the review programme, or no complete dossier was received within the time period specified in Articles 9 and 12(3) of Regulation (EC) No XXXX/2007 by the Member State designated as Rapporteur for the evaluation.

(3) Consequently, and pursuant to Articles 11(2), 12(1) and 13(5) of Regulation (EC) No XXX/2007, the Commission informed the Member States accordingly. That information was also made public by electronic means on 22 June 2007.

(4) Within the period of three months from that publication, no person or Member State indicated an interest in taking over the role of participant for the substances and product-types concerned.

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1 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2006/140/EC of 20 December 2006 (OJ L 414, 30.12.2006, p. 78).

2 OJ L xxx, xx.11.2007, p. xx.

(5) Pursuant to Article 12(5) of Regulation (EC) No XXXX/2007, the substances and product-types concerned should therefore not be included in Annexes I, IA or IB to Directive 98/8/EC.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The substances and the product-types indicated in the Annex to this Decision shall not be included in Annexes I, IA or IB to Directive 98/8/EC.

Article 2

For the purposes of Article 4(2) of Regulation (EC) No XXXX/2007, this Decision shall apply from the day following that of its publication in the *Official Journal of the European Union*.

Article 3

This Decision is addressed to the Member States.

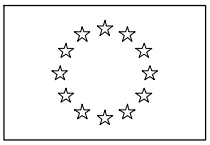
Done at Brussels, […]

For the Commission
Stavros Dimas
Member of the Commission

ANNEX

SUBSTANCES AND PRODUCT-TYPES NOT TO BE INCLUDED IN ANNEXES I, IA OR IB TO DIRECTIVE 98/8/EC

Name	EC number	CAS number	Product-type
Formaldehyde	200-001-8	50-00-0	11
Formaldehyde	200-001-8	50-00-0	12
Formaldehyde	200-001-8	50-00-0	13
2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether / Piperonyl butoxide	200-076-7	51-03-6	19
1,3-dibromo-5,5-dimethylhydantoin	201-030-9	77-48-5	2
1,3-dibromo-5,5-dimethylhydantoin	201-030-9	77-48-5	11
1,3-dibromo-5,5-dimethylhydantoin	201-030-9	77-48-5	12
Naphthalene	202-049-5	91-20-3	19
m-Cresol	203-577-9	108-39-4	2
m-Cresol	203-577-9	108-39-4	3
Hexa-2,4-dienoic acid / Sorbic acid	203-768-7	110-44-1	8
Benzyl benzoate	204-402-9	120-51-4	18
Benzothiazole-2-thiol	205-736-8	149-30-4	2
Benzothiazole-2-thiol	205-736-8	149-30-4	7
Benzothiazole-2-thiol	205-736-8	149-30-4	9
Benzothiazole-2-thiol	205-736-8	149-30-4	11
Benzothiazole-2-thiol	205-736-8	149-30-4	12
Benzothiazole-2-thiol	205-736-8	149-30-4	13
2-hydroxy-4-isopropyl-2,4,6-cycloheptatrien-1-one	207-880-7	499-44-5	10
Sodium bromide	231-599-9	7647-15-6	4
Sodium bromide	231-599-9	7647-15-6	6
Sodium bromide	231-599-9	7647-15-6	13
Boric acid	233-139-2	10043-35-3	18
Ammonium bromide	235-183-8	12124-97-9	2
Ammonium bromide	235-183-8	12124-97-9	4
Ammonium bromide	235-183-8	12124-97-9	6
Cis-tricos-9-ene	248-505-7	27519-02-4	18
3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether / Etofenprox	407-980-2	80844-07-1	2
3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether / Etofenprox	407-980-2	80844-07-1	3
(RS)-3-Allyl-2-methyl-4-oxocyclopent-2-enyl-(1R,3R)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (mixture of 2 isomers: 1R trans : 1RS only 1:1) / Bioallethrin / d-trans-Allethrin	Plant protection product	-	18
Spinosad: fermentation product of soil micro-organisms containing Spinosyn A and Spinosyn D	Plant protection product	-	3



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
COM(2007) XXX

Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include carbon dioxide as an active substance in Annex I thereto

EN

Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include carbon dioxide as an active substance in Annex I thereto

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000[2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes carbon dioxide.

(2) Pursuant to Regulation (EC) No 2032/2003, carbon dioxide has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 14, rodenticides, as defined in Annex V to Directive 98/8/EC.

(3) France was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 15 May 2006 in accordance with Article 10(5) and (7) of Regulation (EC) No 2032/2003.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 21 June 2007, in an assessment report, with a proposal to include carbon dioxide in Annex IA to Directive 98/8/EC, only for use in ready-for-use gas canisters functioning together with a trapping device.

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1 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2007/20/EC (OJ L 94, 04.04.2007, p. 23).

2 OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63.

(5) An active substance listed in Annex IA should normally also be listed in Annex I. Inclusion in Annex I would cover those uses for which products may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, but not those of low-risk products. Such is the case of certain biocidal products used as rodenticides and containing carbon dioxide. It is therefore appropriate to include carbon dioxide in Annex I for product-type 14, in order to ensure that in all Member States authorisations for biocidal products used as rodenticides and containing carbon dioxide can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) The assessment report was modified accordingly, and was reviewed by the Standing Committee on Biocidal Products on 29 November 2007.

(7) The review of carbon dioxide did not reveal any open questions or concerns to be addressed by the Scientific Committee on Health and Environmental Risks.

(8) The evaluation at the Community level was carried out for one specific use. In addition, in accordance with Article 8(5) of the Directive, some information was not submitted, and thus not assessed. It is therefore appropriate that Member States assess those risks to the compartments and populations that have not been representatively addressed in the Community level risk assessment and, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks to acceptable levels.

(9) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance carbon dioxide and also to facilitate the proper operation of the biocidal products market in general.

(10) 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 entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(11) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 14 containing carbon dioxide to ensure that they comply with Directive 98/8/EC.

(12) Directive 98/8/EC should therefore be amended accordingly.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall adopt and publish, by 31 March 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 November 2009.

   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.

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.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, […]

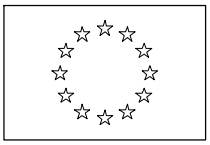
For the Commission
Stavros Dimas
Member of the Commission

ANNEX

The following entry 'No. 7' is inserted in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
"7	carbon dioxide	carbon dioxide EC No: 204-696-9 CAS No: 124-38-9	990 ml/l	1 November 2009	31 October 2011	31 October 2019	14	When assessing the application for authorisation of a product in accordance with Article 5 and Annex VI, Member States shall assess, when relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenarios that have not been representatively addressed at the Community level risk assessment. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels."

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
COM(2007) XXX

Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include difenacoum as an active substance in Annex I thereto

EN

Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include difenacoum as an active substance in Annex I thereto

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000[2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes difenacoum.

(2) Pursuant to Regulation (EC) No 2032/2003, difenacoum has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type14, rodenticides, as defined in Annex V to Directive 98/8/EC.

(3) Finland was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 21 March 2006 in accordance with Article 10(5) and (7) of Regulation (EC) No 2032/2003.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 29 November 2007, in an assessment report.

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1 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2007/20/EC (OJ L 94, 04.04.2007, p. 23).

2 OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63).

(5) The review of difenacoum did not reveal any open questions or concerns to be addressed by the Scientific Committee on Health and Environmental Risks.

(6) It appears from the examinations made that biocidal products used as rodenticides and containing difenacoum may be expected not to present a risk to humans except for accidental incidents with children. Regarding non-target animals and the environment a risk has been identified. However, the target rodents are vermin and thus constitute a danger to public health. Moreover, it has not yet been established that adequate alternatives to difenacoum exist, which are both equally effective and less damaging to the environment. It is therefore justified to include difenacoum in Annex I for a limited period, in order to ensure that in all Member States authorisations for biocidal products used as rodenticides and containing difenacoum can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(7) In the light of the findings of the assessment report, it is appropriate to require that specific risk mitigation measures are applied at product authorisation level to products containing difenacoum and used as rodenticides. Such measures should be aimed at limiting the risk of primary and secondary exposure of humans and non-target animals as well as the long term effects of the substance on the environment.

(8) Because of the identified risks and its characteristics, which render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate difenacoum should be included in Annex I for five years only and should be made subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in Annex I is renewed.

(9) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance difenacoum and also to facilitate the proper operation of the biocidal products market in general.

(10) 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 entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(11) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 14 containing difenacoum to ensure that they comply with Directive 98/8/EC.

(12) Directive 98/8/EC should therefore be amended accordingly.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2
Transposition

1. Member States shall adopt and publish, by 31 March 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 April 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.

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.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, […]

For the Commission
Stavros Dimas
Member of the Commission

ANNEX

The following entry 'No. 9' is inserted in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
"9	Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960 g/kg	1 April 2010	31 March 2012	31 March 2015	14	In view of the fact that the active substance characteristics render it potentially persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, the active substance is to be subject to a comparative risk assessment in accordance with the second subparagraph of Article 10(5)(i) of Directive 98/8/EC before its inclusion in this Annex is renewed. Member States shall ensure that authorisations are subject to the following conditions: (1) The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised. (2) Products shall contain an aversive agent and, where appropriate, a dye. (3) Products shall not be used as tracking powder. (4) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes."

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
COM(2007) XXX

Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include propiconazole as an active substance in Annex I thereto

EN

Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include propiconazole as an active substance in Annex I thereto

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000[2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes propiconazole.

(2) Pursuant to Regulation (EC) No 2032/2003, propiconazole has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to Directive 98/8/EC.

(3) Finland was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 5 April 2006 in accordance with Article 10(5) and (7) of Regulation (EC) No 2032/2003.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 29 November 2007, in an assessment report.

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1 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2007/20/EC (OJ L 94, 04.04.2007, p. 23).

2 OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63.

(5) The review of propiconazole did not reveal any open questions or concerns to be addressed by the Scientific Committee on Health and Environmental Risks.

(6) It appears from the examinations made that biocidal products used as wood preservatives and containing propiconazole may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include propiconazole in Annex I for product type 8, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing propiconazole can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.However, unacceptable risks were identified for the *in situ* treatment of wood outdoors and for treated wood exposed to weathering. Authorisation of these uses will require the submission of data demonstrating that the products can be used without unacceptable risks to the environment.

(7) In the light of the findings of the assessment report, it is appropriate to require that products containing propiconazole and used as wood preservatives must be used with appropriate personal protective equipment, that risk mitigation measures are applied to protect the soil and aquatic compartments and that related instructions are provided, in accordance with Article 10(2)(i)(d) of Directive 98/8/EC.

(8) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance propiconazole and also to facilitate the proper operation of the biocidal products market in general.

(9) 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 entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(10) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 8 containing propiconazole to ensure that they comply with Directive 98/8/EC.

(11) Directive 98/8/EC should therefore be amended accordingly.

(12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall adopt and publish, by 31 March 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 April 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.

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.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, […]

For the Commission
Stavros Dimas
Member of the Commission

ANNEX

The following entry 'No. 8' is inserted in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
"8	propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC No: 262-104-4 CAS No: 60207-90-1	930 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorisations are subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
								In addition, products cannot be authorised for the *in situ* treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures."

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
COM(2007) XXX

Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include tebuconazole as an active substance in Annex I thereto

EN

Draft

COMMISSION DIRECTIVE .../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include tebuconazole as an active substance in Annex I thereto

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[1], and in particular the second subparagraph of Article 16(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market and amending Regulation (EC) No 1896/2000[2] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC. That list includes tebuconazole.

(2) Pursuant to Regulation (EC) No 2032/2003, tebuconazole has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to Directive 98/8/EC.

(3) Denmark was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 11 January 2006 in accordance with Article 10(5) and (7) of Regulation (EC) No 2032/2003.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 11(4) of Regulation (EC) No 2032/2003, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 29 November 2007, in an assessment report.

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1 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2007/20/EC (OJ L 94, 04.04.2007, p. 23).

2 OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63.

(5) The review of tebuconazole did not reveal any open questions or concerns to be addressed by the Scientific Committee on Health and Environmental Risks.

(6) It appears from the examinations made that biocidal products used as wood preservatives and containing tebuconazole may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include tebuconazole in Annex I for product type 8, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing tebuconazole can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC. However, unacceptable risks were identified for the *in situ* treatment of wood outdoors and for treated wood in continuous contact with water. Authorisation of these uses will require the submission of data demonstrating that the products can be used without unacceptable risks to the environment.

(7) In the light of the findings of the assessment report, it is appropriate to require that instructions are provided to indicate that treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and allow losses to be collected for re-use or disposal, in accordance with Article 10(2)(i)(d) of Directive 98/8/EC.

(8) It is important that the provisions of this Directive be applied simultaneously in all the Member States in order to ensure equal treatment of biocidal products on the market containing the active substance tebuconazole and also to facilitate the proper operation of the biocidal products market in general.

(9) 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 entailed and to ensure that applicants who have prepared dossiers can benefit fully from the 10-year period of data protection, which, in accordance with Article 12(1)(c)(ii) of Directive 98/8/EC, starts from the date of inclusion.

(10) After inclusion, Member States should be allowed a reasonable period to implement Article 16(3) of Directive 98/8/EC, and in particular, to grant, modify or cancel authorisations of biocidal products in product-type 8 containing tebuconazole to ensure that they comply with Directive 98/8/EC.

(11) Directive 98/8/EC should therefore be amended accordingly.

(12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 98/8/EC is amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall adopt and publish, by 31 March 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 April 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.

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.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, […]

For the Commission
Stavros Dimas
Member of the Commission

ANNEX

The following entry 'No. 6' is inserted in Annex I to Directive 98/8/EC:

No	Common Name	IUPAC Name Identification Numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Deadline for compliance with Article 16(3) (except for products containing more than one active substance, for which the deadline to comply with Article 16(3) shall be the one set out in the last of the inclusion decisions relating to its active substances)	Expiry date of inclusion	Product type	Specific provisions (*)
"6	tebuconazole	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC No: 403-640-2 CAS No: 107534-96-3	950 g/kg	1 April 2010	31 March 2012	31 March 2020	8	Member States shall ensure that authorisations are subject to the following conditions: In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. In addition, products cannot be authorised for the *in situ* treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures."

(*) For the implementation of the common principles of Annex VI, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/comm/environment/biocides/index.htm