COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Draft

COMMISSION DIRECTIVE ../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include fenpropimorph 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 fenpropimorph 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 1451/2007 of 4 December 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. That list includes fenpropimorph.

(2) Pursuant to Regulation (EC) No 1451/2007, fenpropimorph 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) Spain was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 4 December 2006 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 19 September 2008, in an assessment report.

(5) It appears from the examinations made that biocidal products used as wood preservatives and containing fenpropimorph may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to

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[1] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2008/31/EC of the European Parliament and of the Council (OJ L 81, 20.03.2008, p. 57).

[2] OJ L 325, 11.12.2007, p. 3.

include fenpropimorph in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing fenpropimorph can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) In the light of the findings of the assessment report, it is appropriate to require that risk mitigation measures are applied at product authorisation level to products containing fenpropimorph and used as wood preservatives to ensure that risks are reduced to an acceptable level in accordance with Article 5 of Directive 98/8/EC and Annex VI thereto. In particular, appropriate measures should be taken to protect the soil and aquatic compartments since unacceptable risks to these compartments have been identified during the evaluation. Products intended for industrial use should be used with appropriate protective equipment if the risk identified for industrial users cannot be reduced by other means.

(7) Not all potential uses have been evaluated at the Community level. 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.

(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 fenpropimorph 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 fenpropimorph 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

1. Member States shall adopt and publish, by 31 January 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   They shall apply those provisions from 1 February 2011.

   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

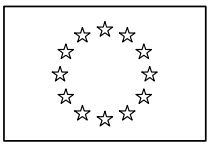
ANNEX

The following entry 'No. 21' 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 (*)
"21	fenpropimorph	Cis-4-[3-(p-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine EC No: 266-719-9 CAS No: 67564-91-4	930 g/kg	1 February 2011	31 January 2013	31 January 2021	8	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. 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 use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means.

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 (*)
								(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 and on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal."

(*) 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,

Draft

COMMISSION DIRECTIVE ../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include sulfuryl fluoride 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 sulfuryl fluoride 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 1451/2007 of 4 December 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. That list includes sulfuryl fluoride.

(2) Commission Directive 2006/140/EC[3] included sulfuryl fluoride as an active substance in Annex I to Directive 98/8/EC for use in product-type 8, wood preservatives, as defined in Annex V to Directive 98/8/EC.

(3) Pursuant to Regulation (EC) No 1451/2007, sulfuryl fluoride has now been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 18, insecticides, as defined in Annex V to that Directive.

(4) Sweden was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 19 June 2007 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(5) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the

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1 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2008/31/EC of the European Parliament and of the Council (OJ L 81, 20.03.2008, p. 57).

2 OJ L 325, 11.12.2007, p. 3.

3 OJ L 414, 30.12.2006, p. 78

findings of the review were incorporated, within the Standing Committee on Biocidal Products on 19 September 2008, in an assessment report.

(6) It appears from the examinations made that biocidal products used as insecticides and containing sulfuryl fluoride may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include sulfuryl fluoride in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as insecticides and containing sulfuryl fluoride can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(7) In the light of the conclusions of the assessment report, it is appropriate to require that products containing sulfuryl fluoride and used as insecticides be authorised only for use by trained professionals in accordance with Article 10(2)(i)(e) of Directive 98/8/EC, and that specific risk mitigation measures are applied at product authorisation level to ensure the safety of operators and of bystanders.

(8) In addition, it is appropriate to require continuous monitoring of sulfuryl fluoride in remote tropospheric air and to require results of such monitoring to be regularly reported to the Commission.

(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 sulfuryl fluoride 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 18 containing sulfuryl fluoride 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

1. Member States shall adopt and publish, by 31 January 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   They shall apply those provisions from 1 February 2011.

   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 is added to entry ‘No. 1’ 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 (*)

			"994 g/kg	1 February 2011	31 January 2013	31 January 2021	18	Member States shall ensure that authorisations are subject to the following conditions: (1) Products shall only be sold to and used by professionals trained to use them. (2) Appropriate measures to protect fumigators and bystanders during fumigation and venting of treated buildings or other enclosures must be taken. (3) Labels and/or safety-data sheets of products shall indicate that, prior to fumigation of any enclosure, all food items must be removed. (4) Concentrations of sulfuryl fluoride in remote tropospheric air are monitored. (5) Member States shall also ensure that reports of the monitoring referred to in point (4) are transmitted by authorisation holders directly to the Commission every fifth year, starting at the latest five years after the authorisation. The limit of detection for the analysis shall be at least 0.5 ppt (equivalent to 2.1 ng sulfuryl fluoride/m^3 of tropospheric air)."

(*) 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,

Draft

COMMISSION DIRECTIVE ../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include boric acid 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 boric acid 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 1451/2007 of 4 December 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. That list includes boric acid.

(2) Pursuant to Regulation (EC) No 1451/2007, boric acid 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) The Netherlands was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 7 July 2006 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 19 September 2008, in an assessment report.

(5) It appears from the examinations made that biocidal products used as wood preservatives and containing boric acid may be expected to satisfy the requirements

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1 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2008/31/EC of the European Parliament and of the Council (OJ L 81, 20.03.2008, p. 57).

2 OJ L 325, 11.12.2007, p. 3.

laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include boric acid in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing boric acid can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) 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 boric acid and used as wood preservatives. In particular, appropriate measures should be taken to protect the soil and aquatic compartments since unacceptable risks to these compartments have been identified during the evaluation. Products should also be used with appropriate protective equipment if the risk identified for professional and industrial users cannot be reduced by other means.

(7) 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 boric acid and also to facilitate the proper operation of the biocidal products market in general.

(8) 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.

(9) 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 boric acid to ensure that they comply with Directive 98/8/EC.

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

(11) 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

1. Member States shall adopt and publish, by 31 January 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   They shall apply those provisions from 1 February 2011.

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

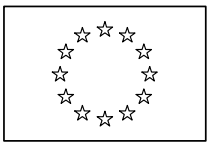
ANNEX

The following entry 'No. 22' 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 (*)
"22	boric acid	boric acid EC No: 233-139-2 CAS No: 10043-35-3	990 g/kg	1 February 2011	31 January 2013	31 January 2021	8	Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for industrial and 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 and on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or

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 (*)
								disposal."

(*) 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,

Draft

COMMISSION DIRECTIVE ../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include boric oxide 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 boric oxide 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 1451/2007 of 4 December 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. That list includes boric oxide.

(2) Pursuant to Regulation (EC) No 1451/2007, boric oxide 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) The Netherlands was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 7 July 2006 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 19 September 2008, in an assessment report.

(5) It appears from the examinations made that biocidal products used as wood preservatives and containing boric oxide may be expected to satisfy the requirements

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1 OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2008/31/EC of the European Parliament and of the Council (OJ L 81, 20.03.2008, p. 57).

2 OJ L 325, 11.12.2007, p. 3.

laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include boric oxide in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing boric oxide can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) 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 boric oxide and used as wood preservatives. In particular, appropriate measures should be taken to protect the soil and aquatic compartments since unacceptable risks to these compartments have been identified during the evaluation. Products should also be used with appropriate protective equipment if the risk identified for professional and industrial users cannot be reduced by other means.

(7) 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 boric oxide and also to facilitate the proper operation of the biocidal products market in general.

(8) 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.

(9) 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 boric oxide to ensure that they comply with Directive 98/8/EC.

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

(11) 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

1. Member States shall adopt and publish, by 31 January 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   They shall apply those provisions from 1 February 2011.

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. 23' 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(*)
"23	boric oxide	Diboron trioxide EC No: 215-125-8 CAS No: 1303-86-2	975 g/kg	1 February 2011	31 January 2013	31 January 2021	8	Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for industrial and 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 and on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or

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(*)
								disposal."

(*) 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,

Draft

COMMISSION DIRECTIVE ../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include disodium tetraborate 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 disodium tetraborate 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 1451/2007 of 4 December 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. That list includes disodium tetraborate.

(2) Pursuant to Regulation (EC) No 1451/2007, disodium tetraborate 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) The Netherlands was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 7 July 2006 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 19 September 2008, in an assessment report.

(5) It appears from the examinations made that biocidal products used as wood preservatives and containing disodium tetraborate may be expected to satisfy the

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[1] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2008/31/EC of the European Parliament and of the Council (OJ L 81, 20.03.2008, p. 57).

[2] OJ L 325, 11.12.2007, p. 3.

requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include disodium tetraborate in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing disodium tetraborate can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) 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 disodium tetraborate and used as wood preservatives. In particular, appropriate measures should be taken to protect the soil and aquatic compartments since unacceptable risks to these compartments have been identified during the evaluation. Products should also be used with appropriate protective equipment if the risk identified for professional and industrial users cannot be reduced by other means.

(7) 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 disodium tetraborate and also to facilitate the proper operation of the biocidal products market in general.

(8) 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.

(9) 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 disodium tetraborate to ensure that they comply with Directive 98/8/EC.

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

(11) 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

1. Member States shall adopt and publish, by 31 January 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   They shall apply those provisions from 1 February 2011.

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. 24' 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(*)
"24	disodium tetraborate	disodium tetraborate EC No: 215-540-4 CAS No (anhydrous): 1330-43-4 CAS No (pentahydrate): 12267-73-1 CAS No (decahydrate): 1303-96-4	990 g/kg	1 February 2011	31 January 2013	31 January 2021	8	Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for industrial and 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 and on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or

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(*)
								disposal."

(*) 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,

Draft

COMMISSION DIRECTIVE ../…/EC

of […]

amending Directive 98/8/EC of the European Parliament and of the Council to include disodium octaborate tetrahydrate 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 disodium octaborate tetrahydrate 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 1451/2007 of 4 December 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. That list includes disodium octaborate tetrahydrate.

(2) Pursuant to Regulation (EC) No 1451/2007, disodium octaborate tetrahydrate 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) The Netherlands was designated as Rapporteur Member State and submitted the competent authority report, together with a recommendation, to the Commission on 7 July 2006 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority report was reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 19 September 2008, in an assessment report.

(5) It appears from the examinations made that biocidal products used as wood preservatives and containing disodium octaborate tetrahydrate may be expected to

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[1] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Directive 2008/31/EC of the European Parliament and of the Council (OJ L 81, 20.03.2008, p. 57).

[2] OJ L 325, 11.12.2007, p. 3.

satisfy the requirements laid down in Article 5 of Directive 98/8/EC. It is therefore appropriate to include disodium octaborate tetrahydrate in Annex I, in order to ensure that in all Member States authorisations for biocidal products used as wood preservatives and containing disodium octaborate tetrahydrate can be granted, modified, or cancelled in accordance with Article 16(3) of Directive 98/8/EC.

(6) 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 disodium octaborate tetrahydrate. In particular, appropriate measures should be taken to protect the soil and aquatic compartments since unacceptable risks to these compartments have been identified during the evaluation. Products should also be used with appropriate protective equipment if the risk identified for professional and industrial users cannot be reduced by other means.

(7) 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 disodium octaborate tetrahydrate and also to facilitate the proper operation of the biocidal products market in general.

(8) 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.

(9) 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 disodium octaborate tetrahydrate to ensure that they comply with Directive 98/8/EC.

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

(11) 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

1. Member States shall adopt and publish, by 31 January 2010 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

   They shall apply those provisions from 1 February 2011.

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

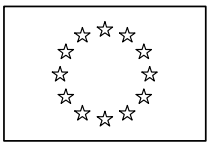
ANNEX

The following entry 'No. 25' 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(*)
"25	disodium octaborate tetrahydrate	disodium octaborate tetrahydrate EC No: 234-541-0 CAS No: 12280-03-4	975 g/kg	1 February 2011	31 January 2013	31 January 2021	8	Member States shall ensure that authorisations are subject to the following conditions: (1) Products authorised for industrial and 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 and on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or

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(*)
								disposal."

(*) 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(2008) XXX final
D001717/01

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 1451/2007 of 4 December 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 1451/2007 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 1451/2007, the Commission informed the Member States thereof. That information was also made public by electronic means on 18 January 2008.

(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 2008/31/EC of the European Parliament and of the Council (OJ L 81, 20.03.2008, p. 57).

2 OJ L 325, 11.12.2007, p. 3.

(5) Pursuant to Article 12(5) of Regulation (EC) No 1451/2007, 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 1451/2007, this Decision shall apply from 1 March 2009.

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	RMS
Ethanol	200-578-6	64-17-5	3	EL
N-(trichloromethylthio)phthalimide / Folpet	205-088-6	133-07-3	6	IT
Fluometuron	218-500-4	2164-17-2	6	EL
Fluometuron	218-500-4	2164-17-2	13	EL
Lignin	232-682-2	9005-53-2	1	EL
Lignin	232-682-2	9005-53-2	2	EL
Lignin	232-682-2	9005-53-2	3	EL
Lignin	232-682-2	9005-53-2	4	EL
Lignin	232-682-2	9005-53-2	6	EL
Lignin	232-682-2	9005-53-2	13	EL
Reaction product of dimethyl adipate, dimethyl glutarate, dimethyl succinate with hydrogen peroxide / Perestane	432-790-1	-	3	HU
N-Didecyl-N-dipolyethoxyammonium borate / Didecylpolyoxethylammonium borate	Polymer	214710-34-6	2	EL
N-Didecyl-N-dipolyethoxyammonium borate / Didecylpolyoxethylammonium borate	Polymer	214710-34-6	6	EL
N-Didecyl-N-dipolyethoxyammonium borate / Didecylpolyoxethylammonium borate	Polymer	214710-34-6	13	EL
Polyvinylpyrrolidone iodine	Polymer	25655-41-8	2	SE
Polyvinylpyrrolidone iodine	Polymer	25655-41-8	4	SE
Polyvinylpyrrolidone iodine	Polymer	25655-41-8	5	SE
Polyvinylpyrrolidone iodine	Polymer	25655-41-8	6	SE