COMMISSION OF THE EUROPEAN COMMUNITIES

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2006/0288 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending

Directive 98/8/EC
concerning the placing of biocidal products on the market, as regards the implementing powers conferred to the Commission

(presented by the Commission)

2006/0288 (COD)

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DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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Directive 98/8/EC
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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4]

Whereas:

(1) Directive 98/8/EC of the European Parliament and of the Council[5] provides that certain measures are to be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[6].

(2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny to be used for the adoption of implementing measures of general scope which seek to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

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5 OJ L 123, 24.4.1998, p.1; corrigendum OJ L150, 8.6.2002, p.71.
6 OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(3) In accordance with the joint statement of the European Parliament, the Council and the Commission[7] on Decision 2006/512/EC, instruments which are already in force must be adjusted in accordance with the applicable procedures. That statement indicates a list of instruments that should be adjusted as a matter of urgency, including Directive 98/8/EC.

(4) In particular power should be conferred on the Commission to amend the Annexes and to adopt the review programme. Since such measures are of general scope and are designed to amend non-essential elements of this Directive and to supplement it by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(5) On grounds of efficiency, and in particular with regard to the time limits imposed to the Commission by Article 11(4), the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of decisions including an active substance in the Directive's positive list.

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

(7) Since the amendments to be made to Directive 98/8/EC are adjustments of a technical nature which only concern the committee procedures, they do not need to be transposed by the Member States. It is therefore not necessary to lay down provisions to that effect.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 98/8/EC is amended as follows:

(1) Article 10 (5) is amended as follows:

(a) In point (i) the third subparagraph is replaced by the following:

"The assessment shall be circulated in accordance with Article 11(2) for decision to be adopted by the Commission in accordance with the procedure laid down in Article 27. That decision, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4)."

(b) In point (ii), point (5) is replaced by the following:

"5. the complete data dossiers of the evaluation serving or having served for entry in Annex I, IA or IB shall be put at the disposal of the Committee referred to in Article 28(4)."

[7] OJ C 255, 21.10.2006, p.1

(2) In Article 11, paragraph 4 is replaced by the following:

"On receipt of the evaluation, the Commission shall, in accordance with Article 27, prepare a proposal without undue delay for a decision to be taken at the latest 12 months after the receipt of the evaluation referred to in paragraph 2. That decision, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4)"

(3) In Article 16, paragraph 2 is replaced by the following:

"Following the adoption of this Directive, the Commission shall commence a 10-year programme of work for the systematic examination of all active substances already on the market on the date referred to in Article 34(1) as active substances of a biocidal product for purposes other than those defined in Article 2(2)(c) and (d). A Regulation will provide for all provisions necessary for the establishment and implementation of the programme including the setting of priorities for the evaluation of the different active substances and a timetable. That Regulation, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4). No later than two years before completion of the work programme, the Commission shall forward to the European Parliament and the Council a report on the progress achieved with the programme.

During that 10-year period and from the date referred to in Article 34(1), it may be decided that an active substance shall be included in Annexes I, IA or IB and under which conditions, or, in cases where the requirements of Article 10 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I, IA or IB. Such measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4)."

(4) In Article 27 paragraph 2 is replaced by the following:

"At the end of the period for comment, the Commission shall prepare a draft for decision in accordance with the relevant procedures referred to in Article 28(2) or 28(4) on the basis of all the following elements:

(a) the documents received from the Member State evaluating the dossiers and;

(b) any advice obtained from advisory scientific committees;

(c) comments received from other Member States and the applicants;

(d) any other relevant information.

(5) Article 28 is amended as follows:

(a) Paragraph 3 is replaced by the following:

" For matters referred to the Standing Committee by virtue of Article 32, Articles 5 and 7 of Decision 1999/468/EC shall apply having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months."

(b) The following paragraph 4 is added:

"4. For matters referred to the Standing Committee by virtue of Article 10, Article 11(4),Article16(2), and Article 27(1)(a) and (2), of this Directive,Article 5a(1) to (4) and (5)(b), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time-limit laid down in Article 5a(3)(c), of Decision 1999/468/EC with regard to Article 11(4), Article 16(2) second subparagraph and Article 27(1)(a) and (2) of this Directive shall be set at one month."

Article 2

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

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*