DIRECTIVE 2008/31/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 March 2008

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

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,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) Directive 98/8/EC of the European Parliament and of the Council [3] 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 [4].

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

(3) In accordance with the statement by the European Parliament, the Council and the Commission [5] concerning Decision 2006/512/EC, for the regulatory procedure with scrutiny to be applicable to instruments adopted in accordance with the procedure referred to in Article 251 of the Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.

(4) The Commission should be empowered to adopt common conditions on research and development, to adapt the annexes and to adopt the review programme. Since those measures are of general scope and are designed to amend non-essential elements of Directive 98/8/EC, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

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

(6) Since the amendments made to Directive 98/8/EC by this Directive are technical in nature and concern committee procedure only, 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

Amendments

Directive 98/8/EC is hereby amended as follows:

1. Article 10(5) shall be amended as follows:

(a) the third subparagraph of point (i) shall be replaced by the following:

'The assessment shall be circulated in accordance with Article 11(2) for a 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) point 5 of point (ii) shall be replaced by the following:

'5. the complete data dossiers of the evaluation serving or having served for entry in Annexes I, IA or IB shall be put at the disposal of the committee referred to in Article 28(1).';

[1] OJ C 161, 13.7.2007, p. 45.
[2] Opinion of the European Parliament of 14 November 2007 (not yet published in the Official Journal) and Council Decision of 3 March 2008.
[3] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2008/16/EC (OJ L 42, 16.2.2008, p. 48).
[4] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
[5] OJ C 255, 21.10.2006, p. 1.

2. Article 11(4) shall be replaced by the following:

'4. 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. Article 16(2) shall be replaced by the following:

'2. Following the adoption of this Directive, the Commission shall commence a 10-year work programme 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). Regulations shall provide for the establishment and implementation of the programme, including the setting of priorities for the evaluation of the different active substances and a timetable. Those regulations, 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 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 will 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 will not be included in Annexes I, IA or IB. Such measures, 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).';

4. Article 17(5) shall be replaced by the following:

'5. Common conditions for the application of this Article, in particular the maximum quantities of active substances or biocidal products that may be released during experiments and the minimum data to be submitted in order to permit an assessment in accordance with paragraph 2, shall be adopted. Those measures, 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).';

5. Article 27(2) shall be replaced by the following:

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

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

(b) any advice obtained from advisory scientific committees;

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

(d) any other relevant information.';

6. Article 28 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. The Commission shall be assisted by a Standing Committee on Biocidal Products.';

(b) paragraph 2 shall be replaced by the following:

'2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.';

(c) paragraph 3 shall be replaced by the following:

'3. Where reference is made to this paragraph, 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.';

(d) the following paragraph shall be added:

'4. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.';

7. Article 29 shall be replaced by the following:

'*Article 29*

Adaptation to technical progress

Measures necessary to adapt Annexes IIA, IIB, IIIA, IIIB, IVA or IVB or the descriptions of product types in Annex V to technical progress or to specify data requirements for each of these product types shall be adopted. Those measures, designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 28(4).'

Article 2

Entry into force

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

Article 3

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 11 March 2008.

For the European Parliament	*For the Council*
The President	*The President*
H.-G. PÖTTERING	J. LENARČIČ