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## **REPORT**

on the 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 extension of certain time periods  
(COM(2008)0618 – C6-0346/2008 – 2008/0188(COD))

Committee on the Environment, S Public Health and Food Safety

Rapporteur: Daciana OctaviSa Sârbu

### ***Symbols for procedures***

- \* Consultation procedure  
*majority of the votes cast*
- \*\*I Cooperation procedure (first reading)  
*majority of the votes cast*
- \*\*II Cooperation procedure (second reading)  
*majority of the votes cast, to approve the common position*  
*majority of Parliament's component Members, to reject or amend the common position*
- \*\*\* Assent procedure  
*majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
- \*\*\*I Codecision procedure (first reading)  
*majority of the votes cast*
- \*\*\*II Codecision procedure (second reading)  
*majority of the votes cast, to approve the common position*  
*majority of Parliament's component Members, to reject or amend the common position*
- \*\*\*III Codecision procedure (third reading)  
*majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

### ***Amendments to a legislative text***

In amendments by Parliament, amended text is highlighted in ***bold italics***. In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a directive of the European Parliament and of the Council on amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods  
(COM(2008)0618 – C6-0346/2008 – 2008/0188(COD))**

**(Codecision procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0618),
  - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0346/2008),
  - having regard to Rule 51 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A6-0076/2009),
1. Approves the Commission proposal as amended;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council and Commission.

### **Amendment 1**

#### **Proposal for a directive – amending act Recital 8**

*Text proposed by the Commission*

(8) The extension of the review programme proposed may not be enough to finalise the evaluation for a number of active substances. On the other hand, a significantly longer extension might work against intensifying the efforts to complete the review programme in a timely manner.  
***Whereas a more flexible procedure to extend the review programme and the corresponding transitional period for any remaining active substances after***

*Amendment*

8) The extension of the review programme proposed may not be enough to finalise the evaluation for a number of active substances. On the other hand, a significantly longer extension might work against intensifying the efforts to complete the review programme in a timely manner.  
***Any extension of the review programme and the corresponding transitional period for any remaining active substances after 14 May 2014 should be limited to a***

*14.5.2013 should be provided for.*

*maximum of 2 years and should take place only if there are clear indications that the legal act intended to replace this Directive will not enter into force before 14 May 2014.*

*Justification*

*The word "transitional" had been omitted accidentally in the draft report. As for the rest, the proposal is part of an agreement between the Parliament, the Council and the Commission.*

**Amendment 2**

**Proposal for a directive – amending act  
Recital 8 a (new)**

*Text proposed by the Commission*

*Amendment*

*(8a) The measures necessary for the implementation of Directive 98/8/EC should 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.*

**Amendment 3**

**Proposal for a directive – amending act  
Recital 8 b (new)**

*Text proposed by the Commission*

*Amendment*

*(8b) In particular, power should be conferred on the Commission to extend the review period and the corresponding transitional period for any remaining active substances for up to two years. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, they must be adopted in line with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.*

## Amendment 4

### Proposal for a directive – amending act Recital 8 c (new)

*Text proposed by the Commission*

*Amendment*

***(8c) In accordance with point 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.***

*Justification*

*The proposal is part of an agreement between the Parliament, the Council and the Commission.*

## Amendment 5

### Proposal for a directive – amending act Article 1 - point 1 - point a Directive 98/8/EC Article 12 - paragraph 1 - point c - point i

*Text proposed by the Commission*

*Amendment*

“(i) until 14 May **2013** for any information submitted for the purposes of this Directive, except where such information is already protected under existing national rules relating to biocidal products. In such cases, the information shall continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, but not beyond 14 May **2013**,”

“(i) until 14 May **2014** for any information submitted for the purposes of this Directive, except where such information is already protected under existing national rules relating to biocidal products. In such cases, the information shall continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, but not beyond 14 May **2014 or, if applicable, not beyond the date to which the transitional period referred to in Article 16(1) is extended in accordance with Article 16(2),**”

### *Justification*

*Adaptation to original amendment as part of an agreement between the Parliament, the Council and the Commission.*

#### **Amendment 6**

##### **Proposal for a directive – amending act**

##### **Article 1 - point 1 - point b**

Directive 98/8/EC

Article 12 - paragraph 2 - point c - point i

##### *Text proposed by the Commission*

“(i) until 14 May **2013** for any information submitted for the purposes of this Directive, except where such information is already protected under existing national rules relating to biocidal products. In such cases, the information shall continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, but not beyond 14 May **2013**,”

##### *Amendment*

“(i) until 14 May **2014** for any information submitted for the purposes of this Directive, except where such information is already protected under existing national rules relating to biocidal products. In such cases, the information shall continue to be protected in that Member State until the expiry of any remaining period of data protection provided for under national rules, but not beyond 14 May **2014 or, if applicable, not beyond the date to which the transitional period referred to in Article 16(1) is extended in accordance with Article 16(2),**”

### *Justification*

*Adaptation to original amendment as part of an agreement between the Parliament, the Council and the Commission.*

#### **Amendment 7**

##### **Proposal for a directive – amending act**

##### **Article 1 - point 2 - point a**

Directive 98/8/EC

Article 16 - paragraph 1

##### *Text proposed by the Commission*

"By way of further derogating from Articles 3(1), 5(1), 8(2) and 8(4), and without prejudice to paragraphs 2 and 3, a Member State may, until 14 May **2013**,

##### *Amendment*

"By way of further derogating from Articles 3(1), 5(1), 8(2) and 8(4), and without prejudice to paragraphs 2 and 3, a Member State may, until 14 May **2014**,

continue to apply its current system or practice of placing biocidal products on the market.”

continue to apply its current system or practice of placing biocidal products on the market. ***If a decision to include an active substance in Annex I or IA sets a later date for compliance with Article 16(3) than 14 May 2014, this derogation shall continue to apply for products including that active substance until the date set in the decision.***

*Justification*

*Adaptation to original amendment as part of an agreement between the Parliament, the Council and the Commission.*

**Amendment 8**

**Proposal for a directive – amending act**

**Article 1 - point 2 - point b - point i**

Directive 98/8/EC

Article 16 - paragraph 2 - subparagraph 1

*Text proposed by the Commission*

“Following the adoption of this Directive, the Commission shall commence a ***thirteen-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).”

*Amendment*

“Following the adoption of this Directive, the Commission shall commence a ***14-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).”;

*Justification*

*Part of an agreement between the Parliament, the Council and the Commission.*

**Amendment 9**

**Proposal for a directive – amending act**

**Article 1 - point 2 - point b - point ii**

Directive 98/8/EC

Article 16 - paragraph 2 - subparagraph 1

*Text proposed by the Commission*

"Depending upon the conclusions of the report, it may be decided, ***in accordance with the procedure laid down in Article 28(3), whether*** the transitional period referred to in the first paragraph and the ***13-year*** period of the work programme ***is to be extended*** for a period ***to be determined***."

*Amendment*

"Depending upon the conclusions of the report, it may be decided ***to extend*** the transitional period referred to in the first paragraph and the ***14-year*** period of the work programme for a period ***of no more than two years. That measure, 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).***"

*Justification*

*Adaptation to original amendment as part of an agreement between the Parliament, the Council and the Commission.*

**Amendment 10**

**Proposal for a directive – amending act**

**Article 1 - point 2 - point b - point iii**

Directive 98/8/EC

Article 16 - paragraph 2 - subparagraph 2

*Text proposed by the Commission*

(iii) in the second subparagraph, the words "During that 10-year period" ***are*** replaced by the words "During that ***thirteen-year*** period".

*Amendment*

(iii) in the second subparagraph, the words "During that 10-year period" ***shall be*** replaced by the words "During that ***14-year*** period".

*Justification*

*Adaptation to original amendment as part of an agreement between the Parliament, the Council and the Commission.*

**Amendment 11**

**Proposal for a directive – amending act**

**Article 2 - paragraph 1 - subparagraph 1**

*Text proposed by the Commission*

1. Member States shall bring into force the laws, regulations and administrative

*Amendment*

1. Member States shall bring into force the laws, regulations and administrative

provisions necessary to comply with this Directive by 14 May 2010 at the latest.  
***They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.***

provisions necessary to comply with this Directive by 14 May 2010 at the latest.

*Justification*

*The provision shall be referred to in a recital. The proposal is part of an agreement between the Parliament, the Council and the Commission.*

## EXPLANATORY STATEMENT

The present Commission proposal amending Directive 98/8/EC on the placing of biocidal products on the market has become necessary after an evaluation of its implementation showed that the ten-year-period until 14 May 2010, foreseen for the evaluation of active substances used in biocidal products with the aim to include them in the Community positive list, will not be enough. As a consequence, the transitional period, during which the biocides market will continue to be regulated by national rules, would expire without the Community positive list being established. In practice this would mean that important products, like for instance disinfectants in hospitals would have to be taken from the market as from 15 May 2010.

In order to avoid this unwanted effect, the Commission proposes a prolongation of the transitional period for three years until 14 May 2013. In case even these three years should not be enough, the Commission introduces the possibility of prolonging it even further by a comitology decision.

The rapporteur welcomes the Commission proposal to extend the current transitional period to allow the completion of the evaluation of active substances used in biocidal products and to give adequate time to Member States to transpose the provisions and to issue the authorisations and registrations for these products, as well as to industry to prepare and submit complete dossiers.

However, the rapporteur, in view of an agreement with the Council and the Commission to reach a first reading agreement in order not to endanger the necessary and urgent adoption of the extension of the transitional period, suggests the following changes to the Commission proposal:

- the extension of the transitional period for four years, instead of three (until 14 May 2014 instead of 14 May 2013) so as to make sure that all biocidal products containing active substances are evaluated in due time creating a market regulated by harmonised rules;
- on the other hand the limitation to a maximum of two years of the possibility to further extend the deadlines for the remaining dossiers through comitology in order to avoid the possibility to endlessly delay the whole process;
- in line with paragraph 34 of the interinstitutional agreement on better law making, the deletion in the articles of the obligation by Member States to communicate to the Commission the texts of their transpositions into national law including correlation tables between those and the Directive and replacing it by the encouragement of Member States in a recital to draw up such tables.

Finally, the rapporteur aims at a joint statement between European Parliament, Council and Commission that the issues of free-riders and data protection are important issues that will need to be addressed as a priority for the full revision of Directive 98/8/EC.

## PROCEDURE

<b>Title</b>	The placing of biocidal products on the market
<b>References</b>	COM(2008)0618 – C6-0346/2008 – 2008/0188(COD)
<b>Date submitted to Parliament</b>	7.10.2008
<b>Committee responsible</b> Date announced in plenary	ENVI 21.10.2008
<b>Rapporteur(s)</b> Date appointed	Daciana Octavia Sârbu 21.11.2008
<b>Discussed in committee</b>	22.1.2009
<b>Date adopted</b>	17.2.2009
<b>Result of final vote</b>	+: 51 -: 0 0: 0
<b>Members present for the final vote</b>	Adamos Adamou, Margrete Auken, Liam Aylward, Irena Belohorská, Maria Berger, Johannes Blokland, John Bowis, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Magor Imre Csibi, Avril Doyle, Mojca Drčar Murko, Jill Evans, Karl-Heinz Florenz, Elisabetta Gardini, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Christa Klaß, Holger Krahmer, Urszula Krupa, Aldis Kuškis, Marie-Noëlle Lienemann, Peter Liese, Marios Matsakis, Linda McAvan, Péter Olajos, Miroslav Ouzký, Vittorio Prodi, Dagmar Roth-Behrendt, Guido Sacconi, Daciana Octavia Sârbu, Carl Schlyter, Richard Seeber, María Sornosa Martínez, Antonios Trakatellis, Evangelia Tzampazi, Thomas Ulmer, Anja Weisgerber, Åsa Westlund, Glenis Willmott
<b>Substitute(s) present for the final vote</b>	Philip Bushill-Matthews, Bairbre de Brún, Jutta Haug, Karsten Friedrich Hoppenstedt, Johannes Lebech, Caroline Lucas, Hartmut Nassauer, Justas Vincas Paleckis, Alojz Peterle