Basic information

2008/0188(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Placing of biocidal products on the market: extension of certain time periods Amending Directive 98/8/EC 1993/0465(COD) **Subject** 3.10.09.02 Plant health legislation	

Key players

European Parliament	**Committee responsible**	**Rapporteur**	**Appointed**
	ENVI Environment, Public Health and Food Safety	SÂRBU Daciana Octavia (PSE)	21/11/2008
Council of the European Union	**Council configuration**	**Meetings**	**Date**
	General Affairs	2957	2009-07-27
European Commission	**Commission DG**	**Commissioner**	
	Environment	DIMAS Stavros	

Key events

Date	Event	Reference	Summary
07/10/2008	Legislative proposal published	COM(2008)0618	Summary
21/10/2008	Committee referral announced in Parliament, 1st reading		
17/02/2009	Vote in committee, 1st reading		Summary
04/03/2009	Committee report tabled for plenary, 1st reading	A6-0076/2009	
23/03/2009	Debate in Parliament		
24/03/2009	Decision by Parliament, 1st reading	T6-0159/2009	Summary
24/03/2009	Results of vote in Parliament		
27/07/2009	Act adopted by Council after Parliament's 1st reading		
16/09/2009	Final act signed		

16/09/2009	End of procedure in Parliament		
06/10/2009	Final act published in Official Journal		

Technical information

Procedure reference	2008/0188(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Amendments and repeals	Amending Directive 98/8/EC 1993/0465(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/68151

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE416.578	18/12/2008	
Amendments tabled in committee		PE418.287	27/01/2009	
Committee report tabled for plenary, 1st reading/single reading		A6-0076/2009	04/03/2009	
Text adopted by Parliament, 1st reading/single reading		T6-0159/2009	24/03/2009	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03624/2009/LEX	16/09/2009	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2008)0618	07/10/2008	Summary
Commission response to text adopted in plenary	SP(2009)3060	04/06/2009	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0042/2009	14/01/2009	

Additional information		
Source	**Document**	**Date**
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act	
Directive 2009/0107 OJ L 262 06.10.2009, p. 0040	Summary

Placing of biocidal products on the market: extension of certain time periods

2008/0188(COD) - 16/09/2009 - Final act

PURPOSE: to extend the 10-year work programme evaluating active substances used in biocidal products with the aim to include them in the Community positive list.

LEGISLATIVE ACT: Directive 2009/107/EC 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.

CONTENT: Directive 98/8/EC provides for a transitional period of 10 years, commencing on 14 May 2000, the date of entry into force of that Directive, during which Member States may apply their national rules or practices for placing biocidal products on the market and, in particular, authorise the marketing of biocidal products containing active substances that are not yet included in the positive list set out in that Directive.

In accordance with Directive 98/8/EC, the Commission has submitted a report on the progress achieved with the 10-year work programme, two years before its completion. It is expected, based on the findings of that report, that the review of a significant number of active substances will not be finalised by 14 May 2010. Furthermore, even for the active substances for which a decision on their inclusion in the positive list set out in Directive 98/8 /EC has been adopted by 14 May 2010, a sufficient time period is necessary for Member States to transpose the relevant acts and to grant, cancel or modify authorisations for the relevant products, in order to comply with the harmonised provisions of Directive 98/8/EC. There is a serious risk that, at the end of the transitional period on 14 May 2010, national rules will no longer apply, while the relevant harmonised rules will not yet have been adopted.

An extension of the 10-year work programme is therefore considered necessary, to permit the finalisation of the review of all active substances notified for evaluation.

The Council adopted a directive extending, by four years **until 14 May 2014**, the deadline for completion of an evaluation of active substances used in biocidal products, following an agreement reached with the European Parliament in the first reading.

The directive also provides for a four-year extension of a transitional period during which the marketing of biocides will continue to be regulated by national rules.

In particular, the Commission should be empowered to extend the review period and the corresponding transitional period for any remaining active substances for **up to two years**. These measures must be adopted in accordance with the regulatory procedure with scrutiny.

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.

ENTRY INTO FORCE: 26/10/2009.

TRANSPOSITION: 14/05/2010.

Placing of biocidal products on the market: extension of certain time periods

2008/0188(COD) - 07/10/2008 - Legislative proposal

PURPOSE: to amend Directive 98/8/EC and extend certain time periods by three years.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: this proposal follows the Commission’s report on the progress of the 10-year work programme for the evaluation of active substances used in biocidal products. The current progress rate of the review programme will not permit its completion by 14 May 2010 as planned. This is mainly due to the fact that, before any review could start, it was necessary to establish an inventory of active substances used in biocidal products placed on the European market of biocidal products, and list the ones that the industry or specific Member States wanted examined in view of the possible inclusion of such products into Annex I or IA of the Directive (the Community positive list). This elaborate exercise has taken three full years to complete.

Overall, 964 active substances were identified, of which 468 were notified for evaluation.

Experience so far indicates that the average time for the evaluation of a regular active substance dossier is four years.

The Directive provides for a transitional period of ten years (14.5.2000- 14.5.2010), during which the biocides market will continue to be regulated by national rules. Gradually, as more and more active substances are evaluated and included in the Community positive list, the national rules for biocidal product authorisations are replaced by the harmonised conditions established by the Directive. However, as the end of the transitional period coincides with the end of the review programme, this means in practice that, on the very next day, only products that contain active substances included in the Community positive list *and* are authorised in accordance with the Directive can be legally placed on the market. Since the review will not terminate before 14/05/2010, all products containing active substances not yet evaluated would have to be withdrawn from the market. Even if all the active substances were evaluated and a decision was adopted for their inclusion, or not, in the Directive's positive list by that date, these decisions would need to be transposed by the Member States and authorisations or registrations for biocidal products containing the substances concerned would have to be issued in accordance with the Directive. This implies the preparation and submission by the industry of complete dossiers on specific biocidal products, their evaluation by the competent authorities, and the issuance of new authorisations or registrations at Member State level and subsequent mutual recognition in other Member States. Only then would the market be regulated by harmonised rules. However, the Directive, as it is now, does not allow for such a period, but requires that the market be fully harmonised by 14/05/2010.

Accordingly, the Commission proposes **the extension of the work programme to 14/05/2013**. The expiry of the transitional period and the end of the review programme will be postponed by three years.

The provisions on data protection will also need to be adjusted to the new deadline of the review programme. Otherwise, there is a risk that the information submitted for the purposes of the Directive from 14/05/20100 until 14/05/2013, will not be protected.

Lastly, a comitology procedure is proposed, in order to extend – if necessary - the review programme and transitional period for any remaining problematic active substance dossiers after 2013.

Placing of biocidal products on the market: extension of certain time periods

2008/0188(COD) - 24/03/2009 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 652 votes to 5, with 17 abstentions, a legislative resolution amending, under the codecision procedure, 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.

The amendments were the result of a compromise negotiated with the Council. The amendments were as follows:

- 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;
- stressing, in a recital, that, in line with paragraph 34 of the interinstitutional agreement on better law making, Member States are encouraged to draw up, for themselves and in the interest of the Community, their own tables which illustrate, to the extent possible, the conformity between this directive and the transposition measures and to publish them.