Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2008/0188(COD)
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	Procedure completed

Key players

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

Key events

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	Results of vote in Parliament		
24/03/2009	Decision by Parliament, 1st reading	T6-0159/2009	Summary
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
	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

Legislative proposal		COM(2008)0618	07/10/2008	EC	Summary
Committee draft report		PE416.578	18/12/2008	EP	
Economic and Social Committee: opinion, report		CES0042/2009	14/01/2009	ESC	
Amendments tabled in committee		PE418.287	27/01/2009	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0076/2009	04/03/2009	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0159/2009	24/03/2009	EP	Summary
Commission response to text adopted in plenary		SP(2009)3060	04/06/2009	EC	
Draft final act		03624/2009/LEX	16/09/2009	CSL	

Additional information

National parliaments	IPEX

Final act

Directive 2009/107
OJ L 262 06.10.2009, p. 0040 Summary

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

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

The Committee on the Environment, Public Health and Food Safety adopted the report drawn up by Daciana Octavia SÂRBU (PES, RO) amending, under the first reading of 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.

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, the report 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.

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

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.

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

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.