

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

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

| Key events |   |  |         |
|------------|---|--|---------|
| Date       | Event   | Reference  | Summary |
| 07/10/2008 | Legislative proposal published                          | COM(2008)0618<br> | 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 <a href="#">1993/0465(COD)</a>      |
| Legal basis                | EC Treaty (after Amsterdam) EC 095                             |
| Stage reached in procedure | Procedure completed  |
| Committee dossier          | ENVI/6/68151   |

| Documentation gateway   |  |  |            |                         |
|---|--|--|------------|-------------------------|
| <b>European Parliament</b>                                      |  |  |            |                         |
| Document type   | Committee                                      | Reference  | Date       | Summary                 |
| Committee draft report  |  | <a href="#">PE416.578</a>  | 18/12/2008 |                         |
| Amendments tabled in committee                                  |  | <a href="#">PE418.287</a>  | 27/01/2009 |                         |
| Committee report tabled for plenary, 1st reading/single reading |  | <a href="#">A6-0076/2009</a>   | 04/03/2009 |                         |
| Text adopted by Parliament, 1st reading/single reading          |  | <a href="#">T6-0159/2009</a>   | 24/03/2009 | <a href="#">Summary</a> |
| <b>Council of the EU</b>  |  |  |            |                         |
| Document type   |  | Reference  | Date       | Summary                 |
| Draft final act   |  | <a href="#">03624/2009/LEX</a>   | 16/09/2009 |                         |
| <b>European Commission</b>                                      |  |  |            |                         |
| Document type   |  | Reference  | Date       | Summary                 |
| Legislative proposal  |  | <a href="#">COM(2008)0618</a><br> | 07/10/2008 | <a href="#">Summary</a> |
| Commission response to text adopted in plenary                  |  | <a href="#">SP(2009)3060</a>   | 04/06/2009 |                         |
| <b>Other institutions and bodies</b>                            |  |  |            |                         |
| Institution/body  | Document type                                  | Reference  | Date       | Summary                 |
| EESC  | Economic and Social Committee: opinion, report | <a href="#">CES0042/2009</a>   | 14/01/2009 |                         |

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

| Final act   |                         |
|---|-------------------------|
| <a href="#">Directive 2009/0107</a><br><a href="#">OJ L 262 06.10.2009, p. 0040</a> | <a href="#">Summary</a> |

## 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 14/05/2010 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.