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will not terminate before 14/05/2010, all products containing active substances not yet evaluated would have to be withdrawn from the market.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.