Making available on the market and use of biocidal products

2009/0076(COD) - 12/06/2009 - Legislative proposal

PURPOSE: to improve the safety of biocidal products used and placed on the market in the European Union and to simplify authorisation procedures.

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

BACKGROUND: Directive 98/8/EC establishes a harmonised regulatory framework for the authorisation and the placing on the market of biocidal products, the mutual recognition of these authorisations within the Community and the establishment at Community level of a positive list of active substances that may be used in biocidal products.

The review of the implementation of the Directive has indicated that for the evaluation of active substances, the simplified procedures provided for in the Directive, notably for low-risk products (Annex IA to the Directive), have no real effect. It has also indicated that the data requirements and data waiving provisions may be unclear or inconsistently applied. In addition, although product authorisation has not yet started, simplification of the procedures concerning the authorisation of biocidal products in Member States may be beneficial in reducing costs and administrative burden for companies and public authorities alike.

IMPACT ASSESSMENT: the impact assessment covers **five main issues** requiring action:

1. **Scope**: including treated materials in the scope of the Directive would significantly increase the costs to industry. However, although the equal treatment of industry and environmental and human health benefits are difficult to quantify, they are likely to be significant;
2. **Product authorisation**: a combination of the Community authorisation for certain products with the strengthening of the mutual recognition process for other products appears to be the most realistic solution;
3. **Data sharing**: mandatory data sharing at product authorisation and active substance approval stage implies the highest total cost savings to applicants, possibly the highest number of safer products remaining on the market and the highest number of animals saved;
4. **Data requirements**: the best option seems to be a combination of data waiving with the use of existing information and a new approach to low risk biocidal products;
5. **Fees charged by Member States**: a partially harmonised fee structure may encourage the development of more new active substances and the retention of more existing active substances. Another option - specific provisions for SMEs - would make the procedure less costly for SMEs.

CONTENT: on 8 October 2008, the Commission submitted a report on the implementation of Directive 98/8/EC and the functioning of the simplified procedures (see COD/1993/0465 under follow-up documents). Based on the conclusions of the report, the present proposal for a revision of Directive 98/8/EC aims to tackle the identified weaknesses of the regulatory framework during the first eight years of its implementation, to improve and update certain elements of the system and to avoid problems anticipated in the future. The main elements of the revision are as follows:

Legal form: the Directive is turned into a Regulation. As a result, there will be no need for national transposition measures, which is also expected to ensure more harmonised implementation of the regulatory framework in the Member States.

Scope: the scope is extended to biocides in materials that might come into contact with food. With regard to materials containing biocidal products, under the current situation, if an article is treated in the EU, then only a biocidal product that is authorised for that purpose may be used. However, if the article is treated with a biocidal product outside the EU and then imported, there is no control over the substance it may incorporate. This could represent risks for human health or for the environment. In addition, this situation is discriminatory to the EU industry, and could lead to the production of treated articles or materials being moved out of the EU in order to circumvent restrictions on certain substances. As part of the revision of the Biocides Directive, it is proposed that **all articles or materials** must be treated only with biocidal products authorised for that purpose in at least one Member State .

Labelling requirements: these have two objectives: (i) to inform consumers that the article was treated with a biocidal product; and (ii) to alert competent authorities in the Member States and trigger any existing inspection provisions aimed at ensuring compliance. The labelling provisions apply equally to EU and non EU manufacturers.

Authorisation: the proposal provides for harmonised procedures for the authorisation of biocidal products. The provisions regarding mutual recognition of authorisations are reworked and clarified, in particular the resolution of disputes between Member States, or between Member States and applicants. Apart from authorisations granted by Member States, a **centralised authorisation system** is proposed. This will be available for products identified as low-risk - without having to go through a separate evaluation of the active substance first- and for products containing new active substances.

The technical and scientific tasks relevant to this centralised system will be carried out by the **European Chemicals Agency (ECHA)**. In addition, ECHA will undertake the coordination of organisational and technical tasks for the evaluation of all applications for inclusion of active substances in Annex I (the Community positive list for active substances) which were until now attributed to the Commission Joint Research Centre.

The **simplified procedures** involving the current Annex IA and IB are repealed, as very little use has been made of them so far. The simplified procedure involving frame formulations is modified so as to allow, within a group of products belonging to the same frame formulation, the replacement of any non-active ingredient by other non-active ingredients (currently, this is restricted to pigments, dyes, and perfumes).

The **rules on comparative assessment** are also modified: the proposed system comprises a first stage where active substances that still give rise to concern and are listed in Annex I, but are also flagged for substitution. Biocidal products containing these active substances may be compared with others that are available on the market for the same or similar use pattern, and if they present significantly higher risk than the latter, their authorisations are refused or cancelled at national level.

Research on animals: the new proposal will also reduce the number of tests on animals. In line with recent policy developments, animal testing may only be carried out once. Following the example of REACH (Community legislation on chemicals), the proposed Regulation shall force undertakings, that make a request for an authorisation, to share the results of their studies on animals, in exchange for equitable compensation. Moreover, tests proving the safety and effectiveness of a biocidal product shall only be required when there is a real need.

Data protection: the data protection system is significantly simplified, without cutting back on any acquired rights under the current system. It also grants protection to data submitted after the inclusion of the active substance in Annex I (mainly during product authorisation): these studies are not protected by the current legislation. The proposed data protection system also covers the case of newly generated studies.

Data requirements: these are modified: (i) the principle of proposing adaptations to the data requirements is formalised and Member States have to inform and assist the applicants with their adaptation requests; (ii) the grounds for waiving of data provided for in REACH will apply also for the proposed Regulation; (iii) the core data requirements are modified and certain long-term animal studies are only required when necessary. Lastly, the **confidentiality** provisions are slightly modified and aligned with those of REACH. This is to facilitate their application by ECHA.

Specific parallel trade rules: for the purpose of facilitating the movement of biocidal products in the EU territory, the proposal provides for specific parallel trade rules: authorised biocidal products that have the same use, contain the same active substance and have essentially identical composition to products authorised in another Member State may be placed on the market of that other Member State via a simplified administrative procedure.

BUDGETARY IMPLICATION: the proposal will have budgetary implications as there is a need to support the European Chemicals Agency (the Agency) in taking up the additional tasks related to the assessment and inclusion of active substances used in biocidal products in Annex I of the Regulation and the centralised authorisation of certain biocidal products. The Agency will receive specific fees from applicants for certain of these activities as well as an annual fee on products centrally authorised by the Community. The revenue from the fees will have to be supplemented by a subsidy from the Community.