Biocidal products for non-agricultural uses: common rules for national authorisations

1993/0465(COD) - 13/06/2005 - Implementing legislative act

LEGISLATIVE ACT : Commission Regulation 1048/2005/EC amending Regulation 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

CONTENT : Article 4 of Commission Regulation 2032/2003/EC lays down that, from the date of entry into force, any existing active substance not listed in Annex I to that Regulation is to be considered as not having been placed on the market for biocidal purposes before 14 May 2000. As a consequence biocidal products containing active substances not listed in Annex I may no longer be placed on the market, unless inclusion into Annex I or IA to Directive 98/8/EC is applied for in accordance with Article 11 of that Directive, and provisional authorisation has been received in accordance with Article 15(2) of that Directive. However, a limited number of active substances have been detected by the Member States which were not identified or notified before the time limit laid down in Commission Regulations 1896 /2000/EC and 1687/2002/EC although there is evidence they were contained in biocidal products placed on the market before 14 May 2000. Some of these active substances are important from a socioeconomic perspective or for protection of public health. It is therefore appropriate to draw up a further list of active substances that should be allowed to remain on the market until 1 September 2006.

Certain substances not included in Annex II to Regulation 2032/2003/EC are applied in uses for which Member States claim that there is evidence demonstrating the essential need for reasons of health, safety, and protection of cultural heritage, or the use is critical for the functioning of society in the absence of technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment or health. It is therefore appropriate to introduce a system for applying for an extension of the period for marketing of biocidal products containing those substances. Such extensions should only be granted for the requesting Member States if the requests are justified, continued use does not give rise to concerns for human health and the environment, and, where appropriate, alternatives are being developed. The extension should only be allowed until 14 May 2010 at the latest.

In accordance with Article 4(2) of Regulation 2032/2003, placing on the market of biocidal products containing active substances not notified, or not notified for the appropriate product types, has to stop on 1 September 2006 at the latest. For certain substances or substance/product type combinations that have so far not been notified, there is now an interest by economic operators to prepare complete dossiers in view of their inclusion into Annex I or IA to Directive 98/8/EC. It is therefore appropriate, to introduce the possibility to prolong the marketing deadline for biocidal products containing such substances, in the product type concerned, provided interested operators submit complete dossiers well before 1 September 2006. If these dossiers are accepted, an extension of the period for placing those products on the market in the product types concerned should be allowed until the end of the evaluation of the complete dossiers, which should take place in parallel with the evaluation of the notified substances for the product types concerned.

For a number of notified existing active substances/product type combinations — in particular those notified for product types 8 and 14 — all participants have withdrawn or not complied with their obligations, and no other economic operator or Member State has expressed an interest to take over the role of participants within the given deadlines. Furthermore, following the recent classification by the competent authorities and the Commission of certain milk hygiene products as biocidal products in product type 3 as defined in Annex V to Directive 98/8/EC, it is appropriate to include into Annex II

certain substances used in those milk hygiene products where producers, formulators or associations believing that these were not concerned by Directive 98/8/EC did not submit notifications before the deadlines established by Regulations 1896/2000/EC and 1687/2002/EC, but have done so before the adoption of this Regulation. Annexes II and III to Regulation 2032/2003/EC should therefore be amended accordingly. Annex V, Parts A, B, C, and D, and Annex VI should also be amended in the light of the provisions contained in this Regulation.

For one substance listed in Annexes I and II to Regulation 2032/2003/EC an incorrect CAS number and for another one an erroneous common name are indicated. Four substances are not listed in Annexes I and III, although they were identified within the deadlines set by Regulation 1896/2000/EC. This should be rectified.

Regulation 2032/2003/EC should therefore be amended accordingly.

This is the aim of the present Regulation.

ENTRY INTO FORCE : 29/07/2005.