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

1993/0465(COD) - 04/11/2003 - Implementing legislative act

LEGISLATIVE ACT : Commission Regulation 2032/2003/EC 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, and amending Regulation 1896/2000 /EC.

CONTENT : under Regulation 1896/2000/EC existing active substances for use in biocidal products had to be identified and those to be evaluated with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC in one or more product types had to be notified no later than 28 March 2002. An additional period for the submission of notifications for existing active substances that had been identified only or had been notified only in respect of certain product types was granted by Commission Regulation 1687/2002/EC of 25 September 2002 on an additional period for notification of certain active substances already on the market for biocidal use as established in Article 4(1) of Regulation 1896/2000/EC. That period expired on 31 January 2003.

It is necessary to establish an exhaustive list of existing active substances that have been identified in accordance with Article 3(1) or Article 5(2) of Regulation 1896/2000/EC or in respect of which equivalent information has been submitted in a notification in accordance with Article 4(1) of that Regulation.

It is also necessary to establish an exhaustive list of existing active substances in respect of which at least one notification has been accepted in accordance with Article 4(2) of Regulation 1896/2000/EC or in which a Member State has expressed an interest in accordance with Article 5(3) of that Regulation. That list should specify the product types concerned.

More specifically, as regards the second phase of the review programme, priorities for the evaluation of existing active substances should be established. The lists of prioritised substances and the dates for submission of complete dossiers should be specified. The task of evaluation should be distributed among the competent authorities of the various Member States. In order to enable new Member States to participate in the review programme after their accession, it is appropriate, for the time being, to designate Rapporteur Member States only in respect of certain product types. A Member State which has indicated an interest in seeking review of a particular active substance should not be designated Rapporteur Member State for that substance.

In order to avoid duplication of work, and in particular to reduce testing involving vertebrate animals, the requirements concerning preparation and submission of the complete dossier should be such as to encourage those whose notifications have been accepted, hereinafter "participants", to act collectively, in particular by submitting collective dossiers. It should be possible for the Rapporteur Member State to make available the reference to any test involving vertebrate animals that has been carried out in respect of a notified existing active substance unless that reference is confidential under Article 19 of Directive 98 /8/EC. Also, in order to gain experience on the appropriateness of data requirements and to ensure that the review of active substances is carried out in a cost-effective way, participants should be encouraged to provide information on the costs of compiling a dossier and on the need to carry out tests on vertebrate animals.

The present Regulation lays down detailed rules for the implementation of the second phase of the programme of work for the systematic examination of all active substances already on the market on 14 May 2000 as active substances of biocidal products referred to in Article 16(2) of Directive 98/8/EC.

ENTRY INTO FORCE : 14/12/2003.