1. By way of derogation from Article 15, an experiment or a test for the purposes of research or development involving the placing on the market of an unauthorised biocidal product or an active substance intended exclusively for use in a biocidal product may only take place in the case of scientific research and development or in the case of product and process-oriented research and development, and under the conditions laid down in the second and third subparagraphs.

In the case of scientific research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.

In the case of product and process-oriented research and development, the person who intends to carry out the experiment or the test shall notify the competent authority prior to the start, provided that the quantities of active substances or biocidal products that may be released during the experiment or test do not exceed one tonne per year. The person shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data and quantities supplied, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The persons concerned shall, if requested, make this information available to the competent authority.
test shall, prior to the placing of the biocidal product or the active substance on the market, notify the information required in the second subparagraph to the competent authority of the Member State where the placing on the market occurs.

2. An unauthorised biocidal product or an active substance for exclusive use in a biocidal product shall not be placed on the market for the purpose of any experiment or test which may involve, or result in, release of the biocidal product into the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and issued a national authorisation for this purpose which limits the quantities to be used and the areas to be treated and which may impose further conditions. The competent authority shall without delay inform the Commission and other competent authorities about the issued national authorisation.

3. Where any experiment or test takes place in a Member State other than the Member State where placing on the market of the biocidal product occurs, the applicant shall obtain experiment or test authorisation from the competent authority of the Member State in the territory of which the experiments or tests are to be conducted.

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects on human or animal health or any unacceptable adverse effect on the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and issued a positive opinion for this purpose which may impose further conditions. In the absence of an opinion from the competent authority within 30 days of the notification of the information required under paragraph 1, the biocidal product or active substance may be placed on the market for the purpose of the notified experiment or test.

3. Where any experiment or test takes place in a Member State other than the Member State where placing on the market of the biocidal product occurs, the applicant shall notify the competent authority of the Member State in the territory of which the experiments or tests are to be conducted. The applicant shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data and quantities supplied, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. The applicant shall, if requested, make this information available to the competent authority.

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects on human or animal health or any unacceptable adverse effect on the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and issued a national authorisation for this purpose which limits the quantities to be used and the areas to be treated and which may impose further conditions. The competent authority shall without delay inform the Commission and other competent authorities about the issued national authorisation.

3. Where any experiment or test takes place in a Member State other than the Member State where placing on the market of the biocidal product occurs, the applicant shall obtain experiment or test authorisation from the competent authority of the Member State in the territory of which the experiments or tests are to be conducted.

If the proposed experiments or tests referred to in paragraphs 1 and 2 may have harmful effects on human or animal health or any unacceptable adverse effect on the environment unless the competent authority has assessed the data submitted by the person interested in the placing of such product on the market and issued a positive opinion for this purpose which may impose further conditions. In the absence of an opinion from the competent authority within 30 days of the notification of the information required under paragraph 1, the biocidal product or active substance may be placed on the market for the purpose of the notified experiment or test.
environment, the competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall without delay inform the Commission and other competent authorities about such measures.
Amendment 336
Amalia Sartori, Catherine Soullie, Françoise Grossetête and others

Report
Christa Klaß
Placing on the market and use of biocidal products

Proposal for a regulation
Article 21 - paragraph 4 a (new)

Text proposed by the Commission

4a. By way of derogation from paragraph 1, a comparative assessment shall not be required for biocidal products whose use has been shown to be safe.

Amendment

Or. en

Justification

To assess whether a product may be removed from the market after being the subject of a comparative evaluation, consideration should always be given in the risk/benefit assessment (see paragraph 3) to the effectiveness of the product and the availability of existing products in sufficient numbers and variety to treat the contamination or infestation concerned. The comparison should focus on biocidal products for which there is an identified risk and where alternatives are needed.
Proposed for a regulation
Article 9 – paragraph 1 – point a

Text proposed by the Commission

(a) its acceptable daily intake, acute reference dose or acceptable operator exposure level is significantly lower than those of the majority of the active substances included in Annex I for the same product type;

Amendment

deleted

Or. en

Justification

This can often be mitigated by changes in the use of the product or by use of personal protective equipment and engineering controls.