Amendment 356
Christa Klaß
on behalf of the PPE Group

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

Proposal for a regulation
Article 16 – paragraph 1 – point d a (new)

Text proposed by the Commission
(da) when nanomaterials are used in biocidal products, the risk to the environment and to health has been assessed specifically as part of the overall risk assessment.

Amendment

Or. en

Justification

Nanomaterials have different characteristics to the same substances in a non-nanomaterial form. The risks posed by biocides with nanomaterials must therefore be investigated separately.
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Proposal for a regulation
Article 46 – paragraphs 1 to 3

Text proposed by the Commission

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, 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.

Amendment

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. 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.
research and development, the person who intends to carry out the experiment or the 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. 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, 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.
15.9.2010

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Proposal for a regulation
Article 16 – paragraph 6 b (new)

Text proposed by the Commission

6b. In order to facilitate the harmonisation of authorisation practices throughout the Union and to reduce the administrative burden on companies and competent authorities, the Commission shall adopt, by means of delegated acts in accordance with Article 71a and subject to the conditions of Articles 71b and 71c, measures specifying the conditions, criteria and procedures for regulating the authorisation and placing on the market of the same product for the same use, under different trade names and by different companies. The criteria and the procedures for such measures shall be based on, but not limited to, the following principles:

(a) no additional evaluation will be performed as it concerns an already authorised product;
(b) authorisation decisions shall be taken within a short timeframe;
(c) authorisation fees shall be low in accordance with the limited administrative work required.

Amendment

Or. en
Justification

In some EU Member States, the current authorisation practice is to permit and facilitate marketing of the same products for the same use, under different trade names and by different companies through a system of different types of authorisation. Because the nature of duplicate and supplementary authorisations is purely administrative and technical, there is no need for a re-evaluation of effects on human health or the environment.