Making available on the market and use of biocidal products

2009/0076(COD) - 19/01/2012 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a legislative resolution on the Council position with a view to the adoption of a regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

Parliament adopted its position in second reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise negotiated between Parliament and Council. They amend the Council's position as follows:

Purpose and scope: as required by Parliament, the amended text clarifies that **special attention shall be paid to the protection of vulnerable groups.**

The Regulation shall not apply to biocidal products or treated articles that are within the scope of the instruments specified in the text, amongst which is Directive 2009/48/EC on the safety of toys.

It will not apply to: (i) food or feed used as repellents or attractants; (ii) biocidal products when used as processing aids.

Nothing in the Regulation shall prevent Member States from restricting or banning the use of biocidal products in the **public supply of drinking water**.

'Biocidal product': the definition in the amended text covers any substance or mixture generated from substances or mixtures which are not themselves biocidal products in the meaning of the Regulation to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

'Substance of concern': this means a substance which fulfils the criteria for being a POP under Regulation (EC) No 850/2004, or which fulfils the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII of Regulation (EC) No 1907/2006.

'Nanomaterial': this is defined as a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

For the purposes of the definition of nanomaterial, 'particle', 'agglomerate' and 'aggregate' are defined.

The Commission shall be empowered to adopt delegated acts in order to adapt the definition of nanomaterial in view of technical and scientific progress and taking into account the Commission Recommendation 2011/696/EU.

With regard to authorisation, the text conforms to Parliament's request and states that risks posed by nanomaterials in biocidal products to health and the environment **must be examined separately.**

A biocidal product shall be eligible for the **simplified procedure only if the biocidal product does not contain a nanomaterial.**

With regard to treated articles, the person responsible for the placing on the market of that treated article shall ensure that the label states the name of all nanomaterials contained in biocidal products, followed by the word 'nano' in brackets.

Approval of active substances: an active substance may only be approved for an initial period **not exceeding 5 years**. The approval shall specify the date of approval and the expiry date of the approval of the active substance.

Exclusion criteria: active substances which are **considered as having endocrine-disrupting properties that may cause adverse effects in humans shall not be approved**. No later than 13 December 2013, the Commission shall adopt delegated acts specifying scientific criteria for the determination of endocrine disrupting properties.

Active substances may be approved if it is shown that at least one of the following conditions is met:

- the risk to humans or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release to the environment;

- it is shown by evidence that the active substance is essential to prevent or to control a serious danger to public or animal health or to the environment; or not approving the active substance would cause disproportionate negative impacts for society when compared with the risk to human health or the environment arising from the use of the substance.

When deciding whether an active substance may be approved in accordance with the first subparagraph, the **availability of suitable and sufficient alternative substances or technologies** shall be a key consideration.

The use of any biocidal product containing active substances approved in accordance with the regulation shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.

Submission and validation of applications: the evaluating competent authority shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fees payable under the regulation and shall reject the application if the applicant fails to pay the fees within 30 days.

Where the evaluating competent authority considers that there are concerns for human health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, it shall document its concerns and include this as part of its conclusions.

Active substances which are candidates for substitution: an active substance shall be considered a candidate for substitution if it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a **respiratory sensitiser**.

Renewal and review of approval: the renewal shall be for 15 years for all product-types to which the approval applies, unless a shorter period is specified in the Regulation renewing the approval of an active substance.

The Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in the regulation are no longer met.

General conditions of authorisation: as Members had asked, the notification of products should be made **at least 30 days in advance** to allow a real market monitoring. The Commission shall, by means of an implementing act, specify procedures for the authorisation of the same biocidal products by the same or different enterprises under the same terms and conditions.

For **applications for Union authorisations**, the **summary of the characteristics of the biocidal product** shall be provided in one of the official languages of the Union accepted by the evaluating competent authority at the time of application and in all official languages of the Union before the authorisation of the product.

Measures geared to the sustainable use of biocidal products: three years after the entry into force of the Regulation, the Commission shall, on the basis of experience gained with the application of the Regulation, present a report on how the Regulation contributes to a sustainable use of biocidal products, including on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to human and animal health and the environment by biocidal products. That report shall, inter alia, examine:

- the promotion of best practices as a means of reducing the use of biocidal products to the minimum;
- the most effective approaches for monitoring the use of biocidal products;
- the development and application of integrated pest management principles with respect to the use of biocidal products;
- the risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens, public spaces, geriatric care centres or in the vicinity of surface or groundwater and whether additional measures are needed to address them;
- the role that the improved performance of the equipment used for the application of biocidal products could make to sustainable use.

On basis of that report, the Commission shall, if appropriate, present a legislative proposal.

Union authorisations: the amended text stipulates that applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 (exclusion criteria) and certain product types:

- from 1 September 2013, the Union authorisation may be granted to biocidal products containing one or more new active substances and biocidal products of product-types 1 (human hygiene), 3 (veterinary hygiene), 5 (drinking water), 18 (insecticides, acaricides and products to control other arthropods) and 19 (repellents and attractants);
- from 1 January 2017, the Union authorisation may be granted to biocidal products of product-types 2 (Disinfectants and algaecides not intended for direct application to humans or animals) , 6 (preservatives for products during storage) and 13 (working or cutting fluid preservatives);

- from 1 January 2020, the Union authorisation may be granted to all categories of biocidal products.

Derogation from the requirements: by way of derogation, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in the Regulation, for a limited and controlled use under the supervision of the competent authority , if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means.

Research and development: any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the relevant competent authority of the Member State where the experiment or test will occur. The notification shall include the identity of the biocidal product or active substance, labelling data and quantities supplied and all available data on possible effects on human or animal health or impact on the environment. The person concerned shall make any other information available to the competent authorities on request.

Labelling: the person responsible for the placing on the market of a treated article shall label it with any relevant instructions for use, including any precautions to be taken, if this is necessary to protect humans and the environment. The supplier of a treated article shall, upon request by a consumer, provide, within 45 days, free of charge, information on the biocidal treatment of the treated article.

The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty in the official language or languages of the Member State of introduction, unless that Member State provides otherwise.

Animal testing: in order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. Any person intending to perform tests or studies shall, in the case of data involving tests on vertebrate animals, submit a **written request to the Agency** to determine whether such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application under the Regulation or Directive 98/8/EC.

Where such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application, the Agency shall, without delay, communicate the name and contact details of the data submitter(s) and data owner(s) to the prospective applicant.

Data owners must **share information** in exchange for **equitable compensation.**

The Regulation shall apply from 1 September 2013.