Making available on the market and use of biocidal products

2009/0076(COD) - 22/09/2010 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 550 votes in favour to 22 against with 80 abstentions, a resolution under the ordinary legislative procedure (formerly the co decision procedure).on the proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products. The main points are as follows:

Precautionary principle and special vulnerability of children: the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market and use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, in order to ensure that active substances or products placed on the market do not have harmful effects on humans, non-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick.

Nanomaterials: there is scientific uncertainty about the safety of nanomaterials for human health and the environment and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has identified some specific health hazards as well as toxic effects on environmental organisms for some nanomaterials. SCENIHR has furthermore found a general lack of high-quality exposure data for both humans and the environment, concluding that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed, validated and standardised. More and more biocidal products contain nanosilver. The use of nanomaterials in biocidal products may increase with the further development of technology. In order to ensure a high level of consumer protection, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for nanomaterials at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly. At present, there is inadequate information on the risks associated with nanomaterials. In order better to assess their safety, the Scientific Committee for Consumer Safety (SCCS) should provide guidance in cooperation with relevant bodies on test methodologies which take into account specific characteristics of nanomaterials. The Commission should regularly review the provisions on nanomaterials in the light of scientific progress.

AFS Convention: in view of the environmental impact that anti-fouling products can have in the water, the Commission must take steps at international level to ensure that the AFS Convention (International Convention on the Control of Harmful Anti-Fouling Systems on Ships) is ratified worldwide and adapted to the Regulation.

Exclusion from the scope: active substances which shall not be included in Annex I include active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen/ mutagen/oxic for reproduction category 1A or 1B. They also include: active substances which, on the basis of the assessment of Union or internationally agreed test guidelines or other peer-reviewed scientific data and information, are considered as having endocrine-disrupting properties that may cause adverse effect in humans, or which are identified under Regulation (EC) No 1907/2006 as having endocrine disrupting properties; persistent, bio-accumulative and toxic; and persistent organic pollutants (POP).

However, these **may be included in Annex I under certain specified circumstances** – for example, if it is shown by evidence that the active substance is necessary to prevent or control a serious danger to public or animal health or to the environment, to food and feed safety, or to the public interest and that there are no effective alternative substances or technologies available.

Member State authorising a biocidal product containing an active substance included in Annex I pursuant to this provision shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods, which are as effective as the biocidal product concerned and shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.

Lastly, not later than 13 December 2013, the Commission shall adopt, by means of delegated acts measures on specific scientific criteria for determining endocrine-disrupting properties. Pending the adoption of those criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties. Substances such as those that are classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered as having such endocrine-disrupting properties.

With regard to **data requirements for an application**, the resolution specifies that a **letter of access to a dossier** may be part of the application. They also make several amendments to provisions on the submission and validation of applications, with particular reference to the time limits, and state that the Agency should observe the same timeframes for the validation of applications as those introduced under Article 20 of REACH.

With respect to active substances which are candidates for substitution, Members considers that non-active isomers do not pose a danger to health or the environment. There is therefore no need to include them among substances that are candidates for substitution.

Renewal and review of an active substance inclusion: unless more strictly specified in the decision to renew the inclusion of an active substance in Annex I, the renewal may be renewed for a period not exceeding 10 years (rather than an indefinite period, as stated in the proposal.)

Parliament also made amendments to the clauses on the submission and validation of applications, and aligned comitolgy provisions with the TFEU.

General principles of authorisation: application for authorisation shall be submitted to the Agency. When an applicant submits an application for national authorisation, that applicant shall, with the agreement of the Member State concerned on whose territory the national authorisation would be applicable, identify the evaluating competent authority in the application itself. Parliament considers that the ECHA should conduct the initial validation of all applications.

Conditions for authorisation include a consideration of cumulative or synergistic effects. Where nanomaterials are used, the risk to the environment and to health has been assessed separately. The resolution states that infestation with harmful organisms shall be avoided by suitable measures of deterrence to banish or repel these organisms. In addition, other precautionary steps have to be taken, such as proper warehousing of goods, compliance with hygiene standards and immediate disposal of waste. Only if these measures show no effect shall further steps be taken. Biocidal products that pose low risks

for humans, animals and the environment shall always be used in preference to others. Biocidal products that are intended to harm, kill or destroy animals that are capable of experiencing pain and distress shall only be applied as a last resort.

Within two years of the date of adoption of the Regulation, mandatory measures shall be established and implemented with a framework directive for Union action in order to achieve the sustainable professional use of biocidal products including the introduction of National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives.

With respect to the criteria for **low-risk biocidal products**, Parliament expanded the criteria for those substances which should not be considered as low risk, including substances that are corrosive, explosive, contain a nanomaterial, and very toxic or toxic. It deleted the derogation in cases of negligible exposure.

Comparative assessment must be carried out in relation to all biocidal products having the same purpose, when sufficient experience has been gained in their use and they have been in use for at least five years. Members state that the Commission shall adopt measures laying down the procedure necessary for the definition of an application for comparative assessment of biocidal products. These measures shall define the criteria and algorithms to be used in a comparative assessment to ensure that there is a uniform application throughout the Union.

National authorisations: the person responsible for the placing of a biocidal product on the market, or his representative, shall submit an application for a national or Union authorisation to the Agency and inform the Agency of the name of the competent authority of the Member State of his choice which shall be responsible for the evaluation of the application (the 'evaluating competent authority'). The Agency shall, within three weeks after the receipt of the application, notify the evaluating competent authority that the application is available in the Agency database.

Mutual recognition procedures: applications for a national authorisation which involve a mutual recognition procedure may be submitted to the competent authority in English. A single authorisation number shall be used in all the Member States involved.

Community authorisations: from 2013 the Community authorisation may be granted to the following categories of biocidal products: (a) biocidal products containing one or more new active substances; (b) low-risk biocidal products. From 2017 the Community authorisation may be granted to all categories of biocidal products with the exception of biocidal products that contain active substances that fall under the provisions on the exclusion criteria. A Member State shall notify the Commission where it restricts or prohibit the Union authorisation for certain biocidal products in the territory of that Member State. Such restriction or prohibition must be justified on specified grounds.

Parliament makes several amendments to provisions on the cancellation, review and amendments of authorisations.

Labelling: the label must show whether the product contains nanomaterials and any specific related risks and, following each reference to nanomaterials, the word "nano" in brackets. Safety data sheets must contain specified information. The resolution states that Member States shall take the necessary measures to provide the public with information about the benefits and risks associated with biocidal products and ways of minimising the use of those products. The Commission shall make available on the internet a list of all active substances available within the internal market.

Treated articles or material: these must contain the words "treated with biocidal products", followed by the name, using wherever possible common nomenclature (e.g. INCI), of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials, where relevant, and for all active substances which are intended to be released under normal or foreseeable conditions of

use from the treated article or material, unless at least equivalent labelling requirements or alternative means to meet information requirements already exist under sector-specific legislation ; the names of all nanomaterials followed by the word "nano" in brackets. They must also contain any hazard statement or precautionary statement set out in the authorisation for the biocidal product but only if the biocidal product is intended to be released under normal or reasonably foreseeable conditions of use.

National helpdesks in Member States: Member States shall establish national helpdesks to provide advice to applicants, in particular to SMEs, and any other interested parties on their respective responsibilities and obligations under this Regulation. These shall be in addition to any assistance provided by the Agency under the terms of the Regulation.

Comitology: Members made certain amendments in order to align the comitology regime to the new system of delegated acts in accordance with Article 290 TFEU, and provided for transitional measures until the new rules on implementing acts are adopted.

Reports: the Commission must submit the following reports:

- a report on the implementation of the Regulation and, in particular, on the functioning of the Community authorisation procedure and mutual recognition, by 1 January 2019 and every three years thereafter ;
- at the latest two years after the entry into force of the Regulation, a report on the assessment of the risks to human health and the environment presented by the use of nanomaterials in biocidal products and on specific measures to be taken with regard to them;
- not later than five years after the entry into force of the Regulation, a report on the impact of the spread of biocidal products in the environment.

Animal testing: given that animal testing should be avoided, testing on vertebrate animals shall be undertaken only as a last resortwhere no alternative solution can be employed without producing an impact on humans or animals. Testing on vertebrate animals shall not be repeated for the purposes of the Regulation. Where those tests or studies have already been submitted in connection with a previous application, the competent authority or the Agency shall, without delay, assess technical equivalence in relation to the comparison source. If the technical equivalence assessment is positive, the competent authority or the Agency shall without delay communicate the name and contact details of the owner of the information to the prospective applicant.

Annexes: Parliament made certain amendments to the Annexes.