Making available on the market and use of biocidal products

2009/0076(COD) - 10/10/2011 - Committee recommendation tabled for plenary, 2nd reading

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading in the report by Christa KLASS (EPP, DE) regarding the Council position at first reading 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.

The committee reinserted several amendments adopted by the European Parliament in forst reading. It recommended that Parliament's position on second reading should modify the Council's position as follows:

Purpose of the Regulation: Members want to specify that the purpose of protecting both human and animal health and the environment is at an equal level as the purpose of the functioning of the internal market, and not just an ancillary purpose. In view of the precautionary principle, it is necessary to ensure that active substances or products placed on the market do not have harmful effects on humans, on-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick.

Scope: Council Directive 98/83/EC on the quality of water intended for human consumption should remain the main legislation applicable biocidal products used for drinking water treatment.

Furthermore, materials and articles intended to come into contact with food, including any biocidal products linked to such materials, are already covered by Regulation (EC) No 1935/2004, and should be excluded from the scope of this regulation.

The report specifies that Member States may allow for **exemptions from this Regulation** in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence or of animal disease control.

Dangerous substances: 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 should be considered a dangerous substance.

Nanomaterials: Members consider that the definition of nanomaterials is an essential element of the regulation and thus needs to be adopted by the legislator. No later than six months after the adoption of the Recommendation concerning the definition of nanomaterials, the Commission shall make a legislative proposal to amend this Regulation to include that definition in this Regulation.

Nanomaterials can have very different characteristics to the same substances in normal form. The risks posed by nanomaterials in biocidal products to the environment and to health must therefore be investigated separately.

Furthermore, in light of the current lack of appropriate risk assessment of nanomaterials, they should not qualify for the simplified authorisation procedure. Where a treated article contains a biocidal product, the

person responsible for the placing on the market of that treated article shall ensure that the label provides certain specified information including the name of all nanomaterials, followed by the word "nano" in brackets.

Inclusion of active substances: an active substance may not be placed on the market for use in a biocidal product unless it is included in Annex I, in accordance with the Regulation. An active substance referred to in Article 5 may only be included in Annex -I for an initial period of 5 years. Substances that come under the exclusion criteria may only be included in Annex 1 for an initial period of 5 years.

Exclusion criteria: Members specify that active substances shall not be approved for inclusion in Annex I if, on the basis of the assessment of Union or internationally agreed test guidelines or other peer-reviewed scientific data and information, including a review of the scientific literature, reviewed by the Agency, they are considered as having **endocrine-disrupting properties** that may cause adverse effects in humans.

No later than 13 December 2013, the Commission shall adopt delegated acts specifying scientific criteria for the determination of endocrine disrupting properties.

Members suggest that active substances may not be included in Annex I unless at least one of the following conditions is fulfilled:

- the exposure of humans or the environment to the active substance in question in a biocidal product, under normal conditions of use, is negligible, meaning that the product is used in closed systems or under other conditions excluding contact with humans;

- 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.

The use of any biocidal product containing active substances included in Annex I shall be subject to appropriate **risk mitigation measures** to ensure that exposure of humans and the environment is minimised.

Member State authorising a biocidal product containing an active substance included in Annex I 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.

Approval of an active substance: in order to preserve Parliament’s rights of control, active substances should continue to be included in an Annex to the Regulation and **decided by means of delegated acts**. The act should include the conditions and relevant dates of inclusion and expiry of inclusion. There should also be a decision in its own right if a substance is not included in Annex I, in order to have a record of all decisions.

Active substances for substitution: active substances must be candidates or substitution if (i) it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser; (ii) there are reasons for concern linked to the nature of the critical effects, in particular developmental neurotoxic or immunotoxic effects.

Renewal and review of approval: unless more strictly specified in the decision to renew the approval of an active substance, the renewal shall be for ten years (and not 15 as the Council had prescribed) for all product-types to which the approval applies.

The Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications, not only serious indications, that any of the conditions laid down) are no longer met. The Commission may also inclusion where there are significant indications that the objectives of Directive 2000/60/EC on water may not be achieved.

General conditions of authorisation: Members consider that the notification of products should be made at least 30 days in advance to allow a real market monitoring. They made certain amendments to make it easier for biocidal products with the same formulation and intended use to be marketed under different brand names and by different manufacturers. As such authorisations relate to biocidal products whose formulations are identical, there is no need to assess their impact on human health and the environment again.

Measures geared to the sustainable use of biocidal products: the committee states that Member States shall establish and implement mandatory measures on the basis of a Union framework directive 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.

The Commission shall submit a legislative proposal for the framework directive within two years of adoption of the regulation.

Mutual recognition: for the purposes of simplification, Members state that in the case of a biocidal product family, one single authorisation number shall be provided for all biocidal products which belong to that product family.

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):

- from 2013 the Union authorisation may be granted to biocidal products containing one or more new active substances;

- from 2017 the Union authorisation may be granted to all categories of biocidal products.

Treated articles or materials: 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 national language or languages of the Member State on whose market the treated article is to be placed. In the case of treated goods which are not produced as part of a series, but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.

Animal testing: any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals, ("the prospective applicant"), shall 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 this Regulation or Directive 98/8/EC for an identical or technically equivalent product.

The request shall be accompanied by fees in accordance with the text.

Furthermore, Members want to align the text relating to data sharing with the provisions in REACH.

Reports: every three years, Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The implementation reports shall be

published on the relevant website of the Commission. The report shall include information on any poisonings and, where available, occupational diseases involving biocidal products, especially regarding vulnerable groups, and the actions undertaken to lower the risk of future cases, and information on the impact on the environment.

- Not later than five years after the entry into force of this Regulation, the Commission shall draw up a report on the impact of the spread of biocidal products in the environment.

- At the latest two years after the entry into force of the Regulation, the Commission shall submit 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.

Public access: the Commission shall make available on the internet a list of all active substances available within the internal market. The persons responsible for the placing on the market of biocidal products shall make available on the internet a list of such products. This website shall serve to increase transparency for consumers and to facilitate an easy and fast collection of data on the properties and conditions of use of these products.

Comitology: the amended text contains several amendments with a view to aligning the comitology procedure to the new system on delegated acts in accordance with Article 290 TFEU. The Regulation must contain detailed provisions on the delegation of power.