Making available on the market and use of biocidal products

2009/0076(COD) - 22/06/2010

The Committee on Environment, Public Health and Food Safety adopted the report drawn up by Christa KLASS 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. It recommended that the European Parliament's position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

Precautionary principle and special vulnerability of children: the purpose of the 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, the aim of which is to safeguard the health of humans, animals 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 to better 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.

Exclusion from the scope: the Regulation will not apply to biocidal products within the scope of Regulation (EC) No 1935/2004 (Food Contact Regulation), Council Directive 98/83/EC on the quality of water intended for human consumption and Directive 2000/60/EC establishing a framework for Community action in the field of water policy.

Inclusion of an active substance in Annex I: Members specify that substances that fall under the exclusion criteria should only be included in Annex I for a maximum period of 5 years. This is in line with the PPP regulation.

Furthermore, active substances as such or in biocidal products may be placed on the market in the Union for use in biocidal products only if they have been included in Annex I in accordance with the provisions of this Regulation. Unless otherwise provided in this Regulation, all manufacturers of an active substance, as such or in a biocidal product, shall submit to the Agency an application for inclusion in Annex I. The committee states that only if manufacturers are obliged to comply with the same data requirements in Annex II will fair treatment be possible.

With regard to **exclusion criteria**: 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. In addition, substances such as those that have to be 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 report specifies that a letter of access to a dossier may be part of the application. Members state that the applicants might not own the data required to support an 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 consider that the criteria for identifying candidates of substitution should be aligned with the criteria for substances to be authorised under Regulation (EC) No 1907/2006 (REACH) (Article 57). Since the Agency will carry out the task of examining if an active substance fulfils any of the criteria, the committee states that consistency between the two regulations is advisable. It also 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.) The committee considers that indefinite authorisations of new active substances will limit the incentive to conduct new research and provide new scientific data. In line with the current directive on biocides as well as the pesticides/plant protection legislation, there is a need for review of the active substances on a regular basis.

The committee 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. The committee 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 report 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.

Mandatory measures shall be established 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**, the committee states that the Commission's proposal does not contain any kind of evaluation at EU-level of low risk active substances. It is completely unclear what active substances a low-risk product can contain. In order to categorise anything as a low-risk product, it is crucial to know what it contains. Therefore, the active substances of a low risk product should as a very minimum be evaluated at an EU-level and be included on Annex I in order for the product to be recognised as a low-risk product.

Members go on to specify that low-risk products that are based on active substances included in Annex I or that are being evaluated with a view to inclusion in Annex I should require access to the data for the active substance. Property and data protection for active substances that have been included in Annex I should not be undermined.

The Commission should, provide technical and scientific guidance and tools, above all for SMEs.

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. The aim is to provide a clearer definition of how the comparative assessment should be carried out. One element to be taken into consideration is the need for sufficient experience in the use of the product. This should be the rule and not the exception.

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. Members state that the ECHA should carry out the initial validation of all applications throughout the Union, so that the evaluating competent authorities can concentrate on actual assessment of the applications. Currently, where the evaluating competent authorities consider both the administrative and the scientific aspects of applications, there have been inconsistencies in their approach. The Agency should observe the same timeframes for the validation of applications as those introduced under REACH.

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.

The report sets out procedures and the time period for the resolution of disputes between Member States.

Community authorisations: the Union authorisation may be granted to any category of biocidal products. The report states that a centralised authorisation system has clear benefits for the functioning of the internal market by ensuring consistent assessments and a harmonised implementation of the requirements in all Member States, driving best practices and same standards of consumer protection across Europe. The Community authorisation procedure should therefore extend to all product categories

instead of only a small minority of products (low risk biocidal products and products with new active substances).

A new clause is inserted on biocidal products with similar conditions of use.

The report makes several amendments to provisions on the **cancellation, review and amendments of authorisations**. It notes that in addition to revision of the inclusion of an active substance in Annex I, an indication (from practical measurements) that the aims of the Water Framework Directive are jeopardised must also be grounds for cancelling or amending the authorisation of a biocidal product.

Derogations and research: under the Commission proposal, a test on an unauthorised biocidal product for research and development purposes which involved the release of the product into the environment would require prior national authorisation. The time required in order to obtain it could hamper innovation. It is proposed instead that a 30-day period be set to allow the authority to assess whether the proposed test gives rise to any concern and to deliver its opinion. The report also makes some amendments to the **provisions on data protection and data sharing**.

Report: the Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Union authorisation procedure and mutual recognition, by **1 January 2016** (instead of 1 January 2023).

Information: 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 report 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.

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.

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.