Making available on the market and use of biocidal products: conditions for access to the market

2013/0150(COD) - 25/02/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 658 votes to 14 with 9 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products with regard to certain conditions for access to the market.

Parliament adopted its position in first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of an agreement between Parliament and Council. The main amendments were as follows:

Processing aids: Members clarified that the Regulation should not apply to biocidal products when used as processing aids within the meaning of Regulation (EC) No 1831/2003 and Regulation (EC) No 1333 /2008.

Biocidal product family: this means a group of biocidal products having: (i) similar uses, (ii) the same active substances, (iii) similar composition with specified variations, and (iv) similar levels of risk and efficacy.

The assessment of the biocidal product family conducted according to the common principles set out in Annex VI shall **consider the maximum risks to human health, animal health and the environment** and the minimum level of efficacy over the whole potential range of products within the biocidal product family.

Conditions for granting an authorisation: a biocidal product shall be authorised provided the active substances are included in Annex I or approved for the relevant product-type and any conditions specified for those active substances are met.

The product must also meet the **criteria** according to Regulation (EC) No 1272/2008 for classification as:

- **acute toxicity by**: (i) acute oral toxicity category 1, 2 or 3; (ii) acute dermal toxicity category 1, 2 or 3; (iii) acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3; (iv) acute inhalation toxicity (vapours) category 1 or 2;
- **specific target organ toxicity by single or repeated exposure category 1;**
- **a category 1A or 1B carcinogen or mutagen;**
- **toxic for reproduction category 1A or 1B.**

Period of grace: where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a

period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed **180 days** for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned.

Assessment of technical equivalence: where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence shall submit an application to the Agency. The latter shall inform the applicant of the fees payable and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Placing on the market: the amended text states that he person responsible for the placing on the market of a treated article shall ensure that the **label** provides the information listed in the Regulation.

Confidentiality: any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation may request that certain information **not be made available**, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned.

Transitory provisions on treated articles: Members introduced amendments to avoid potentially serious adverse effects on economic operators whilst fully respecting the principle of legal certainty. They apply from 1 September 2013.

With regard to access to the dossier, the text provided that the **Agency shall regularly update** the list of active substances for which a dossier has been accepted or validated by a Member State. Following the renewal of the approval of an active substance, the Agency shall remove from the list any substance supplier or product supplier who has not, within 12 months of the renewal, submitted all the relevant data or a letter of access to all the relevant data.

Facilitate enforcement of the Regulation: in order to facilitate good cooperation, coordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement, the Agency should also be given the task of providing support and assistance to Member States with regard to control and enforcement activities by making use of existing structures, where appropriate.