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

2013/0150(COD) - 11/03/2014 - Final act

PURPOSE: to improve the functioning of the internal market by ensuring a high level of protection for the environment and for human health.

LEGISLATIVE ACT: Regulation (EU) No 334/2014 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

CONTENT: the amending Regulation aims to solve problems relating to certain provisions of Regulation (EU) No 528/2012 concerning biocidal products which has been in force since September 2013. In particular, it deletes unforeseen obstacles in terms of market access for new products treated with biocidal products as well as for new active biocidal substances.

The amendments aim, in particular, to:

- clarify that the Regulation should not apply to biocidal products when the latter are used as **'processing aids'** within the meaning of Regulations (EC) No 1831/2003 (4) and (EC) No 1333 /2008;

- ensure that similar biocidal products are considered as part of a **biocidal product family** if they can be satisfactorily assessed based on identifiable maximum risks and minimum level of efficacy;

- provide that a biocidal product will only be authorised if the active substances are **listed in Annex I** of the Regulation or approved for the types of products concerned and if any conditions specified for those active substances are met;

- include specific target organ toxicity by single or repeated exposure category 1 **as a classification criterion**, in order to preclude authorisation for the making available on the market for use by the general public of a biocidal product meeting the criteria for this classification according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures;

- provide a **period of grace not exceeding 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 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;

- extend the scope of **transitional measures concerning treated articles** (the current provisions apply only to treated articles already placed on the market) and provide for a phasing-out period for treated articles for which no application for the approval of the active substance for the relevant product-type is submitted by 1 September 2016;

- ensure the Agency **regularly updates a list of all active substances** for which a complete substance dossier has been submitted and 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 good cooperation**, coordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement.

ENTRY INTO FORCE: 25/04/2014. Amendments made to article 94 (Transitional measures concerning treated articles) and 95 (Transitional measures concerning access to the active substance dossier) of the Regulation will apply from 01/09/2013.