Making available on the market and use of biocidal products

2009/0076(COD) - 22/05/2012 - Final act

PURPOSE: to improve free movement of biocidal products in the Union whilst ensuring a high level of human, animal and environmental protection.

LEGISLATIVE ACT: Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

CONTENT: following in second reading, the Council and the European Parliament adopted a regulation concerning the placing on the market and use of biocidal products. The provisions of the Regulation are based on the **precautionary principle**, the aim of which is to safeguard the health of humans, the health of animals and the environment.

As required by the European Parliament, **particular attention shall be paid to the protection of vulnerable groups.**

The Regulation applies to insecticides, disinfectants and repellents, but not medicines or agricultural pesticides. It aims to **simplify the authorisation procedures** in the internal market through the harmonisation of legislation on biocidal products, while ensuring a high level of protection for both human and animal health and the environment.

The Regulation lays down certain principles.

(1) **The establishment at Union level of a list of active substances which may be used in biocidal products**.

(2) **Conditions for the approval and renewal of approval of active substances :**

- an active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in the text ;
- active substances that are classified as carcinogenic, mutagenic, toxic for reproduction or considered as having endocrine-disrupting properties, shall not be approved except in specified circumstances ;
- the approval of an active substance shall not cover nanomaterials except where explicitly mentioned ;
- an active substance that falls under the exclusion criteria may only be approved for an initial period not exceeding five years ;
- the renewal of an approval of an active substance shall be for 15 years for all product-types to which the approval applies, unless a shorter period is specified in the implementing regulation renewing such an approval ;

- the Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in the Regulation are no longer met.

(3) **The granting of an authorisation for biocidal products:** biocidal products should neither be made available on the market nor used unless authorised in accordance with the Regulation. As requested by the European Parliament, the authorisation holder shall notify each competent authority at least 30 days before placing it on the market.

(4) **The mutual recognition of authorisations within the Union** so as to reduce the administrative burden on producers.

(5) **The making available on the market and the use of biocidal products within one or more Member States or the Union**: the Regulation introduces the possibility of granting an Union authorisation for biocidal products, in addition to the current system of national product authorisation. A first series of product-types may be authorised at Union level as from 2013. From 2020 onwards, most biocidal products will qualify for this procedure.

(6) **The placing on the market of treated articles which are not biocidal products**: articles incorporating pest control chemicals may not be treated with unauthorised chemicals anymore and must be labelled under the conditions specified in the Regulation. These obligations apply to all articles treated with biocidal products on the EU market, including imported ones.

Authorisation holders shall keep records of the biocidal products they place on the market for at least 10 years after placing on the market, or 10 years after the date on which the authorisation was cancelled or expired, whichever is the earlier.

The Agency shall establish and maintain an information system which shall be referred to as the Register for Biocidal Products.

ENTRY INTO FORCE: 17/07/2012.

APPLICATION: from 01/09/2013.

DELEGATED ACTS: the Commission is empowered to adopt delegated acts to supplement or amend the Regulation. The power to adopt delegated acts is conferred on the Commission for a period of five years from 17 July 2012. This shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension. A delegated act shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification (this period may be extended by two months). If objections are made by the European Parliament or the Council, the delegated act shall not enter into force.