Annex: Creosote approval with more stringent conditions proposed

Helsinki, 8 December 2020

Further information about the opinions

The opinions adopted concern applications for the following active substances in the specified product-types:

Creosote for product-type 8

Creosote is used as a wood preservative in product-type 8 as a fungicide and insecticide against wood rotting fungi, against wood rot in soil and water contact, and against insects. Creosote was approved under the Biocidal Products Directive as an existing active substance. This application concerned the renewal of this approval.

The evaluating competent authority of the active substance application is Poland.

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine for product-type 8

Diamine is an existing active substance. It is used as an active substance against wood destroying basidiomycetes, with preventive protection of wood and construction timbers of use classes 1 to 4a. The active substance was considered in the assessment for use in industrial pre-treatment of timber by vacuum pressure impregnation and dipping/surface treatment.

The evaluating competent authority of the active substance application is Portugal.

Ethylene oxide for product-type 2

Ethylene oxide is an existing active substance. The intended, evaluated use of the active substance ethylene oxide is the industrial sterilisation of single use medical devices, which cannot be sterilised by other means, before these are made available on the market.

The evaluating competent authority of the active substance application is Norway.

More information about product-types.

The BPC also adopted an opinion addressing a request from the Commission on the **availability and suitability of alternatives to boric acid and disodium tetraborate pentahydrate** for product-type 8. This request is related to the renewal of these two wood preservatives, which both meet the exclusion criteria due to their toxicity for reproduction. The committee concluded that there are currently no suitable alternatives for certain uses of these active substances. On the other hand, the committee was not able to conclude based on the information available if for other uses there are sufficient suitable alternatives available to substitute them.

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On *Union authorisation,* the adopted opinion concerns an application for a biocidal product containing CMIT/MIT as an active substance (product-types 2, 4, 6, 11, 12 and 13).

The opinions will be available on ECHA's website at: Biocidal Products Committee.

Background information

The role of the Biocidal Products Committee in EU regulatory processes

The Biocidal Products Committee prepares the opinions of the Agency related to several processes under the Biocidal Products Regulation. Each EU Member State is entitled to appoint one member to the BPC for a renewable term of three years.

In relation to applications for the approval of new active substances, companies have to apply for approval of an active substance by submitting a dossier. After a validation check, the evaluating competent authority carries out an evaluation within one year.

The result of the evaluation is forwarded to the BPC, which prepares an opinion within 270 days. The opinion serves as a basis for decision-making by the European Commission and the Member States. The approval of an active substance is granted for a defined number of years, not exceeding 10 years.

Substances, which were on the market before 14 May 2000 and are evaluated under the biocides review programme in an analogous manner to new active substances, are referred to as existing active substances.

During the approval process of an active substance, the evaluating competent authority may conclude that the active substance meets the criteria for substitution of Article 10(1) of the BPR and is therefore a potential candidate for substitution. The objective of this provision is to identify substances of particular concern to public health or the environment and to make sure that these substances are phased-out and replaced by more suitable alternatives over time. The criteria for substitution are based on the intrinsic hazardous properties in combination with the use and include, for example, if the substance meets at least one of the exclusion criteria listed in the BPR or if the substance is a respiratory sensitiser.

For substances that are identified by the evaluating competent authority as a potential candidate for substitution, ECHA will initiate a public consultation to allow interested third parties to submit relevant information, including information on available substitutes. Subsequently, in the preparation of its opinion, the BPC reviews the proposed identification of the active substance as a candidate for substitution.

Active substances which are candidates for substitution will not be approved for more than seven years, even in the case of renewal. If the active substance meets one or more exclusion criteria, it will only be approved for five years. When an active substance is identified as a candidate for substitution, products containing that active substance will have to be subject to a comparative assessment at the time of authorisation and will only be authorised if there are no better alternatives.