Annex to a news alert

Biocidal Products Committee concludes on Union authorisations for disinfectants

ECHA/NR/19/09

Helsinki, 5 March 2019

More information about the opinions

On Union authorisation, the adopted opinions concern applications for a biocidal product (family) containing **iodine/PVP-iodine** used in veterinary hygiene (product-type 3), and applications for a biocidal product (family) containing **propan-2-ol** in disinfectants and algaecides not intended for direct application to humans or animals (e.g. surface disinfection) and in food and feed area (product-types 2 and 4).

The other opinions discussed concern the approval of the following active substances in the specified product-types:

Epsilon-metofluthrin for product-type 19

Epsilon-metofluthrin is a new active substance. It is a pyrethroid used as an insect repellent designed for outdoor use to protect from the effects of biting mosquitoes.

The evaluating competent authority of the active substance application is the United Kingdom.

Azamethiphos for product-type 18

Azamethiphos is an existing active substance. Azamethiphos is used as an active substance in insecticides (product-type 18) to be used by professionals to control house flies indoors in animal houses, either as a paint on product or on a ready to use hang-board.

The evaluating competent authority of the active substance application is the United Kingdom.

Carbendazim for product-type 9

Carbendazim is an existing active substance. Products based on carbendazim are used as a fungicide for preservation of polymerised materials (e.g. plastic) in product-type 9.

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

The adopted opinions will be available 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.