Annex to a news alert

Biocidal Products Committee (BPC) adopted opinions supporting the approval of three active substances – ECHA/NA/17/24

Helsinki, 5 October 2017

More information about the opinions

The adopted opinions concern the approval of the following active substances in the specified product-types (PTs):

Chlorophene for product-types 2 and 3

Chlorophene is an existing active substance. The products containing chlorophene in product-type 2 are intended to be used as a heavy-duty disinfectant for both professional and private use. Professional use includes several applications in hospitals while private use of chlorophene is limited to disinfection of objects, such as washbasins and toilet facilities. In product-type 3 chlorophene is intended to be used in products to control pathogenic micro-organisms in poultry barns and similar facilities by professionals. Disinfection may be performed by the farmers themselves, or it may be performed by contractors who provide cleaning services for animal facilities.

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

Azoxystrobin for product-types 7, 9 and 10

Azoxystrobin is a new active substance. Azoxystrobin is used in biocidal preservative products which are applied to, or incorporated into various end-applications covering protection of paints, silicon coatings, mineral and silicon sealants and grout products (in product-type 7); paper that is used for the production of wall linings (in product-type 9); and building materials such as gypsum boards (in product-type 10). Products containing azoxystrobin will be used by industrial users while the end-use treated items may be used by professionals and non-professionals.

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

PHMB (1415; 4.7) for product-types 1, 2, 4, 5 and 6

PHMB (1415; 4.7) is an existing active substance. PHMB (1415; 4.7) is used both by professional and non-professional users for hygienic hand wash (in product-type 1); for disinfection of equipment and areas (in product-type 2) and for treatment in food and feed areas (in product-type 4); and by professional users for the disinfection of animal drinking water (in product-type 5); and as an antimicrobial preservative for aqueous manufactured products in cans, tanks or other closed containers during storage (in product-type 6).

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

The opinions will be available at the following link in the near future:
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.