

# The Biocidal Products Committee adopts seven opinions. Four other opinions expected to be adopted following written consultation

Helsinki, 5 October 2015

Annex to the news alert ECHA/NA/15/33

# More information about the adopted opinions

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

# Peracetic acid for PTs 1, 2, 3, 4, 5 and 6

Peracetic acid is an existing active substance evaluated in PTs 1 to 6. Uses evaluated include disinfection of human skin (PT 1), laundry disinfection, disinfection of sewage/waste water, disinfection of surfaces in industrial, public and health care areas, CIP (Clean-in-Place) in pharmaceutical and cosmetic industry (PT 2), disinfection of animal houses (PT 3), disinfection in food and feed industry (CIP, dipping of equipment, automated spraying, and manual spraying, foaming) (PT 4), disinfection of animal drinking water (PT 5) and in-can preservation in paper production (PT 6).

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

# BPC opinion pursuant to Article 75 (1)(g) on sulfuryl fluoride in PTs 8 and 18

The request concerns the monitoring data from remote tropospheric air, which the authorisation holder submitted to the European Commission to comply with the decisions on the approval of sulfuryl fluoride (PTs 8 and 18) under the Biocidal Products Directive (BPD). The BPC was asked to give an opinion by the European Commission on whether the previous conclusions with respect to the global warming potential of sulfuryl fluoride under the BPD are still valid. The conclusion of the BPC was that the global warming potential based on the monitoring data submitted is higher than previously estimated. The BPC recommended to continue monitoring and that the global warming potential has to be considered under the renewal process of sulfuryl fluoride.

The following opinions are expected to be adopted at the next meeting following a commenting round on the revised sections in the opinions on the conditions for approval and the elements to be taken into account for product authorisation. These sections will have to be amended in line with the document on "Wording of the conditions of approval of active substances" endorsed at the September 2015 Biocides competent authorities meeting. This document aims to simplify the wording of the approval conditions in the Commission decisions.

## Bardap 26 for PT 8

Didecylmethylpoly(oxyethyl)ammonium propionate (Bardap 26) is an existing active substance evaluated in PT 8.

The field of application of Bardap 26 includes wood preservation for preventive treatment against wood-destroying insects and against wood-discolouring moulds and fungi. The representative product is an aqueous solution, with preventive efficacy against wood-destroying basidiomycetes, against soft rot fungi and insects.

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

### **DBDCB for PT 6**

The active substance 1,2-Dibromo-2,4-dicyanobutane (DBDCB) is an existing active substance evaluated in PT 6.

DBDCB is used as an antimicrobial preservative in PT 6 for water-based decorative paints applied by brush or roller indoors. Paints containing DBDCB may be used by professionals and non-professionals.

The evaluating competent authority of the active substance application is the Czech Republic.

# Ampholyt for PTs 2 and 4

Ampholyt is an existing active substance evaluated in PTs 2, 3 and 4. An opinion on the product type was already adopted by the BPC.

Products containing ampholyt are used as a hard surface disinfectant in hospitals, institutional and industrial areas, including public health areas (PT 2) and in treatments to surfaces, walls, and floors in industrial food and feed preparation areas (PT 4) by professionals to prevent the spread of various micro-organisms.

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

# Further information

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

**Biocidal Products Committee** 

# Background Information

# The role of BPC 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.