

The Biocidal Products Committee adopts 11 opinions

Helsinki, 25 June 2015

Annex to the news alert ECHA/NA/15/22

More information about the adopted opinions

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

Approval of Biphenyl-2-ol for PTs 4 and 6

Biphenyl-2-ol is an existing active substance notified in PTs 1, 2, 3, 4, 6 and 13. The BPC opinions for PTs 1, 2 and 13 have been adopted during BPC-9 in February 2015. PT 3 products containing Biphenyl-2-ol are used to control pathogenic microorganisms in intensive farming. The PT 4 product is a smoke generator preparation used for disinfection of surfaces. PT 6 products are in can preservatives for detergents and household cleaning products and for preservatives of paper additives. The adoption of the opinion for PT 3 was postponed to BPC-13 in December, pending a consultation to be launched on the revised environmental risk assessment.

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

PHMB: approval for PTs 2, 3, 4 and 11; non-approval for PTs 1, 6 and 9

The active substance Poly Hexa Methylene Biguanide (PHMB) is a small size polymer. PHMB is a bactericide which causes an irreversible loss of essential cellular components as a direct consequence of cytoplasmic membrane damage of the target organisms. In PTs 1, 2, 3 and 4, PHMB is used as a disinfectant in, for example, human and veterinary hygiene and food and feed areas. In PTs 6, 9 and 11, PHMB is used as a preservative in, for example, products during storage or liquid-cooling and processing systems.

The BPC confirmed that PHMB is a candidate for substitution by being toxic and very persistent.

No safe use could be demonstrated for the proposed uses of PHMB in PTs 1, 6 and 9. Unacceptable risks were identified for the environment and human health. Based on the evaluated uses, further risk mitigation measures were not considered feasible.

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

Non-approval of Cybutryne for PT 21

Cybutryne is an existing active substance notified in PT 21. Biocidal products containing the algicide Cybutryne were intended to be used for antifouling paints applied to hulls on commercial ships. Cybutryne is an antifoulant against marine algal species.

The BPC confirmed that Cybutryne is a candidate for substitution by being toxic and persistent. No safe use could be demonstrated for the proposed use of Cybutryne. Unacceptable risks were identified for the marine environment. Based on the evaluated use, further risk mitigation measures were not considered feasible.

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

Non-approval of Triclosan for PT 1

Triclosan is an existing active substance notified in PT 1. Triclosan is a bactericidal active ingredient that kills the bacterial cell by disturbing the function of the cell membrane. Triclosan-containing bactericidal soap was intended for use by special professional health care personnel e.g. for surgical operations.

The BPC confirmed that Triclosan is a candidate for substitution by being toxic and very bioaccumulative.

No safe use could be demonstrated for the proposed use of Triclosan. Risk was identified for both surface water and for the non-compartment specific effects relevant to the food chain (secondary poisoning). Based on the evaluated use, further risk mitigation measures were not considered realistic.

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

Cyromazine for PT 18

Cyromazine is an existing active substance notified in PT 18. Cyromazine is an insect growth regulator developed for the control of fly larvae in manure and other breeding sites in animal housing (e.g. cattle, swine, poultry facilities).

Biocidal products containing Cyromazine can be used by professionals and non-professionals after formulation into water soluble granule or water soluble powder. The biocidal product is applied to manure or any decaying organic matter either by: i) direct dispersal of the dry granules; ii) directional spraying after dissolution in water with any spray equipment; or iii) pouring using a watering can after dissolution in water. The adoption of the opinion was postponed to BPC-13 in December 2015, pending a consultation to be launched on the revised environmental risk assessment.

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

The BPC has also confirmed the conclusions of the combined competent authority reports for **DDAC for PT 8** and **ADBAC/BKC for PT 8**.

DDAC and ADBAC in PT 8 have been approved already under the Biocidal Products Directive (Directive 98/8/EC) in 2012 supported by one applicant. A dossier from another applicant was evaluated for each substance at a later stage. The BPC confirmed the conclusions of the combined assessments covering both applicants, meaning that the already existing approval does not need to be amended.

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.