Annex to news: Highlights from March BPC meeting

Helsinki, 8 March 2023

Information about the opinions

See product-types

Active substances:

Nitrogen generated from ambient air (inclusion in Annex I to the Biocidal Products Regulation, BPR)

This is a new active substance submitted under Article 1 of Regulation (EU) No 88/2014. The Biocidal Products Committee (BPC) supports the inclusion of *nitrogen generated from ambient air* in Annex I to the BPR.

The substance is commonly used to control arthropod pests that affect, for example, museum artefacts (wooden items, textiles, etc), stored foods and machinery. It is particularly important for very high-value museum artefacts, which may be affected by fumigants. In these uses, the active substance is used indoors by trained professional users.

Germany is the evaluating competent authority of this application.

Annex I to the BPR lists active substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food. Annex I substances can be eligible for simplified product authorisation.

Union authorisations:

The BPC adopted one opinion supporting Union authorisations for a biocidal product containing the active substance **peracetic acid** which is used to disinfect hard surfaces in clean rooms of pharmaceutical, biopharmaceutical, medical device, healthcare and diagnostic product manufacturing facilities (product-type 2).

Union autorisation application for a biocidal product family containing as active substance a **mixture of CMIT/MIT** for the product-types 6, 11, 12 and 13 will be sent back to the evaluating Member State. The BPC will discuss the updated opinion on this application later.

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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.