Annex to news: Highlights from June BPC meeting

Helsinki, 13 June 2023

Information about the opinions

See product-types

Active substances:

Thermally treated garlic juice (intended new name, formerly named "garlic extract") for product-type 19

This is an existing active substance submitted under Article 7 of the Biocidal Products Regualtion.

The biocidal product is used in outdoor gardens. It deters cats of all ages from defecating in treated areas (lawns, flowerbeds).

The BPC supported the approval of this active substance for product-type 19 by consensus.

Austria is the evaluating competent authority of this application.

Willaertia magna C2c Maky for product-type 11 is a new active substance and it is intended to be used by professionals to prevent the growth of *Legionella pneumophila* in industrial processing water systems. Phagocytosis and elimination of *Legionella pneumophila* is claimed as mode of action, but was not sufficiently investigated in this application.

The BPC supported the non-approval of this active substance for product-type 11 by consensus.

Malta is the evaluating competent authority of this application.

Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) for product-types 2, 3, 4 and 5 (KPMS) in an exsisting active substance**.** Initially, pentapotassium bis(peroxymonosulphate) bis(sulphate) was the notified name of this active substance. It was established that the name is incorrect, primarily due to a violation considering a charge balance. Consequently, the active substance has been renamed to trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) where the positions of the protons are not specified.

In product-type 2, the substanceis intended to be used by professional and non-professional users to disinfect swimming pool water. It is also intended to be used to disinfect equipment and hard surfaces by professional users. KMPS is applied onto surfaces by spraying, mopping and wiping.

In product-type 3, it is intended to be used by professional users in the veterinary hygiene for foot dips and for terminal disinfection of animal houses with a low pressure sprayer.

Product-type 4 uses cover surface disinfection of food and feeding areas by professionals.

Product-type 5 uses covers continuous disinfection of animal drinking wate by professionals. It can be applied manually by dosing the header tank or through a dosing system.

For all product-types (2-5), KMPS shows a broad spectrum of antimicrobial activity and functions as a bactericide, yeasticide, fungicide and virucide.

The BPC supported the approval of this active substance for product-types 2, 3, 4 and 5 by consensus.

Slovenia is the evaluating competent authority of this application.

Union authorisations:

The BPC adopted the following opinions supporting Union authorisations for:

- L(+) Lactic acid for product-type 3. The BPC proposed for the biocidal product family to be authorised. The Netherlands is the evaluating competent authority of this application.
- L-(+)-lactic acid and hydrogen peroxide for product-types 2, 3 and 4. The BPC proposed for the biocidal product to be authorised. France is the evaluating competent authority of this application.

The BPC adopted the following post-authorisation opinions supporting Union authorisations for:

- L(+) Lactic acid for product-type 2. The BPC proposed for the biocidal product to be authorised. Latvia is the evaluating competent authority of this application.
- L-(+)-lactic acid for product-types 1, 2, 3 and 4. The BPC proposed for the biocidal product family to be authorised. Belgium is the evaluating competent authority of this application.

Post-authorisation opinions can be adopted on data submitted after the initial authorisation has been granted by the European Commission. The conditions for post-authorisation are included in the terms and conditions of the authorisation decision. Read more in Post authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation (PDF).

Requests from the European Commission

- **Under Article 38:** Unresolved objections during a mutual recognition procedure for a product-type 5 biocidal product family intended for disinfection of animal drinking water.

  On 15 February 2023, the Commission gave ECHA a mandate to provide an opinion on Question on unresolved objections during a mutual recognition procedure in accordance with Article 36 (1) of the Biocidal Products Regulation of a product-type 5 biocidal product family intended for disinfection of drinking water for animals. The BPC adopted the opinion by consensus. The opinion will only be published once the Commission has taken its decision.

- **Under Article 75(1)(g):** Comparative assessment of anticoagulant rodenticides.

  In May 2021, the European Commission requested ECHA to provide an opinion through the BPC on a comparative assessment of anticoagulant rodenticides (AVKs). This is the second time the BPC has adopted an opinion on the comparative assessment of anticoagulant rodenticides. The first one related to the first renewal, was adopted in March 2017. The second one is related to the second renewal.

  This opinion was adopted in two BPC discussions: in November 2022 the BPC adopted by majority the opinion on the comparative assessment. In the June 2023 meeting, the committee adopted by consensus on the remaining question from the Commission related to a comparison of the hazards and risks of the anticoagulant rodenticide active substances. The BPC concluded that it cannot make a distinction on the risk and hazard profiles of anticoagulant rodenticide substances meaning that all AVKs can be considered equally hazardous.

  Anticoagulant rodenticides work by interfering with the activation of vitamin K, which is critical for blood clotting. When pests are exposed to enough anticoagulants, they die of internal bleeding. Due to the identified risk for the environment and human health, anticoagulant rodenticides have to be handled with caution.

  Reassessing the risk to the environment (soil compartment) from use of ADBAC/BKC in product-type 2 biocidal products

  In November 2022, the European Commission requested ECHA to provide an opinion through the BPC on reassessing the risk to the environment (soil compartment) from use of active substance ADBAC/BKC.

  The BPC delivered its opinion on 2 December 2021. The BPC opinion recommending the approval of ADBAC/BKC was adopted by simple majority. Several Member States retained their reservations on the approval during decision making in the Commission's Standing Committee on Biocidal Products. Subsequently, the Commission requested ECHA to reconsider its opinion with regard to the assessment of the risks to the soil compartment.

  The BPC adopted the opinion concerning the risks to the environment by consensus and maintained its support for approving of ADBAC/BKC for product-type 2.

**

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.