Annex to news: Highlights from December BPC meeting

Helsinki, 8 December 2021

Further information about the opinions

The opinions adopted concern applications for the following active substances in the specified product-types:

Ozone generated from oxygen for product-types 2, 4, 5 and 11

Ozone generated from oxygen is a new active substance submitted under Article 8(4) in combination with Article 93 of the Biocidal Products Regulation (BPR).

Ozone generated from oxygen in product-type 2 is used for disinfection of various aqueous matrices. The intended and evaluated use is disinfection of pool water in public and private swimming pools, performed by professional and non-professional users, respectively.

In product-type 4 products, the intended and evaluated use is disinfection of bottles in the beverage industry before filling. In product-type 5products, the intended and evaluated use is disinfection of drinking water by professional users.

Ozone generated from oxygen in product-type 11 products is used to preserve aqueous cooling and processing liquids. The intented and evaluated use is preservation of cooling water in re-circulating cooling systems.

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

Alkyl (C12-16) dimethylbenzylammonium chloride (C12-16-ADBAC/BKC) for product-types 1 and 2

Alkyl (C12-16) dimethylbenzylammonium chloride (C12-16-ADBAC/BKC) is an existing active substance.

C12-16-ADBAC/BKC is a broad-spectrum biocide intended to be used in product-type 1 products for hand disinfection by non-professional and professional users. In product-type 2 products, the intended use is for disinfection of surfaces, inanimate objects and materials and equipment in several sectors.

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

***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide for product-type 19**

Chrysanthemum cinerariaefolium, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide is an existing active substance.

In product-type 19 products, it is intended to be used as a mosquito repellent outdoors.

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

***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents for product-type 19**

Chrysanthemum cinerariaefolium, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents is an existing active substance.

In product-type 19 products, it is intended to be used as a mosquito repellent outdoors.

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

Didecyldimethylammonium chloride (DDAC) for product-types 1 and 2

Didecyldimethylammonium chloride (DDAC) is an existing active substance.

DDAC is a broad-spectrum biocide intended to be used in product-type 1 products for hand disinfection by non-professional and professional users. The in-use concentration can vary, depending on the area and circumstances, e.g. frequency of use, level of soiling etc. Products based on DDAC in product-type 2 are intended to be used for disinfection of surfaces, inanimate objects and materials, and equipment in several sectors.

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

For **Union authorisation**, the adopted opinions concern the following applications:

- **L(+) Lactic acid** for product-type 1 (human hygiene), for product-type 2 (disinfectants and algaecides not intended for use directly on people or animals), for product-type 3 (veterinary hygiene) and for product-type 4 (food and feed area).
- **Hydrogen peroxide** for product-type 2(disinfectants and algaecides not intended for use directly on people or animals).

The BPC also adopted four opinions addressing **requests from the European Commission**. The requests are the following:

- Evaluation of the level of the risks for human health and for the environment of DBNPA used in biocidal products of product-type 4 [PDF] [EN]
- Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product-types 3 and 18 [PDF] [EN]
- Eligibility of peanut butter active substance for inclusion into Annex I to the BPR [PDF] [EN]
- Questions relating to a guidance on rodent traps developed by the German Environmental Agency [PDF] [EN]

The European Commission takes the final decisions based on BPC's technical and scientific advice.

More information about product-types.

The opinions will be available on ECHA's website at: Biocidal Products Committee.

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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.