Annex to news: Highlights from September BPC meeting

Helsinki, 5 October 2022 (updated 13 October)

Further information about the opinions

Active substances:

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

This is a new active substance submitted under Article 93 of the BPR. The Biocidal Products Committee (BPC) supports the approval of ozone for all these product-types after evaluating the following uses:

- Product-type 2 (disinfectants and algaecides not intended for direct application to humans or animals): automated airborne disinfection of surfaces with gaseous ozone (efficacy testing proved yeasticidal activity) and textile disinfection in the rinse step (efficacy testing proved innate efficacy for bactericidal, yeasticidal and fungicidal activity).

- Product-type 4 (food and feed area): automated airborne disinfection of surfaces with gaseous ozone.

- Product-type 5 (drinking water): disinfection. The efficacy testing proved innate efficacy for bactericidal activity.

- Product-type 11 (preservatives for liquid-cooling and processing systems): disinfection. The efficacy tests that were provided proved innate efficacy (bactericidal).

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

Mecetronium ethyl sulphate (MES) for product-type 1 (human hygiene)

This is an existing active substance. It is used in hygienic and surgical hand disinfection in professional environments such as hospitals, as well as in home dialysis. The properties of the active substance were claimed as bactericidal, yeasticidal and virucidal.

The BPC does not support the approval of MES for product-type 1 as there was insufficient data on whether the active substance could meet the exclusion criteria for endocrine disruption (ED) or bioaccumulation.

Poland is the evaluating competent authority of the active substance application.

Sulphur dioxide generated from sulphur by combustion for product-type 4 (food and feed area)

This is an existing active substance. It is used in sulphur tablets that professional users place in wine barrels before their dry conservation or before filling the barrels with wine. The representative product, the sulphur tablet, starts to release sulphur dioxide after ignition.

The BPC supports the approval of this active substance for product-type 4.

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

Sulphur dioxide released from sodium metabisulphite for product-type 9 (fibre, leather, rubber and polymerised materials preservatives)

This is an existing active substance submitted under Article 7 to the BPR. It is used to control odour causing bacteria, mold and mildew on footwear and other leather, rubber, paper as well as textile goods enclosed in packaging during storage and transport.

The assessed representative biocidal product is a sticker containing the releaser sodium metabisulphite. This ready-to-use product is applied to shoe boxes by professional users before the storage or transport of leather shoes. During storage and transport, the sticker releases sulphur dioxide, which prevents microbial growth.

The BPC supports the approval of the active substance for product-type 9.

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

Union authorisations:

The BPC adopted the following opinions supporting Union authorisations for:

- **Hydrogen peroxide** for product-type 2 (disinfectants and algaecides not intended for direct application to humans or animals), product-type 3 (veterinary hygiene) and for product-type 4 (food and feed area);
- **Peracetic acid** for product-types 2 and 4; and
- Two opinions on **active chlorine released from sodium hypochlorite** for product-types 2, 3 and 4, and one for product-type 5 (disinfection of drinking water for both humans and animals).

Request from the European Commission under Article 15(2):

Review of approval of the active substances iodine and polyvinylpyrrolidone (PVP) iodine

On 17 May 2021, the Commission gave ECHA a mandate to provide opinions on whether the active substances iodine and PVP-iodine are considered to have endocrine disrupting properties for humans or non-target organisms. The scientific criteria for determining ED properties are specified in the Commission Delegated Regulation (EU) No 2017/2100 and in the ECHA and EFSA Guidance for identifying endocrine disruptors.

Iodine and PVP-iodine are disinfectants used, for example in teat disinfection pre- and post-milking and in the food industry. Iodine is also an essential nutrient for mammals, required as a mandatory structural and functional element of thyroid hormones – thyroxine or tetraiodothyronine (T4) and triiodothyronine (T3). Through these hormones, iodine has an important role in energy-yielding metabolism and on the expression of genes that impact many physiological functions, including embryogenesis and growth, and the development of neurological and cognitive functions (EFSA, 2014).

The BPC concluded that these active substances meet the criteria for endocrine disruption.

Sweden was the rapporteur for this review.

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

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More information about product-types.

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.