Annex to news: Highlights from June BPC meeting

Helsinki, 21 June 2022

Further information about the opinions

Active substances:

Formic acid for product-types 2, 3, 4, 5 and 6

Formic acid is an existing active substance. It is intended to be used for product-type 2 (use in disinfectants and algaecides not intended for direct use on people or animals) applications as broad spectrum sanitary surface disinfectant against bacteria, yeasts and fungi for both professional and private use. Product-type 2 private use includes general surface disinfection with ready-to-use formulation and professional/industrial use includes dilution of a concentrated formulation.

In product-types 3 and 4, it is used as broad spectrum surface disinfectant against bacteria, yeasts and fungi for professional use. Product-type 3 use includes disinfection of animal housing (including fogging procedures), animal transportation vehicles (including tyres), of boots, of animal feet and outsides of machinery connected with livestock farming, and product-type 4 use surface/equipment disinfection through concentrated formulations to be diluted.

Product-type 5 applications are used as as broad spectrum disinfectant against bacteria, yeasts, fungi and viruses for professional use, for the use includes animal drinking water disinfection through automatic systems.

Product-type 6 is intended to be used against bacteria and fungi/yeasts as broad spectrum preservatives for industrial, consumer, household and institutional products during storage.

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

Requests from the European Commission under Article 75(1)(g):

The BPC committee also adopted 10 opinions on the following:

- Availability and suitability of alternatives to **hexaflumuron** to renew approval for use in insecticides, acaricides and products to control other arthropods (product-type 18) (one opinion):
  Hexaflumuron is a very persistent, bioaccumulative and toxic substance and, therefore, meets the exclusion criteria. This means that it can only be approved if needed on the grounds of public health or of public interest when no alternatives are available. The committee concluded in its opinion that at present there are no suitable alternatives for all uses of hexaflumuron within the product-type. Mandate

- **Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)** for disinfectants and algaecides not intended for direct application to humans or animals (product-type 2), for preservatives for products during storage (product-type 6), for preservatives for liquid-cooling and processing systems (product-type 11), for slimicides (product-type 12) and for working or cutting fluid preservatives (product-type 13) and **reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1)** for product-types 2, 6, 11 and 13:

  The committee was asked to evaluate the endocrine disrupting properties of these substances based on the initial assessment of Austria. The committee could not conclude on

whether the formaldehyde releasers meet the criteria for endocrine disruption or not. Mandate

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.