Annex to news: Highlights from September BPC meeting

Helsinki, 25 September 2024

Information about the opinions

See product-types

Active substances:

Evaluation of post-approval data submitted for icaridin for product-type 19 and correction of environmental endpoint for the metabolite icaridin-acid

Denmark, as evaluating competent authority, presented two issues regarding the active substance icaridin. The Biocidal Products Committee (BPC)agreed upon:

- post-approval data concerning analytical methods; and
- the correction of an error in quantitative structure-activity relationship (QSAR) predictions of the environmental endpoints for the metabolite icaridin-acid. This correction is important to ensure EU-wide consistency in the assessment of products based on the active substance icaridin.

Union authorisations:

Opinions on the following product families were adopted:

Biocidal product family containing Transfluthrin for product-type 18

The biocidal product family consists of liquid products intended for non-professional users against moths, mosquitoes and flies indoors. These are vapour releasing products and liquids to be used in electric vaporizers.

The opinion on the authorisation was adopted by consensus.

The Netherlands is the evaluating competent authority of this application.

Biocidal product family containing L-(+)-lactic acid for product-type 3

The biocidal product in this family is used in veterinary hygiene by professional users. The product within this product family is a ready to use (RTU) product and effective against bacteria and yeast when used as a post-milking disinfectant.

The opinion on the authorisation was adopted by consensus.

The Netherlands is the evaluating competent authority.

Biocidal product family containing Chlorocresol for product-type 3

The products in this family are used as disinfectants for veterinary hygiene (product-type 3) by non-professional and professional users for the control of bacteria, yeast, viruses and fungi as well as endoparasites (parasitic protozoans and helminth eggs).

The opinion on the non-authorisation was adopted by consensus.

Germany is the evaluating competent authority.

Article 75(1)(g):

Draft BPC opinion on examination of efficacy tier 2 data for the active substance BIT for product-types 6 and 13 (two opinions)

The efficacy tier 2 data of this active substance (acting as preservative in product-types 6 and 13) was examined. It was concluded that the available data can be considered as tier 2, and, therefore, the data requirements have been fulfilled and efficacy has been proven.

The BPC adopted the two opinions by consensus.

Spain is the evaluating competent authority of this case.

See the mandate to ECHA.

Draft BPC opinion on examination of efficacy tier 2 data for the active substance Formic acid for product-type 6

The applicant provided new efficacy tier 2 data for this active substance (acting as preservative in product-type 6). It was concluded that the available data can be considered as tier 2, and, therefore, the data requirements have been fulfilled. Based on the new data it was concluded that efficacy has been proven.

The BPC adopted the opinion by consensus.

Belgium is the evaluating competent authority of this case.

See the mandate to ECHA.

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

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Procedural documents for applications to renew Union authorisations

Union authorisations are granted for a maximum of 10 years and can be renewed. According to the Biocidal Products Regulation, an application for renewal must be submitted 550 days before the authorisation expires. The first Union authorisation will expire at the end of June 2026, meaning the first application for renewal is expected by the end of 2024.

The BPC discussed several key documents to support the renewal process:

- a general working procedure for renewals;
- a procedure for linguistic review of translations for summaries of product characteristics; and
- a document to support decisions on whether a 'full' or 'limited' evaluation is necessary for the renewal.

This material is intended to help the Member States in performing their tasks and reach a harmonised approach across EU.

In addition, a document was created to assist the applicants in preparing their renewal dossiers.

Together, these documents will support all actors in the renewal process, and help improve the quality

of the applications and their compliance with BPR requirements.

The BPC agreed on the documents and they will be made available on ECHA's website.

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.