Annex to a news alert ECHA/NA/16/39

Helsinki, 19 December 2016

Biocidal Products Committee (BPC) adopted opinions supporting the approval of six active substances as follows:

The adopted opinions concern the approval of the following active substances and their product-types (PTs):

Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate for product-types 2, 3 and 4

Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate is an existing active substance. It is used in products for laundry disinfection for professional and non-professional use and for disinfection of surfaces in industrial, public and health care areas for professional use (in product-type 2), for disinfection of surfaces and equipment in animal houses for professional use (in product-type 3) and for disinfection of surfaces and equipment in the food and beverage industry for professional use (in-product type 4).

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

Active chlorine released from sodium hypochlorite for product-types 1, 2, 3, 4 and 5

Active chlorine released from sodium hypochlorite is an existing active substance. In product-type 1 it is used for skin disinfection of the hands and lower forearms by professionals in healthcare and non-professionals. In product-type 2 it is used for treatment of sewage and waste water, disinfection of surfaces in industrial, public and health care areas by professionals, disinfection of surfaces in domestic areas by non-professionals, disinfection of swimming pools and disinfection of textiles during the washing process. In product-type 3 it is used for the disinfection of animal housing and of vehicles used for animal transport by professionals and disinfection of cases and litter trays for pets by non-professionals. The use in product-type 4 is for the disinfection of animal housing and of vehicles used for animal transport by professionals and disinfection of cases and litter trays for pets by non-professionals and in product-type 5 for the disinfection of drinking water for human consumption by professionals.

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

Calcium hypochlorite for product-types 2, 3, 4 and 5

Active chlorine released from sodium hypochlorite is an existing active substance. It is used for the treatment of sewage and waste water and for the disinfection of swimming pools (in product-type 2); for the disinfection of poultry animal housings and transport facilities by professionals (in product-type 3); for the disinfection of surfaces in the food and feed industry by professionals (in product-type 4) and for the disinfection of drinking water for human consumption and of poultry drinking water by professionals (in product-type 5).

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

Active chlorine released from chlorine for product-types 2 and 5

Active chlorine released from chlorine is an existing active substance. In product-type 2 it is used for the treatment of sewage and waste water and for the treatment of public swimming

pools, by professionals in both cases. In product-type 5 active chlorine released from chlorine is used for the disinfection of drinking water for human consumption.

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

MIT for product-type 11

MIT is an existing active substance evaluated in product-types 6, 11, 12 and 13. The BPC has already adopted an opinion on product-type 13. The products containing MIT in product-type 11 are used for the preservation of open and closed liquid cooling and processing systems against harmful microorganisms by preventing the bacterial and fungal growth.

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

OIT for product-type 8

OIT is an existing active substance. Products containing OIT are used fungicides for industrial wood preservation to protect freshly sawn timber from blue staining fungi and surface mould growth during storage and processing.

The evaluating competent authority of the active substance application is the United Kingdom.

Non-approval for MBIT for product-type 13

MBIT is a new active substance. Products containing MBIT in product-type 13 are to be used against a wide variety of microorganisms in metalworking fluid systems. These systems include but are not limited to the metalworking fluids and metal cleaning fluids. Products containing MBIT are to be used exclusively by professionals or industrial users.

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

The reason for the non-approval are the unacceptable risks identified for groundwater for several metabolites of MBIT.

The opinions will be available at the following link in the near future:
Biocidal Products Committee

Background Information

The role of BPC 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.

Further information about BPC is available on the ECHA website at the link below:
https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee