ECHA
EUROPEAN CHEMICALS AGENCY

Annex

# Biocidal Products Committee adopts 14 opinions on 12 active substances

Helsinki, 17 June 2016

## Annex to the news alert ECHA/NA/16/27

## More information about the opinions

Eight adopted opinions concern the renewal of approval of the following active substances used in anticoagulants rodenticide products (product type 14): **chlorophacinone, coumatetralyl, warfarin, bromadiolone, difenacoum, brodifacoum, difethialone, flocoumafen**.

All these eight active substances belong to a group of substances known as anti-vitamin K rodenticides (AVKs) used for the control of rodents (for example *Rattus norvegicus, Rattus rattus* and *Mus musculus*) indoors, in and around farms, buildings, sewers and open areas like waste dumps. The AVKs work by blocking the vitamin K cycle, thus disrupting the normal blood coagulation process and causing uncontrolled haemorrhaging.

Chlorophacinone, coumatetralyl and warfarin are known as first generation (multiple-dose) anticoagulant rodenticides, developed as rodenticides before 1970. Bromadiolone, difenacoum, brodifacoum, difethialone and flocoumafen belong to the second generation (single-dose) anticoagulant rodenticides; they are substantially more potent than the first generation compounds and have been developed beginning in the 1970s to control rodents resistant to the first generation anticoagulants.

The evaluating competent authorities of the active substance renewal applications are: Spain (for chlorophacinone), Denmark (for coumatetralyl), Ireland (for warfarin), Italy (for bromadiolone and brodifacoum), Finland (for difenacoum), Netherlands (for brodifacoum and flocoumafen) and Norway (for difethialone).

It is the first time the BPC adopted an opinion on the renewal of an approval for an active substance.

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

**Peracetic acid for PT 11 and 12**

Peracetic acid is an existing active substance evaluated in product types 1, 2, 3, 4, 5, 6, 11 and 12. The BPC has already adopted opinions on product types 1 to 6.

In product type 11 peracetic acid is used for preservation of cooling water in open re-circulating systems and once-through cooling dosing by professionals. In product type 12 peracetic acid is used as slimicide in the pulp and paper industry by professionals. The target

organisms include bacteria, fungi and algae for product type 11 and bacteria and fungi for product type 12.

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

**Cyanamide for PT 3 and 18**

Cyanamide is an active substance evaluated in product types 3 and 18.

Products containing cyanamide in product type 3 are used by professionals for the disinfection of the liquid manure stored underneath the slatted floor in pig stables against the bacterium *Brachyspira hyodysenteriae* in order to protect fattening pigs against dysenteria. In product type 18 cyanamide is used by professionals as an insecticide for the control of fly larvae (*Musca domestica*) in liquid manure in pig stables.
The evaluating competent authority of the active substance application is Germany.

**Piperonylbutoxide (PBO) for PT 18**

The active substance piperonyl butoxide (PBO) is an active substance evaluated in product type 18.

Products containing piperonyl butoxide are intended for professional indoor use in public and domestic premises and outdoor use in amenity areas and woodlands to control flying insects such as houseflies and mosquitoes. Piperonyl butoxide is used in insecticidal formulations always in combination with other insecticides mainly belonging to the class of pyrethrins and synthetic pyrethroids.

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

***Epsilon*-momfluorothrin for PT 18**

Epsilon-momfluorothrin is a new active substance evaluated in product type 18.

Insecticidal products containing *epsilon*-momfluorothrin are ready to use, household aerosols that are designed to be used by non-professionals (indoors and outdoors) to control flying insects such as mosquitoes and flies and crawling insects such as ants, cockroaches and bed bugs, as a directed spray and as a crack and crevice treatment (indoors and outdoors).

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

## Further information

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.