Annex to a news alert

First opinions on Union authorisation adopted – ECHA/NA/17/30

Helsinki, 20 December 2017

More information about the opinions

On Union authorisation, the adopted opinions concern the applications of two biocidal product families containing iodine/PVP-iodine used in veterinary hygiene (product-type 3).

On active substances, the adopted opinions concern the approval of the following substances in the specified product-types:

Cholecalciferol for product-type 14

Chlorophene is an existing active substance. The products containing cholecalciferol in product-type 14 are used in professional and non-professional control of mice and rats in and around buildings. Cholecalciferol acts by hypervitaminosis, characterised by hypercalcaemia.

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

Formaldehyde for product-type 2

Formaldehyde is an existing active substance. Formaldehyde is used by professionals as a disinfectant in private and public health areas in product-type 2 by wiping and mopping (prophylactic purposes) as well as by fogging/fumigation in cases of danger of an epidemic. After fogging/fumigation, formaldehyde is neutralised with ammonia. The neutralisation product – white, powdered methenamine – is formed and deposits on the surfaces.

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

Empenthrin for product-type 18

Empenthrin is an existing active substance. Empenthrin is used in mothproofing strips made of empenthrin-impregnated filter paper framed with a plastic holder intended for indoor use only by the non-professional (general public). It is intended to protect stored clothing and other textiles in domestic premises in wardrobes and drawers against textile-attacking insects, i.e. the clothes/fur moth (*Tinea pellionella*) and the webbing clothes moth (*Tineola bisselliella*) at all development stages of the insects.

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

Cyphenothrin for product-type 18

Cyphenothrin is an existing active substance. Cyphenothrin is a synthetic pyrethroid insecticide with contact and stomach action. It affects the nervous system of insects, causing pronounced repetitive activity and a prolongation of the transient increase in sodium permeability of nerve membranes in insects and other invertebrates. This results in continual nerve impulse transmission leading to tremors and death. This is demonstrated by the rapid knockdown action that pyrethroid compounds, e.g. cyphenothrin, have against target insects.

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

Penflufen for product-type 8

Penflufen is a new active substance. Penflufen is used for the control of wood-rotting fungi. Products containing penflufen are used for the industrial pre-treatment of wood by penetrative methods (vacuum pressure, double vacuum pressure, vacuum pressure with supercritical CO_2) and by superficial application methods (automated spraying, flow coating, automated and manual dipping and brush/roller) by industrial users, professional users and non-professional users, as appropriate.

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

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

Role of the Biocidal Products Committee in the 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.