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EUROPEAN CHEMICALS AGENCY

Annex

RAC concludes on PFOA restriction. The Committee finalises two opinions for authorisation, and adopts six opinions on harmonised classification and labelling.

Helsinki, 15 September 2015

Restriction proposal on PFOA (pentadecafluorooctanoic acid) and PFOA-related substances

RAC adopted its opinion, in support of the proposal by Germany and Norway to restrict the manufacture, marketing and use of PFOA, its salts and PFOA-related substances, as well as of articles and mixtures containing these substances. PFOA is a persistent, bioaccumulative, and toxic substance (PBT). Due to these properties, it may cause severe and irreversible adverse effects on the environment and human health. Based on their PBT and CMR properties, PFOA and its salt (APFO) have been identified as substances of very high concern (SVHCs) under REACH. PFOA and PFOA-related substances are used in a wide range of industrial applications as well as consumer products. In its opinion, for reasons of enforceability, RAC supported a higher concentration limit, compared to the original proposal. Some additional derogations for industrial sectors posing lower risk in relative terms, and to allow the production and use of the main alternative substance were supported.

Applications for authorisation

RAC adopted the final opinion on the use of trichloroethylene in industrial parts cleaning by vapour degreasing in closed systems where specific requirements (system of use-parameters) exist. RAC also adopted the final opinion on the industrial use of lead chromate in the manufacture of pyrotechnical delay devices contained in ammunition for naval self-protection.

Proposals for harmonised classification and labelling

8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine (Spiroxamine (ISO))

Spiroxamine (ISO) is used as a fungicide in plant protection products. Spiroxamine has a harmonised classification in Annex VI to CLP as harmful if swallowed, if inhaled and in contact with skin (minimum classifications for all routes), as a skin irritant and skin sensitiser (no sub-categorisation). For aquatic hazards, it is classified as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1 and Chronic 1), while no M-factors have been set in Annex VI.

RAC agreed with the proposal by Germany to add M-factors of 100 for both the acute and chronic aquatic classifications, and to confirm the classification as harmful if swallowed, if inhaled and in contact with skin based on data. As for skin sensitisation, RAC concluded that the current category 1 without sub-categorisation should be retained.

RAC also agreed with the proposal by Germany to classify spiroxamine (ISO) as a substance which may cause damage to eyes through prolonged or repeated exposure and which is suspected of damaging the unborn child (Repr. 2; H361d).

Cyproconazole (ISO)

Cyproconazole (ISO) is used as an active substance in pesticides and as a fungicide to protect above-ground wood. Cyproconazole has a harmonised classification in Annex VI to CLP as harmful if swallowed (minimum classification), as a substance which is suspected of damaging fertility or the unborn child and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1 and Chronic 1), while no M-factors have been set in Annex VI.

RAC agreed to the proposal by Ireland to add classifications as a substance which may cause damage to the liver through prolonged or repeated exposure, to retain the acute and chronic aquatic classifications based on data and to add respective M-factors of 10 and 1. Furthermore, RAC concluded that a classification as toxic if swallowed is justified, rather than a classification as harmful if swallowed. As for reproductive toxicity, RAC agreed with Ireland to upgrade the classification for developmental toxicity to category 1B (Repr. 1B; H360D). Finally, RAC did not agree with Ireland to assign a classification for carcinogenicity.

Momfluorothrin (S-1563)*

Momfluorothrin (S-1563*) is a biocidal active substance. It currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by the United Kingdom to classify momfluorothrin as harmful if swallowed, as a substance which may cause damage to the central nervous system and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1 and Chronic 1), with an M-factor of 100 for both the acute and the chronic aquatic hazard. RAC also agreed with the dossier submitter that a classification for carcinogenicity is not justified.

Methylhydrazine

Methylhydrazine is mainly used as a solvent, as an organic intermediate and as a rocket propellant. It currently has no entry in Annex VI to CLP.

RAC agreed with the proposal by the Netherlands to classify methylhydrazine as a substance which may cause cancer (Carc. 1B; H350).

5-chloro-2-(4-chlorophenoxy)phenol (DCPP)

DCPP is a biocidal active substance which is mainly used as a disinfectant in human hygiene and in dishwashing products. DCPP has a harmonised classification in Annex VI to CLP as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1 and Chronic 1), while no M-factors have been set in Annex VI.

RAC agreed to the proposal by Austria to assign an M-factor of 10 to both the acute and the chronic aquatic hazard.

3-[(2*S*)-1-methylpyrrolidin-2-yl]pyridine (Nicotine)

Nicotine is a naturally occurring alkaloid obtained from the leaves of tobacco plants. It is a major constituent in tobacco smoke. Nicotine currently has an existing entry in Annex VI to

CLP as toxic if swallowed (minimum classification) and fatal in contact with skin and as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2).

Based on a proposal submitted by the Netherlands, the Committee agreed to change the Annex VI entry with respect to acute toxicity and to classify nicotine as fatal if swallowed, if inhaled and in contact with skin (Acute Tox. 2 for all routes of exposure). RAC also agreed on setting Acute Toxicity Estimates (ATEs) to be applied where nicotine is part of a mixture: for the oral route, an ATE of 5 mg/kg body weight, for the dermal route an ATE of 70.4 mg/kg body weight and for the inhalation route an ATE of 0.19 mg/L.

In line with the REACH Regulation (Article 85(4)), RAC appointed five co-opted members. The co-opted RAC members will be tasked with evaluating applications for authorisation to support RAC during the peak of applications foreseen in 2016.