

RAC concludes on bisphenol A and decaBDE restrictions. The Committee evaluated four applications for authorisation, agreeing on eight draft opinions for individual uses, and adopted eight opinions on harmonised classification and labelling

Helsinki, 11 June 2015

[Annex to news alert ECHA/NA/15/15](#)

[More information about the adopted opinions](#)

Restriction proposal on bisphenol A

RAC's adopted opinion supports the French proposal to restrict the placing on the market of bisphenol A-containing thermal paper (e.g., point of sale tickets and receipts). RAC considered that the risk for workers (e.g., cashiers) handling thermal paper is not adequately controlled. Significantly, RAC did not identify a risk for consumers. The next step would be for SEAC to continue its discussion of the proposed restriction in September 2015 and is expected to come to a final opinion in December 2015.

Restriction proposal on decaBDE

RAC adopted its opinion, in support of the proposal of ECHA to restrict the use of decaBDE as a flame retardant in substances, mixtures and articles. DecaBDE was identified as a SVHC and included in the Candidate List as persistent, bioaccumulative and toxic/very persistent, very bioaccumulative (PBT/vPvB). These properties as well as the concern that it can be transformed to lower congeners which also have PBT/vPvB properties plus the widespread occurrence in the environment and wildlife are at the heart of the proposal. Another potential impact, in addition to the PBT/vPvB concerns, is that exposure to decaBDE may result in neurotoxicity in mammals, including humans.

Applications for authorisation

RAC agreed on seven draft opinions on the seven uses of trichloroethylene. The uses covered contain the use of the substance in industrial parts' cleaning by vapour degreasing in closed systems where specific requirements (system of use-parameters) exist, the industrial use of the substance as a solvent (a degreasing agent) in closed systems, two similar uses of trichloroethylene in packaging and two uses in formulation, as well as the use of the substance as an extraction solvent for bitumen in asphalt analysis. RAC also agreed on the draft opinion on the industrial use of lead chromate in manufacture of pyrotechnical delay devices contained in ammunition for naval self-protection.

DNEL and carcinogenicity dose-response relationship reference values setting for SVHCs

RAC agreed on two further reference values, namely a carcinogenicity dose-response relationship for 1,2-dichloroethane (EDC) and a DNEL for bis(2-methoxyethyl) ether (Diglyme).

Proposals for harmonised classification and labelling

Tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate

Tefluthrin (ISO) is an insecticide produced by certain species of the chrysanthemum plant. The representative use of tefluthrin (ISO) is as a seed treatment against soil-borne insects in sugar beet. It has currently no entry in Annex VI to CLP.

RAC agreed to the proposal by Germany to classify tefluthrin (ISO) as fatal if swallowed and in contact with skin (Acute Tox. 2 for both routes) and as fatal if inhaled (Acute Tox. 1). RAC did not concur with Germany to classify the substance as causing damage to the nervous system through prolonged or repeated exposure. RAC also agreed to classify tefluthrin (ISO) as very toxic to aquatic life with long lasting effects (Aquatic Acute 1, Aquatic Chronic 1), assigning M-factors of 10000 for both acute and chronic aquatic hazards.

Cyanamide

Cyanamide is a pesticidal and biocidal active substance. It has an existing entry in Annex VI to CLP as toxic if swallowed and harmful if in contact with skin (minimum classifications), irritant to skin and eyes and as a skin sensitiser.

RAC agreed to the proposal by Germany to modify the current entry and to classify cyanamide as toxic if swallowed and in contact with skin and as causing severe skin burns and eye damage (Skin Corr. 1; no sub-category). RAC also agreed to classify cyanamide as a substance which may cause damage to the thyroid through prolonged or repeated exposure while not specifying the route of exposure, and as a substance which is suspected of damaging fertility and the unborn child (Repr. 2; H361fd). In deviation from the Dossier Submitter's proposal, RAC decided not to add a sub-category for skin sensitisation, but to keep the current classification (Skin Sens. 1; no sub-category), and to classify cyanamide as a substance which is suspected of causing cancer (Carc. 2; H351) and as harmful to aquatic life with long lasting effects.

Terbuthylazine (ISO); N-tert-butyl-6-chloro-N'-ethyl-1,3,5-triazine-2,4-diamine

Terbuthylazine (ISO) is a broad spectrum herbicide belonging to the triazine group. It is effective against a wide range of annual and perennial broad leaved weeds. Terbuthylazine (ISO) has currently no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by the United Kingdom to classify terbuthylazine (ISO) as harmful if swallowed and as a substance which may cause damage to organs through prolonged or repeated exposure. RAC also decided to concur with the Dossier Submitter by classifying terbuthylazine (ISO) as very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Chronic 1), assigning M-factors of 10 to both the acute and the chronic aquatic hazard. RAC did not agree to the UK's proposal to classify terbuthylazine (ISO) as a substance which is suspected of causing cancer (Carc. 2; H351) as the criteria for a carcinogenicity classification were not deemed fulfilled.

Fipronil (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile

Fipronil (ISO) is used as biocidal active substance. It has an existing entry in Annex VI to CLP as toxic if swallowed, if inhaled and in contact with skin (minimum classifications), as a substance which causes damage to organs through prolonged or repeated exposure and as very

toxic to aquatic life with long lasting effects (Aquatic Acute 1, Aquatic Chronic 1), with M=10 for the acute aquatic hazard.

The Dossier Submitter from France proposed to review the M-factors for the aquatic hazards. RAC agreed to the proposal by France to set an M-factor of 10000 for the chronic aquatic hazard, but decided on an M-factor of 1000 for the acute aquatic hazard.

Dichlofluanid (ISO); N-[(Dichlorofluoromethyl)thio]-N',N'-dimethyl-N-phenylsulfamide

Dichlofluanid (ISO) is used as biocidal active substance. It has an existing entry in Annex VI to CLP as harmful if inhaled (minimum classification), irritating to eyes, as skin sensitiser and as very toxic to aquatic life with M=10.

RAC agreed to the proposal by the United Kingdom to confirm the classification as harmful if inhaled (Acute Tox. 4) based on data, and also decided to retain the classification as skin sensitiser without specifying a sub-category (Skin Sens. 1).

Dibutyltin dilaurate

Dibutyltin dilaurate is an organotin compound that is used as a catalyst. It has currently no entry in Annex VI to CLP.

RAC agreed to the proposal by Norway to classify dibutyltin dilaurate as a substance which is suspected of causing genetic defects (Muta. 2; H341), which may damage fertility and the unborn child (Repr. 1B; H360FD) and as causing damage to the immune system through prolonged or repeated exposure.

Quinolin-8-ol; 8-hydroxyquinoline

Quinolin-8-ol is a preventive and curative fungicide and bactericide used as active substance in plant protection products and as a laboratory reagent. It currently has no entry in Annex VI to CLP.

RAC agreed to the proposal by Spain to classify quinolin-8-ol as toxic if swallowed, as causing serious eye damage, as a skin sensitiser (Skin Sens. 1; no sub-category), as a substance which may damage the unborn child (Repr. 1B; H360D) and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Aquatic Chronic 1) with M=1 for both the acute and chronic aquatic hazard.

2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (Irgacure 907)

Irgacure 907 is used as photosensitive agent in industrial formulations. The main applications are products like coatings, adhesives and inks for industrial and professional use. It has an existing entry in Annex VI to CLP as harmful if swallowed (minimum classification) and as toxic to aquatic life with long lasting effects (Aquatic Chronic 2).

RAC agreed to the proposal by Industry to add to the Annex VI entry the harmonised classification as a substance which may damage the unborn child (Repr. 1B; H360D). In deviation from the Dossier Submitter's proposal, RAC decided to also classify irgacure 907 as a substance which may damage fertility (H360F) instead of 'suspected' of damaging fertility (H361f).

[Further information](#)

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

[Committee for Risk Assessment](#)

[Authorisation under REACH](#)

[Restriction under REACH](#)

Background Information

The role of RAC in EU regulatory processes

The Committee is responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions and proposals for harmonised classification and labelling. RAC also prepares opinions on specific questions relating to risks of chemicals to human health or the environment and on any other aspects concerning the safety of substances at the Executive Director's request. The final decision for proposals for harmonised classification and labelling, for proposals for restrictions as well as on applications for authorisation will be taken by the European Commission through a committee procedure.

Further information about RAC is available on the ECHA website.