ECHA
EUROPEAN CHEMICALS AGENCY

Annex

RAC continued its deliberations on Bisphenol-A and agreed on a further restriction proposal. The Committee evaluated 12 applications for authorisation, agreeing on 11 of 17 draft opinions for individual uses, and adopted six opinions for harmonised classification and labelling

Helsinki, 18 March 2015

Restriction proposal on bisphenol A (BPA)
RAC continued its deliberations on the French proposal to restrict BPA used as a dye developer in thermal paper used e.g. in point-of-sale tickets and receipts. The proposal aims to address the risks for human health of pregnant workers and of consumers exposed to thermal paper they may handle. As EFSA published its scientific opinion on BPA on 21 January 2015, RAC will consider their findings, taking them into account where appropriate. Amongst other sources, the EFSA opinion covered the risks to consumers from exposure to BPA through the diet. According to Article 95 of REACH, the ECHA Committees are required to work with other Community agencies such as EFSA to avoid conflicts in their opinions and will therefore extend their work to at least the next meeting in June; this will mean that SEAC's work will be similarly extended.

Restriction proposal on ammonium salts
RAC adopted its opinion, in support of the proposal from France to restrict the use of inorganic ammonium salts in cellulose insulation materials. The restriction aims to completely reduce the identified risks (i.e. eye and respiratory irritation) for EU citizens from the release of ammonia from cellulose insulation materials containing inorganic ammonium salts.

Applications for authorisation
The Committee examined 12 applications for authorisation on 17 uses of trichloroethylene; RAC agreed on 11 draft opinions.

Reference carcinogenicity dose response relationship for SVHCs
RAC agreed on the carcinogenicity dose response relationships for MOCA and technical MDA. To increase efficiency, RAC will use these non-binding reference values to evaluate applications for authorisation and applicants are invited to use them in the hazard part of their applications. A further dose-response curve for EDC and a DNEL for diglyme (both solvents) will be subject to a RAC consultation and if possible agreed by written procedure. The reference values will be published on ECHA's website in due course.

Proposals for harmonised classification and labelling

Linalool; (*S,R*)-3,7-dimethyl-1,6-octadien-3-ol; *dl*-linalool [1]
Coriandrol; (*S*)-3,7-dimethyl-1,6-octadien-3-ol; *d*-linalool [2]
Licareol; (*R*)-3,7-dimethyl-1,6-octadien-3-ol; *l*-linalool [3]

Linalool is a ubiquitous fragrance which is widely used in consumer products, including detergents, household products and cosmetics. Linalool currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify linalool and its *d*- and *l*-isomers as a skin sensitiser, but decided to assign a lower potency category (Skin Sens. 1B; H317).

_S_-allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydro-1_H_-pyrazole-1-carbothioate (Fenpyrazamine (ISO))

Fenpyrazamine (ISO) is a fungicide to be used to control grey mould. The substance currently has the following harmonised classification in Annex VI to the CLP Regulation: toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Austria to classify fenpyrazamine (ISO) as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410), and decided to assign an M-factor of 10 to the acute aquatic classification and an M-factor of 1 to the chronic aquatic classification.

(2*R*)-1-(ethylamino)-1-oxopropan-2-yl phenylcarbamate (Carbetamide (ISO))

Carbetamide (ISO) is a systemic herbicide used for the control of annual grasses and broad weeds. It currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify carbetamide (ISO) as harmful if swallowed (Acute Tox. 4; H302), as a substance which is suspected of causing cancer (Carc. 2; H351) and as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411). France also proposed to classify carbetamide (ISO) for reproductive toxicity (Repr. 2; H361d). However, RAC concluded that the prenatal effects fulfil the criteria for a more severe category, as a substance which may damage the unborn child (Repr. 1B; H360D).

2,2-dimethyl-1,3-benzodioxol-4-yl *N*-methylcarbamate (Bendiocarb (ISO))

Bendiocarb (ISO) is used as an insecticide in biocidal products. The substance currently has the following harmonised classifications in Annex VI to the CLP Regulation: toxic if swallowed and if inhaled and harmful in contact with skin and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). No M-factors had been set in Annex VI.

RAC agreed to the proposal by the United Kingdom to classify bendiocarb (ISO) as fatal if swallowed (Acute Tox. 2; H300) and as toxic in contact with skin (Acute Tox. 3; H311) based on the available data. The UK proposed to classify bendiocarb (ISO) as fatal if inhaled (Acute Tox. 2; H330), but RAC concluded that Acute Tox. 3; H331 (toxic if inhaled) is more appropriate. RAC also agreed to assign an M-factor of 10 to the acute aquatic classification and an M-factor of 100 to the chronic aquatic classification.

2-benzyl-4-chlorophenol (Chlorophene (ISO))

Chlorophene (ISO) is a biocide active substance used as a disinfectant for professional and private use. It currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Norway to classify chlorophene (ISO) as harmful if inhaled (Acute Tox. 4; H332), as causing skin irritation (Skin Irrit. 2; H315), as a substance that may cause an allergic skin reaction without a sub-category (Skin Sens. 1; H317), as causing

serious eye damage (Eye Dam. 1; H318), as a substance which is suspected of causing cancer (Carc. 2; H351), as suspected of damaging fertility (Repr. 2; H361f) and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) with an M-factor of 1 for the aquatic acute and an M-factor of 100 for the aquatic chronic classification. RAC also concluded that chlorophene (ISO) should be classified as a substance which may cause damage to kidneys through prolonged or repeated exposure (STOT RE 2; H373 (kidney)), although the dossier submitter had proposed a more severe category.

{(2Z)-3-[(6-chloropyridin-3-yl)methyl]-1,3-thiazolidin-2-ylidene}cyanamide (Thiacloprid (ISO))

Thiacloprid (ISO) is used as an insecticidal plant protection product in foliar spray applications, against sucking insects and beetles in arable crops (primarily oilseed rape). Thiacloprid (ISO) is also marketed as a biocidal active for use in wood preservatives. The substance currently has no harmonised classification in Annex VI to the CLP Regulation.

RAC had agreed during its 31st meeting to the proposal by the United Kingdom to classify thiacloprid (ISO) as toxic if swallowed (Acute Tox. 3; H301) and harmful if inhaled (Acute Tox. 4; H332), as a substance which is suspected of causing cancer (Carc. 2; H351), which may cause drowsiness or dizziness (STOT SE 3; H336) and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) with an M-factor of 100 for both the acute and the chronic aquatic classifications. RAC concluded on the classification of thiacloprid (ISO) as a substance which may damage fertility and the unborn child (Repr. 1B, H360FD), thus classifying in a more severe category for fertility than proposed by the dossier submitter. Classification for developmental effects was not proposed by the dossier submitter.

Further information

Authorisation under REACH

Restriction under REACH