Annex to news

Helsinki, 16 June 2021

Highlights from June RAC and SEAC meetings

Occupational exposure limits

RAC adopted an opinion on the scientific evaluation of occupational exposure limits (OEL) for asbestos. The opinion describes how the level of excess cancer risk depends on the concentration of mixed asbestos fibres in air (the exposure response relationship). This will support the Commission in the review of the current OEL set in *Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos at work*. RAC noted that while the use of all asbestos fibre types is already banned in the EU and stringent control measures apply to asbestos removal work, occupational exposure may still occur e.g. during uncontrolled demolition or maintenance activities involving old asbestos products still in place.

The opinion will be published in July.

REACH restrictions

Undecafluorohexanoic acid (PFHxA), its salts and related substances

RAC adopted its opinion on this restriction proposal (submitted by Germany) concerning the manufacture, use and placing on the market of PFHxA, its salts and related substances. SEAC agreed its draft opinion on this proposal, and a 60-day consultation is scheduled to start at the beginning of July, before the final adoption.

Substances in single-use baby diapers

SEAC and RAC continued their discussions on this restriction proposal submitted by France. The dossier concerns hazardous substances that may be present in single-use baby diapers. It aims to reduce health risks associated with wearing diapers for children and infants under the age of three.

Lead in outdoor shooting and fishing

RAC and SEAC had their first discussions on their opinions on the restriction proposal submitted by ECHA in January 2021. The proposed restriction aims to 'address the risks for human health and the environment posed by the use of lead in ammunition, i.e. gunshot used in terrains other than wetlands, bullets and pellets used both in wetlands and in terrains other than wetlands, as well as of lead in fishing tackle'. The restriction proposal is complementary to the existing restriction on the use of lead gunshot in wetlands.

Dechlorane Plus

Both RAC and SEAC concluded that the restriction proposal submitted by Norway in April 2021 conforms to the requirements for a restriction proposal set in Annex XV to REACH.

Applications for authorisation

RAC and SEAC adopted 11 opinions on applications for authorisation. The adopted opinions concern uses of octyl- and nonylphenol ethoxylates as surfactants in the manufacture of veterinary biologic drugs, as processing aids in imported diagnostics and in the production and use of

in vitro diagnostic devices, which are used in the Life Sciences sector.

RAC and SEAC agreed on nine draft opinions on six applications for authorisation on uses of chromium trioxide, sodium dichromate, 2,2'-dichloro-4,4'-methylenedianiline (MOCA) and octylphenol ethoxylates. Six of the agreed draft opinions concern uses of chromium trioxide in chrome plating for the sanitary and automotive industry sectors, chainsaw cutter links production, as well as in a surface pre-treatment ('etching') step, and for passivation of electrolytic tinplate (ETP). The remaining three opinions are on uses of MOCA in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors, and for offshore energy and renewables sectors, as well as on the use of octylphenol ethoxylates in the manufacturing process of the active pharmaceutical ingredient of a veterinary vaccine.

In addition, RAC agreed on three and SEAC agreed on two draft opinions on three review reports on uses of sodium dichromate as mordant in wool dyeing with dark colours, and the uses of 1,2-dichloroethane in the manufacturing of strong acid cation exchange resins, and for the synthesis of a precursor in the production of an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.

Similarly, SEAC also adopted four addenda and agreed on eight addenda to opinions which had been adopted by the two committees in 2015-2018. Following a request by the European Commission, the applicants needed to submit substitution plans to ECHA, which were not part of the initial applications. The addenda provide SEAC's conclusions on these. News of October 2020.

RAC adopted 9 opinions on harmonised classification and labelling

Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC -; CAS -)

The reaction mass is used in inks and toners, in printing and recorded media reproduction as well as in adhesives and sealants. The substance has no existing entry in the list of harmonised classification and labelling (Annex VI to the CLP Regulation).

RAC agreed to the proposal by Norway to classify the reaction mass as a substance that may damage fertility (Repr. 1B; H360F) and is suspected of causing genetic defects (Muta 2; H341).

Sodium chlorate (EC 231-887-4; CAS 7775-09-9)

Sodium chlorate is mostly used as an intermediate in the synthesis of chlorates, perchlorates and chlorites and also in pulp and paper bleaching agents (manufacture of chlorine dioxide).

The substance has a current harmonised classification and labelling as a solid that may cause fire or explosion, is a strong oxidiser (Ox. Sol. 1; H271), is harmful if swallowed (Acute Tox. 4 *; H302) and is toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Sweden to modify the acute toxicity classification to toxic if swallowed (Acute Tox. 3; H301) with an acute toxicity estimate (ATE) of 100 mg/kg bw and to remove the classification for aquatic toxicity.

Potassium chlorate (EC 223-289-7; CAS 3811-04-9)

Potassium chlorate is used to manufacture potassium chlorate crystals, pyrotechnics and matches and to formulate cosmetics and personal care products.

The substance has a current harmonised classification and labelling as a solid that may cause fire or explosion, is a strong oxidiser (Ox. Sol. 1; H271), is harmful if swallowed (Acute Tox. 4 *; H302), harmful if inhaled (Acute Tox. 4 *; H332) and is toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Sweden to modify the acute toxicity classification to toxic if swallowed (Acute Tox. 3; H301) with an ATE of 100 mg/kg bw as well as to remove the classification for acute inhalation toxicity and for aquatic toxicity.

Triethylamine (EC 204-469-4; CAS 121-44-8)

Triethylamine is used in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

The substance has a current harmonised classification and labelling as a highly flammable liquid and vapour (Flam. Liq. 2; H225), harmful if inhaled (Acute Tox. 4 *; H332), harmful if swallowed (Acute Tox. 4 *; H302), harmful in contact with skin (Acute Tox. 4*; H312), causes severe skin burns and eye damage (Skin Corr. 1A; H314) and may cause respiratory irritation (STOT SE 3; H335) at concentrations greater than or equal to 1 %.

RAC agreed to the proposal by Austria to modify the acute toxicity classifications to toxic if swallowed (Acute Tox. 3; H301) with an ATE of 100 mg/kg bw, toxic in contact with skin (Acute Tox. 3; H311) with an ATE of 300 mg/kg bw, toxic if inhaled (Acute Tox. 3; H331) with an ATE of 7.2 mg/L (vapours) and to add a classification as a substance which causes serious eye irritation (Eye Dam. 1; H318).

Di-n-butylamine (EC 203-921-8; CAS 111-92-2)

Di-n-butylamine is used in manufacture, formulation or re-packing, and at industrial sites.

The substance has a current Annex VI entry as a flammable liquid and vapour (Flam. Liq. 3; H226), harmful if inhaled (Acute Tox. 4 *; H332), harmful in contact with skin (Acute Tox. 4 *; H312) and harmful if swallowed (Acute Tox. 4 *; H302).

RAC agreed to the proposal by Austria to add to the existing classifications that the substance causes severe skin burns (Skin Corr. 1B; H314) and serious eye damage (Eye Dam. 1; H318). Furthermore, RAC agreed to the proposal by the dossier submitter to modify the acute toxicity classification to fatal if inhaled (Acute Tox. 2; H330) with an ATE of 1.2 mg/L (vapours), toxic in contact with skin (Acute Tox. 3; H311) with an ATE of 300 mg/kg bw and toxic if swallowed (Acute Tox. 3; H301) with an ATE of 220 mg/kg bw.

Contrary to the proposal, RAC did not agree to classify di-n-butylamine as a substance that may cause respiratory irritation (STOT SE 3; H335), but recommended instead to add the hazard statement EUH071.

Difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (CAS 119446-68-3)

Difenoconazole is an active substance of a plant protection product (PPP) and is used as a fungicide.

The substance has no existing harmonised classification and labelling under the CLP Regulation.

RAC agreed to the proposal by Spain to classify difenoconazole as harmful if swallowed (Acute Tox. 4; H302) with an ATE of 1 450 mg/kg bw, causes serious eye irritation (Eye Irrit. 2; H319), is very toxic to aquatic life (Aquatic Acute 1; H400, M=10) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1; H410, M=10).

In addition, contrary to the proposal of Spain, RAC agreed that difenoconazole should be classified as a substance suspected of causing cancer (Carc. 2; H351).

4-Nitrosomorpholine (EC 627-564-6; CAS 59-89-2)

4-Nitrosomorpholine has been detected as an impurity in higher amounts in consumer products (e.g. snow sprays).

The substance has no existing harmonised classification and labelling.

RAC agreed to the proposal by Germany to classify 4-nitrosomorpholine as a substance that may cause cancer (Carc. 1B; H350) with a specific concentration limit (SCL) of 0.001 % and which causes damage to the liver (STOT RE 1; H372). In addition, RAC agreed to classify 4-nitrosomorpholine as a substance suspected of causing genetic defects (Muta 2; H341).

N,N-dimethyl-p-toluidine (EC 202-805-4; CAS 99-97-8)

N,N-dimethyl-p-toluidine is used as a formulation in polyacrylic bone cements, as an intermediate in the manufacture of other substances, in textile dyes, finishing and impregnating products; including bleaches and other processing aids, pH-regulators and manufacture of textiles, leather, fur.

The substance is part of an existing Annex VI group entry (Index No. 612-056-00-9) as toxic if inhaled (Acute Tox. 3 *; H331), toxic in contact with skin (Acute Tox. 3 *; H311), toxic if swallowed (Acute Tox. 3 *; H301), may cause damage to organs (STOT RE 2*; H373**) and is harmful to aquatic life with long lasting effects (Aquatic Chronic 3; H412).

Contrary to the proposal by Germany to add the classification that the substance is suspected of causing cancer (Carc. 2; H351), RAC agreed to add that it may cause cancer (Carc. 1B; H350).

Furthermore, RAC agreed with Germany's proposal to modify the classification to harmful if inhaled (Acute Tox. 4; H332) with an ATE of 1.4 mg/L (dusts or mists), toxic if swallowed (Acute Tox. 3; H301) with an ATE of 140 mg/kg bw and may cause damage to the blood and the respiratory tract (STOT RE 2; H373). Furthermore, RAC agreed to remove the classification for acute dermal toxicity.

Metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4H)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one (EC: 244-209-7; CAS: 21087-64-9)

Metribuzin is an active substance with herbicidal activity used for weed control in different agricultural crops, such as potatoes, soybean etc. Metribuzin is a selective triazinone herbicide acting as an inhibitor of photosynthesis, specifically the inhibition of the photosynthetic electron transfer in the second light reaction.

The substance has a current harmonised classification and labelling as harmful if swallowed (Acute Tox. 4 *; H302), very toxic to aquatic life (Aquatic Acute 1; H400, M=10) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1; H410).

RAC agreed to the proposal by Estonia to add that the substance may cause damage to blood

(STOT RE 2; H373) but did not agree with the dossier submitter to include the thyroid as a target organ. RAC also agreed to modify the classification to harmful if swallowed (Acute Tox. 4; H302) with an ATE of 320 mg/kg bw as well as to retain the aquatic toxicity classifications (Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410, M=10).

The opinions will be available on ECHA's website in the near future:
Committee for Risk Assessment
Committee for Socio-economic Analysis

Background information

The role of RAC in EU regulatory processes

The committee is responsible for preparing scientific opinions related to the risks of chemicals to human health and the environment for the following processes:

- applications for authorisation;
- proposals for restrictions;
- proposals for harmonised classification and labelling; and
- occupational exposure limits (OELs).

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 decisions are taken by the European Commission through a comitology procedure.

Further information:
http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment

Background information

Role of SEAC in EU regulatory processes

The committee is responsible for preparing the opinion of the Agency on applications for authorisation and proposals for restrictions. SEAC also prepares opinions on specific questions relating to socio-economic issues and on any other aspects concerning the safety of substances on their own, in preparations or in articles at the Executive Director's request. The final decision 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 SEAC is available on ECHA's website at the link below:
http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis