Annex to news

Helsinki, 20 September 2023

ECHA's Risk Assessment Committee: banning secondary uses of creosote-treated wood necessary

REACH restrictions

Creosote and creosote-related substances

RAC adopted its opinion and SEAC agreed its draft opinion on the restriction proposal submitted by France in October 2022 for placing on the market, reuse and secondary use of wood treated with creosote or related substances. The proposal is complementary to the provisions of the Biocidal Products Regulation and aims to update Annex XVII, entry 31 of REACH.

A 60-day consultation on the agreed SEAC draft opinion is open until 7 November 2023.

Chloroalkanes C14-C17

SEAC adopted its opinion on the restriction proposal submitted by ECHA. The proposal concerns the manufacture, use and placing on the market of substances, mixtures and articles containing medium-chain chlorinated paraffins (MCCPs) as well as other substances that contain chloroalkanes with carbon chain lengths within the range C14 to C17.

Bisphenols with endocrine disrupting properties for the environment and their salts

The German authorities have withdrawn their proposal to restrict bisphenols that have endocrine disrupting properties to the environment from the opinion-making process by ECHA's scientific committees. They intend to re-submit an updated proposal to ECHA once they have considered the information submitted by stakeholders during the six-month consultation and reworked the scope of the restriction.

Once resubmitted, the proposal will be subject to a new consultation and scrutiny by ECHA's scientific committees. The timing of resubmission will be announced through ECHA's Registry of restriction intentions.

PFAS, universal

Both RAC and SEAC discussed their initial draft opinions with a focus on the scope and hazards (RAC only) and food contact materials and packaging on the restriction proposal submitted by Denmark, Germany, the Netherlands, Norway and Sweden in January 2023. A six-month consultation on the restriction proposal is open until 25 September 2023.

Applications for authorisation

RAC and SEAC adopted an opinion on an application for authorisation of chromium trioxide. The adopted opinion concerns functional chrome plating of piston rods for shock absorbers for automotive applications.

In addition, RAC agreed on 12 and SEAC on 10 draft opinions on applications for authorisation of chromium (VI) substances. Both committees also agreed on an opinion on application for authorisation of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-*tert*-OPnEO). The opinions will be adopted at a later stage. The agreed draft opinions concern:

- use of **4-*tert*-OPnEO** as a manufacturing aid in the production of gene therapies;
- use of **chromium trioxide** for Electrolytic Chromium Coating of Steel;
- electroplating (by a job plater) of metal substrates using **chromium trioxide** to achieve functional surfaces;
- use of **chromium trioxide** and **sodium dichromate** for Passivation of Electrolytic Tinplate;
- electroplating of metal substrates using **chromium trioxide** to achieve functional surfaces for the sanitary sector;
- use of **sodium dichromate** for Passivation of Electrolytic Tinplate;
- use of **chromium trioxide** for the hard-chrome plating of hydraulic and pneumatic cylinders for various applications, and inner tubes of motorbike front suspension for the automotive industry;
- industrial use of **chromium trioxide** for functional chrome plating with decorative character of items for the sanitary, hydro-sanitary, taps, household industries, and various other applications (such as handles/locks, pneumatic elements and electrical connection);
- industrial use of **chromium trioxide** for functional chrome plating with the decorative character of brass or stainless-steel drain components for the tap industry to provide thickness, corrosion resistance;
- industrial use of **chromium trioxide** for the plating of brass valves destined for applications involving industrial and technical fluids and brass fittings for oxygen cylinders;
- functional chrome plating of hydraulic cylinders, stems, pistons and rollers using **chromium trioxide**;
- functional chrome plating for hydraulic applications, other cylindrical components and further industrial applications (using **chromium trioxide**) (RAC only);
- **chromium-trioxide**-based functional chrome plating of solid and hollow piston rods for hydraulic applications (RAC only).

RAC adopted nine opinions on harmonised classification and labelling

Clopyralid (ISO); 3,6-dichloropyridine-2-carboxylic acid (EC: 216-935-4; CAS: 1702-17-6)

Clopyralid (ISO) is a contact acting and selective auxin type herbicide. It is used to control a range of broad leaf weeds in cereals and grassland. Clopyralid (ISO) has a current Annex VI entry as a substance that causes serious eye damage (Eye Dam. 1; H318).

RAC agreed to the proposal by Finland to classify clopyralid (ISO), in addition to the current classification, as a substance that is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), with an M-factor of 10. RAC also concurred that the supplemental hazard information that the repeated exposure may cause skin dryness or cracking (EUH066) should be added.

2-bromo-3,3,3-trifluoroprop-1-ene (EC: - ; CAS: 1514-82-5)

The uses of 2-bromo-3,3,3-trifluoroprop-1-ene (2-BTP) include filling of hand-held fire extinguishers and emergency discharge of fire extinguishers within the aviation industry. The substance has no current Annex VI entry.

RAC agreed to the proposal by Spain to classify 2-BTP as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD), may cause respiratory irritation (STOT SE 3; H335) and may cause drowsiness or dizziness (STOT SE 3; H336).

2,3-epoxypropyl o-tolyl ether (EC: 218-645-3; CAS: 2210-79-9)

2,3-epoxypropyl o-tolyl ether is an epoxy substance used in products for building, renovation and construction work such as adhesives, sealants, coatings, fillers, puttie, floorings etc. It is also used in the manufacture of plastic products, fabricated metal products, electrical, electronic and optical equipment, machinery and vehicles, rubber products and mineral products. 2,3-epoxypropyl o-tolyl ether is currently classified as a substance that causes skin irritation (Skin Irrit. 2; H315), may cause an allergic skin reaction (Skin Sens. 1; H317), is suspected of causing genetic defects (Muta. 2; H341) and is toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Denmark to modify the skin sensitisation classification to Skin Sens. 1A; H317.

2-methyl-2*H*-isothiazol-3-one hydrochloride; 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride (EC: 247-499-3; CAS: 26172-54-3)

2-methyl-2*H*-isothiazol-3-one hydrochloride is a broad-spectrum antimicrobial substance and it is intended to be used as a preservative in aqueous solutions, specifically in reagents for scientific research and development in the life science sector and in the production of biomolecules. It is intended to prevent the biodeterioration of the material and is active against bacteria, yeast and fungi. The substance has no current Annex VI entry.

RAC agreed to the proposal by Slovenia to classify 2-methyl-2*H*-isothiazol-3-one hydrochloride as a substance that is toxic if swallowed (Acute Tox. 3; H301, with an ATE=180 mg/kg bw), causes serious eye damage (Eye Dam. 1; H318), causes severe skin burns and eye damage (Skin Corr. 1; H314), may cause an allergic skin reaction (Skin Sens. 1A; H317, with a specific concentration limit of C ≥ 0.0015 %), a substance that is very toxic to aquatic life (Aquatic Acute 1; H400), with an M-factor of 10 and which is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), with an M-factor of 1. RAC also concurred that the supplemental hazard information that the substance is corrosive to the respiratory tract (EUH071) should be added. Furthermore, RAC agreed to add to the classification that the substance is toxic in contact with skin (Acute Tox. 3; H311, with an ATE=320 mg/kg bw) and fatal if inhaled (Acute Tox. 2; H330, with ATE = 0.15 mg/L).

Methyl oct-2-ynoate (EC: 203-836-6; CAS: 111-12-6)

Methyl oct-2-ynoate (folione) is used in air care products, biocides (e.g. disinfectants, pest control products), perfumes and fragrances, polishes and waxes, washing & cleaning products, cosmetics and personal care products. Folione has no current Annex VI entry.

RAC agreed to the proposal by Denmark to classify folione as a substance that may cause an allergic skin reaction (Skin Sens. 1A; H317).

Dinotefuran (ISO); 1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine (EC: -; CAS: 165252-70-0)

Dinotefuran (ISO) is an insecticide for indoor use only as a spot or crevice and crack treatment at or near locations where target pests gather. The substance has no current Annex VI entry.

RAC agreed to the proposal by Belgium to classify dinotefuran (ISO) as a substance that is very toxic to aquatic life (Aquatic Acute 1; H400), with an M-factor of 10 and which is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), with an M-factor of 10. Furthermore, RAC agreed to add to the classification that the substance is harmful if swallowed (Acute Tox. 4; H302, with an ATE = 2 000 mg/kg bw).

Proquinazid (ISO); 6-iodo-2-propoxy-3-propylquinazolin-4(3*H*)-one (EC: - ; CAS: 189278-12-4)

Products containing proquinazid are currently registered in the EU for control of fungal pests in cereals, grapes, orchards, strawberries and fruiting vegetables. The substance is currently classified as a substance that is suspected of causing cancer (Carc. 2; H351), is very toxic to aquatic life (Aquatic Acute 1; H400), with an M-factor of 1, and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), with an M-factor of 10.

RAC agreed to the proposal by Sweden to retain the current classifications for the substance, but also decided to add that the substance causes damage to the thyroid (STOT RE 1; H372) and may cause damage to the liver (STOT RE 2; H373).

3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate (EC: 259-627-5; CAS: 55406-53-6)

3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate (IPBC) is used as a fungicide for protection of wood against wood rotting fungi and wood discolouring fungi (blue stain) indoors and outdoors. IPBC has a current Annex VI entry as a substance that is toxic if inhaled (Acute Tox. 3; H331), harmful if swallowed (Acute Tox. 4; H302), causes damage to the larynx (STOT RE 1; H372), causes serious eye damage (Eye Dam. 1; H318), may cause an allergic skin reaction (Skin Sens. 1; H317), is very toxic to aquatic life (Aquatic Acute 1; H400), with an M-factor of 10, and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), with an M-factor of 1.

RAC agreed to the proposal by Denmark to modify the acute inhalation toxicity classification to fatal if inhaled (Acute Tox. 2; H330), but with an ATE of 0.17 mg/L (dusts/mists). The committee also agreed to add M=10 for the aquatic chronic toxicity classification, as proposed by the dossier submitter.

Captan (ISO); 1,2,3,6-tetrahydro-*N*-(trichloromethylthio)phthalimide (EC: 205-087-0; CAS: 133-06-2)

Captan (ISO), 1,2,3,6-tetrahydro-N-(trichloromethylthio)phthalimide is fungitoxic, preventing disease infection and establishment. Captan inhibits mycelial growth from germinating spores, but has no curative effect on already established infections. It works by contact and has multi-site activity. Captan has a broad action spectrum and can be used on many crops. Captan has current classifications as a substance that is suspected of causing cancer (Carc. 2; H351), is toxic if inhaled (Acute Tox. 3; H331), causes serious eye damage (Eye Dam. 1; H318), may cause an allergic skin reaction (Skin Sens. 1; H317) and is very toxic to aquatic life (Aquatic Acute 1; H400), with an M-factor of 10.

RAC agreed to the proposal by Austria to retain the classifications as Carc. 2; H351, Eye Dam. 1; H318 and Aquatic Acute 1; H400, with an M-factor of 10. RAC agreed to the proposal by the dossier submitter to add that captan causes damage to the respiratory tract (STOT RE 1, H372) and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), with an M-factor of 10. RAC also agreed to the proposal by the dossier submitter to modify the current acute inhalation toxicity classification to fatal if inhaled (Acute Tox. 2; H330), with an ATE of 0.22 mg/L (dusts/mists) and Skin Sens. 1A; H317, with an SCL of 0.001%. Furthermore, RAC decided to classify captan as a substance suspected of damaging fertility (Repr. 2; H361f).

Occupational exposure limits

2-chloro-1,3-butadiene (chloroprene) (EC: 204-818-0 ; CAS: 126-99-8)

The Commission has requested ECHA to evaluate 2-chloro-1,3-butadiene (chloroprene) in accordance with the Directive 2004/37/EC. At the meeting, RAC adopted the opinion on the scientific evaluation of occupational exposure limits (OELs) for chloroprene.

Chloroprene is used mainly in the polymerization of polychloroprene. It is considered to be a non-threshold carcinogen. Consequently, no health-based occupational exposure limit can be identified. Instead, RAC derived an exposure-risk relationship (ERR) expressing the excess cancer risk in function of the air concentration of chloroprene. Furthermore, RAC recommended to have a skin notation.

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

Background information

Role of RAC in EU's 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.

Role of SEAC in EU's 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.