

Annex to news

Helsinki, 22 June 2023

ECHA's committees: EU-wide PFAS ban in firefighting foams warranted

REACH restrictions

PFAS in firefighting foams

SEAC adopted its opinion on the <u>restriction proposal</u> submitted by ECHA in January 2022. The proposal concerns the banning of the placing on the market, formulation and use of firefighting foams containing PFAS. The dossier includes transition periods for certain sectors to maintain fire safety during the transition to PFAS-free foams.

Terphenyl, hydrogenated

SEAC adopted its opinion on the <u>restriction proposal</u> submitted by Italy in April 2022, which restricts the use of *terphenyl*, *hydrogenated* as a substance, in mixtures and in articles.

N,N-dimethylacetamide (DMAC); 1-ethylpyrrolidin-2-one (NEP)

SEAC adopted its opinion on the restriction proposal submitted by the Netherlands in April 2022. The proposal concerns occupational exposure to DMAC and NEP and sets workplace derived no-effect levels (DNELs) above which workers should not be exposed.

Creosote and creosote-related substances

SEAC discussed its second draft opinion on the restriction proposal submitted by France in October 2022 for <u>placing on the market</u>, <u>reuse and secondary use of wood treated with creosote or related substances</u>. The proposal is complementary to the provisions of the <u>Biocidal Products Regulation</u> and aims to update Annex XVII, entry 31 of REACH. The sixmonth consultation on the restriction proposal is open until 22 June 2023.

Chloroalkanes C14-C17

RAC adopted and SEAC agreed their opinions on the <u>restriction proposal</u> submitted by ECHA in July 2022. The dossier 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. A 60-day consultation on the agreed SEAC draft opinion is open until 14 August 2023.

PFAS, universal

Both RAC and SEAC discussed the recommendations to the dossier submitter on the restriction proposal submitted by five countries (Denmark, Germany, the Netherlands, Norway and Sweden) in January 2023. First draft opinions are expected to be discussed in the September plenaries. A six-month consultation on the restriction proposal open until 25 September 2023.

Applications for authorisation

RAC and SEAC adopted two opinions on an application for authorisation of trixylyl phosphate

and five opinions on applications for authorisation of <u>chromium trioxide</u>. The adopted opinions concern:

- industrial use of **trixylyl phosphate** as a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines;
- industrial use of **trixylyl phosphate** as a hydraulic fluid in closed systems to drive and control main steam isolation valves;
- electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector;
- industrial use of chromium trioxide for the hard chrome plating of injection moulds in order to provide hardness, wear resistance and good demoulding properties, critical for the manufacture of high-quality plastic parts;
- use of chromium trioxide in an integrated process to create a hard surface with selective adhesion properties on mandrels used to manufacture screens for Rotary Screen Printing for textile and other (printing) applications;
- the use of chromium trioxide for electroplating of metal substrates with the purpose to create a long-lasting high durability surface with bright look for kitchen and bathroom sanitary ware; and
- electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.

In addition, the committees agreed on 18 draft opinions on applications for authorisation of chromium trioxide. The opinions will be adopted at a later stage. The agreed draft opinions concern:

- industrial use of **chromium trioxide** for the functional chrome plating with decorative character of items for the hydrosanitary sector;
- industrial use of **chromium trioxide** for the plating of coffee machine parts in contact with water and food:
- industrial use of chromium trioxide for the functional chrome plating with decorative character of steel tubes and plates incorporated in machines for the agri-food industry, leisure, household furniture and automotive industries;
- functional chrome plating with decorative character of metal and plastic substrates for sanitary applications (using **chromium trioxide**);
- pre-treatment ("etching") of plastic substrates using chromium trioxide in electroplating processes for sanitary applications;
- functional chrome plating of military gun barrels and outer jacket surfaces using chromium trioxide;
- **chromium trioxide** based functional plating of gun barrel bores and auxiliary parts for assault rifles, carbines and pistols for non-civilian uses;
- the use of **chromium trioxide** based functional chrome plating of gun barrel bores and auxiliary parts for semi-automatic shotguns, over/under, side-by-side shotguns, pistols and carbines for civilian uses;
- industrial use of chromium trioxide for functional chrome plating of actuation and landing gear systems for the aviation industry;
- industrial use of **chromium trioxide** for surface treatment of aluminium alloys for applications in the aerospace industries unrelated to functional chrome plating;
- industrial use of chromium trioxide in functional chrome plating of metallic pieces required in different industrial sectors such as corrugated rolls to meet hardness, wear resistance, corrosion resistance, good surface condition, low friction coefficient and coating adhesion requirements;
- industrial use of **chromium trioxide** for the functional chrome plating of stainless-steel bars, mainly designed to be cylinder rods, used in aggressive and corrosive environments in diverse sectors such as transportation;

- chromium trioxide-based functional chrome plating of axially/rotationally symmetrical components requiring optimal tribological surface properties (resulting from microcracked surface) to ensure low surface friction under lubrication;
- chromium trioxide-based functional chrome plating of axially/rotationally symmetrical
 components requiring high wear resistant surfaces to withstand abrasive forces
 occurring in their application;
- **chromium trioxide**-based functional chrome plating of components with complex 3-dimensional geometry (not axially/rotationally symmetrical) requiring optimal tribological surface properties (resulting from microcracked surface) to ensure low surface friction under lubrication;
- **chromium trioxide**-based functional chrome plating of components with complex 3-dimensional geometry (not axially/rotationally symmetrical) requiring high wear resistant surfaces to withstand abrasive forces occurring in their application;
- industrial use of chromium trioxide for the hard plating of various end-products made
 of steel for the industry manufacturers to provide hardness, corrosion resistance, low
 friction coefficient, good surface roughness, thickness, and excellent surface condition;
 and
- **chromium trioxide**-based functional chrome plating of piston rings for automotive applications.

RAC adopted 14 opinions on harmonised classification and labelling

9-Octadecenoic acid (Z)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt [3] (EC: 271-843-1 [1]; - [2]; 267-966-5 [3]; CAS: 68609-93-8 [1]; - [2]; 67968-63-2 [3])

9-Octadecenoic acid (Z)-, sulfonated, potassium salts is used in the following categories of products (both indoor and outdoor): laboratory reagents (processing aid), intermediate use at industrial sites, air care products, biocidal products, polishes and wax blends, machine wash liquids/detergents, metal surface treatment products, adhesives (water-based, 1- or multi-component, reactive, cementitious) and sealants (reactive or otherwise). The substances have no current Annex VI entry.

RAC agreed to the proposal by the Netherlands to classify 9-Octadecenoic acid (Z)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt [3] as substances that may damage the unborn child (Repr. 1B; H360D).

2,3-epoxypropyl isopropyl ether (EC: 223-672-9; CAS: 4016-14-2)

2,3-epoxypropyl isopropyl ether is used industrially in coatings, paints, laboratory chemicals, and as an intermediate in polymer production. The substance is also used by professionals in washing and cleaning products. 2,3-epoxypropyl isopropyl ether has no current Annex VI entry.

RAC agreed to the proposal by Sweden to classify 2,3-epoxypropyl isopropyl ether as a substance that may damage fertility (Repr. 1B; H360F).

Tetrahydrofurfuryl methacrylate (EC: 219-529-5; CAS: 2455-24-5)

Tetrahydrofurfuryl methacrylate is used in formulation into mixtures, repacking (into coatings and inks), as monomer in polymerisation (wet process, dry process), end use in formulations, application of coatings/adhesives formulation, etc. The substance has no current Annex VI entry.

RAC agreed to the proposal by Austria to classify tetrahydrofurfuryl methacrylate as a substance that may cause an allergic skin reaction (Skin Sens. 1A; H317), may damage the unborn child and is suspected of damaging fertility (Repr. 1B; H360fD).

Bixlozone (ISO); 2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one (EC: -; CAS: 81777-95-9)

Bixlozone is a new active substance for use as a herbicide, with representative uses in winter wheat, winter barley, winter oilseed rape and maize. The substance has no current Annex VI entry and it has not yet been approved according to the Plant Protection Product regulations.

RAC agreed to the proposal by the Netherlands to classify bixlozone as a substance that is very toxic to aquatic life (Aquatic Acute 1; H400), with an M-factor of 1 and which is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), with an M-factor of 10. RAC agreed that no classification for the human hazards is warranted based on the data.

Trimethyl phosphate (EC: 208-144-8; CAS: 512-56-1)

Trimethyl phosphate (TMP) is used as a gasoline additive to prevent spark plug fouling and engine rumble. It is also used as a flame retardant for paints and polymers and it is a raw material for making insecticides. TMP is also used as methylating agent. The substance has no current Annex VI entry.

RAC agreed to the proposal by Austria to classify TMP as a substance that may cause cancer (Carc. 1B; H350), may cause genetic defects (Muta. 1B; H340), may damage fertility and the unborn child (Repr. 1B; H360FD), may cause damage to the nervous system (STOT RE 2; H373 (nervous system)) and is harmful if swallowed (Acute Tox. 4; H302) with an ATE=1300 mg/kg bw.

Barium chromate (EC: 233-660-5; CAS: 10294-40-3)

Barium chromate is used in pyrotechnics, high-temperature batteries, safety matches, as a corrosion inhibitor in metal-joining compounds, as a pigment in paints, in ceramics, in fuses, in metal primers, and in ignition control devices. According to ECHA's disseminated database (ECHA Dissemination, 2021) the substance is used by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance is used at industrial sites in coating products, adhesives and sealants, pH regulators and water treatment products and laboratory chemicals. The substance has no current entry in Annex VI to CLP.

RAC agreed to the proposal by the Netherlands to classify barium chromate as a substance, which may cause cancer (Carc. 1B, H350).

3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate (EC: 223-861-6; CAS: 4098-71-9)

3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate is used as raw material for the industrial manufacture of resins/hardeners for coating materials, adhesives, sealants, elastomers and polyurethanes. 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate has a current entry in Annex VI to CLP as a substance that is toxic if inhaled (Acute Tox. 3*; H331), may cause respiratory irritation (STOT SE 3; H335), causes skin irritation (Skin Irrit. 2; H315), causes serious eye irritation (Eye Irrit. 2; H319), may cause allergy or asthma symptoms or breathing difficulties if inhaled (Resp. Sens. 1; H334), may cause an allergic skin reaction (Skin Sens. 1; H317) and is toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Germany to modify the classifications to fatal if inhaled (Acute Tox. 1; H330, with an ATE=0.030 mg/L (dusts/mists)), causes severe skin burns and eye damage (Skin Corr. 1; H314), causes serious eye damage (Eye Dam. 1; H318), may cause an

allergic skin reaction (Skin Sens. 1A; H317) and to remove the classification as a substance which may cause respiratory irritation (STOT SE 3; H335). RAC also concurred that the supplemental hazard information that the substance is corrosive to the respiratory tract (EUH071) should be added.

Folpet (ISO); N-(trichloromethylthio)phthalimide (EC: 205-088-6; CAS: 133-07-3)

Folpet is a broad-spectrum fungicide with activity against many diseases. When applied before or at the onset of fungal attack, it prevents infection and disease establishment. Folpet has a current Annex VI entry as a substance that is suspected of causing cancer (Carc. 2; H351), is harmful if inhaled (Acute Tox. 4; H332), causes serious eye irritation (Eye Irrit. 2; H319), 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 classification as a substance suspected of causing cancer (Carc. 2; H351) and is very toxic to aquatic life (Aquatic Acute 1; H400, M=10), to add that folpet causes damage to the respiratory tract (STOT RE 1; H372 (respiratory tract), with an SCL for Cat. 1 as C \geq 5%, and for Cat. 2 as 1% \leq C < 5%) and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=10) and to modify to fatal if inhaled (Acute Tox. 2; H330, with an ATE of 0.30 mg/L (dusts or mists)), causes serious eye damage (Eye Dam. 1; H318) and may cause an allergic skin reaction (Skin Sens. 1A; H317, with an SCL of 0.001%). Furthermore, RAC concluded that the supplemental hazard information that repeated exposure may cause skin dryness or cracking (EUH066) should be added.

2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB] (EC: 252-681-0; CAS: 35691-65-7)

2-bromo-2-(bromomethyl)pentanedinitrile (DBDCB) is used in a wide range of products for consumers and occupational use, e. g. dishwashing liquid, household cleaning products and other detergents, car care products, wax and other polishing preparations for floors, adhesives, paints, and metal working fluids. In addition, it is used in veterinary products (e. g. in dog shampoos) and as a preservative in cosmetic products at a maximum authorised concentration of 0.1 %. The substance has no current entry in Annex VI to CLP.

RAC agreed to the proposal by Czechia to classify DBDCB as a substance which is harmful if swallowed (Acute Tox. 4; H302 (ATE=500 mg/kg bw)), fatal if inhaled (Acute Tox. 2; H330 (ATE=0.27 mg/L (dusts or mists)), causes serious eye damage (Eye Dam. 1; H318), may cause an allergic skin reaction (Skin Sens. 1A; H317 with an SCL of 0.001 %)) and toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411). RAC also agreed that the substance may cause damage to the thyroid and central nervous system through prolonged or repeated exposure (STOT RE 2; H373).

Fluoroethylene (EC: 200-832-6; CAS: 75-02-5)

Fluoroethylene has mainly been used in the production of polyvinylfluoride (PVF) and other fluoropolymers. The substance has no current Annex VI entry.

RAC agreed to the proposal by France to classify fluoroethylene as a substance that is suspected of causing genetic defects (Muta. 2; H341) and which may cause cancer (Carc. 1A; H350).

Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1 (EC: 225-935-3; CAS: 5160-02-1)

C.I. Pigment Red 53:1 belongs to the group of β -naphthol azo lake pigments with widespread use, especially in the imparting of colour to printing inks and plastic products, but also for coating and masterbatches. The substance has no current entry in Annex VI to CLP.

RAC agreed to the proposal by Germany to classify C.I. Pigment Red 53:1 as a substance which is suspected of causing cancer (Carc. 2, H351).

1,1-dichloroethylene; vinylidene chloride (EC: 200-864-0; CAS: 75-35-4)

Vinylidene chloride (VDC) is an industrial chemical, which is used as an intermediate in organic synthesis reactions and as a monomer in the production of a variety of polyvinylidene chloride copolymers. These copolymers of vinylidene chloride have a broad spectrum of applications in the plastic industry and the major application is the production of films for food packaging. They are also used in many types of packing materials, as flame retardant coatings for fiber and carpet backing, in piping and as coating for steel pipes and in adhesive applications. VDC is currently classified as an extremely flammable liquid (Flam. Liq. 1; H224), as a substance suspected of causing cancer (Carc. 2; H351) and is harmful if inhaled (Acute Tox. 4*; H332).

The Committee agreed with the proposal by France to retain the classification as extremely flammable liquid (Flam. Liq. 1; H224) and to modify existing classifications to a substance that may cause cancer (Carc. 1B; H350) and is fatal if inhaled (Acute Tox. 1; H330, with an ATE of 0.5 mg/L (dusts or mists)). RAC also agreed with the proposal by the dossier submitter to add that the substance is suspected of causing genetic defects (Muta. 2; H341), is toxic if swallowed (Acute Tox. 3; H301, with an ATE of 200 mg/kg bw), causes damage to the liver, kidney and respiratory tract (STOT RE 1; H372) and is harmful to aquatic life with long lasting effects (Aquatic Chronic 3; H412).

Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide (EC: 289-699-3; CAS: 89997-63-7)/ Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents (EC: 289-699-3; CAS: 89997-63-7)

Chrysanthemum cinerariaefolium extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO2 or hydrocarbon solvents, is intended to be used as insecticide against a wide range of flying and crawling pests except those that are plant parasitic, in various application sites, in- and outdoor. Within the current CLH dossier the use against flies and mosquitoes is intended. The substance is a biocidal active substance, but also a PPP active substance under the name pyrethrins. The substances have no current entry in Annex VI to CLP.

RAC agreed to the proposal by Spain to classify the *chrysanthemum* extracts as substances that are harmful if swallowed (Acute Tox. 4; H302, with an ATE of 700 mg/kg bw), harmful if inhaled (Acute Tox. 4; H332, with an ATE of 2.5 mg/L (dusts or mists)), may cause an allergic skin reaction (Skin Sens. 1B; H317), is very toxic to aquatic life (Aquatic Acute 1; H400, with an M-factor of 1000) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, with an M-factor of 100). Furthermore, RAC agreed to add to the classification that the substance causes damage to the nervous system (STOT SE 1; H370) and may cause damage to the respiratory tract by inhalation (STOT RE 2; H373).

Article 77(3)(c) request on acute toxicity classification of silanamine

On 5 December 2019, RAC had adopted an opinion on the harmonised classification and labelling of silanamine, which concluded that for acute toxicity it should be classified as a substance which is fatal if inhaled (Acute Tox. 2; H330, with an ATE of 0.45 mg/L).

Following adoption and publication of the RAC opinion, manufacturers of the substance provided an additional study, which examined the mechanism for the observed acute toxicity of

HMDZ-treated SAS via the inhalation route. RAC was therefore <u>requested</u>, based on Article 77(3)(c), to review the available information on acute toxicity by inhalation, and, if appropriate, to amend the opinion of 5 December 2019 in relation to the classification for acute toxicity.

RAC took note of the new information and concluded on no classification for acute inhalation toxicity of silanamine.

Occupational exposure limits (OELs)

2,3-epoxypropyl methacrylate (glycidyl methacrylate)

The Commission has requested ECHA to evaluate <u>2,3-epoxypropyl methacrylate (glycidyl methacrylate)</u> in accordance with the Carcinogens, Mutagens or Reprotoxic substances at work directive. At the meeting, RAC adopted an opinion on the scientific evaluation of occupational exposure limits (OELs) for GMA.

GMA is considered to be a non-threshold carcinogen. Consequently, no health-based OEL nor a Short-Term Exposure Limit (STEL) can be identified. Instead, RAC derived an exposure-risk-relationship (ERR) expressing the excess cancer risk as a function of the air concentration of GMA. Furthermore, RAC recommended to have a Skin notation and Skin Sensitisation notation.

RAC noted that later in the regulatory process, when an 8 h OEL is established, also a STEL should be considered.

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.