

Annex to news

Helsinki, 24 March 2023

ECHA's Risk Assessment Committee backs PFAS ban in firefighting foams

REACH restrictions

PFAS in firefighting foams

RAC adopted and SEAC agreed their opinions on the restriction proposal 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. A 60-day consultation on the agreed SEAC draft opinion is open until 15 May 2023.

Terphenyl, hydrogenated

RAC adopted and SEAC agreed their opinions for the restriction proposal submitted by Italy in April 2022, which restricts the use of Terphenyl, hydrogenated as a substance, in mixtures and articles. A 60-day consultation on the agreed SEAC draft opinion is open until 15 May 2023.

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

RAC adopted and SEAC agreed their opinions 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. A 60-day consultation on the agreed SEAC draft opinion is open until 22 May 2023.

Creosote and creosote-related substances

Both RAC and SEAC discussed their first draft opinions on the restriction proposal submitted by France in October 2022 for [placing on the market, re-use and secondary use of wood treated with creosote or related substances](#). The proposal mainly concerns the reuse and secondary use of railway sleepers and telegraph poles treated with creosote and is complementary to the provisions of the [Biocidal Products Regulation](#) and Annex XVII, entry 31 of REACH. The six-month consultation on the restriction proposal is open until 22 June 2023.

BPA and other bisphenols and bisphenol derivatives with endocrine disrupting properties for the environment

Both RAC and SEAC discussed their first draft opinions on the restriction proposal submitted by Germany in October 2022. The proposal concerns the [restriction of the placing on the market of mixtures and articles](#) where the concentration of BPA and other bisphenols is equal to or greater than 10 ppm (0.001 % by weight). The six-month consultation on the restriction proposal is open until 22 June 2023.

Chloroalkanes C14-C17

RAC discussed its second draft opinion on the restriction proposal 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

The six-month consultation on the restriction proposal is open until 22 March 2023.

PFAS, universal

Both RAC and SEAC concluded that the restriction proposal submitted by five countries (Denmark, Germany, the Netherlands, Norway and Sweden) in January 2023 conforms to the requirements for a restriction proposal in Annex XV to REACH. A six-month consultation on the restriction proposal opened on 22 March 2023.

Applications for authorisation

RAC and SEAC agreed on a draft opinion on a review report and 14 draft opinions on applications for authorisation. The agreed draft opinions concern:

- industrial use of **bis(2-methoxyethyl) ether (diglyme)** as a process solvent in one step of the manufacturing of an active pharmaceutical ingredient used in an anti-protozoal drug;
- industrial electroplating of different types of substrates using **chromium trioxide** to achieve functional surfaces with high durability and a bright or matt silvery appearance;
- industrial use of **chromium trioxide** and **sodium dichromate** for passivation of electrolytic tinplate;
- industrial use of **chromium trioxide** for electrolytic chromium coating of steel, also known as tin free steel;
- industrial functional chrome plating of hydraulic cylinders and swivel joints using **chromium trioxide**;
- industrial use of **chromium trioxide** for a pre-treatment step (etching) in the electroplating process for various applications;
- industrial use of **chromium trioxide** to create a long-lasting and high durability chromium decorative surface on plastic substrates in the electroplating process for various applications;
- industrial electroplating of different types of substrates using **chromium trioxide** to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications;
- industrial use of **chromium trioxide** for functional chrome plating with decorative character of sanitary equipment;
- industrial use of **chromium trioxide** for functional chrome plating of parts with at least one axis of symmetry and simple surface geometry;
- industrial use of **chromium trioxide** for functional chrome plating of parts with complex surface geometry and requiring the use of an auxiliary anode;
- industrial use of **chromium trioxide** for hard chromium plating of moulds, dies and custom-made finished parts on any metal base, to provide hardness, wear resistance, corrosion resistance, demoulding properties, low friction ratio, for the manufacture of high-quality metal parts in several sectors such as automotive, pharmaceutical, food and packaging industries;
- industrial **chromium trioxide**-based functional chrome plating of hand tools to achieve a high level of abrasion resistance as well as corrosion and chemical resistance;
- industrial use of **chromium trioxide** for functional chrome plating of piston rods for shock absorbers for automotive applications;
- industrial electroplating of different types of substrates using **chromium trioxide** to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.

RAC adopted 11 opinions on harmonised classification and labelling

2-ethylhexanoic acid, monoester with propane-1,2-diol

(EC: 285-503-5; CAS: 85114-00-7)

Registered uses include consumer uses (coating products and inks and toner) and (wide-spread) uses by professional workers in formulation or re-packing at industrial sites and in manufacturing. The substance has no entry in Annex VI to CLP.

RAC agreed to the proposal by Spain to classify 2-ethylhexanoic acid, monoester with propane-1,2-diol as a substance that may damage the unborn child (Repr. 1B, H360D).

2-phenylpropene (EC: 202-705-0; CAS: 98-83-9)

Used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. It has a current Annex VI entry as a substance which is a flammable liquid (Flam. Liq. 3; H226), causes serious eye irritation (Eye Irrit. 2; H226), may cause respiratory irritation (STOT SE 3; H335) and is toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Germany to add that 2-phenylpropene is suspected of causing cancer (Carc. 2; H351) and may cause an allergic skin reaction (Skin Sens. 1B; H317) and to add Note D, which addresses placing non-stabilised forms of the substance on the market.

Aqueous extract from the germinated seeds of sweet *Lupinus albus* (EC: - ; CAS: -)

Intended to be used as a fungicide. The intended uses included in the active substance approval dossier are spray applications (field and greenhouse) for strawberries and tomatoes. The substance has no current entry in Annex VI to CLP.

RAC agreed to the proposal by the Netherlands for no classification for all considered hazard classes.

Dinitrogen oxide (EC: 233-032-0; CAS: 10024-97-2)

Used for more than 150 years in surgery as an adjuvant in inhalational general anaesthesia. The substance is also used for pain relief during childbirth or for short analgesia during minor medical procedures (e.g. dentistry, emergency, veterinary medicine). It is commonly used in combination with other anaesthetics.

Furthermore, dinitrogen oxide is an industrial chemical used in the food industry as a food additive (E942). It is a propellant in canisters used in many preparations and uses (e.g. to aerate whipping cream, inflate balloons) and an additive to rocket fuels to increase the amount of oxygen available for combustion. In addition, dinitrogen oxide is used in laboratories as an oxidising agent in atomic flame absorption spectrometry.

Recreational misuses of the gas, also called "laughing gas", have been identified as strongly increasing in recent years (ANSES, 2020) due to its euphoric, relaxing and hallucinogenic properties, with various effects for health, including severe ones. The substance has no current entry in Annex VI to CLP.

RAC agreed to the proposal by France to classify dinitrogen oxide as a substance that may damage the unborn child and is suspected of damaging fertility (Repr. 1B; H360Df), may cause drowsiness or dizziness (STOT SE 3; H336), causes damage to the nervous system (STOT RE 1; H372) and harms public health and the environment by destroying ozone in the upper atmosphere (Ozone 1; H420).

N-1-naphthylaniline; N-phenylnaphthalen-1-amine (EC: 201-983-0; CAS: 90-30-2)

Used in the manufacture of rubber products. It has widespread uses by professional workers and is used in polymers, lubricants and greases, hydraulic fluids and metal working fluids. The substance has no current entry in Annex VI to CLP.

RAC agreed to the proposal by Germany to classify *N*-1-naphthylaniline as a substance that is harmful if swallowed (Acute Tox. 4; H302 (ATE=1 200 mg/kg bw)), may cause an allergic skin reaction (Skin Sens. 1; H317), and may cause damage to the blood system and liver through prolonged or repeated exposure (STOT RE 2; H373).

Ozone (EC: 233-069-2; CAS: 10028-15-6)

Generated *in situ* as a biocidal active substance from oxygen and used to disinfect water and ambient air. There are also several non-biocidal uses by operation of an ozonation device utilising the oxidative action of ozone e.g. (non-exhaustive list): ozonation of mineral water and drinking water or water for swimming pools; removal of iron, manganese, arsenic and nitrite, pharmaceutical, medicine, cosmetics, and food industry; production of (ultra-)pure process water, pulp and paper bleaching, semiconductor industry; production of (ultra-)pure process water, off-gas treatment, laminating and coating, sludge reduction, soil and groundwater remediation, ozonation of wastewater. The substance has no current entry in Annex VI to CLP.

RAC agreed to the proposal by Germany to classify ozone as a substance that may cause or intensify fire; oxidiser (Ox. Gas 1; H270), is fatal if inhaled (Acute Tox. 1; H330 (ATE=10 ppmV)), is suspected of causing genetic defects (Muta. 2; H341), is suspected of causing cancer (Carc. 2; H351), causes damage to respiratory system, nervous system and cardiovascular system (STOT SE 1; H370 (C ≥ 0.002 % STOT SE 1; H370, 0.0005 % ≤ C < 0.002 % STOT SE 2; H371)), causes damage to the respiratory system and nervous system through prolonged or repeated exposure (STOT RE 1; H372 (C ≥ 0.05 % STOT RE 1; H372, 0.01 % ≤ C < 0.05 % STOT RE 2; H373)), is very toxic to aquatic life (Aquatic Acute 1; H400 (M=100)) and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410 (M=1)).

Pethoxamid (ISO); 2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl)acetamide (EC: - ; CAS: 106700-29-2)

Intended to be used as a pre-emergence herbicide in soybeans and both a pre-emergence and early post-emergence herbicide in maize to control mono and dicotyledonous weeds. Pethoxamid, a member of the chemical class of chloroacetamides, is a soil-active and selective herbicidal compound, taken up primarily by the roots, but also by the hypocotyls and the cotyledons of young seedlings. The substance has a current Annex VI entry as harmful if swallowed (Acute Tox. 4*; H302), may cause an allergic skin reaction (Skin Sens. 1; H317), is very toxic to aquatic life (Aquatic Acute 1; H400 (M=100)) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410).

RAC agreed to the proposal by Austria to modify the classification to harmful if swallowed (Acute Tox. 4; H302), with an ATE of 980 mg/kg bw, and may cause an allergic skin reaction (Skin Sens. 1A; H317). RAC also agreed to retain the classification as very toxic to aquatic life (Aquatic Acute 1; H400 (M=100)) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410 (but to add M=10)).

Propyl 4-hydroxybenzoate (EC: 202-307-7; CAS: 94-13-3)

Used in formulations – in manufacturing of cosmetic products and pharmaceutical preparations (ointments). The consumer uses include the end use of cosmetic products or pharmaceuticals. The substance has no current entry in Annex VI to CLP.

RAC did not agree to the proposal by Belgium to classify propyl 4-hydroxybenzoate as a substance that is suspected of damaging fertility and the unborn child (Repr. 2; H361fd).

Tetrairon tris(pyrophosphate); ferric pyrophosphate (EC: 233-190-0; CAS: 10058-44-3)

Products containing ferric pyrophosphate are used in agriculture and horticulture to control harmful slug and snail species in all edible and inedible plants grown in field conditions and under protection. The substance has no current entry in Annex VI to CLP.

RAC agreed to the proposal by Poland to classify ferric pyrophosphate as a substance that causes serious eye irritation (Eye Irrit. 2; H319).

Tetraphosphorus trisulphide; phosphorus sesquisulphide

(EC: 215-245-0; CAS: 1314-85-8)

An inorganic compound whose main and only application is in the industry of 'strike anywhere' matches, where it totally replaced white and yellow phosphorus that were used in the 19th century. The toxicity of white and yellow phosphorus, responsible of the "Fossy jaw" disease that caused osteonecrosis of the jaw to many workers, as well as their high reactivity made tetraphosphorus trisulphide the perfect alternative for the matches industry. The substance has a current Annex VI entry as flammable solid (Flam. Sol. 2; H228), a substance that in contact with water releases flammable gases which may ignite spontaneously (Water-react. 1; H260), is harmful if swallowed (Acute Tox. 4*; H302) and is very toxic to aquatic life (Aquatic Acute 1; H400).

RAC agreed to the proposal by Italy to modify the classification to Flam. Sol. 1; H228 and to add that the self-heating of the substance may catch fire (Self-heat. 1; H251). Furthermore, RAC agreed to the proposal to remove water-react. 1; H260 and Aquatic Acute 1; H400 from the existing classification.

 α,α' -propylenedinitrildi-*o*-cresol (EC: 202-307-7; CAS: 94-13-3)

Used at industrial and professional sites as a fuel and lubricant additive, as a process chemical, and as a lubricant in high energy open processes. The substance is also used in fuels relevant for consumers. The substance has no current Annex VI entry.

RAC agreed to the proposal by the Netherlands to classify α,α' -propylenedinitrildi-*o*-cresol as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD).

Occupational exposure limits (OELs)**1,2-dichloropropane (1,2-DCP)**

The European Commission requested RAC to evaluate 1,2-dichloropropane in accordance with the Carcinogens, Mutagens or Reprotoxic substances at work directive (2004/37/EC).

RAC adopted an opinion on the scientific evaluation of occupational exposure limits (OELs) for 1,2-dichloropropane.

1,2-DCP is considered to be a non-threshold carcinogen. Consequently, no health-based occupational exposure limit (OEL) nor a STEL can be identified.

Instead, RAC derived an exposure-risk-relationship (ERR) expressing the excess cancer risk (based on the occurrence of bronchoalveolar adenomas/carcinomas in experimental studies) as a function of the air concentration of 1,2-DCP. Furthermore, a skin notation was recommended.

1,2,3-Trichloropropane (1,2,3-TCP)

The Commission requested RAC to evaluate 1,2,3-trichloropropane in accordance with the Carcinogens, Mutagens or Reprotoxic substances at work directive (2004/37/EC).

RAC adopted an opinion on the scientific evaluation of occupational exposure limits (OELs) for 1,2,3-trichloropropane.

1,2,3-TCP is considered to be a non-threshold carcinogen. Consequently, no health-based occupational exposure limit (OEL) nor a STEL can be identified. Instead, RAC derived an exposure-risk-relationship (ERR) expressing the excess cancer risk (based on the occurrence of total alimentary tract tumours in experimental studies) as a function of the air concentration of 1,2,3-TCP. Furthermore, a skin notation was recommended.

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 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 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.