

Annex to news

Helsinki, 8 December 2022

Highlights from December RAC and SEAC meetings

REACH restrictions

Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for sport shooting

SEAC adopted its opinion on ECHA's proposal to restrict the placing on the market and use of substances containing [PAHs in clay targets for shooting](#). The proposed restriction introduces a 0.005 % weight by weight concentration limit for the sum of 18 indicator PAHs after a one-year transition with a 1 % concentration limit. PAHs are contained in binders used to produce clay targets. SEAC confirmed its considerations that a restriction is, in general, an appropriate EU-wide measure to address the identified risks. SEAC considers that any of the restriction options proposed could be proportionate in terms of the benefits and costs to society. The committee considers that the proposal is the most appropriate EU-wide measure to address the identified risks, taking into account the proportionality of its benefits and costs to society. However, the proposed one-year transition period with a higher concentration limit might not be necessary. RAC [adopted its opinion](#) on the same restriction in September 2022.

Lead in outdoor shooting and fishing

SEAC adopted its opinion on this restriction proposal submitted by ECHA in January 2021, which aims to address risks for human health and the environment posed by the use of lead in outdoor shooting (gunshot, bullets and pellets), as well as lead used in fishing tackle.

The proposal is complementary to the existing restriction on the use of lead gunshot in wetlands. More information at [ECHA's scientific committees support limiting lead use for outdoor shooting and fishing](#), 30 November 2022

Terphenyl, hydrogenated

Both RAC and SEAC discussed their second draft opinions for the restriction proposal submitted by Italy, which intends to restrict the use of Terphenyl, hydrogenated as a substance, in mixtures and articles or parts thereof. A six-month stakeholder consultation will be finished in December 2022.

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

Both RAC and SEAC discussed their second draft opinions for the restriction proposal submitted by The Netherlands in April 2022. The proposal concerns occupational exposure to DMAC and NEP. A six-month stakeholder consultation will be finished in December 2022.

PFASs in firefighting foams

SEAC received an update on the outcome of the third-party consultation on the Annex XV proposal submitted by ECHA in January 2022. The proposal concerns the banning of the formulation and use of firefighting foams containing PFASs. The dossier includes transitional periods for certain sectors to ensure that fire safety is maintained during the transition to firefighting foams that do not contain PFASs.

Creosote and creosote-related substances

Both RAC and SEAC concluded that the restriction proposal submitted by France in October 2022 conforms to the requirements for a restriction proposal in Annex XV on the [placing on the market, re-use and secondary use of wood treated with creosote or related substances](#). The proposal is intended to be complementary to the provisions of the [Biocidal Products Regulation](#) for creosote. The proposal mainly concerns the reuse and secondary use of railway sleepers and telegraph poles treated with creosote. A six-month stakeholder consultation will be launched on 21 December 2022.

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

Both RAC and SEAC concluded that the restriction proposal submitted by Germany in October 2022 conforms to the requirements for a restriction proposal in Annex XV. 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). A six-month stakeholder consultation will be launched on 21 December 2022.

Applications for authorisation

RAC and SEAC adopted four opinions on applications for authorisation and two opinions on review reports for authorisation. The latter two adopted opinions on review reports for authorisation are on the industrial use of **trichloroethylene** as an extraction solvent for the purification of caprolactam from caprolactam oil, and the use of **trichloroethylene** as extraction solvent in the manufacture of polyethylene separators for lead-acid batteries. The other four adopted opinions concern uses of **chromium trioxide** in the functional chrome plating of shock absorber rods.

In addition, RAC and SEAC agreed 16 opinions on applications for authorisation. The agreed opinions concern:

- the industrial use of **trixylyl phosphate** as a hydraulic fluid in closed systems to drive and control [the steam inlet valves of turbines](#) of nuclear power plants;
- the industrial use of **trixylyl phosphate** as a hydraulic fluid in closed systems to drive and control [main steam isolation valves](#) of nuclear power plants;
- the 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 (RSP) for textile and other (printing) applications;
- the 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;
- electroplating of brass substrates using **chromium trioxide** to achieve functional surfaces for architectural fittings;
- the industrial use of **chromium trioxide** for the etching of plastics materials, as a pre-treatment step of the electroplating process, for automotive applications mostly;
- the use of **chromium trioxide** for etching of plastic substrates as a key pre-treatment step for creating an electrically conductive surface to enable electroplating;
- the use of **chromium trioxide** for electroplating of plastic substrates to achieve a protective and durable surface with a silvery finish;
- the use of **chromium trioxide** in functional chrome plating with decorative character for automotive applications;
- etching of plastics with **chromium trioxide** as pre-treatment step for electroplating of plastics for automotive applications;

- electroplating of metal substrates using **chromium trioxide** to achieve functional surfaces for the sanitary sector;
- 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;
- the use of **chromium trioxide** in functional chrome plating with decorative character of metal substrates for sanitary applications;
- 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;
- 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.

RAC adopts 10 opinions on harmonised classification and labelling

1,4-Dichloro-2-nitrobenzene (EC 201-923-3, CAS 89-61-2)

1,4-Dichloro-2-nitrobenzene is used as an intermediate in the production of fine chemicals, pharmaceuticals, pigments, pesticides, and ultraviolet absorbers and as a laboratory agent. In the EU, it is registered for use at industrial sites including the production of pulp, paper, and paper products and textiles, leather, and fur as well as the inclusion into/onto articles like fabrics, textiles, and apparel. The source of exposure of professional workers and consumers to 1,4-dichloro-2-nitrobenzene are cleaning and maintenance products (e.g., washing and cleaning products). The substance has no current Annex VI entry.

RAC agreed to the proposal by the Netherlands to classify 1,4-dichloro-2-nitrobenzene as a substance that may cause cancer (Carc. 1B; H350).

Dibenzoyl peroxide; benzoyl peroxide (EC 202-327-6, CAS 94-36-0)

Dibenzoyl peroxide is used in polymerisation reactions (polymers, resins, rubbers) and as an intermediate, adhesive, sealant, coating resin hardener, and toner by industrial and professional workers. It is also formulated into fillers, adhesives, sealants, cosmetics and personal care products for use by consumers. It has a current entry in Annex VI to the CLP Regulation as a substance which may cause a fire or explosion upon heating (Org. Perox. B; H241), causes serious eye irritation (Eye Irrit. 2; H319) and which may cause an allergic skin reaction (Skin Sens. 1; H317).

RAC agreed to the proposal by Ireland to classify dibenzoyl peroxide as very toxic to aquatic life (Aquatic Acute 1; H400, with M-factor of 10) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, with M-factor of 10).

n-Hexane (EC 203-777-6, CAS 110-54-3)

The largest volume applications for hexane are the uses as fuel and for extraction of oil from seeds, for example from soybeans or peanuts. Other than that, hexane is used as a solvent and reaction medium for "manufacture of polyolefins, synthetic rubbers, and some pharmaceuticals". The substance has a current entry in Annex VI to the CLP Regulation as a highly flammable liquid (Flam. Liq. 2; H225), a substance that may be fatal if swallowed and enters airways (Asp. Tox. 1; H304), causes skin irritation (Skin Irrit. 2; H315), may cause drowsiness or dizziness (STOT SE 3; H336), is suspected of damaging fertility (Repr. 2; H361f***), may

cause damage to organs (STOT RE 2*; H373**) and is toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411). The substance also has a specific concentration limit (SCL) of $C \geq 5\%$ associated with the STOT RE 2; H373 classification.

RAC agreed to the proposal by Germany to modify the STOT RE classification to a substance which causes damage to the nervous system (STOT RE 1; H372 (nervous system)) and to remove the SCL from the STOT RE classification.

Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal) (EC -, CAS -)

Glycerol formal is used at industrial sites in the following products: coatings, adhesives, sealants and elastomers. It is used as a laboratory chemical and as an intermediate. Professional uses also include the use in agrochemicals. Furthermore, the substance is used in consumer products including home care products (air care products, anti-freeze and de-icing products, biocidal products, perfumes and fragrances, pharmaceuticals, polishes and wax blends and washing and cleaning products), fuels, agrochemicals and coatings, adhesives, sealants and elastomers. The substance has no current Annex VI entry.

RAC agreed to the proposal by the Netherlands to classify glycerol formal as a substance that may damage the unborn child and is suspected of damaging fertility (Repr. 1B; H360Df).

Copper (EC 231-159-6, CAS 7440-50-8)

Copper has a large variety of uses. It is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. Much of the copper is used in building constructions, for example in wiring, plumbing, and weatherproofing. Also the transport sector is dependent on copper, for example as a component in motors, wiring, radiators, connectors, brakes, and bearings. Another important use of copper is in the manufacturing of electronic products. Consumer uses of copper consist of, for example, uses of the following products: metals, metal working fluids, welding and soldering products, cosmetics and personal care products, modelling clay, and metal surface treatment products. Furthermore, copper is also used as an active substance in biocidal products. Copper does not have an existing classification but copper flakes are classified as harmful if swallowed (Acute Tox. 4; H302), cause serious eye irritation (Eye Irrit. 2; H319), toxic if inhaled (Acute Tox. 3; H331), 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). Granulated copper also has an existing Annex VI entry as toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Sweden to use the specific surface area of $0.67 \text{ mm}^2/\text{mg}$ (equivalent to the surface area of copper spheres with a diameter of 1 mm) to distinguish between massive and powder copper. RAC also agreed to the proposal to classify copper with a specific surface area $> 0.67 \text{ mm}^2/\text{mg}$ (powder) as 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=1)). Copper with specific surface area $\leq 0.67 \text{ mm}^2/\text{mg}$ (massive) will have no classification.

tert-Butyl 2-ethylperoxyhexanoate (EC 221-110-7; CAS 3006-82-4)

tert-Butyl 2-ethylperoxyhexanoate is used in polymers and plastic products by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The industrial uses reported are the following: industrial use of organic peroxides as polymerisation initiators, cross linking agents or curing agents; other industrial uses of

organic peroxides; use of reactive processing aid at industrial site (no inclusion into or onto article); industrial use of chemicals for polymer processing; industrial use of coatings and paints; industrial use as polymerisation initiator and cross-linking agent; use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into /onto article). Regarding consumer uses, the substance is used in adhesives and sealants, coating and paints, thinners, paint removers and fillers, putties, plasters, modelling clay. The substance has no current Annex VI entry.

RAC agreed to the proposal by France to classify tert-butyl 2-ethylperoxyhexanoate as a substance which may damage fertility or the unborn child (Repr. 1B; H360FD) and may cause an allergic skin reaction (Skin Sens. 1; H317 instead of the proposed classification as Skin Sens. 11B).

Pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl}phenyl) N-methoxy carbamate (EC - ; CAS 175013-18-0)

Pyraclostrobin (ISO) is used as a fungicide in plant protection products. The substance has a current Annex VI entry as toxic if inhaled (Acute Tox. 3*; H331), causes skin irritation (Skin Irrit. 2; H315), 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 Germany that pyraclostrobin (ISO) is suspected of damaging the unborn child (Repr. 2; H361d), is toxic if inhaled (Acute Tox. 3; H331, with an ATE of 0.58 mg/L for dusts or mists), is harmful if swallowed (Acute Tox, 4; H302, with an ATE of 450 mg/kg bw), causes skin irritation (Skin Irrit. 2; H315), may cause respiratory irritation (STOT SE 3; H335), may cause damage to liver and gastrointestinal tract, and also agreed to add nasal cavity as a target organ (STOT RE 2; H373), 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 (M=100)).

Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl (EC 201-993-5, CAS 90-43-7)

Biphenyl-2-ol is used as a post-harvest fungicide in citrus. It has a current entry in Annex VI to the CLP Regulation as a substance which causes skin irritation (Skin Irrit. 2; H315), causes serious eye irritation (Eye Irrit. 2; H318), may cause respiratory irritation (STOT SE 3; H335) and is very toxic to aquatic life (Aquatic Acute 1; H400).

RAC agreed to the proposal by Spain to add the classification as a substance which is suspected of causing cancer (Carc. 2; H351), to modify the existing classifications to indicate that it causes skin corrosion (Skin Corr. 1; H314) and serious eye damage (Eye Dam. 1; H319), to retain the classification as very toxic to aquatic life (Aquatic Acute 1; H400 (but to add the M-factor M=1)) and to add that the substance is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410 (M=1)). The Committee agreed to remove the existing STOT SE 3 classification and to classify biphenyl-2-ol as a skin sensitiser (Skin Sens. 1B; H317).

Fenpropidin (ISO); (R,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine (EC -, CAS 67306-00-7)

Fenpropidin is used as a fungicidal agent in plant protection products. The substance has no current Annex VI entry.

RAC agreed to the proposal by the Czech Republic (Co-Rapporteur Member State Germany) to classify fenpropidin as a substance which is harmful if swallowed (Acute Tox. 4; H302 (ATE=1330 mg/kg bw)), is harmful if inhaled (Acute Tox. 4; H332), causes skin irritation (Skin

Irrit. 2; H315 – contrary to the proposal by the Dossier Submitter, who proposed no classification for this hazard class), causes serious eye damage (Eye Dam. 1; H318), may cause an allergic skin reaction (Skin Sens. 1; H317 – contrary to the proposal by the Dossier Submitter, who proposed sub-category 1B for this hazard class), may cause respiratory irritation (STOT SE 3; H335), may cause drowsiness or dizziness (STOT SE 3; H336 – contrary to the proposal by the Dossier Submitter, who proposed no classification for narcotic effects), may cause damage to the nervous system, eye and lung (STOT RE 2; H373), is suspected of damaging the unborn child (Repr. 2; H361d), is very toxic to aquatic life (Aquatic Acute 1; H400 (M=1000)) and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410 (M=10000)).

Cyclohex-3-ene-1-carbaldehyde derivatives

This dossier concerns 16 Cyclohex-3-ene-1-carbaldehyde derivatives: 2,4-dimethylcyclohex-3-ene-1-carbaldehyde [1]; (1 α ,2 α ,5 α)-2,5-dimethylcyclohex-3-ene-1-carbaldehyde [2]; 2,6-dimethylcyclohex-3-ene-1-carbaldehyde [3]; 3,5-dimethylcyclohex-3-ene-1-carbaldehyde [4]; 3,6-dimethylcyclohex-3-ene-1-carbaldehyde [5]; 4,6-dimethylcyclohex-3-ene-1-carbaldehyde [6]; reaction mass of 3,5-dimethylcyclohex-3-ene-1-carbaldehyde and 2,4-dimethylcyclohex-3-ene-1-carbaldehyde [7]; dimethylcyclohex-3-ene-1-carbaldehyde [8]; dimethylcyclohex-3-ene-1-carbaldehyde [9]; 1,2,4(or 1,3,5)-trimethylcyclohex-3-ene-1-carbaldehyde [10]; 1,3,4-trimethylcyclohex-3-ene-1-carbaldehyde [11]; 2,2,4-trimethylcyclohex-3-ene-1-carbaldehyde [12]; 2,4,6-trimethylcyclohex-3-enecarbaldehyde [13]; isocyclocitral [14]; 3,5,6-trimethylcyclohex-3-ene-1-carbaldehyde [15] and 4,6,6-trimethylcyclohex-3-ene-1-carbaldehyde [16]. These substances are used as a fragrance in the following products: cleaning and furnishing care products, laundry and dishwashing products, personal care products and air care products. Furthermore, they are used as food additives. These substances have no current Annex VI entry.

RAC agreed to the proposal by Germany to classify these as substances which may cause an allergic skin reaction (Skin Sens. 1; H317 instead of the proposed classification as Skin Sens. 1A).

Occupational exposure limits (OELs)

Cobalt and inorganic cobalt compounds

The European Commission made a request to evaluate [cobalt and inorganic cobalt compounds](#) in accordance with the Carcinogens, Mutagens and Reprotoxic Substances Directive (2004/37/EC). RAC adopted an opinion on the following airborne occupational exposure limit values for cobalt and inorganic cobalt compounds:

OEL as 8-hour TWA ¹ :	1 µg Co/m ³ (inhalable fraction) 0.5 µg Co/m ³ (respirable fraction)
STEL:	not relevant
BLV:	not established
BGV:	Females: 2 µg Co/L urine Males: 0.7 µg Co/L urine

Notations:	"skin sensitisation" and "respiratory sensitisation"
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The opinion will be published early 2023.

Polycyclic aromatic hydrocarbons (PAHs)

The Commission has made a request to identify and assess approaches to monitoring exposure to [combinations of different PAHs](#), to recommend the most appropriate approach and to include a recommendation on whether an airborne occupational exposure limit for benzo-a-pyrene (CAS 50-32-8) (or other substances) is a suitable marker of overall PAH exposure. If appropriate, an occupational exposure limit shall be complemented by other limit values such as biological limit value (BLV) and biological guidance value (BGV) and notations. RAC adopted an opinion on the following airborne occupational exposure limit values for PAHs:

OEL as 8-hour TWA ^[1] :	None
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RAC agreed on the cancer exposure-risk relationship (ERR) based on benzo-a-pyrene to be used for PAHs. RAC agreed to recommend that once an OEL is recommended by the Working Party on Chemicals of the DG-EMPL Advisory Committee on Safety and health (WPC-ACSH), based on the ERR recommended by RAC, a corresponding BLV using the metabolite 3-OHBP in urine could be set using the appropriate correlation equation presented in the RAC opinion. RAC agreed to recommend a BGV for the metabolite 1-OHP in urine which can be selected either based on the European level data or, when available, on the national data. RAC also agreed to propose a "skin" notation.

DNEL setting for DOTE - Request under Article 77(3)(c)

In May 2022, RAC [was requested](#) to review the draft background report prepared by ECHA and to recommend a derived no effect level (DNEL) for [DOTE](#) based on it.

^[1] The proposed OEL is based on a mode of action-based threshold for the carcinogenicity of cobalt compounds.

DOTE is on the REACH Authorisation List (Annex XIV) because it is considered toxic to reproduction. Before ECHA receives the applications for authorisation from companies, RAC is asked to recommend DNEL values to assist applicants in the risk characterisation of their application. The DNELs and dose response (DR) relationships serve as non-legally binding reference values.

DOTE cannot be used after 1 May 2025 unless a company has an authorisation from the European Commission. The latest date for companies to apply for authorisation is 1 November 2023. RAC agreed the following reference DNELs for DOTE:

Reference DNELs for exposure of DOTE with regards to developmental effects	
Worker, long-term inhalation	0.025 mg DOTE/m ³
Worker, long-term dermal	1.8 mg/kg bodyweight/day
General population, long-term oral	0.0032 mg DOTE/kg bodyweight/day

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.