

## Annex to news: Highlights from June RAC and SEAC meetings

Helsinki, 13 June 2024

### REACH restrictions

#### PFAS, universal

RAC and SEAC were given an overview of upcoming plenary discussions on the REACH [restriction proposal](#) submitted in January 2023 by Denmark, Germany, the Netherlands, Norway and Sweden.

In the June 2024 plenary meetings, RAC and SEAC provisionally concluded on specific consumer uses of PFAS, such as ski wax, cosmetics and other consumer mixtures, and on the industrial use of PFAS in metal plating and manufacture of metal products. Furthermore, RAC provisionally concluded on hazards of PFAS and scope of the proposed restriction and SEAC continued discussing the general approach proposed.

### REACH applications for authorisation

RAC and SEAC **agreed** on the following seven draft opinions. These will be sent to their respective applicants for commenting:

- Uses of 4-nonylphenol, branched and linear, ethoxylated (4-NPnEO) by Chemetall GmbH (Use 1 see [here](#), Use 2 see [here](#));
- Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-*tert*-OPnEO) by [bioMérieux SA](#);
- Uses of 4-*tert*-OPnEO by PPG Europe B.V. and a co-applicant (Use 1 see [here](#), Use 2 see [here](#));
- Use of potassium dichromate by [TURDUS TESTERS OF CAPACITY](#); and
- Use of tetraethyllead by [Shell Nederland Raffinaderij B.V.](#)

In addition, SEAC also **agreed** on the following four draft opinions:

- Use of chromium trioxide by [Fratelli Creola S.r.l.](#) (agreed by RAC in November 2023); and
- Uses of bis(2-ethylhexyl) phthalate (DEHP) by Baxter SA and co-applicants (Use 1 see [here](#), Use 2 see [here](#), Use 3 see [here](#)) (scheduled for agreement by RAC in September 2024).

RAC and SEAC **adopted** the following opinions, after considering comments submitted by the applicants.

- Use of chromium trioxide by [Thoma Metallveredelung GmbH](#);
- Use of chromium trioxide by [Metalplast sas](#) and a co-applicant; and
- Use of chromium trioxide by [LMC S.r.l.](#)

The following committees' opinions were **adopted** automatically before the June plenary, as the applicants chose not to comment on them:

- Uses of sodium dichromate by [Liebherr-Aerospace Lindenberg GmbH](#);

- Uses of chromium trioxide by [BWI Poland Technologies Sp. z. o.o.](#), [Benoni S.r.l.](#) and a co-applicant, [Egal srl](#), [ASO Cromsteel S.A.](#) and a co-applicant, [Sirio Galv S.R.L.](#), [SK Nexilis Poland sp. z o.o.](#), [ArcelorMittal Belgium NV/SA](#), [HDO Druckguß- und Oberflächentechnik GmbH](#) and a co-applicant and [Tecnofiniture S.r.l.](#); and
- Use of acids generated from chromium trioxide and their oligomers by [Micron srl](#).

*The adopted combined RAC and SEAC opinions on applications for authorisation will be available on [ECHA's website](#) in the near future.*

### CLP: RAC adopted seven opinions on harmonised classification and labelling

RAC opinions for harmonised classification and labelling will be available on [ECHA's website](#) in the near future.

Substance	Uses <sup>1</sup>	Existing classification	Proposal by Dossier Submitter	RAC opinion <sup>2</sup>
<a href="#">2,2',6,6'-tetra-tert-butyl-4,4'-methylene-diphenol</a> (EC: 204-279-1, CAS: 118-82-1)	Antioxidant and stabilizer in e.g. lubricants and greases and washing and cleaning products	No current entry in Annex VI to CLP	Aquatic Chronic 1, M-factor=10 000 (very toxic to aquatic life with long lasting effects)  (Austria)	RAC agreed to the proposal by Austria.
<a href="#">Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)</a> (EC: 274-778-7, CAS: 70693-62-8)	Biocidal active substance (bactericide, fungicide, virucide).	No current entry in Annex VI to CLP	Acute Tox. 4, H302 (ATE=500 mg/kg bw) (harmful if swallowed) Skin Corr. 1, H314 (causes severe skin burns and eye damage) Eye Dam. 1, H318 (causes serious eye damage) Aquatic Acute 1, H400 (M-factor=1) (very toxic to aquatic life) Aquatic Chronic 3, H412 (harmful to aquatic life with long lasting effects)  (Slovenia)	RAC agreed to the proposal by Slovenia but agreed that for aquatic chronic, classification as Aquatic Chronic 2, H411 (toxic to aquatic life with long lasting effects) was warranted.  RAC recommends to add classification as STOT RE 1; H372 (eyes) (causes damage to eyes through prolonged or repeated exposure).

<sup>1</sup> Information on uses is based on the info provided in the CLH dossier.

<sup>2</sup> The RAC opinions will be published in the [Registry of Intentions](#) in due course.

Substance	Uses <sup>1</sup>	Existing classification	Proposal by Dossier Submitter	RAC opinion <sup>2</sup>
<a href="#">Piperonal</a> (EC: 204-409-7, CAS: 120-57-0)	Solid crystalline product used in the formulation of fragrances and end-products, formulation of tobacco flavours, in industrial washing and cleaning products and as a chemical intermediate. It is also used in waxes, polishes, and washing and cleaning products for professional and consumer uses. Additional consumer uses include in air care products, tobacco products, biocides and cosmetics.	No current entry in Annex VI to CLP	Repr. 1B; H360FD (may damage fertility; may damage the unborn child) Skin Sens. 1; H317 (may cause an allergic skin reaction)  (Ireland)	RAC agreed to the proposal by Ireland.
<a href="#">N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine</a> (EC: 212-344-0, CAS: 793-24-8)	An antidegradant (antioxidant and antiozonant) added to tire rubber to protect the rubber polymer from reaction with oxygen (O <sub>2</sub> ) and ozone (O <sub>3</sub> ).	No current entry in Annex VI to CLP	Acute Tox. 4, H302 (ATE=890 mg/kg bw) (harmful if swallowed) Skin Sens. 1A, H317 (may cause an allergic skin reaction) Repr. 1B, H360FD (may damage fertility; may damage the unborn child) Aquatic Acute 1, H400, (M-factor=10 000) (very toxic to aquatic life) Aquatic Chronic 1, H410 (M-factor=10, changed to M-factor=10 000 after the consultation) (very toxic to aquatic life with long lasting effects)  (Austria)	RAC agreed to the proposal by Austria, but for reproductive toxicity RAC concluded that the substance should be classified as Repr. 1B; H360Fd (may damage fertility; suspected of damaging the unborn child).  RAC also agreed to add the classification as STOT RE 2; H373 (liver) (may causes damage to liver through prolonged or repeated exposure).

Substance	Uses <sup>1</sup>	Existing classification	Proposal by Dossier Submitter	RAC opinion <sup>2</sup>
<a href="#">Thymol; 5-methyl-2-(propan-2-yl)phenol</a> (EC: 201-944-8, CAS: 89-83-8)	Plant protection product used in the production of grapes and pome fruits.	Acute Tox. 4*; H302 Skin Corr. 1; H314 Aquatic Chronic 2; H411	Acute Tox. 4; H302 (ATE=500 mg/kg bw) (harmful if swallowed) Skin Corr. 1; H314 + inclusion of EUH071 "corrosive to the respiratory tract" (causes severe skin burns and eye damage) Eye Dam. 1; H318 (causes serious eye damage) Skin Sens. 1; H317 (may cause an allergic skin reaction) STOT SE 3; H336 (may cause drowsiness or dizziness) Aquatic Chronic 3; H412 (harmful to aquatic life with long lasting effects)  (Spain)	RAC agreed to the proposal by Spain, but for STOT SE concluded instead that classification as STOT SE 1; H370 (nervous system) was warranted and that STOT RE 1; H372 (nervous system) should be added.
<a href="#">Bronopol</a> (EC: 200-143-0, CA: 52-51-7)	Used e.g. in disinfection of chemical toilets, as bactericide, used to control the growth of bacteria, in in-can preservation of washing and cleaning fluids and human hygienic products, as preservatives for liquid-cooling and processing systems, in slimicides.	Acute Tox. 4*; H302 STOT SE 3; H335 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Acute 1; H400 (M=10)	Acute Tox. 3; H331 (ATE=0,59 mg/L (dusts/mists)) (toxic if inhaled) Acute Tox. 4; H312 (ATE=1600 mg/kg bw) (harmful in contact with skin) Acute Tox. 3; H301 (ATE=190 mg/kg bw)	RAC agreed to the proposal by Spain but concluded that instead of Skin Irrit. 2, classification as Skin Corr. 1; H314 (causes severe skin burns and eye damage) was warranted.

Substance	Uses <sup>1</sup>	Existing classification	Proposal by Dossier Submitter	RAC opinion <sup>2</sup>
			(toxic if swallowed) Eye Dam. 1; H318 (causes serious eye damage) STOT SE 3; H335 (causes respiratory tract irritation) Aquatic Acute 1; H400 (M=100) (very toxic to aquatic life) Aquatic Chronic 1; H410 (M=10) (very toxic to aquatic life with long lasting effects) EUH044  (Spain)	RAC also concluded that the substance should be classified as Skin Sens. 1; H317 (may cause an allergic skin reaction) and that EUH071 should be added
<a href="#">4,4'-methylenediphenol; bisphenol F</a> (EC: 210-658-2, CAS: 620-92-8)	Used as a monomer in polycarbonate and epoxy resins (intermediate use). For example, the epoxy resin BFDGE (Bisphenol F Diglycidyl Ether) is made from BPF, and BPF is also a component in NOGE (novolac glycidyl ethers) prepared from formaldehyde, phenol and epichlorohydrin. Applications that include the use of BPF-derived epoxy resins are coatings, lacquers, pipe linings, industrial floors, road and bridge deck toppings, adhesives, plastics, water pipes, dental sealants, and food packaging.	No current entry in Annex VI to CLP	Repr. 1B; H360F (may damage fertility)  (Sweden)	RAC agreed to the proposal by Sweden.

## OEL: RAC adopted two opinions on occupational exposure limits under the Carcinogens, Mutagens or Reprotoxic substances Directive (2004/37/EC)

RAC opinions for OELs will be available on [ECHA's website](#) in the near future.

Substance	Uses	RAC opinion
<a href="#">1,3-Butadiene</a> (EC number: 203-450-8; CAS RN: 106-99-0)	Used as an intermediate for polymerisation and copolymerisation.  Production of synthetic rubber, thermoplastic resins and latex.	RAC derived an exposure-risk relationship (ERR) expressing the excess cancer risk in function of the air concentration of 1,3-butadiene.  Furthermore, RAC did not recommend any other value or notation.
<a href="#">Boron and its compounds</a> (EC numbers: 233-139-2, 215-575-5, 215-540-4, 215-125-8 and CAS RN: 10043-35-3, 1332-77-0, 1330-43-4, 1303-86-2 respectively)	Widespread industrial, professional and consumer uses, such as abrasives, adhesives, agriculture, cellulose insulation, glass and ceramics, detergent, coatings and paints, paper and board products and articles, lubricants, metal working fluids, heat transfers, textile dye products, welding and soldering and photo chemicals.	RAC derived an occupational exposure limit (OEL) below which workers are protected from exposure to boron and its compounds at their workplace.  Furthermore, RAC recommended a short-term limit value to protect from local irritant effects (in the respiratory tract).

See OEL activity list at: <https://echa.europa.eu/oels-activity-list>

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The committees' opinions for all processes 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 decisions are taken by the European Commission through a comitology procedure.