

Annex to news: Highlights from September RAC and SEAC meetings

Helsinki, 26 September 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 meetings, RAC and SEAC provisionally concluded on their evaluation of specific uses of PFAS in the petroleum and mining sector. Discussions were also held on two additional sectors: textiles, upholstery, leather, apparel and carpets (TULAC) and food contact material and packaging. However, discussion for these will continue in the next meetings. Furthermore, RAC continued discussing the general approach proposed (waste stage and emissions).

REACH applications for authorisation

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

- Uses of chromium trioxide by Airbus Helicopters Technik GmbH (Use 1 see [here](#), Use 2 see [here](#));
- Use of sodium dichromate by [Airbus Helicopters Technik GmbH](#);
- Use of sodium dichromate by [AD International BV](#);
- Use of potassium dichromate by [LYNRED](#);
- Use of chromium trioxide by [CIRCUIT FOIL LUXEMBOURG SARL](#);
- Use of tetraethyllead by [Trafigura Ventures V.B.V.](#);
- Use of tetraethyllead by [Warter Fuels Spółka Akcyjna](#), and
- Use of chromium trioxide by [Ramboll Belgium BVBA \(for Indestructible Paints Limited\)](#).

In addition, RAC also **agreed** on the following three draft opinions:

- 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](#)) (agreed by SEAC in June 2024).

SEAC **agreed** also on the following draft opinion:

- Use of arsenic acid by [CIRCUIT FOIL LUXEMBOURG SARL](#) (scheduled for agreement at the RAC plenary meeting in November 2024)

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

- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant;
- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant;
- Use of chromium trioxide by [Henkel Global Supply Chain B.V.](#), potassium dichromate by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and sodium dichromate by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#);
- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#);

- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant;
- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant;
- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant;
- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant, potassium dichromate by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#), and sodium dichromate by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#);
- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant;
- Use of chromium trioxide by [Henkel Global Supply Chain B.V.](#), and sodium dichromate by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#);
- Use of chromium trioxide by [Boeing Distribution Deutschland GmbH](#) and co-applicants;
- Use of chromium trioxide by [CROMITAL S.P.A.](#) (for Türkiye Şişe ve Cam Fabrikaları A.S.) and co-applicants, sodium dichromate by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and co-applicants, sodium chromate by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant, and potassium dichromate by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant;
- Use of dichromium tris(chromate) by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and a co-applicant, chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and co-applicants, potassium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#), and sodium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#) and a co-applicant;
- Use of chromium trioxide by [Boeing Distribution Deutschland GmbH](#) and co-applicants;
- Use of chromium trioxide by [Boeing Distribution Deutschland GmbH](#) and co-applicants;
- Use of chromium trioxide by [Boeing Distribution Deutschland GmbH](#) and co-applicants, and sodium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#) and a co-applicant;
- Use of chromium trioxide by [Boeing Distribution Deutschland GmbH](#) and co-applicants, potassium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#), sodium chromate by [Boeing Distribution Deutschland GmbH](#) and a co-applicant, and sodium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#) and a co-applicant;
- Use of chromium trioxide by [Boeing Distribution Deutschland GmbH](#) and co-applicants, potassium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#), and sodium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#) and a co-applicant;
- Use of chromium trioxide by [Boeing Distribution Deutschland GmbH](#) and co-applicants, and sodium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#) and a co-applicant;
- Use of chromium trioxide by [HAAS GROUP INTERNATIONAL SP. Z.O.O](#) and co-applicants;
- Use of sodium dichromate by [Brenntag Chemicals Distribution \(Ireland\) Ltd](#) and a co-applicant, and chromium trioxide by [Boeing Distribution Deutschland GmbH](#) and co-applicants;
- Uses of chromium trioxide by Safran Landing Systems and co-applicants (Use 1 see [here](#), Use 2 see [here](#)); and
- Use of chromium trioxide by [Safran Aircraft Engines](#).

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

- Use of chromium trioxide by [Fratelli Creola S.r.l.](#);
- Uses of 4-nonylphenol, branched and linear, ethoxylated (4-NPnEO) by Chemetall GmbH (Use 1 see [here](#), Use 2 see [here](#));

- Uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-*tert*-OPnEO) by [bioMérieux SA](#), and PPG Europe B.V. (for PRC DeSoto International Inc. and for PPG Industries (UK) Ltd.) (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.](#)

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 13 opinions on harmonised classification and labelling

Substance	Uses ¹	Existing classification	Proposal by Dossier Submitter	RAC opinion ²
Talc ($Mg_3H_2(SiO_3)_4$) (EC 238-877-9, CAS 14807-96-6)	Used in a wide variety of different processes of manufacturing in different industries, as filling component (including in pharmaceuticals), carrier, separator, processing aid (reactive or non-reactive), and anticaking agent (food). Cosmetic-grade talc is used in cosmetics, in personal care products and body powders.	No current entry in Annex VI to CLP	Carc. 2; H351 (suspected of causing cancer) STOT RE 1; H372 (lungs, inhalation) (causes damage to the lungs via inhalation) (the Netherlands)	RAC agreed to the proposal by the Netherlands for STOT RE but adopted a more severe classification for carcinogenicity (Carc. 1B; H350).
eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol (EC 202-589-1, CAS 97-53-0)	Washing and cleaning products, biocides, air care products, polishes and waxes, cosmetics and personal care products and perfumes and fragrances.	No current entry in Annex VI to CLP	Acute Tox. 4; H302 (ATE = 1 930 mg/kg bw) (harmful if swallowed) Skin Irrit. 2; H315 (causes skin irritation) Eye Irrit. 2; H319 (causes serious eye irritation) STOT SE 3; H336 (may cause drowsiness or dizziness) Aquatic Chronic 2; H411 (toxic to aquatic life with long lasting effects) (Spain)	RAC agreed to the proposal by Spain, except for skin corrosion/irritation, where the DS had proposed Skin Irrit. 2; H315, but RAC recommended no classification.

¹ Information on uses is based on the info provided in the CLH dossier.

² The RAC opinions will be published in the Registry of CLH Intentions in due course.

Substance	Uses ¹	Existing classification	Proposal by Dossier Submitter	RAC opinion ²
			Skin Sens. 1B; H317 (may cause an allergic skin reaction) (Denmark)	RAC agreed to the proposal by Denmark.
3,5-dimethylpyrazole (EC 200-657-5, CAS 67-51-6)	Used in formulation or re-packaging of polymers, at industrial sites in polymers, coating products and processing aids and in manufacturing as an intermediate to manufacture another substance or to manufacture plastic products and machinery and vehicles.	No current entry in Annex VI to CLP	Acute Tox. 4; H302 (ATE = 1700 mg/kg bw) (harmful if swallowed) Repr. 1B; H360FD (may damage fertility; may damage the unborn child) STOT RE 2; H373 (liver, blood) (may cause damage to the liver and blood) (Belgium)	RAC agreed to the proposal by Belgium.
Borate minerals group: Ulexite (CaNaH₁₂(BO₃)₅ × 2H₂O) [1] ulexite (CaNaH₁₂(BO₃)₅ × 2H₂O), calcined [2] (EC - [1] 296-662-5 [2], CAS 1319-33-1 [1] 92908-33-3 [2]); Colemanite (CaH(BO₂)₃ × 2H₂O) [1] boron calcium oxide (B₆Ca₂O₁₁), hydrate (1:5) [2] colemanite, calcined [3] (EC - [1] - [2] 296-640-5 [3], CAS 1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3]); Tincalconite (B₄Na₂O₇ × 5H₂O) (EC -, CAS 12045-88-4)	Borates are essential ingredients in the production of frits (powdered glass) used by the ceramic industry in ceramic glazes and enamels.	No current entry in Annex VI to CLP	Repr. 1B; H360FD (may damage fertility; may damage the unborn child) (Sweden)	RAC agreed to the proposal by Sweden.

Substance	Uses ¹	Existing classification	Proposal by Dossier Submitter	RAC opinion ²
[Ethane-1,2-diylbis[nitrilo-bis(methylene)]]tetrakisphosphonic acid (EC 215-851-5, CAS 1429-50-1) [Ethylenebis[nitrilo-bis(methylene)]]tetrakisphosphonic acid, calcium sodium salt (EC 287-370-9, CAS 85480-89-3) [Ethylenebis[nitrilo-bis(methylene)]]tetrakisphosphonic acid, potassium salt (EC 251-910-1, CAS 234274-30-1) [Ethylenebis[nitrilo-bis(methylene)]]tetrakisphosphonic acid, sodium salt (EC 244-742-5, CAS 22036-77-7)	Used in water softeners, air care products, fillers, putties, plasters, modelling clay, polishes and waxes, washing and cleaning products, and cosmetics and personal care products.	No current entry in Annex VI to CLP	Carc. 1B; H350 (C ≥ 1 %) (may cause cancer) (Germany)	RAC agreed to the proposal by Germany, but with a GCL of 0.1 %.
2-pyrrolidone; pyrrolidin-2-one (EC 210-483-1, CAS 616-45-5)	The substance is used in ink and toners, in coatings, in imaging and printing mixtures and as a laboratory chemical, as well as a catalyst in polymerisation, an intermediate in the pharmaceutical industry and as a solvent for animal injection.	No current entry in Annex VI to CLP	Repr. 1B; H360D (may damage the unborn child) (Norway)	RAC agreed to the proposal by Norway, but with a SCL of 3 %.
Thermally treated garlic juice (-)	The substance is a biocide and a plant protection product.	No current entry in Annex VI to CLP	Skin Sens. 1B, H317 (may cause an allergic skin reaction) (Austria)	RAC agreed to the proposal by Austria.

Substance	Uses ¹	Existing classification	Proposal by Dossier Submitter	RAC opinion ²
Rape oil; rape seed oil (EC 232-299-0, CAS 8002-13-9)	The substance is a plant protection product.	No current entry in Annex VI to CLP	Aquatic Chronic 4; H413 (may cause long lasting harmful effects to aquatic life) (the Netherlands)	RAC agreed to the proposal by the Netherlands, except for the proposed classification by the DS for chronic aquatic toxicity, where RAC recommended no classification.
Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol (EC 403-640-2, CAS 107534-96-3)	The substance is a fungicide to control multiple fungal diseases in crops and as a wood preservative.	The substance has a current Annex VI entry as Repr. 2; H361d***, Acute Tox. 4; H302, Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=10.	Repr. 1B; H360FD (may damage fertility; may damage the unborn child), Acute Tox. 4; H302 (harmful if swallowed; ATE (oral)=1 700 mg/kg bw), STOT RE 2; H373 (eyes) (may cause damage to eyes through prolonged or repeated exposure), Aquatic Acute 1; H400, (very toxic to aquatic life; M=1), Aquatic Chronic 1; H410, (very toxic to aquatic life with long lasting effect; M=10) (Denmark)	RAC agreed to the proposal by Denmark, and in addition recommended to add liver as a target organ through prolonged or repeated exposure: STOT RE 2; H373 (eyes, liver) (may cause damage to eyes and liver through prolonged or repeated exposure).

The opinions will be available on ECHA's website in the near future: <https://echa.europa.eu/registry-of-clh-intentions-until-outcome>

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
Silicon carbide fibres EC 206-991-8, CAS RN 409-21-2	Used as reinforcement material in ceramic composites. Result from SiC whiskers or fibrous impurities formed during production of angular SiC or present in products containing angular SiC, which are used as abrasive, heating elements ...	RAC agreed to use the asbestos ERR to compensate for the severe limitations of animal studies on SiC fibres, and taking into account the similarity in mechanism of action, and similar cancer incidences in animal studies. Furthermore, RAC did not recommend any other value or notation.
Pyrocatechol EC 204-427-5, CAS RN 120-80-9	Used in production of adhesives, petroleum additive, electronics industry, electroplating	RAC derived an occupational exposure limit (OEL) below which workers are protected from exposure to pyrocatechol at their workplace. Furthermore, RAC recommended notations for skin and skin sensitisation

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

The committees' web pages: [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.