Annex to news: Highlights from March RAC and SEAC meetings

Helsinki, 21 March 2024

REACH restrictions

PFAS, universal

RAC and SEAC were given an overview of the topics to be covered in the next plenary discussions on the REACH restriction proposal submitted by Denmark, Germany, the Netherlands, Norway and Sweden in January 2023. In the March 2024 plenary meetings, RAC and SEAC focused on the evaluation of certain consumer uses of PFAS, such as ski wax, cosmetic products and other consumer mixtures. Furthermore, RAC discussed hazards of PFAS and SEAC the general approach proposed.

Applications for authorisation

RAC and SEAC adopted two opinions on two applications for authorisation of chromium trioxide. The adopted opinions concern:

- Use of **chromium trioxide** for the hard-chrome plating of hydraulic and pneumatic cylinders for various applications, and inner tubes of motorbike front suspension for the automotive industry;
- functional chrome plating of hydraulic cylinders, stems, pistons and rollers using **chromium trioxide**.

In addition, RAC agreed on 24 and SEAC on 25 *draft* opinions on applications for authorisation and review reports for authorisation of chromium (VI) substances. The opinions will be adopted at a later stage. The agreed draft opinions concern:

- industrial use of **chromium trioxide** for hard chrome plating to provide key functional properties such as wear resistance (...) in the manufacturing of landing and braking system parts for aeronautical applications exclusively supplied by Safran Landing Systems without technical limitations with the identified alternative;
- industrial use of **chromium trioxide** for hard chrome plating in the manufacturing and the repairing of landing gear parts exclusively supplied by Safran Landing Systems and for which there is not yet potential alternatives identified as part of the substitution process;
- industrial use of slurry mixtures containing **chromium trioxide** for the surface treatment of aircraft engines parts including turbines and compressors;
- formulation of mixtures with soluble **Cr(VI) compounds** for use in aerospace and defence industry and its supply chains for surface treatments (two draft opinions – one on a review report for authorisation and one on an application for authorisation);
- passivation of stainless steel using **chromium trioxide** or **sodium dichromate** in aerospace and defence industry and its supply chains (two draft opinions);
- chromate rinsing after phosphating using **chromium trioxide** in aerospace and defence industry and its supply chains (two draft opinions);
- slurry coatings using **chromium trioxide** in aerospace and defence industry and its supply chains;
- pre-treatments: deoxidising, pickling, etching and/or desmutting using **chromium trioxide** or **sodium dichromate** in aerospace and defence industry and its supply chains (two draft opinions);

- anodising using **chromium trioxide** in aerospace and defence industry and its supply chains (two draft opinions);
- anodise sealing using **chromium trioxide**, **potassium dichromate**, **sodium chromate** and/or **sodium dichromate** in aerospace and defence industry and its supply chains (two draft opinions);
- chemical conversion coating using **chromium trioxide**, **sodium dichromate** and/or **potassium dichromate** in aerospace and defence industry and its supply chains (two draft opinions);
- electroplating using **chromium trioxide** in aerospace and defence industry and its supply chains (two draft opinions);
- passivation of (non-Al) metallic coatings using **chromium trioxide** or **sodium dichromate** or **potassium dichromate** in aerospace and defence industry and its supply chains (two draft opinions);
- inorganic finish stripping using **chromium trioxide** in aerospace and defence industry and its supply chains (two draft opinions); and
- electroplating (by a long-term contractual supplier) of metal substrates using **chromium trioxide** to achieve functional surfaces with decorative character (SEAC only; RAC agreed on this draft opinion in November 2023).

RAC adopted 19 opinions on harmonised classification and labelling.

Pyriproxyfen (ISO); 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine; 4-phenoxyphenyl (*RS*)-2-(2-pyridyloxy) propyl ether (EC: 429-800-1; CAS: 95737-68-1)

Pyriproxyfen is an insecticide, for the control of various insect pest species in various crops, including citrus fruit and pome fruit, tomatoes and ornamentals. Pyriproxyfen has a current Annex VI entry as a substance that is very toxic to aquatic life (Aquatic Acute 1; H400) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410).

RAC agreed to the proposal by the Netherlands to add an M-factor of 10 to the existing aquatic acute classification and an M-factor of 1 000 to the existing aquatic chronic classification.

Ten borate substances

Sweden submitted ten dossiers addressing the following substances:

No	Chemical name	EC number	CAS number
1	magnesium metaborate	237-235-5	13703-82-7
2	sodium metaborate, anhydrous [1]; boric acid (HBO2), sodium salt, tetrahydrate [2]; and any other hydrated form	231-891-6 [1]; - [2]	7775-19-1 [1]; 10555-76-7[2]
3	potassium pentaborate	234-371-7	11128-29-3
4	potassium metaborate	237-262-2	13709-94-9
5	dipotassium tetraborate	215-575-5	1332-77-0
6	dipotassium octaborate	-	12008-39-8
7	diammonium decaborate	234-521-1	12007-89-5
8	calcium tetraborate	234-511-7	12007-56-6
9	calcium metaborate (Ca(BO2)2) and calcium tetraborate (CaB4O7), amorphous reaction products of boric acid with lime	-	-
10	pentaboron sodium octaoxide	234-522-7	12007-92-0

These substances are mainly used in lubricants and greases in vehicles or machinery. They have no current Annex VI entry.

Based on the proposal by the dossier submitter, RAC agreed that the above-mentioned borates should be classified as substances that may damage fertility and the unborn child (Repr. 1B; H360FD) with Note 11 (The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is ≥ 0.3 %). The generic concentration limit for substances classified as Repr. 1B of ≥ 0.3 % applies.

Undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3]; other inorganic salts of undecafluorohexanoic acid [4] (EC: 206-196-6[1]; 220-881-7[2]; 244-479-6[3]; - [4] ; CAS: 307-24-4[1]; 2923-26-4[2]; 21615-47-4[3]; - [4])

Undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3] and other inorganic salts of undecafluorohexanoic acid [4] are used in the manufacture of polymers and in the manufacture of plastic products, including compounding and conversion. The substances have no current Annex VI entry.

RAC agreed to the proposal by Germany to classify undecafluorohexanoic acid, PFHxA [1]; sodium undecafluorohexanoate, NaPFHx [2]; ammonium undecafluorohexanoate, APFHx [3] and other inorganic salts of undecafluorohexanoic acid [4] as substances that may damage the unborn child (Repr. 1B; H360D).

These substances fall under the scope of the REACH restriction proposal for undecafluorohexanoic acid (PFHxA), its salts and related substances, prepared by Germany. PFHxA and its salts are a subgroup of per- and polyfluoroalkyl substances (PFAS).

Benzobicyclon (ISO); 3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-(phenylthio)bicyclo[3.2.1]oct-3-en-2-one (EC: -; CAS: 156963-66-5)

Benzobicyclon (ISO) is envisaged to be used to control monocotyledonous (grass and non-grass) weed species in rice. It is a systemic herbicide, absorbed principally by the roots. The substance has no current Annex VI entry.

RAC agreed to the proposal by Malta to classify benzobicyclon (ISO) as a substance that is very toxic to aquatic life (Aquatic Acute 1; H400) with an M-factor of 100 and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410) with an M-factor of 100.

Sodium bromide (EC: 231-599-9; CAS: 7647-15-6)/**Potassium bromide** (EC: 231-830-3; CAS: 7758-02-3)/**Calcium bromide** (EC: 232-164-6; CAS: 7789-41-5)

Sodium/potassium/calcium bromide are mainly used in industrial settings as a processing aid or precursor for the manufacture and preparation of oilfield chemicals, fine chemicals, and water treatment chemicals. The substances have no current Annex VI entry.

RAC agreed to the proposal by Sweden to classify sodium bromide, potassium bromide and calcium bromide as substances that may damage fertility and the unborn child (Repr. 1B; H360FD), may cause harm to breast-fed children (Lact.; H362), may cause drowsiness or dizziness (STOT SE 3; H336) and causes damage to the nervous system (STOT RE 1; H372 (nervous system)). RAC also concluded that these substances may cause damage to the thyroid (STOT RE 2; H373 (thyroid)).

Dimethachlor (ISO); 2-chloro-*N*-(2,6-dimethylphenyl)-*N*-(2-methoxyethyl)acetamide (EC: 256-625-6; CAS: 50563-36-5)

Dimethachlor (ISO) is used as a herbicide for pre-emergence or early post-emergence control of annual grasses and annual broadleaved weeds in winter or spring oilseed rape. The substance has a current Annex VI entry: Acute Tox. 4*; H302, Skin Sens. 1; H317, Aquatic Acute 1; H400, Aquatic Chronic 1; H410.

RAC agreed to the proposal by Croatia to classify dimethachlor (ISO) as a substance that is suspected of causing cancer (Carc. 2; H351), is 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) with an M-factor of 10 and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410) with M-factor of 10. RAC also agreed to add an oral ATE of 1600 mg/kg bw to the acute toxicity classification.

1-amino-4-hydroxy-2-phenoxyanthraquinone (EC: 241-442-6; CAS: 17418-58-5)

1-amino-4-hydroxy-2-phenoxyanthraquinone is a dye, mainly used for dyeing textiles, leather, and paper, as well as plastics and rubber. Other professional and/or consumer uses also reported include in coatings and photochemicals. The substance has no current Annex VI entry.

RAC agreed to the proposal by Sweden to classify 1-amino-4-hydroxy-2-phenoxyanthraquinone as a substance that may cause an allergic skin reaction (Skin Sens. 1A; H317).

Metyltetraprole (ISO);1-[2-({[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5*H*-tetrazol-5-one (EC: - ; CAS: 1472649-01-6)

Metyltetraprole (ISO) is a novel broad spectrum fungicide which is intended to be used in agriculture and horticulture. The substance has no current Annex VI entry.

RAC agreed to the proposal by France to classify metyltetraprole (ISO) as a substance suspected of causing cancer (Carc. 2; H351), and which is very toxic to aquatic life (Aquatic Acute 1; H400) with an M-factor of 10 and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410) with M-factor of 1.

Article 77(3)(c) requests

Request to review the harmonised classification and labelling opinion on lithium carbonate ($LiCO_3$), lithium chloride (LiCl), lithium hydroxide (LiOH)

ECHA received a request from the European Commission on a new study (Boyle et al. (2017)) and also on any relevant additional data related to cardiac foetal malformations compared to the information considered in the opinion of RAC adopted on 16 September 2021 on lithium carbonate (EC: 209-062-5), lithium chloride (EC: 231-212-3) and lithium hydroxide (EC: 215-183-4). RAC was asked to review the submitted information, clarify the evidence available and the association between exposure to lithium salts and cardiac foetal malformations, and, if necessary, amend its opinion.

RAC took note of the new information and concluded by consensus that the classification as Repr. 1A for developmental toxicity is still warranted.

RAC also agreed on read-across between the inorganic lithium compounds lithium carbonate, lithium chloride and lithium hydroxide, with regard to systemic toxicity, including developmental toxicity.

Request to review the harmonised classification and labelling opinion on methyl methacrylate (MMA)

On 18 March 2021, RAC adopted an opinion on methyl methacrylate (MMA, EC: 201-297-1), concluding that the substance should be classified as Resp. Sens. 1; H334, in line with the proposal from the dossier submitter (France). Following the adoption and publication of the RAC opinion, manufacturers of the substance provided additional evidence, including a summary of information on the actual exposures of the sensitised individuals whose case reports formed the basis of the RAC conclusions, which could challenge the causality of the association between MMA exposure and occupational asthma. Based on a request from the Commission, the Executive Director of ECHA gave the mandate to RAC to review the opinion of 18 March 2021 in relation to the classification for respiratory sensitisation.

RAC took note of the new information and concluded by consensus that the previous classification as Resp. Sens. 1; H334, is still warranted.

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.