# Annex to news: Highlights from November RAC and SEAC meeting

Helsinki, 7 December 2023

## REACH restrictions

### Creosote and creosote-related substances

Following the 60-day consultation on the agreed SEAC draft opinion, SEAC adopted its opinion 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 is complementary to the provisions of the Biocidal Products Regulation and aims to update Annex XVII, entry 31 of REACH. This concludes the final step of ECHA Committees' assessment, and the opinion will be provided to the European Commission for decision making.

### PFAS, universal

RAC and SEAC were given an overview of the consultation outcome on the restriction proposal submitted by Denmark, Germany, the Netherlands, Norway and Sweden in January 2023. The consultation ran from 22 March to 25 September 2023 and saw the highest number of submitted comments for a restriction proposal in the history of the EU (over 5 600).

In the March 2024 plenary meetings, RAC and SEAC will focus on the evaluation of certain consumer uses of PFAS, such as ski wax, cosmetic products and other consumer mixtures.

## Applications for authorisation

RAC and SEAC adopted seven opinions on three applications for authorisation of chromium trioxide. The adopted opinions concern **chromium trioxide**-based functional chrome plating of:

- axially/rotationally symmetrical components to ensure low surface friction under lubrication;
- axially/rotationally symmetrical components requiring high wear resistant surfaces to withstand abrasive forces;
- components with complex 3-dimensional geometry (not axially/rotationally symmetrical) to ensure low surface friction under lubrication;
- components with complex 3-dimensional geometry (not axially/rotationally symmetrical) requiring high wear resistant surfaces to withstand abrasive forces;
- gun barrels and outer jacket surfaces;
- gun barrel bores and auxiliary parts for assault rifles, carbines and pistols for non-civilian uses;
- gun barrel bores and auxiliary parts for semi-automatic shotguns, over/under, side-by-side shotguns, pistols and carbines for civilian.

In addition, RAC agreed on 14 and SEAC on 15 draft opinions on applications for authorisation of chromium (VI) substances. The opinions will be adopted at a later stage. The agreed draft opinions concern:

- industrial use of **sodium dichromate** for the sealing after anodizing of aluminium alloys and passivation of metallic coatings of actuation and landing gear system parts for the aviation industry;

- industrial use of **chromium trioxide** for a pre-treatment step (etching) in the electroplating process for plastic materials with various applications;
- industrial use of **chromium trioxide** for plating on plastic materials to create a long-lasting high durability chromium decorative surface;
- industrial use of **chromium trioxide** for the functional chrome plating of shock absorber rods and strut rods, cylinders and reservoir tubes mounted on passive or semi-active dampers for automotive applications;
- functional chrome plating of mechanical components (including hydraulic cylinders, columns, moulds and various machinery parts) using **chromium trioxide**;
- industrial use of **chromium trioxide** for the pre-treatment step (etching) in the electroplating process of small sized plastic items for various sectors;
- **chromium trioxide** based functional chrome plating of semi-finished steel products (bars, cylinder tubes and linear shafts) for the manufacture of hydraulic and pneumatic components;
- dilution of **chromic acid** solution at concentrations lower than 0.1 % for the use in passivation baths;
- industrial use of **chromium trioxide** for the functional chrome plating with decorative character for different applications;
- industrial use of **chromium trioxide** for the functional chrome plating of food slicer's circular blades;
- industrial use of **chromium trioxide** for functional chrome plating of work rolls for use in the production of flat metal products;
- industrial use of **chromium trioxide** for the hard-chrome plating of a wide variety of items with large dimensions and complex geometries used in energy generation and supply, off-shore oil and gas extraction and manufacturing industries;
- use of **chromium trioxide** for electroplating of metal substrates with the purpose to creating a long-lasting high durability surface for sanitary and industrial applications (RAC only);
- electroplating of metal substrates using **chromium trioxide** to achieve functional surfaces with decorative character (RAC only);
- **chromium trioxide** use: manufacture of passivated copper foil used in lithium-ion batteries (SEAC only);
- **chromium-trioxide**-based functional chrome plating of solid and hollow piston rods for hydraulic applications (SEAC only; RAC agreed on this draft opinion in September 2023);
- functional chrome plating for hydraulic applications, other cylindrical components and further industrial applications (using **chromium trioxide**) (SEAC only; RAC agreed on this draft opinion in September 2023).

## RAC adopted eight opinions on harmonised classification and labelling

***Melaleuca alternifolia*, ext. [1] *Melaleuca alternifolia*, essential oil; tea tree oil [2]**
(EC: 285-377-1 [1]; CAS: 85085-48-9 [1] 68647-73-4 [2])

Tea Tree Oil is an active substance in plant protection products, intended for large-scale use in the field (e.g. tomato and grape) and in the greenhouse (e.g. tomato) to control fungal diseases (e.g. powdery mildew and grey mould). The substance has no current Annex VI entry and the proposal was submitted by Poland

RAC agreed that Tea Tree Oil may damage fertility (Repr. 1B; H360F), is suspected of damaging the unborn child (Repr. 2; H360d) and causes skin irritation (Skin Irrit. 2; H315) and may cause an allergic skin reaction (Skin Sens. 1B; H317)

Furthermore, RAC agreed that Tea Tree Oil warrants a classification as a flammable liquid (Flam. Liq. 3; H226), as a substance which is harmful if inhaled (Acute Tox. 4; H332) with an ATE of 3.60 mg/L (dusts/mists), harmful if swallowed (Acute Tox. 4; H302) with an ATE of

1050 mg/kg bw, known to cause human aspiration toxicity hazard (Asp. Tox. 1; H304), may cause drowsiness or dizziness (STOT SE 3; H336), and that is very toxic to aquatic life (Aquatic Acute 1; H400) with M-factor of 1 and is toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H 411).

**Flazasulfuron (ISO); 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-trifluoromethyl-2-pyridylsulfonyl)urea** (EC: -; CAS: 104040-78-0)

Flazasulfuron is an active substance used in plant protection products as a herbicide, for the control of annual grasses and sedges. Flazasulfuron 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). The dossier was submitted by Spain.

RAC agreed to add an M-factor of 1000 to the existing classification for acute aquatic toxicity and an M-factor of 100 to the existing classification for chronic aquatic toxicity. In addition, RAC agreed to classify flazasulfuron as a substance that may cause damage to muscle and liver (STOT RE 2; H373 (muscle, liver)) and that is suspected of damaging the unborn child (Repr. 2; H361d).

**Fosthiazate (ISO); S-sec-butyl O-ethyl (2-oxo-1,3-thiazolidin-3-yl)phosphonothioate** (EC: -; CAS: 98886-44-3)

Fosthiazate is an organophosphate with nematicidal and insecticidal activity. It is an active substance in plant protection products. When applied to the soil, fosthiazate becomes systemic in plants with absorption occurring via the roots. Fosthiazate has a current Annex VI entry as a substance that is toxic if inhaled (Acute Tox. 3*; H331), toxic if swallowed (Acute Tox. 3*; H301), harmful in contact with skin (Acute Tox. 4*; H312), may cause an allergic skin reaction (Skin Sens. 1; H317), is very toxic to aquatic life (Aquatic Acute 1; H400) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410). The dossier was submitted by Germany.

RAC agreed to modify the acute toxicity classifications to toxic if inhaled (Acute Tox. 3; H331), with an ATE of 0.56 mg/L (dusts/mists), toxic if swallowed (Acute Tox. 3; H301), with an ATE of 57 mg/kg and to toxic in contact with skin (Acute Tox. 3; H311), with an ATE of 860 mg/kg bw.

RAC also agreed to add to the Annex VI entry that the substance causes eye irritation (Eye Irrit. 2; H319), may damage the unborn child and is suspected of damaging fertility (Repr. 1B; H361Df), may cause harm to breast-fed children (Lact.; H362), causes damage to the nervous system through prolonged or repeated exposure (STOT RE 1; H372 (nervous system)), may cause damage to adrenals through prolonged or repeated exposure (STOT RE 2; H373 (adrenals)), is very toxic to aquatic life (Aquatic Acute 1; H400; M=1) and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410; M=1).

**Tetra(sodium/potassium)7-[(E)-{2-acetamido-4-[(E)-(4-{[4-chloro-6-({2-[(4-fluoro-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazine-2-yl)amino]propyl}amino)-1,3,5-triazine-2-yl]amino}-5-sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalenetrisulfonate; [substance having a complex composition with <80% of the above constituents and other reaction side products]; Reactive Brown 51** (EC: 466-490-7; CAS: -)

Reactive Brown 51 is a colorant used in textile dyes and impregnating products. Reactive Brown 51 has no current Annex VI entry. The dossier was submitted by Sweden.

RAC agreed to classify reactive Brown 51 as a substance that may damage fertility (Repr. 1B; H360F) and may cause an allergic skin reaction (Skin Sens. 1A; H317).

**Methacrylic acid, monoester with propane-1,2-diol; [HPMA]** (EC: 248-666-3; CAS: 27813-02-1)

HPMA is used in the following products: adhesive and sealants, polymers and cosmetics and personal care products. The substance does not have a current Annex VI entry. The dossier was submitted by France.

RAC agreed to classify HPMA as a substance that may cause drowsiness or dizziness (STOT SE 3; H335), causes serious eye irritation (Eye Irrit. 2; H319) and may cause an allergic skin reaction (Skin Sens. 1; H317). Furthermore, RAC agreed to add Note D and an SCL of 10% for STOT SE 3 to the Annex VI entry for HPMA.

**2-hydroxyethyl methacrylate; [HEMA]** (EC: 212-782-2; CAS: 868-77-9)

HEMA is used in the following products: adhesive and sealants, polymers and cosmetics and personal care products. HEMA has a current entry in Annex VI as a substance that causes skin irritation (Skin Irrit. 2; H315), causes serious eye irritation (Eye Irrit. 2; H319), may cause an allergic skin reaction (Skin Sens. 1; H317) and Note D. The dossier was submitted by France.

RAC agreed to add to the current classification that HEMA may cause drowsiness or dizziness (STOT SE 3; H335), and also agreed to add an SCL of 10%.

**4-phenylbenzophenone** (EC: 218-345-2; CAS: 2128-93-0)

4-phenylbenzophenone is used as a photo-initiator in multiple applications, such as graphic arts, wood coatings, plastic coatings, metal coatings, electronics, or adhesives to induce polymerisation of unsaturated oligomers, such as acrylates. 4-phenylbenzophenone has no current Annex VI entry. The proposal was submitted by Germany.

RAC agreed to classify 4-phenylbenzophenone as a substance that may damage fertility or the unborn child (Repr. 1B; H360FD), may cause an allergic skin reaction (Skin Sens. 1B; H317), is very toxic to aquatic life (Aquatic Acute 1; H400; M=10) and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410; M=1).

**Penconazole (ISO); 1-[2-(2,4-dichlorophenyl)pentyl]-1*H*-1,2,4-triazole** (EC: 266-275-6; CAS: 66246-88-6)

Penconazole is an agricultural fungicide which is used by foliar application to control a wide range of diseases in fruits and vegetables. The substance has a current Annex VI entry as a substance that is harmful if swallowed (Acute Tox. 4; H302), is suspected of damaging the unborn child (Repr. 2; H361d), is very toxic to aquatic life (Aquatic Acute 1; H400), with an M-factor of 1, and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410), with an M-factor of 1. The dossier was submitted by Norway.

RAC agreed to retain the current Annex VI entry, but to add an ATE of 970 to the acute oral toxicity classification and to increase the M-factor for long-term aquatic hazard classification to M=10. RAC also agreed to add to the Annex VI entry that penconazole is a substance that may cause damage to the liver (STOT RE 2; H373 (liver)).

## Occupational exposure limits

### Nitrosamines (NDEA, NDMA, NDPA and NDELA)

Nitrosamines are used in industrial sectors such as rubber, metal processing, chemical, leather and textiles, and foundries (iron and steel).

The European Commission has requested ECHA to evaluate nitrosamines, namely N-

Nitrosodiethylamine (diethylnitrosamine) [NDEA] (EC number 200-226-1; CAS RN 55- 18-5), N-Nitrosodimethylamine (dimethylnitrosamine) [NDMA] (EC number 200-549-8; CAS RN 62-75-9), N-Nitroso di-n-propylamine [NDPA] (EC number 210-698-0; CAS RN 621-64-7) and N-Nitrosodiethanoamine (2,2'-(Nitrosoimino)bisethanol) [NDELA] (EC number 214-237-4; CAS RN 1116-54-7) in accordance with the Carcinogens, Mutagens or Reprotoxic substances Directive (Directive 2004/37/EC). During the meeting, RAC adopted its opinion on the scientific evaluation of occupational exposure limits (OELs) for these substances.

Nitrosamines are considered non-threshold carcinogens. Consequently, no health-based occupational exposure limit (OEL) can be determined. Instead, RAC derived exposure-risk relationships (ERR) expressing the excess cancer risk as a function of nitrosamines concentration in the workplace air. Furthermore, RAC recommended to have a skin notation for these substances.

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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.