

## Annex to news

Helsinki, 22 March 2022

### Highlights from March RAC and SEAC meetings

#### REACH restrictions

##### Lead in outdoor shooting and fishing

RAC and SEAC had their fourth discussions on their opinions 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 ammunition (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.

##### Dechlorane Plus

RAC adopted its final opinion on the restriction proposal submitted by Norway in April 2021, which aims to address risks for people and the environment from Dechlorane Plus. SEAC also agreed its draft opinion on the proposal, which is now open for [a 60-day stakeholder consultation](#) until 16 May 2022, before it is adopted during SEAC's June plenary.

Dechlorane Plus is a chlorinated substance mainly used as a flame retardant. It is identified as a substance of very high concern due to its very persistent and very bioaccumulating properties. The substance has been proposed for inclusion in the Stockholm Convention on persistent organic pollutants and consequent global elimination.

##### 2,4-dinitrotoluene

SEAC had its first discussions on the restriction proposal. The dossier was prepared by ECHA following [Article 69\(2\) of REACH](#), which requires ECHA to propose restrictions for substances subject to authorisation (i.e. those listed in Annex XIV) where these are concluded to pose a risk to people or the environment because of their use in articles. Both RAC and SEAC will have their next discussions in their June plenary meetings, where RAC plans to adopt and SEAC to agree their respective opinions.

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

Both RAC and SEAC had their first discussion on the restriction proposal prepared by ECHA in October 2021. The proposal concerns the placing on the market and use of substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting.

##### PFASs in firefighting foams

Both RAC and SEAC concluded that the restriction proposal submitted by ECHA in January 2022 conforms to the requirements for a restriction proposal under REACH. A six-month stakeholder consultation will be launched on **23 March** 2022.

## Applications for authorisation

RAC and SEAC adopted an opinion on the industrial use of **1,2-dichloroethane** as a solvent for the synthesis of polyepichlorohydrin. Polyepichlorohydrin is used as a precursor in the production of glycidyl azide polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.

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

- the use of **sodium dichromate** as an anticorrosion agent of the carbon steel in sealed circuits of gas absorption appliances up to 1.05 % w/w (corresponding to 0.42 % w/w as Cr(VI)) in the refrigerant solution;
- the use of **chromium trioxide** for industrial site electroplating of different types of substrates 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 of high-quality stainless-steel press plates for the premium wood-based materials industry;
- the use of **4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and 4-nonylphenol, branched and linear, ethoxylated** as a component of buffer solutions to produce antigens (cell extraction, cell lysis, coating of biological antigens onto articles, inactivation of micro-organisms that produce targeted antigen and solvent exchange) and in-process and final quality control of antigens intended for use as veterinary and human health laboratory reagents in scientific research and development and *in vitro* diagnostic applications;
- the industrial use of **4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated** for virus inactivation in the manufacture of Andexanet alfa for treatment of adult patients treated with a direct factor Xa (FXa) inhibitors when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding; and
- the use of **chromium trioxide** for electroplating of metal substrates with the purpose of creating a long-lasting high durability surface with a bright look for kitchen and bathroom sanitary ware (functional plating with decorative character).

Additionally, SEAC agreed on a draft opinion on the use of chromium trioxide for decorative/functional applications in the furniture, sanitary and automotive sectors.

## Occupational exposure limits

### 1,4-dioxane

RAC adopted an opinion on the scientific evaluation of occupational exposure limits (OELs) for 1,4-dioxane. The Commission has made a request to evaluate exposure to 1,4-dioxane to assess the option of an airborne occupational exposure limit (OEL), other limit values (BLV/BGV) and notations. 1,4-dioxane was previously classified as category 2 carcinogen, but has a new classification as a category 1B carcinogen, bringing it into the scope of the Carcinogens and Mutagens Directive (CMD). 1,4-dioxane already has an indicative occupational exposure limit value (IOELV) under the Chemical Agents Directive (CAD) and as a result of its reclassification, it is necessary to review the current IOELV and to replace it with an OEL under CMD. RAC agreed on the following airborne occupational exposure limit values for 1,4-dioxane:

OEL as 8-hour TWA:	7.3 mg/m <sup>3</sup> (2 ppm)
STEL:	73 mg/m <sup>3</sup> (20 ppm)

BLV:	45 mg 2-hydroxyethoxyacetic acid/g creatinine
BGV:	-

Notations:	skin
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The opinion will be published in May.

### Isoprene

RAC adopted an opinion on the scientific evaluation of occupation exposure limits (OELs) for isoprene. The Commission has made a request to evaluate exposure to isoprene to assess the option of an airborne occupational exposure limit, other limit values (BLV/BGV) and notations. Isoprene (2-methyl-(1,3)butadiene) is a carcinogen, classified as category 1B and is a monomer used for the polymerisation of elastomers. RAC agreed on the following airborne occupational exposure limit values for isoprene:

OEL as 8-hour TWA:	3 ppm (8.5 mg/m <sup>3</sup> )
STEL:	-
BLV:	-
BGV:	-

Notations:	none
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The opinion will be published in May.

### RAC adopts 10 opinions on harmonised classification and labelling

#### Reaction mass of: N,N'-Ethane-1,2 diylbis(decanamide) 12-Hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide and N,N'-Ethane-1,2-diylbis(12-hydroxyoctadecanamide)[Thixatrol Plus] (EC 430-050-2; CAS -)

Thixatrol Plus is used as a rheological additive in coating products, fillers, putties, plasters, modelling clay, finger paints and adhesives and sealants. It has an existing entry in Annex VI to the CLP Regulation as a substance which may cause an allergic skin reaction (Skin Sens. 1; H317) and is toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

RAC agreed to Spain's proposal to modify the existing Annex VI entry for Thixatrol Plus to very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1; H410, M=10) and to add the classification as very toxic to aquatic life (Aquatic Acute 1; H400, M=100).

#### $\alpha$ -methyl-1,3-benzodioxole-5-propionaldehyde [1], (S)- $\alpha$ -methyl-1,3-benzodioxole-5-propionaldehyde; (2S)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [2], (R)- $\alpha$ -methyl-1,3-benzodioxole-5-propionaldehyde; (2R)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [3] ][Helional] (EC 214-881-6 [1]; CAS 1205-17-0 [1], 737776-68-0 [2], 73776-59-9 [3])

Helional is used in washing and cleaning products, air care products, polishes and waxes, perfumes and fragrances, cosmetics and personal care products and biocides (e.g. disinfectants, pest control products). The substances have no existing entry in Annex VI to the CLP Regulation.

RAC agreed to Denmark's proposal to classify Helional as substances that may cause an allergic skin reaction (Skin Sens. 1B; H317).

**2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol [Disperse Blue 106]** (EC 271-183-4; CAS 68516-81-4)

Disperse Blue 106 is mainly used to dye or print fabrics made of synthetic fibres such as polyester, nylon, triacetate, cellulose, polyamide, and acrylic fibres. These fibres are used in turn to produce garments that are mostly worn directly on the skin, e.g. leggings, bodysuits, suits, dresses, brassieres, tights, and jacket lining. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to Germany's proposal to classify Disperse Blue 106 as a substance that may cause an allergic skin reaction (Skin Sens. 1A; H317, with a specific concentration limit  $C \geq 0.001\%$ ).

**2,3-epoxypropyl neodecanoate** (EC 247-979-2; CAS 26761-45-5)

2,3-epoxypropyl neodecanoate is used in adhesives and sealants, and has widespread uses across activities and areas by professional workers. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to Denmark's proposal to classify 2,3-epoxypropyl neodecanoate as a substance that is suspected of causing genetic defects (Muta. 2; H341) and may cause an allergic skin reaction (Skin Sens. 1A; H317, with a specific concentration limit  $C \geq 0.001\%$ ).

**Acetone oxime** (EC 204-820-1; CAS 127-06-0)

Acetone oxime is used as an anti-skinning agent for the preparation of coatings/printing inks. Acetone oxime is also used as an intermediate for the manufacture of other substances/products. Intermediate use of oximes mainly covers the manufacture of oxime silanes, which are applied as cross-linkers for silicon sealants. Exposure of the general public is possible through the use of paints, printing inks and silicon sealants in non-industrial settings. Acetone oxime has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to Austria's proposal to classify acetone oxime as a substance that may cause cancer (Carc. 1B; H350), may cause drowsiness or dizziness (STOT SE 3; H336), may cause damage to the blood system (STOT RE 2; H373), is harmful in contact with skin (Acute Tox. 4; H312, with an ATE=1 100 mg/kg bw), causes serious eye damage (Eye Dam. 1; H318) and may cause an allergic skin reaction (Skin Sens. 1; H317).

**Propyl 3,4,5-trihydroxybenzoate** (EC 204-498-2; CAS 121-79-9)

Widespread uses for professional workers are registered for the substance. Furthermore, propyl 3,4,5-trihydroxybenzoate or propyl gallate (E310) is used as an antioxidant authorised as a food additive. Additional exposure for consumers is expected from food contact materials and propyl 3,4,5-trihydroxybenzoate is also permitted in cosmetics without any concentration limits. The substance is also used in pH regulators and water treatment products. Propyl 3,4,5-trihydroxybenzoate has an existing Annex VI entry as harmful if swallowed (Acute Tox. 4\*; H302) and may cause an allergic skin reaction (Skin Sens. 1; H317).

RAC agreed to Germany's proposal to add an ATE=1 700 mg/kg bw to the acute toxicity

classification (Acute Tox. 4; H302) and to classify propyl 3,4,5-trihydroxybenzoate as very toxic to aquatic life (Aquatic Acute 1; H400, M=1) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1; H410, M=1).

#### **(3E)-dec-3-en-2-one** (EC -; CAS 18402-84-1)

(3E)-dec-3-en-2-one is intended to be used as a plant growth regulator in potatoes during storage. The product is applied by hot fogging. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the Netherlands' proposal to classify the substance as harmful if inhaled (Acute Tox. 4; H332, ATE=1.5 mg/L (dusts and mists)) and corrosive to respiratory tract (EUH071), which may be fatal if swallowed and enters airways (Asp. Tox. 1; H304), causes skin irritation (Skin Irrit. 2; H315), and is toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

#### **Hexyl salicylate** (EC 228-408-6; CAS 6259-76-3)

Hexyl salicylate is a fragrance ingredient used in many fragrance compounds. It may be found in fragrances used in decorative cosmetics, fine fragrances, shampoos, toilet soaps and other toiletries as well as in non-cosmetic products such as household cleaners and detergents. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify hexyl salicylate as a substance that may cause an allergic skin reaction (Skin Sens. 1; H317) and that it warrants classification as a substance suspected of damaging the unborn child (Repro. 2; H361d).

#### **Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range $\geq 30$ nm to $< 3$ $\mu$ m and a length $\geq 5$ $\mu$ m and aspect ratio $> 3:1$ , including Multi-Walled Carbon Nanotubes, MWCNT** (EC -; CAS -)

Multi-Walled Carbon Nanotubes (MWCNTs) possess several properties which make them useful for industrial applications in new or enhanced materials and products (e.g. tensile strength, electrical and thermal conductivity). MWCNTs are used in antistatic and electro-paintable thermoplastics, anti-fouling coatings, batteries (Li-ion), textiles, structural composites (e.g. for windmill blades and high performance sporting goods) and possibly printed electronics (conductive inks) and conductive coatings for displays and touch screens. CNTs are used in thin heat mats, gas- and biosensors, and high-durability epoxy-paints. The substances have no existing Annex VI entry.

RAC agreed to Germany's proposal to classify MWCNTs as substances that may cause cancer via inhalation (Carc. 1B; H350i) and cause damage to the lungs via inhalation (STOT RE 1; H372). RAC also agreed to add specific concentration limits of  $C > 1$  % for STOT RE 1 and  $0.1 > C < 1$  % for STOT RE 2.

#### **Sulfur** (EC 231-722-6; CAS 7704-34-9)

Sulfur is a fungicide and acaricide active substance used for many years in Europe on various crops. The substance is currently classified as causing skin irritation (Skin Irrit. 2; H315).

RAC disagreed with the proposal by France and Slovenia to add to the existing classification that sulfur causes serious eye irritation (Eye Irrit. 2; H319) and that sulfur may cause respiratory irritation (STOT SE 3; H335).

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.