

## Annex to news

Helsinki, 22 September 2021

### Highlights from September RAC and SEAC meetings

#### REACH restrictions

##### Undecafluorohexanoic acid (PFHxA), its salts and related substances

SEAC was given an update on the outcome of the 60-day consultation on its draft opinion on the restriction proposal (submitted by Germany). This concerned the manufacture, use and placing on the market of PFHxA, its salts and related substances. SEAC agreed its draft opinion, while RAC had already adopted its opinion on this proposal in June 2021.

SEAC is expected to finalise its opinion in December 2021.

##### Substances in single-use baby diapers

RAC concluded discussions on this restriction proposal submitted by France, adopting its opinion, while SEAC agreed its opinion, which will now be subject to a consultation. [The consultation](#) started on 15 September and will close on 14 November 2021, after which SEAC will finalise its opinion in December 2021.

The proposal concerns hazardous substances that may be present in single-use baby diapers. It aims to reduce health risks associated with wearing diapers for children and infants under the age of three. See [news from 10 September 2021](#).

##### Lead in outdoor shooting and fishing

RAC and SEAC had their second discussions on their opinions on this restriction proposal submitted by ECHA in January 2021, which aims to address the 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's Restriction working group and the SEAC plenary had their first discussions on their respective opinions on the restriction proposal submitted by Norway in April 2021, which aims to address risks for people and the environment from Dechlorane Plus™. Dechlorane Plus™ is a chlorinated substance mainly used as a flame retardant. It is 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

Both RAC and SEAC concluded that the restriction proposal submitted by ECHA in July 2021 conforms to the requirements for a restriction proposal set in Annex XV to REACH. A six-month stakeholder consultation was launched on 22 September 2021. 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.

### Applications for authorisation

RAC and SEAC agreed on three opinions on an application for authorisation and two review reports. The agreed opinions concern:

- use of chromium trioxide in the functional chrome plating of engine valves and valve actuation;
- use of trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin; and
- industrial formulation of a chromium trioxide solution for the passivation of copper foil used in the manufacture of lithium ion batteries (LiB) for motorised vehicles.

Additionally, SEAC agreed on a draft opinion on the industrial use of 1,2-dichloroethane as a solvent for the synthesis of a precursor in the production of an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.

SEAC also agreed on a document: *SEAC's approach to assessing changes in producer surplus*, which will be published on ECHA's website.

Lastly, SEAC also adopted an addendum to an earlier opinion which the committees had adopted in 2015. Following a request by the European Commission, applicants needed to submit substitution plans to ECHA, which were not part of the initial applications. The addenda provide SEAC's conclusions on the substitution plans. See [news from October 2020](#).

## RAC adopted 19 opinions on harmonised classification and labelling

### Dimethyl propylphosphonate (EC 242-555-3; CAS 18755-43-6)

Dimethyl propylphosphonate is an industrial chemical used in rigid foam, foam granules, rebounded PUR and CASE (coatings, adhesives, sealants and elastomers) applications by industrial and professional workers. It is also incorporated into articles which may be used by consumers. The substance has no existing entry in Annex VI to CLP.

RAC agreed to the proposal by Ireland to classify dimethyl propylphosphonate as a substance that may cause genetic defects (Muta. 1B; H340) and which may damage the unborn child and which is suspected of damaging fertility (Repr. 1B; H360Df).

### Clothianidin(ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanine (EC 433-460-1; CAS 210880-92-5)

Clothianidin (ISO) is an insecticide and is an active substance in the meaning of Regulations (EU) No. 528/2012 and (EC) No. 1107/2009. The substance has a current harmonised classification and labelling (i.e. Annex VI entry) as harmful if swallowed (Acute Tox. 4 \*; H302), is very toxic to aquatic life (Aquatic Acute 1; H400) and is toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=10).

RAC agreed to the proposal by Germany to add to the existing classifications that clothianidin is suspected of damaging fertility (Repr. 2; H361f) and causes damage to nervous system (STOT SE 1; H370). Furthermore, RAC agreed to add an ATE of 390 mg/kg bw to the acute oral toxicity classification, M=10 to the aquatic acute and M=100 to the aquatic chronic toxicity classification. However, RAC did not agree that clothianidin is suspected of damaging the unborn child (Repr. 2; H361d).

**Hydrogen sulphide, hydrogen sulfide (EC: 231-977-3; CAS: 7783-06-4)**

Hydrogen sulphide is used by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing, agriculture, forestry and fishing. Further uses are the manufacture of chemicals, pulp, paper and paper products, food products, textile, leather, wood and wood products. The substance has a current Annex VI entry as gas under pressure (Press. Gas, Note U), extremely flammable gas (Flam. Gas 1; H220), fatal if inhaled (Acute Tox. 2\*; H330) and very toxic to aquatic life (Aquatic Acute 1; H400).

RAC agreed to the proposal by Germany to retain the classification as gas under pressure (Press. Gas, Note U) and to modify the classification as an extremely flammable gas (Flam. Gas 1A; H220) and fatal if inhaled (Acute Tox. 2; H330, with an ATE of 440 ppmV (gases)).

**Resorcinol; 1,3-benzenediol (EC 203-585-2; CAS 108-46-3)**

Resorcinol is used by consumers, by professional workers (widespread uses), in formulation or re-packing and at industrial sites, e.g., in the manufacture of rubber products and in wood adhesives, flame retardants, UV stabilisers, and dyes. It is also used in personal care products such as hair colourants, anti-acne preparations, and peels. The substance has a current Annex VI entry as harmful if swallowed (Acute Tox. 4\*; H302), causes skin irritation (Skin Irrit. 2; H315), causes serious eye irritation (Eye Irrit. 2; H319) and is very toxic to aquatic life (Aquatic Acute 1; H400).

RAC agreed to the proposal by Finland to add classifications as a substance which may cause an allergic skin reaction (Skin Sens. 1B, instead of Skin Sens. 1A as proposed by Finland) and which causes damage to the nervous system (STOT SE 1; H370). RAC also agreed to modify the classifications as a substance which is harmful if swallowed (Acute Tox. 4; H302, removing the minimum classification and adding an ATE of 500 mg/kg bw) and very toxic to aquatic life (Aquatic Acute 1; H400, adding M=1).

**1-phenylethan-1-one (1-phenylethylidene)hydrazone (EC 211-979-0; CAS 729-43-1)**

1-phenylethan-1-one (1-phenylethylidene)hydrazone (or acetophenone azine) is used as a chemical intermediate. and is present in consumer products such as sports equipment. The substance has no existing entry in Annex VI to CLP.

RAC agreed to the proposal by France to classify 1-phenylethan-1-one (1-phenylethylidene)hydrazone as a substance that may cause an allergic skin reaction (Skin Sens. 1; H317).

**Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC 278-355-8; CAS 75980-60-8)**

The substance is a photoinitiator used in the polymerisation of unsaturated oligomers such as acrylates, after exposure to UV light. The substance has a current Annex VI entry as a substance suspected of damaging fertility (Repr. 2; H361f).

RAC agreed to the proposal by Sweden to modify the existing classification to indicate that the substance may damage fertility and is suspected of damaging the unborn child (Repr. 1B; H360Fd) and to add that it may cause an allergic skin reaction (Skin Sens. 1B; H317).

**Cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide (EC 261-043-0; CAS 57966-95-7)**

Cymoxanil is a fungicide used in agriculture, viticulture and horticulture. The substance has a current Annex VI entry as suspected of damaging fertility and the unborn child (Repr. 2; H361fd), may damage the blood system and thymus (STOT RE 2; H373), 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, M=1) and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=1).

RAC agreed to the proposal by Lithuania and Finland to add that cymoxanil may also damage the eyes (STOT RE 2; H373) and to add an oral ATE of 360 mg/kg bw. Furthermore, RAC agreed to retain the current skin sensitisation classification (Skin Sens. 1; H317) for this substance.

**Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea (EC 206-354-4; CAS 330-54-1)**

Diuron is an existing pesticide active substance (algicide and herbicide) approved in accordance with Directive 91/414/EEC. The substance has a current Annex VI entry as harmful if swallowed (Acute Tox. 4\*; H302), is suspected of causing cancer (Carc. 2; H351), may cause damage to organs (STOT RE 2\*; H373\*\*), is very toxic to aquatic life (Aquatic Acute 1; H400) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=10).

RAC agreed to the proposal by Germany to change the carcinogenicity classification to may cause cancer (Carc. 1B; H350) and to indicate blood system as a target organ for the STOT RE classification (STOT RE 2; H373). RAC also agreed to retain the classification as Aquatic Acute 1 and Aquatic Chronic 1 and to add M=100 for both and to remove the classification for acute toxicity via the oral route (Acute Tox. 4\*; H302).

**9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylium chloride; Basic Red 1 (EC 213-584-9; CAS 989-38-8)**

Basic Red 1 is a rhodamine-based pigment used in the laboratory, as well as industrially and professionally. It may be found in products like inks and toners but also as a binding agent in paints and coatings or adhesives. The substance has no existing entry in Annex VI to CLP.

RAC agreed to the proposal by Germany to classify Basic Red 1 as toxic if swallowed (Acute Tox. 3; H301, with an ATE of 280 mg/kg bw), causes serious eye damage (Eye Dam. 1; H318), may cause an allergic skin reaction (Skin Sens. 1; H317, instead of the proposed Skin Sens. 1B), 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, with M=1).

**Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[( $\alpha,\alpha,\alpha$ -trifluoro-m-tolyl)oxy]picolinanilide (EC -; CAS 137641-05-5)**

Picolinafen is a herbicide used as an active substance in plant protection products. The substance has no existing entry in Annex VI to CLP.

RAC agreed to the proposal by Germany to classify picolinafen as a substance that may cause damage to blood system and thyroid (STOT RE 2; H373), is very toxic to aquatic life (Aquatic Acute 1; H400, M=1000) and is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=1000).

**2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A (TBBPA) (EC 201-236-9; CAS 79-94-7)**

Tetrabromobisphenol A (TBBPA) is a brominated flame retardant (BFR) commonly used in electronics to meet fire safety standards. It is also used in printed circuit boards, paper and textiles. The substance has a current Annex VI entry as 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 Norway and Denmark to classify TBBPA as a substance that may cause cancer (Carc. 1B; H350).

### **Benzyl alcohol (EC 202-859-9; CAS 100-51-6)**

Benzyl alcohol is a colourless liquid with a faint, nondescript odour, which is used as a solvent, preservative, and fragrance ingredient. The substance has a current Annex VI entry as harmful if swallowed (Acute Tox. 4\*; H302) and harmful if inhaled (Acute Tox. 4\*; H332).

RAC agreed to the proposal by Germany to add classifications as a substance which causes serious eye irritation (Eye Irrit. 2; H319) and may cause an allergic skin reaction (Skin Sens. 1B; H317). Furthermore, RAC agreed to add an oral ATE of 1 200 mg/kg bw to the classification as harmful if swallowed (Acute Tox. 4; H302) as well as to remove the acute inhalation toxicity minimum classification (Acute Tox. 4\*; H332).

### **Dibutyltin maleate (EC 201-077-5; CAS 78-04-6)**

Dibutyltin maleate is used in the manufacture and professional use of plastic products. The substance has no existing entry in Annex VI to CLP.

RAC agreed to the proposal by Austria to classify dibutyltin maleate as a substance which is suspected of causing genetic defects (Muta. 2; H341), may damage fertility and the unborn child (Repr. 1B; H360FD), causes damage to the immune system (STOT RE 1; H372), is fatal if inhaled (Acute Tox. 2; H330, with an ATE of 0.317 mg/L (dusts or mists)), harmful if swallowed (Acute Tox. 4; H302, with an ATE of 510 mg/kg bw), causes severe skin burns and eye damage (Skin Corr. 1; H314) and causes serious eye damage (Eye Dam. 1; H318).

### **Dibutyltin oxide (EC 212-449-1; CAS 818-08-6)**

Dibutyltin oxide is used, for example, in adhesives and sealants, coatings and paints, thinners and paint removers, in laboratory chemicals, leather treatment products, paper and board treatment products, polymer preparations and compounds, textile dyes, and impregnating products, etc. The substance has no existing entry in Annex VI to CLP.

RAC agreed to the proposal by Austria to classify dibutyltin oxide as suspected of causing genetic defects (Muta. 2; H341), may damage fertility and the unborn child (Repr. 1B; H360FD), causes damage to immune system (STOT RE 1; H372), is toxic if swallowed (Acute Tox. 3; H301, with an ATE of 170 mg/kg bw) and causes serious eye damage (Eye Dam. 1; H318). Contrary to Austria's proposal to classify dibutyltin oxide as a substance that causes severe skin burns and eye damage (Skin Corr. 1; H314), RAC agreed to classify it as a substance that causes skin irritation (Skin Irrit. 2; H315).

### **[1] Lithium carbonate; [2] lithium chloride; [3] lithium hydroxide (EC [1] 209-062-5; [2] 231-212-3; [3] 215-183-4; CAS: [1] 554-13-2; [2] 7447-41-8; [3] 1310-65-)**

Lithium carbonate is the starting material for the production of lithium salts. It is used in the manufacture of aluminium and as a flux in the glass, enamel and ceramic industries, and in the construction industry. Lithium chloride is used to absorb moisture in air conditioning systems and in batteries and in welding and brazing fluxes in the production of lightweight alloys. Lithium hydroxide (monohydrate) is used in alkaline storage batteries and for manufacturing of lithium soaps. Lithium hydroxide (anhydrous) is used as an additive to potassium hydroxide in big industrial batteries and in the production of lithium stearate. Lithium is also used as a pharmaceutical in psychiatric medication. The substances have no existing entry in Annex VI to CLP.

RAC agreed to the proposal by France to classify lithium carbonate, lithium chloride and lithium

hydroxide as substances that may damage fertility and the unborn child (Repr. 1A, H360FD). In addition, RAC agreed that these substances may cause harm to breast-fed children (Lact.; H362).

**Nonylphenol, branched and linear, ethoxylated (with average molecular weight <352 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC 500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5; and others; CAS 127087-87-0; 9016-45-9; 26027-38-3; 68412-54-4; 27986-36-3; 20427-84-3; 27176-93-8; 1119449-38-5 and others)**

Nonylphenol ethoxylates (NPEs) are surface-active substances (detergents) and fall under the Prior Informed Consent Regulation (PIC, EC/649/2012). The substance has no existing entry in Annex VI to CLP.

RAC agreed to the proposal by The Netherlands to classify nonylphenol, branched and linear, ethoxylated (with average molecular weight <352 g/mol) 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=10).

**Nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight <704 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC 230-770-5; 248-743-1; 247-555-7; 248-293-6 and others; CAS 127087-87-0; 9016-45-9; 7311-27-5; 27942-27-4; 26264-02-8; 27177-05-5; 14409-72-4 and others)**

Nonylphenol ethoxylates (NPEs) are surface-active substances (detergents) and fall under the Prior Informed Consent Regulation (PIC, EC/649/2012). The substance has no existing entry in Annex VI to CLP.

Contrary to the proposal by The Netherlands to classify the substance as Aquatic Chronic 2 (H411), RAC agreed to classify nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight <704 g/mol) 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=10).

**Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤1 540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC -; CAS 127087-87-0; 9016-45-9 and others)**

Nonylphenol ethoxylates (NPEs) are surface-active substances (detergents) and fall under the Prior Informed Consent Regulation (PIC, EC/649/2012). The substance has no existing entry in Annex VI to CLP.

Contrary to the proposal by The Netherlands not to classify nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤1 540 g/mol) for aquatic environmental hazards, RAC agreed to classify the substance 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=10).

### **Article 77(3)(c) request on classification for environmental toxicity of lead**

On 30 November 2018, RAC had adopted an opinion on the harmonised classification and labelling of lead, which concluded that for both the massive and the powder forms, it should be classified 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=10).

New information had been provided by industry on the chronic toxicity of lead in the pond snail *Lymnea stagnalis* (OECD TG 243) and RAC was requested, based on Article 77(3)(c) of the REACH Regulation, to review its opinion of 30 November 2018 on the environmental classification of lead.

RAC took note of the new information and concluded that lead warrants classification as Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410, M=1 000.

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.