# Annex to a news release

Helsinki, 22 September 2020

## ECHA's committees back restricting over 1 000 skin sensitising chemicals used in clothing and other articles

## REACH restrictions

### Calcium cyanamide

SEAC adopted its final opinion in support of ECHA's proposal to restrict the placing on the market of calcium cyanamide used as a fertiliser. SEAC concludes that it is uncertain whether the restriction proposed by the Dossier Submitter on calcium cyanamide (CAS 156-62-7, EC 205-861-8) is the most appropriate EU-wide measure to address the identified risks. There is insufficient information to definitively conclude on the proportionality of the socio-economic benefits to the socio-economic costs as demonstrated in the justification supporting this opinion.

### Cobalt salts

SEAC adopted its final opinion on ECHA's proposal to restrict five cobalt salts. SEAC considers that the restriction initially proposed by the Dossier Submitter is not the most appropriate EU-wide measure. Taking into account the conditions of the restriction as proposed by the Committee for Risk Assessment (RAC) in February 2020, SEAC concluded that it is uncertain whether the restriction as amended by RAC is the most appropriate EU-wide measure. The uncertainties are related to proportionality aspects, to the discussion of whether a binding occupational exposure limits (BOEL) would be a more appropriate risk management measure to address the risks to workers and to the limitation of the restriction to the five specific substances under consideration.

### Formaldehyde

SEAC also adopted its final opinion on ECHA's proposal to restrict the placing on the market of articles releasing formaldehyde at concentrations greater than 0.124 mg/m$^3$ and that a formaldehyde concentration of 0.1 mg/m$^3$ shall not be exceeded in the interiors of road vehicles and aircraft. Both committees concluded that an EU-wide restriction is the most appropriate mean to address the risks to EU citizens. SEAC's opinion supported the proposal but included several proposed modifications to its scope and conditions.

### Skin sensitising substances

SEAC also adopted its final opinion in support of the proposal by France and Sweden to restrict skin sensitising substances in finished textile, leather, hide and fur articles, placed on the market for the first time. This follows an earlier opinion by the Committee for Risk Assessment (RAC) in March 2020. Both committees concluded that an EU-wide restriction is the most appropriate means to address the risks to EU citizens. In addition, SEAC concluded that the expected benefits and costs to society of the proposal mean that it is likely to be proportionate.

### Intentionally added microplastics

Consultation on the agreed SEAC opinion has finished and the committee is expected to adopt its opinion at its December 2020 meeting.

## Applications for authorisation

RAC and SEAC adopted 12 opinions on applications for authorisation. The adopted opinions concern uses of octyl- and nonylphenol ethoxylates in production of *in vitro* testing devices for Life Sciences sector, and in manufacture of biopharmaceuticals.

RAC agreed on 10 draft opinions on applications for authorisation of uses of octylphenol ethoxylates in the Life Sciences and pharmaceutical sectors. SEAC agreed on 12 draft opinions on the uses of octylphenol ethoxylates in the Life Sciences and pharmaceutical sectors. Another four draft opinions agreed by SEAC related to the uses of octyl- and nonylphenol ethoxylates in Aerospace and Defence sector.

Furthermore, RAC and SEAC discussed key issues in six applications for authorisation, which were received by ECHA in May 2020. Of these, five are related to the uses of chromium trioxide in chrome plating. The another one is on uses of bis(2-methoxyethyl) ether (diglyme) in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification.

## Harmonised classification and labelling: RAC adopted 15 opinions

**Trimethylolpropane triacrylate** (EC: 239-701-3; CAS: 15625-89-5)

The substance trimethylolpropane triacrylate (TMPTA) is used in industrial applications of coatings and inks in dry process and in polymerisation in the polymer industry. TMPTA is also used by professionals for indoor printing with ink cartridges in dry process.

TMPTA has an existing Annex VI entry as a substance that causes skin irritation (Skin Irrit. 2; H315), serious eye irritation (Eye Irrit. 2; H319) and may cause an allergic skin reaction (Skin Sens. 1; H317).

RAC agreed to the proposal by France to also classify TMPTA as suspected of causing cancer (Carc. 2; H351), 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).

**4,4'-oxydi(benzenesulphonohydrazide)** (EC: 201-286-1; CAS: 80-51-3)

4,4'-Oxydi(benzenesulphonohydrazide) is used in polymers and for the manufacture of plastic products and rubber products. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify 4,4'-Oxydi(benzenesulphonohydrazide) as a substance the heating of which may cause a fire (Selt-react. D; H242), 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).

**Toluene-4-sulphonohydrazide** (EC: 216-407-3; CAS: 1576-35-8)

Toluene-4-sulphonohydrazide is used for the manufacture of rubber products, plastic products and chemicals. It has no current Annex VI entry.

RAC agreed to the proposal by Germany to classify toluene-4-sulphonohydrazide as a substance the heating of which may cause a fire (Self-react. D; H242).

**N-(2-nitrophenyl)phosphoric triamide** (EC: 477-690-9; CAS: 874819-71-3)

N-(2-nitrophenyl)phosphoric triamide is used by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance is an additive for urea based fertilizers. The substance has no current Annex VI entry.
RAC agreed to the proposal by Austria to classify N-(2-nitrophenyl)phosphoric triamide as a substance that may damage fertility but which is suspected of damaging the unborn child (Repr. 1B; H360Fd) and as a substance that may cause damage to the kidney (STOT RE 2; H373).

**1,3-bis(1-isocyanato-1-methylethyl)benzene** (EC: 220-474-4; CAS: 2778-42-9)

1,3-bis(1-isocyanato-1-methylethyl)benzene is used at industrial sites and in manufacturing. The substance has no current Annex VI entry.

RAC agreed to the proposal by Germany to classify 1,3-bis(1-isocyanato-1-methylethyl)benzene as a substance that may cause allergy or asthma symptoms or breathing difficulties if inhaled (Resp. Sens. 1; H334) and that may cause an allergic skin reaction (Skin Sens. 1A; H317).

**Bis(isocyanatomethyl)benzene** (EC: 222-852-4; CAS: 3634-83-1)

Bis(isocyanatomethyl)benzene is used at industrial sites and in manufacturing. The substance has no current Annex VI entry.

RAC agreed to the proposal by Germany to classify bis(isocyanatomethyl)benzene as a substance that may cause allergy or asthma symptoms or breathing difficulties if inhaled (Resp. Sens. 1; H334) and that may cause an allergic skin reaction (Skin Sens. 1A; H317) with an SCL of 0.001%.

**2,4,6-triisopropyl-m-phenylene diisocyanate** (EC: 218-485-4; CAS: 2162-73-4)

2,4,6-triisopropyl-m-phenylene diisocyanate is used at industrial sites and in manufacturing. The substance has no current Annex VI entry.

RAC agreed to the proposal by Germany to classify 2,4,6-triisopropyl-m-phenylene diisocyanate as a substance that may cause allergy or asthma symptoms or breathing difficulties if inhaled (Resp. Sens. 1; H334) and that may cause an allergic skin reaction (Skin Sens. 1; H317).

**1,5-naphthylene diisocyanate** (EC: 221-641-4; CAS: 3173-72-6)

1,5-naphthylene diisocyanate is used in formulation or re-packing, at industrial sites and in manufacturing. The substance has an existing Annex VI entry as harmful if inhaled (Acute Tox. 4*; H332), causes skin irritation (Skin Irrit. 2; H315), causes serious eye irritation (Eye Irrit. 2; H319), may cause allergy or asthma symptoms or breathing difficulties if inhaled (Resp. Sens. 1: H334), may cause respiratory irritation (STOT SE 3; H335) and is harmful to aquatic life with long lasting effects (Aquatic Chronic 3; H412).

RAC agreed to the proposal by Germany to add to the existing classifications that it is a substance which may cause an allergic skin reaction (Skin Sens. 1A; H317) and to split the entry such that the modified adopted classification as a substance which is fatal if inhaled (Acute Tox. 2) with an ATE of 0.27 mg/L for dusts and mists, applies to 1,5-naphthylene diisocyanate containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm.

**Cumene** (EC: 202-704-5; CAS: 98-82-8)

Cumene is mainly used as an intermediate (approximately 95%) for the production of phenol and acetone. In addition, the substance is a minor constituent of gasolines and solvents. The substance has an existing Annex VI entry as flammable liquid and vapour (Flam. Liq. 3; H226), may be fatal if swallowed and enters airways (Asp. Tox. 1; H304), may cause respiratory irritation (STOT SE 3; H335) and toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Denmark to also classify cumene as a substance that may cause cancer (Carc. 1B; H350). Contrary to the proposal by Denmark, RAC did not agree that cumene should be classified as suspected of causing genetic defects (Muta. 2).

**Divanadium pentaoxide; vanadium pentoxide** (EC: 215-239-8; CAS. 1314-62-1)

Divanadium pentaoxide is used for the production of vanadium compounds and as an intermediate in the production of vanadium and steel alloys. It is also used as a catalyst e.g. in developing solutions or for the oxidation of sulfide to sulfate. The substance has a current Annex VI entry as suspected of causing genetic defects (Muta. 2; H341), suspected of damaging unborn child (Repr. 2; H361d), harmful if swallowed and inhaled (Acute Tox. 4 *; H302 and H332), may cause respiratory irritation (STOT SE 3; H335), causes damage to organs (STOT RE 1; H372) and toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by France to add to the classification that the substance may cause cancer (Carc. 1B; H350) and may cause harm to breast-fed children (Lact.; H362) and to add to the existing STOT RE 1 classification that it causes damage to the respiratory tract via inhalation. RAC also agreed that it is toxic if swallowed (Acute Tox. 3; H301, ATE = 220 mg/kg bw), but modified the existing acute toxicity classification via inhalation to fatal if inhaled (Acute Tox. 2; H330, ATE = 0.05 mg/L (dusts or mists)). RAC also adopted a modification of the proposal by the dossier submitter, that the substance is suspected of damaging fertility as well as the unborn child (H361fd). Furthermore, RAC agreed by simple majority to maintain the existing classification as suspected of causing genetic defects (Muta. 2; H341).

**Theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione** (EC: 200-385-7; CAS: 58-55-9)

Theophylline is a naturally occurring substance in certain plants, e.g. black tea, coffee and cocoa. It is a substance with wide dispersive use, predominantly used as an anti-asthmatic drug in the pharmaceutical sector (99%). One percent is used in cosmetic applications. The substance has no current Annex VI entry. RAC agreed to the proposal by the Netherlands to classify the substance as a substance that may damage the unborn child (Repr. 1B; H360D).

**Barium diboron tetraoxide** (EC: 237-222-4; CAS: 13701-59-2)

Barium diboron tetraoxide is used for manufacturing of coatings and paints, thinners and paint removers in the industry, and by professional workers and consumers. The substance has an existing Annex VI entry as harmful if swallowed and harmful if inhaled (Acute Tox. 4*; H302 and H332).

RAC agreed to the proposal by Sweden to add to the classification that the substance may damage fertility and the unborn child (Repr. 1B; H360FD). Further, RAC agreed to modify the existing classification to toxic if swallowed (Acute Tox. 3; H301, ATE=100 mg/kg bw) and harmful if inhaled (Acute Tox. 4; H332, ATE=1.5 mg/L).

**Dibutyltin bis(2-ethylhexanoate)** (EC: 220-481-2; CAS: 2781-10-4)

Dibutyltin bis(2-ethylhexanoate) is used in articles, formulations and in manufacturing. The technical function of the substance during formulation is as a stabiliser. The substance has no current Annex VI entry.

RAC agreed to the proposal by Norway to classify dibutyltin bis(2-ethylhexanoate) as a substance suspected of causing genetic defects (Muta. 2; H341), that may damage fertility and the unborn child (Repr. 1B; H360FD) and that causes damage to the immune system (STOT RE 1; H372).

**Dibutyltin di(acetate)** (EC: 213-928-8; CAS: 1067-33-0)

Dibutyltin di(acetate) is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance has no current Annex VI entry.

RAC agreed to the proposal by Norway to classify dibutyltin di(acetate) as a substance suspected of causing genetic defects (Muta. 2; H341), that may damage fertility and the unborn child (Repr. 1B; H360FD) and that causes damage to the immune system (STOT RE 1; H372).

**Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone** (EC: 220-529-2; CAS: 2797-61-5)

Quinoclamine (ISO) is an active substance used in plant protection products. It has no current Annex VI entry.

RAC agreed to the proposal by Sweden and Denmark to classify the substance as suspected of causing cancer (Carc. 2; H351), suspected of damaging the unborn child (Repr. 2; H361d), harmful if swallowed (Acute Tox. 4; H302), causes serious eye irritation (Eye Irrit. 2; H319), may case an allergic skin reaction (Skin Sens. 1A; H317), may cause damage to blood system and kidneys, as well as very toxic to aquatic life (Aquatic Acute 1; H400, M=10) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=10).

The opinions will be available on ECHA's website in the near future.
http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment
http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis

## Background information

### The 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.

Further information:
http://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment

## Background information

### 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.

Further information about SEAC is available on ECHA's website at the link below:
http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis