Annex to a news release

Helsinki, 14 December 2020

Committees raise concern over persistent and toxic chemical in clay targets

REACH restrictions

Intentionally added microplastics

SEAC adopted its final opinion supporting ECHA's proposal to restrict intentionally added microplastics. SEAC concluded that the proposed restriction is the most appropriate EU-wide measure to address the identified risks taking into account the proportionality of its socio-economic benefits to costs and provided that the scope or conditions are modified, as proposed by SEAC. In June 2020, RAC had adopted its opinion supporting ECHA's proposal. RAC concluded that the proposed restriction (including the updated conditions of the restriction) is the most appropriate EU-wide measure to limit the emissions of intentionally added microplastics to the environment.

- Press release

Undecafluorohexanoic acid (PFHxA), its salts and related substances

SEAC and RAC continued their discussions on this restriction proposal submitted by Germany concerning the manufacture, use and placing on the market of PFHxA, its salts and the related substances. Due to their unique properties, perfluorinated substances like perfluorohexanoic acid (PFHxA) are used to manufacture articles and products in large quantities in the EU. The opinion development has been extended on this proposal for two reasons: the high number of comments received through the wide stakeholder consultation and to allow more time for evaluating the derogation requests. Agreement is expected in March 2021.

Substances in single-use baby diapers

Both RAC and SEAC concluded that the restriction proposal submitted by France in October 2020 conforms to the requirements for a restriction proposal set in Annex XV. The dossier concerns hazardous substances detected in single-use baby diapers. It aims at reducing health risks associated with the wearing of single-use baby diapers by children and infants under the age of three. The six-month consultation will be launched on 21 December 2020.

Applications for authorisation

RAC and SEAC adopted 24 opinions on applications for authorisation. The adopted opinions concern uses of:

- octyl- and nonylphenol ethoxylates in the production of *in vitro* testing devices for the life sciences sector, medicinal product delivery devices and in the manufacture of biopharmaceuticals; and
- coal tar pitch, high temp. and anthracene oil in the manufacture of formulations for various industrial uses and of clay targets.

RAC and SEAC estimated that continued use of CTPHT in clay targets will pollute our environment each year with several hundred tonnes of PAHs. There are also health risks to people through the environment, for example, through food. Moreover, there are alternatives available to using CTPHT in clay targets. Because of these reasons, the committees raised substantial concerns over the use of CTPHT in clay targets in their opinions.

RAC agreed on 14 draft opinions on applications for authorisation of uses of octyl- and nonyl phenol ethoxylates in the life sciences and pharmaceutical sectors, as well as four draft opinions in uses related to the aerospace sector.

SEAC agreed on 10 draft opinions on the uses of octyl- and nonylphenol ethoxylates in the life sciences and pharmaceutical sectors.

Another five draft opinions agreed by RAC and SEAC related to the uses of chromium (VI) substances in surface treatment (etching, plating and electrolytic tin passivation).

In addition, RAC and SEAC also agreed on the draft opinion on the review report on the industrial use of trichloroethylene as process chemical.

Furthermore, RAC and SEAC discussed key issues in six applications for authorisation and three review reports, which were received by ECHA in August 2020. Of these, four are related to the uses of chromium (VI) substances in surface treatment (etching, plating and electrolytic tin passivation). The another one is on uses of 4,4'-methylenebis[2-chloroaniline] (MOCA) in manufacture of high-performance polyurethanes for two different end-use sectors. And another one is on the use of octylphenol ethoxylate in the manufacture of veterinary active pharmaceutical ingredient. One of the review reports is on the use of sodium dichromate as mordant in wool dyeing. Another two are on the uses of 1,2-dichloroethane (EDC) as a swelling agent for beads for ion exchange resins, and as solvent for oligomers in propellents and explosives.

RAC adopted 12 opinions on harmonised classification and labelling

C. I. Disperse Blue 124 (EC 239-203-6; CAS 15141-18-1)

Disperse dyes, including Disperse Blue 124 (DB124) and Disperse Blue 106 (DB106), obtained from DB124 by hydrolysis, are mainly used to dye or print fabrics made of synthetic fibres such as polyester, nylon, triacetate, cellulose, polyamide, and acrylic fibres. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify C.I. Disperse Blue 124 as a substance that may cause an allergic skin reaction (Skin Sens. 1A; H317) with an SCL of 0.001%.

Bentazone (ISO) (EC 246-585-8; CAS 25057-89-0)

Bentazone (ISO) acts as a selective post-emergent herbicide against broadleaved weeds in a broad range of crops, including cereals, maize, legume vegetables (pulses), bulb vegetables and forage crops (alfalfa, clover). Bentazone (ISO) has an existing Annex VI entry as harmful if swallowed (Acute Tox. 4*; H302), causes serious eye irritation (Eye Irrit. 2; H319), may cause an allergic skin reaction (Skin Sens. 1; H317) and is harmful to aquatic life with long-lasting effects (Aquatic Chronic 3; H412).

RAC agreed to the proposal by the Netherlands to modify the acute toxicity classification to harmful if swallowed (Acute Tox. 4; H302) with an ATE of 1 600 mg/kg bw and to add that the substance is suspected of damaging the unborn child (Repr. 2; H361d). Furthermore, RAC agreed to keep the classification that the substance may cause an allergic skin reaction (Skin Sens. 1; H317), and agreed to remove the existing Annex VI entry for chronic aquatic toxicity.

Margosa, ext. (EC 283-644-7; CAS 84696-25-3)

Margosa, ext. [from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents] is an active substance in the meaning of Regulation (EU) No 528/2012.

The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify margosa, ext. [from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents] as a substance that is suspected of damaging the unborn child (Repr. 2; H361d), that may cause an allergic skin reaction (Skin Sens. 1; H317) and that is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=10).

Perfluroheptanoic acid (PFHpA) (EC 206-798-9; CAS 375-85-9)

Perfluoroheptanoic acid is a degradation product from C8 per- and polyfluorinated substances. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Belgium to classify PFHpA as a substance that is suspected of damaging the unborn child (Repr. 1B; H360D) and that causes damage to the liver (STOT RE 1; H372).

Bisphenol S (EC 201-250-5; CAS 80-09-1)

Bisphenol S is used in articles, by professional workers, in formulation, or re-packaging at industrial sites and in manufacturing. The substance has no current entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Belgium to classify bisphenol S as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD).

Melamine (EC 203-615-4; CAS 108-78-1)

Melamine is used in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance has no current entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify melamine as a substance suspected of causing cancer (Carc. 2; H351). RAC also agreed that the substance may cause damage to the urinary tract (STOT RE 2; H373), contrary to STOT RE 1; H372 (urinary tract) classification, proposed by the dossier submitter.

Valifenalate (EC -; CAS 283159-90-0)

Valifenalate is an active substance in the meaning of Regulation (EU) No 1107/2009. The substance has no current entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Hungary to classify valifenalate as a substance that is suspected of causing cancer (Carc. 2; H351) and that is toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

Isopyrazam (EC -; CAS 881685-58-1)

Isopyrazam is an active substance in the scope of Regulation (EC) 1107/2009. It is a broad-spectrum foliar fungicide. The substance has no current entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Norway to classify isopyrazam as a substance that may damage the unborn child (Repr. 1B; H360D), may cause an allergic skin reaction (Skin Sens. 1B; H317), is very toxic to aquatic life (Aquatic Acute 1; H400, M=10) and toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411, M=10). In addition, RAC agreed to classify isopyrazam

as a substance suspected of causing cancer (Carc. 2; H351).

6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta-PSCA Na TEA) (EC 701-271-4; CAS -)

Penta-PSCA Na TEA is used in lubricants, grease and metal working fluids. The substance has no current entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Austria to classify penta-PSCA Na TEA as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD) and that causes serious eye irritation (Eye Irrit. 2; H319).

6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA) (EC 206-798-9; CAS 375-85-9)

Tetra-PSCA is used in lubricants, grease and metal working fluids. The substance has no current entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Austria to classify tetra-PSCA as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD) and that causes serious eye irritation (Eye Irrit. 2; H319).

6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA) (EC 701-162-1; CAS -)

Penta-PSCA is used in lubricants, grease and metal working fluids. The substance has no current entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Austria to classify penta-PSCA as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD).

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

RAC adopted its opinion on the divanadium pentaoxide dossier at RAC-54 in September 2020. However, due to new information relevant to the classification conclusion for acute inhalation toxicity, exceptionally and in the interest of accuracy and transparency, the Chair decided to take the opinion back to RAC to discuss this information.

RAC took note of the new information, but did not change its earlier classification conclusion as a result of the new information.

Article 77(3)(c) request on 2-butoxyethanol; ethylene glycol monobutyl ether (EGBE) (EC 203-905-0; CAS 111-76-2)

On 14 September 2018, RAC adopted an opinion on the harmonised classification and labelling of EGBE, which concluded that regarding acute inhalation toxicity the substance should be classified as toxic if inhaled (Acute Tox. 3; H331). New information was provided by industry addressing the adopted classification for acute inhalation toxicity, and RAC was requested, based on Article 77(3)(c), to review its opinion of 14 September 2018 in relation to the classification for acute inhalation toxicity.

RAC took note of the new information, but concluded that the classification agreed by the Committee in 2018 as Acute Tox. 3; H331, with an ATE of 3.0 mg/L/4h is still warranted.

Requests under Article 77(3)(c)

RAC and SEAC adopted their final opinions on a request from the European Commission under Article 77(3)(c) regarding revisions of derogations from the PFOA/PFCAs restriction.

The opinions will be available on ECHA's website in the near future.
Committee for Risk Assessment
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