Annex to a news

Helsinki, 23 March 2021

Highlights from March RAC and SEAC meetings

REACH restrictions

Intentionally added microplastics

RAC adopted a supplementary opinion on an Article 77(3)(c) request on the proposed restriction on intentionally-added microplastics, taking into account new elements which emerged after RAC had adopted its final opinion in June 2020.

More: Request to the Committee for Risk Assessment to prepare a supplementary opinion on the restriction dossier on intentionally-added microplastics

Undecafluorohexanoic acid (PFHxA), its salts and related substances

The opinion development process has been extended on this restriction proposal (submitted by Germany) concerning the manufacture, use and placing on the market of PFHxA, its salts and related substances. Agreement is expected in June 2021 instead.

Substances in single-use baby diapers

SEAC and RAC commenced their discussions on this restriction proposal submitted by France. The dossier concerns hazardous substances, that may be present 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.

Lead in outdoor shooting and fishing

Both RAC and SEAC concluded that the restriction proposal submitted by ECHA in January 2021 conforms to the requirements for a restriction proposal set in Annex XV. The proposed restriction aims at 'addressing the risks for human health and the environment posed by the use of lead in ammunition, i.e. gunshot used in terrains other than wetlands, bullets and pellets used both in wetlands and in terrains other than wetlands, as well as of lead in fishing tackle' as per the request of the Commission. The restriction proposal is complementary to the existing restriction on the use of lead gunshot in wetlands. The six-month consultation will be launched on 24 March 2021.

Applications for authorisation

RAC and SEAC adopted three opinions on applications for authorisation. The adopted opinions concern uses of octylphenol ethoxylates as a surfactant in the manufacture of biopharmaceuticals and in an *in-vitro* diagnostic device developer solution.

RAC and SEAC agreed on 11 draft opinions on applications for authorisation of uses of chromium trioxide and bis(2-methoxyethyl) ether (diglyme). Nine of the agreed draft opinions concern uses of chromium trioxide in chrome plating for the sanitary and automotive industry sectors, as well as in a surface pre-treatment (so called 'etching') step, and as colouring and hardening agent for stainless steel plates. The remaining two opinions are on uses of diglyme as a carrier solvent in fluoropolymer surface modification.

Similarly, SEAC also agreed on four addenda to opinions which had been adopted by the two Committees in 2016-2018. Following a request by the European Commission, the applicants submitted to ECHA substitution plans, which were not parts of the application reports during the days of their original submission, and the addenda provide SEAC's conclusions on these.

RAC adopted 15 opinions on harmonised classification and labelling

Ethyl acrylate (EC 205-438-8, CAS 140-88-5)

Ethyl acrylate is used in articles, in formulation or re-packing, at industrial sites and in manufacturing. The substance has current Annex VI entries as highly flammable liquid and vapour (Flam. Liq. 2; H225), harmful if swallowed (Acute Tox. 4*; H302), harmful in contact with skin (Acute Tox. 4*; H312), harmful if inhaled (Acute Tox. 4*; H332), causes skin irritation (Skin Irrit. 2; H315) with an SCL of 5%, causes serious eye irritation (Eye Irrit. 2; H319) with an SCL of 5%, may cause an allergic skin reaction (Skin Sens. 1; H317) and may cause respiratory irritation (STOT SE 3; H335) with an SCL of 5%.

RAC agreed to the proposal by Austria to modify the acute toxicity classifications to harmful if swallowed (Acute Tox. 4; H302) with an ATE of 1120 mg/kg bw, harmful in contact with skin (Acute Tox. 4; H312) with an ATE of 1800 mg/kg bw and toxic if inhaled (Acute Tox. 3; H331) with an ATE of 9 mg/L (vapours).

Methyl acrylate (EC 202-500-6, CAS, 96-33-3)

Methyl acrylate is used in articles, at industrial sites and in manufacturing. The substance has current Annex VI entries as highly flammable liquid and vapour (Flam. Liq. 2; H225), harmful if swallowed (Acute Tox. 4*; H302), harmful in contact with skin (Acute Tox. 4*; H312), harmful if inhaled (Acute Tox. 4*; H332), 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 may cause respiratory irritation (STOT SE 3; H335).

RAC agreed to the proposal by Austria to modify the acute toxicity classifications to harmful if swallowed (Acute Tox. 4; H302) with an ATE of 500 mg/kg bw, harmful in contact with skin (Acute Tox. 4; H312) with an ATE of 1100 mg/kg bw and toxic if inhaled (Acute Tox. 3; H331) with an ATE of 3 mg/L (vapours).

Allyl methacrylate (EC 202-473-0, CAS 96-05-9)

Allyl methacrylate is used by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance has current Annex VI entries as flammable liquid and vapour (Flam. Liq. 3; H226), harmful if swallowed (Acute Tox. 4*; H302), harmful in contact with skin (Acute Tox. 4*; H312), toxic if inhaled (Acute Tox. 3*; H331) and very toxic to aquatic life (Aquatic Acute 1; H400).

RAC agreed to the proposal by Austria to modify the acute toxicity classifications to harmful if swallowed (Acute Tox. 4; H302) with an ATE of 400 mg/kg bw, toxic in contact with skin (Acute Tox. 3; H311) with an ATE of 300 mg/kg bw and fatal if inhaled (Acute Tox. 2; H330) with an ATE of 1.5 mg/L (vapours).

4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF (EC 216-036-7, CAS 1478-61-1)

Bisphenol AF (BPAF) is used e.g. as a reactive process regulator in polymer materials and in rubber production and processing. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify BPAF as a substance that may damage fertility (Repr. 1B; H360F).

Benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro- 2-(4-hydroxy-phenyl)propan-2-yl]phenolate (EC 479-100-5, CAS 577705-90-9)

Benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro- 2-(4-hydroxy-phenyl)propan-2-yl]phenolate (BDDP-BPAF) is used e.g. in fluoropolymers manufacturing. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify BDDP-BPAF as a substance that may damage fertility (Repr. 1B; H360F).

Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethyl-idene]bis[phenol] (1:1) (EC 278-305-5, CAS 75768-65-9)

Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethyli-dene]bis[phenol] (1:1) (BTP-BPAF) is used e.g. in fluoropolymers manufacturing. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify BTP-BPAF as a substance that may damage fertility (Repr. 1B; H360F).

Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxy-phenyl)propan-2-yl]phenolate (1:1) (EC -, CAS -)

Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(di-ethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1) (reaction mass BDDP-BPAF) is used e.g. in vulcanization system of fluoro-elastomers and in the manufacture of fine chemicals and rubber products. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify reaction mass BDDP-BPAF as a substance that may damage fertility (Repr. 1B; H360F).

Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethyl-idene]bis[phenol] (1:1) (EC -, CAS -)

Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltri-phenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1) (reaction mass BTP-BPAF) is used e.g. in manufacturing of rubber articles and as a fluoro-elastomer. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Sweden to classify reaction mass BTP-BPAF as a substance that may damage fertility (Repr. 1B; H360F).

3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate, TODI (EC 202-112-7, CAS 91-97-4)

TODI is used in articles and at industrial sites. The substance has no existing entry in Annex VI to the CLP Regulation.
RAC agreed to the proposal by France and Germany to classify TODI as a substance that is

suspected of causing cancer (Carc. 2; H351), may cause allergy or asthma symptoms or breathing difficulties (Resp. Sens. 1; H334) and may cause an allergic skin reaction (Skin Sens. 1A; H317) with an SCL of 0.001%.

Cinnamaldehyde (EC 203-213-9 and 604-377-8, CAS 104-55-2 and 14371-10-9)

Cinnamaldehyde is used in cosmetics, cleaning agents, polishes and wax blends, air care products, biocidal products and pharmaceuticals. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Denmark to classify cinnamaldehyde as a substance that may cause an allergic skin reaction (Skin Sens. 1A; H317) with an SCL of 0.01%.

Foramsulfuron (ISO) (EC -, CAS 173159-57-4)

Foramsulfuron (ISO) is a sulfonyl-urea herbicide mainly used in corn and sugarbeet. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Finland to classify foramsulfuron (ISO) as a substance that is suspected of causing cancer (Carc. 2; H351), 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=100).

Mepiquat chloride (ISO) (EC 246-147-6, CAS 24307-26-4)

Mepiquat chloride (ISO) is a plant growth regulator which is mainly used in cereals. The substance has current Annex VI entries as harmful if swallowed (Acute Tox. 4*; H302) and harmful to aquatic life with long lasting effects (Aquatic Chronic 3; H412).

RAC agreed to the proposal by Finland to modify the acute toxicity classification to toxic if swallowed (Acute Tox. 3; H301), but with an oral ATE of 270 mg/kg bw, and to add harmful if inhaled (Acute Tox. 4; H332) with an ATE of 2.8 mg/L (dusts or mists). Contrary to the proposal by the Dossier Submitter, RAC did not agree to classify mepiquat chloride (ISO) as a substance which may cause damage to the nervous system (STOT SE 2; H371 (nervous system)) or a substance which is suspected of damaging the unborn child (Repr. 2; H361d). However, the Committee agreed to retain the classification as harmful to aquatic life with long lasting effects (Aquatic Chronic 3; H412).

Transfluthrin (ISO) (EC 405-060-5, CAS 118712-89-3)

Transfluthrin is a fast-acting pyrethroid insecticide intended for use by non-professional users and is approved for product-type 18 uses (insecticides, acaricides and products to control other arthropods). The substance has a current Annex VI entry as a substance which causes skin irritation (Skin Irrit. 2; H315), is 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 Germany to add classifications as a substance which is harmful if swallowed (Acute Tox. 4; H302) with an ATE of 583 mg/kg bw, suspected of causing cancer (Carc. 2; H351), causes damage to the nervous system (STOT SE 1; H370), and to add M-factors to the classifications as a substance which is very toxic to aquatic life (Aquatic Acute 1; H400, M=1000) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=1000).

Benfluralin (ISO) (EC 217-465-2, CAS 1861-40-1)
Benfluralin (ISO) is an active substance in the scope of the Regulation (EC) 1107/2009. The

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

RAC agreed to the proposal by Norway to classify benfluralin (ISO) as a substance suspected of causing cancer (Carc. 2; H351), suspected of damaging the unborn child (Repr. 2; H361d), 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), is 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). Contrary to the Dossier Submitter, RAC did not agree to classify benfluralin (ISO) as a substance which may cause harm to breast-fed children (Lact.; H362) and which may cause damage to organs (STOT SE 2; H371).

Methyl methacrylate (EC 201-297-1, CAS 80-62-6)

RAC adopted its opinion on the methyl methacrylate dossier at RAC-52B in October 2020. However, due to new information relevant to the classification for respiratory sensitisation, exceptionally and in the interest of accuracy and transparency, the Chair of the Committee 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 (Resp. Sens. 1; H334) as a result of the new information.

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