Annex to news

Helsinki, 9 June 2022

Highlights from June RAC and SEAC meetings

REACH restrictions

Lead in outdoor shooting and fishing

RAC adopted and SEAC agreed 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 outdoor shooting (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. The consultation on the draft SEAC opinion will be launched on 29 June 2022 for 60 days. SEAC is expected to adopt its opinion in December 2022.

More:
- RAC backs restricting lead in outdoor shooting and fishing, 31 May 2022
- Lead in outdoor shooting and fishing: SEAC agrees draft opinion, 3 June 2022

Dechlorane Plus

SEAC adopted its opinion on this restriction proposal submitted by Norway, following the consultation on the draft SEAC opinion which finished on 16 May 2022. Dechlorane Plus is primarily used as a flame retardant in plastic and has very persistent and very bioaccumulating hazard properties. SEAC reconfirmed that a restriction is, in general, an appropriate EU-wide measure to address the identified risks and that any of the restriction options proposed could be proportionate in terms of the benefits and costs to society.

2,4-dinitrotoluene (2,4-DNT)

RAC and SEAC concluded their opinions on this restriction proposal. The proposal 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 they pose a risk to people or the environment because of their use in articles. The consultation on the draft SEAC opinion will be launched on 15 June 2022 for 60 days. SEAC is expected to adopt its opinion in September 2022.

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

RAC discussed its draft opinion for the restriction proposal submitted by ECHA in October 2021. SEAC did not discuss the opinion at its plenary meeting and is scheduled to agree its draft opinion in September 2022.

PFASs in firefighting foams

RAC and SEAC discussed their first draft opinions for the restriction proposal submitted by ECHA in January 2022 which concerns the banning of the formulation and use of firefighting foams containing PFASs. The proposal includes transitional periods for certain sectors to ensure that fire safety is maintained during the transition to firefighting foams that do not contain PFASs.

Creosote and creosote-related substances

Both RAC and SEAC concluded that the restriction proposal submitted by France in February 2022 did not conform to the requirements for a restriction proposal in Annex XV. The proposal concerns the restriction of creosote and creosote-related substances and is intended to be complementary to the provisions of the biocidal products regulation for creosote. France may resubmit a revised proposal within 60 days.

Terphenyl, hydrogenated

Both RAC and SEAC concluded that the restriction proposal for terphenyl, hydrogenated submitted by ECHA in October 2021 conforms to the requirements of Annex XV for a restriction proposal. A six-month stakeholder consultation will be launched in June 2022.

N,N-dimethylacetamide; 1-ethylpyrrolidin-2-one (NEP)

Both RAC and SEAC concluded that the restriction proposal submitted by The Netherlands in April 2022 conforms to the requirements of Annex XV for a restriction proposal. The proposal concerns occupational exposure to DMAC and NEP. A six-month stakeholder consultation will be launched in June 2022.

RAC adopts 10 opinions on harmonised classification and labelling

Glyphosate (EC 213-997-4, CAS 1071-83-6)

Glyphosate is an active substance used in herbicide plant protection products (to control plants). It is one of the most widely used active substances in pesticides. Glyphosate has an existing entry in Annex VI to the CLP Regulation as a substance that causes serious eye damage (Eye Dam. 1; H318) and is toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Sweden to retain the current classification of glyphosate.

More: Glyphosate: no change proposed to hazard classification, news release ECHA/NR/22/10, 30 May 2022

7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate (EC 219-207-4, CAS 2386-87-0)

7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate is a cycloaliphatic liquid epoxy resin used in a number of industrial sectors including inks and coatings, electricity and electronics. It is also used in the manufacture of polymers. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Ireland to classify 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate as a substance which may cause an allergic skin reaction (Skin Sens. 1; H317), which is suspected of causing genetic defects (Muta. 2; H341) and which may cause damage to the nasal cavity through prolonged or repeated exposure (STOT RE 2; H373 (nasal cavity)).

Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl}naphthalene-2,7-disulfonate; [3]

(EC 241-164-5 [1], - [2], - [3], CAS 17095-24-8 [1], - [2], 100556-82-9 [3])

The three substances are used as a colouring agent for textiles and black toner particles. The substances have no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify these as substances which may cause allergy or asthma symptoms or breathing difficulties if inhaled (Resp. Sens. 1A; H334) and may cause an allergic skin reaction (Skin Sens. 1; H317).

2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (EC 438-340-0, CAS 119344-86-4)

2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one is used as a photoinitiator in UV-inks and coatings in various formulations, industrial and wide dispersive and widespread professional uses, as well as in article service life uses. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Austria to classify 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one as a substance which may damage fertility but (in contrast to the proposal from Austria) as a substance which is suspected of damaging the unborn child (Repr. 1B; H360Df instead of Repr. 1B; H360FD), which is very toxic to aquatic life (Aquatic Acute 1; H400 (M-factor of 1)) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410 (M-factor of 1)).

Formic acid ... % (EC 200-579-1, CAS 64-18-6)

Formic acid … % is used in the industrial manufacture of polymers and resins, in polymer processing, industrial use as a processing aid, industrial use in laboratories and also as an intermediate, in coatings and in cleaning agents. Formic acid…% has an existing entry in Annex VI to the CLP Regulation as a substance that causes severe skin burns and eye damage (Skin Corr. 1A; H314).

RAC agreed to the proposal by Belgium to add to the current classification that formic acid … % is a flammable liquid (Flam. Liq. 3; H226, with C >85 %), may be corrosive to metals (Metal Corr. 1; H290, but with no specific concentration limit assigned), is harmful if swallowed (Acute Tox. 4; H302, with an ATE=500 mg/kg bw), toxic if inhaled (Acute Tox. 3; H331, with an ATE=7.4 mg/L (vapours)) and causes serious eye damage (Eye Dam. 1; H318, with C > 10 %). Furthermore, RAC agreed to add the supplementary hazard statement EUH071 to the labelling of the substance.

Dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid (EC 217-635-6, CAS 1918-00-9)

Dicamba is a herbicide which is used on field crops and has a systemic effect on a range of broadleaf weeds. The substance is currently classified as harmful if swallowed (Acute Tox. 4*, H302), causes serious eye damage (Eye Dam. 1; H318) and is harmful to aquatic life with long lasting effects (and Aquatic Chronic 3; H412).

RAC agreed to the proposal by Denmark to add to the classification that dicamba is harmful if inhaled (Acute Tox. 4; H332, with an ATE=4.0 mg/L), suspected of causing cancer (Carc. 2; H351), may cause respiratory irritation (STOT SE 3; H335) and may cause drowsiness or dizziness (STOT SE 3; H336). Furthermore, RAC agreed to classify the substance as very toxic to aquatic life (Aquatic Acute 1; H400, with M=1) and toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411). RAC also agreed to add an ATE=1 500 to the oral toxicity classification (Acute Tox. 4; H302).

Peracetic acid … % (EC 201-186-8, CAS 79-21-0)

Peracetic acid … % is a biocidal active substance with bactericidal, fungicidal, and virucidal activity. Peracetic acid is mainly used as a bactericide, fungicide or virucide. Moreover, indications of potential efficacy against amoebae and algae have been reported. Peracetic acid … % has an existing entry in Annex VI to the CLP Regulation as a flammable liquid (Flam. Liq. 3; H226), heating may cause fire (Org. Perox. D****; H242), harmful if inhaled (Acute Tox. 4*; H332), harmful in contact with skin (Acute Tox. 4*; H312), harmful if swallowed (Acute Tox. 4*; H302), causes severe skin burns and eye damage (Skin Corr. 1A; H314) and is very toxic to aquatic life (Aquatic Acute 1; H400).

RAC agreed to the proposal by Finland to remove the classification as a flammable liquid (Flam. Liq. 3; H226), and to retain the classification as very toxic to aquatic life (Aquatic Acute 1; H400, M=10). In addition RAC agreed to modify the classification as heating may cause fire (Org. Perox. D; H242) by removing the **** and adding the note T. RAC also agreed to modify the existing acute toxicity classifications to fatal if inhaled (Acute Tox. 2; H330, with an ATE=0.2 mg/L (dusts and mists)), fatal in contact with skin (Acute Tox. 2, H310, with an ATE=60 mg/kg bw) and toxic if swallowed (Acute Tox. 3; H301, with an ATE=80 mg/kg bw). Furthermore, RAC agreed to add to the classification that peracetic acid … % is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410; M=100).

Formaldehyde … % (EC 200-001-8, CAS: 50-00-0)

Formaldehyde … % is an existing biocidal active substance approved in accordance with Regulation (EU) No 528/2012. It is used in adhesives and sealants, paints and coating products, inks and toners, polymers, fuels, biocides (e.g. disinfectants, pest control products), polishes and waxes, washing and cleaning products, cosmetics, personal care products, machine wash liquids/detergents, automotive care products, fragrances and air fresheners, metal, wooden and plastic construction and building materials, flooring, furniture, toys, textiles (e.g. curtains, carpet, clothing), footwear, leather products, paper and cardboard products, electronic equipment. The substance is currently classified as toxic if inhaled (Acute Tox. 3*; H331), toxic in contact with skin (Acute Tox. 3*; H311), toxic if swallowed (Acute Tox. 3*; H301), causes severe skin burns and eye damage (Skin Corr. 1B; H314), may cause an allergic skin reaction (Skin Sens. 1; H317), is suspected of causing genetic defects (Muta. 2; H341) and may cause cancer (Carc. 1B; H350).

RAC agreed to the proposal by Germany to modify the existing classifications to fatal if inhaled (Acute Tox. 2; H330, with an ATE=100 ppm (gases)), harmful if swallowed (Acute Tox. 4; H302, with an ATE=500 mg/kg bw) and may cause an allergic skin reaction (Skin Sens. 1A; H317). Contrary to the proposal by the dossier submitter, RAC did not agree to classify the substance as toxic in contact with skin (Acute Tox. 3; H311) or as a flammable gas (Flam. Gas 1B; H221).

S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC -; CAS 87392-12-9)

S-metolachlor is a herbicide in maize and sunflower. The substance has an existing entry in Annex VI to the CLP Regulation as a substance that may cause an allergic skin reaction (Skin Sens. 1; H317), 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 to the existing classification that the substance is suspected of causing cancer (Carc. 2; H351) and M=10 for both aquatic acute and chronic hazards. RAC did not agree with the dossier submitter to classify s-metolachlor as suspected of

damaging the unborn child (Repr. 2; H361d) and may cause damage to skin (STOT RE 2; H373 (skin)), but agreed to add the supplementary hazard statement EUH066.

Silver

Silver is used in biocidal products. It is used in products categorised in the following product types: disinfectants and algaecides not intended for direct application to humans or animals, food and feed area disinfection, drinking water disinfection, preservatives for liquid-cooling and processing systems. Some of these uses may result in a vast range of consumer applications. Apart from biocidal use, silver is widely used by industry, professionals and consumers. Silver has no current Annex VI entry.

RAC agreed to classify silver as a substance that may cause damage to the nervous system (STOT RE 2; H373 (nervous system)) and is suspected of damaging fertility (Repr. 2; H361f). RAC did not support the proposal by Sweden to classify silver as a substance that may cause an allergic skin reaction (Skin Sens. 1; H317), is suspected of causing genetic defects (Muta. 2; H341) and may damage the unborn child (Repr. 1B; H360D). For the aquatic toxicity classification, RAC decided to split the classification as follows – to recommend no classification for silver massive (particle diameter ≥ 1 mm), 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) for silver powder (particle diameter > 100 nm < 1 mm) and the same classification for silver nano (particle diameter > 1 nm ≤ 100 nm), but with acute and chronic M-factors of 1 000.

Applications for authorisation

RAC and SEAC agreed on 10 opinions on applications for authorisation and two opinions on review reports for authorisation. The agreed opinions concern:

- the use of **trichloroethylene** used as extraction solvent in the manufacture of polyethylene separators for lead-acid batteries;
- the industrial use of **trichloroethylene** as an extraction solvent for the purification of caprolactam from caprolactam oil;
- the use of **4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated** as a detergent in the purification of lipidated OspA proteins subsequently used in the manufacturing of a Lyme disease vaccine candidate;
- the use of **4-nonylphenol, branched and linear, ethoxylated** in mixing epoxy resin, resulting in mixtures for the manufacture of glass fibre articles for critical composite helicopter parts;
- the industrial use of **chromium trioxide** in the pre-treatment (etch) in the chrome plating process of automotive plastic components;
- the industrial use of **chromium trioxide** in the chrome plating of automotive plastic components;
- the use of **chromium trioxide** in electroplating of different types of substrates to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications;
- four uses of **chromium trioxide** in the functional chrome plating of shock absorber rods for the automotive industry; and
- the industrial use of **2,2'-dichloro-4,4'-methylenedianiline (MOCA)** in the manufacture of hot cast polyurethane products.

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.