Annex to news: Scientific committees support further restrictions of PFAS

Helsinki, 9 December 2021

REACH restrictions

Undecafluorohexanoic acid (PFHxA), its salts and related substances

In December 2021, SEAC adopted its final 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. RAC had already adopted its opinion on this proposal in June 2021. Due to the changes proposed by RAC in its opinion and the need to fully assess the large number of comments submitted to the consultation on the SEAC draft opinion, three additional months were made available to SEAC as per Article 71(3) of REACH.

Following the outcome of a 60-day stakeholder consultation (where 161 comments were received), amendments were made to the SEAC draft opinion agreed in June 2021.

In summary: SEAC considers that action is required at EU level to address the risks from PFHxA, its salts and related substances. This is to ensure a consistent level of protection of people and the environment across the EU and to maintain free movement of goods within the Union. The committee supports a restriction in general. However, while SEAC concluded that a restriction on certain uses was likely to be proportionate (e.g. textiles in consumer apparel, paper and cardboard in food contact materials and cosmetic products), uncertainties in the available information prevented SEAC from concluding that the proposed restriction as a whole was the most appropriate means to address the identified risk.

Substances in single-use baby diapers

SEAC adopted its final opinion on the restriction proposal submitted by France. The committee considers that it has not been demonstrated that the potential benefits of the proposed restriction are larger than the potential negative impacts and costs. There is insufficient justification for an EU-wide restriction and no basis for SEAC to support it. This conclusion is based on the following arguments:

- RAC's conclusion that there is not enough scientific evidence to conclude that certain chemicals found in single-use diapers or nappies pose a risk. This conclusion follows an evaluation of a proposal to restrict formaldehyde, PAHs, dioxins, furans and PCBs in baby diapers throughout the EU;
- Uncertainty on whether the substances in scope are detected in single-use baby diapers above the proposed migration levels;
- Uncertainty about the sources of any of the substances in scope that may be detected in the diapers. When it is not known where the substances come from, it is unclear what the diaper manufacturers and their supply chains would need to do to eliminate or reduce them;
- Uncertainty on whether industry would be able to comply with the proposed restriction and whether there are suitable measures available to eliminate or reduce the substances;

- Difficulty to reach a conclusion on the associated costs considering the uncertainties related to what industry would need to do, if anything, to comply with the restriction; and

- The benefits of the proposed restriction are not demonstrated. This conclusion is underpinned by the fact that there are no epidemiological studies or other quantification of negative health effects for children wearing single-use diapers, and by RAC's conclusion on risk.

SEAC considers, however, that the restriction proposed by France would have been practicable, monitorable and the most appropriate measure if an EU-wide risk related to single-use baby diapers would have been demonstrated. This would have limited the migration of formaldehyde and the sum of 17 detected or quantified PAHs, the sum of quantified PCDD/Fs and DL-PCBs, the sum of quantified PCBs.

RAC adopted its opinion on the restriction proposal in September. See news from 10 September 2021.

Lead in outdoor shooting and fishing

RAC and SEAC had their third 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 second 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 identifed as 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

RAC had its first discussions on the restriction proposal. 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. SEAC will have its first discussions at SEAC-54, closer to the end of a six- month stakeholder consultation, which will finish on 22 March 2022.

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

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

Applications for authorisation

RAC and SEAC adopted an opinion on the use of chromium trioxide and sodium dichromate for passivation of electrolytic tinplate.

In addition, RAC and SEAC agreed on five opinions on applications for authorisation. The agreed opinions concern:

- the use of dichromium tris(chromate) in the post treatment (reactive rinse) stage of autodeposition coating;
- the use of chromium trioxide in functional chrome plating of components with diverse geometries and dimensions for application in demanding industry sectors such as mechanical engineering, metalworking and processing, aerospace, automotive and medical technology;
- formulation of chromium trioxide-based electrolyte for electroplating process;
- the use of chromium trioxide in functional chrome plating of cylinders used in the rotogravure printing and embossing industry, and
- the use of chromic acid in the functional electroplating of brass-made sanitary articles with the specific purpose of obtaining a final Cr(0) coating that provides a surface with high durability and chemical resistance.

Additionally, RAC agreed on a draft opinion on the use of chromium trioxide for decorative/functional application in the furniture, sanitary and automotive sector.

RAC also updated the A-listing criteria for opinions on applications for authorisation. The updated document will soon be published on ECHA's website.

RAC adopted 11 opinions on harmonised classification and labelling

Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC: 255-894-7; CAS: 42576-02-3)

Bifenox, also in the form of potassium or ammonium salts, is an active substance (herbicide) in many plant protection products. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Poland to classify bifenox as a substance that is very toxic to aquatic life (Aquatic Acute 1; H400, M=1000) and which is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=1000). Furthermore, RAC decided to classify bifenox as harmful if swallowed (Acute Tox. 4; H302, with an ATE of 1500 mg/kg bw).

Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC: 275-728-7; CAS: 71626-11-4)

Benalaxyl is an active substance in pesticides, belonging to the phenylamide group name and acylalanine chemical group of systemic fungicides with apoplastic translocation which inhibits mycelial growth of fungi and germination of zoospores (fungistatic action). 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 Romania to add to the classification of benalaxyl that it is harmful if swallowed (Acute Tox. 4; H302) but with an oral ATE of 1000 mg/kg bw (the dossier submitter proposed 2000 mg/kg bw). RAC also agreed to add M=1 for both the aquatic acute and

aquatic chronic toxicity classifications. Contrary to the proposal by the dossier submitter, RAC found that benalaxyl does not warrant classification as a substance which causes damage to nervous system (STOT SE 2; H371) nor as suspected of causing cancer (Carc. 2; H351).

Tetramethylene dimethacrylate (EC: 218-218-1; CAS: 2082-81-7)

Tetramethylene dimethacrylate is used in different coating products, fillers, putties, plasters, modelling clay, paints, adhesives and sealants. It has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Finland to classify tetramethylene dimethacrylate as a substance that may cause an allergic skin reaction (Skin Sens. 1B; H317).

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (EC: 276-957-5; CAS: 72869-86-4)

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate is used in adhesives and sealants, coating products, polymers, inks and toners, laboratory chemicals and cosmetics and personal care products. It is also used in printing and recorded media reproduction, health services and scientific research and development, as well as for the manufacture of wood and wood products, pulp, paper and paper products and plastic products. It has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Finland to classify 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate as a substance that may cause an allergic skin reaction (Skin Sens. 1B; H317).

2,2'-ethylenedioxydiethyl dimethacrylate (EC: 203-652-6; CAS: 109-16-0)

2,2'-ethylenedioxydiethyl dimethacrylate is used in adhesives and sealants. As a liquid monomer, it is used in applications that come into contact with skin or nails. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Finland to classify 2,2'-ethylenedioxydiethyl dimethacrylate as a substance that may cause an allergic skin reaction (Skin Sens. 1B; H317).

2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol (EC: 221-665-5; CAS: 3179-89-3)

2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol (Disperse Red 17) is used to dye fabrics made of synthetic fibres such as polyester fibres. It is also used as a non-reactive hair colouring agent in oxidative hair dye formulations and as a non-reactive hair colouring agent (direct dye) in semi-permanent hair dye formulations. Disperse Red 17 is suspected to be used as colorant in tattoo inks and it may also be used for dyeing spectacle frames. The substance has no current Annex VI entry.

RAC agreed to the proposal by Germany to classify Disperse Red 17 as a substance that may cause an allergic skin reaction (Skin Sens. 1; H317).

4-methylimidazole (EC: 212-497-3; CAS: 822-36-6)

4-methylimidazole is used as an intermediate for chemical reactions in the manufacture of chemicals and chemical products. Furthermore, 4-methylimidazole occurs in food and beverages as it is formed in the Maillard reaction process. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Norway to classify 4-methylimidazole as a substance that may

cause cancer (Carc. 1B; H350) and which may damage fertility and is suspected of damaging the unborn child (Repr. 1B; H360Fd).

3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (EC 211-477-1; CAS 647-42-7)

3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol is used as an intermediate. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Germany to classify 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol as a substance that may cause damage to teeth and bones (STOT RE 2; H373), although the dossier submitter had proposed 'skeletal system' as the target organ. RAC did not agree with the dossier submitter to classify the substance as toxic to aquatic life with long lasting effects (Aquatic Chronic 2; H411), but decided that it warrants classification as a substance that is very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410, M=1).

1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC: 220-120-9; CAS: 2634-33-5)

1,2-benzisothiazolin-3-one is used with biocidal purposes as disinfectant or as preservative. It can also be used in scientific research and development and as a co-formulant in Plant Protection Products. The substance has a current Annex VI entry: Acute Tox. 4*; H302, Skin Irrit. 2; H315, Eye Dam. 1; H318, Skin Sens. 1; H317 (C ≥ 0.05 %) and Aquatic Acute 1; H400.

RAC agreed to the proposal by Spain to classify 1,2-benzisothiazolin-3-one as a substance that is harmful if swallowed (Acute Tox. 4; H302 with an ATE of 450 mg/kg), fatal if inhaled (Acute Tox. 2; H330 with an ATE of 0.21 mg/L, dusts and mists), 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). In addition, the Committee agreed that the substance may cause an allergic skin reaction, but that it met the criteria in CLP for Skin Sens. 1A; H317 and lowered the specific concentration limit to C ≥ 0.036 % for classification in this hazard class. RAC also disagreed with the dossier submitter on the removal of classification for skin irritation and decided that the substance should retain its existing harmonised classification (Skin Irrit. 2; H315).

1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.; Reaction mass of N-phenyl,N'-o-tolyl-phenylene diamine, N,N'-diphenyl-p-phenylene diamine and N,N'-di-o-tolyl-phenylene diamine (EC: 273-227-8; CAS: 68953-84-4)

1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs is not naturally found in the environment; it is used in synthetic materials such as polymers. Release to the environment of this substance is likely to occur from: outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials), outdoor use in long-life materials with high release rate (e.g. tyres, treated wooden products, treated textile and fabric, brake pads in trucks or cars, sanding of buildings (bridges, facades) or vehicles (ships)) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, footwear, leather products, paper and cardboard products, electronic equipment). The substance has no current Annex VI entry.

RAC agreed to the proposal by Germany to classify 1,4-benzenediamine, N,N'-mixed Ph and tolyl derivs as a substance that may cause an allergic skin reaction (Skin Sens. 1; H317), and which may damage fertility and the unborn child (Repr. 1B; H360FD).

Sulphur dioxide (EC: 231-195-2; CAS: 7446-09-5)

Sulfur dioxide is used as a fungicide in the context of the BPR. Additionally, it has a broad spectrum of uses within industrial settings including winemaking, water treatment and metal purification. The substance has a current Annex VI entry as a gas under pressure, may explode

if heated (Press. Gas; H280, with Notes U and 5), causes severe skin burns and eye damage (Skin Corr. 1B; H314) and is toxic if inhaled (Acute Tox. 3*; H331).

RAC did not agree to the proposal by Germany to add to the current classification that the substance is suspected of causing genetic defects (Muta. 2; H341) and concluded instead that it not be classified due to inconclusive data. RAC also did not support the proposal that it may cause an allergic skin reaction (Skin Sens. 1; H317) or that the substance may cause respiratory irritation (STOT SE 3; H335). RAC also concluded that sulfur dioxide should be classified as a substance that causes damage to respiratory system via the inhalation route (STOT SE 1; H370). Furthermore, RAC agreed to add an ATE of 1000 ppmV (gases) to the acute inhalation toxicity classification (Acute Tox. 3; H331).

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.