Annex to a news release

Helsinki, 17 June 2020

ECHA's committees recommend restricting a subgroup of PFAS

REACH restrictions

Intentionally added microplastics

RAC adopted its opinion in support of the proposal by ECHA. 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. SEAC agreed on its draft opinion and concluded that the proposed restriction is the most appropriate EU-wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its costs. The 60-day consultation on the SEAC draft opinion launches on 1 July 2020.

Calcium cyanamide

RAC and SEAC also supported ECHA's proposal to restrict the placing on the market of calcium cyanamide used as a fertiliser. The 60-day consultation on the SEAC draft opinion launches on 24 June 2020.

Skin sensitising substances

SEAC also agreed on its draft opinion on France and Sweden's proposal to restrict skin sensitising substances in finished textile, leather, hide and fur articles, placed on the market for the first time. In March 2020, RAC concluded that the restriction proposed by the dossier submitter is the most appropriate EU-wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability. The 60-day consultation on the SEAC draft opinion launches on 24 June 2020.

Perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances

SEAC adopted its final opinion in support of the proposal by Norway. SEAC concluded that the proposed restriction is the most appropriate EU-wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its costs.

Cobalt salts and formaldehyde

Consultations on the agreed SEAC opinions (cobalt salts and formaldehyde) have finished and the committee is expected to adopt its opinions at its September 2020 meeting.

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Scientific evaluations on occupational exposure limits

RAC adopted its opinions on occupational exposure limits (OELs) for lead and its compounds, and diisocyanates, which will be the subject of a separate news.

Applications for authorisation

RAC and SEAC adopted seven opinions on applications for authorisation. The first adopted opinion concerns the use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances in the refrigerant solution.

The other adopted opinions are on five uses of octylphenol ethoxylates and one use of nonylphenol ethoxylates in production of *in vitro* testing devices for Life Sciences sector.

RAC agreed on 31 draft opinions on applications for authorisation of uses of octyl- and nonylphenol ethoxylates; pitch, coal tar, high temperature and anthracene oil. SEAC agreed on 19 draft opinions on the uses of octyl- and nonylphenol ethoxylates.

RAC agreed on three draft opinions on the use of pitch, coal tar, high temperature, and two them included also use of anthracene oil, to manufacture formulations for various industrial uses. The other 28 draft opinions were on the uses of octylphenol ethoxylates and nonylphenol ehoxylates in the life sciences and pharmaceutical sectors.

SEAC agreed on 19 uses of octyl- and nonylphenol ethoxylates in the life sciences and pharmaceutical sectors.

Furthermore, RAC and SEAC discussed key issues in 11 applications for authorisation and one review report, which were received by ECHA in February 2020. Of these, eight are related to the uses of octylphenol ethoxylates and nonylphenol ethoxylates in formulation and use of *in vitro* diagnostic assays, manufacturing of human and veterinary pharmaceuticals, as well as in the Aerospace industrial sector. The other three are on uses of chromium (VI) substances in surface treatment applications. The review report is on the industrial use of trichloroethylene as process chemical in enclosed systems. The committees will continue their work on the opinion development on these applications for authorisation and the review report.

Harmonised classification and labelling – RAC adopted 11 opinions

Tellurium (EC: 236-813-4; CAS: 13494-80-9)

The substance tellurium is used in the processing of alloys, production of electronic devices, thin film production by physical vapour deposition and in coatings and photovoltaic solar cells.

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

RAC agreed to the proposal by the Netherlands to classify tellurium as a substance that may damage the unborn child (Repr. 1B). Furthermore, RAC agreed to classify the substance as suspected of damaging fertility (Repr. 2) and that may cause harm to breast-fed children (Lact.; H362).

Tellurium dioxide (EC: 231-193-1; CAS: 7446-07-3)

The substance tellurium dioxide is used in the manufacture of basic metals, including alloys and the manufacture of other non-metallic mineral products, e.g. plasters, cement. Further uses are in rubber production, and in the glass and ceramic industry as a colouring agent.

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

RAC agreed to the proposal by the Netherlands to classify tellurium as a substance that may damage the unborn child (Repr. 1B). Furthermore, RAC agreed to classify the substance as suspected of damaging fertility (Repr. 2) and that may cause harm to breast-fed children (Lact.; H362).

Piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether (EC: 200-076-7; CAS: 51-03-6)

The substance piperonyl butoxide is a synergist and a biocidal active substance in the scope of the Biocidal Product Regulation.

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

RAC agreed to the proposal by Greece to classify piperonyl butoxide as a substance that may cause respiratory irritation (STOT SE 3) and as very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1). Furthermore, RAC agreed to classify the substance as causing serious eye irritation (Eye Irritation 2).

Trichlorosilane (EC: 233-042-5; CAS: 10025-78-2)

The substance trichlorosilane is used as an intermediate in the production of other silicon-based substances, as a monomer in the production of silicone polymers and resins (usually in combination with other chlorosilanes), in the semiconductor industry and as a laboratory reagent in research and development activities.

The substance has an existing entry in Annex VI to the CLP Regulation as extremely flammable liquid and vapour (Flam. Liq. 1), catching fire spontaneously if exposed to air (Pyr. Liq. 1), harmful if swallowed (Acute Tox. 4*), harmful if inhaled (Acute Tox. 4*) as well as causing severe skin burns and eye damage (Skin Corr. 1A).

RAC agreed to the proposal by Germany to keep the classification as extremely flammable liquid and vapour (Flam. Liq. 1) and harmful if swallowed (Acute Tox. 4), and to remove the classification as catching fire spontaneously if exposed to air (Pyr. Liq. 1) and harmful if inhaled (Acute Tox. 4). Furthermore, RAC agreed to the proposal by Germany to add the supplementary hazard statement code EUH071 as well as the following hazards to the classification of the substance – in contact with water releases flammable gases which may ignite spontaneously (Water-react. 1), causing serious eye damage (Eye Dam. 1) and toxic if inhaled (Acute Tox. 3). Contrary to the proposal to modify the classification as a substance causing severe skin burns and eye damage (Skin Corr. 1B), RAC also agreed to retain the existing classification as Skin Corr. 1A.

Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate (EC: 227-561-6; CAS: 5888-33-5)

The substance isobornyl acrylate is an acrylic monomer that polymerises when exposed to sources of free radicals. It is used in plastic materials, also for valves, tubes lining, stoppers, sealants, coatings and inks, and also in the plastic materials used for the production of medical devices for diabetes patients.

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

Contrary to the proposal from Germany (for classification as Skin Sens. 1), RAC agreed to classify the substance as a substance that may cause an allergic skin reaction (Skin Sens 1A).

Clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine (EC: 277-728-2; CAS: 74115-24-5)

The substance clofentezine (ISO) is an active substance used as acaricide in plant protection products (PPP).

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

RAC agreed to the proposal by Spain to classify the substance as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1). However, the Committee did not agree with the dossier submitter to classify the substance as suspected of causing cancer (Carc. 2).

Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid (EC: 216-485-9; CAS: 1596-84-5)

The substance daminozide (ISO) is a plant protection product and is used as a plant growth regulator.

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

RAC agreed to the proposal by Czech Republic and Hungary to classify the substance as suspected of causing cancer (Carc. 2). The dossier submitters had originally proposed to classify the substance as a substance that may cause cancer (Carc. 1B), but changed their proposal during the opinion development process.

2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol (TBNPA) (EC: 253-057-0; CAS: 36483-57-5 and 1522-92-5)

The substance TBNPA is used as flame retardant, in the manufacture of polymers, plastic products and chemicals and as an intermediate.

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

RAC agreed to the proposal by Norway to not classify the substance for STOT RE and to classify the substance as a substance that may cause cancer (Carc. 1B). The Committee did not agree with the dossier submitter to classify the substance as a substance that may cause genetic defects (Muta. 1B), but agreed to a less severe classification - as a substance suspected of causing genetic defects (Muta. 2). Furthermore, RAC agreed with the DS to not classify the substance for reproductive toxicity.

Benzophenone (EC: 204-337-6; CAS: 119-61-9)

The substance benzophenone is used in air care products, polishes and waxes, washing and cleaning products, anti-freeze products, biocides (e.g. as a odoriferous agent in disinfectants, pest control products), inks and toners, perfumes and fragrances, pharmaceuticals and cosmetics and personal care products.

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

Contrary to the proposal by Denmark to classify the substance as suspected of causing cancer (Carc. 2), RAC agreed to a more severe classification, as a substance that may cause cancer (Carc. 1B).

Fluopicolide (ISO) (EC: 607-285-6; CAS: 239110-15-7)

The substance fluopicolide (ISO) is a fungicide. It has no existing entry in Annex VI to the CLP Regulation.

The dossier submitter (Austria) had proposed no classification for all human health classes assessed. RAC agreed to classify fluopicolide as a substance suspected of damaging the unborn child (Repr. 2).

2-Ethylhexanoic acid and its salts (EC: - ; CAS: -).

The substance 2-EHA is used in anti-freeze products, laboratory chemicals, metal working fluids, coating products, lubricants and greases. 2-EHA salts are reported to be present in coatings, inks, adhesives, sealants, elastomers, anti-freezing agents, lubricants and greases, heat transfer and hydraulic fluids.

2-EHA has an existing entry in Annex VI to the CLP Regulation as a substance suspected of damaging the unborn child (Repr. 2).

The dossier submitter (Spain) has proposed to add also the salts of 2-EHA to the existing entry on 2-EHA. RAC agreed to classify 2-EHA and its salts as substances that may damage the unborn child (Repr. 1B).

Article 77 (3) (c) request - DTPA-H5 (EC: 200-652-8)**, DTPA-K5** (EC: 404-290-3) **and DTPA-Na5** (EC: 205-391-3)

On 9 June 2017, RAC had adopted its opinion on the harmonised classification and labelling of DTPA-H5, DTPA-K5 and DTPA-Na5, which concluded that these substances should be classified as substances that may damage the unborn child (Repr. 1B). Additional information was provided by industry addressing the adopted classification for reproductive toxicity of these substances and RAC was requested, based on the Article 77(3)(c), to review the additional information and, if necessary, to amend the opinion of 9 June 2017.

RAC concluded that the classification agreed by the Committee in 2017 as Repr 1B is still warranted. However, RAC agreed that it is justified to add an SCL of 3% based on the low potency of DTPA-H_5, DTPA-K_5 and DTPA-Na_5.

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