

5 December 2018

Annex to a news release

RAC concludes on 19 opinions for harmonised classification and labelling and adopts its opinion on a restriction of substances used in tattoo inks. SEAC adopts a restriction proposal on C9-C14 PFCAs, their salts and precursors.

Helsinki, 5 December 2018

The Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) agreed on two restriction proposals.

C9-C14 PFCAs, their salts and precursors

SEAC adopted its final opinion, in support of the proposal by Germany and Sweden, to restrict the manufacturing, use, placing on the market and import of C9-C14 PFCAs (PFNA; PFDA; PFUnDA; PFDoDA; PFTrDA; PFTDA), their salts and precursors. This restriction is intended to prevent a switch by industry using PFOA-based substances to longer-chain PFCAs to fulfil the same role in the end products after the restriction for PFOA, its salts and PFOA-related substances will become effective in 2020. PFOA has been used because of its special properties such as high friction resistance, dielectric properties, resistance to heat and chemical agents, low surface energy, and water, grease, oil, and dirt repellence. Alternatives to C9-C14 PFCAs, as well as to PFOA, are currently being used.

SEAC reconfirmed 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. Having considered the 15 comments received during the public consultation on the draft opinion agreed in September 2018, SEAC introduced a higher threshold for impurities in certain fluoropolymers and made some adjustments in the justification for its opinion.

Substances used in tattoo inks and permanent make-up

RAC adopted its final opinion, in support of ECHA's proposal (prepared in collaboration with Denmark, Italy and Norway) to restrict the placing on the market and use of tattoo inks and permanent make-up containing a wide range of chemicals, e.g. carcinogens, mutagens, reprotoxicants, sensitisers and irritating substances.

SEAC agreed on its draft opinion on this restriction proposal. The public is invited to submit comments on the opinion between 12 December 2018 and 11 February 2019. After the consultation, SEAC will incorporate the comments and adopt its final opinion.

The Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) adopted three final authorisation opinions.

The committees discussed and adopted one opinion on the application for authorisation on the use of chromium trioxide to modify the properties of surfaces made of plastic, and two opinions on the review report for the use of PVC recyclate containing DEHP.

The Committee for Risk Assessment (RAC) adopted 19 opinions on harmonised classification and labelling**Potassium (oxido-NNO-azoxy)cyclohexane; cyclohexylhydroxydiazene 1-oxide, potassium salt; [K-HDO]**

The substance K-HDO is an active substance used in biocidal products as a fungicide.

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

RAC agreed to the proposal by Austria to classify the substance K-HDO for physical hazards as flammable solid category 1 (Flam. Sol. 1), as toxic if swallowed (Acute Tox. 3) with an acute toxicity estimate (ATE; oral) of 136 mg/kg bw for mixtures containing the substance; as a substance causing skin irritation and serious eye damage (Skin Irrit. 2 and Eye Dam. 1) and that may cause damage to liver through prolonged or repeated exposure (STOT RE 2). RAC also agreed to classify K-HDO for long-lasting aquatic hazards (Aquatic Chronic 2). Contrary to the proposal from Austria, RAC did not propose to include the gastrointestinal tract and kidney as target organs for repeated exposure toxicity classification.

Bis(N-hydroxy-N-nitrosocyclohexylaminato-O,O')copper; bis(N-cyclohexyl-diazanium-dioxy)-copper; [Cu-HDO]

The substance Cu-HDO is an active substance used in biocidal products.

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

RAC agreed to the proposal by Austria to classify the substance Cu-HDO for physical hazards as flammable solid category 1 (Flam. Sol. 1), as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE) of 360 mg/kg bw for mixtures containing the substance, as substance causing serious eye damage (Eye Dam. 1) and that may cause damage to liver through prolonged or repeated exposure (STOT RE 2). RAC also agreed to classify Cu-HDO for aquatic acute and chronic hazards (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 1 for environmental hazards.

Contrary to the proposal from Austria, RAC did not propose to include the gastrointestinal tract and kidney as target organs for repeated exposure toxicity classification.

Thiencarbazone-methyl (ISO); methyl 4-[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonylsulfamoyl]-5-methylthiophene-3-carboxylate

The substance thiencarbazone-methyl (ISO) is an active substance used in plant protection products as a herbicide.

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

RAC agreed to the proposal by the United Kingdom to classify the substance for hazards to aquatic environment as Aquatic Acute 1 and Aquatic Chronic 1 with multiplying factors of 1 000.

2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate; [DOTE]

The substance DOTE is an industrial chemical mostly used in articles, in formulation or re-packing, at industrial sites and in manufacturing.

The substance has an existing entry in Annex VI to the CLP Regulation (Repr. 1B; H360D).

RAC agreed to the proposal by Germany to classify DOTE as a substance that causes damage to immune system through prolonged or repeated exposure (STOT RE 1). Contrary to the proposal by Germany, RAC agreed to retain the existing classification for toxicity to reproduction (Repr. 1B; H360D) and to add classification for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) without multiplying factors.

Hexythiazox (ISO); trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxo-3-thiazolidine-carboxamide

The substance Hexythiazox (ISO) is an active substance used in plant protection products.

The substance has an existing entry in Annex VI to the CLP Regulation for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by Finland to add multiplying factors of 1 to the environmental classification.

Flurochloridone (ISO); 3-chloro-4-(chloromethyl)-1-[3-(trifluoromethyl)phenyl]pyrrolidin-2-one

The substance Flurochloridone (ISO) is an active substance used in plant protection products as a herbicide.

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

RAC agreed to the proposal by Spain to classify Flurochloridone (ISO) as harmful if swallowed (Acute Tox. 4) and to assign an acute toxicity estimate (ATE) of 500 mg/kg bw for mixtures containing the substance, as a substance that may cause an allergic skin reaction (Skin Sens. 1), as a substance that may damage the unborn child and, contrary to the proposal by Spain to classify as a substance that may damage fertility, to instead classify as a substance suspected of damaging fertility (Repr. 1B; H360DF). RAC also agreed on the proposal to classify Flurochloridone for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 100.

Iprovalicarb (ISO) isopropyl [(2S)-3-methyl-1-{{1-(4-methylphenyl)ethyl}amino}-1-oxobutan-2-yl]carbamate

The substance iprovalicarb (ISO) is an active substance used in plant protection products as a fungicide.

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

RAC agreed to the proposal by Ireland to classify the substance as suspected of causing cancer (Carc. 2; H351).

2,4-dinitrophenol

The substance 2,4-dinitrophenol is an industrial chemical used as an intermediate in the manufacture of other chemicals and as an additive in the manufacture of textiles, leather and fur. Since the early 20th century, it has been used (without a formal authorisation) as a weight loss agent, primarily for people who are attempting to lose fat but retain muscles.

The substance has an existing entry in Annex VI to the CLP Regulation for acute toxicity through all routes of exposure and for repeated dose toxicity (Acute Tox. 3 and STOT RE 2).

RAC agreed to the proposal by Germany to classify 2,4-dinitrophenol for acute toxicity through oral and dermal routes of exposure as fatal if swallowed and if in contact with skin and assigned acute toxicity estimates (ATEs) for mixtures containing the substance (ATE(oral)=30 mg/kg bw, ATE(dermal)=300 mg/kg bw).

Contrary to the proposal by Germany, RAC agreed to classify 2,4-dinitrophenol as a substance that causes damage through prolonged or repeated exposure (STOT RE 1) without specifying the target organ or the route of exposure.

Phosphine

The substance phosphine is an active substance used in plant protection products as an insecticide and as an industrial chemical in semiconductor products and for the manufacture of electrical, electronic and optical equipment.

The substance has an existing entry in Annex VI to the CLP Regulation for physical hazards as Press. Gas, Flam. Gas 1, for human health hazards for skin corrosion (Skin Corr. 1B), acute toxicity via the inhalation route of exposure (Acute Tox. 2*) and for hazards to aquatic environment (Aquatic Acute 1).

RAC agreed to the proposal by France to modify the existing acute toxicity classification and classify phosphine as fatal if inhaled (Acute Tox. 1) with an acute toxicity estimate (ATE) of 10 ppm/Volume for gas.

Dibenzo[def,p]chrysene

The substance dibenzo[def,p]chrysene is an industrial chemical that belongs to the group of polycyclic aromatic hydrocarbons (PAHs). PAHs are contained in petroleum and coal streams, and potentially in material derived thereof.

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

RAC agreed to the proposal by Germany to classify dibenzo[def,p]chrysene as a substance suspected of causing genetic defects (Muta. 2; H341) and that may cause cancer (Carc. 1B; H350) with a specific concentration limit of 0.001 % for mixtures containing the substance.

4,5-dichloro-2-octyl-2H-isothiazol-3-one [DCOIT]

The substance DCOIT (4,5-dichloro-2-octyl-2H-isothiazol-3-one) is an active substance used in biocidal products.

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

RAC agreed to the proposal by Norway to classify DCOIT as a substance harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE) of 567 mg/kg bw and to add a supplemental hazard information EUH071 for substances corrosive to the respiratory tract.

In addition, in accordance with the proposal by Norway, RAC agreed to classify DCOIT as a substance that causes severe skin burns without sub-categorisation and eye damage (Skin Corr. 1) and that may cause an allergic skin reaction (Skin. Sens. 1A). Contrary to the proposal by Norway, RAC classified DCOIT as fatal if inhaled (Acute Tox. 2) with an ATE of 0.16 mg/L and set different specific concentration limits (SCL) for mixtures containing the substance (0.025% for skin irritation and 0.0015% for skin sensitisation). RAC further agreed to the proposal by Norway to classify the substance for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 100.

Octhilinone (ISO); 2-octyl-2H-isothiazol-3-one; [OIT]

The substance octhilinone (ISO) [OIT] is an active substance used in biocidal products.

The substance has an existing entry in Annex VI of the CLP Regulation – minimum classifications for acute toxicity through all routes of exposure (Acute Tox. 4* for oral route and Acute Tox. 3* for dermal and inhalation routes), for skin corrosion (Skin Corr. 1B) and skin sensitisation (Skin Sens. 1) with a specific concentration limit of 0.05% for mixtures containing the substance as well as for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by the United Kingdom to modify the existing acute toxicity classifications as toxic if swallowed (Acute Tox. 3) with an acute toxicity estimate (ATE) of 125 mg/kg bw, as toxic in contact with skin (Acute Tox. 3) with an ATE of 311 mg/kg bw and as fatal if inhaled (Acute Tox. 2) with an ATE of 0.27 mg/L (dust and mist) for mixtures containing the substance. RAC further agreed to the proposal by the United Kingdom to retain the existing classifications for eye damage and skin corrosion, to add a supplemental hazard information EUH071 for substances corrosive to respiratory tract and to add multiplying factors of 100 to the hazards for aquatic environment.

Contrary to the proposal by the United Kingdom, RAC agreed to set a lower specific concentration limit for skin sensitisation (Skin Sens. 1A, SCL 0.0015 %) instead of 0.005%.

Pirimiphos-methyl (ISO)

The substance Pirimiphos-methyl (ISO) is an active substance used in plant protection products as an insecticide.

The substance has an existing entry in Annex VI of the CLP Regulation for Acute Tox. 4* and for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by the United Kingdom to classify pirimiphos-methyl (ISO) as harmful if swallowed (Acute Tox. 4) and to assign an acute toxicity estimate (ATE) of 1 414 mg/kg bw for mixtures containing the substance, as a substance causing damage to the nervous system through prolonged or repeated exposure (STOT RE 1) and for hazards to aquatic environment (Aquatic Acute 1 and Aquatic chronic 1) with multiplying factors of 1 000.

3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide; fluxapyroxad

The substance Fluxapyroxad is an active substance used in plant protection products as a fungicide.

The substance has no existing Annex VI entry.

RAC agree to the proposal by the United Kingdom to classify Fluxapyroxad for hazards to aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 1.

In addition, contrary to the proposal by the United Kingdom, RAC classified Fluxapyroxad as a substance that may cause harm to breast-fed children (Lact., H362).

Oxathiapiprolin (ISO); 1-(4-{4-[5-(2,6-difluorophenyl)-4,5-dihydro-1,2-oxazol-3-yl]-1,3-thiazol-2-yl}piperidin-1-yl)-2-[5-methyl-3-(trifluoromethyl)-1H-pyrazol-1-yl]ethanone

The substance Oxathiapiprolin (ISO) is an active substance used in plant protection products as a fungicide.

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

RAC agreed to the proposal by Ireland to classify Oxathiapiprolin (ISO) for hazards to the aquatic environment (Aquatic Chronic 1) with a multiplying factor of 1.

m-bis(2,3-epoxypropoxy)benzene; resorcinol diglycidyl ether

Resorcinol diglycidyl ether is an industrial chemical used as an epoxy resin and as a reactive diluent in the production of other epoxy resins.

The substance has an existing entry in Annex VI to the CLP Regulation for acute toxicity via oral and dermal routes of exposure (Acute Tox. 4), as a skin and an eye irritant (Skin Irrit. 2, Eye Irrit. 2) as a substance suspected of causing genetic defects (Muta. 2; H341) and carcinogenicity (Carc. 2; H351) and for hazards to aquatic environment (Aquatic Chronic 3).

RAC agreed to the proposal by the Netherlands to confirm the classification for acute oral toxicity (Acute Tox. 4) and to modify the acute dermal toxicity (Acute Tox. 3), but contrary to the proposal by the Netherlands, RAC applied converted acute toxicity point estimate (ATEs) of ATE(oral)=500 mg/kg bw and ATE(dermal)=300 mg/kg bw. RAC further agreed to the proposal by the Netherlands to classify resorcinol diglycidyl ether as a substance that may cause cancer (Carc. 1B; H350).

Silthiofam (ISO); N-allyl-4,5-dimethyl-2-(trimethylsilyl)thiophene-3-carboxamide

The substance silthiofam (ISO) is an active substance used in plant protection products as a fungicide.

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

RAC agreed to the proposal by Ireland to classify silthiofam (ISO) as a substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2) and for aquatic chronic hazards (Aquatic Chronic 2). Contrary to the proposal by Ireland, RAC did not classify silthiofam (ISO) for toxicity to reproduction.

Hexyl 2-(1-(diethylamino)hydroxyphenyl)methanoyl)benzoate; hexyl 2-[4-(diethylamino)-2-hydroxybenzoyl]benzoate (Uvinul A Plus)

The substance Uvinul A Plus is an industrial chemical used in cosmetics and personal care products as a UV filter.

The substance has an existing entry in Annex VI to the CLP Regulation for environmental hazards as Aquatic Chronic 4.

RAC did not agree to the proposal by Germany to change the environmental classification to category 1 as a substance that is very toxic to aquatic life with long-lasting effects. Instead, based on recent studies, RAC agreed that Uvinul A Plus does not warrant classification for hazards to the aquatic environment.

Lead

Lead has a large variety of uses. It has two entries in Annex VI to the CLP Regulation for massive and powder forms for toxicity to reproduction (Repr. 1A; H360FD).

RAC agreed to the proposal by Denmark to classify lead as very toxic to aquatic life and as very

toxic to aquatic life with long-lasting effects (Aquatic Acute 1 and Aquatic Chronic 1) and to add multiplying factors of 10 to the classifications.

This classification for hazards to the aquatic environment applies to both existing entries in Annex VI to the CLP Regulation.

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 the opinion of the Agency on applications for authorisation, proposals for restrictions and proposals for harmonised classification and labelling. 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 decision for proposals for harmonised classification and labelling, 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 RAC is available on ECHA's website at the link below:

<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>