19 September 2018

Annex to a news release

RAC concludes on 14 opinions for harmonised classification and labelling, RAC and SEAC agree on the restriction proposal for group of perfluorinated substances.

Helsinki, 19 September 2018

The Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) agreed on one restriction proposal

C9-C14 PFCAs, their salts and precursors

RAC 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 repellency. Alternatives to C9-C14 PFCAs as well as to PFOA are currently being used.

SEAC agreed on the draft opinion on this restriction proposal. A public consultation on the socio-economic aspects of the proposed restriction will be launched on 19 September 2018 and will remain open until 19 November 2018.

The Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) agreed on Article 77(3)(c) request to review a proposal for an additional derogation to the restriction of PFOA, its salts and PFOA-related substances

Both Committees adopted their opinions on an Article 77(3)(c) request to review a proposal for an additional derogation to the restriction of PFOA, its salts and PFOA-related substances (entry 68 of Annex XVII to REACH). This request is related to the use of perfluorooctance bromide (PFOB) for the manufacturing of pharmaceutical products for the treatment of pulmonary diseases. PFOB is excluded from the scope of the PFOA restriction, but it contains perfluorooctance iodide (PFOI) as an impurity in concentrations above the concentration threshold in the PFOA restriction. PFOI is a PFOA-related substance and thus covered by the restriction. Both Committees supported the inclusion of this additional derogation into the PFOA restriction.

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

The Committees discussed and adopted six opinions on applications for authorisation on the uses of chromium trioxide for [formulation and] chrome plating, dichromium tris(chromate), strontium chromate and pentazinc chromate octahydroxide in the aerospace and defence sectors.

The Committees for Risk Assessment (RAC) adopted 14 opinions on harmonised classification and labelling

Tribenuron-methyl (ISO); methyl 2-[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)-N-methylcarbamoylsulfamoyl]benzoate

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

The substance has an existing entry in Annex VI to the CLP Regulation for Skin Sens. 1, Aquatic Acute 1 and Aquatic Chronic 1 (M = 100).

RAC agreed to the proposal by Sweden to classify tribenuron-methyl (ISO) as a substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2) and to add a multiplying factor of 100 to the existing aquatic acute classification.

Dichlorodioctylstannane

The substance dichlorodioctylstannane is an industrial chemical used in closed processes as an intermediate in the manufacture of other substances.

The substance has an existing entry in Annex VI to the CLP Regulation for Acute Tox. 3*, STOT RE 1 and Aquatic Chronic 3.

RAC agreed to the proposal by Sweden to classify dichlorodioctylstannane as a substance that may damage the unborn child (Repr. 1B; H360D) and to set a specific concentration limit of 0.03 % for developmental toxicity. RAC also agreed to modify the acute toxicity classification for the inhalation route into category 2 with an acute toxicity estimate (ATE) of 0.0975 mg/l for mixtures containing the substance.

Trimethoxy(methyl)silane

The substance trimethoxy(methyl)silane is an industrial chemical used in adhesives and sealants, coating products and textile treatment products and dyes.

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

RAC did not find the available skin sensitisation data conclusive and thus, contrary to the proposal by Sweden, did not classify trimethoxy(methyl)silane as a skin sensitiser.

Sodium N-(hydroxymethyl)glycinate; [formaldehyde released from sodium N-(hydroxymethyl)glycinate]

The substance sodium N-(hydroxymethyl)glycinate is an active substance releasing formaldehyde used in biocidal products.

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

RAC supported the proposal by Austria to classify sodium N-(hydroxymethyl)glycinate as a substance that may cause cancer (Carc. 1B; H350) and as suspected of causing genetic defects (Muta 2; H341), assigning additional notes 9 and 8 to carcinogenicity and mutagenicity for classification of mixtures. RAC further supported the proposal to classify the substance as harmful if swallowed (Acute Tox. 4, ATE = 1050 mg/kg bw), causing skin irritation (Skin Irrit. 2), serious eye irritation (Eye Irrit. 2) and as a substance that may cause an allergic skin reaction (Skin

Sens. 1). In addition, contrary to the proposal by Austria, RAC classified sodium N-(hydroxymethyl)glycinate as a substance toxic if inhaled (Acute Tox. 3, ATE = 3 mg/l) and that may cause respiratory irritation (STOT SE 3).

4-{[(6-chloropyridin-3-yl)methyl](2,2-difluoroethyl)amino}furan-2(5H)-one; flupyradifurone

The substance flupyradifurone is an active substance used in plant protection products as an insecticide.

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

RAC agreed to the proposal by the Netherlands to classify flupyradifurone as a substance harmful if swallowed (Acute Tox. 4, ATE = 500 mg/kg bw), that may cause damage to the muscles through prolonged or repeated exposure (STOT RE 2) and for aquatic acute and chronic hazards (Aquatic Acute 1 and Aquatic Chronic 1). RAC also agreed to add multiplying factors of 10 to the environmental hazards. Contrary to the proposal by the Netherlands, RAC did not classify the substance for toxicity to reproduction.

Hymexazol (ISO); 3-hydroxy-5-methylisoxazole

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

The substance has an existing entry in Annex VI to the CLP Regulation for Acute Tox 4*, Eye Dam. 1 and for hazards to the aquatic environment (Aquatic Chronic 3).

RAC agreed to the proposal by Finland to classify hymexazol (ISO) as a substance that may damage the unborn child (Repr. 2; H361d), as a skin sensitiser (Skin Sens. 1) and for hazards to the aquatic environment (Aquatic Chronic 2). RAC also supported the proposal to confirm the existing classification for acute oral toxicity.

2-butoxyethanol; ethylene glycol monobutyl ether

The substance 2-butoxyethanol is an industrial chemical mainly used as a solvent.

The substance has an existing entry in Annex VI to the CLP Regulation as Acute Tox. 4* for all routes of exposure (minimum classification), Skin Irrit. 2 and Eye Irrit. 2.

RAC agreed to the proposal by Germany to classify 2-butoxyethanol as a substance toxic if inhaled (Acute Tox. 3, ATE = 3 mg/l) and harmful if swallowed (Acute Tox. 4, ATE = 1200 mg/kg bw).

Contrary to the proposal by Germany, RAC did not modify the existing classification for eye irritation and agreed to remove the existing classification as harmful in contact with skin. In addition, RAC did not support that the substance be classified as causing damage to the blood through prolonged or repeated exposure.

Geraniol; (2E)-3,7-dimethylocta-2,6-dien-1-ol

The substance geraniol is a fragrance used in cosmetics and in cleaning and maintenance products.

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

RAC agreed to classify geraniol as a substance that may cause allergic skin reaction (Skin Sens. 1) but, contrary to the proposal by Denmark, did not agree to specify the sub-category given the uncertainty about the potency of the substance.

Citral

The substance citral is a fragrance used in cosmetics and a variety of household products for cleaning and maintenance.

The substance has an existing entry in Annex VI to the CLP Regulation as Skin Irrit. 2 and Skin Sens. 1.

RAC did not agree to the proposal by Denmark to specify the subcategory for the existing harmonised classification for skin sensitisation due to uncertainties about the potency of the substance.

Dioctyltin dilaurate; [1] stannane, dioctyl-, bis(coco acyloxy) derivs. [2]

The substance dioctyltin dilaurate is an industrial chemical used in consumer's products, by professional workers at industrial sites and in the manufacture of other substances.

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

RAC agreed to the proposal by Sweden to classify dioctyltin dilaurate as a substance that causes damage to the immune system through prolonged or repeated exposure (STOT RE 1) and as a substance that may damage the unborn child (Repr. 1B, H360D).

Mesotrione (ISO); 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione

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

The substance has an existing entry in Annex VI to the CLP Regulation as Aquatic Acute 1 and Aquatic Chronic 1.

RAC agreed to the proposal by the United Kingdom to classify mesotrione (ISO) as a substance suspected of damaging the unborn child (Repr. 2), and to add multiplying factor of 10 to the existing environmental classifications.

Contrary to the proposal by the United Kingdom, RAC agreed to classify mesotrione (ISO) as a substance that may cause damage to eyes and the nervous system through prolonged or repeated exposure (STOT RE 2).

Mecetronium etilsulfate; N-ethyl-N,N-dimethylhexadecan-1-aminium ethyl sulfate; [MES]

The substance mecetronium ethyl sulphate [MES] is an active substance used in biocidal products as a disinfectant in human hygiene.

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

RAC agreed to the proposal by Poland to classify mecetronium ethyl sulphate as a substance that causes severe skin burns and eye damage (Skin Corr. 1, Eye Dam. 1) and for environmental hazards (Aquatic Acute 1, Aquatic Chronic 1). However, contrary to the proposal by Poland, RAC assigned higher multiplying factors, i.e. M = 100 for aquatic acute hazard and M = 1000 for

chronic aquatic hazard.

Contrary to the proposal by Poland, RAC did not classify the substance for acute oral and dermal toxicity but assigned an additional labelling indicating that the substance is corrosive to the respiratory tract (EUH071).

Pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc

The substance zinc pyrithione is an active substance used in biocidal products including disinfectants, various preservatives, and antifouling products. The substance is also used in wash-off and leave-on hair products in cosmetics.

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

RAC agreed to the proposal by Sweden to classify zinc pyrithione as a substance that may damage the unborn child (Repr. 1B; H360D), toxic if swallowed (Acute Tox. 3, ATE = 221 mg/kg bw), fatal if inhaled (Acute Tox. 2, ATE = 0.14 mg/l), causes damage to organs through prolonged or repeated exposure (STOT RE 1), and causing serious eye damage (Eye Dam. 1). RAC further agreed to classify zinc pyrithione for aquatic hazards Aquatic Acute 1 and Aquatic Chronic 1, adding a multiplying factor of 1000 for aquatic acute hazard and a multiplying factor of 10 for chronic aquatic hazard.

Butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime

The substance butanone oxime is an industrial chemical used in paints, primers, varnishes and coatings.

The substance has an existing entry in Annex VI of the CLP Regulation: Carc. 2, Acute Tox. 4*, Skin Sens. 1, and Eye Dam. 1.

RAC agreed to the proposal from Germany to retain the classification Eye Dam. 1 and to classify the substance as a substance that may cause drowsiness or dizziness (STOT SE 3), as toxic if swallowed (Acute Tox. 3, ATE = 100 mg/kg bw), and as harmful in contact with skin (Acute Tox. 4, ATE = 1100 mg/kg bw). In addition, RAC agreed to modify the classification for carcinogenicity as a substance which may cause cancer (Carc. 1B; H350).

Contrary to the proposal by Germany, RAC agreed to additionally classify the substance as Skin Irrit. 2., a substance that may cause damage to the upper respiratory tract after single exposure (STOT SE 1), and a substance that may cause damage to the blood system through prolonged or repeated exposure (STOT RE 2). However, RAC did not support the proposal to modify the existing classification as Skin Sens. 1.

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