10 December 2019

Annex to a news release ECHA/NR/19/44

Helsinki, 10 December 2019

The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) concluded on two restriction proposals

N,N-Dimethylformamide (DMF)

SEAC adopted its final opinion in support of the proposal by Italy to restrict the uses of the substance on its own or in mixtures in a concentration equal or greater than 0.3 %. 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.

Siloxanes (D4, D5 and D6)

RAC adopted its opinion, in support of the proposal by ECHA, to restrict placing on the market of D4, D5 and D6 as substances, as contituents of other substances, or in mixtures in a concentration equal or greater than 0.1% w/w of each substance.

SEAC agreed on its draft opinion in support of the proposal by ECHA. 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. The 60-day consultation on the SEAC draft opinion launches on 18 December 2019.

The Committee for Risk Assessment (RAC) adopted ten opinions on harmonised classification and labelling

(3aS,5S,6R,7aR,7bS,9aS,10R,12aS,12bS)-10-[(2S,3R,4R,5R)-3,4-dihydroxy-5,6-dimethylheptan-2-yl]-5,6-dihydroxy-7a,9a-dimethylhexadecahydro-3H-benzo[c]indeno[5,4-e]oxepin-3-one; 24-Epibrassinolide (EC n/a, CAS 78821-43-9)

The substance 24-Epibrassinolide is a new active substance in plant protection products acting as an elicitor and plant activator.

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

RAC agreed to the proposal by Austria to classify 24-epibrassinolide for hazards to the aquatic environment as a substance that may cause long lasting harmful effects to aquatic life (Aquatic Chronic 4).

Carbendazim (ISO); methyl benzimidazol-2-ylcarbamate (EC 234-232-0, CAS 10605-21-7)

The substance carbendazim (ISO) is an active substance used in plant protection and biocidal products.

The substance has an existing entry in Annex VI to the CLP Regulation as a substance that may cause genetic defects (Muta. 1B; H340), may damage fertility and the unborn child (Repr. 1B; H360FD) and for hazards to the aquatic environment as very toxic to aquatic life and very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Aquatic Chronic 1).
RAC agreed to the proposal by Germany to also classify carbendazim (ISO) as a substance that may cause an allergic skin reaction (Skin Sens. 1) and to add a multiplying factor of 10 to the

acute and chronic aquatic hazards.

Cypermethrin (ISO); α-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cypermethrin cis/trans +/- 40/60 (EC 257-842-9, CAS 52315-07-8)

The substance cypermethrin (ISO) is an active substance used in biocidal products as an insecticide.

The substance has an existing entry in Annex VI to the CLP Regulation as harmful if swallowed and if inhaled (Acute Tox. 4*; minimum classifications for both routes), as a substance that may cause respiratory tract irritation (STOT SE 3) and for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by Belgium to classify cypermethrin (ISO) as a substance that may cause damage to the nervous system through prolonged or repeated exposure (STOT RE 2), as harmful if swallowed and if inhaled (Acute Tox. 4) with acute toxicity estimates (ATE; oral) of 500 mg/kg and (ATE; inhalation) of 3,3 mg/L, respectively. RAC agreed to assign multiplying factors of 100 000 to the acute and chronic aquatic classifications based on more recent data provided during the parallel process for renewal of this biocide.

Tetrafluoroethylene (EC 204-126-9, CAS 116-14-3)

The substance tertafluoroethylene is a widely used industrial chemical.

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

RAC agreed to the proposal by Ireland to classify tetrafluoroethylene as a substance that may cause cancer (Carc. 1B; H350) without specifying a route of exposure.

Thiamethoxam (ISO); 3-(2-chloro-thiazol-5- ylmethyl)-5- methyl[1,3,5]oxadiazinan-4-ylidene-N-nitroamine (EC 428-650-4, CAS 153719-23-4)

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

The substance has an existing entry in Annex VI to the CLP Regulation as a substance harmful if swallowed (Acute Tox. 4*(minimum classification)) and for hazards to the aquatic environment as a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with a multiplying factor of 10 for the acute hazard.

RAC agreed to the proposal by France to classify thiamethoxam (ISO) as Repr. 2; H361, but RAC proposed to further specify that thiamethoxam (ISO) warrants classification as a substance suspected of damaging fertility and the unborn child (Repr. 2; H361fd), as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE; oral) of 780 mg/kg bw (instead of 800 mg/kg bw) and to add a multiplying factor of 10 to the chronic aquatic hazard.

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide (EC 272-697-1, CAS 68909-20-6)

The substance silanamine is an active substance in biocidal products used as an insecticide.

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

RAC agreed by a simple majority to the proposal by France to classify silanamine as a substance that may cause damage to the lungs through inhalation through prolonged or repeated exposure (STOT RE 2). RAC further agreed to add supplemental hazard statement EUH066 (repeated exposure may cause skin dryness or cracking). In addition, RAC agreed that silanamine warranted classification as fatal if inhaled (Acute Tox. 2).

Trinexapac-ethyl (ISO); ethyl 4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate; ethyl (1RS, 4EZ)-4-[cyclopropyl(hydroxy)methylene]-3,5-dioxocyclohexanecarboxylate (EC -, CAS 95266-40-3)

The substance trinexapac-ethyl (ISO) is an active substance used in plant protection products. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by Lithuania to classify trinexapac-ethyl (ISO) as a substance that may cause an allergic skin reaction (Skin Sens. 1B) and for hazards to the aquatic environment as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with a multiplying factor of 1. In addition, contrary to the proposal by Lithuania, RAC agreed that trinexapac-ethyl (ISO) warrants the classification as a substance that may cause damage to the gastrointestinal tract through prolonged or repeated exposure (STOT RE 2).

1,4-dimethylnaphthalene (EC 209-335-9, CAS 571-58-4)

The substance 1,4-dimethylnaphthalene is an active substance in plant protection products. The substance has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by the Netherlands to classify 1,4-dimethylnaphthalene as a substance that may be fatal if swallowed and enters airways (Asp. Tox. 1) and as a substance that causes serious eye irritation (Eye Irrit. 2). In addition, contrary to the proposal by the Netherlands, RAC agreed that 1,4-dimethylnaphthalene warranted classification as harmful if swallowed (Acute Tox. 4) and assigned an acute toxicity estimate (ATE; oral) of 1300 mg/kg. RAC further agreed to the proposal by the Netherlands to classify the substance for hazards to the aquatic environment as very toxic to aquatic life (Aquatic Acute 1) with multiplying factor of 1, but concluded that 1,4-dimethylnaphthalene warrants the classification as harmful for aquatic life with long lasting effects (Aquatic Chronic 3) instead of chronic category 2.

Imazamox (ISO); (RS)-2-(4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl)-5-methoxymethylnicotinic acid (EC -, CAS 114311-32-9)

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

The substance has an existing entry in Annex VI to the CLP Regulation for hazards to the aquatic environment as very toxic to aquatic life and very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by France to classify imazamox (ISO) as suspected of damaging the unborn child (Repr. 2; H361d) and to add multiplying factors of 10 for both environmental hazards.

3-methylpyrazole (EC 215-925-7, CAS 1453-58-3)

The substance 3-methylpyrazole is an industrial chemical used in fertilisers.

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

RAC agreed to the proposal by Belgium to classify 3-methylpyrazole as a substance that may

damage the unborn child (Repr. 1B; H360D), a substance that may cause damage to the lungs (STOT RE 2), as harmful if swallowed (Acute Tox. 4) with acute toxicity estimate of 500 mg/kg bw (ATE; oral), and as causing severe skin burns and eye damage (Skin Corr. 1 and Eye Dam. 1).

The Committees agreed on draft opinions and discussed key issues in new applications for authorisation

RAC agreed on 14 draft opinions and SEAC agreed on 25 draft opinions on the uses of chromium (VI) substances, coal tar pitch, high temperature, anthracene oil and octyl- and nonylphenol ethoxylates

RAC agreed the use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances, and the use of sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of sodium chlorite. In addition, RAC agreed on 11 uses of octyl- and nonylphenol ethoxylates in the Life Sciences sector.

SEAC agreed on the use of chromium trioxide for the manufacture of electrolytic chromium/chromium oxide coated steel, the five formulation uses of coal tar pitch, high temperature and anthracene oil, as well as 19 various uses of octyl- and nonylphenol ethoxylates, such us in the Life Sciences sector, in production of medical devices, in vitro diagnostic products used by professional diagnostic laboratories, in the siliconisation of glass containers used as primary packaging for medicinal products, and manufacture of pharmaceutical products.

Both Committees agreed on a draft opinion on the use of octylphenol ethylates as a lysing agent for the permeabilization of the host cell membrane to release adenovirus particles used for the manufacture of vaccines.

Furthermore, RAC and SEAC discussed key issues in 17 applications for authorisation, which were received by ECHA in August 2019. Of theese, roughly one half is related to the formulation and use of in vitro diagnostic assays, the other half consists of the uses of octyl- and nonylphenol ethoylates in virus inactivation, and manufacturing of pharmaceuticals. The committees will continue their work on the opinion development on these applications for authorisation.

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