18 June 2019

Annex to a news release

RAC concludes on 10 opinions for harmonised classification and labelling and RAC and SEAC agree one restriction on plastic and rubber granulates containing PAHs.

Helsinki, 18 June 2019

The Committee for Risk Assessment adopted and the Committee for Socio-economic Analysis (SEAC) agree on one restriction proposal

Plastic and rubber granulates containing PAHs

RAC adopted its draft opinion in support of the restriction proposal prepared by the Netherlands to restrict the use of granules and 'mulches' used as infill material in synthetic turf pitches and in loose forms on playgrounds and in sports applications. The basis for this dossier is a concern for human health resulting from the current concentration limits for polycyclic aromatic hydrocarbons (PAHs) in end-of-life tyre (ELT)-derived rubber infill granules used in synthetic turf pitches. The primary concern is to address risks to individuals playing and performing sports activities (e.g. football) on artificial turf pitches with rubber granules (rubber crumb) made of recycled tyres.

SEAC agreed its draft opinion in support of the proposal by the Netherlands. 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 public consultation on the SEAC draft opinion launches on 19 June 2019.

The Committee for Risk Assessment (RAC) adopted 10 opinions on harmonised classification and labelling

2-phenoxyethanol (EC 204-589-7, CAS 122-99-6)

The substance 2-phenoxyethanol is an active substance used in biocidal products.

The substance has an existing entry in Annex VI to the CLP Regulation for acute oral toxicity (Acute Tox. 4*, minimum classification) and for eye irritation (Eye Irrit. 2).

RAC agreed to the proposal by the United Kingdom to classify 2-phenoxyethanol as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE; oral) of 1 394 mg/kg bw to classify and label mixtures containing the substance and as a substance that causes serious eye damage (Eye Dam. 1) and may cause respiratory tract irritation (STOT SE 3).

6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol (EC 204-327-1, CAS 119-47-1)

The substance 6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol is an industrial chemical used in consumer and professional products as well as at industrial sites.

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

RAC agreed to the proposal by Denmark to classify 6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol as a substance that may damage fertility (Repr. 1B; H360F).

Diflufenican (ISO); N-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide; 2',4'-difluoro-2-(α,α,α-trifluoro-m-tolyloxy)nicotinanilide (EC -, CAS 83164-33-4)
The substance diflufenican (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 hazards to the aquatic environment with long-lasting effects (Aquatic Chronic 3).

RAC agreed to the proposal by the United Kingdom to classify diflufenican (ISO) as a substance that is very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1), but contrary to the proposal by the United Kingdom, RAC assigned higher multiplying factors: of 10 000 for aquatic acute toxicity and 1 000 for aquatic chronic toxicity.

Tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate (EC 432-770-2, CAS 139189-30-3)

The substance tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate is an industrial chemical used as a flame retardant in electronic products.

The substance has an existing entry in Annex VI to the CLP Regulation as a substance that may cause an allergic skin reaction (Skin Sens. 1).

RAC agreed to the proposal by the United Kingdom that based on the available data, classification for skin sensitisation is not warranted for tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate.

3-aminomethyl-3,5,5-trimethylcyclohexylamine (EC 220-666-8, CAS 2855-13-2)

The substance 3-aminomethyl-3,5,5-trimethylcyclohexylamine is an industrial chemical used professional products and at industrial sites.

The substance has an existing entry in Annex VI to the CLP Regulation for acute oral and dermal toxicity (Acute Tox. 4*, minimum classifications), for skin corrosion (Skin Corr. 1B), as a substance that may cause an allergic skin reaction (Skin Sens. 1) and for hazards to aquatic environment (Aquatic Chronic 3).

RAC agreed to the proposal by Germany to classify 3-aminomethyl-3,5,5-trimethylcyclohexylamine as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE; oral) of 1 030 mg/kg bw, and to modify the existing classification for skin sensitisation by adding a subcategory (Skin. Sens. 1A). In addition, contrary to the proposal by Germany, RAC assigned a specific concentration limit (SCL) of 0.001 % for skin sensitisation for mixtures containing the substance. RAC also agreed to the proposal by Germany that the substance does not warrant classification for hazards to the aquatic environment.

Azamethiphos (ISO); S-[(6-chloro-2-oxooxazolo[4,5-b]pyridin-3(2H)-yl)methyl] O,O-dimethyl thiophosphate (EC 252-626-0, CAS 35575-96-3)

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

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

RAC agreed to the proposal by the United Kingdom to classify azamethiphos (ISO) as harmful

if swallowed (Acute Tox. 4) and as toxic if swallowed with an acute toxicity estimates (ATE; oral) of 500 mg/kg bw and (ATE; inhalation) of 0.5 mg/L for dusts and mists, as a substance that may cause an allergic skin reaction (Skin Sens. 1) and for hazards to aquatic environment as a substance that is very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1) with multiplying factors of 1 000 for both hazards. In addition, contrary to the proposal by the United Kingdom, RAC agreed to classify azamethiphos (ISO) as a substance that causes damage to the nervous system (STOT SE 1) and as suspected of causing cancer (Carc. 2; H351).

Imidacloprid (ISO); 1-(6-chloropyridin-3-ylmethyl)-N-nitroimidazolidin-2-ylidenamine (EC 428-040-8, CAS 138261-41-3)

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

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

RAC agreed to the proposal by Germany to classify imidacloprid (ISO) as toxic if swallowed (Acute Tox. 3) with an acute toxicity estimate (ATE; oral) of 131 mg/kg bw 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 multiplying factors of 100 and 1 000 respectively.

[S-(Z,E)]-5-(1-hydroxy-2,6,6-trimethyl-4-oxocyclohex-2-en-1-yl)-3-methylpenta-2,4-dienoic acid; S-abscisic acid (EC 244-319-5, CAS 21293-29-8)

The substance S-abscisic acid 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 the Netherlands to classify S-abscisic acid as very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1) with multiplying factors of 1 for both hazards.

2,2-dibromo-2-cyanoacetamide (DBNPA) (EC 233-539-7, CAS 10222-01-2)

The substance 2,2-dibromo-2-cyanoacetamide 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 Denmark to classify the substance as toxic if swallowed (Acute Tox. 3) and as fatal if inhaled (Acute Tox. 2) but assigned ATEs which were different to those proposed by Denmark: an ATE (oral) of 118 mg/kg bw (instead of 167 mg/kg bw) and an ATE (inhalation) of 0.24 mg/L (instead of 0.275 mg/L). RAC further agreed to classify the substance as causing damage to the respiratory tract through prolonged or repeated exposure (STOT RE 1; inhalation), as a substance causing skin irritation (Skin. Irrit. 2), as a substance causing serious eye damage (Eye. Dam. 1) and as a substance that may cause an allergic skin reaction (Skin Sens. 1). RAC also agreed to classify 2,2-dibromo-2-cyanoacetamide as a substance that is very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1) with multiplying factors of 1 for both hazards.

RAC did not agree to the proposal by Denmark to classify 2,2-dibromo-2-cyanoacetamide as a substance causing damage to the thyroid through prolonged or repeated exposure.

5-Chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone (Pyriofenone) (EC -, CAS 688046-61-9)

The substance pyriofenone 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 the United Kingdom to classify pyriofenone as a substance suspected of causing cancer (Carc. 2; H351) and as very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1) with a multiplying factor of 1.

The Committees agreed on eight draft opinions and discussed key issues in 11 new applications for authorisation.

RAC and SEAC agreed on eight draft opinions on the uses of chromium trioxide. Six of the agreed draft opinions are on uses of the substance in the sanitary sector. The other two draft opinions are on uses of chromium trioxide for passivation of tinplated steel, and for electrolytic chromium coating of steel.

Furthermore, RAC and SEAC discussed key issues in 11 applications for authorisation, which were received by ECHA in February 2019. Seven of the applications are on 14 uses of octyl- and nonylpenol ethoxylates in the life sciences sector. Three other applications for authorisation are on three uses of chromium (VI) substances in surface treatment, in electrochemical synthesis and as a anti-corrosion agent in refrigerant solution. The remaining application for authorisation is on the use of coal tar pitch, high temperature related to the civilian and military aerospace industry. The committee will continue its work on the opinion development on these applicaions 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