Annex to a news alert

Restriction proposal on diisocyanates and several authorisation applications agreed by RAC and SEAC – ECHA/NA/17/29

Helsinki, 8 December 2017

The Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) agreed on restriction proposals on diisocyanates and on lead stabilisers in PVC articles

Diisocyanates

RAC adopted its opinion, in support of the proposal by Germany, to restrict the use of diisocyanates at the workplace. The main goal of this restriction proposal is to prevent new cases of respiratory sensitisation among all workers and professionals who may be exposed to diisocyanates at the workplace. Diisocyanates are used in a wide range of sectors and applications (e.g. foams, sealants, coatings) throughout the EU, with a total tonnage of about 2.5 million tonnes per year. SEAC agreed 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.

Lead

RAC also adopted its opinion, in support of the proposal by ECHA, to restrict the use of lead stabilisers in PVC articles. The proposal mainly targets articles used for building and construction applications, such as window and door profiles; tubes, pipes and hoses; floor coverings in rolls or tiles; shutters and blinds; and many others. Articles, mainly made of rigid PVC, comprise the large majority (more than 70 %) of all PVC uses. The proposal is aimed at further reducing human exposure to lead, which can occur through direct and particularly through indirect exposure via the environment. Time-limited derogations have been proposed to allow a) recycling of PVC to continue as a viable waste management practice, b) for PVC-silica separators in lead-acid batteries and c) for PVC articles covered under existing other legislation. SEAC agreed 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 Committees for Risk Assessment (RAC) Socio-economic Analysis (SEAC) agreed on draft authorisation opinions and adopted final opinions

RAC agreed on five and SEAC agreed on eight draft opinions on specific uses of **chromium (VI)** substances and **1,2-dichloroethane (EDC)** under the authorisation procedure. The draft opinions will be sent to the applicants for comments before final adoption.

The Committees also finalised their work on six applications for authorisation by adopting the opinions on eight uses of substances of very high concern. Five of them are specific uses of **chromium (VI) compounds** (sodium chromate, chromium trioxide, sodium and potassium dichromates) in the aerospace and aviation sector. The other two were with regard to the uses of bis(2-methoxyethyl) ether (**diglyme**) as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification while preserving article structural integrity (as in-house processes and downstream user processes). The Committees also adopted the opinion on the industrial use of 2,2’-dichloro-4,4’-methylenedianiline (**MOCA**) as a curing agent/chain extender in cast polyurethane elastomer production.

Furthermore, the Committee agreed on the RAC note on the carcinogenicity dose-response relationship of coal-tar pitch, high temperature (CTP-HT). To increase efficiency, RAC will use these non-binding reference values to evaluate applications for authorisation and applicants are invited to use them in the risk assessment part of their applications. The reference value will be published on the ECHA's website in due course.

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

2-phenylhexanenitrile

2-phenylhexanenitrile is used as an ingredient in fragrance mixtures.

The substance has an existing entry in Annex VI of the CLP Regulation as harmful if swallowed (Acute Tox. 4*; H302 - minimum classification) and for environmental hazards (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410).

RAC agreed to the proposal by Spain to confirm the classification for acute toxicity as a substance harmful if swallowed, and additionally agreed on an acute toxicity estimate (ATE) of 500 mg/kg bw (oral route) to be used to classify mixtures, to remove the acute aquatic classification and to modify the aquatic chronic classification in category 2 – as a substance toxic to aquatic life with long-lasting effects.

Carboxin (ISO); 2-methyl-N-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide

Carboxin (ISO) is an active substance used as a fungicide applied to the seeds of small grain cereals (wheat, barley, oats, rye and triticale).

The substance does not have an existing entry in Annex VI of the CLP Regulation.

RAC agreed to the proposal by the United Kingdom to classify as a substance that may cause damage to the kidneys through prolonged or repeated exposure (STOT RE 2; H373 (kidneys)). RAC also agreed to classify the substance that may cause an allergic skin reaction (Skin Sens. 1; H317), and the substance very toxic to aquatic life and very toxic to aquatic life with long-lasting effects (Aquatic Acute 1; H400, Aquatic Chronic 1; H410) with a multiplying factor of 1 for mixtures.

Metaflumizone (ISO); 4-{2-({[4-(trifluoromethoxy)phenyl]carbamoyl}hydrazono)-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile

Metaflumizone (ISO) is used as an insecticide indicated for veterinary treatment against fleas and ticks.

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

RAC agreed to the proposal by Denmark to classify as a substance that is suspected of damaging the unborn child or that may cause harm to breast-fed children, as a substance that may cause damage through prolonged or repeated exposure without specifying the routes of exposure or target organs (STOT RE 2; H373). In addition, RAC agreed to add classification as suspected of damaging fertility (Repr. 2; H361fd, Lact.; H362).

Pyridate (ISO); O-(6-chloro-3-phenylpyridazin-4-yl) S-octyl thiocarbonate

Pyridate (ISO) is an active substance used as a herbicide in agriculture and horticulture.

The substance has an existing entry in Annex VI of the CLP Regulation with the classifications as Skin Irrit. 2; H315, Skin Sens. 1; H317 and for environmental hazards (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410).

RAC agreed to the proposal by Austria to retain the classification for skin irritation and to add a multiplying factor of 1 for acute environmental hazard and a factor of 10 for chronic environmental hazard.

Contrary to the proposal by Austria, RAC agreed to keep the existing classification for skin sensitisation (Skin Sens. 1; H317) and to add classification for acute oral toxicity as harmful if swallowed (Acute Tox. 4; H302) instead of classifying the substance for target organ toxicity after single exposure.

2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)

The substance is used as a light stabiliser in coatings.

The substance has an existing entry in Annex VI of the CLP Regulation for environmental hazards as a substance that may cause long lasting harmful effects to aquatic life.

RAC did not agree to the proposal by Germany to remove the existing classification based on new experimental data, as they did not find there was sufficient evidence provided for removing the existing classification.

Dibutylbis(pentane-2,4-dionato-O,O')tin

Dibutylbis(pentane-2,4-dionato-O,O')tin is used as a catalyst in several chemical product categories.

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

RAC agreed to the proposal by Sweden to classify as a substance that causes damage through prolonged or repeated exposure (STOT RE 1; H372) and as presumed human reproductive toxicant (Repr. 1B; H360FD).

2-methylimidazole

2-methylimidazole is an industrial chemical used as a chemical intermediate for various applications and products.

The substance does not have an existing entry in Annex VI of the CLP Regulation.

RAC agreed to the proposal by Sweden to classify the substance as presumed human reproductive toxicant (Repr. 1B; H360Df).

Cyflumetofen (ISO)

Cyflumetofen (ISO) is an active substance used as an acaricide on ornamental crops, nursery trees and perennial ornamentals and to public greens.

The substance does not have an existing entry in Annex VI of the CLP Regulation.

RAC agreed to the proposal by the Netherlands to classify cyflumetofen as a substance that may cause an allergic skin reaction (Skin Sens. 1A; H317) and as suspected of causing cancer (Carc. 2; H351).

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