15 June 2018

Annex to a news release

Helsinki, 15 June 2018

SEAC adopted one restriction proposal

Lead and its compounds in shot

SEAC adopted its final opinion, in support of the proposal by ECHA, to restrict lead and its compounds in gunshot for shooting with a shotgun within a wetland or where spent gunshot would land within a wetland.

The restriction proposal had been developed and submitted by ECHA following a request from the European Commission. One of the main aims of the restriction was to harmonise the diverse existing Member State approaches to address the risks arising from the use of lead gunshot in wetlands. It was primarily justified on the basis of the many deaths of waterbirds caused by ingesting lead gunshot. Sub-lethal effects were also taken into account.

In its final opinion SEAC concluded that further action on a European-wide level is required to address the risks associated with lead gunshot in wetlands. Furthermore, SEAC concluded that the effective implementation of the African-Eurasian Waterbird Agreement (AEWA) requires a consistent minimum level of protection of waterbirds across the Union, which would be achieved by the proposed restriction.

RAC agreed on five and SEAC on seven draft opinions on applications for authorisation and on four draft opinions on the review reports

RAC agreed on five draft opinions and SEAC on seven draft opinions on four and six applications for authorisation respectively, on uses of chromium (VI) substances, DBP and diglyme. In addition, for the first time in the history of the REACH Regulation, the Committees agreed on four draft opinions on the two review reports. Each authorisation decision by the Commission for a substance on Annex XIV contains a time-limited review period. Close to its expiry, and if the substitution still cannot be done by the authorisation holder, a review report has to be submitted to ECHA. Both of the review reports are about uses of DEHP-containing PVC recyclate.

RAC agreed on the RAC note on carcinogenicity dose-response relationship for high temperature coal tar pitch (CTPHT)

Coal tar pitch, high temperature (CTPHT) was recently added to Annex XIV of REACH due to its carcinogenic and PBT and vPvB properties. RAC agreed on a further note in its series on reference dose-response relationship or derived no effect levels, on this occasion, dose responses for the carcinogenicity of CTPHT and its PBT and vPvB properties. The RAC note is available on ECHA's website.

The derived dose-response relationships serve as non-legally binding reference values.

Reference values in the form of derived no-effect levels (DNELs) for threshold substances and/or dose-response relationships for non-threshold (mainly) carcinogens are published in advance of applications for authorisation, thereby providing greater consistency and better use of the legally defined periods of opinion development in the RAC. They provide applicants with a clear signal as to how RAC is likely to evaluate the hazards of the risk assessment of an application for authorisation.

RAC adopted 13 opinions on harmonised classification and labelling

Paclobutrazol (ISO)

The substance paclobutrazol (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 the United Kingdom to classify paclobutrazol (ISO) as a substance suspected of damaging the unborn child (Repr. 2; H361d) and harmful if swallowed (Acute Tox. 4) and inhaled (Acute Tox. 4); additionally, RAC agreed on acute toxicity estimates (ATEs) for inhalation (ATE = 3.13 mg/L, dust and mist) and oral (ATE = 490 mg/kg bw) routes. RAC also agreed to classify paclobutrazol (ISO) as a substance causing serious eye irritation (Eye Irrit. 2) and for environmental hazards as a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1), adding multiplying (M) factors of 10 for both acute and chronic aquatic hazards.

Dimethyl disulphide

The substance dimethyl disulphide (DMDS) is an industrial chemical used as an intermediate for chemical synthesis and as a processing aid in refineries and petrochemical sites. It is also proposed to be used as an active substance in plant protection products in accordance with Regulation (EC) No 1107/2009.

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

RAC agreed to the proposal by industry to classify DMDS as a flammable liquid (Flam. Liq. 2) and as a substance causing acute toxicity via inhalation route (Acute Tox. 3) and serious eye irritation (Eye Irrit. 2). For environmental hazards, RAC also agreed to classify DMDS as a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1), adding multiplying (M) factors of 1 and 10 respectively.

Contrary to the proposal by industry, RAC agreed to classify DMDS as toxic if swallowed (Acute Tox. 3), adding acute toxicity estimates (ATEs) for the oral and inhalation routes, as a substance that causes damage to upper respiratory tract via inhalation (STOT SE 1), as a substance that may cause drowsiness or dizziness (STOT SE 3), and as a substance that may cause an allergic skin reaction (Skin. Sens. 1).

2,2-bis(bromomethyl)propane-1,3-diol

The substance 2,2-bis(bromomethyl)propane-1,3-diol is an industrial chemical used in polymers and in the manufacture of plastic products as a flame retardant.

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

RAC agreed to the proposal by Norway to classify 2,2-bis(bromomethyl)propane-1,3-diol as a substance that may cause cancer (Carc. 1B; H350) and may cause mutagenetic effects (Muta. 1B; H341).

Bis(α,α-dimethylbenzyl) peroxide

The substance bis(a,a-dimethylbenzyl)peroxide is an industrial chemical used in the formulation of mixtures, in re-packaging materials and in the manufacture of plastics, rubber products and other chemicals.
The substance has an existing entry in Annex VI to the CLP Regulation, where it is classified as Org. Perox. F, Skin Irrit. 2, Eye Irrit. 2 and Aquatic Chronic 2.

Contrary to the proposal by Norway, RAC agreed to classify bis(a,a-dimethylbenzyl)peroxide) as a substance suspected of damaging the unborn child (Repr. 1B; H360D) and to keep the classifications for skin and eye irritation.

N-(hydroxymethyl)acrylamide (NMA)

The substance N-(hydroxymethyl)acrylamide (NMA) is an industrial chemical manufactured and used (in polymer products) at industrial sites only.

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

RAC agreed to the proposal by France to classify NMA as a substance that may cause cancer (Carc. 1B; H350), may cause mutagenetic effects (Muta. 1B; H341), and causes damage to the peripheral nervous system through prolonged or repeated exposure (STOT RE 1).

Glyoxylic acid … %

The substance glyoxylic acid is an industrial chemical mainly used as a corrosion inhibitor and as an anti-scaling agent in the industrial manufacturing of cleaning products.

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

RAC agreed to the proposal by Germany to classify glyoxylic acid (… %) as a substance that causes serious eye damage (Eye Dam. 1) and may cause an allergic skin reaction (Skin Sens. 1B). RAC also agreed to add Note B, requiring the concentration of the substance in aqueous solution be stated (as a percentage) on the label by manufacturers, since the hazards may vary at different concentrations.

2-methyl-1,2-benzisothiazol3(2H)-one; [MBIT]

The substance 2-Methyl-1,2-benzisothiazol3(2H)-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 Poland to classify 2-methyl-1,2-benzisothiazol3(2H)-one as a substance causing severe eye damage (Eye Dam. 1) and as a substance that may cause an allergic skin reaction (Skin Sens. 1A). For environmental hazards, RAC agreed to classify MBIT as a substance very toxic to aquatic life (Aquatic Acute 1) and toxic to aquatic life with long-lasting effects (Aquatic Chronic 2), with a multiplying (M) factor of 1.

Contrary to the proposal by Poland, RAC agreed to classify MBIT as causing severe skin burns (Skin Corr. 1C), harmful in contact with skin (Acute Tox. 4) and toxic if inhaled (Acute Tox. 3), adding acute toxicity estimates (ATEs) for both routes. In addition, RAC agreed to set a specific concentration limit of 15 ppm (0.0015 %) for skin sensitisation.

Trimethoxyvinylsilane; trimethoxy(vinyl)silane

The substance trimethoxyvinylsilane is an industrial chemical used in polymers, adhesives and sealants, coating products, non-metal-surface treatment products and laboratory chemicals.

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

RAC agreed to the proposal by Sweden to classify trimethoxyvinylsilane as a substance that may cause an allergic skin reaction (Skin. Sens. 1B).

Tris(2-methoxyethoxy)vinylsilane

The substance tris(2-methoxyethoxy)vinylsilane is an industrial chemical mainly used in polymers.

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

RAC agreed to the proposal by Austria to classify tris(2-methoxyethoxy)vinylsilane as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD).

Azoxystrobin (ISO)

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

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

RAC agreed to the proposal by the United Kingdom to classify azoxystrobin (ISO) as toxic if inhaled (Acute Tox. 3), adding an acute toxicity estimate (ATE). RAC also agreed to add multiplying factors of 10 to the existing environmental hazards.

Bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme

The substance tetraglyme is an industrial chemical used mainly as a solvent in paints and coatings.

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

RAC agreed to the proposal by Austria to classify tetraglyme as substance that may damage fertility and the unborn child. RAC agreed to specify both fertility and developmental effects of tetraglyme (Repr. 1B; H360FD).

Nitric acid … %

The substance nitric acid is an industrial chemical used in various applications.

The substance has an existing entry in Annex VI to the CLP Regulation as Ox. Liq. 2 and Skin Corr. 1A with specific concentration limits for these hazard classes.

RAC agreed to the proposal by Germany to classify nitric acid … % as:

a. nitric acid … % in concentrations above 70 % - fatal if inhaled - (Acute Tox. 1)
b. nitric acid at or below concentrations of 70 % - toxic if inhaled - (Acute Tox. 3) with an ATE for inhalation of 2,65 mg/L (dust and mist), and additional labelling with EUH071 (corrosive to the respiratory tract).

Granulated copper

This is an active substance used in biocidal products and has no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by France to classify granulated copper as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2). Contrary to the proposal by France, RAC did not classify the substance for eye irritation.

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