

16 March 2018

## Annex to a news release

### **RAC adopted and SEAC agreed on one restriction proposal. SEAC adopted two restriction proposals.**

Helsinki, 16 March 2018

#### **Lead and its compounds in shot**

RAC 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 existing diverse Member State approaches to address the risks from the use of lead gunshot in wetlands. It was primarily justified based on the acute and sub-lethal effects, principally death, that occur in waterbirds after ingesting lead gunshot.

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 21 March 2018 and will remain open until 20 May 2018.

#### **Diisocyanates**

SEAC adopted its final opinion, in support of the restriction proposal by Germany, to manage the use of diisocyanates in the workplace, primarily through training of workers. 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 in 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 reconfirmed 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. Having considered the 20 comments received during the public consultation on the draft opinion agreed in December 2017, SEAC made some adjustments in the justification for its opinion.

#### **Lead in PVC**

SEAC adopted by consensus its final 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 exposure and particularly through indirect exposure via the environment. Time-limited derogations were agreed 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 reconfirmed 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. Having considered the seven comments received during the public consultation on the

draft opinion agreed in December 2017, SEAC made some adjustments in the justification for its opinion.

## **RAC agreed on seven and SEAC on five draft opinions on six applications for authorisation.**

The Committees also agreed on seven draft opinions in RAC and five draft opinions in SEAC on six [upstream] applications for authorisation on uses of chromium (VI) substances. These draft opinions, as part of the opinion development process as is set by the REACH Regulation, will be consulted with the respective applicants. If the applicants comment on the draft opinions, the agreed opinions will be taken back to the Committees for another round of discussion before the adoption of the RAC and SEAC final opinions.

## **RAC adopted fourteen opinions on harmonised classification and labelling.**

### **Octamethylcyclotetrasiloxane; [D4]**

Octamethylcyclotetrasiloxane; [D4] is an industrial chemical used in an exceptionally wide variety of consumer products, including washing and cleaning products, polishes and waxes, cosmetics and personal care products, lubricants and greases.

The substance has an existing entry in Annex VI to the CLP Regulation with classifications as Repr. 2; H361f\*\*\* and as Aquatic Chronic 4.

RAC agreed to the proposal by Germany to modify the existing environmental classification and to classify the substance as very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1) with a multiplying (M) factor of 10.

### **Branched hexatriacontane**

Branched hexatriacontane (a C<sub>36</sub> branched alkane) is an industrial chemical used in synthetic automotive and industrial lubricants.

The substance has an existing entry in Annex VI to the CLP Regulation as a substance that may cause long lasting harmful effects to aquatic life (Aquatic Chronic 4).

RAC agreed to the proposal by the United Kingdom to remove the current classification based on the absence of chronic toxicity using a weight-of-evidence approach including information from read-across data of similar substances.

### **2-methoxyethyl acrylate**

2-methoxyethyl acrylate is an industrial chemical used as an intermediate and in the production of chemicals, rubber products and plastic products.

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

RAC agreed to the proposal by France to classify the substance as flammable liquid (Flam Liq. 3), as harmful if swallowed (Acute Tox. 4) and toxic if inhaled (Acute Tox. 3), and additionally agreed on acute toxicity estimates (ATEs) to be used to classify mixtures, causing severe skin burns and eye damage (Skin Corr. 1C, Eye Dam. 1), as substance that may cause an allergic skin reaction (Skin Sens. 1), as suspected of causing genetic defects (Muta. 2; H341) and as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD). RAC also agreed

to add the supplemental hazard information EUH071 (corrosive to the respiratory tract).

### **Diisooctyl phthalate**

Diisooctyl phthalate (DIOP) is an industrial chemical primarily used as a plasticiser for synthetic rubber and vinyl, cellulosic and acrylate resins in a variety of consumer products.

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

RAC agreed to the proposal by France to classify DIOP as a substance that may damage fertility and the unborn child (Repr. 1B; H360FD).

### **Imiprothrin (ISO)**

Imiprothrin (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 with the classifications as Acute Tox. 4\* (minimum classification), Aquatic Acute 1 and Aquatic Chronic 1.

RAC agreed to the proposal by the United Kingdom to classify imiprothrin (ISO) as harmful if swallowed (Acute Tox. 4) and inhaled (Acute Tox. 4); additionally RAC agreed on acute toxicity estimates (ATEs) to be used to classify mixtures. RAC also agreed to add multiplying factors of 10 to the existing environmental hazards classification. Contrary to the proposal from the United Kingdom, RAC did not classify the substance for developmental toxicity. In addition, RAC agreed to classify imiprothrin as a suspected carcinogen (Carc. 2; H351) and for its neurotoxic properties as substance that may cause damage to the nervous system by oral and inhalation routes (STOT SE 2, nervous system, oral and inhalation).

### **Silicon carbide fibres (diameter <3 µm, length > 5 µm and aspect ratio ≥ 3:1)**

Silicon carbide fibres (SiC) are industrial chemicals differing in their form (size and shape) and including SiC whiskers, crude and grains; these are used in ceramic, refractory and foundry industries.

Silicon carbide fibres fulfilling the WHO definition (WHO, 1985; diameter <3 µm, length >5 µm and aspect ratio ≥3:1) have no existing entry in Annex VI to the CLP Regulation.

RAC agreed to the proposal by the Netherlands to classify all forms of SiC fibres (diameter <3 µm, length >5 µm and aspect ratio ≥3:1) as substances that may cause cancer through inhalation (Carc. 1B; H350i).

### **Pymetrozine (ISO)**

Pymetrozine (ISO) is an active substance used in plant protection products as an insecticide. The substance has an existing entry in Annex VI to the CLP Regulation for carcinogenicity and for environmental hazard (Carc. 2; H351 and Aquatic Chronic 3).

RAC agreed to the proposal from Germany to classify pymetrozine (ISO) as suspected of damaging fertility and the unborn child (Repr. 2; H361fd) and as very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1), adding a multiplying (M) factor of 1.

### **Margosa, ext. [cold-pressed oil of Azadirachta indica seeds without shells extracted with super-critical carbon dioxide]**

Margosa extract (as described above) is an active substance used in biocidal products as a repellent or attractant.

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

RAC agreed to the proposal by Germany to not classify the substance for human health hazards, but contrary to the initial proposal from Germany, RAC agreed to classify the substance as harmful to aquatic life with long-lasting effects (Aquatic Chronic 3).

### **Ipconazole (ISO)**

Ipconazole 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 from the United Kingdom to classify ipconazole (ISO) as harmful if swallowed (Acute Tox. 4), and additionally agreed on an acute toxicity estimate (ATE) to be used to classify mixtures; as a substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2; eyes, skin, liver) and as very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1), adding a multiplying (M) factor of 100. Contrary to the proposal from the United Kingdom, RAC agreed to classify ipconazole (ISO) as a substance that may damage the unborn child (Repr. 1B; H360D).

### **Ethofumesate (ISO) ( $\pm$ )-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate**

Ethofumesate (ISO) is an active substance used in plant protection products as an herbicide.

The substance has an existing entry in Annex VI to the CLP Regulation for chronic aquatic effects (Aquatic Chronic 2).

RAC agreed to the proposal by Germany to classify the substance as very toxic to aquatic life (Aquatic Acute 1) and to modify the existing classification for chronic aquatic effects (Aquatic Chronic 1), adding a multiplying (M) factor of 1 for mixtures.

### **L-(+)-lactic acid; (2S)-2-hydroxypropanoic acid**

L-(+)-lactic acid is an active substance used in biocidal products as a disinfectant in human hygiene products.

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

RAC agreed to the proposal by Germany to classify the substance as causing serious eye damage (Eye Dam. 1). RAC also agreed to add the supplemental hazard information EUH071 (corrosive to the respiratory tract).

Contrary to the proposal by Germany, RAC agreed to classify L-(+)-lactic acid as corrosive to skin (Skin Corr. 1C).

### **1,2-benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9-rich; [1] di-“isononyl” phthalate; [2] (DINP)**

Diisononyl phthalate (DINP) is an industrial chemical primarily used as a plasticiser for synthetic PVC.

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

Contrary to the proposal by Denmark, RAC agreed not to classify DINP for reproductive toxicity.

**(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol; mefentrifluconazole**

Mefentrifluconazole is a new 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 mefentrifluconazole as a substance that may cause an allergic skin reaction (Skin. Sens. 1) and as 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 for both acute and chronic aquatic hazards.

**MCPA-thioethyl**

MCPA-thioethyl (ISO) is an active substance used in plant protection products as an herbicide and plant growth regulator.

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

RAC agreed to the proposal by Poland to classify the substance as harmful if swallowed (Acute Tox. 4) and additionally agreed on acute toxicity estimate (ATE) to be used to classify mixtures. RAC also agreed to classify MCPA-thioethyl (ISO) 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 a multiplying (M) factor of 10 for mixtures. Contrary to the proposal by Poland, RAC agreed to classify MCPA-thioethyl as substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2; liver).

**RAC adopted three scientific evaluations on occupational exposure limits on nickel and its compounds, benzene and acrylonitrile.**

RAC adopted its opinions on evaluating three dossiers prepared by ECHA on occupational exposure limits (OELs) for nickel and its compounds, benzene and acrylonitrile, which will be the subject of a separate press release.

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>