24 September 2019

# Annex to a news release

## ECHA's committees conclude on two restrictions and 15 harmonised classification and labelling opinions

Helsinki, 24 September 2019

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

### N,N-Dimethylformamide (DMF)

RAC adopted its draft opinion in support of the restriction proposal prepared 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 agreed on its draft opinion in support of the proposal by Italy. 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 25 September 2019.

### Plastic and rubber granulates containing PAHs

SEAC adopted its final opinion by simple majority, supporting the proposal by the Dutch National Institute for Public Health and the Environment (RIVM) and following an earlier opinion by the Committee for Risk Assessment (RAC) in June. The restriction proposal lowers the total concentration limit of eight PAHs to 20 mg/kg (0.002 % by weight). The concentration limits for PAHs in mixtures supplied to the general public are currently set at 100 mg/kg or 1 000 mg/kg for each of the substances. The PAHs all have been identified as causing cancer and the proposed concentration limits will be closer to the limit values for individual PAHs in articles supplied to the general public (entry 50 of REACH Restrictions list).

Currently, the levels of PAHs measured in granular infill material and mulches pose, at most, a very low level of concern (ECHA study, 2017). The aim of the proposed restriction is to ensure that the cancer risk from PAH exposure remains at a low level for those coming into contact (inhalation and skin contact) with the granules and mulches. This includes, for example, footballers, children playing on the pitches or playgrounds and workers installing and maintaining such surfaces.

SEAC concluded that the proposed restriction is the most appropriate measure to control the risks posed by these substances, and that the measures proposed would be proportionate to the risk with limited economic impact. The proposal does not affect existing fields but will ensure that the material used for maintaining (refilling) the fields is below the new limit.

→ Press release (18 September 2019)

**The Committee for Risk Assessment (RAC) adopted 15 opinions on harmonised classification and labelling**

**mecoprop-P (ISO); (R)-2-(4-chloro-2-methylphenoxy)propionic acid** (EC: 240-539-0; CAS: 16484-77-8)

The substance mecoprop-P (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 acute oral toxicity (Acute Tox. 4*, minimum classification), for causing serious eye damage and for hazards to the aquatic environment (Aquatic Chronic 2).

RAC agreed to the proposal by the United Kingdom to classify mecoprop-P (ISO) as harmful if swallowed (Acute Tox. 4) with an acute toxicity estimate (ATE; oral) of 431 mg/kg bw to classify and label mixtures containing the substance.

Contrary to the proposal by the United Kingdom, RAC agreed to classify the substance as very toxic to aquatic life and very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Aquatic Chronic 1) with multiplying factors of 10 for both hazards.

**methyl salicylate** (EC 204-317-7; CAS 119-36-8)

The substance methyl salicylate is an industrial chemical mainly used in fragrances and cosmetics.

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 harmful if swallowed (Acute Tox. 4) but assigned an acute toxicity estimate (ATE; oral) of 890 mg/kg bw (instead of 580 mg/kg bw). RAC further agreed to classify methyl salicylate as a substance that may cause an allergic skin reaction (Skin Sens. 1B) and as harmful to aquatic life with long lasting effects (Aquatic Chronic 3).

RAC did not agree to the proposal by France to classify methyl salicylate as a substance that may damage the unborn child (Repr. 1B; H360D) but classified the substance as suspected of damaging the unborn child (Repr. 2; H361d).

**4-methylpentan-2-one; isobutyl methyl ketone** (EC 203-550-1; CAS 108-10-1)

The substance 4-methylpentan-2-one is an industrial chemical with wide dispersive use.

The substance has an existing entry in Annex VI to the CLP Regulation as a highly flammable liquid and vapour (Flam. Liq. 2), for acute toxicity via the inhalation route of exposure (Acute Tox. 4*, minimum classification), for causing serious eye irritation (Eye Irrit. 2), as a substance that after repeated exposure may cause skin dryness and cracking (EUH066) and that may cause respiratory irritation (STOT SE 3).

RAC agreed to the proposal by Austria to classify the substance as harmful if inhaled (Acute Tox. 4), with an acute toxicity estimate (ATE; inhalation) of 11 mg/L for vapours and to retain the classifications for eye irritation (Eye Irrit. 2) and the additional hazard statement EUH066. Contrary to the proposal by Austria, RAC did not agree to retain the classification for respiratory irritation (STOT SE 3; H335). In addition, RAC agreed to the proposal by Austria to classify isobutyl methyl ketone as a substance that may cause drowsiness or dizziness (STOT SE 3) and a substance suspected of causing cancer (Carc. 2; H351).

**clomazone (ISO); 2-(2-chlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one** (EC -; CAS: 81777-89-1)

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

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 harmful if swallowed and if inhaled (Acute Tox. 4) with acute toxicity estimates of 767.5 mg/kg bw (ATE; oral) and of 4.85 mg/L for dusts or mists (ATE; inhalation). RAC also agreed to classify clomazone (ISO) 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 1 for both hazards.

Contrary to the proposal by Denmark, RAC did not classify clomazone for toxicity to reproduction.

**citric acid** (EC: 201-069-1; CAS:77-92-9)

The substance citric acid is an active substance in biocidal products used as a disinfectant and as an algaecide.

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

RAC agreed to the proposal by Belgium to classify citric acid as a substance causing serious eye irritation (Eye Irrit. 2) and that may cause respiratory irritation (STOT SE 3).

RAC did not agree to the proposal by Belgium to classify citric acid as a substance causing skin irritation.

**desmedipham (ISO); ethyl 3-phenylcarbamoyloxyphenylcarbamate** (EC: 237-198-5; CAS: 13684-56-5)

The substance desmedipham (ISO) is an active substance in plant protection products used as a non-systemic contact herbicide.

The substance has an existing entry in Annex VI to the CLP Regulation for hazards to the aquatic environment as a substance very toxic to aquatic life (Aquatic Acute 1) with a multiplying factor of 10 and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1).

RAC agreed to the proposal by Finland to classify desmedipham (ISO) as a substance suspected of damaging the unborn child (Repr. 2; H361d) and to add a multiplying factor of 10 to the chronic aquatic hazard.

Contrary to the proposal by Finland, RAC did not classify desmedipham (ISO) as a substance that may cause damage to organs (blood) through prolonged or repeated exposure.

**phenmedipham (ISO); methyl 3-(3-methylcarbaniloyloxy)carbanilate** (EC: 237-199-0; CAS: 13684-63-4)

The substance phenmedipham (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 a substance very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1).

RAC agreed to the proposal by Finland to add multiplying factors of 10 to the environmental classifications.

Contrary to the proposal by Finland, RAC did not classify phenmedipham (ISO) as a reproductive toxicant, as a carcinogen nor as a substance that may cause damage to organs (blood) through prolonged or repeated exposure.

**triticonazole** (EC: 603-543-7; CAS: 131983-72-7)

The substance triticonazole is an active substance in plant protection products used as a fungicide.

The substance has an existing entry in Annex VI to the CLP Regulation for chronic hazards to the aquatic environment (Aquatic Chronic 2; H411).

RAC agreed to the proposal by Austria to classify triticonazole as a substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2) 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 1 for both hazards.

In addition, contrary to the proposal by Austria, RAC classified the substance as suspected of damaging fertility (Repr. 2; H361f).

**boric acid [1]; Diboron trioxide [2]; Tetraboron disodium heptaoxide, hydrate [3]; Disodium tetraborate, anhydrous [4]; Orthoboric acid sodium salt [5]; Disodium tetraborate decahydrate [6]; Disodium tetraborate pentahydrate [7]**

Boric acid and borates are industrial chemicals used as intermediates for the production of other chemicals or as substances in the manufacture of e.g. glasses, metals, cements, lubricants, greases, inks and cleaning products. Some borates are also active substances in biocidal products as antimicrobials and wood preservative agents. Boric acid and various borates have an existing harmonised classification and labelling in Annex VI of CLP as toxic to reproduction (Repr. 1B, H360FD) and specific concentration limits (SCLs) to classify substances and mixtures varying from 3.1 % to 8.5 % w/w.

RAC agreed to the proposal by Sweden to remove the existing specific concentration limits (SCLs) from these substances and to assign the generic concentration limit (GCL) of 0.3 % instead, in order to ensure that mixtures and preparations are appropriately classified and labelled, in line with the CLP Guidance.

**trifloxystrobin (ISO); methyl (E)-methoxyimino-{(E)-α-[1-(α,α,α-trifluoro-m-tolyl)ethylideneaminooxy]-o-tolyl}acetate** (EC: 604-237-6; CAS: 141517-21-7)

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

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) and for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1).

RAC agreed to the proposal by the United Kingdom to classify trifloxystrobin (ISO) 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 10, respectively.

In addition, contrary to the proposal by the United Kingdom, RAC classified trifloxystrobin (ISO) as a substance that may cause harm to breast-fed children (Lact.; H362).

**esfenvalerate (ISO); (S)-α-cyano-3-phenoxybenzyl-(S)-2-(4-chlorophenyl)-3-methylbutyrate** (EC: -; CAS: 66230-04-4)

The substance esfenvalerate (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 toxic if swallowed and if inhaled (Acute Tox. 3*, minimum classifications), as a substance that may cause an allergic skin reaction (Skin Sens. 1) and for hazards to the aquatic environment as very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) with multiplying factor of 10 000.

RAC agreed to the proposal by the United Kingdom to classify the substance for acute toxicity through oral and inhalation routes of exposure (Acute Tox. 3) and to add acute toxicity estimates of 88.5 mg/kg (ATE; oral) and of 0.53 mg/L for dusts or mists (ATE; inhalation), to retain the classifications for skin sensitisation (Skin Sens. 1) and for hazards to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1) adding a multiplying factor of 10 000 to the chronic hazard. RAC further agreed to the proposal by the United Kingdom to classify esfenvalerate (ISO) as a substance that may cause damage to organs through prolonged or repeated exposure (STOT RE 2).

In addition, contrary to the proposal by the United Kingdom, RAC classified esfenvalerate (ISO) as a substance that causes damage to the nervous system (STOT SE 1).

**ethametsulfuron-methyl (ISO); methyl 2-[(4-ethoxy-6-(methylamino)-1,3,5-triazin-2-yl)carbamoylsulfamoyl]benzoate** (EC n/a; CAS 97780-06-8)

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

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

RAC agreed to the proposal by the United Kingdom to classify ethametsulfuron-methyl (ISO) as a substance that causes serious eye irritation (Eye Irrit. 2) 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 1 000 and 100 respectively.

**dimethomorph (ISO); (E,Z)-4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl)morpholine** (EC: 404-200-2; CAS: 110488-70-5; (1135441-72-3))

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

The substance has an existing entry in Annex VI to the CLP Regulation as toxic to aquatic life with long lasting effects (Aquatic Chronic 2).

RAC agreed to the proposal by the Netherlands to retain the existing environmental classification (Aquatic Chronic 2) and to classify dimethomorph (ISO) as a substance that may damage fertility (Repr. 1B; H360F). However, contrary to the proposal by the Netherlands, RAC did not classify dimethomorph as a substance that may damage the unborn child.

**emamectin benzoate (ISO); (4''R)-4''-deoxy-4''-(methylamino)avermectin B1 benzoate** (EC: -; CAS 155569-91-8 (formerly CAS 13751274-4 and 179607-18-2)

The substance emamectin benzoate (ISO) is an active substance in plant protection products

used as an insecticide.

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

RAC agreed to the proposal by the Netherlands to classify emamectin benzoate (ISO) as a substance which is toxic if swallowed, if inhaled and if in contact with skin (Acute Tox. 3) and to add acute toxicity estimates of 60 mg/kg bw (ATE; oral), 0.663 mg/L for dusts or mists (ATE; inhalation) and 300 mg/kg bw (ATE; dermal). RAC also agreed with the Netherlands to classify the substance as causing serious eye damage (Eye Dam. 1), as causing damage to the nervous system through prolonged or repeated exposure (STOT RE 1) 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 10 000 for both hazards.

In addition, contrary to the proposal by the Netherlands, RAC classified emamectin benzoate (ISO) as a substance that causes damage to the nervous system (STOT SE 1) and set specific concentration limits for STOT RE (STOT RE 1; H372: C ≥ 5 %; STOT RE 2; H373: 0,5 % ≤ C < 5 %) for mixtures containing the substance.

**1,2-epoxy-4-epoxyethylcyclohexane; 4-vinylcyclohexene diepoxide** (EC: 203-437-7; CAS: 106-87-6)

The substance 1,2-epoxy-4-epoxyethylcyclohexane is an industrial chemical used as a chemical intermediate and as a diluent for other diepoxides and epoxy resins.

The substance has an existing entry in Annex VI to the CLP Regulation as toxic if swallowed, if in contact with skin and if inhaled (Acute Tox. 3*, minimum classifications) and as suspected of causing cancer (Carc. 2; H351).

RAC agreed to the proposal by the Netherlands to classify 4-vinylcyclohexene diepoxide as a substance that may cause cancer (Carc. 1B; H350) and as a substance that may damage fertility (Repr. 1B; H360F).

Contrary to the proposal by the Netherlands, RAC agreed to classify the substance as harmful if swallowed (Acute Tox. 4) and as toxic if inhaled (Acute Tox. 3) with acute toxicity estimates of 1 847 mg/kg bw (ATE; oral) and of 0.5 mg/L (ATE; inhalation) and agreed to remove the classification for acute dermal toxicity. In addition, RAC classified 4-vinylcyclohexene diepoxide as suspected of causing genetic defects (Muta 2; H341).

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

RAC agreed on five draft opinions and SEAC agreed on 18 draft opinions on the uses of chromium (VI) substances, coal tar pitch, high temperature and octyl- and nonylphenol ethoxylates. Both Committees agreed on the use of chromium trioxide in surface treatment for the manufacture of grain-oriented electrical steel used in magnetic circuits of electric devices, the use of coal tar pitch, high temperature as precursor of carbon matrix in the manufacturing of carbon-carbon composite parts, including nozzle throats, for civilian and military aerospace launchers, the use of octylphenol ethoxylates in a washing buffer to purify biological active pharmaceutical ingredients during the production of two medicinal products, and the formulation and use of octylphenol ethoxylates in two *in vitro* diagnostic products used by professional diagnostic laboratories.

Furthermore, RAC and SEAC discussed key issues in 27 applications for authorisation, which were received by ECHA in May 2019. Of the 27, 19 applications for authorisation are on variety of uses of octyl- and nonylphenol ethoxylates, including formulation and use of *in vitro* diagnostic assays, manufacturing and packaging of medicinal products, and manufacturing of chro-

matography resins. Seven of the applications are on five uses of pitch, coal tar, high temperature in formulation of mixtures, and two uses of the substance in manufacturing of targets for shooting. The remaining application for authorisation is on the use of chromium trioxide for the manufacture of Electrolytic Chromium/Chromium oxide Coated Steel (ECCS). 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