

Report
of the 14th Meeting of the Committee for Risk Assessment
Working Group on Harmonised Classification and Labelling
(RAC-70 CLH WG)

ECHA Conference Centre (Telakkakatu 6, Helsinki)
via Webex

Monday 1 July 2024 (10.00)
to
Wednesday 3 July 2024 (18:00)

Summary Record of the Proceedings

1. Welcome and apologies

The Chair of RAC, Roberto Scazzola, welcomed the participants to the 14th meeting of the RAC Working Group on CLH.

He informed that he would co-chair the meeting jointly with Stine Husa, Simon Uphill and Ricardo Simoes. Written consultations were organised on all dossiers prior to the working group meeting for RAC-70, apart from the human health part of the draft opinion on Fluazaindolizine (ISO), on which the RAC consultation will exceptionally be organised prior to RAC-70.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/CLH/A/14/2024), which was adopted with no modification (see Annex I).

3. Declarations of conflicts of interests to the Agenda

The Chair and the co-chairs declared no potential conflicts with the adopted agenda and invited all participants to declare any potential conflicts of interest. Declaration of potential conflict of interest on cases scheduled for the discussion are provided in Annex III to this Report.

4. Harmonised classification and labelling (CLH)

4.1 Hazard classes to be proposed by the group for agreement (without plenary debate) by A-listing at RAC-70

The Working Group agreed to propose the following hazard classes to RAC-70 for A-listing (without discussing them in the WG) based on the supportive written comments received from members during the consultation:

- **3,5-dimethylpyrazole:** *acute oral toxicity, STOT RE*
- **3,4-dimethyl-1H-pyrazole:** *acute toxicity via all routes*
- **3,4-dimethyl-1H-pyrazol-1-ium dihydrogen phosphate:** *acute dermal and inhalation toxicity, adverse effects on or via lactation*
- **Thermally treated garlic juice:** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, hazards to the aquatic environment, hazards to the Ozone layer*
- **Fluazaindolizine (ISO):** *hazards to the aquatic environment*
- **[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid:** *mutagenicity*
- **[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt:** *mutagenicity*
- **[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt:** *mutagenicity*
- **[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt:** *mutagenicity*
- **Rape oil; rape seed oil:** *acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation*
- **Tebuconazole (ISO):** *acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation*
- **Eugenol (dossier from the Spanish Competent Authority):** *physical hazards, acute inhalation and dermal toxicity, STOT RE, reproductive toxicity, aquatic acute hazard, hazard to the Ozone layer*

4.2 Hazard classes for discussion

4.2.1. 3,5-dimethylpyrazole (EC 200-657-5, CAS 67-51-6)

The co-Chair welcomed an expert accompanying the Regular Stakeholder Observer (CEFIC). She then provided some general information on the uses of **3,5-dimethylpyrazole**, existing harmonized classification, proposed classification by the Dossier Submitter (BE) and legal deadline.

Acute oral toxicity, reproductive toxicity and STOT RE were the hazard classes open for comments during the Consultation.

The Working Group discussed the proposed hazard classes and reached the following conclusions.

<p>The WG recommends to:</p> <p>Finalise the discussion on reproductive toxicity-fertility and development at RAC-70 (provisionally agreed by the WG as Repr. 1B; H360FD). The Rapporteur was asked to consider including supporting information from the two other substances.</p> <p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> • Acute oral toxicity – Acute Tox. 4; H302 (ATE=1700 mg/kg bw) • STOT RE – STOT RE 2; H373 (liver, blood) • Reproductive toxicity: <ul style="list-style-type: none"> ○ Lactation – No classification 	<p>Rapporteur to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for final discussion and adoption at RAC-70.</p> <p>The hazard classes going for plenary discussion: reproductive toxicity (fertility and development).</p>
<p>4.2.2 3,4-dimethyl-1H-pyrazole (EC 429-130-1, CAS 2820-37-3)</p>	
<p>The co-Chair welcomed an expert accompanying the Regular Stakeholder Observer (CEFIC). She then provided some general information on the uses of 3,4-dimethyl-1H-pyrazole, existing harmonized classification, proposed classification by the Dossier Submitter (BE) and legal deadline.</p> <p>Acute toxicity via all routes, carcinogenicity, reproductive toxicity and STOT RE were the hazard classes open for comments during the Consultation.</p> <p>The Working Group discussed the proposed hazard classes and reached the following conclusions.</p> <p>The expert accompanying the CEFIC Regular Stakeholder Observer commented on carcinogenicity.</p>	
<p>The WG recommends to:</p> <p>Finalise the discussion on carcinogenicity and reproductive toxicity-fertility and development at RAC-70 (provisionally agreed by the WG as Carc. 2; H351 and Repr. 2; H361f). The Rapporteur was asked to consider including supporting information from the two other substances.</p> <p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> • Acute oral toxicity – Acute Tox. 4; H302 (ATE=500 mg/kg bw) • Acute dermal toxicity – Acute Tox. 4; H312 (ATE=1100 mg/kg bw) • Acute inhalation toxicity – Acute Tox. 4; H332 (ATE=2.1 mg/L (dusts/mists)) • STOT RE - STOT RE 2; H373 (nasal cavity) 	<p>Rapporteur to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for final discussion and adoption at RAC-70.</p> <p>The hazard classes going for plenary discussion: carcinogenicity, reproductive toxicity (fertility and development).</p>

<ul style="list-style-type: none"> • Reproductive toxicity: <ul style="list-style-type: none"> ○ Lactation – No classification 	
4.2.3. 3,4-dimethyl-1H-pyrazol-1-ium dihydrogen phosphate (EC 424-640-9, CAS 202842-98-6)	
<p>The co-Chair welcomed an expert accompanying the Regular Stakeholder Observer (CEFIC). She then provided some general information on the uses of 3,4-dimethyl-1H-pyrazol-1-ium dihydrogen phosphate, existing harmonized classification, proposed classification by the Dossier Submitter (BE) and legal deadline.</p> <p>Acute toxicity via all routes, reproductive toxicity and STOT RE were the hazard classes open for comments during the Consultation.</p> <p>The Working Group discussed the proposed hazard classes and reached the following conclusions.</p> <p>The expert accompanying the CEFIC Regular Stakeholder Observer commented on acute oral toxicity, STOT RE and reproductive toxicity.</p>	
<p>The WG recommends to:</p> <p>Finalise the discussion on reproductive toxicity-fertility and development at RAC-70 (provisionally agreed by the WG as Repr. 1B; H360FD). The Rapporteur was asked to consider the information provided by Industry (presentation, including the publications) and to include supporting information from the two other substances.</p> <p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> • Acute dermal toxicity – No classification • Acute inhalation toxicity – No classification • Acute oral toxicity – Acute Tox. 4; H302 (ATE=500 mg/kg bw) • STOT RE – STOT RE 2; H373 (nasal cavity) • Reproductive toxicity: <ul style="list-style-type: none"> ○ Lactation – No classification 	<p>SECR to share with RAC the slides provided by Industry.</p> <p>Rapporteur to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for final discussion and adoption at RAC-70.</p> <p>The hazard classes going for plenary discussion: reproductive toxicity (fertility and development).</p>
4.2.4. Borate minerals group:	
<ul style="list-style-type: none"> 4.2.4.1. ulexite (CaNaH₁₂(BO₃)₅ × 2H₂O) [1] ulexite (CaNaH₁₂(BO₃)₅ × 2H₂O), calcined [2] (EC - [1] 296-662-5 [2], CAS 1319-33-1 [1] 92908-33-3 [2]) 4.2.4.1. colemanite (CaH(BO₂)₃ × 2H₂O) [1] boron calcium oxide (B₆Ca₂O₁₁), hydrate (1:5) [2] colemanite, calcined [3] (EC - [1] - [2] 296-640-5 [3], CAS 1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3]) 4.2.4.3. tincalconite (B₄Na₂O₇ × 5H₂O) (EC -, CAS 12045-88-4) 	
<p>The co-Chair welcomed the Dossier Submitter representatives and the Occasional Stakeholder Observer (IMA-Europe). He then provided some general information on the</p>	

<p>uses of borate minerals group, existing harmonized classification, proposed classification by the Dossier Submitter (SE) and legal deadline.</p> <p>Reproductive toxicity was the only hazard classes open for comments during the Consultation.</p> <p>The Working Group discussed the proposed hazard classes and reached the following conclusions.</p> <p>The expert accompanying the CEFIC Regular Stakeholder Observer commented on the Note 11.</p>	
<p>The WG concurs with the DS that read-across to boric and other borates is relevant and aligned with the previous assessments of borates by RAC.</p> <p>The WG recommends to:</p> <ul style="list-style-type: none"> • Finalise the discussion on reproductive toxicity-fertility and development at RAC-70 (provisionally agreed by the WG as Repr. 1B; H360FD). <p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> • Reproductive toxicity: <ul style="list-style-type: none"> ○ Lactation – No classification (due to inconclusive data) 	<p>Rapporteur to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for final discussion and adoption at RAC-70.</p> <p>The hazard classes going for plenary discussion: reproductive toxicity (fertility and development).</p>
<p>4.2.5. Thermally treated garlic juice (EC -, CAS -)</p>	
<p>The co-Chair welcomed the Dossier Submitter representative and provided some general information on the uses of thermally treated garlic juice, existing harmonized classification, proposed classification by the Dossier Submitter (AT) and legal deadline.</p> <p>Explosives, flammable liquids, self-reactive substances and mixtures, pyrophoric liquids, substances or mixtures which in contact with water emit flammable gases, oxidising liquids, corrosive to metals, desensitised explosives, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitization, skin sensitization, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, hazards to the aquatic environment, hazards for the Ozone layer were the hazard classes open for comments during the Consultation.</p> <p>The Working Group discussed the proposed hazard classes and reached the following conclusions.</p>	
<p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> • Physical hazards – No classification • Acute toxicity via all routes – No classification • Skin corrosion/irritation – No classification • Serious eye damage/eye irritation – No classification • Respiratory sensitisation – No classification 	<p>Rapporteurs to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for adoption at RAC-70.</p>

<ul style="list-style-type: none"> • Skin sensitisation – Skin Sens. 1B; H317 • STOT SE – No classification • STOT RE – No classification • Mutagenicity – No classification • Carcinogenicity – No classification • Reproductive toxicity – No classification • Aspiration hazard – No classification • Hazards to the aquatic environment – No classification • Hazards to the Ozone layer – No classification 	<p>The hazard classes going for plenary discussion: none.</p>
<p>4.2.6. Fluazaindolizine (ISO); 8-chloro-N-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide (EC -, CAS 1254304-22-7)</p>	
<p>The co-Chair welcomed the Dossier Submitter representatives and then provided some general information on the uses of fluazaindolizine (ISO), existing harmonized classification, proposed classification by the Dossier Submitter (MT) and legal deadline.</p> <p>Explosives, flammable solids, self-reactive substances and mixtures, pyrophoric solids, self-heating substances or mixtures, substances or mixtures which in contact with water emit flammable gases, oxidising solids, organic peroxides, corrosive to metals, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazards to the aquatic environment were open for comments during the Consultation, except for respiratory sensitisation.</p> <p>The Working Group discussed physical hazards and hazards to the aquatic environment and reached the following conclusions.</p>	
<p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> • Physical hazards – No classification • Aquatic toxicity – No classification for aquatic acute toxicity and Aquatic Chronic 2; H411 	<p>SECR to table the updated opinion for final discussion and adoption at RAC-70.</p> <p>The hazard classes going for plenary discussion: human health hazards.</p>
<p>4.2.7. [ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid (EC 215-851-5, CAS 1429-50-1)</p>	
<p>The co-Chair welcomed the Dossier Submitter representative and an expert accompanying the Regular Stakeholder Observer (CEFIC). He then provided some general information on the uses of [ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, existing harmonized classification, proposed classification by the Dossier Submitter (DE) and legal deadline.</p> <p>Mutagenicity, carcinogenicity and STOT RE were the hazard classes open for comments during the Consultation.</p> <p>The Working Group discussed the proposed hazard classes and reached the following conclusions.</p>	

<p>The expert accompanying the CEFIC Regular Stakeholder Observer commented on carcinogenicity.</p>	
<p>The WG recommends to:</p> <ul style="list-style-type: none"> Finalise the discussion on carcinogenicity at RAC-70 (provisionally agreed on Carc. 1B; H350 (with GCL of 0.1%)). <p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> Mutagenicity – No classification (due to inconclusive data) STOT RE – No classification (due to inconclusive data). 	<p>Rapporteur to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for adoption at RAC-70.</p> <p>The hazard classes going for plenary discussion: carcinogenicity.</p>
<p>4.2.8. [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt (EC 287-370-9, CAS 85480-89-3)</p>	
<p>See above (point 4.2.7).</p>	
<p>4.2.9. [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt (EC 251-910-1, CAS 234274-30-1)</p>	
<p>See above (point 4.2.7).</p>	
<p>4.2.10. [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt (EC 244-742-5, CAS 22036-77-7)</p>	
<p>See above (point 4.2.7).</p>	
<p>4.2.11. 2-pyrrolidone; pyrrolidin-2-one (EC 210-483-1, CAS 616-45-5)</p>	
<p>The co-Chair welcomed the Dossier Submitter representatives and an expert accompanying the Regular Stakeholder Observer (CEFIC). He then provided some general information on the uses of 2-pyrrolidone; pyrrolidin-2-one, proposed classification by the Dossier Submitter (NO) and legal deadline.</p> <p>Reproductive toxicity was the only hazard class open for comments during the Consultation. The Working Group discussed it and reached the following conclusions.</p> <p>The expert accompanying the CEFIC Regular Stakeholder Observer commented on developmental toxicity.</p>	
<p>The WG recommends to:</p> <ul style="list-style-type: none"> Finalise the discussion on reproductive toxicity-development at RAC-70 (provisionally agreed by the WG as Repr. 1B; H360D with SCL = 3 %). <p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> Reproductive toxicity: 	<p>Rapporteurs to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for discussion and adoption at RAC-70.</p>

<ul style="list-style-type: none"> ○ Fertility – No classification ○ Lactation – No classification (due to lack of data) 	<p>The hazard classes going for plenary discussion: developmental toxicity.</p>
<p>4.2.12. Rape oil; rape seed oil (EC 232-299-0, CAS 8002-13-9)</p>	
<p>The co-Chair welcomed an expert accompanying the Regular Stakeholder Observer (CropLife Europe) and provided some general information on the uses of rape oil, proposed classification by the Dossier Submitter (NL) and legal deadline.</p> <p>All relevant hazard classes were open for comments during the Consultation. The Working Group discussed the proposed hazard classes and reached the following conclusions.</p> <p>The expert accompanying the CropLife Europe Regular Stakeholder Observer commented on the composition of the substance.</p>	
<p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> • Physical hazards – No classification • Acute toxicity via oral, dermal, and inhalation route – No classification • Serious eye damage/eye irritation – No classification • Skin corrosion/irritation – No classification • Respiratory sensitisation – No classification (due to lack of data) • Skin sensitisation – No classification • Mutagenicity – No classification (due to lack of data) • Carcinogenicity – No classification (due to lack of data) • Reproductive toxicity: <ul style="list-style-type: none"> ○ Fertility – No classification (due to inconclusive data) ○ Development – No classification (due to inconclusive data) ○ Lactation – No classification (due to inconclusive data) • STOT SE – No classification • STOT RE – No classification (due to inconclusive data) • Aspiration hazard – No classification • Aquatic toxicity (acute and chronic) – No classification 	<p>Rapporteurs to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for adoption at RAC-70.</p> <p>The hazard classes going for plenary discussion: none.</p>
<p>4.2.13. Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol (EC 403-640-2; CAS 107534-96-3)</p>	

The co-Chair welcomed the Dossier Submitter representative, an expert accompanying the Regular Stakeholder Observer (CEFIC), and an expert accompanying the Regular Stakeholder Observer (CropLife Europe). He then provided some general information on the uses of **tebuconazole (ISO)**, proposed classification by the Dossier Submitter (DK) and legal deadline.

Acute toxicity, skin corrosion/skin irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard were the hazard classes open for comments during the Consultation.

The Working Group discussed the proposed hazard classes and reached the following conclusions.

The expert accompanying the CropLife Europe Regular Stakeholder Observer commented on fertility and sexual function, and development.

The WG recommends to:

- Finalise the discussion on reproductive toxicity-fertility and development at RAC-70 (provisionally agreed by the WG as Repr. 1B; H360FD).

The WG recommends A-listing at RAC-70 the following classification:

- **Acute toxicity via oral route** – Acute toxicity 4; H302 (ATE = 1700 mg/kg bw)
- **Acute toxicity dermal and inhalation route** – No classification
- **Skin Corrosion/irritation** – No classification
- **Serious eye damage/eye irritation** – No classification
- **Respiratory sensitisation** – No classification
- **Skin sensitisation** – No classification
- **Mutagenicity** – No classification
- **Carcinogenicity** – No classification (due to inconclusive data)
- **Reproductive toxicity:**
 - **Lactation** – No classification (due to lack of data)
- **STOT SE** – No classification
- **STOT RE** – STOT RE 2; H373 (eyes, liver)
- **Aspiration hazard** – No classification (due to lack of data)

Rapporteurs to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.

SECR to table the updated opinion for adoption at RAC-70.

The hazard classes going for plenary discussion: fertility and developmental toxicity.

4.2.14. Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol (EC 202-589-1; CAS 97-53-0) (dossier from the Spanish Competent Authority)

The co-Chair welcomed the Dossier Submitter representatives, the Occasional Stakeholder Observer (EFEO), as well as the Occasional Stakeholder Observer (IFRA) with an accompanying expert. He then provided some general information on the uses of **eugenol**, proposed classification by the Dossier Submitter (ES) and legal deadline.

All relevant hazard classes were open for comments during the Consultation, except for skin sensitisation (on which a separate dossier has been prepared by DK).
 The Working Group discussed the proposed hazard classes and reached the following conclusions.

The WG recommends A-listing at RAC-70 the following classification:

- **Physical hazards** – No classification
- **Acute oral toxicity** – Acute Tox. 4; H302 (ATE=1930 mg/kg bw)
- **Acute inhalation toxicity** – No classification
- **Acute dermal toxicity** – No classification
- **Skin corrosion/irritation** – No classification
- **Serious eye damage/eye irritation** – No classification (due to inconclusive data)
- **Mutagenicity** – No classification (due to inconclusive data)
- **Carcinogenicity** – No classification
- **Reproductive toxicity** – No classification
- **STOT SE** – STOT SE 3; H336
- **STOT RE** – No classification
- **Aquatic toxicity** – No classification for aquatic acute toxicity and No classification for aquatic chronic toxicity
- **Hazardous to the Ozone layer** – No classification

SECR to consider combining the opinion for this dossier and for the DK dossier on Eugenol.

Rapporteurs to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.

SECR to table the updated opinion for adoption at RAC-70.

The hazard classes going for plenary discussion: none.

4.2.15. Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol (EC 202-589-1; CAS 97-53-0) (dossier from the Danish Competent Authority and includes only Skin Sensitisation)

The co-Chair welcomed the Dossier Submitter representatives, the Occasional Stakeholder Observer (EFEO), as well as the Occasional Stakeholder Observer (IFRA) with an accompanying Expert. He then provided some general information on the uses of **eugenol**, proposed classification by the Dossier Submitter (DK) and legal deadline.

Skin sensitisation was the only hazard class open for comments during the Consultation, except for skin sensitisation.

The Working Group discussed the proposed hazard classes and reached the following conclusions.

The WG recommends A-listing at RAC-70 the following classification:

- **Skin sensitisation** – Skin Sens. 1B; H317

SECR to consider combining the opinion for this dossier and for the ES dossier on Eugenol.

Rapporteur to revise the opinion in accordance with the discussion

	<p>in the Working Group and to provide it to SECR.</p> <p>SECR to table the updated opinion for adoption at RAC-70.</p> <p>The hazard classes going for plenary discussion: none.</p>
<p>4.2.16. Talc (Mg₃H₂(SiO₃)₄) (EC 238-877-9; CAS 14807-96-6)</p>	
<p>The Chair welcomed the Dossier Submitter representative, the Occasional Stakeholder Observer (IMA-Europe) with an accompanying expert, as well as an accompanying expert to the Regular Stakeholder Observer (Eurometaux), and an accompanying expert to the Regular Stakeholder Observer (CEFIC). He then provided some general information on the uses of talc (Mg₃H₂(SiO₃)₄), existing harmonized classification, proposed classification by the Dossier Submitter (NL) and legal deadline.</p> <p>Carcinogenicity and STOT RE were the only hazard classes open for comments during the Consultation.</p> <p>Only STOT RE and lung carcinogenicity (including lung overload) were discussed in the RAC-69 CLH WG, while pheochromocytomas were discussed in the June plenary and ovarian cancer will be discussed in the July WG/September plenary.</p> <p>The Occasional Stakeholder Observer (IMA-Europe), the expert accompanying the Occasional Stakeholder Observer (IMA-Europe), the expert accompanying the Eurometaux Regular Stakeholder Observer and the expert accompanying the CEFIC Regular Stakeholder Observer commented on carcinogenicity.</p>	
<p>Carcinogenicity</p> <p>The WG took note of Rapporteurs assessment of ovarian cancer in humans.</p> <p>The WG concluded that overall, the available case-control studies provide evidence for a positive association of perineal talc exposure and ovarian cancer risk.</p> <p>The WG concluded that overall, strong evidence for a positive association of talc use and risk for ovarian cancer is not apparent in the cohort studies, however the WG took note of the limitations of studies and that a positive association of 'ever' perineal talc use by women with patent reproductive tract or women without prior tubal ligation and ovarian cancer risk has been suggested by a meta-analysis.</p> <p>The WG concluded that overall, the meta-analyses consistently demonstrate a moderate and statistically significant positive association of perineal talc use and risk of ovarian cancer with some additional evidence for</p>	<p>Rapporteurs to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p> <p>SECR to organise a RAC consultation on the updated opinion and to table the updated opinion for the final discussion at RAC-70.</p> <p>The hazard classes going for plenary discussion: carcinogenicity.</p>

<p>dose-response. The association appeared to be driven by case-control studies.</p> <p>The WG concluded that clinical and laboratory studies have demonstrated that talc from talc powder products used in the genital area can migrate to the ovaries.</p> <p>The WG concluded that it is plausible that talc particles can induce oxidative stress and subsequent chronic inflammation of the ovarian surface epithelium by direct action of talc, similarly as it was proposed as initial step in the development of lung cancer in female rats.</p> <p>The WG furthermore concluded on biological plausibility of the hypothesis that due to increased oxidative stress and inflammation mechanisms such as secretion of mediators promoting cell proliferation, and inhibition of apoptosis are induced, leading to tumour formation and progression to malignancy.</p> <p>The WG took note of the outcome of the Bradford Hill criteria analysis to evaluate causality of ovarian cancer findings.</p> <p>Overall, the WG recommends considering the highly consistent findings of a statistically significant positive association between 'ever' genital/perineal use of talc powder and risk of ovarian cancer as limited evidence for the carcinogenic potential of talc after perineal use.</p> <p>At RAC-70, RAC will continue discussion on ovary cancers in humans (final conclusions) and agree on the overall carcinogenicity classification.</p>	
<p>4.2.17. Silver nitrate (EC 231-853-9, CAS 7761-88-8)</p>	
<p>The Chair welcomed the Dossier Submitter representatives, an expert accompanying the Eurometaux Regular Stakeholder Observer, as well as an expert accompanying the CEFIC Regular Stakeholder Observer. He then provided some general information on the uses of silver nitrate, proposed classification by the Dossier Submitter (SE) and legal deadline. All relevant hazard classes, except for aspiration hazard and the hazard to the ozone layer, were open for comments during the Consultation.</p> <p>The Working Group discussed the proposed hazard classes and reached the following conclusions.</p> <p>The expert accompanying the Eurometaux Regular Stakeholder Observer commented on physical hazards, aquatic toxicity and HH read-across principles. The Eurometaux Regular Stakeholder Observer commented on aquatic toxicity.</p>	
<p>The WG recommends A-listing at RAC-70 the following classification:</p> <ul style="list-style-type: none"> • Physical hazards – Ox. Sol. 1; H271 (including Note T), Met. Corr. 1; H290 and 	<p>Rapporteurs to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.</p>

<p>No classification for the other hazard classes considered</p> <ul style="list-style-type: none"> • Aquatic toxicity – Aquatic Acute 1; H400 (M=1000) and Aquatic Chronic 1; H410 (M=100) <p><u>Human Health</u> The Rapporteurs presented and the WG took note of the toxicokinetic and read-across principles.</p> <p>The WG agreed with the Rapporteurs` proposal for read-across with AgAc and AgCl.</p> <p>The WG considered the read-across with AgNP is also applicable, however hazard could be underestimated compared to silver salts as the silver ion seem to be less bioavailable after AgNP exposure. The WG did not support the read-across with silver zeolites and other ion exchangers for the lower relevance for AgNO₃ classification purpose.</p>	<p>SECR to organise a RAC consultation on the updated opinion (part of HH) and to table the updated opinion for further discussion at RAC-70.</p> <p>The hazard classes going for plenary discussion: part of HH hazard classes.</p>
---	--

5 AOB

The Secretariat presented and the WG took note of the new ODD template to be applied for the CLH process.

6 Adoption of the report from the Working Group

Before the Chair thanked the participants and closed the meeting, the Working Group adopted the report of its 14th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I Agenda of the 14th Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling

Annex II List of participants

Annex III Declarations of potential conflicts of interest

ANNEX I: Final agenda

25 June 2024
RAC WG/A/CLH/14/2024

**14th Meeting of the Committee for Risk Assessment Working Group
on Harmonised Classification and Labelling (RAC-70 CLH WG)**

**Monday 1 July at 10:00 -
Wednesday 3 July ends at 18:00**

Times are Helsinki times
Virtual meeting

Draft Agenda

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/CLH/14/2024
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Harmonised classification and labelling (CLH)

**4.1. Hazard classes to be proposed for agreement without plenary debate
(A-list) in RAC-70:**

- **3,5-dimethylpyrazole:** *acute oral toxicity, STOT RE*
- **3,4-dimethyl-1H-pyrazole:** *acute toxicity via all routes*
- **3,4-dimethyl-1H-pyrazol-1-ium dihydrogen phosphate:** *acute dermal and inhalation toxicity, adverse effects on or via lactation*
- **Thermally treated garlic juice:** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, hazards to the aquatic environment, hazards to the Ozone layer*
- **Fluazaindolizine (ISO):** *hazards to the aquatic environment*
- **[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid:** *mutagenicity*
- **[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt:** *mutagenicity*
- **[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt:** *mutagenicity*

- **[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt:** *mutagenicity*
- **Rape oil; rape seed oil:** *acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, aspiration hazard*
- **Tebuconazole (ISO):** *acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation*
- **Eugenol (dossier from the Spanish Competent Authority):** *physical hazards, acute inhalation and dermal toxicity, STOT RE, reproductive toxicity, aquatic acute hazard, hazard to the Ozone layer*

4.2. CLH dossiers

- 4.2.1. 3,5-dimethylpyrazole (EC 200-657-5, CAS 67-51-6)
- 4.2.2. 3,4-dimethyl-1*H*-pyrazole (EC 429-130-1, CAS 2820-37-3)
- 4.2.3. 3,4-dimethyl-1*H*-pyrazol-1-ium dihydrogen phosphate (EC 424-640-9, CAS 202842-98-6)
- 4.2.4. Borate minerals group:
 - 4.2.4.1. ulexite ($\text{CaNaH}_{12}(\text{BO}_3)_5 \times 2\text{H}_2\text{O}$) [1] ulexite ($\text{CaNaH}_{12}(\text{BO}_3)_5 \times 2\text{H}_2\text{O}$), calcined [2] (EC - [1] 296-662-5 [2], CAS 1319-33-1 [1] 92908-33-3 [2])
 - 4.2.4.1. colemanite ($\text{CaH}(\text{BO}_2)_3 \times 2\text{H}_2\text{O}$) [1] boron calcium oxide ($\text{B}_6\text{Ca}_2\text{O}_{11}$), hydrate (1:5) [2] colemanite, calcined [3] (EC - [1] - [2] 296-640-5 [3], CAS 1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3])
 - 4.2.4.3. tincalconite ($\text{B}_4\text{Na}_2\text{O}_7 \times 5\text{H}_2\text{O}$) (EC -, CAS 12045-88-4)
- 4.2.5. Thermally treated garlic juice (EC -, CAS -)
- 4.2.6. Fluazaindolizine (ISO); 8-chloro-*N*-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-*a*]pyridine-2-carboxamide (EC -, CAS 1254304-22-7)
- 4.2.7. [ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid (EC 215-851-5, CAS 1429-50-1)
- 4.2.8. [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt (EC 287-370-9, CAS 85480-89-3)
- 4.2.9. [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt (EC 251-910-1, CAS 234274-30-1)
- 4.2.10. [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt (EC 244-742-5, CAS 22036-77-7)
- 4.2.11. 2-pyrrolidone; pyrrolidin-2-one (EC 210-483-1, CAS 616-45-5)
- 4.2.12. Rape oil; rape seed oil (EC 232-299-0, CAS 8002-13-9)
- 4.2.13. Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol (EC 403-640-2; CAS 107534-96-3).
- 4.2.14. Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol (EC 202-589-1; CAS 97-53-0) (dossier from the Spanish Competent Authority)
- 4.2.15. Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol (EC 202-589-1; CAS 97-53-0) (dossier from the Danish Competent Authority and includes only Skin Sensitisation)
- 4.2.16. Talc ($\text{Mg}_3\text{H}_2(\text{SiO}_3)_4$) (EC 238-877-9; CAS 14807-96-6)
- 4.2.17. Silver nitrate (EC 231-853-9, CAS 7761-88-8)

For discussion

Item 5 – AOB

Item 6 – Adoption of the Report from the WG

For discussion and agreement

ANNEX II: List of participants

RAC members	
Angeli	Karine
Barański	Bogusław
Biró	Anna
Brovkina	Julija
Docea	Anca
Esposito	Dania
Facchin	Manuel
Fernandez	Mariana F.
Geoffroy	Laure
Hakkert	Betty
Hoffmann	Frauke
Kadikis	Normunds
Kloslova	Zuzana
Leinonen	Riitta
Losert	Annemarie
Manusadžianas	Levonas
Martínek	Michal
Menard Srpčič	Anja
Mendas Starcevic	Gordana
Mohammed	Ifthekhar Ali
Murray	Brendan
Neumann	Michael
Piña	Benjamin
Pribu	Mihaela
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Schlüter	Urs
Schuur	Gerlienke
Spetseris	Nikolaos
Stalter	Daniel
Tekpli	Nina
Tobiassen	Lea Stine
Tsitsimpikou	Christina
Užomeckas	Žilvinas
Wildemann	Tanja

Members' advisers	
Capolupo Marco	Esposito Dania
Catone Tiziana	Aquilina Gabriele
Geraets Liesbeth	Hakkert Betty
Jankowska Agnieszka	Barański Boguslaw
Meys Catherine	Rodriguez Wendy

Moilanen Marianne	Leinonen Riitta
Russo Maria Teresa	Aquilina Gabriele
Suutari Tiina	Leinonen Riitta
van Herwijnen Rene	Hakkert Betty

Dossier submitters	Substance
Axelstad Marta	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
Birgander Pernilla	Silver nitrate
Bjørge Christine	2-pyrrolidone; pyrrolidin-2-one
Blom Cecile	2-pyrrolidone; pyrrolidin-2-one
Cilia Nicole	Fluazaindolizine (ISO); 8-chloro-N-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide
Guendel Ulrike	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid; [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt; [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt; [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt
Hahlbeck Edda	Silver nitrate
Holmer Marie Louise	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
Jacobsen Pernille Rosenskjold	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
Jensen Stine	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
Johansson Tommy	Borate minerals group: ulexite (CaNaH ₁₂ (BO ₃) ₅ × 2H ₂ O) [1] ulexite (CaNaH ₁₂ (BO ₃) ₅ × 2H ₂ O), calcined [2]; colemanite (CaH(BO ₂) ₃ × 2H ₂ O) [1] boron calcium oxide (B ₆ Ca ₂ O ₁₁), hydrate (1:5) [2] colemanite, calcined [3]; tinalconite (B ₄ Na ₂ O ₇ × 5H ₂ O);
Marinovich Marina	Fluazaindolizine (ISO); 8-chloro-N-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide
Österwall Christoffer	Silver nitrate
Sanz Manuel	Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol (ES)
Tobiassen Lea Stine	Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol (DK)

Invited Experts	
Moeller Ruth	Hoffman Frauke

European Commission/EU Agencies	
Ceridono Mara	COM
Pinte Jérémy	COM
Castoldi Anna	EFSA

Regular stakeholder observers	
De Backer Liisi	CEFIC
Ruelens Paul	CropLife Europe
Violaine Verougstraete	Eurometaux

Occasional stakeholder observers		Substance
Arregui Cristina	IFRA	Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol
Doome Roger	IMA-Europe	Borate minerals group: ulexite (CaNaH ₁₂ (BO ₃) ₅ × 2H ₂ O) [1] ulexite (CaNaH ₁₂ (BO ₃) ₅ × 2H ₂ O), calcined [2]; colemanite (CaH(BO ₂) ₃ × 2H ₂ O) [1] boron calcium oxide (B ₆ Ca ₂ O ₁₁), hydrate (1:5) [2] colemanite, calcined [3]; tincalconite (B ₄ Na ₂ O ₇ × 5H ₂ O); Talc (Mg ₃ H ₂ (SiO ₃) ₄)
Zippel Maja	EFEO	Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol

Stakeholder Experts		Substance
Borm Paul	Eurometaux	Talc (Mg ₃ H ₂ (SiO ₃) ₄)
Eichler-Haeske Jens-Olaf	BASF	2-pyrrolidone; pyrrolidin-2-one
Faulhammer Frank	BASF	3,4-dimethyl-1H-pyrazole; 3,4-dimethyl-1H-pyrazol-1-ium dihydrogen phosphate
Goodyear Andrew	European Biocidal Silver Task Force	silver nitrate
Hajjar Kalila	Fediol	Rape oil; rape seed oil
Ledirac Nathalie	Eurofins Agrosience	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
Mertens Jelle	EPMF	silver nitrate
Moxon Mary	TGS CRO on behalf Bayer company	Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol
Mundt Kenneth	IMA Europe - Expert	Talc (Mg ₃ H ₂ (SiO ₃) ₄)
Rovida Costanza	Italmatch Chemicals GB Ltd	[ethane-1,2-diybis[nitrilobis(methylene)]]tetrakisphosphonic acid;

		[ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt; [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt; [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt
Vey Matthias	IFRA	Eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol
Zanotti Russo Matteo	Manetti & Roberts	Talc ($Mg_3H_2(SiO_3)_4$)

ECHA staff	
Scazzolo (Chair of RAC)	Roberto
Uphill (Co-chair)	Simon
Simoës (Co-chair)	Ricardo
Husa (Co-chair)	Stine
Altieri	Andrea
Artlidge	George
Atanasova	Marina
Bichlmaier	Bohumila
Ludborz	Arnis
Marchetto	Flavio
Nieminen	Taru
Nygren	Jonas
Orispää	Katja
Parikka	Petra
Perazzolo	Chiara
Purje	Aino
Richarz	Andrea
Sadam	Diana
Sobanska	Marta
Spjuth	Linda

ANNEX III (RAC-70CLHWG-1)

The following participants, including those for whom the Chairman declared the interest on their behalf, declared potential conflicts of interest with the Agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Harmonised classification & labelling		
Talc ($Mg_3H_2(SiO_3)_4$) NL	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
NEW DOSSIERS		
1) Borate minerals group 2) Silver nitrate SE	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
<p>Eugenol</p> <p>ES</p>	Benjamin PINA	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Marieta FERNANDEZ	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
<p>Thermally treated garlic juice</p> <p>AT</p>	Annemarie LOSERT	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Manuel FACCHIN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
<p>1) [ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid</p> <p>2) [ethylenebis[nitrilobis(methylene)]]tetrakisphosph</p>	Frauke HOFFMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
<p>onic acid, calcium sodium salt</p> <p>3) [ethylenebis[nitri lobis(methylene)]]tetrakisphosph onic acid, potassium salt</p> <p>4) [ethylenebis[nitri lobis(methylene)]]tetrakisphosph onic acid, sodium salt</p> <p>DE</p>	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Urs SCHLUETER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Daniel STALTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
<p>Rape seed oil</p> <p>NL</p>	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
<p>1) 3,5-dimethylpyrazole 2) 3,4-dimethyl-1H-pyrazole 3) 3,4-dimethyl-1H-pyrazol-1-ium dihydrogen phosphate</p> <p>BE</p>	Wendy RODRIGUEZ	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
<p>2-pyrrolidone</p> <p>NO</p>	Kirsten RAKKESTAD	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
<p>1) Tebuconazole (ISO) 2) Eugenol (Skin Sens.)</p> <p>DK</p>	Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Peter Hammer SÖRENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.