RAC WG/CLH/R/5/2022

27 April 2022

Report
of the 5th Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling (RAC-61 CLH WG)

ECHA Conference Centre (Telakkakatu 6, Helsinki) via Webex

Thursday 21 April 2022 at 10.00 to Wednesday 27 April at 12.40

Summary Record of the Proceedings

1. Welcome and apologies

The Chair of RAC, Tim Bowmer, welcomed the participants to the 5th meeting of the RAC Working Group on CLH and reminded them that the Committee had agreed on the establishment of the group at RAC-56 in March 2021, with the first full working group meeting taking place in October 2021 ahead of RAC-59.

He informed that the meeting would be jointly chaired by the Deputy Chair of RAC Johanna Peltola-Thies and by officers of the CLH team: Kirsi Myohanen, Ari Karjalainen, Ricardo Simoes and Simon Uphill.

Written consultations were organised on all dossiers prior to the working group meeting for RAC-61.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/CLH/5/2022), which was adopted with no modification and is attached to this Report as Annex I.

3. Declarations of conflicts of interests to the Agenda

The Chair informed that he had no potential conflicts with the agenda to declare and requested all participants to declare any potential conflicts of interest to any of the agenda items. Several participants of the meeting declared a potential conflict of interest on cases scheduled for the discussion as presented in Annex III to this Report. The Chairs then all

declared that they had no potential interests related to any of the agenda points for the meeting.

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-61

The Working Group agreed to propose the following hazard classes to RAC-61 for A-listing (without discussing them in the WG) based on the written comments received from members during the consultation:

- **7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:** skin sensitisation, mutagenicity, STOT RE
- **Formic acid …%:** serious eye damage/eye irritation
- **Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl] phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl}naphthalene-2,7-disulfonate:** skin sensitisation
- **2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one:** STOT RE
- **Peracetic acid …%:** EUH071
- **Formaldehyde …%:** skin sensitisation

4.2 Hazard classes for discussion

4.2.1 Glyphosate

The Chair welcomed the Dossier Submitter representatives, the EEB, CropLife, CEFIC and ClientEarth Regular Stakeholder Observers with their accompanying experts, the HEAL Occasional Stakeholder Observer with the accompanying expert as well as the observers from EFSA. He informed that **glyphosate** is an active substance used in PPPs to control plants, which means it is a herbicide. The substance has current Annex VI entry as Eye Dam. 1; H318 and Aquatic Chronic 2; H411. The previous opinion for this substance was adopted by RAC in March 2017.

Physical hazards (solid substance), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and hazardous to the aquatic

environment were the hazard classes open for comments during the Consultation. During the opinion development some published articles which are potentially relevant to classification of glyphosate for physical hazards, respiratory sensitisation, STOT SE (respiratory irritation), germ cell mutagenicity, carcinogenicity, reproductive toxicity and hazardous to the aquatic environment were identified which were not summarised in the CLH report. A targeted consultation of these documents was therefore organised 29/03-14/04/2022. The legal deadline for the adoption of an opinion is 17 March 2023.	
Human Health *Acute toxicity* The WG recommended no classification for acute toxicity via oral, dermal and inhalation routes. In relation to the acute inhalation toxicity, it was recommended to reflect in the revised opinion that the studies where the MMAD of the particles was < 4 µm were given greater weight and that data from sprayed aerosols are lacking. The WG recommended A-listing of the following hazard classes at RAC-61. *STOT SE* The WG recommended no classification and A-listing at RAC-61. *Skin corrosion/irritation* The WG recommended no classification and A-listing at RAC-61. *Serious eye damage/eye irritation* The WG recommended retaining the classification as Eye Dam. 1; H318 and A-listing at RAC-61. *Respiratory sensitisation* The WG recommended no classification based on insufficient data and A-listing at RAC-61. *Skin sensitisation* The WG recommended no classification and A-listing at RAC-61. *STOT RE* The WG recommended no classification and A-listing at RAC-61.	**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 final discussion and adoption at RAC-61. **The hazard classes going for plenary discussion: Mutagenicity, carcinogenicity, reproductive toxicity, hazardous to the aquatic environment.**

Mutagenicity The WG recommended no classification, but some of the issues raised in the discussion would be further reflected in the opinion, including the role of bioavailability of glyphosate and in vivo Comet assay data from liver as well as the data from the Bolognesi (2009) study. The WG also recommended that the uncertainties noted in the 2017 opinion regarding the Ames test in bacteria should be also reflected in the current opinion. The overall conclusion on mutagenicity and the above aspects of this hazard class will be discussed briefly at RAC-61. *Carcinogenicity* The WG took note of the Rapporteur's analysis of the animal and human data and recommended no classification, however some of the issues raised in the discussion would be further reflected in the opinion, including uncertainties in the human exposure data reported by Andreotti et al (2018) and whether other epidemiology studies (incl. Leon et al 2019) would have relevant information to add to the opinion. In the extensive animal tests, the Rapporteur is asked to reflect in the opinion, the issues raised in the discussion in relation to the role of findings observed at high doses vs MTD, statistical vs biological significance, role of oxidative stress, the use of HCD, and WoE. The overall conclusion on carcinogenicity and the above aspects of this hazard class will be discussed briefly at RAC-61. *Reproductive toxicity* Fertility The WG recommended no classification and suggested a brief summary and discussion at RAC-61. Developmental toxicity The WG recommended no classification and suggested a brief summary and discussion at RAC-61. Lactation The WG recommended no classification and suggested a brief summary and discussion at RAC-61.	

Physical hazards The WG recommended no classification and A-listing at RAC-61. Hazardous to the aquatic environment The WG took note of the Rapporteurs` analysis and agreed that they should further elaborate and assess the quality of the individual experimental fish and plant studies, comparing them with the respective OECD Guidelines and validity criteria, taking into account the comments from the targeted consultation. It was further agreed to evaluate the SSD presented in the Fan et al. (2022) paper and one Member offered to support the Rapporteurs in this. An amended draft opinion will be provided by the Rapporteurs by 6 May and the discussion will be continued at RAC-61. The WG recommended retaining the classification as Aquatic Chronic 2, pending further assessment. It was noted that the acute hazard class was still open.	
The expert accompanying the CropLife Regular Stakeholder Observer commented on STOT RE. The expert accompanying the EEB Regular Stakeholder Observer, the expert accompanying the CropLife Regular Stakeholder Observer, the HEAL Occasional Stakeholder Observer and the expert accompanying the HEAL Occasional Stakeholder Observer commented on mutagenicity. The expert accompanying the ClientEarth Regular Stakeholder Observer, the HEAL Occasional Stakeholder Observer, the expert accompanying the HEAL Occasional Stakeholder Observer and the expert accompanying the CropLife Regular Stakeholder Observer commented on carcinogenicity. The HEAL Occasional Stakeholder Observer and the expert accompanying the CropLife Regular Stakeholder Observer commented on reproductive toxicity. The CropLife Regular Stakeholder Observer and the expert accompanying the CEFIC Regular Stakeholder Observer commented on aquatic toxicity.	
4.2.2. Formic acid ...%	
The co-Chair welcomed the Dossier Submitter representatives and informed that **formic acid...%** is used in industrial manufacture of polymers and resins, in polymer processing, industrial use as processing aid, industrial use in laboratories and also as an intermediate, in coatings and in cleaning agents. The substance has current Annex VI entry as Skin Corr. 1A; H314. The DS (BE) proposes to add to the current classification Flam. Liq. 3; H226, Metal Corr. 1; H290, Acute Tox. 4; H302, Acute Tox. 3; H331 and Eye Dam. 1; H318. Selected physical hazards (flammable liquids, corrosive to metals), acute oral and inhalation toxicity and serious eye damage/eye irritation were the hazard classes open	

<table>
<tr><td colspan="2">for comments during the Consultation.
The legal deadline for the adoption of an opinion is 28 January 2023.</td></tr>
<tr><td>Physical hazards
The WG recommended to classify formic acid…% as Flam. Liq. 3; H226 (C > 85%) and A-listing at RAC-61.

The WG recommended to classify the substance as Metal Corr. 1; H290 and A-listing at RAC-61.

Human Health
Acute oral toxicity
The WG recommended to classify the substance as Acute Tox. 4; H302 (ATE=500 mg/kg bw) and A-listing at RAC-61.

Acute inhalation toxicity
The WG recommended to classify the substance as Acute Tox. 3; H331 (ATE=7.4 mg/L (vapours)) and to add EUH071.
The classification is also for A-listing at RAC-61.

Serious eye damage/eye irritation
The WG recommended to classify the substance as Eye Dam. 1; H318 (C ≥ 10%) and A-listing at RAC-61.</td><td>Rapporteur 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-61.

The hazard classes going for plenary discussion: None.</td></tr>
<tr><td colspan="2">4.2.3. Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl] phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl}naphthalene-2,7-disulfonate; [3]</td></tr>
<tr><td colspan="2">The co-Chair welcomed the Dossier Submitter representatives and informed that 4-amino-5-hydroxy-3,6-bis[…]naphthalene-2,7-disulphonate is used as a colouring agent for textiles and black toner particles. The substance has no current Annex VI entry.
The DS (DE) proposes to classify 4-amino-5-hydroxy-3,6-bis[…]naphthalene-2,7-disulphonate as Resp. Sens. 1A; H334, Skin Sens. 1; H317.
Respiratory sensitisation and skin sensitisation were the hazard classes open for comments during the Consultation.
The legal deadline for the adoption of an opinion is 15 January 2023.</td></tr>
<tr><td>Human Health
Respiratory sensitisation
The WG recommended to classify the substance as Resp. Sens. 1A; H334 based on available human data and A-listing at RAC-61.</td><td>Rapporteur to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.

SECR to table the updated</td></tr>
</table>

Skin sensitisation The WG recommended to classify the substance as Skin Sens. 1; H317 and A-listing at RAC-61.	opinion for adoption at RAC-61. **The hazard classes going for plenary discussion: None.**
4.2.4. 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	
The co-Chair welcomed the Dossier Submitter representatives and informed that **2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one** is used as a photoinitiator in UV-inks and coatings in various formulation, industrial and wide dispersive and widespread professional uses, as well as in article service life uses. The substance has no current Annex VI entry. The DS (AT) proposes <u>to classify</u> 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one as Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 1) and Aquatic Chronic 1; H410 (M = 1). Reproductive toxicity, specific target organ toxicity – repeated exposure, hazardous to the aquatic environment were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 16 December 2022.	
<u>Human Health</u> *Reproductive toxicity* The WG recommended to classify the substance as Repr. 1B; H360Df, no classification for effects on or via lactation, and A-listing at RAC-61. *Specific target organ toxicity – repeated exposure* The WG recommended no classification for STOT RE hazard class and A-listing at RAC-61. <u>Hazardous to the aquatic environment</u> The WG recommended to classify the substance as Aquatic Acute 1; H400 (M=1) based on calculated EC_{50} daphnids and Aquatic Chronic 1; H410 (M=1) based on not rapid degradability, potential for bioaccumulation and 32 d-NOEC value of 0.031 mg/L for body weight and length of *Pimephales promelas*, and A-listing at RAC-61.	**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-61. **The hazard classes going for plenary discussion: None.**
4.2.5. Dicamba (ISO)	
The Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. He informed that **dicamba** is a herbicide, it is used on field crops and has a systemic effect on a range of broadleaved weeds. The substance has current Annex VI entry as Acute Tox. 4*, H302, Eye Dam. 1; H318 and Aquatic Chronic 3; H412.	

The DS (DN and RO) proposes to classify the dicamba as follows: Acute Tox. 4; H302 (remove the existing minimum classification and add ATE=1581 mg/kg bw), Acute Tox. 4; H332 (ATE=4.46 mg/L), Eye Dam. 1; H318, Carc. 2; H351, STOT SE 3; H335, STOT SE 3; H336, Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1) (the DS changed their proposal to Aquatic Chronic 2; H411 after the Consultation). Selected physical hazards (explosives, flammable solids, self-heating substances or mixtures, oxidising solids), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment and hazardous for the ozone layer were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 13 October 2022.	
<u>Physical hazards</u> The WG provisionally recommended no classification for all four physical hazards that were open for consultation, but with a request for further assessment of the available EEC A-series tests against the CLP criteria to be included in the revised opinion for a brief discussion and conclusion at RAC-61. <u>Human Health</u> *Acute oral toxicity* The WG recommended to classify dicamba as Acute Tox, 4; H302 (ATE=1500 mg/kg bw) and A-listing at RAC-61. *Acute dermal toxicity* The WG recommended no classification and A-listing at RAC-61. *Acute inhalation toxicity* The WG recommended to classify the substance as Acute Tox. 4; H332 (ATE=4.0 mg/L) and A-listing at RAC-61. *STOT SE* The WG recommended to classify dicamba as STOT SE 3; H335 (resp. tract irritation) and H336 (drowsiness/dizziness). The opinion will be updated to take into account the comments on the reduction in neurotoxicity over 7 days after exposure and hyperplasia of the respiratory tract. The hazard class is recommended for A-listing at RAC-61. *Skin irritation* The WG recommended no classification and A-listing	**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 final discussion and adoption at RAC-61. **The hazard classes going for plenary discussion: Physical hazards, carcinogenicity.**

at RAC-61. *Serious eye damage/eye irritation* The WG recommended to classify dicamba as Eye Dam. 1; H318 and A-listing at RAC-61. *Skin sensitisation* The WG recommended no classification and A-listing at RAC-61. *STOT RE* The WG recommended no classification and A-listing at RAC-61. RAC noted that there were clear signs of neurotoxicity, but above the guidance values – this was agreed to be reflected in the revised opinion. *Mutagenicity* The WG recommended no classification and A-listing at RAC-61. *Carcinogenicity* The WG recommended no classification based on inconclusive data. The Rapporteur was asked to add more detail on the epidemiological study by Lerro (2020) and on the rat study in the revised opinion. RAC noted that in rats, the carcinogenic potential of dicamba had not been fully investigated due to inadequate dosing. The hazard class will be discussed briefly at RAC-61. *Reproductive toxicity* Fertility The WG recommended no classification and A-listing at RAC-61. Developmental toxicity The WG recommended no classification and A-listing at RAC-61. Lactation The WG recommended no classification and A-listing at RAC-61. <u>Hazardous to the aquatic environment</u> The WG recommended to classify dicamba as Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 2; H411. The Rapporteur was asked to indicate in the revised	

opinion that the *Myriophyllum spicatum* study driving the classification is appropriate for assessing the acute aquatic toxicity. The WG recommended A-listing of these hazard classes at RAC-61. <u>Hazardous to the ozone layer</u> The WG recommended no classification and A-listing of this hazard class at RAC-61.	
The CropLife Regular Stakeholder Observer commented on aquatic acute toxicity.	
4.2.6. Peracetic acid …%	
The co-Chair welcomed the Dossier Submitter representative and informed that **peracetic acid…%** is a biocidal active substance with strong bactericidal, fungicidal, and virucidal activity. Peracetic acid is mainly used as a bactericide, fungicide or virucide. Moreover, indications of potential efficacy against amoeboe and algae have been reported. The substance has current Annex VI entry as Flam. Liq. 3; H226, Org. Perox. D****; H242, Acute Tox. 4*; H332, Acute Tox. 4*; H312, Acute Tox. 4*; H302, Skin Corr. 1A; H314 and Aquatic Acute 1; H400. The DS (FI) proposes <u>to retain</u> Org. Perox. D****; H242 and Aquatic Acute 1; H400, <u>to add</u> Aquatic Chronic 1; H410, <u>to modify</u> Acute Tox. 2; H330, Acute Tox. 2; H310, Acute Tox. 3; H301, <u>to remove</u> Flam. Liq. 3; H226. The DS also proposes <u>to add</u> inhalation ATE=0.204 mg/L (dusts and mists), dermal ATE=56.1 mg/kg bw, oral ATE=70 mg/kg bw and M=10, M=100. Selected physical hazards (flammable liquids, organic peroxides), acute toxicity via all routes and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 24 December 2022.	
<u>Physical hazards</u> The WG recommended to remove classification as Flam. Liq. 3 as it does not fulfil the criteria. The WG could not agree on retaining or removing the current classification of peracetic acid…% as Org. Perox. D****; H242, and on the addition of Note T. SECR is requested to support the Rapporteur to propose the most appropriate option for Org. Perox. classification from regulatory point of view and present it along with the corresponding arguments in a revised presentation for a brief discussion in plenary.	**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 final discussion and adoption at RAC-61. **The hazard classes going for plenary discussion: Physical hazards.**

Human Health The WG recommended to include EUH071 and A-listing at RAC-61. *Acute oral toxicity* The WG recommended to classify the substance as Acute Tox. 3; H301 (ATE=80 mg/kg bw) and A-listing at RAC-61. *Acute dermal toxicity* The WG recommended to classify peracetic acid…% as Acute Tox. 2; H310 (ATE=60 mg/kg bw) and A-listing at RAC-61. The Rapporteur was asked to reflect the uncertainties in the revised opinion. *Acute inhalation toxicity* The WG recommended to classify the substance as Acute Tox. 2; H330 (ATE=0.2 mg/L (dusts and mists)) and A-listing at RAC-61. Hazardous to the aquatic environment The WG recommended to classify the substance as Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=100). The Rapporteur was asked to reflect the discussion for the finalisation of the opinion. The WG recommended A-listing of these hazard classes at RAC-61.	

4.2.7. Formaldehyde …%

The co-Chair welcomed the Dossier Submitter representative and the expert accompanying the CEFIC Regular Stakeholder Observer. She informed that **formaldehyde…%** is an existing biocidal active substance approved in accordance with Regulation (EU) No 528/2012. It is used in adhesives and sealants, paints and coating products, fillers, putties, plasters, modelling clay, inks and toners, polymers, fuels, biocides (e.g. disinfectants, pest control products), polishes and waxes, washing and cleaning products, cosmetics, personal care products, machine wash liquids/detergents, automotive care products, fragrances and air fresheners, metal, wooden and plastic construction and building materials, flooring, furniture, toys, textiles (e.g. curtains, carpet, clothing), footwear, leather products, paper and cardboard products, electronic equipment. The substance has an existing Annex VI entry as Acute Tox. 3*; H331, Acute Tox. 3*; H311, Acute Tox. 3*; H301, Skin Corr. 1B; H314, Skin Sens. 1; H317, Muta. 2; H341 and Carc. 1B; H350.
The DS (DE) proposes to modify the classification to Flam. Gas 1B; H221, Acute Tox. 2; H330 (ATE=490 ppm (gases)); Acute Tox. 3; H311 (ATE=270 mg/kg bw), Acute Tox. 4; H302 (ATE=640 mg/kg bw) and Skin Sens. 1A, H317 (C ≥ 0.2 %).

Selected physical hazards (explosives, flammable gases, oxidising gases, gases under pressure, flammable liquids, self-reactive substances, pyrophoric liquids, substances which in contact with water emit flammable gases, oxidising liquids, organic peroxides, corrosive to metals), acute toxicity via all routes and skin sensitisation were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 29 December 2022.	
<u>Physical hazards</u> The WG recommended to retain Note D and to add Note F. The WG recommended no classification for corrosive to metals due to inconclusive data. The WG recommended no classification for the other physical hazard classes considered and not to add Note T. The WG agreed to A-list these hazard classes at RAC-61. <u>Human Health</u> *Acute oral toxicity* The WG recommended to classify the substance as Acute Tox. 4; H302 (ATE=500 mg/kg bw) and A-listing at RAC-61. *Acute dermal toxicity* The WG recommended no classification and to have a brief discussion at RAC-61. *Acute inhalation toxicity* The WG recommended to classify the substance as Acute Tox. 2; H330 (ATE=100 ppm (gases)) and A-listing at RAC-61. *Skin sensitisation* The WG recommended to classify the substance as Skin Sens. 1A; H317 (no SCL) and A-listing at RAC-61. The WG recommended to include EUH071 and A-listing at RAC-61. The WG recommended not to add Note 5 and A-listing at RAC-61.	**Rapporteur** 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 final discussion and adoption at RAC-61. **The hazard classes going for plenary discussion: Acute dermal toxicity.**
4.2.8. S-metolachlor (ISO)	
The co-Chair welcomed the DS representatives and the expert accompanying the CropLife Regular Stakeholder Observer and informed that **S-metolachlor** is a herbicide	

in maize and sunflower. The substance has current entry as Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.
The DS (DE) proposes to add Carc. 2; H351, Repr. 2; H361d, STOT RE 2; H373 (skin) and M=10 for both aquatic acute and chronic hazards. The DS proposes to retain Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.
Germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.
The dossier was discussed at RAC-60 CLH WG, where it was agreed to organise a targeted consultation on the new carcinogenicity data received. The targeted consultation was organised on 21/02-07/03/2022.
The legal deadline for the adoption of an opinion is 24 November 2022.

Carcinogenicity The WG took note of the new information on carcinogenicity and the outcome of the targeted consultation. Based on the carcinogenicity studies in rats and mice in addition to the epidemiology data, the WG recommended to classify the substance as Carc. 2; H351 and to have a brief discussion at RAC-61.	**Rapporteur** 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 final discussion and adoption at RAC-61. **The hazard classes going for plenary discussion: Carcinogenicity.**

4.2.9. Silver

The Chair welcomed the Dossier Submitter representatives, the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers as well as the Occasional Stakeholder Observer from EPMF with the accompanying expert. He informed that **silver** is used in biocidal products. It is used in products categorised into the following product types: disinfectants and algaecides not intended for direct application to humans or animals, food and feed area disinfection, drinking water disinfection, preservatives for liquid-cooling and processing systems. Some of these uses may result in a vast range of consumer applications. Apart from biocidal use, silver is widely used by industry, professionals and consumers. Silver has no current Annex VI entry.

The DS (SE) proposes to classify silver as Skin Sens. 1; H317, Muta. 2; H341, Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 10) and Aquatic Chronic 1; H410 (M = 10). The DS proposes to classify nanosilver as Skin Sens. 1; H317, Muta. 2; H341, Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 1000) and Aquatic Chronic 1; H410 (M = 100).

Selected physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE,

<table>
<tr><td colspan="2">STOT RE, hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.

The Committee has discussed the dossier at RAC-58 plenary meeting, at RAC-59 CLH WG, at RAC-59 plenary meeting, at RAC-60 CLH WG and at RAC-60 plenary meeting.

The legal deadline for the adoption of an opinion was 16 March 2022. The deadline has been extended until 30 July 2022.</td></tr>
<tr><td><u>Human Health</u>

STOT RE
The WG recommended to classify silver as STOT RE 2; H373 (brain) based on several studies showing effect on the hippocampus and on spatial learning and memory. The new (2022) OECD TG 443 EOGRTS study on silver acetate was considered as a supporting study.
The Rapporteur was requested to indicate in the revised opinion the key study/ies behind the proposed classification and to add a section to the RAC General Comments in the opinion on the recent toxicokinetic study provided. He was also requested to address the copper deficiency mode of action proposed by Industry.
The WG recommended a final brief discussion at RAC-61.

Carcinogenicity
The WG recommended no classification for carcinogenicity due to inconclusive data. The Chair pointed out that this did not necessarily mean that there was a data gap in this case.
The WG recommended A-listing of this hazard class at RAC-61.

Exceptionally, as the adoption of an opinion on silver is past the process deadline, the remaining hazard class, toxicity to reproduction will be considered in full at RAC-61, without discussion beforehand in the working group.</td><td>Rapporteur to revise the opinion in accordance with the discussion in the Working Group and to provide it to SECR.

SECR to organise a RAC written consultation and to table the updated opinion for final discussion and adoption at RAC-61.

The hazard classes going for plenary discussion: STOT RE, reproductive toxicity.</td></tr>
<tr><td colspan="2">The Eurometaux Regular Stakeholder Observer, the expert accompanying the Eurometaux Regular Stakeholder Observer and the expert accompanying the EPMF Occasional Stakeholder Observer commented on STOT RE.</td></tr>
</table>

5. AOB

No items were raised under Any Other Business at the meeting.

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 5th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I **Agenda of the of the 5th 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

23 March 2022
RAC WG/CLH/5/2022
DRAFT

5th Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling (RAC-61 CLHWG)

Thursday 21 April starts at 10:00 -
Wednesday 27 April ends at 16:45

Times are Helsinki times
Virtual meeting

Final Agenda

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/CLH/5/2022
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Harmonised classification and labelling (CLH)

5.1 Hazard classes to be proposed for agreement without plenary debate (A-list) in RAC-61

- 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate: *skin sensitisation, mutagenicity, STOT RE*
- Formic acid ...%: *serious eye damage/eye irritation*
- Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl] phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl}naphthalene-2,7-disulfonate [3]: *skin sensitisation*
- 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one: *STOT RE*
- Peracetic acid …%: *EUH071*
- Formaldehyde …%: *skin sensitisation*

5.2 CLH dossiers

4.2.1. Glyphosate (EC 213-997-4; CAS 1071-83-6)
4.2.2. Formic acid ...% (EC 200-579-1; CAS 64-18-6)
4.2.3. Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl] phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl}naphthalene-2,7-disulfonate [3]
4.2.4. 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (EC 438-340-0; CAS 119344-86-4)
4.2.5. Dicamba (ISO) (EC 217-635-6; CAS 1918-00-9)
4.2.6. Peracetic acid …% (EC 201-186-8; CAS 79-21-0)
4.2.7. Formaldehyde …% (EC 200-001-8; CAS 50-00-0)
4.2.8. S-metolachlor (ISO) (EC -; CAS 87392-12-9)
4.2.9. Silver (EC 231-131-3; CAS 7440-22-4)

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	
Aquilina	Gabriele
Barański	Bogusław
Biró	Anna
Bjørge	Christine
Docea	Anca
Facchin	Manuel
Gebel	Tom
Geoffroy	Laure
Hakkert	Betty
Kadiķis	Normunds
Karadjova	Irina
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Martínek	Michal
Mendas	Gordana
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Neumann	Michael
Paris	Pietro
Pęczkowska	Beata
Pribu	Mihaela
Printemps	Nathalie
Rodriguez	Wendy
Santonen	Tiina
Schulte	Agnes
Schuur	Gerlienke
Sogorb	Miguel
Sørensen	Peter Hammer
Spetseris	Nikos
Srpčič	Anja Menard
Tobiassen	Lea Stine
Užomeckas	Žilvinas
Varnai	Veda

Members' advisers	
Catone Tiziana	Aquilina Gabriele
Dallet Mélissa	Geoffroy Laure
De Groot Stan	Schuur Gerlienke

Esposito Dania	Paris Pietro
Hoffmann Frauke	Schulte Agnes
Lindeman Birgitte	Bjørge Christine
Pace Emanuela	Paris Pietro
Russo Maria Teresa	Aquilina Gabriele
Saksa Jana	Moldov Raili
Sonnenburg Anna	Stahlmann Ralf
Suutari Tiina	Leinonen Riitta
van Herwijnen René	Schuur Gerlienke

Dossier submitters	**Substance**
Birgander Pernilla	Silver
Boquist Pernilla	Silver
Brusila Elina	Peracetic acid …%
Gall Andrea	S-Metolachlor
Herremans Yannick	Formic Acid
Jacobsen Pernille	dicamba
Kaartinen Tomi	Peracetic acid
Kinzl Maximilian	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one
Lundberg Katarina	Glyphosate
Mauritz Ilse	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one
Schulte Petra	Formaldehyde …%
Tuhkunen Sari	Peracetic acid …%
van Duijn Luuk	Glyphosate
Willenbockel Christian Tobias	S-Metolachlor
DS FR	Glyphosate
DS HU	Glyphosate

Regular stakeholder observers	
De Backer Liisi	Cefic
Van de Broeck Steven	Cefic - Formaldehyde
Duguy Helene	ClientEarth
Evans Benedict	MedTech Europe
Romano Mozo Dolores	EEB
Ruelens Paul	CropLife Europe
Verougstraete Violaine	Eurometaux - Glyphosate
Waeterschoot Hugo	Eurometaux - Silver

Occasional Industry stakeholder observers	
Alami Anissa	EPMF - Silver

Lyssimachou Angeliki	HEAL - Glyphosate

Stakeholder experts		**Substance**
Clausing Peter	ClientEarth/ Pesticide Action Network – PAN Germany	Glyphosate
Portier Christopher Jude	HEAL/ Emory University	Glyphosate
Leibold Edgar	Cefic/Formacare	Formaldehyde
Manson Philip	Cefic/ Bayer company on behalf of the Glyphosate Renewal Group	Glyphosate
Raffray Mark	Eurometaux/ Raffray Biosciences Ltd	silver
Knasmüller Siegfried	EEB / Medical University of Vienna Center for Cancer Research	Glyphosate
Aveyard Lindsay	EPMF/ GPC Consulting CC	Silver
Lloyd Sara	CropLife Europe/Sygenta	S-metolachlor, Dicamba
Saltmiras David	CropLife Europe/ Bayer company acting on behalf of the Glyphosate Renewal Group expert	Glyphosate

European Commission		**DG**
Kilian	Karin	DG ENV
Pinte	Jérémy	DG GROW
Williams	Mark	DG SANTE

EFSA	
Ippolito	Alessio
Castoldi	Anna Federica
Lanzoni	Anna
De Lentdecker	Chloé
Mangas	Iris
Parra Morte	Juan Manuel
Panzarea	Martina
Terron	Andrea

ECHA staff	
Bichlmaier Suchanová	Bohumila
Bowmer (Co-chair)	Tim
De La Flor Tejero	Ignacio
Jones	Stella
Karjalainen	Antti
Karjalainen (Co-chair)	Ari
Korjus	Pia
Lapenna	Silvia
Ludborzs	Arnis

Marchetto	Flavio
Mattiuzzo	Marco
Mulsant	Octavie
Myohanen (Co-chair)	Kirsi
Nygren	Jonas
O'Rourke	Regina
Peltola-Thies	Johanna
Perazzolo	Chiara
Prevedouros	Kostas
Rahkonen	Olli
Sadam	Diana
Saez	Monica
Simoes (Co-chair)	Ricardo
Sobanska	Marta
Sosnowski	Piotr
Spjuth	Linda
Uphill (Co-chair)	Simon
Zhivin	Sergey

ANNEX III: Declarations of potential conflicts of interest

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		
Silver **SE**	Bert-Ove LUND	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.
	Ifthekhar Ali MOHAMMED	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.
Glyphosate **SE**	Bert-Ove LUND	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.
	Ifthekhar Ali MOHAMMED	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.
Glyphosate **NL**	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		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.
Glyphosate **HU**	Anna BIRO	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.
S-metolachlor (ISO) **DE**	Agnes SCHULTE	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.
	Tom Gebel	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.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Harmonised classification & labelling		
7-oxabicyclo **IE**	Brendan MURRAY	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.
Formic acid …% **BE**	Wendy RODRIGUEZ	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.
Peracetic acid …% **FI**	Tiina SANTONEN	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.
	Riitta LEINONEN	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.
1) Tetrasodium	Agnes SCHULTE	Working for the CA submitting the

Dossier / DS	RAC Member	Reason for potential CoI / Working for
2) **Formaldehyde ...%** **DE**		dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement in no 1.
	Tom Gebel	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.
	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.
Butan-1-one **AT**	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. Personal involvement.
	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. Personal involvement.
Dicamba (ISO) **DK**	Peter Hammer SORENSEN	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

Dossier / DS	RAC Member	Reason for potential CoI / Working for
		involvement.
	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. No personal involvement.
Dicamba (ISO) **RO**	Michaela PRIBU	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.