RAC WG/CLH/R/7/2022

27 October 2022

Report
of the 7th Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling (RAC-63 CLH WG)

ECHA Conference Centre (Telakkakatu 6, Helsinki) via Webex

Monday 24 October 2022(14.00) to Thursday 27th October (14.30)

Summary Record of the Proceedings

1. Welcome and apologies

The Deputy Chair of RAC, Johanna Peltola-Thies, welcomed the participants to the 7th 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.

She informed that the meeting would be jointly chaired by officers of the CLH team: Kirsi Myöhänen, Ricardo Simoes, Simon Uphill, as well as by the Chair of RAC, Tim Bowmer.

1. Written consultations were organised on all dossiers prior to the working group meeting for RAC-63, except for pyraclostrobin (ISO) on which for operational reasons a RAC consultation on the human health part of the draft opinion will be separately organised prior to RAC-63. Regarding the request under Article 77(3)(c) to set a DNEL for DOTE/MOTE, a RAC consultation on the draft note will also be organised prior to RAC-63.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/CLH/7/2022), 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 Deputy Chair informed that she 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 other Chairs 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-63

The Working Group agreed to propose the following hazard classes to RAC-63 for A-listing (without discussing them in the WG) based on the written comments received from members during the consultation:

- 1,4-Dichloro-2-nitrobenzene: *carcinogenicity, germ cell mutagenicity*
- Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl: *acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, STOT RE, hazards to the aquatic environment*
- Dibenzoyl peroxide; benzoyl peroxide: *hazards to the aquatic environment*
- Fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine: *hazards to the aquatic environment*
- *n*-Hexane: *STOT RE*
- Ozone: *hazards to the aquatic environment*
- Pyraclostrobin (ISO); methyl *N*-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate: *hazards to the aquatic environment*
- Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal): *reproductive toxicity (development, lactation)*
- *Tert*-butyl 2-ethylperoxyhexanoate (TBPEH): *reproductive toxicity (fertility)*

4.2 Hazard classes for discussion

4.2.1 Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl (EC: 201-993-5; CAS: 90-43-7)

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the CropLife Regular Stakeholder Observer. He informed that **biphenyl-2-ol** is used as a post-harvest fungicide in citrus. The substance is currently classified as Skin Irrit. 2; H315, Eye Irrit. 2; H319, STOT SE 3; H335 and Aquatic Acute 1; H400.

The DS (ES) proposes to classify biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl as Skin Corr. 1; H314, Eye. Dam. 1; H318, Carc. 2; H351, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=1).

Selected physical hazards (organic peroxides; 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, STOT RE, hazards to the aquatic environment and hazards to the ozone layer were open for comments during the Consultation. The deadline for the adoption of an opinion is 23 August 2023.	
Physical hazards The group recommended no classification and A-listing at RAC-63. <u>*Human Health*</u> *Acute toxicity* The group recommended no classification and A-listing at RAC-63. *Skin corrosion/irritation* The group recommended to classify the substance as Skin Corr. 1; H315 and A-listing at RAC-63. *Serious eye damage/eye irritation* The group recommended to classify the substance as Eye Dam. 1; H318 and A-listing at RAC-63. *Respiratory sensitisation* The group recommended no classification and A-listing at RAC-63. *STOT RE* The group recommended no classification and A-listing at RAC-63. *STOT SE* The group recommended to remove the current classification as STOT SE 3; H335 and A-listing at RAC-63. *Skin sensitisation* The working group considered the human data relevant to classification. The Rapporteur was asked to amend the draft opinion in relation to the human data and it was agreed to discuss this hazard class further at RAC-63. *Mutagenicity* The group 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-63. **The hazard classes going for plenary discussion: Skin sensitisation and developmental toxicity.**

at RAC-63. *Carcinogenicity* The group recommended to classify biphenyl-2-ol as Carc. 2; H351 based on urinary bladder tumours and A-listing at RAC-63. *Reproductive toxicity* *Fertility* The group recommended no classification and A-listing at RAC-63. *Development* The Rapporteur was asked to amend the draft opinion and it was agreed to discuss this hazard class further at RAC-63. *Lactation* The group recommended no classification and A-listing at RAC-63. *Environment* *Aquatic acute toxicity* The group recommended to classify the substance as Aquatic Acute 1; H400 (M=1) and A-listing at RAC-63. *Aquatic chronic toxicity* The group recommended to classify the substance as Aquatic Chronic 1; H410 (M=1) and A-listing at RAC-63. *Hazard to the ozone layer* The group recommended no classification for hazards to the ozone layer and A-listing at RAC-63.	
The expert accompanying the CropLife Regular Stakeholder commented on skin sensitisation, mutagenicity, carcinogenicity and reproductive toxicity.	
4.2.2. Copper (EC: 231-159-6; CAS: 7440-50-8)	
The Chair welcomed the Dossier Submitter's representative, the Occasional Stakeholder Observer from European Copper Institute as well as the expert accompanying the Eurometaux Regular Stakeholder Observer. He informed that **copper** has a large variety of uses in the metallurgy, building, transport and electronics sectors amongst many others. Consumer and professional uses of copper consist of, for example,: metals, metal working fluids, welding and soldering products, cosmetics and personal care products, modelling clay, and metal surface treatment products. Furthermore, copper is also used as an active substance in biocidal products.	

Unlike many copper salts, copper metal, Cu^0) does not have a current harmonised classification. There are two exceptions: copper flakes (coated with aliphatic acid) are classified as Acute Tox. 4; H302, Eye Irrit. 2; H319, Acute Tox. 3; H331, Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410, while granulated copper [particle length: from 0,9 mm to 6,0 mm; particle width: from 0,494 to 0,949 mm] also has an existing Annex VI entry as Aquatic Chronic 2; H411. Some uses of both the above active substances are currently approved in biocidal products. The DS (SE) proposes to classify copper as: Copper ≤ 0.67 mm^2/mg (massive, equivalent to a copper sphere of 1mm diameter) – No Classification, and Copper > 0.67 mm^2/mg (powder) - Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=1). The DS further proposed to amend the entries for copper flakes and granulated copper accordingly, since both forms would be fully covered by the entry proposed for copper. However, this was considered to be outside the remit of RAC. Hazards to the aquatic environment were the only hazard classes open for comments during the Consultation. The deadline for the adoption of an opinion is 4 May 2023.	
The working group concluded that there is no evidence to indicate that copper is rapidly transformed to non-bioavailable forms. The group recommended that there is sufficient evidence to conclude that copper is not bioaccumulative. This is in contrast to the DS who concluded that due to the essentiality of copper in aquatic organisms an assessment is not necessary. The group concluded that following the CLP criteria, the classification of copper metal forms should be based on the specific surface area of 0.67 mm^2/mg as a limit between copper massive and all other copper powders. The group agreed that the extensive available aquatic toxicity and T/Dp data should be pH banded for hazard assessment, based on the properties of copper in the aquatic environment and the relationship between pH and toxicity. Furthermore, as dissolved organic carbon (DOC) also has an influence on toxicity, both non-normalised and available toxicity data normalised to 2	**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-63. **The hazard classes going for plenary discussion: Hazards to the aquatic environment.**

mg/L DOC were compared with the CLP criteria and the most stringent outcome used for classification. The group agreed with the Rapporteur on the choice of environmental reference values (ERV) in each pH band for acute and chronic hazard to be compared with the CLP criteria. According to the guidance, the classification of copper massive would depend on the generation, or not of copper particles (< 1 mm) during the normal handling and use and if such 'produced' particles are relevant for classification of the massive form. The group concluded that the available evidence (survey by the DS) indicates that particles < 1 mm are not generated from reasonable handling and use of copper. Consequently, the hazard of massive copper will be assessed based on data for massive copper itself. The group noted that the DS had calculated copper release for particles with a specific surface area of 107 mm^2/mg (discarding the respective experimental data) by instead including experimental data for particles with a surface area of 60 mm^2/mg. The group recommended the following classification outcomes: Copper [specific surface area ≤ 0.67 mm^2/mg] – no classification; Copper [specific surface area > 0.67 mm^2/mg] – Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=1). The Rapporteur was asked to make a summary presentation at RAC-63, including the selection of the data supporting the regression to calculate the 7 day T/Dp data at pH 6 and the calculation of T/Dp data at pH 5.5. It is noted that different approaches do not affect the classification outcomes.	
The Eurometaux Regular Stakeholder Observer commented on environmental transformation of copper, the use of biotic ligand models, the forms of copper and the proposed classification. The expert accompanying the Eurometaux Regular Stakeholder Observer commented on the forms of copper. The Occasional Stakeholder Observer form the European Copper Institute commented on environmental transformation of copper, biotic ligand models, the forms of copper and the proposed classification.	

4.2.3. Cyclohex-3-ene-1-carbaldehyde derivatives (EC: - CAS: -)	
The co-Chair welcomed the Dossier Submitter representative and specified that this dossier concerns 2,4-dimethylcyclohex-3-ene-1-carbaldehyde [1]; (1α,2α,5α)-2,5-dimethylcyclohex-3-ene-1-carbaldehyde [2]; 2,6-dimethylcyclohex-3-ene-1-carbaldehyde [3]; 3,5-dimethylcyclohex-3-ene-1-carbaldehyde [4]; 3,6-dimethylcyclohex-3-ene-1-carbaldehyde [5]; 4,6-dimethylcyclohex-3-ene-1-carbaldehyde [6]; reaction mass of 3,5-dimethylcyclohex-3-ene-1-carbaldehyde and 2,4-dimethylcyclohex-3-ene-1-carbaldehyde [7]; dimethylcyclohex-3-ene-1-carbaldehyde [8]; dimethylcyclohex-3-ene-1-carbaldehyde [9]; 1,2,4(or 1,3,5)-trimethylcyclohex-3-ene-1-carbaldehyde [10]; 1,3,4-trimethylcyclohex-3-ene-1-carbaldehyde [11]; 2,2,4-trimethylcyclohex-3-ene-1-carbaldehyde [12]; 2,4,6-trimethylcyclohex-3-enecarbaldehyde [13]; isocyclocitral [14]; 3,5,6-trimethylcyclohex-3-ene-1-carbaldehyde [15] and 4,6,6-trimethylcyclohex-3-ene-1-carbaldehyde [16] – with the "nick name" **cyclohex-3-ene-1-carbaldehyde derivatives**. These substances are used as a fragrance in the following products: cleaning and furnishing care products, laundry and dishwashing products, personal care products, and air care products. Furthermore, they are used as food additive. These substances have no current Annex VI entry. The DS (DE) proposes to classify cyclohex-3-ene-1-carbaldehyde derivatives as Skin Sens. 1B; H317. Skin sensitisation was the only hazard class open for comments during the Consultation. The deadline for the adoption of an opinion is 30 July 2023.	
The group supported the grouping approach and the read-across used by the DS, as the 16 congeners have a similar structural pattern, similar physicochemical properties and are expected to cause the same type of effects. Furthermore, the group noted that the recognised limitations do not significantly affect the grouping approach. The group recommended to classify the substances as Skin Sens. 1; H317 (contrary to the DS proposal for 1B), since due to possible variability in potency across the group category 1A cannot be completely ruled out. The group recommended to A-list this hazard class at RAC-63.	**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-63. **The hazard classes going for plenary discussion: None.**
4.2.4. Fenpropidin (ISO); (R,S)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine (EC: 614-049-6; CAS: 67306-00-7)	
The co-Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. He informed that **fenpropidin** is used as a fungicidal agent in plant protection products. The substance has no current Annex VI entry.	

The DS (CZ, supported by DE) proposes to classify fenpropidin as Acute Tox. 4; H302, Acute Tox. 4; H332, Eye Dam. 1; H318, Skin Sens. 1B; H317, Repr. 2; H361d, STOT SE 3; H335, STOT RE 2; H373 (nervous system), Aquatic Acute 1; H400 (M=1000) and Aquatic Chronic 1; H410 (M=100). Selected physical hazards (explosive, flammable liquid, self-reactive substance or mixture, pyrophoric liquid, self-heating substance, substance or mixture which in contact with water emits flammable gas, oxidising liquid, substance or mixture 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, STOT RE and hazards to the aquatic environment were open for comments during the Consultation. The deadline for the adoption of an opinion is 24 February 2023.	
Physical hazards The group recommended no classification and A-listing at RAC-63. <u>*Human Health*</u> *Acute oral toxicity* The group recommended to classify fenpropidin as Acute Tox. 4; H302 (ATE=1330 mg/kg bw) and A-listing at RAC-63. *Acute inhalation toxicity* The group recommended Acute Tox. 4; H332 and A-listing at RAC-63. *Acute dermal toxicity* The group recommended no classification and A-listing at RAC-63. *STOT SE* The group recommended STOT SE 3; H335 (may cause respiratory irritation) and A-listing at RAC-63. The group recommended to discuss STOT SE 3 (narcotic effects) classification further at RAC-63. *Skin corrosion/irritation* The group recommended to classify fenpropidin as Skin Irrit. 2; H315 (contrary to the DS proposal for no classification) and A-listing at RAC-63. *Serious eye damage/eye irritation* The group recommended to classify the substance as Eye Dam. 1; H318 and A-listing at RAC-63.	**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-63. **The hazard classes going for plenary discussion: STOT SE (narcotic effects), developmental toxicity.**

Respiratory sensitisation The group recommended no classification due to lack of data and A-listing at RAC-63. *Skin sensitisation* The group recommended to classify the substance as Skin Sens. 1; H317 and A-listing at RAC-63. *STOT RE* The group recommended to classify fenpropidin as STOT RE 2; H373 (nervous system, eye and lung) and A-listing at RAC-63. The group recommended no classification for STOT RE liver effects, as the observed effects were inconsistent &/or not severe enough to warrant the classification, and to A-list at RAC-63. The group supported the Rapporteurs' interpretation of immune system effects as inconclusive. No classification of fenpropidin as STOT RE for immune effects was supported, and to A-list at RAC-63. The group recommended not to specify the route of exposure for STOT RE (contrary to the DS proposal) and to A-list at RAC-63. *Mutagenicity* The group agreed on no classification and A-listing at RAC-63. *Carcinogenicity* The group agreed on no classification and A-listing at RAC-63 pending the Rapporteurs addressing in the opinion the deficiencies in the studies. *Reproductive toxicity* *Fertility* The group recommended no classification based on inconclusive data and A-listing at RAC-63. *Development* The group recommended Repr. 2; H361d and to have a targeted discussion to address questions related to this hazard class that were introduced by the industry expert.	

Lactation The group recommended no classification and A-listing at RAC-63. *<u>Environment</u>* *Aquatic acute toxicity* The group recommended to classify the substance as Aquatic Acute 1; H400 (M=1000) and A-listing at RAC-63. *Aquatic chronic toxicity* The group recommended to classify the substance as Aquatic Chronic 1; H410 (M=10000) and A-listing at RAC-63.	
The expert accompanying the CropLife Regular Stakeholder Observer commented on developmental toxicity.	
4.2.5. Ozone (EC: 233-069-2; CAS: 10028-15-6)	
The Chair welcomed the Dossier Submitter's representative and informed that **ozone** is generated *in situ* as a biocidal active substance from oxygen and used to disinfect water and ambient air. There are also several non-biocidal uses by operation of an ozonation device utilising the oxidative action of ozone e.g. (non exhaustive): ozonation of mineral water and drinking water or water for swimming pools: removal of iron, manganese, arsenic and nitrite, pharmaceutical, medicine, cosmetics, and food industry: production of (ultra-)pure process water, pulp and paper bleaching, semiconductor industry: production of (ultra-)pure process water, off-gas treatment, laminating and coating, sludge reduction, soil and groundwater remediation, ozonation of wastewater. The substance has no current Annex VI entry. The DS (DE) proposes to classify ozone as Ox. Gas 1; H270, Acute Tox. 1; H330, Muta. 2; H341, Carc. 2; H351, STOT SE 1; H370, STOT SE 3; H335, STOT RE 1; H372, Aquatic Acute 1; H400 (M = 100), Aquatic Chronic 1; H410 (M = 1). All hazard classes (physical hazards as well as hazards to human health and the environment) with the exception of skin sensitisation, aspiration hazard and/or hazardous to the ozone layer, in the event that there are no data for these hazard classes were the hazard classes open for comments during the Consultation. The deadline for the adoption of an opinion is 30 August 2023.	
<u>Physical hazards</u> The group recommended to classify the substance as Ox. Gas 1; H270 and A-listing at RAC-63. *<u>Human Health</u>* *Acute toxicity* The group recommended to classify the substance as Acute Tox. 1; H330 (ATE=10 ppmV) and A-listing at RAC-63.	**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-63.

STOT SE The group recommended to classify the substance as STOT SE 1; H370 (respiratory system, nervous system) and A-listing at RAC-63. Specific concentration limits will be discussed at the RAC-63 plenary meeting. Effects on cardiovascular system will be discussed at the RAC-63 plenary meeting. The group recommended no classification for STOT SE 3 respiratory irritation, since more severe effects on respiratory system were leading to classification under STOT SE 1. *STOT RE* The group recommended to classify the substance as STOT RE 1; H372 (respiratory system, nervous system) and A-listing at RAC-63. The opinion will be revised to consider less weight for neurotoxicity data observed in the offspring and to better reflect the difference of effects and effective doses between STOT SE and RE. SCLs will be discussed at the RAC-63 plenary meeting. Effects on cardiovascular system will be discussed at the RAC-63 plenary meeting. Impact of exposure durations will be analysed. *Mutagenicity* The group recommended to classify the substance as Muta. 2; H341 and A-listing at RAC-63. The group noted that classification as Muta. 1B cannot be, however, excluded due to a data gap. The opinion will be revised to include information on local genotoxicity and dominant lethal test in mice. *Reproductive toxicity* The group recommended no classification for sexual function and fertility, nor for developmental toxicity based on inconclusive data and A-listing at RAC-63. Effects on or via lactation will be presented and discussed at RAC-63. *Skin irritation/corrosion* The group recommended no classification for skin irritation/corrosion due to inconclusive data, and A-listing at RAC-63. *Serious eye damage/irritation* The group recommended no classification for serious	**The hazard classes going for plenary discussion: Reproductive toxicity (effects on or via lactation only), SCL values for STOT SE 1 (respiratory system, nervous system), SCL values for STOT RE 1 (respiratory system, nervous system), as well as effects on cardiovascular system.** **Carcinogenicity is left for RAC-64.**

eye damage/irritation based on conclusive data, and A-listing at RAC-63. The wording in the opinion will be revised with respect to severity, since the data did not allow an estimation. *Respiratory sensitisation* The group recommended no classification for respiratory sensitisation and A-listing at RAC-63. *Environment* *Aquatic acute toxicity* The group recommended to classify the substance as Aquatic Acute 1; H400 (M=100) and A-listing at RAC-63. *Aquatic chronic toxicity* The group recommended to classify the substance as Aquatic Chronic 1; H410 (M=1) and A-listing at RAC-63.	
4.2.6. Pyraclostrobin (ISO); methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl}phenyl) N-methoxy carbamate (EC: - CAS: 175013-18-0)	
The co-Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. She informed that exceptionally the HH part of the draft opinion is not discussed in this working group, but was left for the RAC consultation after the meeting and discussion at RAC-63. The co-Chair noted that **pyraclostrobin** is used as a fungicidal agent in plant protection products. The substance has a current Annex VI entry as Acute Tox. 3 *; H331, Skin Irrit. 2; H315, Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410. The DS (DE) proposes to modify the classification to Repr. 2; H361d, Acute Tox. 3; H331 (ATE=0.58 mg/L (dusts or mists)), Acute Tox. 4; H302 (ATE=450 mg/kg bw), STOT SE 3; H335, STOT RE 2; H373 (liver, gastrointestinal tract), Skin Irrit. 2; H315, Aquatic Acute 1; H400 (M=100) 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, desensitised explosives), 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, STOT RE, hazardous to the aquatic environment and hazardous to the ozone layer were open for comments during the Consultation. The deadline for the adoption of an opinion is 22 March 2023.	
Physical hazards The group recommended no classification and A-listing at RAC-63.	**Rapporteur** to revise the draft opinion in accordance with the discussion in the Working

Aquatic acute toxicity The group recommended to classify the substance as Aquatic Acute 1; H400 (M=100) and A-listing at RAC-63. *Aquatic chronic toxicity* The group recommended to classify the substance as Aquatic Chronic 1; H410 (M=100) and A-listing at RAC-63. *Hazard to the ozone layer* The group recommended no classification and A-listing at RAC-63.	Group and to provide it to SECR. **SECR** to organise a RAC consultation on the HH part of the draft opinion. **SECR** to table the updated opinion for final discussion and adoption at RAC-63. **The hazard classes going for plenary discussion: All HH hazards.**
4.2.7. Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal) (EC: - CAS: -)	
The co-Chair welcomed the Dossier Submitter representative and informed that **glycerol formal** is used at industrial sites in the following products: coatings, adhesives, sealants and elastomers. It is used as laboratory chemicals and as an intermediate. Professional uses also include the use in agrochemicals. The substance is also used in consumer products including home care products (air care products, anti-freeze and de-icing products, biocidal products, perfumes and fragrances, pharmaceuticals, polishes and wax blends and washing and cleaning products), fuels, agrochemicals and coatings, adhesives, sealants and elastomers. The substance has no current Annex VI entry. The DS (NL) proposes to classify the substance as Repr. 1B; H360Df. Reproductive toxicity was the only hazard class open for the Consultation. The deadline for the adoption of an opinion is 4 May 2023.	
Reproductive toxicity *Development* The group recommended to classify the substance as Repr. 1B; H360D and A-listing at RAC-63. *Fertility* The group recommended to classify the substance as Repr. 2; H361f based on consistent effects on male reproductive organs in rats, also observed in supportive studies in other species. The group recommended to A-list this hazard class at RAC-63. *Lactation* The group recommended no classification for lactation and A-listing at RAC-63.	**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-63. **The hazard classes going for plenary discussion: None.**

4.2.8. *tert*-Butyl 2-ethylperoxyhexanoate (TBPEH) (EC: 221-110-7; CAS: 3006-82-4)	
The Co-chair welcomed the Dossier Submitter representatives and informed that ***tert*-butyl 2-ethylperoxyhexanoate** is used in polymers and plastic products by consumers, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The industrial uses reported are the following: industrial use of organic peroxides as polymerisation initiators, cross linking agents or curing agents; other industrial uses of organic peroxides; use of reactive processing aid at industrial site (no inclusion into or onto article); industrial use of chemicals for polymer processing; industrial use of coatings and paints; industrial use as polymerisation initiator and cross-linking agent; use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into /onto article). Regarding consumer uses, the substance is used in adhesives and sealants, coating and paints, thinners, paint removers and fillers, putties, plasters, modelling clay. The substance has no current Annex VI entry. The DS (FR) proposes to classify *tert*-butyl 2-ethylperoxyhexanoate as Repr. 1B; H360FD, Skin Sens. 1B; H317. Reproductive toxicity and skin sensitisation were the hazard classes open for comments during the Consultation. The deadline for the adoption of an opinion is 13 July 2023.	
Reproductive toxicity *Fertility* The group recommended to classify the substance as Repr. 1B; H360F and A-listing at RAC-63. *Developmental toxicity* The group discussed classification of the substance as Repr. 1B or Repr. 2. Effects on pup mortality and pup weight relevant for classification were seen in the rat studies (PNDT/Screening/EOGRTS) at 1000 mg/kg bw/d. The group recommended to further investigate the rabbit PNDT study based on the individual data in the study report that will be provided by the DS. The data on rat and rabbit studies will be re-considered for the plenary RAC-63. *Lactation* The group recommended no classification for lactation and A-listing at RAC-63. *Skin sensitisation* The group recommended to classify the substance as Skin Sens. 1; H317 and A-listing at RAC-63.	**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-63. **The hazard classes going for plenary discussion: Developmental toxicity.**

5. Requests under Article 77(3)(c) request DNEL setting for DOTE/MOTE (Request to the Committee for Risk Assessment to set a DNEL for 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE))	

The Rapporteurs presented the second version of the draft note.
 	
The Working Group recommended to RAC to use:
 	
The following absorption values:
- 50 % for inhalation absorption
- 20 % for oral absorption
- 0.1 % for dermal absorption
 	
Most relevant studies for DNEL derivation
- The NOAEL for (slight) developmental effects from the rabbit PNDT study with DOTE of 20 mg DOTE/kg bw/day (9 mg DOT/kg bw/d)
- The NOAEL for increase in stillbirths from the rat 2-generation study with DOTI:MOTI of about 1.6 mg DOTE/kg bw/day (0.7 mg DOT/kg bw/d / 1.6 mg DOTI:MOTI/kg bw/d)
 	
Assessment Factors (AFs)
- Default AFs for interspecies and intraspecies variability and exposure duration
- Quality of database:
  o AF 4 for rabbit studies since less sensitive species
  o AF 1 for read-across (DOTE and DOTI close analogues)
  o AF of 5 (e.g., rat 2-generation study) and 10 (e.g., rabbit PNDT study) for immuno-developmental effects, that occur at lower doses, shown for other octyltin substances (i.e., DOTC) to be further investigated
 	
Point of departure
- 1.6 mg DOTE/kg bw/day from the DOTI:MOTI study (lowest DNEL)
 	
DNEL derivation (depending on the AF 5 or 10 for immunodevelopmental effects)
- Worker, long-term inhalation: 0.013 or 0.026 mg DOTE/m^3
- Worker, long-term dermal: 0.90 or 1.80 mg DOTE/kg bw/day
- General population, long-term oral: 0.0016 or 0.0032 mg DOTE/kg bw/d
	Secretariat to launch the RAC consultation.
	
	Rapporteurs to revise draft note, taking into account RAC comments from the Working Group as well as written commenting round.
	
	Secretariat to table the revised draft note for discussion and agreement at RAC-63

General remark Developmental immunotoxic effects to be considered under reproductive (developmental) toxicity (Annex XIV)	

6. AOB

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

7. 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 7th Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I **Agenda of the of the 7th 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

12 October 2022
RAC WG/CLH/7/2022

7th Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling (RAC-63 CLH WG)

Monday 24 October at 14:00 -
Thursday 27 October ends at 15:30

Times are Helsinki times
Virtual meeting

Final draft Agenda

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/CLH/7/2022
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-63

- 1,4-Dichloro-2-nitrobenzene: *carcinogenicity, germ cell mutagenicity*
- Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl: *acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, STOT RE, hazards to the aquatic environment*
- Dibenzoyl peroxide; benzoyl peroxide: *hazards to the aquatic environment*
- Fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine: *hazards to the aquatic environment*
- *n*-Hexane: *STOT RE*
- Ozone: *hazards to the aquatic environment*
- Pyraclostrobin (ISO); methyl *N*-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate: *hazards to the aquatic environment*
- Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal): *reproductive toxicity (development, lactation)*
- *Tert*-butyl 2-ethylperoxyhexanoate (TBPEH): *reproductive toxicity (fertility)*

CLH dossiers

4.2.1. Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl (EC: 201-993-5; CAS: 90-43-7)

4.2.2. Copper (EC: 231-159-6; CAS: 7440-50-8)

4.2.3. Cyclohex-3-ene-1-carbaldehyde derivatives (2,4-dimethylcyclohex-3-ene-1-carbaldehyde [1]; (1α,2α,5α)-2,5-dimethylcyclohex-3-ene-1-carbaldehyde [2]; 2,6-dimethylcyclohex-3-ene-1-carbaldehyde [3]; 3,5-dimethylcyclohex-3-ene-1-carbaldehyde [4]; 3,6-dimethylcyclohex-3-ene-1-carbaldehyde [5]; 4,6-dimethylcyclohex-3-ene-1-carbaldehyde [6]; reaction mass of 3,5-dimethylcyclohex-3-ene-1-carbaldehyde and 2,4-dimethylcyclohex-3-ene-1-carbaldehyde [7]; dimethylcyclohex-3-ene-1-carbaldehyde [8]; dimethylcyclohex-3-ene-1-carbaldehyde [9]; 1,2,4(or 1,3,5)-trimethylcyclohex-3-ene-1-carbaldehyde [10]; 1,3,4-trimethylcyclohex-3-ene-1-carbaldehyde [11]; 2,2,4-trimethylcyclohex-3-ene-1-carbaldehyde [12]; 2,4,6-trimethylcyclohex-3-enecarbaldehyde [13]; isocyclocitral [14]; 3,5,6-trimethylcyclohex-3-ene-1-carbaldehyde [15] and 4,6,6-trimethylcyclohex-3-ene-1-carbaldehyde [16])

4.2.4. Fenpropidin (ISO); (*R*,*S*)-1-[3-(4-tert-butylphenyl)-2-methylpropyl]piperidine (EC: 614-049-6; CAS: 67306-00-7)

4.2.5. Ozone (EC: 233-069-2; CAS: 10028-15-6)

4.2.6. Pyraclostrobin (ISO); methyl *N*-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate (EC: - CAS: 175013-18-0) – only Physical hazards and hazards to the Ozone layer will be discussed, while the HH part of the ODD will be prepared for RAC-63

4.2.7. Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal) (EC: - CAS: -)

4.2.8. *Tert*-butyl 2-ethylperoxyhexanoate (TBPEH) (EC: 221-110-7; CAS: 3006-82-4)

For discussion

Item 5 – Requests under Article 77(3)(c)

5.1 DNEL setting for DOTE/MOTE (Request to the Committee for Risk Assessment to set a DNEL for 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE))

For discussion

Item 6 – AOB

Item 7 – Adoption of the Report from the Working Group

For discussion and agreement

ANNEX II: List of participants

RAC members	
Angeli	Karine
Barański	Bogusław
Biró	Anna
Facchin	Manuel
Geoffroy	Laure
Hakkert	Betty
Karadjova	Irina
Landvik Tekpli	Nina
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Martínek	Michal
Menard Srpčič	Anja
Mendas Starcevic	Gordana
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Neumann	Michael
Pęczkowska	Beata
Pribu	Mihaela
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Schulte	Agnes
Schuur	Gerlienke
Sogorb	Miguel
Sørensen	Peter Hammer
Spetseris	Nikos
Tobiassen	Lea Stine
Tsitsimpikou	Christina
Užomeckas	Žilvinas
Varnai	Veda

Members' advisers	
Bjørge Christine	Tekpli Nina
Capolupo Marco	Paris Pietro
Hoffmann Frauke	Schulte Agnes
Moilanen Marianne	Leinonen Riitta
Orthen Bruno	Gebel Thomas
Panieri Emiliano	Paris Pietro
Russo Maria Teresa	Aquilina Gabriele
Saksa Jana	Moldov Raili

Stalter Daniel	Agnes Schulte
Stuhldreier Fabian	Gebel Thomas
Suutari Tiina	Leinonen Riitta
van Herwijnen Rene	Hakkert Betty

Dossier submitters	**Substance**
Sanz Manuel Tenorio Gómez María	Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl
Akerblom Nina	copper
Stalter Daniel	Cyclohex-3-ene-1-carbaldehyde derivatives
Čapková Katarína	fenpropidin
Rudzok Susanne	Ozone
Choi Judy	Pyraclostrobin
Geraets Lisbeth	Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol
Maniere Isabelle Charles Sandrine	TBPEH

Regular stakeholder observers	
De Backer Liisi	Cefic
Evans Benedict	MedTech Europe
Robinson Jan	AISE
Ruelens Paul	CropLife Europe
Waeterschoot Hugo	Eurometaux

Occasional stakeholder observers	
Baken Stijn	European Copper Institute

Stakeholder experts		**Substance**
Mackie Carol	Eurometaux/ Regulatory Compliance Ltd	Copper
Mostert Volker	CropLife Europe/Company Extera on behalf Lanxess	Biphenyl-2-ol; 2-phenylphenol; 2-hydroxybiphenyl
Tesch Sheila	CropLife Europe/Tesh Consultants on behalf Syngenta	Fenpropidin
Werner Christoph	CropLife Europe/BASF	Pyraclostrobin

European Commission		**DG**
Corvi	Raffaella	DG EMPL
Kilian	Karine	DG ENV
Pinte	Jérémy	DG GROW

EFSA		
Bastaki	Maria	

ECHA staff	
Bowmer (Co-chair)	Tim
Peltola-Thies (Co-chair)	Johanna
Myöhänen (Co-chair)	Kirsi
Simoes (Co-chair)	Ricardo
Uphill (Co-chair)	Simon
Bichlmaier Suchanová	Bohumila
Alami-Eerikinharju	Wafa
Korjus	Pia
Lapenna	Silvia
Ludboržs	Arnis
Marchetto	Flavio
Mattiuzzo	Marco
Müller	Jakob
Nygren	Jonas
O'Rourke	Regina
Perazzolo	Chiara
Prevedouros	Kostas
Rahkonen	Olli
Reuter	Ulrike
Ryan	Paul
Sadam	Diana
Sobanska	Marta
Sosnowski	Piotr
Spjuth	Linda
Stromberg	Minna
Zhivin	Sergey

ANNEX III: Declarations of potential conflicts of interest

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Harmonised classification & labelling		
Ozone **DE**	Agnes Schulte	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.
	Michael Neumann	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.
***n*-Hexane** **DE**	Agnes Schulte	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.
	Michael Neumann	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance -

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		no other mitigation measures applied. No personal involvement.
Cyclohex-3-ene-1-carbaldehyde derivatives (2,4-dimethylcyclohex-3-ene-1-carbaldehyde [1]; (1α,2α,5α)-2,5-dimethylcyclohex-3-ene-1-carbaldehyde [2]; 2,6-dimethylcyclohex-3-ene-1-carbaldehyde [3]; 3,5-dimethylcyclohex-3-ene-1-carbaldehyde [4]; 3,6-dimethylcyclohex-3-ene-1-carbaldehyde [5]; 4,6-dimethylcyclohex-3-ene-1-carbaldehyde [6]; reaction mass of 3,5-dimethylcyclohex-3-ene-1-carbaldehyde and 2,4-dimethylcyclohex-3-ene-1-carbaldehyde [7]; dimethylcyclohex-3-ene-1-carbaldehyde [8]; dimethylcyclohex-3-ene-1-carbaldehyde [9]; 1,2,4(or 1,3,5)-trimethylcyclohex-3-ene-1-carbaldehyde [10]; 1,3,4-trimethylcyclohex-3-ene-1-carbaldehyde [11]; 2,2,4-trimethylcyclohex-3-ene-1-carbaldehyde [12]; 2,4,6-trimethylcyclohex-3-enecarbaldehyde [13]; isocyclocitral [14]; 3,5,6-trimethylcyclohex-3-ene-1-carbaldehyde [15] and 4,6,6-trimethylcyclohex-3-ene-1-carbaldehyde [16]) **DE**	Agnes Schulte	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.
	Michael Neumann	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.
Pyraclostrobin (ISO); methyl *N*-(2-{[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxymethyl}phenyl) *N*-methoxy carbamate **DE**	Agnes Schulte	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
	Michael Neumann	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.
Reaction mass of 1,3-dioxan-5-ol and 1,3-dioxolan-4-ylmethanol (glycerol formal) **NL**	Gerlienke Schuur	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.
1,4-Dichloro-2-nitrobenzene **NL**	Gerlienke Schuur	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.
Tert-butyl 2-ethylperoxyhexanoate (TBPEH) **FR**	Karine Angeli	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
	Laure Geoffroy	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.
Copper **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.