RAC WG/CLH/R/3/2021

28 October 2021

Report
of the 3rd Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling (RAC-59 CLH WG)

ECHA Conference Centre (Telakkakatu 6, Helsinki) via Webex

Monday 25 October 2021 at 10.00 to Thursday 28 October 2021 at 18.15

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Tim Bowmer, welcomed the participants to the 3rd meeting of the RAC Working Group on CLH and reminded that RAC had agreed on the establishment of the group at RAC-56 in March 2021. He noted that for the first time, all RAC-59 CLH dossiers are for discussion in the CLH Working Group. Written consultations were organised in the Committee on all dossiers prior to the meeting. The Chair also informed the participants that for the first time, the group will be chaired by other ECHA staff (Ari Karjalainen, Ricardo Simoes and Simon Uphill), in addition to the RAC Chair and Deputy Chair.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/CLH/3/2021), 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 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 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-59

The Working Group agreed to propose the following hazard classes to RAC-59 for A-listing (without discussing them in the WG):

- **Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate:** hazardous to the aquatic environment
- **7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate:** skin sensitisation
- **2,2'-ethylenedioxydiethyl dimethacrylate:** skin sensitisation
- **Hexyl salicylate:** skin sensitisation
- **2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol:** skin sensitisation
- **Tetramethylene dimethacrylate:** skin sensitisation

4.2 Hazard classes for discussion

4.2.1 Sulfur dioxide (EC: 231-195-2; CAS: 7446-09-5)

The Chair welcomed the Dossier Submitter representative, the experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers, the Occasional Stakeholder Observer from CIRFS with an accompanying expert, the Occasional Stakeholder Observer from the Only Representative Organisation as well as the experts from EFSA.

He explained that **sulfur dioxide** is used as a fungicide in the context of BPR. Additionally, it has a broad spectrum of uses within industrial settings including winemaking, water treatment and metal purification. The substance has current Annex VI entry as Press. Gas; H280 (Notes U and 5), Skin Corr. 1B; H314, Acute Tox. 3*; H331.

The DS (DE) proposes to add Skin Sens. 1; H317, Muta. 2; H341 and STOT SE 3; H335, to modify Acute Tox. 3; H331 (ATE = 1041 ppmV (gases)) and to retain Press. Gas, Notes U and 5 and Skin Corr. 1B; H314.

Selected physical hazards (flammable gases (including chemically unstable gases), oxidising gases, gases under pressure), acute inhalation toxicity, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity and STOT SE were the hazard classes open for comments during the Consultation.

At RAC-58, the Committee agreed to classify the substance as Press. Gas, Notes U and 5, Acute Tox. 3; H331 (ATE = 1000 ppmV (gases)) and on no classification for respiratory sensitisation. RAC also agreed to discuss skin sensitisation (including the read across argument for local effects), STOT SE (applicability of the data to the criteria for either Category 1 or 2), germ cell mutagenicity and carcinogenicity further at the 3rd RAC CLH Working Group meeting.

Legal deadline for the adoption of an opinion is 10 February 2022.

Human Health *STOT SE* There were questions from IND representatives regarding the doses at which the effects were	**Rapporteurs** to revise the opinion in accordance with the discussion in the WG and to provide it to SECR.

observed and if these could be close to doses at which Acute toxicity effects were observed. It was also mentioned by industry that there are a range of chemical contaminants that could potentially be present in the reported mine explosions. The Rapporteurs responded that several of the studies report effects from doses as low as 10 ppm which is far from the ATE values determined. There was a wide range of arguments discussed, including the reversibility of the effects and the occupational studies including effects in the deep lung. Most of the comments supported STOT SE 1 (Causes damage to the respiratory system by inhalation) and the group proposed that this hazard class can be A-listed for RAC-59. *Skin sensitization* For this endpoint the group considered that the proposed read across from sulphites, bisulphites and metabisulphites was not valid. There was no evidence supporting skin absorption of SO_2 or that sulphites can be formed on the skin. Hence, if the read across were to be accepted it would require a complex set of assumptions to justify it. These assumptions were not supported by other data available to the WG. In particular, it was noted that SO_2 is a very common air impurity in some industries (e.g. paper/pulp) and in outdoor air and still, after many decades of exposure, there are no reported skin allergies from dermatological clinics that could be associate with SO_2. Hence the available epidemiology data is not supportive of the read across hypothesis. The group considered whether the conclusion on No Classification was due to lack of data (some data is indeed lacking but the conclusion is seen as clear) but was unable to resolve this. The Secretariat and Rapporteurs are to address this in the opinion ahead of RAC 59. *Mutagenicity* The group discussed the scoring of the main studies (Meng and Ziemann) since both were considered to have some deficiencies and uncertainties. Although the Meng studies lacked positive controls, the results were sufficiently high that the group considered that their absence would not impair the reliability of the results.	**SECR** to table the updated opinion for final discussion and adoption at RAC-59. **The hazard classes going for plenary discussion: mutagenicity.**

In the studies by Ziemann it was considered that the doses might have been too low (below the MTD). It was also taken into consideration that the mouse strain used in the Meng *et al.* studies may have been particularly sensitive to SO_2. Concerns were also raised regarding the mouse strain used in the Meng *et al.* studies but since this is a widely accepted strain in studies outside Europe it was not considered sufficient reason to reduce the reliability of this study. Industry representatives introduced some questions regarding the analytical methods used for SO_2 determination and the observations made on timing for the mitotic cycle, but the Rapporteur indicated that the timing was compatible with the OECD Guideline where chromosomal aberration detection by using colchicine as the arresting agent is concerned. It was considered that the main studies were the ones where SO_2 was used (Meng and Ziemann) and there could be many reasons for the differences in the results (age of the animals, different sensitivities to SO_2, reporting issues in both studies) but that there is also positive evidence from studies with other substances from which read across was accepted and epidemiological studies in several different countries where the concern for the mutagenic properties of SO_2 had been raised. Given that there are various threads of positive evidence that could not be discarded, the majority of the WG considered that a proposal for Muta. 2 can be taken to RAC-59 although some further discussion will be needed. Several members considered that no classification was more appropriate, e.g. due to inconclusive data. The Secretariat and the Rapporteurs are to address this in the opinion ahead of RAC-59. *Carcinogenicity* The WG considered that the available animal data were conclusive and not supportive of classification for Carcinogenicity. It was proposed to A-list this hazard class at RAC-59. Furthermore, the WG took note of the EFSA presentation of their work on this substance.	

The expert accompanying the Cefic Regular Stakeholder Observer commented on read across, STOT SE and skin sensitisation. The CIFRS Occasional Stakeholder observer as well as his accompanying expert commented on STOT SE.	
4.2.2 Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3)	
The co-Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer and informed that **bifenox**, also in the form of potassium or ammonium salts, is an active substance (herbicide) in many plant protection products. The substance has no current Annex VI entry. The DS (PL) proposes to classify bifenox as Aquatic Acute 1; H400 (M = 1000) and Aquatic Chronic 1; H410 (M = 1000). 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, organic peroxides, corrosive to metals), 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 to the ozone layer were the hazard classes open for comments during the Consultation. Legal deadline for the adoption of an opinion is 26 May 2022.	
<u>Physical hazards</u> The WG recommended no classification and A-listing at RAC-59. Two of the hazard classes, explosives and self-reactive substance were considered not classified due to inconclusive data. <u>Human Health</u> *Acute oral toxicity* The WG did not support the DS and recommended to classify bifenox as Acute Tox 4; H302 (ATE = 1500 mg/kg bw) – based on the results of the study on acute oral toxicity in mice. *Acute dermal and inhalation toxicity* The WG recommended no classification based on conclusive data and recommended for A-listing at RAC-59. *STOT SE* The WG recommended no classification and recommended for A-listing at RAC-59. *STOT RE* The WG agreed to continue the discussion on this	**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-59. **The hazard classes going for plenary discussion: STOT RE and reproductive toxicity – fertility.**

hazard class at RAC-59 with further information to be made available in the form of study reports. *Skin irritation/corrosion* The WG recommended no classification and A-listing at RAC-59. *Serious eye damage/eye irritation* The WG recommended no classification and A-listing at RAC-59. *Skin sensitisation* The WG recommended no classification based on conclusive data after the applicant provided the copy of original study report during the meeting, and WG recommended A-listing at RAC-59. *Mutagenicity* The WG recommended no classification based on conclusive data from *in vitro* studies and recommended A-listing at RAC-59. *Carcinogenicity* The WG recommended no classification based on inconclusive data and recommended A-listing at RAC-59. *Reproductive toxicity* *Fertility* The WG recommended no classification but agreed to finalise the discussion at RAC-59 (whether the data is conclusive). Original data from repeated dose toxicity studies will be checked to have support on non-existence of effects for testes/ovary, to better be able to consider data as conclusive. *Development* The WG recommended no classification based on conclusive data and recommended A-listing at RAC-59. The conclusion on effects on pup body weight will be elaborated in the opinion. *Lactation* The WG recommended no classification based on conclusive data and recommended A-listing at RAC-59. The conclusion on effects on pup body weight will be elaborated in the opinion.	

Environment *Aquatic acute toxicity* The WG agreed with the DS that the lowest endpoint for acute toxicity corresponds to the *Scenedesmus subspicatus* study E_rC_{50} = 0.00042 mg/L. The WG thus agreed to recommend classification as Aquatic Acute 1; H400 (M = 1000). *Aquatic chronic toxicity* Bifenox is not rapidly degradable as ultimate degradation < 70 % after 28 d. Rapid primary degradation occurs but no information on degradation products, so not rapidly degradable via primary degradation route. Bifenox is bioaccumulative in aquatic environment - a fish BCF of > 500 is available. The rapporteurs will check the log K_{ow} values for consistency and adjust the opinion accordingly. The WG noted that there is adequate chronic data available for invertebrates, algae and macrophytes. The lowest endpoint corresponds to the E_rC_{10} = 0.000025 mg/L for *M. spicatum* and thus the WG recommended the classification as Aquatic Chronic 1; H410 (M = 1000). *Hazardous to the ozone layer* The WG agreed with the DS that bifenox is not considered as hazardous to the ozone layer. The above-mentioned hazard classes for Environment are proposed to be agreed by A-listing at RAC-59.	
The expert accompanying the CropLife Regular Stakeholder Observer commented on acute toxicity, skin sensitisation, mutagenicity and carcinogenicity.	
4.2.3. Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate 275-728-7; CAS 71626-11-4)	
The Deputy Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer and informed that **benalaxyl** is an active substance for pesticide belonging to the phenylamide group name and acylalanine chemical group of systemic fungicide with apoplastic translocation which inhibits mycelial growth of fungi and germination of zoospores (fungistatic action). The substance has current Annex VI entry as Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The DS (RO) proposes to add Carc. 2; H351, Acute Tox. 4; H302 (ATE = 2000 mg/kg bw),	

STOT SE 2; H371 (nervous system) and M=1 for both aquatic acute and aquatic chronic hazards and to retain Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.

Selected physical hazards (explosives, flammable solids, pyrophoric solids, self-heating substances, oxidising solids), acute oral toxicity, carcinogenicity, STOT SE and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 5 May 2022.

Human Health The WG agreed to recommend classification as Acute Tox. 4; H302 (oral ATE = 1000 mg/kg bw). LD_{50} could not be determined quantitatively, hence the ATE was selected in order to be sufficiently protective (dose level corresponding to 20 % mortality). The WG agreed on no classification for physical hazards and STOT SE. The group also recommended no classification for carcinogenicity due to inconclusive data because of the too low dosing in the rat study. RAC recommended rewording the ODD on the neoplastic nature of the tumours observed in the mouse study. It was agreed to propose these hazard classes for A-listing, except for carcinogenicity, on which a brief presentation will be made at RAC-59. Environment The WG agreed to recommend classification as Aquatic Acute 1; H400 (M = 1) and Aquatic Chronic 1; H410 (M = 1). It was agreed to propose these hazard classes for A-listing at RAC-59.	**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-59. **The hazard classes going for plenary discussion: carcinogenicity.**
The expert accompanying the CropLife Regular Stakeholder Observer commented on acute toxicity.	

4.2.4 Hexyl salicylate (EC 228-408-6; CAS 6259-76-3)

The Deputy Chair welcomed the Dossier Submitter representative and informed that **hexyl salicylate** is a fragrance ingredient used in many fragrance compounds. It may be found in fragrances used in decorative cosmetics, fine fragrances, shampoos, toilet soaps and other toiletries as well as in non-cosmetic products such as household cleaners and detergents. Hexyl salicylate has no current Annex VI entry.
The DS (FR) proposes to classify the substance as Skin Sens. 1; H317.
Selected physical hazards (explosives, flammable liquids, self-reactive substances, pyrophoric

liquids, substances which in contact with water emit flammable gases, oxidising liquids, organic peroxides, corrosive to metals), skin sensitisation and reproductive toxicity were the hazard classes open for comments during the Consultation. Legal deadline for the adoption of an opinion is 8 June 2022.	
The WG recommended no classification for the physical hazards. The WG agreed to recommend classifying hexyl salicylate as Skin Sens. 1; H317. The above-mentioned hazard classes are proposed to be agreed by A-listing. The WG took note of the presentations by the Rapporteurs and the ECHA Secretariat on the read across from salicylic acid and methyl salicylate to hexyl salicylate. However, it was not possible for the group to come to a conclusion regarding the rate of hydrolysis of hexyl salicylate and whether the read-across as proposed by the DS was appropriate. It was agreed that the Secretariat will launch a targeted consultation on the QSAR information, on a non-confidential version of the study report for the skin absorption (to be acquired by the DS) and on the study reports of Belsito *et al.*, 2007 and the RIFM assessment. Due effort will be carried out by ECHA and the DS to find and evaluate also further studies not yet cited in the CLH dossier, where necessary. The main focus of the further work is to clarify the rate and relevance of the hydrolysis for the oral route of exposure. Compilation of the information for the targeted consultation will be prepared by the DS with the support of ECHA Secretariat.	**SECR** to organise a targeted consultation on the new information. **Rapporteur** to revise the opinion in accordance with the discussion in the Working Group and the outcome of the targeted consultation, and to provide it to SECR. **SECR** to table the updated opinion for further discussion at RAC-60 CLH WG. Read across and reproductive toxicity will be discussed during the RAC-60 CLH WG (January 2022), to allow for sufficient time to organise the targeted consultation. **The hazard class going for plenary discussion at RAC-59: none.**

4.2.5 4-methylimidazole (EC 212-497-3; CAS 822-36-6)

The Chair welcomed the Dossier Submitter representatives and informed that **4-methylimidazole** is used as an intermediate for chemical reactions in manufacture of chemicals and chemical products. Also, 4-methylimidazole occurs in food and beverages as it is formed in the Maillard reaction process. The substance has no current Annex VI entry.
The DS (NO) proposes to classify the substance as Carc. 1B; H350 and Repr. 1B; H360Fd.
Germ cell mutagenicity, carcinogenicity and reproductive toxicity were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 16 June 2022.	
The group agreed on no classification for germ cell mutagenicity based on conclusive data. The group agreed to propose to classify 4-methylimidazole as Carc. 1B; H350, as it increased the incidence of lung neoplasia in both sexes of a single species, the mouse, in a well-conducted NTP study following GLP. It was agreed to propose classifying the substance as Repr. 1B for sexual function and fertility, due to clear effects on male fertility in the absence of systemic toxicity and also on female fertility in particular due to effects even at lower doses in the absence of maternal toxicity. The group also agreed to recommend the classification as Repr. 2 for developmental toxicity due to evidence of adverse effects (pup survival on PND 1-4 in the F1 and F2 generation, and limited support from increased incidence of male pups with areolae/nipples and undescended testis). The group briefly discussed the possibility of read across from the closely related 2-methyl- and vinyl-imidazole where developmental toxicity was concerned but decided that this was not needed. The WG proposed to include in the Opinion that the effects on sexual maturation (onset of puberty) may also be indicative of developmental toxicity. The group considered that classification for lactation is not warranted. The Rapporteurs and the working group, following a thorough discussion, supported the classifications as proposed by the Dossier Submitter and recommended A-listing of all hazard classes at RAC-59.	**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-59. **The hazard classes going for RAC-59 plenary discussion: none.**
4.2.6 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (EC 211-477-1; CAS 647-42-7)	
The Deputy Chair and the co-Chair informed that **3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol** is used as an intermediate. The substance has no current Annex VI entry. The DS (DE) initially proposed to classify the substance as STOT RE 2; H373 (skeletal system) and Aquatic Chronic 2; H411. On the reply to the Consultation comments, they decided to	

<table>
<tr><td colspan="2">include liver as second target organ for the STOT RE classification, hence their final proposal is STOT RE 2; H373 (skeletal system, liver).
STOT RE and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 20 July 2022.</td></tr>
<tr><td>STOT RE
The WG noted with regards to STOT RE that severe effects on teeth below the (eq.) GV for Cat. 2 (mottled, broken, misaligned teeth, delamination of the lower incisors tip surface, irregular alignment of the ameloblasts at maturation stage in the incisors and cell infiltration of the gingiva) were observed in 28 and 90-d studies in rats and in 1-gen studies in rats and mice and recommended classification accordingly. Effects on bones (incomplete decalcification) were also noted below the (eq.) GV for Cat. 2 in the only two studies that examined it (28-d inhalation study in rats and 1-gen study in mice). The WG considered that it would be clearer to specify ‘teeth’ and bones’ as target organs in this case over the more general ’skeletal system’.
The group considered that the data on liver effects was not conclusive enough, in particular due to lack of quantitative information on the effects, to add ‘liver’ as a target organ. It was noted that mortality was high in some long-term studies and should be further discussed in the opinion. The WG found the discussion and conclusions to be clear and recommended A-listing at RAC-59.

Aquatic environment
• The WG agreed with the DS to consider 6:2 FTOH as not rapidly degradable and that it has a low potential for aquatic bioaccumulation based on the BCF in fish below 500.
• The WG agreed with the DS that based on the most sensitive fish species LC_{50} for *Pimephales promelas* of 4.84 mg/L, no classification for Aquatic Acute hazards is warranted.
• The WG proposed to classify 6:2 FTOH as a not rapidly degradable substance based on 122-day NOEC for *Oryzias latipes* of 0.0231 mg/L (mean measured) based on hatching success as Aquatic Chronic 1; H410 with an M-factor of 1.
The working group recommended A-listing of these hazard classes at RAC-59.</td><td>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-59.

The hazard classes going for RAC-59 plenary discussion: none.</td></tr>
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4.2.7 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5)

The Deputy Chair and the co-Chair welcomed the Dossier Submitter representatives, and the experts accompanying the Cefic and AISE Regular Stakeholder Observers and informed that **1,2-benzisothiazolin-3-one** is used with biocidal purposes as disinfectant or as preservative. It also can be used in scientific research and development, as a co-formulant in Plant Protection Products. The substance has the following current Annex VI entry: Acute Tox. 4*; H302, Skin Irrit. 2; H315, Eye Dam. 1; H318, Skin Sens. 1; H317 (C ≥ 0.05 %) and Aquatic Acute 1; H400.

The DS (ES) proposed to retain Eye Dam. 1; H318 and Aquatic Acute 1; H400 and to add (M = 1), to add Acute Tox. 2; H330 (ATE = 0.25 mg/L, dusts or mists) and Aquatic Chronic 1; H410 (M = 1), to modify Acute Tox. 4*; H302 by removing * and adding ATE = 454 mg/kg and Skin Sens. 1B; H317 (C ≥ 0.05 %), and to remove Skin Irrit. 2; H315.

Acute toxicity via oral and inhalation routes, skin corrosion/irritation, skin sensitisation, hazardous to the aquatic environment and hazardous to the ozone layer were the hazard classes open for comments during the Consultation.
Legal deadline for the adoption of an opinion 13 August 2022.

<u>Acute toxicity</u> *Oral* The LD_{50} values of all five studies are in the range for Category 4 (300 < LD_{50} ≤ 2 000 mg/kg bw), therefore RAC agrees with the DS's proposal that the substance is classified as Acute Tox. 4; H302 (Harmful if swallowed), with an ATE value of 450 mg/kg bw. *Inhalation* Two studies give LC_{50} values, which correspond to Category 2 (0.05 < LC_{50} ≤ 0.5 mg/L). The WG proposes to use the lowest LC_{50}, calculated for males in the Anonymous 2007 study to derive an ATE. The WG concluded that the substance warrants the classification of Acute Tox. 2; H330 (Fatal if inhaled), with an ATE of 0.21 mg/L (dust and mist). Acute toxicity is proposed by the WG for A-listing at RAC-59. <u>Skin corrosion/irritation</u> The WG concluded to retain the classification of the substance as Skin Irrit. 2; H315 based on human data. This hazard class is proposed by the WG for A-listing at RAC-59.	**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-59. **The hazard classes going for plenary discussion: SCL for Skin Sens. 1A; H317.**

Skin sensitisation The WG recommends that Skin Sens. 1A; H317 is warranted based on two positive human data in HRIPT tests: sensitization occurred at induction doses 64.45 µg /cm^2 (Davies R.E. et al., 1975) (criterion < 500 µg/cm^2), and at 90.6 µg/cm^2 (Basketter D.A. et al., 1999). In addition, diagnostic patch test data indicate that there is a relatively high and substantial incidence of reactions (4.4 % in selected dermatitis patients), in relation to relatively low exposure (concentrations < 1.0 %). The WG was of the opinion that an SCL for the substance cannot be derived from the studies of dermal patients who developed BIT allergy after a long history of dermatitis, defective skin barrier, exposure to other irritants and constant use of occlusive gloves. The WG recommended to set an SCL of 0.036 %(360 ppm) for the substance, on the basis of the Basketter et al. 1999 HRIPT study, in which none of the volunteers were sensitized by 360 ppm of the substance (45 µg/cm^2), while 5/58 volunteers (9 %) were sensitized by the substance using 725 ppm of the substance (90.6 µg/cm^2). This hazard class is proposed by the WG for A-listing at RAC-59, except the SCL value which will be listed for endorsement at the RAC-59 plenary. Environment *Degradation* The WG recommended that despite the ultimate photolysis in water and rapid aerobic degradation in soil and seawater BIT is not ultimately degraded to > 70 % within 28 days (equivalent to a half-life < 16 days), or proven to be rapidly transformed to non-classifiable products. Consequently, BIT does not fulfil the criteria for rapid degradability according to the CLP criteria. *Bioaccumulation* Estimated BCF 3.162 L/kg and the experimental mean steady-state BCF 6.95 L/kg for whole fish in *Lepomis macrochirus* is below the CLP trigger value of ≥ 500. The experimentally determined log K_{OW} 0.70 and the estimated log K_{OW} 0.64 are below the CLP trigger value of ≥ 4.	

Experimental BCF of 6.95 L/kg was not normalized to a lipid content of 5 %, however the log K_{OW} of BIT suggests that it will not bioaccumulate in the aquatic environment and the mean steady-state BCF is comparable to the estimated BCF value. The WG recommends that BIT is not bioaccumulative according to the CLP criteria. *Aquatic toxicity* Aquatic Acute 1; H400 based on E_rC_{50} = 0.1087 mg/L (geomean) for *Pseudokirchneriella subcapitata*. As this acute toxicity value falls within the 0.1 < L(E)C_{50} ≤ 1 mg/L range, the acute M-factor is 1. Aquatic Chronic 1; H410 based on E_rC_{10} = 0.0268 mg/L (geomean) for *Pseudokirchneriella subcapitata*. As this chronic toxicity value falls within the 0.01 < NOEC ≤ 0.1 mg/L range, the chronic M-factor is 1. <u>Hazards to the ozone layer</u> The substance does not meet the CLP classification criteria and consequently does not warrant classification as Hazardous to the Ozone Layer. Environmental hazards are proposed by the WG for A-listing at RAC-59.	
The expert accompanying the Cefic Regular Stakeholder Observer commented on skin sensitization.	

4.2.8 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.; Reaction mass of N-phenyl,N'-o-tolyl-phenylene diamine, N,N'-diphenyl-p-phenylene diamine and N,N'-di-o-tolyl-phenylene diamine (EC 273-227-8; CAS 68953-84-4)

The Deputy Chair and the co-Chair welcomed the Dossier Submitter representative and informed that **1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.** is not naturally found in the environment; it is used in synthetic materials such as polymers. Release to the environment of this substance is likely to occur from: outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials), outdoor use in long-life materials with high release rate (e.g. tyres, treated wooden products, treated textile and fabric, brake pads in trucks or cars, sanding of buildings (bridges, facades) or vehicles (ships)) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, footwear, leather products, paper and cardboard products, electronic equipment). The substance has no current Annex VI entry.

The DS (DE) proposes to classify the substance as Skin Sens. 1; H317 and Repr. 1B; H360FD.

Skin sensitisation and reproductive toxicity were the hazard classes open for comments during the Consultation. Legal deadline for the adoption of an opinion 2 September 2022.	
Skin sensitisation The WG recommends that Skin Sens. 1 is warranted based on one positive GPMT study and supportive evidence from the presence of the constituent DPPD (classified as Skin Sens. 1) at concentrations well above trigger value for the classification of mixtures. This hazard class is proposed by the WG for A-listing at RAC-59. Toxicity to reproduction *Fertility* The WG recommends that classification for fertility as Repr. 1B is warranted for BENPAT, based on consistent, adverse effects observed on female fertility (gestational length, dystocia, post-implantation loss, pup mortality). The effects on female fertility were observed in the absence of marked maternal toxicity and considered to be relevant to humans. Members considered that the potential mode of action through prostaglandin inhibition was insufficiently supported by clear evidence to show that it would not be relevant to humans, nor were mechanistic studies available with BENPAT itself. The working group therefore proposed fertility for A-listing at RAC-59. *Development* The WG recommended to further discuss the developmental toxicity at RAC-59, in particular the uncertainties, the linkage of effects with dystocia and if effects are variations or malformations. The WG discussed category 2 or 1B; with a preference for category 1B. *Lactation* The WG agreed on no classification and to propose this hazard class for A-listing at RAC-59. *Reproductive toxicity potency group* The discussion on potency provided by the DS is based on an EC_{10} for polycystic kidneys and post-implantation loss. Some more wording on other effects is needed. The group agreed that the data did not indicate the need for a SCL.	**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-59. **The hazard classes going for RAC-59 plenary discussion: develop-mental toxicity.**

The expert accompanying the Cefic Regular Stakeholder Observer commented on reproductive toxicity. She also noted that the industry comments made in the Consultation on the dossier and in the WG meeting have not been adequately addressed, in particular with regard to how the available data support the presumption that the effects observed in rats can be extrapolated to humans.	
4.2.9 Silver (EC 231-131-3; CAS 7440-22-4) 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 Eruopean Precious Metals Fed. with an 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, STOT RE, hazardous to the aquatic environment were the hazard classes open for comments during the Consultation. At RAC-58, the Committee held a key issues discussion on this dossier. Legal deadline for the adoption of an opinion is 16 March 2022.	
Due to the still ongoing RAC consultation on the draft ODD during the meeting of the group, it was decided to take these hazard classes for plenary discussion in RAC-59, without recommending A-listing. Physical hazards The WG recommended no classification for physical hazards. The data on bulk silver was considered by RAC applicable also to silver nanoparticles. The secretariat will revise the reason for no classification for certain physical hazards to be in line with the CLP Regulation and UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria. Human Health	**Rapporteurs/SECR** to prepare the second draft opinion in accordance with the discussion in the Working Group and to provide it to SECR. RAC was encouraged to provide comments also on the first draft ODD on which the RAC consultation was ongoing until 8 November. **SECR** to table the second draft opinion for further discussion at RAC-59. **The hazard classes going for RAC-59 plenary discussion: physical hazards, acute toxicity,**

Acute Toxicity *Oral* The WG recommended no classification for acute oral toxicity. The top dose of the GLP and guideline compliant study on Ag NPs corresponded to 410 mg Ag eq./kg (with no deaths), which is below the threshold dose of 2 000 mg/kg bw. Due to still ongoing RAC consultation on the draft ODD, it was decided to take the hazard class for plenary discussion in RAC-59. Industry to provide an additional study providing evidence with macro scale silver. *Dermal* The WG recommended no classification for acute dermal toxicity. The top dose of the GLP and guideline compliant study on Ag NPs corresponded to 410 mg Ag eq./kg (with no deaths), which is below the threshold dose of 2 000 mg/kg bw. It was commented that there was however no concern due to low absorption through skin. *Inhalation* The WG recommended no classification for acute inhalation toxicity, silver (bulk and nano-forms) based on conclusive data (LC_{50} value above the ATE triggering classification). STOT SE The WG recommended no classification for STOT SE. Skin corrosion/irritation The WG recommended no classification based on conclusive data. Serious eye damage/eye irritation The WG recommended no classification based on conclusive data. <u>Environment</u> *Rapid Transformation* Provisionally no rapid transformation based on no evidence for rapid transformation. New data package to be reviewed by the Rapporteur. New transformation modelling to be submitted by Industry for assessment by the rapporteur. *Bioaccumulation* Needs further investigation to see if a clear conclusion	**STOT SE, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitization, skin sensitization, mutagenicity (first discussion), environment.** **[Carcinogenicity, reproductive toxicity and STOT RE for January 2022 WG and RAC-60.]**

can be reached with the available data. ECHA to examine CLP guidance to assist RAC's assessment. *Aquatic toxicity* Acute BLM for silver is lacking for algae, no chronic BLM models developed for Ag. Normalization tool for Ag is not also developed. The WG agreed that there was no need to normalise the ecotoxicity datasets for pH, DOC or hardness. The BLM model will not be considered further. Aquatic Acute – the WG agreed with the rapporteur that the proposed Acute ERV of 0.22 µg/L in *Daphnia* should be used. This was supported by Industry. The draft opinion will be revised regarding the studies included. Aquatic Chronic – the WG agreed with the rapporteur that an Acute ERV of 0.1 µg/L in microalgae should be used. Industry noted that this study was carried out as part of a testing proposal under substance evaluation with an amended medium and as such was not a standard study. The Rapporteur considered the study to be fully valid. An alternative study raised by Industry with an ERV value of 0.16 µg/L will be examined by the Rapporteur. Industry to send the study to ECHA. The rapporteur was requested to further look at the SSD to refine analysis or remove if not needed to support the chronic ERV. *Solubility of Ag* For massive silver, the Rapporteur noted that in the D/Tp test provided, only one of the triplicate batches had provided a measured solubility above the LOQ. The result had been expressed as the mean of the single measured value and zero dissolution for the two other replicates. The WG agreed to use the only measured value as the best scientifically justifiable way forward. A new equation for Ag loadings at 0.1 mg/L has to be derived based on this concentration and used for further classification of massive silver and silver powder. With regard to the solubility of the nano forms in Daphnia test medium, the WG noted that the dissolution data from the D/Tp study provided was difficult to interpret due to agglomeration of the nanoparticles. The WG noted that despite	

shortcomings with a similar dissolution test using algal test medium the data can be used for classification. The WG agreed that the properties of nano particles justify classifying them as soluble salts but the rapporteur will explore both the soluble salts and standard metals approach (using ERV and Dissolution data). Industry noted that a potentially helpful additional study on dissolution from silver nano particles is available and they will submit this to ECHA. *Forms of silver* The WG noted that besides nano forms, which are a special case, the assessment of the forms of silver follows the same framework that ECHA/RAC used for lead. RAC to review all data and comment in the ongoing RAC consultation.	
The Eurometaux Regular Stakeholder Observer, the experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers, the EPMF Occasional Stakeholder Observer and the expert accompanying the EPMF Occasional Stakeholder Observer commented on several aspects of the draft opinions.	

5. AOB

No any other business was discussed 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 its report of the 3rd Meeting, requesting the Secretariat to make any necessary editorial changes.

Annex I **Agenda of the of the 3rd 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

14 October 2021
RAC WG/CLH/3/2021

3rd Meeting of the Committee for Risk Assessment Working Group on Harmonised Classification and Labelling (RAC-59 CLHWG)

Monday 25 October July starts at 10:00 -
Thursday 28 October ends at 18:15

Times are Helsinki times
Virtual meeting

Final Agenda

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/CLH/3/2021
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-59

- Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate: hazardous to the aquatic environment
- 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate: skin sensitisation
- 2,2'-ethylenedioxydiethyl dimethacrylate: skin sensitisation
- Hexyl salicylate: skin sensitisation
- 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol: skin sensitisation
- Tetramethylene dimethacrylate: skin sensitisation

5.2 CLH dossiers

4.2.1. Sulfur dioxide (EC: 231-195-2; CAS: 7446-09-5)
4.2.2. Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3)
4.2.3. Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC 275-728-7; CAS 71626-11-4)
4.2.4. Hexyl salicylate (EC 228-408-6; CAS 6259-76-3)
4.2.5. 4-methylimidazole (EC 212-497-3; CAS 822-36-6)
4.2.6. 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (EC 211-477-1; CAS 647-42-7)

4.2.7. 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5)
4.2.8. 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs. ; Reaction mass of N-phenyl,N'-o-tolyl-phenylene diamine, N,N'-diphenyl-p-phenylene diamine and N,N'-di-o-tolyl-phenylene diamine (EC 273-227-8; CAS 68953-84-4)
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	
Barański	Bogusław
Biró	Anna
Bjørge	Christine
de la Flor Tejero	Ignacio
Doak	Malcolm
Docea	Anca Oana
Facchin	Manuel
Hakkert	Betty
Husa	Stine
Karadjova	Irina
Leinonen	Riitta
Lund	Bert-Ove
Martinek	Michal
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Paris	Pietro
Pęczkowska	Beata
Pribu	Mihaela
Printemps	Nathalie
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sogorb	Miguel A.
Sørensen	Peter Hammer
Stahlmann	Ralf
Spetseris	Nikolaos
Tobiassen	Lea Stine
Tsakovska	Ivanka
Tsitsimpikou	Christina
Užomeckas	Žilvinas
Varnai	Veda Marija

RAC members' apologies	
Losert	Annemarie
Neumann	Michael

Members' advisers	
Algharably Engi	(Ralf Stahlmann)
Boel Els	(Wendy Rodriguez)
Granato Giuseppe	(Pietro Paris)
Häschke Denise	(Ralf Stahlmann)
Hauzenberger Ingrid	(Losert Annemarie)
Hoffmann Frauke	(Agnes Schulte)
Panieri Emiliano	(Pietro Paris)
Partosch Falko	(Ralf Stahlmann)
Russo Maria Teresa	(Aquilina Gabriele)
Sachno Dmitrij	(Ralf Stahlmann)
Saksa Jana	(Raili Moldov)
Sebbio Claudia	(Pietro Paris)
Sonnenburg Anna	(Ralf Stahlmann)
Suutari Tiina	(Leinonen Riitta)
van Herwijnen Rene	(Gerlienke Schuur)
Vriend Jelle	(Betty Hakkert)

Dossier submitters	Substance
Aue Annakatrin (DE)	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol and and 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.
Birgander Pernilla (SE)	Silver
Lindeman Birgitte (NO)	4-methylimidazole
Boqvist Pernilla (SE)	Silver
De la Usada Molinero Eduardo (ES)	[BIT] 1,2-benzisothiazol-3(2H)-one
Dominiak Dorota (PL)	Bifenox
Frank Ulrike (SE)	Silver
Gonzalez Marquez Maria Luisa (ES)	[BIT] 1,2-benzisothiazol-3(2H)-one
Hahlbeck Edda (SE)	Silver
Kerkhof Odile (FR)	Hexyl salicylate
Kneuer Carsten (DE)	Sulfur Dioxide
Landvik Tekpli Nina (NO)	4-methylimidazole (EC 212-497-3)
Martin Vallejo Myriam (ES)	[BIT] 1,2-benzisothiazol-3(2H)-one
Myhre Oddvar (NO)	4-methylimidazole
Ruiz Lopez Elena Fuensanta (ES)	[BIT] 1,2-benzisothiazol-3(2H)-one
Van der Hagen Marianne (NO)	4-methylimidazole

Regular stakeholder observers	
Barry Frank	Frank (ETUC)
De Backer	Liisi (Cefic)
Robinson	Jan (A.I.S.E.)
Ruelens	Paul (CropLife Europe)
Van de Broeck	Steven (Cefic)
Verougstraete	Violaine (Eurometaux)
Waeterschoot	Hugo (Eurometaux)

Occasional Industry stakeholder observers	
Alami	Anisa (EPMF) - Silver
Ballach	Jochen (CIRFS) - Sulphur dioxide and Silver
Drohmann	Dieter (ORO) - Sulphur dioxide

Stakeholder experts		Substance
Arjis Katrien	EPMF/Arche Consulting	Silver
Aveyard Lindsay	Eurometaux/ GPC Consulting Ltd	Silver
Battersby Rodger	Eurometaux/ EBRC Consulting	Sulphur dioxide
Holmes Thomas	CropLife Europe/ ADAMA	Bifenox
Kern Petra	A.I.S.E./P&G	[BIT] 1,2-benzisothiazol-3(2H)-one
Mertens Jelle	Cefic/EPMF	Silver
Monsieurs Katrien	Cefic/ Apeiron-Team	1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.; Reaction mass of N-phenyl, N'-o-tolyl-phenylene diamine, N,N'-diphenyl-p-phenylene diamine and N,N'-di-o-tolyl-henylene diamine
Ott Wolfgang	CIRFS/Kelheim Fibres	Sulphur dioxide and Silver
Stollhofer Germaine	Cefic/Thor GmbH	[BIT] 1,2-benzisothiazol-3(2H)-one
Wang Wendy	CropLife Europe/ FMC	Benalaxyl
Weil Torsten	Cefic/ EBRC Consulting	Sulphur dioxide

European Commission		DG
Kilian	Karin	DG ENV
Pinte	Jérémy	DG GROW

EU Agencies Observer		
Crebelli	Riccardo (Sulphur dioxide)	Istituto Superiore di Sanità
Gürtler	Rainer (Sulphur dioxide)	BfR
Istace	Frederique	EFSA
Rincon	Ana	EFSA

ECHA staff	
Bowmer	Tim (Co-chair)
Hellsten	Kati
Jones	Stella
Karjalainen	Ari (Co-chair)
Lapenna	Silvia
Ludboržš	Arnis
Myohanen	Kirsi
Nygren	Jonas
O'Rourke	Regina
Papadaki	Lina
Peltola-Thies	Johanna (Co-chair)
Perazzolo	Chiara
Prevedouros	Konstantinos
Sadam	Diana
Simoes	Ricardo (Co-chair)
Sobanska	Marta
Spjuth	Linda
Uphill	Simon (Co-chair)

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.
Sulphur dioxide **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on these substances - no other mitigation measures applied. No personal involvement.
	Urs SCHLUTER	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		
Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox **PL**	Boguslaw BARANSKI	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.
	Beata PECZKOWSKA	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.
Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate **RO**	Mihaela PRIBU	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.
1) **Tetramethylene dimethacrylate** 2) **7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate** 3) **2,2'-ethylenedioxydiethyl dimethacrylate** **FI**	Tiina SANTONEN	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.
	Riitta LEINONEN	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.
Hexyl salicylate **FR**	Nathalie PRINTEMPS	Working for the CA submitting the dossiers; asked to refrain from

Dossier / DS	RAC Member	Reason for potential CoI / Working for
		voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
4-methylimidazole **NO**	Christine BJÖRGE	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.
	Stine HUSA	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.
1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one **ES**	Ignacio de la FLOR TEJERO	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.
	Miguel SOGORB	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.
1) 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs. ; Reaction mass of N-phenyl,N'-o-tolyl-phenylene diamine, N,N'-diphenyl-p-phenylene	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. Personal involvement.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
diamine and N,N'-di-o-tolyl-phenylene diamine **2) 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol** **3) 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol** **a)** **DE**	Urs SCHLUTER	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.