RAC/M/59/2021

Final

16 December 2021

Minutes of the 59th Meeting

of the Committee for Risk Assessment

(RAC-59)

Monday 22 November, 14.00 to Friday 26 November, 13.00

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair, Tim Bowmer, informed the Committee on the following general topics in his opening address, noting that the Johanna Peltola Thies, Deputy Chair of RAC would chair some agenda items:

The annual interviews with members and regular stakeholders were held from late Summer into the Autumn. Combined with the RAC-58 post-meeting survey, this information helps the better planning and management of the Committee. The Chair thanked all those who took the time to participate, noting that the response rate to the survey was close to 70% of the membership.

RAC is still operating in remote mode. A return to in-person meetings is hoped for in 2022, we are aiming tentatively to hold the CLH working group in April, followed by RAC 61 in June, both in Helsinki and both in-person. However, developments with Covid-19 in many EU/EEA countries may affect this plan.

The Chair noted that this was the first meeting in which all substance-related agenda items (with the exception of Art. 77(3)c) had been discussed in advance by the three working groups, enabling the plenary meeting to be shortened to one week. He thanked the members and especially the Rapporteurs who made this change possible.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/59/2021**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-59 minutes.
4. Appointment of (co-)rapporteurs	
4.1 Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers, restriction dossiers, applications for authorisation and OELs, as listed in the restricted document in the Interact collaboration tool. The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted dossiers for the above-mentioned processes.	-
5. Report from other ECHA bodies and activities	
5.1 RAC work plan for all processes The Chair presented the RAC work plan for the end of 2021 – beginning of 2022.	
5.2 Annual Declaration of Interests exercise – New declaration tool to be presented to the RAC members The Committee took note of the New declaration tool.	
6. Request under Article 77(3)(c)	
6.1 Reference DNEL/PNEC values or dose-response curves considering updated properties of DEHP, BBP, DIBP and DBP	

The Chair welcomed the experts accompanying the CEFIC Regular Stakeholder Observer. He reminded that on 28 July 2021, the European Commission submitted *Request to ECHA's Executive Director to request RAC to deliver, in accordance with Art. 77(3)(c) of REACH, an opinion on reference DNEL/PNEC values or dose-response curves considering updated properties of DEHP, BBP, DIBP and DBP* which resulted in the *Request to the Committee for Risk Assessment to examine the feasibility of finding a threshold in the context of applications for authorisation and review reports in the cases of bis(2-ethylhexyl) phthalate (DEHP) and dibutyl phthalate (DBP).* ECHA has prepared the Background document for the potential identification of thresholds for endocrine disrupting effects in humans (DEHP and DBP) and the environment (DEHP) addressing all the relevant points in the COM request.

The Rapporteur presented the updated Background Document prepared by ECHA, following the discussion in the Committee. RAC agreed that at this point in time, with the information available to the Committee, it is not possible to derive DNELs, PNECs (or Dose-Response curves) for the human health or environmental ED properties of DEHP and DBP (DBP human health only) as requested by the Commission. RAC pointed out that thresholds for such effects may be identified in the future, and that they may be more sensitive than the current RAC DNELs for reproduction. RAC adopted the updated Background Document as its opinion by consensus.	**Rapporteur**, with the support from SECR, to revise the Opinion in accordance with the discussion in RAC. **SECR** to make an editorial check of the opinion document in consultation with the Rapporteur. **SECR** to forward the adopted opinion to COM and publish it on the ECHA website before 31 December 2021.

The expert accompanying the Cefic Regular Stakeholder Observer provided several comments, noting that in their view reproductive toxicity is the most sensitive endpoint.

7. Health based exposure limits at the workplace

No items tabled.

8. Harmonised classification and labelling (CLH)

8.1 Report from the October 2021 RAC CLH WG

The Secretariat presented the Report of the 3rd Meeting of the Committee for Risk Assessment Working Group on CLH held on 25-28 October 2021. The 4th Meeting of the RAC Working Group on CLH will be held on 24-28 January 2022.	

8.2 CLH dossiers

8.2.1 Hazard classes for agreement without plenary debate

1. Sulfur dioxide (EC: 231-195-2; CAS: 7446-09-5): skin sensitisation, carcinogenicity, STOT SE

2. Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3): physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity, carcinogenicity, developmental toxicity, lactation, hazardous to the aquatic environment, hazardous to the ozone layer

3. Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC 275-728-7; CAS 71626-11-4): physical hazards, acute oral toxicity, STOT SE, hazardous to the aquatic environment

4. 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5): acute toxicity via all routes, skin corrosion/irritation, skin sensitisation, hazardous to the aquatic environment

5. 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): skin sensitisation, fertility, lactation

6. Tetramethylene dimethacrylate (EC 218-218-1; CAS 2082-81-7): skin sensitisation

7. 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (EC 276-957-5; CAS 72869-86-4): skin sensitisation

8. 2,2'-ethylenedioxydiethyl dimethacrylate (EC 203-652-6; CAS 109-16-0): skin sensitisation

9. 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol (EC 221-665-5; CAS 3179-89-3): skin sensitisation

10. 4-methylimidazole (EC 212-497-3; CAS 822-36-6): carcinogenicity, reproductive toxicity, germ cell mutagenicity

11. 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (EC 211-477-1; CAS 647-42-7): STOT RE, hazardous to the aquatic environment

8.2.2 Substances with hazard classes for agreement in plenary session

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

8.2.2.2 Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3)

8.2.2.3 Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC 275-728-7; CAS 71626-11-4)

8.2.2.4 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5)

8.2.2.5 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)

8.2.2.6 Silver (EC 231-131-3; CAS 7440-22-4)

8.2.2.1 Sulphur dioxide (EC: 231-195-2; CAS: 7446-09-5)

The Chair welcomed the Dossier Submitter's 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, the Occasional Stakeholder Observer from CONCAWE as well as the representative 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.
Legal deadline for the adoption of an opinion is 10 February 2022.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Press. Gas, Notes U and 5, Acute Tox. 3; H331 (ATE=1000 ppmV (gases), Skin Corr. 1B; H314, STOT SE 1; H370 (respiratory system, inhalation)] RAC agreed on no classification for the other hazard classes considered.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the Eurometaux Regular Stakeholder Observer and the Occasional Stakeholder Observer from CIFRS commented on mutagenicity.

8.2.2.2 Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3)

The Chair welcomed the expert accompanying the CropLife Europe 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.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302 (ATE=1500 mg/kg bw), Aquatic Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=1000)] RAC agreed on no classification for the other hazard classes considered.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

8.2.2.3 Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC 275-728-7; CAS 71626-11-4)

The Deputy Chair welcomed the expert accompanying the CropLife Regular Stakeholder Observer and the representative from EFSA. She informed that **benalaxyl** is an active substance belonging to the phenylamide group name and acylalanine chemical group of systemic fungicides with apoplastic translocation which inhibits mycelial growth of fungi and germination of zoospores (fungistatic action). The substance has a 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.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302 (ATE=1000 mg/kg bw), Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=1)] RAC agreed on no classification for the other hazard classes considered.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

8.2.2.4 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5)

The 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.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302 (ATE = 450 mg/kg), Acute Tox. 2; H330 (ATE = 0.21 mg/L, dust or mist), Skin Sens. 1A; H317 (C ≥ 0.036 %), Eye Dam. 1; H318, Skin Irrit. 2; H315, Aquatic Acute 1; H400 (M = 1), Aquatic Chronic 1; H410 (M = 1)] RAC noted that the recommended SCL [360 ppm] should be reviewed at an appropriate time in the light of new data. RAC agreed on no classification for the other hazard classes considered.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the Cefic regular stakeholder observer representative and the expert accompanying the AISE Regular Stakeholder Observer commented on SCL setting for the skin sensitization hazard class.

8.2.2.5 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 Chair welcomed the Dossier Submitter representative and the expert accompanying the Cefic regular stakeholder observer 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.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1; H317, Repr. 1B; H360FD] RAC agreed on no classification for the other hazard classes considered.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the Cefic regular stakeholder observer representative commented on developmental toxicity.	
8.2.2.6 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 European Precious Metals Fed. (EPMF) 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. <u>At RAC-58</u>, the Committee held a key issues discussion on this dossier. Legal deadline for the adoption of an opinion is 16 March 2022.	
<u>Physical hazards</u> RAC agreed on no classification for physical hazards (for silver, micro- and nano-forms). <u>Human Health</u> Acute Toxicity *Oral* RAC agreed on no classification for acute oral toxicity. *Dermal*	**Rapporteurs** to prepare the revised draft opinion in accordance with the discussion in RAC-59 and to provide it to SECR. **SECR** to launch a RAC written consultation on the revised draft opinion and to table it for discussion at the January CLH working group. **Hazard classes for discussion in January WG/RAC-60: Mutagenicity,**

RAC agreed on no classification for acute dermal toxicity based on the available data. *Inhalation* RAC agreed on no classification for acute inhalation toxicity. STOT SE RAC agreed on no classification for STOT SE. Skin corrosion/irritation RAC agreed on no classification. Serious eye damage/eye irritation RAC agreed on no classification. Respiratory sensitisation RAC agreed on no classification due to inconclusive data. Skin sensitisation RAC did not support the DS proposal to classify as Skin Sens. 1; H317, but agreed on no classification. Mutagenicity RAC discussed the database on germ cell mutagenicity for silver and the possibility of having a single entry or a split entry for the Ag NP and Ag bulk forms depending on e.g. whether the data on Ag NPs is considered relevant for bulk Ag. The discussion will continue in the RAC-60 WG and be concluded at RAC-60. <u>Environment</u> *Rapid Transformation* RAC took note of the new data submitted by Industry. RAC found no evidence to indicate silver is rapidly transformed to non-bioavailable forms. *Bioaccumulation* RAC concluded that although data for invertebrates indicates some bioaccumulation potential at this trophic level, BCF data for fish indicates the CLP criteria are not met. This is supported by information on removal silver mechanisms in fish. On the basis, RAC concludes that silver has a low potential for	**carcinogenicity, reproductive toxicity, STOT RE, forms of silver.**

bioaccumulation for the purpose of classification. *Aquatic toxicity* RAC concluded that that no normalisation for water chemistry parameters is needed and that the BLM model will not be considered. RAC concluded that the following ERV values are reliable and can be considered for classification of silver: • Acute aquatic toxicity: 0.22 µg/L *Daphnia magna* • Chronic aquatic toxicity: deterministic 0.10 µg/L *Pseudokirchneriella subcapitata* probabilistic 0.08-0.09 µg/L, used as supportive information. *Solubility of Ag* RAC agreed with the analysis of the Rapporteur and the T/Dp values for massive, powder, and nano silver at 1 and 0.1 mg/L loadings over 7 and 28 days, respectively. *Forms of silver* RAC agreed to use the soluble salt approach for nano silver and classify as Aquatic Acute 1, M = 1000 and Aquatic Chronic 1, M = 1000. RAC provisionally concluded that pure massive silver (≥ 1 mm) does not produce particles < 1 mm through reasonable handling and use. The complete classification, provisionally agreed by RAC, for silver would then be: *Silver ≥ 1 mm:* No classification *Silver > 100 nm < 1 mm* Aquatic Acute 1, M = 10 Aquatic Chronic 1, M = 10 *Silver 1-100 nm* Aquatic Acute 1, M = 1000 Aquatic Chronic 1, M = 1000 Rapporteur to represent whether reasonable use of the massive can generate particle < 1	

mm of pure silver and clarify definition of generated particles < 1 mm.	
The industry experts accompanying the regular Eurometaux and Cefic stakeholder observers, and the occasional EPMF stakeholder observer commented on the toxicokinetics/bioavailability, skin sensitisation, mutagenicity, bioaccumulation, ecotoxicity.	
9. Restrictions	
9.1 General Restriction issues	
9.1 Report from the November 2021 RAC REST WG	
RAC took note of the Report of the 3rd meeting of the Committee for Risk Assessment working group on restrictions held on 3-4 November 2021. Furthermore, RAC discussed the working group ways of working, including different opinion cycles. The 4th meeting of the RAC working group on restrictions will be held on 9-10 February 2022.	
9.2 Restriction Annex XV dossiers	
9.2.1 Conformity check	
9.2.1.1 Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting	
The Chair, welcomed the Dossier Submitter's representatives from ECHA, the expert (Coal Chemicals Europe sector group), accompanying the regular CEFIC stakeholder observer, as well as the occasional stakeholder observer from CONCAWE. He informed the participants that the dossier has been submitted by ECHA in October 2021 and concerns on the placing on the market and use of substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting.	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
The expert (Coal Chemicals Europe sector group), accompanying the regular CEFIC stakeholder observer commented on the concentration limit in the PAH in rubber granules restriction and about the composition of substances stating that most of the composition (of CTPHT for instance) cannot be analytically identified.	
9.2.2 Opinion development	
9.2.2.1 Lead and its compounds in outdoor shooting and fishing – third draft opinion	

The Chair, welcomed the Dossier Submitter's representatives from ECHA, invited experts from UNEP/AEWA, the regular stakeholder observers, and their accompanying experts (from Arche Consulting, International Lead Association (ILA), Cambridge University and University of Guelph) as well as the occasional stakeholder observers from CONCAWE, European Anglers Alliance (EAA), European Plastics Converters (EuPC), European Federation for Hunting and Conservation (FACE) and FITASC/ISSF. He informed the participants that the restriction dossier had been submitted in January 2021 and concerns lead in outdoor shooting and fishing.

The rapporteurs presented the recommendations and conclusions from RAC-59 Restriction working group. Based on the recommendations of the Restriction working group which met on 03-04/11/2021, RAC-59 provisionally agreed on: – Qualitative Risk Assessment (QRA); – Alternatives; and – Risk management options for hunting, sports shooting and fishing The rapporteurs will continue their work on the QRA, RMMs at shooting ranges (based on a new proposal from the DS), potential derogations and practicality and enforceability, and will present the next version of the opinion at the February Restriction working group and RAC-60. The detailed follow-up tasks recommended by the Restriction working group were noted. Final discussion is expected at RAC-60, including the assessment of comments from the third-party consultation.	**Rapporteurs** to prepare the fourth draft opinion, taking into account RAC-59 working group on restrictions discussions and the outcome of the third-party consultation, by mid-January 2022. **Secretariat** to table the fourth draft opinion for discussion at the RAC-60 working group on restrictions in February 2022.

The expert accompanying the regular stakeholder observer from EUROMETAUX commented on the assessment of the risks from jacketed bullets. The expert accompanying the regular stakeholder observer from EEB commented on the need for derogations and on alternatives. The regular stakeholder observer from EUROMETAUX commented on risks of alternatives. The occasional stakeholder observer from FITASC/ISSF commented on risks during sports shooting, on alternatives (related to ballistic topic) and on risk management measures at shooting ranges. The occasional stakeholder observer from FACE commented on the list of specific species of birds at risk, alternatives and risk management measures at shooting ranges for bullets. The invited experts from UNEP/AEWA supported the qualitative risk assessment and questioned the RMMs for shooting ranges and whether derogations are needed for encapsulated lures (plugs) and for jacketed bullets. Furthermore, the Dossier Submitter representatives provided clarifications to some comments raised.

9.2.2.2 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo-[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™)– second draft opinion

The Deputy Chair welcomed the Dossier Submitter's representatives from Norway. She also welcomed the regular stakeholders as well as the occasional stakeholder observers from CONCAWE. She informed the participants that the restriction dossier had been submitted in April 2021 and concerns risks for human health and the environment from emissions of Dechlorane Plus.	
Based on the recommendations of the Restriction Working group which met on 03-04/11/2021, RAC-59 agreed on: – Identity and scope of the restriction – Hazard assessment – Emissions and exposure assessment – Monitoring data – Risk characterization – Alternatives – Operational conditions – Insufficiency of existing RRM instruments – Justification that the proposed restriction is the most appropriate EU wide measure The detailed follow up tasks recommended by the RESTR WG were noted. In addition, RAC asked the rapporteurs to add a specific reference to Annex I section 6.5 of REACH to the risk characterisation conclusions in the opinion. RAC further took note of the scope of REACH restrictions in general vis-a-vis the waste lifecycle stage.	**Rapporteurs** to prepare the third draft opinion, taking into account the working group recommendations, the RAC-59 plenary outcome and that of the third-party consultation (the latter to the extent possible), by end of January 2022. **Secretariat** to table the third draft opinion for discussion at the RAC-60 working group on restrictions in February 2022 and for adoption at RAC-60 plenary in March 2022.
The Dossier Submitter commented on the difference between R01 and R02.	
9.2.2.3 2,4-dinitrotoluene – first draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA. He informed the participants that the restriction dossier had been submitted in July 2021 and concerns the placing on the market or use of 2,4 dinitrotoluene in articles for supply to the general public or to professional workers in concentrations greater than 0.1 % weight by weight. In accordance with Article 69(2) of REACH, ECHA considers that there are uses of the substance which may lead to a non-adequately controlled risk from 2,4-DNT presence in articles. The Chair noted that the Art. 69(2) restriction proposal for a substance already on Annex XIV an for which no applications had been received needed to be dealt with quickly and efficiently, reflecting its technical nature to prevent imports.	
Based on the recommendations of the Restriction working group which met on 03-04/11/2021, RAC-59 agreed on: - Scope and conditions - Hazards and risk evaluation	**RAC members** to provide the remaining written comments on the 1st draft opinion via the ongoing SCIRCABC Newsgroup by 10 December 2021.

- Exposure assessment 'seat-belt pre-tensioner', plastic, civilian shooting/hunting	**Rapporteur** to take the discussions (as well as written comments and the outcome of third party consultation) into account for the next version of the opinion. **Secretariat** to table the item for RAC REST WG agenda (4-5 May 2022) and for the RAC-61 agenda for discussion and adoption.
There were no Stakeholder interventions	
10. Authorisation	
10.1 General authorisation issues	
10.1.1. Update on incoming/future applications	
The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2022 and timelines. RAC took note of the information.	
10.1.2. Revision of A-listing criteria	
The ECHA Secretariat presented the revised A-listing criteria. RAC agreed the revised A-listing criteria.	**SECR** to publish the A-listing criteria on the ECHA website.
10.1.3. Report from the October AFA Working Group and the Capacity Building Seminar on Assessment of human biomonitoring data	
The Secretariat presented the Report of the 9th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group and the Capacity Building Seminar on assessment of biomonitoring data. RAC took note of the Report.	
10.2 Authorisation applications	
10.2.1. Discussion on key issues	
10.2.1.1 3 applications for authorisation (chromium trioxide, MOCA) and 2 review reports (TCE) from August 2021 submission window	
RAC discussed the key issues in 5 AfAs / 6 uses. Presentation was made available on the S-CIRCABC and on the Interact Portal. The case of 246_MOCA_Courbis/Courbis Synthèse should be reviewed keeping in mind previous authorisations.	

10.3 Agreement on draft opinions

10.3.1. Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate

10.3.1.1 231_CT_Kesseboehmer (1 use)
10.3.1.2 232_DtC_Monroe (1 use)
10.3.1.3 233_CT_Betz-Chrom (1 use)
10.3.1.4 234_CT_KWalter (use 1 only)
10.3.1.5 235_CA_Neoperl (1 use) -

The Deputy Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 9th meeting the RAC AFA WG the five draft opinions have been proposed for agreement via the A-listing procedure. ECHA Secretariat presented the summary of the draft opinions.

RAC agreed by consensus the five draft opinions on the following Application cases.

10.3.1.1 231_CT_Kesseboehmer (1 use) **Use1:** *Use of chromium trioxide for decorative/functional application in the furniture, sanitary and automotive sector.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented and on associated trends in exposure during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. RAC agreed: 1. additional conditions for the authorisation The applicant shall investigate the feasibility to use RPE for workers during the manual tasks at plating line for research and development. The applicant shall continue to investigate the feasibility to use liquid CrO_3 solution instead of solid CrO_3.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

2. monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programme for Cr(VI): Occupational inhalation exposure The applicant shall implement their monitoring programmes for Cr(VI) exposure, which shall : (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(IV) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. 2. The information gathered via the measurements referred to in paragraphs 1 and related contextual information shall be used by the applicants to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the	

combined exposure for the different groups of workers. 3. The applicants shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraphs 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available by the applicants, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report The applicant should continue to conduct annual biomonitoring programme for the workers potential exposed to Cr(VI). The biomonitoring should be based on validated methodologies and protocols for Cr(VI) exposure and in case of urinary sampling include pre- and post-shift sampling. The measurements referred to in section 8.1 paragraph 1, section 9.1 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report.	
10.3.1.2 232_DtC_Monroe (1 use) **Use1:** *Use of dichromium tris(chromate) in a post-treatment step of the auto-deposition coating process of shock absorbers for automotive vehicles.* RAC concluded that the operational conditions and risk management measures described in the application are **not** appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure and releases during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. The exposure of workers and the general population to the substance is estimated to be as described in section 2 of the justification to this opinion. The risk for workers and the general population from exposure to the substance is estimated to be as described in section 3 of the justification to this opinion. The use applied for may result in up to 0.01 kg Cr(VI) per year releases of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation The applicant shall, within 6 months after the granting of an authorisation, use the information gathered via the measurements and related contextual information referred to in Section 8.1 to review the RMMs and OCs in place. In line with the hierarchy of control principles, the applicant shall introduce engineering controls such as local exhaust ventilation and wet scrubbers to reduce workplace exposure and emissions to the environment to as low a level as technically and practically feasible. 2. monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure	

monitoring programmes for Cr(VI), which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal sampling for workers (for WCSs 3 - 8) and static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant´s site. 2. The applicant shall conduct the first monitoring campaign within 3 months after the granting of an authorisation.	

3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with section 7.1, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report The applicant should continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). The biomonitoring should be based on validated methodologies and protocols for Cr(VI) exposure and in case of urinary sampling include pre and post-shift sampling. The results of the measurements referred to in sections 7, 8, and section 9, as well as the outcome and conclusions of the review and any actions taken in accordance with sections 7 and 8, should be documented and included in any subsequent review report.	
10.3.1.3 233_CT_Betz-Chrom (1 use) **Use1:** *Chromium trioxide-based functional chrome plating of components with diverse geometries and dimensions, requiring specialized equipment and process knowledge, for applications in demanding industry sectors such as mechanical engineering, metalworking and processing, aerospace, automotive, and medical technology.* RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

operational conditions and risk management measures implemented and on trends in exposure and releases during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. RAC agreed: 1. additional conditions for the authorisation The applicant shall continue the efforts to minimize the workers' exposure to Cr(VI) by implementing state of the art RMMs as result of research projects (such as LEGOLAS). The applicant shall investigate the feasibility, and implement the findings, with regard to respiratory protective equipment (RPE) selection for the tasks with potential exposure to Cr(VI) (e.g. "plating (manual)", "sampling" (manual), "weekly maintenance by surface treatment staff", "maintenance & cleaning involving maintenance staff"), considering the comfort of the workers during the use. 2. monitoring arrangements for the authorisation 1. The applicant shall continue to implement the following programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes, which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal sampling for the workers involved in plating, sampling, concentration adjustment and maintenance activities (WCSs 2, 3, 4, 5 and 6) and static inhalation exposure sampling;	

(iv) be representative of: a. the full range of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. 3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome	

and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report The applicant should continue to conduct the annual biomonitoring programme for the workers potentially exposed to Cr(VI). The biomonitoring should be based on validated methodologies and protocols for Cr(VI) exposure, and in case of urinary sampling include pre and post-shift sampling The results of the measurements referred to in sections 8 paragraph 1, and 9 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, should be documented and included in any subsequent review report.	
10.3.1.4 234_CT_Kwalter (use 1 only, see further below for use 2) **Use1:** *Formulation of chromium trioxide-based electrolyte for electroplating process.* RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC agreed: 1. additional conditions for the authorisation The applicant shall • ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks and workers will be trained to do this test adequately, • investigate the feasibility to enclose the area around the filling point of the mixing tank with solid CrO_3 as maximum possible with a guaranteed effectiveness of the LEV system. 2. monitoring arrangements for the authorisation 1 The applicant shall • ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks and workers will be trained to do this test adequately, • investigate the feasibility to enclose the area around the filling point of the mixing tank with solid CrO_3 as maximum possible with a guaranteed effectiveness of the LEV system. 3. recommendations for the review report The results of the feasibility study as mentioned in section 7 and the results of the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, should be documented and included in any subsequent authorisation review report. In addition, any subsequent authorisation review report should contain clear information that supports the air and wastewater abatement efficiencies.	
10.3.1.5 235_CA_Neoperl (1 use) **Use1:** *The use of chromic acid in the functional electroplating of brass-made sanitary articles with the specific purpose of obtaining a final*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

Cr(0) coating that provides a surface with high durability and chemical resistance. RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented and on trends in exposure and releases during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. RAC agreed: 1. additional conditions for the authorisation For rare maintenance tasks performed under WCS9, the applicant shall investigate the feasibility to implement additional measures to reduce further the exposure of workers, taking into account the hierarchy of control principles, such as improved cleaning practices to minimise the exposure to Cr(VI) (e.g., reduce it to Cr(III)) before workers are allowed to enter the bath to remove the sludge and remaining liquid. 2. monitoring arrangements for the authorisation 1. The applicants shall implement the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure: the applicant shall implement a monitoring programmes for Cr(VI) exposure, which shall: (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in	

exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of: a.the range of tasks undertaken where exposure to Cr(IV) is possible; b. the OCs and RMMs typical for each of these tasks; c.the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue their quarterly monitoring programme for Cr(VI) emission of wastewater; (ii) the applicant shall conduct air emission measurements at least annually at emission point or more frequently in the periods following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraphs 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.	

3. The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraphs 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report The applicant should continue to conduct the annual biomonitoring programme for the workers potentially exposed to Cr(VI). The biomonitoring should be based on validated methodologies and protocols for Cr(VI) exposure and in case of urinary sampling include at least pre and post-shift sampling. The information gathered via the measurements referred to in section 8.1 paragraph 1 and 9.1 paragraph 1, as well as the outcome and conclusions of the review and any action taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report.	
10.3.2. Draft opinions for agreement with plenary debate	
10.3.2.1 234_CT_Kwalter (use 2 only) - Deputy Chair	
Use2: *Chromium trioxide-based functional chrome plating of cylinders used in the rotogravure printing and embossing industry.* RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion including a minimum list of OCs and RMMs with regard to mist suppressants. **SECR** to send the draft opinion to the applicant for commenting.

operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure during the review period. This information should also be included in a possible review report.
The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.

RAC agreed:

1. additional conditions for the authorisation

   All the downstream users of chromium trioxide covered by this Use shall comply with the minimum RMMs and OCs listed in Section 1.3.

   In addition, the applicant shall:

   - Prepare and provide their downstream users with the OCs and RMMs provided in the CSR by additional means, e.g., detailed guidance for the downstream users on the OCs and RMMs,
   - promote the use of a new connection system ("Quick Connect"-system) that includes a new removal head connected to a pump via a hose and containers that featured an integrated and fixed immersion tube, measures that prevent contact to CrO_3 and unintentional dripping when changing the containers,
   - promote the use of a valve and pump system for sampling once this product is being developed,

2. monitoring arrangements for the authorisation

   1. The downstream users shall implement at all their sites the following monitoring programmes:

      (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall:

      (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure;

(ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and/or static inhalation exposure sampling; (iv) be representative of: a. the range of all tasks undertaken where exposure to Cr(IV) is possible; b. the operational conditions and risk management measures typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed and their frequency during measurements; (b) Environmental releases: (i) the downstream users shall conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process; (i) the monitoring programmes for air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's downstream users' sites. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the downstream users to confirm the effectiveness of the operational conditions and risk management measures in place at their sites and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the downstream users shall also review and, if needed, update their assessment of the combined	

exposure for the different groups of workers. 3. The downstream users shall ensure that the application of RMMs is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the downstream users, upon request, to the competent national authority of the Member State where the downstream user is located. 3. recommendations for the review report In relation to the concerns about the inherent uncertainties of the applied survey the applicant should perform a new survey among their downstream users two years before the end of the review period, a survey that should be designed in such a way that a maximum and representative response is obtained. The results of the new survey and the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, should be documented and included in any subsequent authorisation review report. The draft opinion has been agreed by RAC by consensus.	
10.4 Adoption of final opinions	
10.4.1 221_CT_SD_USSK (1 use) – Deputy Chair	
Use1: *Use of Chromium Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).* RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in	**Rapporteurs** together with **SECR** to do the final editing of the final opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.

limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The exposure to workers was estimated to be at maximum: - inhalation (µg Cr(VI)/m^3): 0.244 (highest exposure estimate) - dermal (µg Cr(VI)/kg bw/d): 25.3 (highest exposure estimates) For reference, as of January 2020, the binding occupational exposure limit (BOEL) for inhalation for Cr(VI) is 10 µg Cr(VI)/m^3 (transitional value until 17 January 2025, after which 5 µg Cr(VI)/m^3 applies). The exposure to the general population was estimated to be: - inhalation, local (µg Cr(VI)/m^3): 0.011 - oral: local (µg Cr(VI)/kg bw/d): 0.148 The excess lifetime cancer risk for workers (40 years of exposure) - directly exposed is estimated to be at maximum: o inhalation: 8.8×10^{-4} o RCR dermal (reproductive toxicity): 0.59 - indirectly exposed is estimated to be at maximum: o inhalation: 4.40×10^{-5} o oral: 2.96×10^{-5}. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation a) The applicant shall continue and implement at least annual occupational/workers' exposure monitoring programmes for Cr(VI). Those programmes shall be based on relevant standard methodologies or protocols, comprise static and/or personal inhalation exposure sampling and be representative of:	

i. the range of tasks undertaken where exposure to Cr(VI) is possible, including tasks involving maintenance workers; ii. the OCs and RMMs typical for each of these tasks; iii. the number of workers potentially exposed. b) The applicant shall continue and implement monitoring of Cr(VI) emissions to wastewater and air from local exhaust ventilation at least annually. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicant's site. c) The information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicant to review and confirm the effectiveness of proposed RMM and OCs and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. d) The applicant shall ensure that the application of RMMs at his site is in accordance with the hierarchy of control principles, and refine the worker and HvE assessments if necessary. e) The information from the measurements referred to in points (a) and (b), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report The information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report.	

The final opinion has been adopted by RAC by consensus.	
12. Minutes of RAC-59	
12.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-59	
RAC adopted the final minutes by consensus at the plenary meeting.	**SECR** to upload the table with Summary Record of the Proceedings and Conclusions and Action points from RAC-58 to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-59

1. Tetramethylene dimethacrylate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	tetramethylene dimethacrylate	218-218-1	2082-81-7	Skin Sens. 1B	H317	GHS07 Wng	H317			
RAC opinion	TBD	tetramethylene dimethacrylate	218-218-1	2082-81-7	Skin Sens. 1B	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	tetramethylene dimethacrylate	218-218-1	2082-81-7	Skin Sens. 1B	H317	GHS07 Wng	H317			

2. 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	276-957-5	72869-86-4	Skin Sens. 1B	H317	GHS07 Wng	H317			
RAC opinion	TBD	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	276-957-5	72869-86-4	Skin Sens. 1B	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	276-957-5	72869-86-4	Skin Sens. 1B	H317	GHS07 Wng	H317			

3. 2,2'-ethylenedioxydiethyl dimethacrylate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2,2'-ethylenedioxydiethyl dimethacrylate	203-652-6	109-16-0	Skin Sens. 1B	H317	GHS07 Wng	H317			
RAC opinion	TBD	2,2'-ethylenedioxydiethyl dimethacrylate	203-652-6	109-16-0	Skin Sens. 1B	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	2,2'-ethylenedioxydiethyl dimethacrylate	203-652-6	109-16-0	Skin Sens. 1B	H317	GHS07 Wng	H317			

4. 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol	221-665-5	3179-89-3	Skin Sens. 1	H317	GHS07 Wng	H317			
RAC opinion	TBD	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol	221-665-5	3179-89-3	Skin Sens. 1	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol	221-665-5	3179-89-3	Skin Sens. 1	H317	GHS07 Wng	H317			

5. 4-methylimidazole

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	4-methylimidazole	212-497-3	822-36-6	Carc. 1B Repr. 1B	H350 H360Fd	GHS08 Dgr	H350 H360Fd			
RAC opinion	TBD	4-methylimidazole	212-497-3	822-36-6	Carc. 1B Repr. 1B	H350 H360Fd	GHS08 Dgr	H350 H360Fd			
Resulting Annex VI entry if agreed by COM	TBD	4-methylimidazole	212-497-3	822-36-6	Carc. 1B Repr. 1B	H350 H360Fd	GHS08 Dgr	H350 H360Fd			

6. 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal[#]	TBD	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol	211-477-1	647-42-7	STOT RE 2 Aquatic Chronic 2	H373 (skeletal system) H411	GHS08 GHS09 Wng	H373 (skeletal system) H411			
RAC opinion	TBD	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol	211-477-1	647-42-7	STOT RE 2 Aquatic Chronic 1	H373 (teeth, bones) H410	GHS08 GHS09 Wng	H373 (teeth, bones) H410		M = 1	
Resulting Annex VI entry if agreed by COM	TBD	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol	211-477-1	647-42-7	STOT RE 2 Aquatic Chronic 1	H373 (teeth, bones) H410	GHS08 GHS09 Wng	H373 (teeth, bones) H410		M = 1	

7. sulfur dioxide

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	016-011-00-9	sulfur dioxide	231-195-2	7446-09-5	Press. Gas Acute Tox. 3* Skin Corr. 1B	H331 H314	GHS04 GHS06 GHS05 Dgr	H331 H314			U, 5
Dossier submitters proposal	016-011-00-9	sulfur dioxide	231-195-2	7446-09-5	**Retain** Press. Gas Skin. Corr. 1B **Add** Muta. 2 STOT SE 3 Skin Sens. 1 **Modify** Acute Tox. 3	**Retain** H331 H314 **Add** H341 H335 H317	**Retain** GHS04 GHS06 GHS05 Dgr **Add** GHS08	**Retain** H331 H314 **Add** H341 H335 H317		**Add** inhalation: ATE = 1041 ppmV (gases)	**Retain** U, 5
RAC opinion	016-011-00-9	sulfur dioxide	231-195-2	7446-09-5	**Retain** Press. Gas Skin. Corr. 1B **Add** STOT SE 1 **Modify** Acute Tox. 3	**Retain** H331 H314 **Add** H370 (respiratory system, inhalation)	**Retain** GHS04 GHS06 GHS05 Dgr **Add** GHS08	**Retain** H331 H314 **Add** H370 (respiratory system, inhalation)		**Add** inhalation: ATE = 1000 ppmV (gases)	**Retain** U, 5
Resulting Annex VI entry if agreed by COM	016-011-00-9	sulfur dioxide	231-195-2	7446-09-5	Press. Gas Acute Tox. 3 STOT SE 1 Skin. Corr. 1B	H331 H370 (respiratory system, inhalation) H314	GHS04 GHS06 GHS08 GHS05 Dgr	H331 H370 (respiratory system, inhalation) H314		inhalation: ATE = 1000 ppmV (gases)	U, 5

8. bifenox (ISO); methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	bifenox (ISO); methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate	255-894-7	42576-02-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1000 M = 1000	
RAC opinion	TBD	bifenox (ISO); methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate	255-894-7	42576-02-3	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		oral: ATE = 1500 mg/kg bw M = 1000 M = 1000	
Resulting Annex VI entry if agreed by COM	TBD	bifenox (ISO); methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate	255-894-7	42576-02-3	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		oral: ATE = 1500 mg/kg bw M = 1000 M = 1000	

9. Benalaxyl (ISO); methyl *N*-(2,6-dimethylphenyl)-*N*-(phenylacetyl)-*DL*-alaninate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	616-104-00-X	benalaxyl (ISO); **methyl *N*-(2,6-dimethylphenyl)-*N*-(phenylacetyl)-*DL*-alaninate**	275-728-7	71626-11-4	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	616-104-00-X	benalaxyl (ISO); methyl *N*-(2,6-dimethylphenyl)-*N*-(phenylacetyl)-*DL*-alaninate	275-728-7	71626-11-4	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Carc. 2 Acute Tox. 4 STOT SE 2	**Retain** H400 H410 **Add** H351 H302 H371 (nervous system)	**Retain** GHS09 Wng **Add** GHS08 GHS07	**Retain** H410 **Add** H351 H302 H371 (nervous system)		**Add** oral: ATE = 2000 mg/kg bw M = 1 M = 1	
RAC opinion	616-104-00-X	benalaxyl (ISO); methyl *N*-(2,6-dimethylphenyl)-*N*-(phenylacetyl)-*DL*-alaninate	275-728-7	71626-11-4	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Acute Tox. 4	**Retain** H400 H410 **Add** H302	**Retain** GHS09 Wng **Add** GHS07	**Retain** H410 **Add** H302		**Add** oral: ATE = 1000 mg/kg bw M = 1 M = 1	
Resulting Annex VI entry if agreed by COM	616-104-00-X	benalaxyl (ISO); methyl *N*-(2,6-dimethylphenyl)-*N*-(phenylacetyl)-*DL*-alaninate	275-728-7	71626-11-4	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		oral: ATE = 1000 mg/kg bw M = 1 M = 1	

10. 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-088-00-6	1,2-benzisothiazolin-3-one (BIT)	220-120-9	2634-33-5	Acute Tox. 4* Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1	H302 H315 H318 H317 H400	GHS07 GHS05 GHS09 Dgr	H302 H315 H318 H317 H400		Skin Sens. 1; H317: C ≥ 0.05 %	
Dossier submitters proposal	613-088-00-6	1,2-benzisothiazol-3(2*H*)-one; 1,2-benzisothiazolin-3-one	220-120-9	2634-33-5	**Retain** Eye Dam. 1 Aquatic Acute 1 **Add** Acute Tox. 2 Aquatic Chronic 1 **Modify** Acute Tox. 4 Skin Sens. 1B **Remove** Skin Irrit. 2	**Retain** H302 H318 H400 **Add** H330 H410 **Modify** H317 **Remove** H315	**Retain** GHS05 GHS09 Dgr **Add** GHS06 **Remove** GHS07	**Retain** H302 H318 **Add** H330 **Modify** H317 H410 **Remove** H315		**Add** oral: ATE = 454 mg/kg bw inhalation: ATE = 0.25 mg/L (dusts or mists) M = 1 M = 1 **Modify** Skin Sens. 1B; H317: C ≥ 0.05 %	
RAC opinion	613-088-00-6	1,2-benzisothiazol-3(2*H*)-one; 1,2-benzisothiazolin-3-one	220-120-9	2634-33-5	**Retain** Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1 **Add** Acute Tox. 2 Aquatic Chronic 1 **Modify** Acute Tox. 4 Skin Sens. 1A	**Retain** H302 H315 H318 H400 **Add** H330 H410 **Modify** H317	**Retain** GHS05 GHS09 Dgr **Add** GHS06 **Remove** GHS07	**Retain** H302 H318 H315 **Add** H330 **Modify** H317 H410		**Add** oral: ATE = 450 mg/kg bw inhalation: ATE = 0.21 mg/L (dusts or mists) M = 1 M = 1 **Modify** Skin Sens. 1A; H317: C ≥ 0.036 %	
Resulting Annex VI entry if agreed by COM	613-088-00-6	1,2-benzisothiazol-3(2*H*)-one; 1,2-benzisothiazolin-3-one	220-120-9	2634-33-5	Acute Tox. 2 Acute Tox. 4 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H330 H302 H315 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H330 H302 H315 H318 H317 H410		oral: ATE = 450 mg/kg bw inhalation: ATE = 0.21 mg/L (dusts or mists) Skin Sens. 1A; H317: C ≥ 0.036 % M = 1 M = 1	

11. 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

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	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	273-227-8	68953-84-4	Repr. 1B Skin Sens. 1	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			
RAC opinion	TBD	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	273-227-8	68953-84-4	Repr. 1B Skin Sens. 1	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			
Resulting Annex VI entry if agreed by COM	TBD	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	273-227-8	68953-84-4	Repr. 1B Skin Sens. 1	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			

Part III. List of Attendees of the RAC-59 meeting

RAC members	
Aquilina	Gabriele
Barański	Bogusław
Biró	Anna
Bjørge	Christine
Brovkina	Julija
Chiurtu	Elena (co-opted member)
de la Flor	Ignacio
Deviller	Geneviève (co-opted member)
Doak	Malcolm
Docea	Anca
Facchin	Manuel
Ginnity	Bridget (co-opted member)
Hakkert	Betty
Husa	Stine
Kadikis	Normunds
Karadjova	Irina
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Martinek	Michal
Mendas	Gordana
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Neumann	Michael
Paris	Pietro
Pęczkowska	Beata
Printemps	Nathalie
Rodriguez	Wendy
Santonen	Tiina
Schlueter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sogorb	Miguel
Sørensen	Peter Hammer
Spetseris	Nikolaos
Stahlmann	Ralf
Tobiassen	Lea Stine
Tsakovska	Ivanka
Tsitsimpikou	Christina
Uzomeckas	Žilvinas
van der Haar	Rudolf (co-opted member)
Varnai	Veda
Viegas	Susana
Xanthos	Theodore

Apologies members	
Geoffroy	Laure
Hartwig	Andrea (co-opted member)
Pribu	Mihaela
Menard Srpčič	Anja

Members' advisers		
Algharably	Engi	(Stahlmann Ralf)
Bil	Wieneke	(Hakkert Betty)_Article 77(3)c Lead
Hoffmann	Frauke	(Schulte Agnes)
Häschke	Denise	(Stahlmann Ralf)
Marinkovic	Marino	(Schuur Gerlienke)_ Article 77(3)c Lead
Munch	Pernille Steenkæ	(Lea Stine Tobiassen)
Partosch	Falko	(Stahlmann Ralf)
Russo	Maria Teresa	(Aquilina Gabriele)
Sachno	Dmitrij	(Stahlmann Ralf)
Seba	Julie	(Rodriguez Wendy)
Sonnenburg	Anna	(Stahlmann Ralf)_Bifenox
Stalter	Daniel	(Schulte Agnes)
Suutari	Tiina	(Leinonen Riitta)
van Herwijnen	Rene	(Schuur Gerlienke)_CLH: Silver
Vriend	Jelle	(Hakkert Betty)_ CLH: 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.; Reaction mass of N-phenyl,N'-o-tolyl-phenylene

SEAC Rapporteurs		
Thiele	Karen	Restrictions: Lead in outdoor shooting and fishing
Urban	Klaus	Restrictions: Lead in outdoor shooting and fishing

Invited experts		**Substance**
Cromie	Ruth (AEWA Technical Committee)	Restrictions: Lead in outdoor shooting and fishing
Dereliev	Sergey (UNEP/AEWA)	Restrictions: Lead in outdoor shooting and fishing

Dossier submitters		**Substance**
Aue	Annakatrin (DE)	CLH: 1,4-Benzenediamine, N,N'-mixed Ph and tolyl derivs.
Birgander	Pernilla (SE)	CLH - Silver
Boqvist	Pernilla (SE)	CLH - Silver
Correll Myhre	Ingunn (NO)	Dechlorane Plus
de la Usada Molinero	Eduardo (ES)	CLH: 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one [BIT]
Fotland	Tor Øystein	Dechlorane Plus
Hahlbeck	Edda (SE)	CLH: silver
Kneuer	Carsten (DE)	CLH: Sulphur dioxide (SO2)
Kopangen	Marit (NO)	Dechlorane plus
Persson Dahlberg	Marie Johanne (NO)	Dechlorane plus

Regular stakeholder observers

Cassart	Michel (PlasticsEurope)
Duguy	Hélène (ClientEarth)
Ramon Serrano	Blanca (Cefic – replacing Liisi De Backer for CLH)
Robinson	Jan (A.I.S.E.)
Romano	Dolores (EEB)
Ruelens	Paul (CropLife Europe)
Van de Broeck	Steven (CEFIC for restrictions)
Verougstraete	Violaine (Eurometaux)
Waeterschoot	Hugo (Eurometaux for CLH Silver and restrictions Lead)

Occassional stakeholders		**Substance**
Alami	Anissa (EPMF)	CLH: Silver
Ballach	Jochen (CIRFS)	CLH: Sulphur dioxide
Drohmann	Dieter (ORO)	CLH: Sulphur dioxide (SO2)
Kappel	Jan (EAA)	Restrictions: Lead in outdoor shooting and fishing
Niemela	Helena (CONCAWE)	Agenda items 1-3; 5.1; General CLH; CLH A-listing; Sulphur dioxide; Report from the November restriction WG; Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting; 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo-[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™); Lead in outdoor shooting and fishing and items 11-12.
Palinkas	Jean-Francois (FITASC)	Restrictions: Lead in outdoor shooting and fishing
Puustinen	Seppo (FACE)	Restrictions: Lead in outdoor shooting and fishing

Stakeholder experts		**Substance**
Arijs	Katrien (EPMF/ ARCHE Consulting)	CLH: Silver
Battersby	Rodger V. (Eurometaux/ EBRC Consulting GmbH)	CLH: Sulphur dioxide (SO2)
Burzlaff	Arne (Cefic/ EBRC Consulting GmbH)	CLH: Sulphur dioxide (SO2)
Holmes	Thomas (CropLife Europe/Adama)	CLH: Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox
Höke	Hartmut	Restrictions: Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting
Kern	Petra (A.I.S.E./ P&G)	CLH: 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one
Mertens	Jelle (Cefic/EPMF)	CLH: Silver
Monsieurs	Katrien (Cefic/ Apeiron-Team)	CLH: 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
Ott	Wolfgang (CIRFS/Kelheim Fibres GmbH)	CLH: Sulphur dioxide (SO2
Pain	Debbie (EEB/Department of Zoology, Cambridge University)	Restrictions: Lead in outdoor shooting and fishing
Raffray	Mark (Eurometaux/ Raffray Biosciences Ltd)	CLH: Silver
Sarginson	Nigel (Cefic/ European Plasticisers SG)	Article 77(3)c - Reference DNEL/PNEC values or dose-response curves considering updated properties of DEHP, BBP, DIBP and DBP
Stollhofer	Germaine (Cefic/ Thor GmbH)	CLH: 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one
Verdonck	Frederik (Eurometaux/Arche Consulting)	Restrictions: Lead in outdoor shooting and fishing
Wang	Wendy (CropLife Europe/FMC)	CLH: Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate
Williams	Cris (Cefic/ILA)	Restrictions: Lead in outdoor shooting and fishing

European Commission		**DG**
Bertato	Valentina	DG ENV
Blass	Ana	DG GROW
de Bustos	Aurora	DG GROW
Kilian	Karin	DG ENV
Lekatos	Stylianos	DG GROW
Pirselova	Katarina	DG ENV
Roebben	Gert	JRC
Tosetti	Patrizia	DG SANTE

EU Agency Observers		
Rincon	Anna	EFSA
Volk	Katharina	EFSA

ECHA staff	
Blainey	Mark
Bowmer	Tim (Chair)
Gmeinder	Michael
Henrichson	Sanna
Karjalainen	Ari
Kokkola	Leila
Lapenna	Silvia
Lefevre	Sandrine
Logtmeijer	Christiaan
Ludborzs	Arnis
Marchetto	Flavio
Marquez-Camacho	Mercedes

Mazzolini	Anna
Myöhänen	Kirsi
Nurmi	Väinö
Orispää	Katja
O'Rourke	Regina
Peltola-Thies	Johanna (vice-Chair)
Reuter	Ulrike
Rheinberger	Christoph
Roggeman	Maarten
Sadam	Diana
Simoes	Ricardo
Simpson	Peter
Smilovici	Simona
Sosnowski	Piotr
Thierry-Mieg	Morgane
Uphill	Simon
van Haelst	Anniek
Väänänen	Virpi
Wilk	Mateusz
Zeiger	Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-59 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-59 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-59 meeting

22 November 2021
RAC/A/59/2021

Registration deadline 4 November 2021
rac@echa.europa.eu

Final Agenda

59th meeting of the Committee for Risk Assessment

22-26 November 2021

Virtual meeting

22 November starts at 14.00
26 November ends at 13.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/59/2021

For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

4.1 Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits

For agreement

Closed session

Item 5 – Report from other ECHA bodies and activities

5.1 RAC Work Plan for all processes

For information

5.2 Annual Declaration of Interests exercise – New declaration tool to be presented to the RAC members

For information

Item 6 – Requests under Article 77(3)(c)

6.1 Reference DNEL/PNEC values or dose-response curves considering updated properties of DEHP, BBP, DIBP and DBP

For discussion/adoption

Item 7 –Health based exposure limits at the workplace

No agenda items.

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the October CLH WG

RAC/59/2021/01
For information

8.2 CLH dossiers

1. Hazard classes for agreement without plenary debate (A-list)

1. Sulfur dioxide (EC: 231-195-2; CAS: 7446-09-5): skin sensitisation, carcinogenicity, STOT SE
2. Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3): physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity, carcinogenicity, developmental toxicity, lactation, hazardous to the aquatic environment, hazardous to the ozone layer
3. Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC 275-728-7; CAS 71626-11-4): physical hazards, acute oral toxicity, STOT SE, hazardous to the aquatic environment
4. 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5): acute toxicity via all routes, skin corrosion/irritation, skin sensitisation, hazardous to the aquatic environment
5. 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): skin sensitisation, fertility, lactation
6. Tetramethylene dimethacrylate (EC 218-218-1; CAS 2082-81-7): skin sensitisation
7. 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate (EC 276-957-5; CAS 72869-86-4): skin sensitisation
8. 2,2'-ethylenedioxydiethyl dimethacrylate (EC 203-652-6; CAS 109-16-0): skin sensitisation
9. 2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol (EC 221-665-5; CAS 3179-89-3): skin sensitisation
10. 4-methylimidazole (EC 212-497-3; CAS 822-36-6): carcinogenicity, reproductive toxicity, germ cell mutagenicity
11. 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol (EC 211-477-1; CAS 647-42-7): STOT RE, hazardous to the aquatic environment

2. **Hazard classes for agreement [with plenary debate]**

1. Sulfur dioxide (EC: 231-195-2; CAS: 7446-09-5): germ cell mutagenicity
2. Methyl 5-(2,4-dichlorophenoxy)-2-nitrobenzoate; bifenox (EC 255-894-7; CAS 42576-02-3): STOT RE, fertility
3. Benalaxyl (ISO); methyl N-(2,6-dimethylphenyl)-N-(phenylacetyl)-DL-alaninate (EC 275-728-7; CAS 71626-11-4): carcinogenicity
4. 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one (EC 220-120-9; CAS 2634-33-5): SCL for skin sensitisation
5. 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): developmental toxicity
6. Silver (EC 231-131-3; CAS 7440-22-4): physical hazards, acute toxicity, STOT SE, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, hazardous to the aquatic environment

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the November restriction WG

RAC/59/2021/02
For information

9.2 Restriction Annex XV dossiers

1. Conformity check and key issues discussion

    1. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting

For discussion and agreement

2. Opinion development

    1. Lead in outdoor shooting and fishing – third draft opinion

For discussion/agreement (appropriate sections)

    2. 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo-[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("Dechlorane Plus") – second draft opinion

For agreement (appropriate sections)

    3. 2,4-dinitrotoluene – first draft opinion

For agreement (appropriate sections)

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications
b) Revision of A-listing criteria

RAC/59/2021/03
For discussion and agreement

c) Report from the October AFA Working Group and the Capacity Building Seminar on Assessment of human biomonitoring data

RAC/59/2021/04
For information/discussion

10.2 Authorisation applications

1. Discussion on key issues

1. 3 applications for authorisation (chromium trioxide, MOCA) and 2 review reports (TCE) from August 2021 submission window

For discussion

10.3 Agreement on draft opinions

A. Draft opinions for agreement without plenary debate (A-list)

1. 231_CT_Kesseboehmer (1 use)
2. 232_DtC_Monroe (1 use)
3. 233_CT_Betz-Chrom (1 use)
4. 234_CT_Kwalter (use 1 only)
5. 235_CA_Neoperl (1 use)

For agreement

B. Draft opinions for agreement with plenary debate

1. 234_CT_Kwalter (use 2 only)

For discussion and agreement

10.4 Adoption of opinions

1. 221_CT_SD_USSK (1 use)

For discussion and adoption

Item 11 – AOB

Item 12 – Minutes of RAC-59

12.1 Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-59

For adoption

Annex II (RAC 59)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 59 meeting.

Document number	Title
RAC/A/59/2021	Final Draft Agenda
RAC/59/2021/01	Report from the October CLH WG
RAC/59/2021/02	Report from the November restriction WG
RAC/59/2021/03	General authorisation issues: Revision of A-listing criteria
RAC/59/2021/04	Report from the October AFA Working Group and the Capacity Building Seminar on Assessment of human biomonitoring data

ANNEX III (RAC-59)

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)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Restrictions		
Dechlorane Plus (NO)	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
	Christine BJØRGE	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
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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
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.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Gabriele Aquilina	Member of the EFSA WG on sulphur dioxide and sulphites as food additives.
Health based exposure limits at the workplace		
None		
Article 77.3(c)		
None		

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.
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.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
	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 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**	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.
	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		
DE	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.