RAC/M/69/2024

10 June 2024

Minutes of the 69th Meeting

of the Committee for Risk Assessment

(RAC-69)

Monday, 3 June 2024 at 10.00
Thursday, 6 June end at 17.15

Summary Record of the Proceedings,

Conclusions and action points

Chair's opening address

The Chair of RAC, Roberto Scazzola opened the meeting and provided opening remarks on importance of the work of RAC, schedule of the meeting and the expected Committee's workload for the rest of 2024.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/69/2024**) was adopted with amendments (i.e. removing one agenda point from the agenda).	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-69 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 harmonised classification and labelling (CLH) dossiers, applications for authorisation, occupational exposure limits and the restriction dossiers 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. Work plan and General RAC procedures	
5.1. Report on RAC related activities and RAC work plan for all processes The Chair presented the RAC work plan until end of 2024 and early 2025.	
5.2.b) Update on potential new tasks for the committees (Joint RAC and SEAC session) The Secretariat presented, and RAC and SEAC discussed the update on potential new tasks for the committees.	**SECR** to continue updating the Committees regarding the progress made in onboarding new tasks.

5.2.c) Good practices in RAC & SEAC opinion-making (Joint RAC and SEAC session) The Chairs presented and RAC and SEAC discussed the good practices in RAC and SEAC opinion-making.	**SECR** to continue enhancing the cooperation between RAC and SEAC.

6. Request under Article 77(3)(c)

n/a

7. Health based exposure limits at the workplace

7.1 Opinions for discussion

7.1.1. 4,4-Isopropylidenediphenol (Bisphenol A) (EC number: 201-245-8; CAS RN: 80-05-7)

The Chair welcomed the representatives from the Government and Industry Interest Groups Working Party on Chemicals, of DG Employment, of EFSA, the Occasional Stakeholder Observer from PRE (Plastics Recyclers Europe), as well as experts accompanying the CEFIC Regular Stakeholder Observer and the PlasticsEurope Regular Stakeholder Observer. He informed that the Commission had requested ECHA to evaluate **4,4-Isopropylidenediphenol (Bisphenol A),** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 19 December 2023 until 19 February 2024 and the deadline for this request is 23 February 2025.
The Government Interest Group representative commented on the assessment factors and POD as proposed by ECHA.

The Rapporteurs presented the key issues in relation to the opinion development on this dossier. RAC took note and provided some supporting suggestions.	**Rapporteurs** to prepare the first draft opinion on the dossier and to provide it to SECR. **SECR** to organise a RAC consultation on the first draft RAC opinion prior to RAC-70. **SECR** to table the opinion for the discussion on the first draft opinion at RAC-70.

7.2 Opinions for adoption

7.2.1 1,3-Butadiene (EC number: 203-450-8; CAS RN: 106-99-0)

The Chair welcomed the representatives from the Government and Industry Interest Groups Working Party on Chemicals, of DG Employment, an Occasional Stakeholder Observer from ETRMA and an expert accompanying the CEFIC Regular Stakeholder Observer. He informed that the Commission had requested ECHA to evaluate **1,3-butadiene,** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 21 September 2023 until 20 November 2023 and the deadline for this request is 23 February 2025.

The Rapporteurs presented and RAC discussed the revised draft opinion on the scientific evaluation of limit values for 1,3-butadiene. RAC agreed that no threshold can be currently identified for carcinogenicity of 1,3-butadiene and therefore an exposure-risk relationship (ERR) is to be derived. RAC agreed on the ERR, as presented in the draft opinion. The Rapporteurs were asked to add under the Summary table in the opinion that the ERR is based on mortality rather than on incidence data, which is expected to result in an underestimation of risk. RAC agreed not to derive a BOEL based on reproductive toxicity observed in animals due to marked uncertainties in the extrapolation of animal data to humans related to interspecies differences in sensitivity to 1,3-butadiene metabolism and toxicity. The Rapporteurs were asked to revise the opinion accordingly. RAC agreed not to propose any STEL. RAC agreed that a BLV and BGV are not proposed. RAC agreed not to propose any notations, but to add a point on groups at extra risks. RAC adopted by consensus its opinion (with the modifications agreed at RAC-69). A short round of consultation with RAC will be carried out on the revised opinion before publication.	**Rapporteurs** to revise the opinion in accordance with the agreed modifications at RAC-69 and to provide it to SECR. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.
7.2.2 Boron and its compounds (EC numbers: 233-139-2, 215-575-5, 215-540-4, 215-125-8 and CAS RN: 10043-35-3, 1332-77-0, 1330-43-4, 1303-86-2 respectively)	
The Chair welcomed the representatives from the Government and Industry Interest Groups Working Party on Chemicals, of DG Employment, an Occasional Stakeholder Observer from IMA-Europe with an accompanying expert as well as an expert accompanying the Eurometaux Regular Stakeholder Observer. He informed that the Commission had requested ECHA to evaluate **boron and its compounds, including boric acid, dipotassium tetraborate, disodium tetraborate and boric oxide,** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 31 October 2023 until 12 January 2024 and the deadline for this request is 23 February 2025. The Occasional Stakeholder Observer from IMA-Europe and his accompanying expert commented on the assessment factors for fertility, local irritant effects, the scope of the OEL, the STEL and biomonitoring. The expert accompanying the Eurometaux stakeholder observer commented on the STEL.	

The Rapporteurs presented and RAC discussed the revised draft opinion on the scientific evaluation of limit values for 'boron and its compounds'. RAC did not identify any scientific evidence that effects are mediated by a non-threshold MoA, as neither a direct endocrine nor a direct genotoxic mechanism is supported by the available data. RAC agreed on the following derived limit values: OEL – 8h TWA - An OEL of 0.3 mg/m^3 (agreement on AF for exposure duration = 6) for Boron is derived based on adverse effects on male fertility, - An 8h TWA value of 0.67 mg/m^3 (agreement on AF for intraspecies differences (GP) = 10) is derived for developmental toxicity. If RAC would have followed the guidance, an AF of 5 should have been used for intraspecies extrapolation. Therefore, the Rapporteurs were asked to include an explanation in the opinion, why a deviation from the guidance was considered appropriate. Several RAC members noted that a guidance update on this point would be appropriate for scientific reasons. RAC agreed to the pragmatic approach to use the lower value of the exposure range of 0.6 mg B/m^3 and no additional AF for local irritant effects. RAC agreed to recommend the 8h-TWA value to apply to any compound releasing boric acid and which meets the criteria for classification as reproductive toxicant category 1A/1B according to CLP. RAC agreed to recommend a STEL based on local irritant effects in workers - the value is derived based on effect incidences related to 15-minute exposure intervals, the calculated value for local irritant effects to the respiratory tract is 0.6 mg B/m^3. RAC agreed to recommend the STEL for any substance releasing boric acid in aqueous solution. RAC agreed to not propose a BLV, BGV and any notation. <u>RAC adopted by consensus its opinion</u> (with the modifications agreed at RAC-69).	**Rapporteurs** to revise the opinion in accordance with the agreed modifications at RAC-69 and to provide it to SECR. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.
8. Harmonised classification and labelling (CLH)	

8.1. General CLH issues

8.1.1. Report from the April CLH Working Group

The Secretariat presented the Report of the 13th Meeting of the Committee for Risk Assessment Applications for Classification and Labelling Working Group which took place on 23-25 April 2024. RAC took note of the Report.	

8.2. CLH dossiers

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

- 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol: *aquatic toxicity*
- Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate): *physical hazards, acute toxicity via all routes, skin corrosion/irritation, eye damage/eye irritation, skin sensitisation, respiratory sensitisation, mutagenicity, carcinogenicity, sexual function and fertility, effect on or via lactation, STOT SE, STOT RE, aquatic toxicity hazardous to the Ozone layer*
- Piperonal; 1,3-benzodioxole-5-carbaldehyde: *skin sensitisation, effect on or via lactation*
- N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine: *acute toxicity, skin sensitisation, effect on or via lactation, STOT RE, aquatic toxicity*
- Thymol; 5-methyl-2-(propan-2-yl)phenol: *physical hazards, acute toxicity via all routes, serious eye damage/eye irritation, skin corrosion/irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, aquatic toxicity, hazardous to the Ozone layer*
- Bronopol; 2-bromo-2-nitropropane-1,3-diol: *physical hazards, acute toxicity via al routes, serious eye damage/eye irritation, skin corrosion/irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, sexual function and fertility, effect on or via lactation, aquatic toxicity*
- Talc ($Mg_3H_2(SiO_3)_4$): *STOT RE*
- 4,4'-methylenediphenol; bisphenol F: *reproductive toxicity – development, effect on or via lactation*

8.2.2. Hazard classes for agreement with plenary debate

8.2.2.1. **Piperonal; 1,3-benzodioxole-5-carbaldehyde** (EC 204-409-7; CAS 120-57-0): *reproductive toxicity – fertility and development*

The Chair welcomed the Dossier Submitter representative and the IFRA (International Fragrance Association) Occasional Stakeholder Observer with and accompanying expert. He then provided some general information on the uses of piperonal, existing harmonized classification, proposed classification by the Dossier Submitter (IE) and legal deadline.
Skin sensitisation and reproductive toxicity were the only hazard classes open for comments during the Consultation.

The expert/observer accompanying the Occasional Stakeholder Observer (IFRA) commented on reproductive toxicity (fertility and development).

RAC discussed the Working Group recommendations and <u>adopted by consensus the opinion</u> with a proposal for the harmonised classification and labelling as indicated in Table 1. [Repr. 1B; H360FD, Skin Sens. 1; H317]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteur. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.2. Talc ($Mg_3H_2(SiO_3)_4$) (EC 238-877-9; CAS 14807-96-6): *carcinogenicity*	
The Chair welcomed the Dossier Submitter representative, the EFSA representative, the IMA-Europe (Industrial Monerals Association - Europe) Occasional Stakeholder Representative with an accompanying expert, as well as experts accompanying the CEFIC Regular Stakeholder Observer and the Eurometaux Regular Stakeholder Observer. He then provided some general information on the uses of **talc ($Mg_3H_2(SiO_3)_4$),** existing harmonized classification, proposed classification by the Dossier Submitter (NL) and legal deadline. Carcinogenicity and STOT RE were the only hazard classes open for comments during the Consultation. Only STOT RE and lung carcinogenicity (including lung overload) were discussed in the RAC-69 CLH WG, while pheochromocytomas and ovarian cancer will be discussed in the June plenary and July WG/September plenary. The EFSA representative commented on the physical properties of talc. The expert accompanying the CEFIC Regular Stakeholder Observer, the Occasional Stakeholder Observer (IAM-Europe) and the expert accompanying the Eurometaux Regular Stakeholder Observer commented on carcinogenicity.	
<u>Carcinogenicity</u> RAC supported the recommendations of the CLH WG that there is some (limited) evidence of carcinogenic activity in the lungs of female rats. Observers commented on the mentioned evidence. Based on the available data in animals indicating a high background incidence, RAC concluded in agreement with the DS that the increased incidences of pheochromocytomas in the rat should not be considered as supporting data for classification purposes. RAC considered the mode of action of the increased incidences in benign and malignant pheochromocytomas as being secondary to hypoxia as uncertain. In the RAC-70 CLH WG, RAC will continue discussion on carcinogenicity (ovarian cancer).	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC-69 and to provide it to SECR. **SECR** to organise a written consultation in RAC on the remaining parts of the opinion and to table the updated opinion for further discussion at RAC-70 CLH WG and RAC-70.

8.2.2.3. N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine (EC 212-344-0; CAS 793-24-8): reproductive toxicity – *fertility and development*	
The Chair welcomed the ETRMA (European Tyre& Rubber Manufacturers Association) Occasional Stakeholder Observer and an expert accompanying the Cefic Regular Stakeholder. He then provided some general information on the uses of ***N*-1,3-dimethylbutyl-*N'*-phenyl-*p*-phenylenediamine,** existing harmonized classification, proposed classification by the Dossier Submitter (AT) and legal deadline. Acute toxicity, skin sensitisation, reproductive toxicity, STOT RE and hazards to the aquatic environment were the only hazard classes open for comments during the Consultation.	
RAC discussed the Working Group recommendations and adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Repr. 1B; H360Fd, Acute Tox. 4; H302 (ATE=890 mg/kg bw), Skin Sens. 1A; H317, STOT RE 2; H373 (liver), Aquatic Acute 1; H400 (M=10 000), Aquatic Chronic 1; H410 (M=10 000)]	**Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.4. Thymol; 5-methyl-2-(propan-2-yl)phenol (EC 201-944-8; CAS 89-83-8): *STOT SE and STOT RE*	
The Chair welcomed the Dossier Submitter representative and provided some general information on the uses of **thymol; 5-methyl-2-(propan-2-yl)phenol**, existing harmonized classification, proposed classification by the Dossier Submitter (ES) and legal deadline. All relevant hazard classes were open for comments during the Consultation, except for respiratory sensitisation.	
RAC discussed the Working Group recommendations and adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 4; H302 (ATE=500 mg/kg bw), Eye Dam. 1; H318, Skin Corr. 1; H314, Skin Sens. 1; H317, STOT SE 1; H370 (nervous system), STOT RE 1; H372 (nervous system), Aquatic Chronic 3; H412, EUH071]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.5. 4,4'-methylenediphenol; bisphenol F (EC 210-658-2, CAS 620-92-8): *reproductive toxicity – fertility*	
The Deputy Chair welcomed the EFSA representative and provided some general information on the uses of **4,4'-methylenediphenol; bisphenol F**, existing harmonized classification, proposed classification by the Dossier Submitter (SE) and legal deadline. Reproductive toxicity was the only hazard class open for comments during the Consultation.	
RAC discussed the Working Group recommendations and adopted by consensus the opinion with a proposal for the	**Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs.

harmonised classification and labelling as indicated in Table 1. [Repr. 1B; H360F]	**Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.6. Bronopol; 2-bromo-2-nitropropane-1,3-diol (EC 200-143-0, CAS 52-51-7): *reproductive toxicity – development*	
The Deputy Chair welcomed the Dossier Submitter representative and the experts accompanying the CropLife Regular Stakeholder Observer and the CEFIC Regular Stakeholder Observer. He then provided some general information on the uses of **bronopol; 2-bromo-2-nitropropane-1,3-diol,** proposed classification by the Dossier Submitter (ES) and legal deadline. All relevant hazard classes were open for comments during the Consultation, except for respiratory sensitisation, aspiration hazard and the hazard to the Ozone layer.	
RAC discussed the Working Group recommendations and adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 3; H331 (ATE=0.59 mg/L (dusts/mists)), Acute Tox. 4; H312 (ATE=1600 mg/kg bw), Acute Tox. 3; H301 (ATE=190 mg/kg bw), Eye Dam. 1; H318, Skin Corr. 1; H314, Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=100), Aquatic Chronic 1; H410 (M=10)]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
9. Restrictions	
9.1. General restriction issues	
9.1.1. Report from the May REST Working Group	
The Secretariat provided an update on the upcoming restriction dossier to be submitted in 2025. Furthermore, the Secretariat informed that the May REST Working Group was cancelled.	**Members** to volunteer for the pools of (co-)rapporteurs. **Secretariat** to confirm the dates of the upcoming WG meetings.
9.1.2. Review of the Conformity Check procedure	
The Secretariat provided an update on the review of the Conformity check procedure.	**Secretariat** to table the topic for discussion in September 2024.
9.2. Restriction Annex XV dossiers	
9.2.1. Opinion Development	

9.2.1.1. Universal per- and polyfluoroalkyl substances (UPFAS) – Draft opinion with focus on hazards (cont.), metal plating and manufacture of metal products, and pending issues from the RAC68 plenary (consumer mixtures, cosmetics and ski wax)	
The Chair welcomed the Dossier Submitter representatives from Denmark, Germany, the Netherlands, Norway and Sweden, as well as the Occasional Stakeholder Observers together with their accompanying experts from ASD, Aqua Europe, CEWEP, COCIR, CONCAWE, EEPIA, EuChemS, EPEE, EuPC, ETRMA, EuChemS, EurEau, FEC, Orgalim, Plastics Recyclers Europe, TIC Council and the accompanying experts to the Regular Stakeholder Observers from Cefic, CropLife Europe, EEB, Eurometaux, MedTech and PlasticsEurope. The dossier was submitted in January 2023 and proposes to restrict the manufacture, placing on the market and use of PFAS, i.e. universal PFAS (UPFAS). All uses of PFASs are covered by this restriction proposal except for the use of PFASs in fire-fighting foams. The observers and their accompanying experts from Cefic, CropLife, ECPA, EEB, EFPIA, EuChemS, EurEAU, Eurometaux, EuPC, FEC, PlasticsEurope, PRE commented on number of issues covering hazard assessment, emissions and exposure, and on sector specific elements. The Dossier Submitter (DS) representatives as well as the Commission observers provided clarifications and comments related to scope, hazards and on sector specific elements.	
RAC took note of the updates to the draft opinion in line with discussions at RAC-68. Furthermore, RAC provisionally agreed with conclusions regarding the scope, and with overall conclusions on hazards assessment. RAC noted the following additional elements regarding scope: → RAC does not consider that the exclusion of the sub-groups from the scope is justified, although it is recognised that there may be exceptions for the general very persistent property of PFAS. → RAC considers that a mechanism for the evaluation of the degradability of individual PFAS could be appropriate although recognises that this is not part of the current restriction proposal and should be further discussed with the Dossier Submitter. Regarding waste stage (emissions and exposure), RAC noted the following: → Landfilling is considered as a relevant source of PFAS releases into the environment. → RAC agreed that incineration at more than 1 100°C is the only way to destroy PFAS and reduce their contribution to environmental pollution. → RAC noted uncertainties linked to a potential overestimation of the incineration effectiveness in the Dossier Submitter's proposal. It was proposed	**Rapporteurs** to make the editorial changes in the draft opinion taking into account the comments received from the RAC written commenting round and discussions in RAC-69. **SECR** to table further discussions as follows: RAC-70 meetings in September 2024 (tentative): o Textiles, upholstery, leather, apparel, carpets (TULAC); o Food contact materials and packaging; and o Petroleum and mining. RAC-71 meetings in December 2024 (tentative): o Fluorinated gases; o Transport; and o Construction products More information about the committees' plans will be announced as work advances. This

to apply an efficiency of 99% for incineration of hazardous and municipal waste. RAC will consider, inter alia, if a different factor could be applied. → RAC discussed relevance of additional information to be further considered. → RAC agreed with the Dossier Submitter that wastewater treatment is ineffective in removing PFAS. RAC concluded to use a release factor of 1. Furthermore, RAC supported rapporteurs' approach to risk characterisation, with the modifications presented at the meeting. <u>Metal plating and manufacture of metal products</u> RAC supported the rapporteurs' evaluation on the sector-specific elements for metal plating and manufacture of metal products i.e. volumes, emissions, risk characterization, risk of alternatives, effectiveness in reducing the identified risk, conclusion on specific sector/use specific derogations, and summary of uncertainties. Therefore, RAC provisionally agreed on the sector specific elements on metal plating and manufacture of metal products. <u>Updates from RAC-68 on pending issues related to ski wax, consumer mixtures, and cosmetics</u> RAC took note of the updates and RAC provisionally agreed with conclusions regarding the sector specific elements on ski wax, consumer mixtures, and cosmetics. Furthermore, RAC noted that the release factors for waste landfill will be still reviewed by the rapporteurs and any resulting changes in the emissions, already discussed for these sectors, will be updated.	information will be communicated in conjunction with the committee meetings.
10. Authorisation	
10.1. General authorisation issues	
10.1.1. Report from the May AFA Working Group	
The Secretariat presented the Report of the 19th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 7 May 2024.	

RAC took note of the Report.	
10.1.2. Update on incoming/future applications and horizontal issues	
The Secretariat presented an update on Applications for Authorisation and Review Reports pipeline.	
10.2 Authorisation applications	
10.2.1. Discussion on key issues	
Rapporteurs presented AFA Key issues in 10 applications for authorisation (13 uses) from November 2023 submission window.	**RAC members** to provide comments on draft opinions during RAC consultations in July and August 2024.
10.2.2. Discussion on key issues	
Rapporteurs presented AFA Key issues in application for authorisation 364_CT_CTACSub2 (12 uses).	**RAC members** to provide comments on draft opinions during RAC consultations in August and September 2024.
10.3. Agreement on draft opinions	
10.3.1. Draft opinions for agreement without plenary debate (A-list)	
ECHA Secretariat presented the summary of the draft opinions for agreement without plenary debate (A-list): 1. 348_RR1_NPE_Chemetall (2 uses) 2. 349_RR1_OPE_Biomerieux (1 use) 3. 350_RR1_OPE_PPG (2 uses) 4. 351_PD_Turdus (1 use) RAC agreed by consensus the six draft opinions on the Application listed in Annex IV.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicants for commenting.
10.3.2. Draft opinions for discussion and agreement with plenary debate	
10.3.2.1. 352_DEHP_Baxter (3 uses)	
(Postponed until RAC-70)	
10.3.2.2. 353_TEL_Shell (1 use)	
Use1: *Use of tetraethyl lead in the formulation of aviation fuel.* RAC discussed:	**Rapporteur** together with **SECR** to do the final editing of the draft opinion.

- lack of a DNEL/dose-response value (set by RAC) preventing exposure-risk quantification and other benchmark values, including Pb-blood levels. 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. RAC agreed: Section 7: additional conditions for the authorisation The applicant shall carry out and document detailed feasibility studies on: 1. the implementation of a vapour recovery system for the unloading of TEL solutions from the ISO containers to the storage tank; 2. the implementation of additional technical measures (such as dry break coupling) to prevent the occurrence of spills or drips during disconnection of the hose after the transfer operations of TEL solution. The feasibility studies shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to minimise the workers' exposure to TEL as low a level as technically and practically feasible must be implemented and reviewed during the review period. In any case, the applicant shall provide additional training to the workers involved in the transfer tasks to ensure that the risk of spillage of TEL solution during disconnection of the hose after the transfer is further minimised. Such training shall be conducted within 6 months of the granting of an authorisation for this use and repeated regularly thereafter. Section 8: monitoring arrangements for the authorisation with additional request in point 7: The applicant shall continue the existing annual biomonitoring programme for the workers potentially exposed to TEL. The results of the biomonitoring programme should be reported following the "Format for reporting of occupational exposure data by downstream users", in the respective Excel sheet for biomonitoring, as it can be found on the ECHA homepage. Section 9: recommendations for the review report	**SECR** to send the draft opinion to the applicant for commenting.

RAC agreed on the draft opinion by consensus.	
10.4. Adoption of opinions	
10.4.1. 302_CT_Thoma_Metallveredelung (1 use)	
Use 1: *Functional chrome plating for hydraulic applications, other cylindrical components and further industrial applications.* The rapporteur presented applicants comments on the draft opinion and informed RAC that those comments addressed only the SEAC sections of the draft opinion. Therefore, the rapporteur recommended RAC to adopt the final opinion without changes in RAC sections. RAC adopted the final opinion by consensus.	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.
10.4.2. 312_CT_Meetalplast (use 1 only)	
Use 1: *Industrial use of hexavalent chromium for a pre-treatment step (etching) in the electroplating process for plastic materials with various applications.* The rapporteur presented applicants comments on the draft opinion and informed RAC that those comments addressed only the SEAC sections of the draft opinion. Therefore, the rapporteur recommended RAC to adopt the final opinion without changes in RAC sections. RAC adopted the final opinion by consensus.	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.
10.4.3. 321_CT_LMC (1 use)	
Use 1: *Industrial use of chromium trioxide for the functional chrome plating of food slicer's circular blades.* The rapporteur presented applicants comments on the draft opinion and informed RAC that those comments addressed only the SEAC sections of the draft opinion. Therefore, the rapporteur recommended RAC to adopt the final opinion without changes in RAC sections. RAC adopted the final opinion by consensus.	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.
11. Drinking Water Directive	
11.1. Update on the DWD related issues	
The Secretariat presented: - update on the DWD legislation, - progress in the work on guidance documents,	

- results of survey after joint RAC and RAC DWD WG Session 14-15 March, - plans on development of the DWD process in 2024.	
12. AOB	
A representative of the European Commission DG GROW reported on the work of the REACH Committee on applications for authorisation and restrictions proposals. RAC took note of the report.	
13. Minutes of RAC-68	
13.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-69	
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-69 to the ECHA Website.

CLH Opinions at RAC-69

1. 2,2',6,6'-tetra-*tert*-butyl-4,4'-methylenediphenol

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',6,6'-tetra-*tert*-butyl-4,4'-methylenediphenol	204-279-1	118-82-1	Aquatic Chronic 1	H410	GHS09 Wng	H410		M = 10000	
RAC opinion	TBD	2,2',6,6'-tetra-*tert*-butyl-4,4'-methylenediphenol	204-279-1	118-82-1	Aquatic Chronic 1	H410	GHS09 Wng	H410		M = 10000	
Resulting Annex VI entry if agreed by COM	TBD	2,2',6,6'-tetra-*tert*-butyl-4,4'-methylenediphenol	204-279-1	118-82-1	Aquatic Chronic 1	H410	GHS09 Wng	H410		M = 10000	

2. trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)

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	trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)	274-778-7	70693-62-8	Acute Tox 4 Skin Corr. 1 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 3	H302 H314 H318 H400 H412	GHS07 GHS05 GHS09 Dgr	H302 H314 H410	EUH 071	oral: ATE = 500 mg/kg bw M = 1	
RAC opinion	TBD	trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)	274-778-7	70693-62-8	Acute Tox 4 STOT RE 1 Skin Corr. 1 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 2	H302 H372 (eye) H314 H318 H400 H411	GHS07 GHS08 GHS05 GHS09 Dgr	H302 H372 (eye) H314 H410	EUH 071	oral: ATE = 500 mg/kg bw M = 1	
Resulting Annex VI entry if agreed by COM	TBD	trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate)	274-778-7	70693-62-8	Acute Tox 4 STOT RE 1 Skin Corr. 1 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 2	H302 H372 (eye) H314 H318 H400 H411	GHS07 GHS08 GHS05 GHS09 Dgr	H302 H372 (eye) H314 H410	EUH 071	oral: ATE = 500 mg/kg bw M = 1	

3. piperonal; 1,3-benzodioxole-5-carbaldehyde

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	piperonal; 1,3-benzodioxole-5-carbaldehyde	204-409-7	120-57-0	Repr. 1B Skin Sens. 1	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			
RAC opinion	TBD	piperonal; 1,3-benzodioxole-5-carbaldehyde	204-409-7	120-57-0	Repr. 1B Skin Sens. 1	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			
Resulting Annex VI entry if agreed by COM	TBD	piperonal; 1,3-benzodioxole-5-carbaldehyde	204-409-7	120-57-0	Repr. 1B Skin Sens. 1	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			

4. *N*-1,3-dimethylbutyl-*N*'-phenyl-*p*-phenylenediamine

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	*N*-1,3-dimethylbutyl-*N*'-phenyl-*p*-phenylenediamine	212-344-0	793-24-8	Repr. 1B Acute Tox. 4 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H360FD H302 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360FD H302 H317 H410		oral: ATE = 890 mg/kg bw M = 10000 M = 10000	
RAC opinion	TBD	*N*-1,3-dimethylbutyl-*N*'-phenyl-*p*-phenylenediamine	212-344-0	793-24-8	Repr. 1B Acute Tox. 4 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H360Fd H302 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360Fd H302 H317 H410		oral: ATE = 890 mg/kg bw M = 10000 M = 10000	
Resulting Annex VI entry if agreed by COM	TBD	*N*-1,3-dimethylbutyl-*N*'-phenyl-*p*-phenylenediamine	212-344-0	793-24-8	Repr. 1B Acute Tox. 4 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H360Fd H302 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360Fd H302 H317 H410		oral: ATE = 890 mg/kg bw M = 10000 M = 10000	

5. thymol; 5-methyl-2-(propan-2-yl)phenol

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	604-032-00-1	thymol; 5-methyl-2-(propan-2-yl)phenol	201-944-8	89-83-8	Acute Tox. 4* Skin Corr. 1B Aquatic Chronic 2	H302 H314 H411	GHS07 GHS05 GHS09 Dgr	H302 H314 H411			
Dossier submitters proposal	604-032-00-1	thymol; 5-methyl-2-(propan-2-yl)phenol	201-944-8	89-83-8	**Add** STOT SE 3 Eye Dam. 1 Skin Sens. 1 **Modify** Acute Tox. 4 Skin Corr. 1 Aquatic Chronic 3	**Retain** H302 H314 **Add** H336 H318 H317 **Modify** H412	**Retain** GHS07 GHS05 Dgr **Remove** GHS09	**Retain** H302 H314 **Add** H336 H317 **Modify** H412	**Add** EUH071	**Add** oral: ATE = 500 mg/kg bw	
RAC opinion	604-032-00-1	thymol; 5-methyl-2-(propan-2-yl)phenol	201-944-8	89-83-8	**Add** STOT SE 1 STOT RE 1 Eye Dam. 1 Skin Sens. 1 **Modify** Acute Tox. 4 Skin Corr. 1 Aquatic Chronic 3	**Retain** H302 H314 **Add** H370 (nervous system) H372 (nervous system) H318 H317 **Modify** H412	**Retain** GHS07 GHS05 Dgr **Add** GHS08 **Remove** GHS09	**Retain** H302 H314 **Add** H370 (nervous system) H372 (nervous system) H317 **Modify** H412	**Add** EUH071	**Add** oral: ATE = 500 mg/kg bw	
Resulting Annex VI entry if agreed by COM	604-032-00-1	thymol; 5-methyl-2-(propan-2-yl)phenol	201-944-8	89-83-8	Acute Tox. 4 STOT SE 1 STOT RE 1 Skin Corr. 1 Eye Dam. 1 Skin Sens. 1 Aquatic Chronic 3	H302 H370 (nervous system) H372 (nervous system) H314 H318 H317 H412	GHS07 GHS05 GHS08 Dgr	H302 H370 (nervous system) H372 (nervous system) H314 H317 H412	EUH071	oral: ATE = 500 mg/kg bw	

6. 4,4'-methylenediphenol; bisphenol F

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	604-RST-VW-Y	4,4'-methylenediphenol; bisphenol F	210-658-2	620-92-8	Repr. 1B	H360F	GHS08 Dgr	H360F			
RAC opinion	604-RST-VW-Y	4,4'-methylenediphenol; bisphenol F	210-658-2	620-92-8	Repr. 1B	H360F	GHS08 Dgr	H360F			
Resulting Annex VI entry if agreed by COM	604-RST-VW-Y	4,4'-methylenediphenol; bisphenol F	210-658-2	620-92-8	Repr. 1B	H360F	GHS08 Dgr	H360F			

7. bronopol; 2-bromo-2-nitropropane-1,3-diol

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	603-085-00-8	bronopol; 2-bromo-2-nitropropane-1,3-diol	200-143-0	52-51-7	Acute Tox. 4* Acute Tox. 4* STOT SE 3 Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1	H312 H302 H335 H315 H318 H400	GHS05 GHS07 GHS09 Dgr	H312 H302 H335 H315 H318 H400		M=10	
Dossier submitters proposal	603-085-00-8	bronopol; 2-bromo-2-nitropropane-1,3-diol	200-143-0	52-51-7	**Retain** STOT SE 3 Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1 **Add** Acute Tox. 3 Aquatic Chronic 1 **Modify** Acute Tox. 4 Acute Tox. 3	**Retain** H312 H335 H315 H318 H400 **Add** H331 H410 **Modify** H301	**Retain** GHS05 GHS07 GHS09 Dgr **Modify** GHS06	**Retain** H312 H335 H315 H318 **Add** H331 **Modify** H301 H410	**Add** EUH044	**Add** inhalation: ATE = 0.588 mg/L (dust/mist) dermal: ATE = 1600 mg/kg bw oral: ATE = 193 mg/kg bw M=10 **Modify** M=100	
RAC opinion	603-085-00-8	bronopol; 2-bromo-2-nitropropane-1,3-diol	200-143-0	52-51-7	**Retain** Eye Dam. 1 Aquatic Acute 1 **Add** Acute Tox. 3 Skin Sens. 1 Aquatic Chronic 1 **Modify** Acute Tox. 4 Acute Tox. 3 Skin Corrosion 1 **Remove** STOT SE 3	**Retain** H312 H318 H400 **Add** H331 H317 **Modify** H301 H314 **Remove** H335	**Retain** GHS05 GHS09 **Add** Dgr **Modify** GHS06 **Delete** GHS07	**Retain** H312 H318 **Add** H331 H317 **Modify** H301 H314 H410 **Remove** GHS07	**Add** EUH071 EUH044	**Add** inhalation: ATE = 0.59 mg/L (dust/mist) dermal: ATE = 1600 mg/kg bw oral: ATE = 190 mg/kg bw M = 100 M = 10	
Resulting Annex VI entry	603-085-00-8 or	bronopol; 2-bromo-2-nitropropane-1,3-diol	200-143-0	52-51-7	Acute Tox. 3 Acute Tox. 4	H331 H312	GHS05 GHS06	H331 H312	EUH071 EUH044	inhalation: ATE = 0.59 mg/L (dust/mist)	

if agreed by COM	TBD				Acute Tox. 3 Skin Corr. 1 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H314 H318 H317 H400 H410	GHS09 Dgr	H301 H314 H317 H410		dermal: ATE = 1600 mg/kg bw oral: ATE = 190 mg/kg bw M = 100 M = 10	

Part III. List of Attendees of the RAC-69 meeting

RAC members	
Angeli	Karine
Aquilina	Gabriele
Barański	Bogusław
Biró	Anna
Brovkina	Julija
Chiurtu	Elena-Ruxandra
Christodoulou	Sotirios
Deviller	Genevieve
Docea	Anca Oana
Esposito	Dania
Facchin	Manuel
Fernández	Mariana
Geoffroy	Laure
Hakkert	Betty
Hartwig	Andrea
Hoffmann	Frauke
Karadjova	Irina
Kloslova	Zuzana
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Manusadzianas	Levonas
Martinek	Michal
Menard Srpčič	Anja
Mendas Starcevic	Gordana
Mohammed	Ifthekhar Ali
Murray	Brendan
Neumann	Michael
Piña	Benjamin
Pribu	Mihaela
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schuur	Gerlienke
Sørensen	Peter Hammer
Spetseris	Nikolaos
Stalter	Daniel
Tekpli	Nina
Tobiassen	Lea Stine
Tsitsimpikou	Christina
Užomeckas	Žilvinas

van der Haar	Rudolf
Varnai	Veda Marija
Viegas	Susana
Wildemann	Tanja

RAC Members' advisers		**Nominated by**
Beestra	Renske	Betty Hakkert and Gerlienke Schuur
Bjørge	Christine	Kirsten Eline Rakkestad
Broderick	Mike	Brendan Murray
Catone	Tiziana	Gabriele Aquilina
Granato	Giuseppe	Dania Esposito
Jankowska	Agnieszka	Beata Peczkowska
Marinkovic	Marino	Gerlienke Schuur
Moeller	Ruth	Annemarie Losert
Moilanen	Marianne	Riitta Leinonen
Panieri	Emiliano	Dania Esposito
Pink	Mario	Nina Tekpli
Russo	Maria Teresa	Gabriele Aquilina
Smith	Jenny	Brendan Murray
Suutari	Tiina	Riitta Leinonen

SEAC Members' advisers (joint session)	**Nominated by**
Stephanie MOSER-CASTAN	Simone FANKHAUSER
Sabrina Moro IACOPINI	Stefano CASTELLI
Roberta LAVALLE	
Audun HEGGELUND	Marit MÅGE
Achim HELMEDACH	Karen THIELE
Oliver PETERS	
Emil Kingo ERIKSEN	Ida Petersen SVOSTRUP
Sofia ANTONIADOU	Nikoletta SOFIKITI
Arianne DE BLAEIJ	Silke GABBERT
Sebastiana HARD	
Elvia RUFO JIMENEZ	

European Commission		**DG**
André	Viviane	DG ENV
Beekman	Martijn	DG GROW
Bertato	Valentina	DG ENV
Ceridono	Mara	DG ENV
Dunauskiene	Lina	DG GROW

Faraulo	Fabio	DG EMPL (OELs)
Gallego	Mateo	DG ENV
Roebben	Gert	DG GROW
Schutte	Katrin	DG ENV
Streck	Georg	DG GROW
Tanase	Marian	DG EMPL
EU Agency Observers		
Croera	Cristina	EFSA
Mech	Agnieska	EFSA
Rainieri	Sandra	EFSA

Invited experts		**Role/Substance**
Kondeva	Magdalena	RAC member nominee
Levy	Patrick	Working Party on Chemicals (WPC)
Musu	Tony	Working Party on Chemicals (WPC)
Saarikoski	Sirkku	Working Party on Chemicals (WPC)
Smith	Jenny	RAC member nominee

SEAC Rapporteurs		
Castan-Moser	Stephanie	UPFAS (advisor to Simone Fankhauser)
Cogen	Simon	UPFAS
Fankhauser	Simone	UPFAS

Dossier submitters		**Substance**
Baumbusch	Angelika	(NO) - UPFAS
Borg	Daniel	(SE) – UPFAS
Carlsson-Feng	Mattias	(SE) – UPFAS
Dannenberg	Carl	(DE) - UPFAS
de Blaeij	Arianne	(NL) - UPFAS
De Kort	Thijs	(NL) – UPFAS
De la Usada	Eduardo	(ES) - Bronopol
Drost	Wiebke	(DE) - UPFAS
Fernandez	Marietta	(ES) – Bisphenol F
Gayarre	Javier	(ES) - Thymol
Heebøl	Anna	(DK) - UPFAS
Heggelund	Audun	(NO) – UPFAS
Houlihan	Margarete	(IE) - Piperonal
Johansson	Tommy	(SE) – UPFAS, 3 x bromides
Nielsen	Peter Juhl	(DK) - UPFAS
Posner	Stefan	(SE) – UPFAS
Sanders	Marion	(NL) - UPFAS
Sanz	Manuel	(ES) -Thymol
Simpson	Peter	(NL) - UPFAS
Staude	Claudia	(DE) - UPFAS
Vriend	Jelle	(NL) - Talc

Regular stakeholder observers	

Bird	Jasmin	Plastics Europe (Bisphenol A)
Byrne	Dominic	Plastics Europe
De Backer	Liisi	Cefic
Duguy	Hélène	ClientEarth
Hermann	Christine	EEB
Ruelens	Paul	CropLife Europe
Santos	Roumiana	MedTech Europe
Verougstraete	Violaine	Eurometaux

Regular SEAC stakeholder observers (joint session)		
Byrne	Dominic	Plastics Europe
Duguy	Hélène	ClientEarth
Hermann	Christine	EEB
Janosi	Amaya	Cefic
Santos	Roumiana	MedTech Europe
Waeterschoot	Hugo	Eurometaux

Occasional stakeholders		**Substance**
Consoli	Elisa (ASD-Europe)	UPFAS, AFA: Chemetall, PPG, RAC and SEAC joint session
Corridori	Ricardo (COCIR)	UPFAS
De Badereau	Vincent (EPEE)	UPFAS
De Bruycker	Leen (WECEP)	UPFAS
De Kort	Patrick (PRE)	REST: UPFAS, OEL: Bisphenol A
Di Caprio	Elisabetta (Concawe)	UPFAS
Doome	Roger (IMA-Europe)	CLH: Talc, OEL: Boron compounds
Dvorakova	Dana (IFRA)	CLH: Piperonal
Glüge	Juliane (EuChemS)	UPFAS
Loebel	Oliver (EurEau)	UPFAS, DWD
Mateos Basco	Julio (Orgalim)	UPFAS
Mathioudaki	Stella (ETRMA)	OEL: Butadiene, CLH: N-1,3-dimethylbutyl
Monje Gama	Alberto (TIC Council)	UPFAS
Strehl	Gernot (FEC)	UPFAS
Tillieux	Geoffroy (EuPC)	UPFAS
Weiss	Aharon (Aqua Europe)	UPFAS
Winther	Toke (EFPIA)	UPFAS

Stakeholder experts		**Substance**
Al Husainy	Wasma (Cefic)	Bronopol
Barber	David (CropLife Europe)	UPFAS
Bock	Ronald (Plastics Europe)	UPFAS
Borm	Paul (Eurometaux)	Talc
Hareng	Lars (CropLife Europe)	Bronopol
Hedfors	Cecilia (EEB)	UPFAS
Henry	Barbara (Cefic)	UPFAS

Hunziker	Rene (Cefic)	Bisphenol A
Janisch	Wilhelm (MedTech Europe)	UPFAS
Jenkinson	Peter (IFRA)	Piperonal
Kirman	Christopher (Cefic)	OEL: 1,3-Butadiene
Levy	Len (IMA-Europe)	Boron and it's compounds
Magurany	Kelly (TIC Council)	UPFAS
Mundt	Kenneth (IMA-Europe)	Talc
Ogunbemi	Afolarin (Cefic)	N-1,3-dimethylbutyl
Passeri	Marco (Eurometaux)	UPFAS
Perfetti	Marco (EPEE)	UPFAS
Russo	Matteo (Cefic)	Talc
Schenten	Julian (ClientEarth)	Joint session
Sondenheimer	Kevin (Plastics Europe)	Bisphenol A
Speziale	Lighea (CEWEP)	UPFAS
Van Wely	Eric (CEFIC)	UPFAS
Vandenberghe	Arthur (Orgalim)	UPFAS
Wieske	Martin (Eurometaux)	Boron and it's compounds

SEAC members (joint session)
ANASTASIOU Christos
ARGYROPOULOS Christos
BRIGNON Jean-Marc
BÜCKER Michael
CASTELLI Stefano
CAVALIERI Luisa (co-opted)
COGEN Simon
DOLENC Darko
FANKHAUSER Simone
FREUDENTHAL Oona
GABBERT Silke
GRACIA Ignacio
ISKRA Jernej
JANSSEN Martien
JOMINI Stéphane
JONES Derrick (co-opted)
JOYCE John
KIISKI Johanna
LEAHY Eimear
LÜDEKE Andreas
MÅGE Marit
PIÑEROS Juan
REALE Priscilla
RODRIGUEZ Manuel
ROUW Aart (co-opted)
RUZGYS Karolis
SERRA Alexandra
SOFIKITI Nikoletta
SPITERI Jonathan (co-opted)
THIELE Karen
TŐKÉS Gábor

ŽELJEŽIĆ Davor

ECHA staff
Scazzola Roberto (Chair)
Sosnowski Piotr (Deputy Chair)
Ahtiainen Heini
Atanasova Marina
Bin Essi
Bock Theresa
Bohumila Bichlmaier
Cartlidge George
de la Flor Tejero Ignacio
Etholen Anita
Galetsa Feindt Athina E.
Gmeinder Michael
Hammer Jort
Henrichson Sanna
Husa Stine
Karjalainen Antti
Konstantinos Kiakos
Lazic Nina
Lefevre Sandrine
Lisboa Patricia
Logtmeijer Christiaan
Loukou Christina
Ludborzs Arnis
Marchetto Flavio
Mercedes Marquez-Camacho
Mesquita Rochelly
Miotto Anna
Mushtaq Fesil
Nicot Thierry
Niemela Helena
Nieminen Veneta
Nogueroles Marta
Nygren Jonas
Orispää Katja
Parikka Petra
Peltola Jukka
Perazzolo Chiara
Pillet Monique
Portugal Laura
Purje Aino
Regil Pablo
Richarz Andrea
Roggeman Maarten
Sadam Diana
Salo Marta
Simoes Ricardo
Spjuth Linda
Stoyanova Evgenia
Tarvainen Emma
Thierry-Mieg Morgane
Vazquez Rodriguez Jesus
Volpi Daniele
Väänänen Virpi
Wilk Mateusz

Zarogiannis Panos
Zeiger Bastian
Zellino Carolina
Zhivin Sergey

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-69 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-69 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-69 meeting

ANNEX IV List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-69 meeting without plenary debate (A-list)

15 May 2024
RAC/A/69/2024

Final Draft Agenda
69th meeting of the Committee for Risk Assessment
(RAC-69)
3-6 June 2024

Face-to-face/Hybrid meeting*

Monday, 3 June starts at 10.00
Thursday, 6 June ends at 17.15

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/69/2024

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 – Work plan and General RAC procedures

5.1. Report on RAC related activities and RAC Work Plan for all processes

For information

5.2. General RAC procedures

a) Update on potential new tasks for the committees

For information

Joint RAC and SEAC session

**RAC members are expected to participate physically in the meeting. Regular RAC stakeholders may participate either physically or remotely. Occasional stakeholders, all stakeholder experts and dossier submitters are expected to participate remotely.*

b) Good practices in RAC & SEAC opinion-making

For information and discussion

Joint RAC and SEAC session

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

To be determined.

For adoption

Item 7 –Health based exposure limits at the workplace

7.1 Opinions for discussion

1. 4,4-Isopropylidenediphenol (Bisphenol A) (EC number: 201-245-8; CAS RN: 80-05-7)

For information

7.2 Opinions for adoption

1. 1,3-Butadiene (EC number: 203-450-8; CAS RN: 106-99-0)
2. Boron and its compounds (EC numbers: 233-139-2, 215-575-5, 215-540-4, 215-125-8 and CAS RN: 10043-35-3, 1332-77-0, 1330-43-4, 1303-86-2 respectively)

For discussion and adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

1. Report from the April CLH Working Group

For information
RAC/69/2004/01

8.2 CLH dossiers

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

- **2,2',6,6'-tetra-*tert*-butyl-4,4'-methylenediphenol:** *aquatic toxicity*
- **Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, eye damage/eye irritation, skin sensitisation, respiratory sensitisation, mutagenicity, carcinogenicity, sexual function and fertility, effect on or via lactation, STOT SE, STOT RE, aquatic toxicity, hazardous to the Ozone layer*
- **Piperonal; 1,3-benzodioxole-5-carbaldehyde:** *skin sensitisation, effect on or via lactation*
- ***N*-1,3-dimethylbutyl-*N*'-phenyl-*p*-phenylenediamine:** *acute toxicity, skin sensitisation, effect on or via lactation, STOT RE, aquatic toxicity*

- **Thymol; 5-methyl-2-(propan-2-yl)phenol:** *physical hazards, acute toxicity via all routes, serious eye damage/eye irritation, skin corrosion/irritation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, aquatic toxicity, hazardous to the Ozone layer*
- **Bronopol; 2-bromo-2-nitropropane-1,3-diol:** *physical hazards, acute toxicity via all routes, serious eye damage/eye irritation, skin corrosion/irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, sexual function and fertility, effect on or via lactation, aquatic toxicity*
- **Talc ($Mg_3H_2(SiO_3)_4$):** *STOT RE*
- **4,4'-methylenediphenol; bisphenol F:** *reproductive toxicity – development, effect on or via lactation*

2. Hazard classes for agreement with plenary debate

2.1. Piperonal; 1,3-benzodioxole-5-carbaldehyde (EC 204-409-7; CAS 120-57-0): *reproductive toxicity – fertility and development*

2.2. Talc ($Mg_3H_2(SiO_3)_4$) (EC 238-877-9; CAS 14807-96-6): *carcinogenicity*

***2.3.* *N*-1,3-dimethylbutyl-*N*'-phenyl-*p*-phenylenediamine** (EC 212-344-0; CAS 793-24-8): *reproductive toxicity – fertility and development*

2.4. Thymol; 5-methyl-2-(propan-2-yl)phenol (EC 201-944-8; CAS 89-83-8): *STOT SE and STOT RE*

2.5. 4,4'-methylenediphenol; bisphenol F (EC 210-658-2, CAS 620-92-8): *reproductive toxicity – fertility*

2.6. Bronopol; 2-bromo-2-nitropropane-1,3-diol (EC 200-143-0, CAS 52-51-7): *reproductive toxicity – development*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the May REST Working Group
2. Review of the Conformity Check procedure

For information

9.2 Restriction Annex XV dossiers

1. Opinion development

a. Universal per- and polyfluoroalkyl substances (UPFAS) – Draft opinion with focus on hazards (cont.), metal plating and manufacture of metal products, and pending issues from the RAC-68 plenary (consumer mixtures, cosmetics and ski wax)

For discussion

**RAC members are expected to participate physically in the meeting. Regular RAC stakeholders may participate either physically or remotely. Occasional stakeholders, all stakeholder experts and dossier submitters are expected to participate remotely.*

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the May AFA Working Group

For information
RAC/69/2004/02

2. Update on incoming/future applications and horizontal issues

For information

10.2 Authorisation applications

1. Discussion on key issues

1. 354_RR1_CT_Airbus (2 uses)
2. 355_RR1_SD_Airbus (1 use)
3. 356_RR1_SD_AD-International (1 use)
4. 357_RR1_PD_Lynred (1 use)
5. 358_RR1_AsA_Circuit (1 use)
6. 359_RR1_CT_Circuit (1 use)
7. 360_DOTE_Galata (3 uses)
8. 361_TEL_Trafigura (1 use)
9. 362_TEL_Warter-Fuels (1 use)
10. 363_CT_Indestructible_Paint_Turbines (1 use)

For information

2. Discussion on key issues

1. 364_CT_CTACSub2 (12 uses)

For information

10.3 Agreement on draft opinions

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

1. 348_RR1_NPE_Chemetall (2 uses)
2. 349_RR1_OPE_Biomerieux (1 use)
3. 350_RR1_OPE_PPG (2 uses)
4. 351_PD_Turdus (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 352_DEHP_Baxter (3 uses)
2. 353_TEL_Shell (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 302_CT_Thoma_Metallveredelung (1 use)
2. 312_CT_Metalplast (Use 1 only)
3. 321_CT_LMC (1 use)

For discussion and adoption

Item 11 – Drinking Water Directive

11.1 Update on the DWD related issues

For information/discussion

Item 12 – AOB

Item 13 – Minutes of RAC-68

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-69

For adoption

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Annex II

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-68 meeting.

RAC/A/69/2024	RAC-69 final Draft Agenda
RAC/69/2024/01	General CHL issues: Report from the April CLH Working Group
RAC/69/2024/02	General authorisation issues: Report from the May AFA Working Group

ANNEX III (RAC-69)

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 SCHLUETER	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		
Universal PFAS **DE**	Michael NEUMANN Urs SCHLUETER Frauke HOFFMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
DE	Daniel STALTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
DK	Peter Hammer SOERENSEN Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
NL	Betty HAKKERT Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

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AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NO	Kirsten Eline RAKKESTAD Nina TEKPLI	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
SE	Bert-Ove LUND 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.
NEW DOSSIERS		

Harmonised classification & labelling

Talc ($Mg_3H_2(SiO_3)_4$) **NL**	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
4,4'-methylenediphenol; bisphenol F **SE**	Bert-Ove LUND	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.
	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
1) **Thymol; 5-methyl-2-(propan-2-yl)phenol** 2) **Bronopol; 2-bromo-2-nitropropane-1,3-diol** **ES**	Benjamin PINA	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Marieta FERNANDEZ	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1) **2,2',6,6'-tetra-*tert*-butyl-4,4'-methylenediphenol** 2) ***N*-1,3-dimethylbutyl-*N*'-phenyl-*p*-phenylenediamine** **AT**	Annemarie LOSERT	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement in no 1. Person involvement in no 2.
	Manuel FACCHIN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) **SI**	Anja MENARD	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.
Piperonal; 1,3-benzodioxole-5-carbaldehyde **IE**	Brendan MURRAY	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

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Annex IV

Table 1. List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-69 meeting without plenary debate (A-list).

Conclusions / agreements / adoptions
348_RR1_NPE_Chemetall (2 uses) **Use1:** *The formulation of a hardener component containing NPE within Aerospace two-part polysulfide sealants.* RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for results in 0 kg per year releases of the substance to the environment. RAC agreed: Section 7: additional conditions for the authorisation - none Section 8: monitoring arrangements for the authorisation - none Section 9: recommendations for the review report – none. **Use2:** *Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1% w/w of NPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a).* RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for results in 0 kg per year releases of the substance to the environment. RAC agreed: Section 7: additional conditions for the authorisation - none Section 8: monitoring arrangements for the authorisation - none Section 9: recommendations for the review report – none.
349_RR1_OPE_Biomerieux (1 use) **Use1:** *Industrial use of 4-tert-OPnEO for its non-ionic detergent properties, used for the extraction of biological material which is further formulated and coated on articles intended for clinical and industrial in vitro testing applications.* RAC concluded that the operational conditions and risk management measures described in the review report are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

The use applied for result in 0 kg per year releases of the substance to the environment (according to qualitative assessment).

RAC agreed:
Section 7: additional conditions for the authorisation - none
Section 8: monitoring arrangements for the authorisation
Section 9: recommendations for the review report.

350_RR1_OPE_PPG (2 uses)

Use1: *Repackaging hardener formulations containing OPE as a surfactant in a concentration above 0.1%, to be used within two-part polysulphide sealants by Airbus and their associated supply chains.*

RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are adhered to.
The use applied for results in 0 kg per year releases of the substance to the environment.

RAC agreed:
Section 7: additional conditions for the authorisation - none
Section 8: monitoring arrangements for the authorisation - none
Section 9: recommendations for the review report – none.

Use2: *Mixing, by Airbus, and their associated supply chains, including the Applicant, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1% w/w of OPE for Aerospace and Defence uses that are exempt from authorisation under REACH Art. 56(6)(a).*

RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are adhered to.
The use applied for results in 0 kg per year releases of the substance to the environment.

RAC agreed:
Section 7: additional conditions for the authorisation - none
Section 8: monitoring arrangements for the authorisation - none
Section 9: recommendations for the review report – none.

351_PD_Turdus (1 use)

Use1: *Industrial use of a potassium dichromate-based mixture for the manufacture of single-use chemical breathalysers.*

Regarding the exposure to Cr(VI) associated with use of potassium dichromate, RAC concluded that the operational conditions and risk management measures described in the application for authorisation are not appropriate and effective in limiting the

risk for the workers but they are appropriate and effective in limiting the risk for humans via environment.

RAC agreed:
Section 7: additional conditions for the authorisation

1. The applicant shall implement technical improvements to the OCs/RMMs, more specifically:
   a. The applicant shall install a fume hood with glass walls in the laboratory for preparation of the reagent (WSC 2) limiting the emission of Cr(VI) to the air of the working environment. The effectiveness of local ventilation system installed should be at least annually checked to confirm the effectiveness of the operational conditions and risk management measures in place.

   This measure shall be implemented within 12 months of the granting of an authorisation for this use and be followed by a measurement campaign to validate the effectiveness of the applied technical improvements.

Section 8: monitoring arrangements for the authorisation
Section 9: recommendations for the review report.