RAC/M/70/2024

25 September 2024

Minutes of the 70th Meeting

of the Committee for Risk Assessment

(RAC-70)

Monday, 16 September 2024 at 09.00
Friday, 20 September end at 13.15

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/70/2024**) was adopted without amendments.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-70 minutes.
3. Declarations of conflicts of interest to the Agenda	
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. Update of RAC accredited stakeholders' list (closed session) The Committee agreed on the updated stakeholder list.	**SECR** to publish the agreed list on ECHA´s webpage.

5.2. Selection of RAC co-opted members (closed session) The Chair presented the outcome of the open call for candidates for co-option to the Committee under Art. 85(4). He introduced all candidates. RAC agreed to nominate five co-opted members for a three year term and to place five candidates on the reserve list.	**SECR** to complete all administrative tasks to co-opt the new members.
6. Request under Article 77(3)(c)	
n/a	
7. Health based exposure limits at the workplace	
7.1 General OEL issues	
7.1.1. OEL regulatory framework presentation by DG EMPL	
RAC took note of the OEL regulatory framework presentation made by DG EMPL.	
7.2 Opinions for discussion	
7.2.1 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 and the experts accompanying the EuPC, CEFIC and AISE Regular Stakeholder Observers. 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 representative of the Industry Interest Group Working Party on Chemicals and the expert accompanying the EuPC Regular Stakeholder Observer commented on reproductive toxicity.	
The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for 4,4'-Isopropylidenediphenol (Bisphenol A) under the OEL process. **Toxicokinetics** RAC discussed the toxicokinetics part and supported the Rapporteurs proposal for the absorption percentages as presented. RAC noted that the first-pass effect, difference in enterohepatic clearance, and route of exposure are	**Rapporteurs** to prepare the revised draft opinion on the dossier and to provide it to SECR. **SECR** to organise a RAC consultation on the revised draft RAC opinion. **SECR** to possibly organise an *ad hoc* RAC working group in

uncertainties in the OEL derivation. RAC noted that route-to-route extrapolation further is a large uncertainty. RAC agreed not to use the HEDF (as used by EFSA), and rather use the default AFs (from ECHA guidance) and to add more text on uncertainties in the opinion. **Inhalation toxicity** RAC agreed that after repeated inhalation exposure to BPA, local effects at the respiratory tract were found with a NOAEC of 10 mg/m^3. RAC instead noted that the current (binding) OEL is based on this effect (and NOAEC). RAC noted that sexual function and fertility were not investigated after inhalation exposure. **Mutagenicity and carcinogenicity** RAC noted that on the basis of the available data, there is no firm basis to conclude that BPA is mutagenic or carcinogenic. **Reproductive toxicity** <u>Female fertility</u> After discussing the existing information related to female fertility, the Rapporteurs presented two options to RAC. RAC supported option 2, and, in line with the ECHA report, consider a NOAEL of 2.5 mg/kg bw/day as a PoD, based on effects to the histopathology of uterus and ovaries in the NTP Clarity study (2018)/Camacho et al. (2019). The Rapporteurs confirmed that all remaining uncertainties around the existing data will be dealt with in the next version of the opinion, either by an assessment factor or by qualitative text. <u>Male fertility</u> RAC noted that a lot of data is available, resulting in an unclear profile of BPA with regards to male fertility. RAC discussed the possible ways forward, also discussing the evaluation of the reliability of the studies, the difference in appreciation of various previous evaluations of a sister committee/institute and the pros and cons of evaluation of all individual studies of the large BPA database. RAC agreed to continue the discussion, if possible, in an *ad hoc* working group meeting, to be organised before RAC-71.	order to have more detailed discussions on the dossier (before RAC-71). **SECR** to table the opinion for further discussion at RAC-71.
7.3.1 Silicon carbide fibres	

The Chair welcomed the representatives from the Government and Industry Interest Groups Working Party on Chemicals and of DG Employment. He informed that the Commission had requested ECHA to evaluate **silicon carbide fibres,** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 2 April 2024 until 3 June 2024 and the deadline for this request is 23 February 2025.	
The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for silicon carbide fibres. RAC agreed that no threshold can be currently identified for carcinogenicity of silicon carbide fibres and therefore an exposure-risk relationship (ERR) is to be derived. As ERR for SiC fibres, RAC agreed to use the RAC (2021) asbestos ERR. RAC agreed not to derive a BOEL. RAC agreed not to propose any STEL, BLV or BGV. RAC agreed not to propose any notations. <u>RAC adopted by consensus its opinion</u> (with the modifications agreed at RAC-70).	**Rapporteurs** to revise the opinion in accordance with the agreed modifications at RAC-70 and to provide it to SECR. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.
7.3.2 Pyrocathechol	
The Chair welcomed the representatives from the Government and Industry Interest Groups Working Party on Chemicals and of DG Employment. He informed that the Commission had requested ECHA to evaluate **1,2-dihydroxybenzene (pyrocatechol),** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 2 April 2024 until 3 June 2024 and the deadline for this request is 23 February 2025. The Government Industry Group Working Party on Chemicals commented on establishing a BOEL.	
The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for 1,2-dihydroxybenzene (pyrocatechol). RAC agreed to use submucosal hyperplasia in the glandular stomach of the rats exposed to pyrocatechol in the diet as a critical effect for the evaluation of occupational exposure limits. A more elaborate justification of why hyperplasia and not tumour incidence was chosen as a critical effect for evaluation will be added to the RAC opinion.	**Rapporteurs** to revise the opinion in accordance with the agreed modifications at RAC-70 and to provide it to SECR. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

$BMDL_{10}$ obtained by model averaging using EFSA's Benchmark dose modelling tool was confirmed as a Point of Departure (PoD) for further steps in the evaluation. RAC agreed to apply an additional assessment factor of 10 due to marked differences in incidence rates of glandular stomach tumours between available rat studies and other uncertainties in the database. RAC did not agree with the Rapporteurs' proposal to apply an additional uncertainty factor of 2 to cover for overall uncertainties and limitations of the database. The calculations for the derived OEL value will be updated in the RAC opinion. RAC agreed not to propose any STEL. RAC agreed that a BLV and BGV are not proposed. RAC agreed to propose a Skin notation and a Skin sensitisation notation. The Rapporteurs were asked to include more information about skin sensitisation in the RAC opinion. RAC agreed to retain in the RAC opinion the derived 8h-TWA value (0.2 mg/m3) and to omit an ERR derivation. RAC adopted by consensus its opinion (with the modifications agreed at RAC-70).	

8. Harmonised classification and labelling (CLH)

8.1. General CLH issues

8.1.1. Report from the July CLH Working Group

The Secretariat presented the Report of the 14th Meeting of the Committee for Risk Assessment Applications for Classification and Labelling Working Group which took place on 1-3 July 2024. RAC took note of the Report.	

8.2. CLH dossiers

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

- **3,5-Dimethylpyrazole***: acute oral toxicity, STOT RE, adverse effects on or via lactation*
- **3,4-Dimethyl-1*H*-pyrazole:** *acute toxicity via all routes, STOT RE, adverse effects on or via lactation*
- **3,4-Dimethyl-1*H*-pyrazol-1-ium dihydrogen phosphate:** *acute toxicity via all routes, STOT RE, adverse effects on or via lactation*

- **Borate minerals group:** *adverse effects on or via lactation*
- **Thermally treated garlic juice:** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, respiratory sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, hazards to the aquatic environment, hazards to the Ozone layer*
- **Fluazaindolizine (ISO):** *physical hazards, hazards to the aquatic environment*
- **[Ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid:** *mutagenicity, STOT RE*
- **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt:** *mutagenicity, STOT RE*
- **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt:** *mutagenicity, STOT RE*
- **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt** *mutagenicity, STOT RE*
- **2-Pyrrolidone:** *reproductive toxicity – fertility and effects on or via lactation*
- **Rape oil; rape seed oil:** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, hazards to the aquatic environment*
- **Tebuconazole (ISO):** *acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, effects on or via lactation, aspiration hazard*
- **Eugenol (dossier from the Spanish Competent Authority):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, mutagenicity, carcinogenicity, STOT SE, STOT RE, reproductive toxicity, hazard to the aquatic environment, hazard to the Ozone layer*
- **Eugenol (dossier from the Danish Competent Authority and includes only Skin Sensitisation):** *skin sensitisation*
- **Silver nitrate:** *physical hazards, hazards to the aquatic environment*

8.2.2. Hazard classes for agreement with plenary debate

8.2.2.1 3,5-Dimethylpyrazole (EC 200-657-5, CAS 67-51-6): *reproductive toxicity – fertility and development*

The Chair welcomed an expert accompanying the CEFIC Regular Stakeholder. He then provided some general information on the uses of **3,5-dimethylpyrazole,** existing harmonized classification, proposed classification by the Dossier Submitter (BE) and legal deadline.
Acute oral toxicity, reproductive toxicity and STOT RE were the hazard classes open for comments during the Consultation.
The expert accompanying the CEFIC Regular Stakeholder Observer commented on fertility.

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 = 1 700 mg/kg bw), STOT RE 2; H373 (liver, blood)]	**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	**Borate minerals group:** *reproductive toxicity – fertility and development*
8.2.2.1	Ulexite ($CaNaH_{12}(BO_3)_5 \times 2H_2O$) [1] ulexite ($CaNaH_{12}(BO_3)_5 \times 2H_2O$), calcined [2] (EC - [1] 296-662-5 [2], CAS 1319-33-1 [1] 92908-33-3 [2])
8.2.2.2	Colemanite ($CaH(BO_2)_3 \times 2H_2O$) [1] boron calcium oxide ($B_6Ca_2O_{11}$), hydrate (1:5) [2] colemanite, calcined [3] (EC - [1] - [2] 296-640-5 [3], CAS 1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3])
8.2.2.3	Tincalconite ($B_4Na_2O_7 \times 5H_2O$) (EC -, CAS 12045-88-4)

The Chair welcomed the Dossier Submitter representative and the Occasional Stakeholder Observer (PSCI). He then provided some general information on the uses of **borate minerals group,** existing harmonized classification, proposed classification by the Dossier Submitter (SE) and legal deadline.
Reproductive toxicity was the only hazard classes open for comments during the Consultation.
The Working Group discussed the proposed hazard classes and reached the following conclusions.

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, Note 11]	**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.

8.2.3	**[Ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid** (EC 215-851-5, CAS 1429-50-1): *carcinogenicity*
8.2.4	**[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt** (EC 287-370-9, CAS 85480-89-3): *carcinogenicity*
8.2.5	**[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt** (EC 251-910-1, CAS 234274-30-1): *carcinogenicity*
8.2.6	**[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt** (EC 244-742-5, CAS 22036-77-7): *carcinogenicity*

The Deputy Chair welcomed an expert accompanying the CEFIC Regular Stakeholder Observer. He then provided some general information on the uses of **[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid,**

[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium, sodium salt, [Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt and **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt,** existing harmonized classification, proposed classification by the Dossier Submitter (DE) and legal deadline. Mutagenicity, carcinogenicity and STOT RE were the 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. [Carc. 1B; H350]	**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 Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.7 2-Pyrrolidone; pyrrolidin-2-one (EC 210-483-1, CAS 616-45-5): *reproductive toxicity – development*	
The co-Chair welcomed the Dossier Submitter representatives and an expert accompanying the Regular Stakeholder Observer (CEFIC). He then provided some general information on the uses of **2-pyrrolidone; pyrrolidin-2-one,** proposed classification by the Dossier Submitter (NO) and legal deadline. Reproductive toxicity was the only hazard class open for comments during the Consultation. The Working Group discussed it and reached the following conclusions.	
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; H360D with SCL = 3 %]	**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.
8.2.8 Tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol (EC 403-640-2; CAS 107534-96-3): *reproductive toxicity – fertility and development*	

The Chair welcomed the Dossier Submitter representative, an expert accompanying the Regular Stakeholder Observer (CEFIC), and an expert accompanying the Regular Stakeholder Observer (CropLife Europe). He then provided some general information on the uses of **tebuconazole (ISO),** proposed classification by the Dossier Submitter (DK) and legal deadline. Acute toxicity, skin corrosion/skin irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard were the hazard classes open for comments during the Consultation. The Working Group discussed the proposed hazard classes and reached the following conclusions. The CropLife Europe Regular Stakeholder Observer and an expert accompanying him commented on fertility and sexual function, and development and on quality of RAC assessment.	
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. Rapporteur was tasked to provide some additional details in the assessment of the relevant studies. [Repr. 1B; H360FD, Acute toxicity 4; H302 (ATE = 1 700 mg/kg bw), STOT RE 2; H373 (eyes, liver)]	**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.
8.2.9 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 EMA representatives, the IMA-Europe Occasional Stakeholder Observer with an accompanying expert, the PSCI Occasional Stakeholder Observer, as well as the experts accompanying the CEFIC and Eurometaux Regular Stakeholder Observers. 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. The opinion on this dossier has been discussed already in the RAC-69 CLH WG, RAC-69 and RAC-70 CLH WG. The IMA-Europe Occasional Stakeholder Observer, his accompanying expert, the expert accompanying the CEFIC Regular Stakeholder Observer, the expert accompanying the Eurometaux Regular Stakeholder Observer, the EMA representative, the EFSA representative and the Eurometaux Regular Stakeholder Observer commented on carcinogenicity.	
Carcinogenicity RAC considered in details all the available findings and took stock of the previous discussions and agreements held in previous meetings. Following extensive discussion, RAC concluded by consensus that Talc warrants **Carc. 1B** classification according to CLP criteria. This was based on the following aspects:	**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.

* RAC noted that under CLP Regulation Annex I, Table 3.6.1 "..., *on a case-by-case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals*." * RAC concluded that there is sufficient evidence that talc can induce tumours at different sites (non-systemic at port-of-entry/after translocation via different routes of exposure) and in different species based on limited evidence in animals (lung tumours in female rats) and limited evidence in humans (ovarian tumours in women). * RAC noted that the analogous mode of action for both tumour types (lung tumours in rats and ovarian tumours in women) is biologically plausible and therefore supports combined weighting of the carcinogenicity evidence. * RAC also concluded that experimental animal data with inferred causality (talc being the causative agent), supports causal interpretation of ovarian cancer studies in humans. * RAC considered that less weight should be placed on rat pheochromocytomas (due to very high background incidences above HCD), but noted that this is a rare tumour type, which is considered, in principle, of human relevance. * Overall, RAC concluded that due to these aspects discussed in detail, the case of talc carcinogenicity is considered applicable to the specific paragraph of CLP reported above (Annex I, Table 3.6.1). RAC also discussed the possibility to state the route of exposure based on inadequacy or lack of data demonstrating carcinogencity for some routes. However, RAC noted that CLP criteria (Annex I, Table 3.6.3) indicates that "*state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard*". Therefore, RAC concluded that no specific route of exposure can be designated due to inadequacy or lack of data demonstrating the lack of carcinogenicity via other routes (such as oral or dermal). Finally, the Rapporteurs were tasked by RAC to transparently reflect on the uncertainties in the final RAC opinion, including the use of the provision in Annex I, Table 3.6.1 relating to the use, on a case-by-case basis, of limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals to justify classification in category 1B (including emphasizing that the	**Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

use of this provision is considered applicable to the case at stake but application to other cases should require a case-by-case approach). RAC <u>adopted by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Carc. 1B; H350, STOT RE 1; H372 (lungs, inhalation)]	

8.2.10	**Bourgeonal group:** *all relevant hazard classes*
8.2.10.1	2-(4-*tert*-butylbenzyl) propionaldehyde (EC 201-289-8, CAS 80-54-6)
8.2.10.2	4-*tert*-butylbenzoic acid (EC 202-696-3, CAS 98-73-7)
8.2.10.3	3-(4-*tert*-butylphenyl)propionaldehyde [1] 4-*tert*-butyltoluene [2] 4-*tert*-butylbenzaldehyde [3] methyl 4-*tert*-butylbenzoate [4] (EC 242-016-2 [1] 202-675-9 [2] 213-367-9 [3] 247-768-5 [4], CAS 18127-01-0 [1] 98-51-1 [2] 939-97-9 [3] 26537-19-9 [4])

The Chair welcomed the DS representatives, the Occasional Stakeholder Observers from IFRA, PSCI and EFEO, as well as the accompanying experts to the IFRA and EFEO Occasional Observers. He then provided some general information on the uses of **bourgeonal group,** 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.

The experts accompanying the IFRA and EFEO Occasional Stakeholder Observers commented on reproductive toxicity.

The Rapporteur presented and RAC discussed the first draft opinions on the Bourgeonal group and the Cyclamal group dossiers. The conclusions below apply to both groups. **Reproductive toxicity** <u>Fertility</u> RAC preliminary agreed with the read across approach as used by the DS. RAC preliminary agreed that Repr. 1B classification is warranted, based on read across proposed. RAC concluded that the available data demonstrate clear evidence for adverse effects on sexual function and fertility for all members of both groups. Additional support comes from the harmonised classification of Lysmeral and TBBA as Repr 1B, H360F. <u>Development</u>	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to organise a RAC consultation on the revised draft opinion and to table it for further discussion at RAC-71 CLH WG and RAC-71.

RAC discussed the uncertainties related to the read across proposed by the DS and will continue the discussion in further meetings. <u>Lactation</u> RAC preliminary agreed not to classify the substances for lactation. RAC will continue the discussion on the dossiers in RAC-71 CLH WG and RAC-71.	
8.2.11 Cyclamal group: *all relevant hazard classes* 8.2.11.1 *p*-cymene; 1-isopropyl-4-methylbenzene and 3-*p*-cumenyl-2-methylpropionaldehyde (EC 202-796-7, CAS 99-87-6) and 8.2.11.2 2-methyl-3-(4-isopropylphenyl)propanal [1]; 3-(*p*-cumenyl)propionaldehyde; 3-(4-isopropylphenyl)propanal [2] ; 4-isopropylbenzaldehyde; cuminic aldehyde [3] ; 4-isopropylbenzoic acid; cuminic acid [4] (EC 203-161-7 [1]; 231-885-3 [2]; 204-516-9 [3]; 208-642-5 [4], CAS 103-95-7 [1]; 7775-00-0 [2]; 122-03-2 [3]; 536-66-3 [4])	
The Chair welcomed the DS representatives, the Occasional Stakeholder Observers from IFRA, PSCI and EFEO, as well as the accompanying experts to the IFRA and EFEO Occasional Observers. He then provided some general information on the uses of **cyclamal group,** 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. The experts accompanying the IFRA and EFEO Occasional Stakeholder Observers commented on reproductive toxicity.	
See above (under point 8.2.10).	
8.2.12 Silver nitrate (EC 231-853-9, CAS 7761-88-8): *part of HH hazard classes*	
The Chair welcomed the Dossier Submitter representatives, the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers and the AISE Occasional Stakeholder Observer with an accompanying expert. He then provided some general information on the uses of **silver nitrate,** proposed classification by the Dossier Submitter (SE) and legal deadline. All relevant hazard classes, except for aspiration hazard and the hazard to the ozone layer, were open for comments during the Consultation. The expert accompanying the Eurometaux Regular Stakeholder Observer commented on acute toxicity, skin corrosion, eye irritation, skin sensitisation, The expert accompanying the CEFIC Regular Stakeholder Observer commented on skin sensitisation.	
RAC agreed on the following classification:	**Rapporteurs** to revise the opinion (HH) in accordance with

• ***Physical hazards*** – Ox. Sol. 1; H271 (including Note T), Met. Corr. 1; H290 and No classification for the other hazard classes considered • ***Acute oral toxicity –*** Acute Tox. 2; H300 (ATE=50 mg/kg bw) • ***Acute dermal toxicity –*** No classification (due to inconclusive data) • ***Acute inhalation toxicity –*** No classification (due to lack of data) • Addition of ***EUH071*** • ***STOT SE –*** No classification (due to inconclusive data) • ***Skin corrosion/irritation –*** Skin Corr. 1A; H314 • ***Serious eye damage/eye irritation*** – Eye Dam. 1; H318 • ***Respiratory sensitisation –*** No classification • ***Skin sensitisation –*** Skin Sens. 1; H317 • ***Aquatic toxicity*** – Aquatic Acute 1; H400 (M=1000) and Aquatic Chronic 1; H410 (M=100) The other HH hazard classes (reproductive toxicity, mutagenicity and STOT RE) will be discussed in the RAC-71 CLH WG and RAC-71. The discussion on carcinogenicity is postponed due to the new study that will be provided by Industry in the last quarter of 2024.	the discussion in RAC and to provide it to Secretariat. **Secretariat** to organise a RAC consultation on the revised draft opinion (HH) and to table it for further discussion at RAC-71 CLH WG and RAC-71.
9. Restrictions	
9.1. General restriction issues	
9.1.1. Report from the September REST Working Group	
The Secretariat informed that the September REST Working Group was cancelled.	**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 launch a written consultation in October/November and to table the topic for discussion in November 2024. **Members** to provide comments in the RAC written consultation.
9.2. Restriction Annex XV dossiers	

9.2.1. Opinion development on Universal per- and polyfluoroalkyl substances (UPFAS) – a) state of play and next steps b) Evaluation of sector-/use-specific aspects of UPFAS restriction proposal: i. Waste emissions (cont.) ii. Textiles, upholstery, leather, apparel, carpets (TULAC) iii. Food contact materials and packaging iv. Petroleum and mining	
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 AESGP, ASD, APPLiA, Aqua Europe, Animal Health Europe, CEWEP, CONCAWE, EFPIA, EuChemS, Euroheat and Power, EPEE, ESF, EuPC, Euratex, Eurelectric, EurEau, FEC, IOGP, Orgalim, Plastics Recyclers Europe, PU Europe, TEPPFA, TIC Council and the accompanying experts to the Regular Stakeholder Observers from AISE, Cefic, CropLife Europe, Client Earth, 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. <u>Waste stage and emissions</u> The observers and their accompanying experts from CEWEP, ClientEarth, CONCAWE, EEB, EurEAU, PlasticsEurope, and PRE commented on number of issues covering emissions and exposure. The Dossier Submitter (DS) representatives provided clarifications and comments related to emissions. <u>Textiles, upholstery, leather, apparel, carpects (TULAC)</u> The observers and their accompanying experts from ClientEarth, EEB, EURATEX, ESF commented on number of issues related to sector specific elements. Furthermore, the Dossier Submitter (DS) representatives and the Commission observer provided clarifications to the scope and comments on emissions. <u>Food contact materials and packaging</u> The observers and their accompanying experts from APPLiA, ClientEarth, CropLife Europe, EEB, FEC, and PlasticsEurope commented on number of issues related to sector specific elements. Furthermore, the Dossier Submitter (DS) representatives provided clarifications to release factors and derogations. <u>Petroleum and mining</u> The observers and their accompanying experts from ClientEarth, Concawe, EEB, Eurometaux and IOGP commented on number of issues related to sector specific elements. Furthermore, the Dossier Submitter (DS) representatives provided additional clarifications.	
Regarding emissions and exposure, RAC noted the following updates since RAC-69: <u>Fluoropolymer emission factors (cont).</u> → During their lifecycle, fluoropolymers can lead to emissions of particles and to leachables emissions (consisting for instance of PFAS–based processing aids not chemically bound to the polymer) leaching out of the polymer and of PFAAs and PFAA precursors generated during incineration. RAC	**Rapporteurs** to make the changes in the draft opinion taking into account the comments received from the RAC written commenting round and discussions in RAC-70. **SECR** to table further discussions as follows:

considered that it is important to distinguish between the particle and leachables emissions because of concerns associated with fluoropolymer (micro)particles differ from those of non-polymeric PFAS. → RAC agreed that for the estimation of fluoropolymer emissions, the release factors should be applied to the amount of non-polymeric leachables present in fluoropolymer, rather than the total polymer weight. → RAC proposed to use 1000 ppm as a conservative estimate of leachables (non-polymeric PFAS) present in fluoropolymers. → RAC recognised that emissions of particles from fluoropolymer uses are likely to occur in many uses. However, it might not be possible to address these releases in a quantitative way in many cases. <u>Landfill</u> → Landfilling is considered as a relevant source of PFAS to the environment (water, ground water, soil and air). → For the case of PFAAs and PFAA precursors, the Dossier Submitter uses a release factor 0.0336 (account for both water and soil emissions). RAC agreed with the use of this release factor but noted that for PFAAs and PFAA precursors not included in matrices, a release factor of 1 is more appropriate. → For the case of polymeric PFAS, the Dossier Submitter proposed a release factor of 0.0016. However, RAC considered to use a release factor of 0.0336, based on ECHA Guideline R.18. For the specific case of Fluoropolymers the release factor of 0.0336 should be applied over the amount of leachable PFAS estimated in the material (1000ppm). → RAC recognised that the release of microparticles is also possible in landfills but did not consider feasible to quantify these releases. <u>Incineration</u> → RAC agreed that incineration in hazardous waste incinerators (e.g. rotary kilns) at ≥1100 °C is the most effective way of PFAS destruction, although it may not result in complete mineralisation. → Combustion at lower temperatures (e.g. in municipal incineration facilities with temperatures typically <1 100C) and/or insufficient oxygen supply might lead to transformation of longer-chain PFAS (including fluoropolymers) to short-chain, more thermally stable PFAS and <u>thus is not considered to be effective by RAC</u>.	<u>RAC-71 November 2024 (tentative)</u> → Textiles, upholstery, leather, apparel, carpets (TULAC) (cont); → Food contact materials (FCM) and packaging (cont); and → Construction products <u>Following plenaries (tentative)</u> → Applications of fluorinated gases → Transport → Energy More information about the committees' plans will be announced as work advances. This information will be communicated in conjunction with the committee meetings.

→ RAC proposed to apply an emission factor of 0.01 for incineration of hazardous waste (in line with the previous RAC opinion on PFAS in firefighting foams). → RAC proposed an emission factor of 0.02 for incineration of non-hazardous waste and highlights the higher uncertainties associated with this estimate. <u>Wastewater treatment</u> → RAC confirmed the earlier outcome from RAC-69 regarding wastewater treatment effectiveness. → In addition, RAC agreed with the Dossier Submitter that the use of a release factor of 0.5 for fluoropolymer particle releases might be appropriate. However, RAC noted that there is limited information on the volume of fluoropolymer particles entering wastewater and therefore this release factor has not been applied by the Dossier Submitter for the calculation of particles emissions. <u>Textiles, upholstery, leather, apparel, carpets (TULAC)</u> In general, RAC supported the rapporteurs' evaluation on the sector-specific elements for TULAC 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. However, additional work might be required for example for protective equipment. Furthermore, RAC noted that there will be further changes, based on the agreements on the general approach and the RAC comments received on this sector. <u>Updates from RAC-66 on pending issues related to food contact materials and packaging:</u> RAC took note of the updates and RAC provisionally agreed with conclusions regarding the sector specific elements on food contact materials and packaging. RAC supported the rapporteurs' evaluation on the sector-specific elements for FCM 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. Furthermore, RAC noted that there will be further changes, based on the agreements on the general approach and the RAC comments received on this sector.	

Petroleum and mining RAC supported the rapporteurs' evaluation on the sector-specific elements for petroleum and mining i.e. volumes, emissions, risk characterization and effectiveness in reducing the identified risk. Regarding risk of alternatives, potential specific sector/use specific derogations and uncertainties: → RAC concluded that some chemical alternatives are considered less hazardous than PFAS for use as anti-foaming agents (safer alternatives). → RAC concluded that most of the alternatives listed by the Dossier Submitter for PFAS oil and gas tracers have severe hazards and are therefore not considered safer alternatives for PFAS. → RAC noted, however, that possible alternatives (d13C and d18O) might be less hazardous, (RAC notes insufficient data available in the Background Document.) → Some of the proposed alternatives lack sufficient data, hindering an assessment by RAC. This applies to fluorinated benzophenols which have been suggested as alternatives for water-tracers but may have persistent properties. RAC however noted that there might be differences between fluorinated benzophenols in terms of their persistence. → The derogation for oil/gas tracers is supported by RAC considering the hazard profile of most of the alternatives but noted that there may be some alternatives less hazardous than PFAS. → RAC proposed to require additional RMMs to ensure PFAS emissions are minimised. Therefore, RAC provisionally agreed with conclusions regarding the sector-specific elements on petroleum and mining.	
10. Authorisation	
10.1. General authorisation issues	
10.1.1. 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	

No content under this agenda item.	
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. 354_RR1_CT_Airbus (2 uses) 2. 355_RR1_SD_Airbus (1 use) 3. 356_RR1_SD_AD-International (1 use) 4. 359_RR1_CT_Circuit (1 use) 5. 361_TEL_Trafigura (1 use) 6. 362_TEL_Warter-Fuels (1 use) 7. 363_CT_Indestructible_Paint_Turbines (1 use) RAC agreed by consensus the eight draft opinions on the Application listed in Annex IV. RAC discussed: - Overlap between REACH and other workers protection legislation and its impact for practice to reduce workers exposure - Difficulty to compare exposure data due to differences in approach to exposure assessment by applicants/authorisation holders in initial AFAs and RRs.	**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)	
Use1: *Formulation of DEHP mixtures for application in immediate packaging of medicines and medical devices.* RAC discussed: - appropriateness and effectiveness of OCs and RMMs, - available measurements and modelling results, - timing by when the applicant has to implement the RMMs they have promised to implement (end of 2024), - effectiveness of the implemented OCs and RMMs should be confirmed by the measurement data. RAC concluded that the operational conditions and risk management measures for the endocrine disrupting properties of the substance described in the application are:	**Rapporteur** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

• not appropriate and effective in limiting the risk to workers for the Lessines and Medolla sites, however they are expected to be appropriate when the OCs and RMMs are fully implemented. • expected to be appropriate and effective in limiting the risk to workers for the Castlebar and Marsa sites (potential future sites), when the OCs and RMMs are fully implemented, as expected to be implemented in the Lessines and Medolla sites. • appropriate and effective in limiting the risk to the general population and the environment for the Lessines and Medolla sites. • expected to be appropriate and effective in limiting the risk to the general population and the environment for the Castlebar and Marsa sites (potential future sites). RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall implement at all sites (including any future site) all OCs and RMMs as already planned and technical improvements to the OCs/RMMs to minimise the DEHP concentration at the workplace and reduce workers' exposure to DEHP, as already described in the CSR and in Annex I, and additionally: i. Installation of ventilation systems with adequate abatement systems where emissions/exposures are expected, particularly at the extruders and cold mixers. 2. The applicant shall implement at all sites (including any future site) technical improvements to the OCs/RMMs to minimise the emissions of DEHP to the environment, as already described in the CSR and in Annex 1. These conditions 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. 3. Without prejudice to points 1-3 above, the applicant and their DUs shall carry out and document a detailed feasibility study on: i. the possibility to limit further the open handling and manual activities with DEHP and DEHP-containing mixtures during sampling and quality controls through the implementation of closed or automated systems.	

The feasibility study 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 further reduce workplace exposure to DEHP to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation with additional request in point 6: For the Castlebar and Marsa sites (future sites), the applicant shall conduct the monitoring programmes mentioned in 1.a (i) and 1.b (i) to ensure the impacts of the expansion are closely monitored. Section 9: recommendations for the review report **Use2:** *Use of DEHP-containing plastics for immediate packaging of medicinal products.* RAC discussed: - outcome of the discussion on Use 1 above will apply also to the Use 2, - advice to provide biomonitoring in order to assess exposure to DEHP. RAC concluded that the operational conditions and risk management measures for the endocrine disrupting properties of the substance described in the application are: • not appropriate and effective in limiting the risk to workers for the Lessines, Castlebar and Marsa sites. • not expected to be appropriate and effective in limiting the risk to workers for the Medolla site (potential future site) • appropriate and effective in limiting the risk to the general population and the environment for the Lessines, Castlebar and Marsa sites • expected to be appropriate and effective in limiting the risk to the general population and the environment for the Medolla site (potential future site) RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall implement at all sites (including any future site) all OCs and RMMs as already planned and technical improvements to the OCs/RMMs to minimise the DEHP concentration at the workplace and reduce workers' exposure to	

DEHP, as already described in the CSR and in Annex I, and additionally: i. Installation of ventilation systems with adequate abatement systems where emissions/exposures are expected, particularly at the extruders and for the waste management, 2. The applicant shall implement at all sites (including any future site) technical improvements to the OCs/RMMs to minimise the emissions of DEHP to the environment, as already described in the CSR and in Annex 1. These conditions 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. 3. Without prejudice to points 1-3 above, the applicant and their DUs shall carry out and document a detailed feasibility study on: ii. the possibility to limit further the open handling and manual activities with DEHP and DEHP-containing mixtures during sampling and quality controls through the implementation of closed or automated systems. The feasibility study 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 further reduce workplace exposure to DEHP to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation with additional request in point 6: For the Castlebar and Marsa sites (future sites), the applicant shall conduct the monitoring programmes mentioned in 1.a (i) and 1.b (i) to ensure the impacts of the expansion are closely monitored. Section 9: recommendations for the review report **Use 3:** Use of DEHP-based mixtures as a lubricating/sealing agent for the insertion of port closures into empty bags and assembly/connection of parts, that are used in immediate packaging of medicines RAC discussed: - scope of the available measurement data,	

- involvement of workers in operations of Uses 1 and 2, in addition to Use 3. RAC concluded that the operational conditions and risk management measures for the endocrine disrupting properties of the substance described in the application are: • not appropriate and effective in limiting the risk to workers for the Lessines and Castlebar sites. • not expected to be appropriate and effective in limiting the risk to workers for the Marsa and Medolla sites (potential future sites). • appropriate and effective in limiting the risk to the general population and the environment for the Lessines and Castlebar sites. • expected to be appropriate and effective in limiting the risk to the general population and the environment for the Marsa and Medolla sites (potential future sites). RAC agreed: Section 7: additional conditions for the authorisation The applicant shall implement at all sites (including any future site) technical improvements to the OCs/RMMs to minimise the DEHP concentration at the workplace and reduce workers' exposure to DEHP, as already described in the application and in Annex I. The applicant shall implement technical improvements to the OCs/RMMs to minimise the emissions of DEHP to the environment, as already described in the application and in Annex I: For the Marsa and Medolla sites (potential future sites), collection and disposal for adequate treatment of all waste generated from the processes. These conditions 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. Without prejudice to points 1-2 above, the applicant and their DUs shall carry out and document a detailed feasibility study on: i. the possibility to limit further the open handling and manual activities with DEHP and DEHP-containing mixtures during filling of steel drums, mixing process by agitation, sampling and quality	

controls through the implementation of closed or automated systems. The feasibility study 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 further reduce workplace exposure to DEHP to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation with additional request in point 6: 6. For the Medolla and Marsa sites, the applicant shall conduct the monitoring programmes mentioned in 1.a (i) and 1.b (i) at least until the plant functions at full capacity to ensure the impacts of the expansion are closely monitored. Afterwards, the applicant may reduce the frequency of measurements, once they can clearly demonstrate to the national Competent Authority of the Member State where the use takes place, that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions function appropriately. Section 9: recommendations for the review report RAC agreed on the draft opinions by consensus.	
10.3.2.2. 357_RR1_PD_Lynred (1 use)	
Use1: *Industrial use of potassium dichromate-based mixtures during the step of final etching of CZT layers during the production of opto-electronic components gathering a readout and an infrared detecting circuit with the MCT technology.* RAC discussed: - RAC members comments on appropriateness of RMMs and OCs and representativeness of the measurements data used for exposure assessment. Regarding the exposure to Cr(VI) associated with the use of potassium dichromate, RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk for the workers and for the general population via the environment, provided that they are implemented and adhered to. Regarding the reproductive hazards associated with the use of potassium dichromate, RAC concluded that the risk	**Rapporteur** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

assessment presented in the review report demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to. RAC agreed: Section 7: additional conditions for the authorisation None Section 8: monitoring arrangements for the authorisation Section 9: recommendations for the review report RAC agreed on the draft opinion by consensus.	
10.3.2.3. 358_RR1_AsA_Circuit (1 use)	
Use1: *Industrial use of arsenic acid for the treatment of copper foil used in the manufacture of printed circuit board.* RAC discussed: - Relation between air monitoring data and biomonitoring data and high values of biomonitoring - Concerns related to the methodology of the biomonitoring - Potential dermal and hand-to-mouth exposure and/or other routes of exposure, and a condition for the authorisation holder to investigate biomonitoring results - Appropriateness of existing operational conditions and risk management measures. RAC agreed that the operational conditions and risk management measures described in the review report are **not** appropriate and effective in limiting the risk. RAC requested the Rapporteur to revise the draft opinion to address the discussion during the plenary to justify the conclusion that OCs and RMMs are not appropriate and to propose additional hard condition for the authorisation.	**Rapporteur** together with **SECR** to do address the discussion in draft opinion. **SECR** to launch RAC consultation on the revised draft opinion and then schedule the draft opinion for discussion at RAC-71 in November/December 2024.
10.4. Adoption of opinions	
10.4.1. 11 ADCR RRs, 10 ADCR AfAs	
1. 325_ADCR_Anodise_sealing (1 use) 2. 326_ADCR_Anodising (1 use) 3. 327_ADCR_Chemical_conversion_coating (1 use) 4. 328_ADCR_Chromate_rinsing (1 use) 5. 329_ADCR_Electroplating (1 use) 6. 330_ADCR_Finish_stripping (1 use) 7. 331_ADCR_Formulation (1 use) 8. 332_ADCR_Passivation_metallic_coatings (1 use)	**Rapporteurs** together with **SECR** to do the final editing of the final opinions. **SECR** to send the final opinions to the applicant, the European Commission and MS CAs.

9. 333_ADCR_Pre-treatments (1 use) 10. 334_ADCR_Stainless_steel_passivation (1 use) 11. 335_ADCR_RR_Anodising (1 use) 12. 336_ADCR_RR_Anodise_sealing (1 use) 13. 337_ADCR_RR_Chemical_conversion_coating (1 use) 14. 338_ADCR_RR_Chromate_rinsing (1 use) 15. 339_ADCR_RR_Electroplating (1 use) 16. 340_ADCR_RR_Finish_stripping (1 use) 17. 341_ADCR_RR_Formulation (1 use) 18. 342_ADCR_RR_Passivation_metallic_coatings (1 use) 19. 343_ADCR_RR_Pre-treatments (1 use) 20. 344_ADCR_RR_Slurry_coating (1 use) 21. 345_ADCR_RR_Stainless_steel_passivation (1 use) The rapporteurs presented applicants comments on the draft opinions: - No changes were made to RAC's conclusions in the draft opinions following the applicant's/AH's comments. - No major modifications were made to the RAC opinions as the consequence of the comments received by the RAC members during consultation on the draft final opinions. - Certain modifications were made to the draft final opinions to address comments, mostly of editorial nature, as well as some misinterpretations and clarifications provided by the ADCR consortium as part of their comments. RAC adopted the final opinions by consensus.	
346_CT_Safran_landing_systems (2 uses)	
Use 1: *Industrial use of chromium trioxide for hard chrome plating to provide key functional properties such as wear resistance (...) in the manufacturing of landing and braking system parts for aeronautical applications exclusively supplied by Safran Landing Systems without technical limitations with the identified alternative.* **Use 2:** *Industrial use of chromium trioxide for hard chrome plating in the manufacturing and the repairing of landing gear parts exclusively supplied by Safran Landing Systems and for which there is not yet potential alternatives identified as part of the substitution process.*	**Rapporteur** together with **SECR** to do the final editing of the final opinions. **SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

The adviser to the rapporteur presented applicants comments. The following RAC conclusions have been made: - The detailed calculation of the new release factor, specific data used for the calculations, refined exposure scenarios on the basis of new data (i.e. any changes in duration and/or frequency activities or PPE used related to WCS 5 and 6) and the risk assessment is not available for RAC. - The currently used abatement system is temporary and its constant adaptation and/or automation would be the next step that, probably, in this case would need control measurements to confirm the previously obtained results from the temporary system. Therefore, the rapporteur recommended RAC to adopt the final opinions without changes in RAC sections. RAC adopted the final opinion by consensus.	
347_CT_Safran_Aircraft_Engines (1 use)	
Use 1: *Industrial use of slurry mixtures containing chromium trioxide for the surface treatment of aircraft engines parts including turbines and compressors.* The rapporteurs presented applicants comments on the draft opinion and informed RAC that after consideration of the applicants comments they propose to change implementation time of the proposed additional conditions for the authorisation from 12 to 24 months. The rapporteurs proposed no additional changes in other RAC conclusions. 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 latest round of consultation on draft DWD Guidance documents (June-July 2024) - Update on the work of the informal group on Toxicokinetics - Plan for finalising the Guidance documents - RAC-DWD IT tools user group - Other DWD news.	
12. AOB	

None.	
13. Minutes of RAC-70	
13.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-70	
RAC adopted the final minutes 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-70

1. eugenol; 2-methoxy-4-(prop-2-en-1-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	No current Annex VI entry										
Dossier submitters proposal	TBD	eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol	202-589-1	97-53-0	Acute Tox. 4 STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1A Aquatic Chronic 2	H302 H336 H315 H319 H317 H411	GHS07 GHS09 Wng	H302 H336 H315 H319 H317 H411		oral ATE = 1930 mg/kg bw	
RAC opinion	TBD	eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol	202-589-1	97-53-0	Acute Tox. 4 STOT SE 3 Skin Sens. 1B	H302 H336 H317	GHS07 Wng	H302 H336 H317		oral ATE = 1930 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	eugenol; 2-methoxy-4-(prop-2-en-1-yl)phenol	202-589-1	97-53-0	Acute Tox. 4 STOT SE 3 Skin Sens. 1B	H302 H336 H317	GHS07 Wng	H302 H336 H317		oral ATE = 1930 mg/kg bw	

2. thermally treated garlic juice

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	thermally treated garlic juice	N/A	N/A	Skin Sens. 1B	H317	GHS07 Wng	H317			
RAC opinion	TBD	thermally treated garlic juice	N/A	N/A	Skin Sens. 1B	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	thermally treated garlic juice	N/A	N/A	Skin Sens. 1B	H317	GHS07 Wng	H317			

3. rape oil; rape seed oil

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	rape oil; rape seed oil	232-299-0	8002-13-9	Aquatic Chronic 4	H413		H413			
RAC opinion	TBD	rape oil; rape seed oil	232-299-0	8002-13-9	No classification	-	-	-			
Resulting Annex VI entry if agreed by COM	TBD	rape oil; rape seed oil	232-299-0	8002-13-9	No classification	-	-	-			

4. talc ($Mg_3H_2(SiO_3)_4$)

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	Talc ($Mg_3H_2(SiO_3)_4$)	238-877-9	14807-96-6	Carc. 2 STOT RE 1	H351 H372 (lungs, inhalation)	GHS08 Dgr	H351 H372 (lungs, inhalation)			
RAC opinion	TBD	Talc ($Mg_3H_2(SiO_3)_4$)	238-877-9	14807-96-6	Carc. 1B STOT RE 1	H350 H372 (lungs, (inhalation)	GHS08 Dgr	H350 H372 (lungs, inhalation)			
Resulting Annex VI entry if agreed by COM	TBD	Talc ($Mg_3H_2(SiO_3)_4$)	238-877-9	14807-96-6	Carc. 1B STOT RE 1	H350 H372 (lungs, inhalation)	GHS08 Dgr	H350 H372 (lungs, inhalation)			

5. 3,5-dimethylpyrazole

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	3,5-dimethylpyrazole	200-657-5	67-51-6	Repr. 1B Acute Tox. 4 STOT RE 2	H360FD H302 H373 (liver, blood)	GHS08 GHS07 Dgr	H360FD H302 H373 (liver, blood)		oral: ATE = 1700 mg/kg bw	
RAC opinion	TBD	3,5-dimethylpyrazole	200-657-5	67-51-6	Repr. 1B Acute Tox. 4 STOT RE 2	H360FD H302 H373 (liver, blood)	GHS08 GHS07 Dgr	H360FD H302 H373 (liver, blood)		oral: ATE = 1700 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	3,5-dimethylpyrazole	200-657-5	67-51-6	Repr. 1B Acute Tox. 4 STOT RE 2	H360FD H302 H373 (liver, blood)	GHS08 GHS07 Dgr	H360FD H302 H373 (liver, blood)		oral: ATE = 1700 mg/kg bw	

6. [ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid

1. [ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt

2. [ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt

3. [ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt

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	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid	215-851-5	1429-50-1	Carc. 1B	H350	GHS08 Dgr	H350		Carc. 1B; H350: C ≥ 1 %	
RAC opinion	TBD	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid	215-851-5	1429-50-1	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid	215-851-5	1429-50-1	Carc. 1B	H350	GHS08 Dgr	H350			

7.

	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	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt	287-370-9	85480-89-3	Carc. 1B	H350	GHS08 Dgr	H350		Carc. 1B; H350: C ≥ 1 %	
RAC opinion	TBD	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt	215-851-5	1429-50-1	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt	287-370-9	85480-89-3	Carc. 1B	H350	GHS08 Dgr	H350			

8.

	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	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt	251-910-1	34274-30-1	Carc. 1B	H350	GHS08 Dgr	H350		Carc. 1B; H350: C ≥ 1 %	
RAC opinion	TBD	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt	251-910-1	34274-30-1	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt	251-910-1	34274-30-1	Carc. 1B	H350	GHS08 Dgr	H350			

	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	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt	244-742-5	22036-77-7	Carc. 1B	H350	GHS08 Dgr	H350		Carc. 1B; H350: C ≥ 1%	
RAC opinion	TBD	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt	244-742-5	22036-77-7	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt	244-742-5	22036-77-7	Carc. 1B	H350	GHS08 Dgr	H350			

7. ulexite ($CaNaH_{12}(BO_3)_5 \times 2H_2O$) [1], ulexite ($CaNaH_{12}(BO_3)_5 \times 2H_2O$), calcined [2];
4. colemanite ($CaH(BO_2)_3 \times 2H_2O$) [1]; boron calcium oxide ($B_6Ca_2O_{11}$), hydrate (1:5) [2],
5.colemanite, calcined [3]; tincalconite ($B_4Na_2O_7 \times 5H_2O$)

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	005-RST-VW-Y	ulexite ($CaNaH_{12}(BO_3)_5.2H_2O$) [1] ulexite ($CaNaH_{12}(BO_3)_5.2H_2O$), calcined [2];	- [1] 296-662-5 [2]	1319-33-1 [1] 92908-33-3 [2]	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11
RAC opinion	005-RST-VW-Y	ulexite ($CaNaH_{12}(BO_3)_5.2H_2O$) [1] ulexite ($CaNaH_{12}(BO_3)_5.2H_2O$), calcined [2];	- [1] 296-662-5 [2]	1319-33-1 [1] 92908-33-3 [2]	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11
Resulting Annex VI entry if agreed by COM	005-RST-VW-Y	ulexite ($CaNaH_{12}(BO_3)_5.2H_2O$) [1] ulexite ($CaNaH_{12}(BO_3)_5.2H_2O$), calcined [2];	- [1] 296-662-5 [2]	1319-33-1 [1] 92908-33-3 [2]	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11

Note 11: The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is ≥ 0.3 %.

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	005-RST-VW-Y	colemanite ($CaH(BO_2)_3.2H_2O$) [1] boron calcium oxide ($B_6Ca_2O_{11}$), hydrate (1:5) [2] colemanite, calcined [3]	- [1] - [2] 296-640-5 [3]	1318-33-8 [1] 854267-07-5 [2]	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11#

				92908-12-8 [3]							
RAC opinion	005-RST-VW-Y	colemanite ($CaH(BO_2)_3.2H_2O$) [1] boron calcium oxide ($B_6Ca_2O_{11}$), hydrate (1:5) [2] colemanite, calcined [3]	- [1] - [2] 296-640-5 [3]	1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3]	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11#
Resulting Annex VI entry if agreed by COM	005-RST-VW-Y	colemanite ($CaH(BO_2)_3.2H_2O$) [1] boron calcium oxide ($B_6Ca_2O_{11}$), hydrate (1:5) [2] colemanite, calcined [3]	- [1] - [2] 296-640-5 [3]	1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3]	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11#

Current draft for Note 11. To be confirmed by the Commission Regulation

Note 11: The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is ≥ 0.3 %.

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	005-RST-VW-Y	tincalconite ($B_4Na_2O_7.5H_2O$)	-	12045-88-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11#
RAC opinion	005-RST-VW-Y	tincalconite ($B_4Na_2O_7.5H_2O$)	-	12045-88-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11#
Resulting Annex VI entry if agreed by COM	005-RST-VW-Y	tincalconite ($B_4Na_2O_7.5H_2O$)	-	12045-88-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			11#

Current draft for Note 11. To be confirmed by the Commission Regulation

Note 11: The classification of mixtures as reproductive toxicant is necessary if the sum of the concentrations of individual boron compounds that are classified as reproductive toxicant in the mixture as placed on the market is ≥ 0.3 %.

8. 2-pyrrolidone; pyrrolidin-2-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	No current Annex VI entry										
Dossier submitters proposal	TBD	2-pyrrolidone; pyrrolidin-2-one	210-483-1	616-45-5	Repr. 1B	H360D	GHS08 Dgr	H360D			
RAC opinion	TBD	2-pyrrolidone; pyrrolidin-2-one	210-483-1	616-45-5	Repr. 1B	H360D	GHS08 Dgr	H360D		SCL = 3%	
Resulting Annex VI entry if agreed by COM	TBD	2-pyrrolidone; pyrrolidin-2-one	210-483-1	616-45-5	Repr. 1B	H360D	GHS08 Dgr	H360D		SCL = 3%	

9. tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1- ylmethyl)pentan-3-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	603-197-00-7	tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	403-640-2	107534-96-3	Repr. 2 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H361d*** H302 H400 H410	GHS08 GHS07 GHS09 Wng	H361d*** H302 H410		M = 1 M = 10	
Dossier submitters proposal	603-197-00-7	tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	403-640-2	107534-96-3	**Add** STOT RE 2 **Modify** Repr. 1B **Retain** Acute Tox. 4	**Add** H373 (eyes) **Modify** H360FD **Retain** H302	**Modify** Dgr **Retain** GHS08 GHS07	**Add** H373 (eyes) **Modify** H360FD **Retain** H302		**Add** oral: ATE = 1700 mg/kg bw	

RAC opinion	603-197-00-7	tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	403-640-2	107534-96-3	**Add** STOT RE 2 **Modify** Repr. 1B **Retain** Acute Tox. 4	**Add** H373 (eyes, liver) **Modify** H360FD **Retain** H302	**Modify** Dgr **Retain** GHS08 GHS07	**Add** 373 (eyes, liver) **Modify** H360FD **Retain** H302		**Add** oral: ATE = 1700 mg/kg bw	
Resulting Annex VI entry if agreed by COM	603-197-00-7	tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	403-640-2	107534-96-3	Repr. 1B Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H360FD H302 H373 (eyes, liver) H400 H410	GHS08 GHS07 GHS09 Dgr	H360FD H302 H373 (eyes, liver) H410		oral: ATE = 1700 mg/kg bw M = 1 M = 10	

Part III. List of Attendees of the RAC-70 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
Jankowska	Agnieszka
Kadikis	Normunds
Karadjova	Irina
Kloslova	Zuzana
Kondeva-Burdina	Magdalena
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Manusadzianas	Levonas
Martinek	Michal
Menard Srpčič	Anja
Mendas Starcevic	Gordana
Mohammed	Ifthekhar Ali
Neumann	Michael
Piña	Benjamin
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schuur	Gerlienke
Smith	Jenny
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
Dumke	Carolin	Urs Schlüter
Catone	Tiziana	Gabriele Aquilina
Marinkovic	Marino	Gerlienke Schuur
Moeller	Ruth	Annemarie Losert
Moilanen	Marianne	Riitta Leinonen
Murray	Brendan	Jenny Smith
Panieri	Emiliano	Dania Esposito
Pink	Mario	Nina Tekpli
Russo	Maria Teresa	Gabriele Aquilina
Suutari	Tiina	Riitta Leinonen

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)
Podniece	Zinta	DG EMPL
Roebben	Gert	DG GROW
EU Agency Observers		
Barthelemy	Eric	EFSA
Mech	Agnieska	EFSA
Smeraldi	Camilla	EFSA
van Doesum-Wolters	Franciska	EMA
De Vries	Corinne	EMA

Invited experts		**Role/Substance**
Zlochova	Tereza	RAC member nominee
Levy	Patrick	Working Party on Chemicals (WPC)
Saarikoski	Sirkku	Working Party on Chemicals (WPC)

SEAC Rapporteurs		
Cogen	Simon	UPFAS
Fankhauser	Simone	UPFAS

Dossier submitters		**Substance**
Averbeck	Frauke	(DE) - UPFAS
Axelstad	Marta	(DK) - Tebuconazole
Baumbusch	Angelika	(NO) - UPFAS
Birgander	Pernilla	(SE) - Silver Nitrate

Blom	Cecile	(NO) – 2-pyrrolidone
Borje	Christine	(NO) – 2-pyrrolidone
Carlsson-Feng	Mattias	(SE) – UPFAS
de Blaeij	Arianne	(NL) - UPFAS
De Kort	Thijs	(NL) – UPFAS
Drost	Wiebke	(DE) - UPFAS
Hard	Sebastiana	(NL) - UPFAS
Heebøl	Anna	(DK) - UPFAS
Heggelund	Audun	(NO) – UPFAS
Holmer	Marie Louise	(DK) - Tebuconazole
Ivarsson	Jenny	(SE) - UPFAS
Jensen	Stine	(DK) - Tebuconazole
Johansson	Tommy	(SE) – UPFAS
Mork	Anna-Karin	(SE) - Borate minerals group, Bougeonal group and Cyclamal group
Nielsen	Peter Juhl	(DK) - UPFAS
Posner	Stefan	(SE) – UPFAS
Sanders	Marion	(NL) - UPFAS
Silins	Ilona	(SE) – Bourgenoal and Cyclamal Group
Simpson	Peter	(NL) - UPFAS
Vriend	Jelle	(NL) - Talc

Regular stakeholder observers	
Representative	**Organisation**
Christine HERMANN	EEB
Hélène DUGUY	ClientEarth
Jan ROBINSON	A.I.S.E
Jasmin BIRD	Plastics Europe (Bisphenol A)
Liisi DE BACKER	Cefic
Patrik MUELLER	Plastics Europe
Paul RUELENS	CropLife Europe
Roumiana SANTOS	MedTech Europe
Steven VAN DEN BROECK	Cefic
Violaine EROUGSTRAETE	Eurometaux

Occasional stakeholder observers		
Representative	**Organisation**	**Substance**
Aharon WEISS	Aqua Europe	UPFAS
Alberto MONJE GAMA	TIC Council - international association representing independent testing, inspection and certification	UPFAS
Barbara BRUSCA	AESGP - Association of the European Self-Care Industry	UPFAS
Cristina ARREGUI	IFRA - International Fragrance Association	Bourgenoal and cyclamal group

Dario DAINELLI	FEC - Federation of the European Cookware, Cutlery & Houseware Industries	UPFAS
Elisa CONSOLI	ASD - European Aerospace, Security and Defence industry	UPFAS, ADCR, Ctac2
Elisabetta DI CAPRIO	Concawe	UPFAS
Franziska DECKER	APPLiA - Home Applciance Industry Association	UPFAS
Gabrielle VAN MELKEBEKE	IOGP - International Association of Oil & Gas Producers	UPFAS
Geoffroy TILLIEUX	EuPC – European Plastic Converters	UPFAS
Henk VANHOUTTE	ESF - European Safety Federation	UPFAS
Jaume COLOMER	AnimalHealthEurope	UPFAS
Jean-Pierre TAVERNE	TEPPFA - The European Plastic Pipes and Fittings Association	UPFAS
Jessica GARCIA	Eurelectric	UPFAS
Julio MATEOS BASCO	Orgalim	UPFAS
Leen DE BRUYKER	CEWEP - Confederation of European Waste-to-Energy Plants	UPFAS
Maja ZIPPEL	EFEO - European Federation of Essential Oils	Bourgenol and cyclamal group
Mauro SCALIA	EURATEX - European Apparel and Textile Confederation	UPFAS
Oliver LOEBEL	EurEau - European Federation of National Associations of Water Services	UPFAS, DWD
Patrick DE KORT	PRE – Plastic Recyclers Europe	UPFAS
Domenico PERONE	PU Europe - The polyurethane insulati on industry	UPFAS
Raphaël HÉLIOT	AVERE - European association representing and advocating for electromobility	UPFAS
Roger DOOME	IMA-Europe	Talc
Toke WINTHER	EFPIA - European Federation of Pharmaceutical Industries and Association	UPFAS
Vera ENGELBRECHT	PSCI - PETA Science Consortium International e.V.	
Victoria LIENARD	Euroheat & Power	UPFAS
Vincent DE BADEREAU	EPEE - European Partnership for Energy and the Environment	UPFAS

Accompanying Experts		
Representative	**Organisation**	**Substance**
Andreas NATSCH	IFRA Expert	Cyclamal Group
Andrew GOODYEAR	C European Biocidal Silver Task Force - **Cefic Expert**	Silver Nitrate
Anette STINGS	Daikin - **EPEE Expert**	UPFAS
Angelica CANDIDO	Cefic Expert	UPFAS
Antonio CLEMENTE	Baker Hughes - **IOGP Expert**	UPFAS
Arthur VANDENBERGHE	Orgalim Expert	UPFAS
Audrey BATOON	Lanxess – **Cefic Expert**	3,5-dimethylpyrazole
Celia HEDFORS	Swedish Society for Nature Conservation (SSNC) - **Client Earth Expert**	UPFAS
Christel VAN DEN EEDE	AnimalHealthEurope	UPFAS
Corinna MUTTER	SPECTARIS - **MedTechEurope Expert**	UPFAS
Cynthia MESTANZA	Euromines - **Eurometaux Expert**	UPFAS
David BARBER	Bayer - **CropLife Europe Expert**	UPFAS
Eric VAN WELY	Dupont - **ESF Expert**	UPFAS
Hanna HOLMQUIST	EEB Expert	UPFAS
Jelle MERTENS	EPMF – **Eurometaux Expert**	silver nitrate
Karsten NÖDLER	EurEau Expert	UPFAS
Kelly MAGURANY	TIC Council Expert	UPFAS
Kenneth MUNDT	IMA-Europe Expert	Talc
Kevin SONDENHEIMER	PlasticsEurope Expert	Bisphenol A
Lighea SPEZIALE	CEWEP Expert	UPFAS
Lisa SKEDUNG	RISE Research Institute of Sweden – **EEB Expert**	UPFAS (TULAC)
Marco PERFETTI	Chemours - **PU Europe Expert**	UPFAS
Matteo ZANOTTI RUSSO	Manetti & Roberts - **Cefic Expert**	Talc
Nathalie LEDIRAC	CropLifeEurope Expert	Tebuconazole
Nathalie PRINTEMPS	Corteva – **CropLifeEurope Expert**	Fluazaindolizine
Paul BROM	Nanoconsult - **Eurometaux Expert**	Talc
Paul TRUSTY	Haleon - **AESGP Expert**	UPFAS
Patrick HELLEWEGEN	EFEO Expert	Bourgeonal Group
Peter JENKINSON	IFRA Expert	Bourgenoal Group
René HUNZIKER	Cefic Expert	Bisphenol A
Ronald BOCK	FP group - **PlasticsEurope Expert**	UPFAS
Rovida COSTANZE	Italmatch Chemicals GB Ltd - **Cefic Expert**	ethylenebis group
Sabine LINDNER	Plastics Europe Expert	DWD
Sebastian COBA	PRE - Plastics Recyclers Europe	UPFAS
Stefan SCHULTE	BASF – **Cefic Expert**	2-Pyrrolidone; pyrrolidin-2-one
Stefan THUMM	Bayern - **EURATEX Expert**	UPFAS

Strehl GERNOT	FEC Expert	UPFAS
Tim GREAVES	ExxonMobile - **Concawe Expert**	UPFAS
Vanessa ROCHA	EFEO Expert	Cyclamal Group
Yohann BOILEAU	Groupe SEB - **APPLiA Expert**	UPFAS

ECHA staff
Scazzola Roberto (Chair)
Sosnowski Piotr (Deputy Chair)
Ahtiainen Heini
Atanasova Marina
Bin Essi
Bohumila Bichlmaier
de la Flor Tejero Ignacio
Gmeinder Michael
Hammer Jort
Henrichson Sanna
Husa Stine
Karjalainen Antti
Konstantinos Kiakos
Lazic Nina
Lefevre Sandrine
Lisboa Patricia
Logtmeijer Christiaan
Loukou Christina
Ludborzs Arnis
Mercedes Marquez-Camacho
Mushtaq Fesil
Nicot Thierry
Niemela Helena
Nygren Jonas
Orispää Katja
Peltola Jukka
Perazzolo Chiara
Pillet Monique
Portugal Laura
Regil Pablo
Richarz Andrea
Roggeman Maarten
Sadam Diana
Simoes Ricardo
Spjuth Linda
Tarvainen Emma
Thierry-Mieg Morgane
Vazquez Rodriguez Jesus
Zarogiannis Panos
Zeiger Bastian
Zhivin Sergey

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-70 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-70 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-70 meeting

ANNEX IV List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-70 meeting without plenary debate (A-list)

16 September 2024
RAC/A/70/2024

Final Agenda
70th meeting of the Committee for Risk Assessment
(RAC-70)

16-20 September 2024

Face-to-face/Hybrid meeting*

Monday, 16 September starts at 09.00
Friday, 20 September ends at 13.15

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/70/2024
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Action points from the previous meetings. 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 – No remote connection

*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 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 Update of RAC accredited stakeholders' list (closed session)

For discussion and agreement
RAC/70/2024/01
Restricted document
Closed session –
No remote connection

5.3 Selection of RAC co-opted members (closed session)

For discussion and agreement
RAC/70/2024/02
Restricted document
Closed session –
No remote connection

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

None.

For adoption

Item 7 –Health based exposure limits at the workplace

7.1 General OEL issues

1. OEL regulatory framework presentation by DG EMPL

7.2 Opinions for discussion

6. 4,4-Isopropylidenediphenol (Bisphenol A)

For discussion

7.3 Opinions for discussion and adoption

1. Silicon carbide fibres
2. Pyrocatechol

For adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the July CLH Working Group

For information
RAC/70/2024/03

8.2 CLH dossiers

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

- **3,5-Dimethylpyrazole:** *acute oral toxicity, STOT RE, adverse effects on or via lactation*
- **3,4-Dimethyl-1*H*-pyrazole:** *acute toxicity via all routes, STOT RE, adverse effects on or via lactation*
- **3,4-Dimethyl-1*H*-pyrazol-1-ium dihydrogen phosphate:** *acute toxicity via all routes, STOT RE, adverse effects on or via lactation*
- **Borate minerals group:** *adverse effects on or via lactation*
- **Thermally treated garlic juice:** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, respiratory sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, hazards to the aquatic environment, hazards to the Ozone layer*
- **Fluazaindolizine (ISO):** *physical hazards, hazards to the aquatic environment*
- **[Ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid:** *mutagenicity, STOT RE*
- **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt:** *mutagenicity, STOT RE*
- **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt:** *mutagenicity, STOT RE*
- **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt:** *mutagenicity, STOT RE*
- **2-Pyrrolidone:** *reproductive toxicity – fertility and effects on or via lactation*
- **Rape oil; rape seed oil:** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, hazards to the aquatic environment*
- **Tebuconazole (ISO):** *acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, effects on or via lactation, aspiration hazard*
- **Eugenol (dossier from the Spanish Competent Authority):** *physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, mutagenicity, carcinogenicity, STOT SE, STOT RE, reproductive toxicity, hazard to the aquatic environment, hazard to the Ozone layer*
- **Eugenol (dossier from the Danish Competent Authority and includes only Skin Sensitisation):** *skin sensitisation*
- **Silver nitrate:** *physical hazards, hazards to the aquatic environment*

2. Hazard classes for agreement with plenary debate

8.2.1 **3,5-Dimethylpyrazole** (EC 200-657-5, CAS 67-51-6): *reproductive toxicity – fertility and development*

8.2.2 **Borate minerals group:** *reproductive toxicity – fertility and development*

8.2.2.1 Ulexite ($CaNaH_{12}(BO_3)_5 \times 2H_2O$) [1] ulexite ($CaNaH_{12}(BO_3)_5 \times 2H_2O$), calcined [2] (EC - [1] 296-662-5 [2], CAS 1319-33-1 [1] 92908-33-3 [2])

8.2.2.2 Colemanite ($CaH(BO_2)_3 \times 2H_2O$) [1] boron calcium oxide ($B_6Ca_2O_{11}$), hydrate (1:5) [2] colemanite, calcined [3] (EC - [1] - [2] 296-640-5 [3], CAS 1318-33-8 [1] 854267-07-5 [2] 92908-12-8 [3])

8.2.2.3 Tincalconite ($B_4Na_2O_7 \times 5H_2O$) (EC -, CAS 12045-88-4)

8.2.3 **[Ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid** (EC 215-851-5, CAS 1429-50-1): *carcinogenicity*

8.2.4 **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, calcium sodium salt** (EC 287-370-9, CAS 85480-89-3): *carcinogenicity*

8.2.5 **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt** (EC 251-910-1, CAS 234274-30-1): *carcinogenicity*

8.2.6 **[Ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt** (EC 244-742-5, CAS 22036-77-7): *carcinogenicity*

8.2.7 **2-Pyrrolidone; pyrrolidin-2-one** (EC 210-483-1, CAS 616-45-5): *reproductive toxicity – development*

8.2.8 **Tebuconazole (ISO);** 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol (EC 403-640-2; CAS 107534-96-3): *reproductive toxicity – fertility and development*

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

8.2.10 Burgeonal group: *all relevant hazard classes*

8.2.10.1 2-(4-*tert*-butylbenzyl) propionaldehyde (EC 201-289-8, CAS 80-54-6)

8.2.10.2 4-*tert*-butylbenzoic acid (EC 202-696-3, CAS 98-73-7)

8.2.10.3 3-(4-*tert*-butylphenyl)propionaldehyde [1] 4-*tert*-butyltoluene [2] 4-*tert*-butylbenzaldehyde [3] methyl 4-*tert*-butylbenzoate [4] (EC 242-016-2 [1] 202-675-9 [2] 213-367-9 [3] 247-768-5 [4], CAS 18127-01-0 [1] 98-51-1 [2] 939-97-9 [3] 26537-19-9 [4])

8.2.11 Cyclamal group: *all relevant hazard classes*

8.2.11.1 *p*-cymene; 1-isopropyl-4-methylbenzene and 3-*p*-cumenyl-2-methylpropionaldehyde (EC 202-796-7, CAS 99-87-6) and

8.2.11.2 2-methyl-3-(4-isopropylphenyl)propanal [1]; 3-(*p*-cumenyl)propionaldehyde; 3-(4-isopropylphenyl)propanal [2] ; 4-isopropylbenzaldehyde; cuminic aldehyde [3] ; 4-isopropylbenzoic acid; cuminic acid [4] (EC 203-161-7 [1]; 231-885-3 [2]; 204-516-9 [3]; 208-642-5 [4], CAS 103-95-7 [1]; 7775-00-0 [2]; 122-03-2 [3]; 536-66-3 [4])

***8.2.12* Silver nitrate** (EC 231-853-9, CAS 7761-88-8): *part of HH hazard classes*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

- Review of the Conformity Check procedure

For discussion

9.2 Restriction Annex XV dossiers

a) Opinion development on Universal per- and polyfluoroalkyl substances (UPFAS) restriction proposal -state of play and next steps

For information

b) Evaluation of sector-/use-specific aspects of UPFAS restriction proposal:
   i. Waste emissions (cont.)
   ii. Textiles, upholstery, leather, apparel, carpets (TULAC)
   iii. Food contact materials and packaging
   iv. Petroleum and mining

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

1. Update on incoming/future applications and horizontal issues

For information/discussion

10.2 Authorisation applications

No content under this agenda item.

10.3 Agreement on draft opinions

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

1. 354_RR1_CT_Airbus (2 uses)
2. 355_RR1_SD_Airbus (1 use)
3. 356_RR1_SD_AD-International (1 use)
4. 359_RR1_CT_Circuit (1 use)
5. 361_TEL_Trafigura (1 use)
6. 362_TEL_Warter-Fuels (1 use)
7. 363_CT_Indestructible_Paint_Turbines (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 352_DEHP_Baxter (3 uses)
2. 357_RR1_PD_Lynred (1 use)
3. 358_RR1_AsA_Circuit (1 use)

For discussion and agreement

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10.4 Adoption of opinions

1. 325_ADCR_Anodise_sealing (1 use)
2. 326_ADCR_Anodising (1 use)
3. 327_ADCR_Chemical_conversion_coating (1 use)
4. 328_ADCR_Chromate_rinsing (1 use)
5. 329_ADCR_Electroplating (1 use)
6. 330_ADCR_Finish_stripping (1 use)
7. 331_ADCR_Formulation (1 use)
8. 332_ADCR_Passivation_metallic_coatings (1 use)
9. 333_ADCR_Pre-treatments (1 use)
10. 334_ADCR_Stainless_steel_passivation (1 use)
11. 335_ADCR_RR_Anodising (1 use)
12. 336_ADCR_RR_Anodise_sealing (1 use)
13. 337_ADCR_RR_Chemical_conversion_coating (1 use)
14. 338_ADCR_RR_Chromate_rinsing (1 use)
15. 339_ADCR_RR_Electroplating (1 use)
16. 340_ADCR_RR_Finish_stripping (1 use)
17. 341_ADCR_RR_Formulation (1 use)
18. 342_ADCR_RR_Passivation_metallic_coatings (1 use)
19. 343_ADCR_RR_Pre-treatments (1 use)
20. 344_ADCR_RR_Slurry_coating (1 use)
21. 345_ADCR_RR_Stainless_steel_passivation (1 use)
22. 346_CT_Safran_landing_systems (2 uses)
23. 347_CT_Safran_Aircraft_Engines (1 use)

For discussion and adoption

Item 11 – Drinking Water Directive

1. Update on Drinking Water Directive (DWD)

For information

Item 12 – AOB

Item 13 – Minutes of RAC-70

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-70

For adoption

Annex II

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

RAC/A/70/2024	RAC-70 final Draft Agenda
RAC/70/2024/01	General CHL issues: Report from the April CLH Working Group
RAC/70/2024/01 RESTRICTED	Annual update of RAC accredited stakeholders´ list
RAC/70/2024/02 RESTRICTED	Selection of co-opted members to RAC (Closed 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.*

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	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.
DK	Peter Hammer SOERENSEN	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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
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.
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.
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.
NEW DOSSIERS		
1) Borate minerals group **2) Silver nitrate** **3) Burgeonal groups** **4) Cyclamal groups** **SE**	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.

**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.*

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	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.
Eugenol **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.
Thermally treated garlic juice **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.
	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. No personal involvement.
1) **[ethane-1,2-diylbis[nitrilobis(methylene)]]tetrakisphosphonic acid** 2) **[ethylenebis[nitrilobis(methylene)]]tetrakisphosph**	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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
onic acid, calcium sodium salt **3) [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, potassium salt** **4) [ethylenebis[nitrilobis(methylene)]]tetrakisphosphonic acid, sodium salt** **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.
	Urs SCHLUETER	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.
	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. No personal involvement.
Rape seed oil **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.

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Annex IV

Table 1. List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-70 meeting without plenary debate (A-list).

Conclusions / agreements / adoptions
354_RR1_CT_Airbus (2 uses) **Use1:** *Functional chrome plating.* 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. RAC agreed: Section 7: additional conditions for the authorisation 1. The authorisation holder shall ensure that workers perform a 'fit check' of the seal, of their respiratory protective equipment (RPE) any time before taking on relevant tasks and workers shall be trained to do this test adequately. 2. The authorisation holder shall perform a quantitative risk assessment for the environmental exposure via the oral route. This assessment shall be conducted within 12 months of the granting of an authorisation for this use. 3. The authorisation holder shall carry out and document a detailed feasibility study on: a) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen; b) the replacement of solid Cr(VI) substances by a liquid solution, or the implementation of a closed/automated system to perform the dilution of solid Cr(VI) (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions (e.g. fix-piping from the containers or mixing tanks, to the plating baths) The feasibility study 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 further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation Section 9: recommendations for the review report. **Use2:** *Surface treatment for applications in the aeronautics and aerospace industries (unrelated to Functional chrome plating or Functional chrome plating with decorative character).* Regarding the exposure to Cr(VI) associated with use of chromium trioxide, RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk for the workers. The proposed additional conditions for the authorisation are expected to result in

operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.
RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk for the general population via the environment.

RAC agreed:
Section 7: additional conditions for the authorisation

1. The authorisation holder shall immediately discontinue the activity in which the worker is requested to hold manually the jigs during the Cr(VI) treatment process; this applies until the process is modified so that it is not necessary for workers to stay nearby the Cr(VI)-containing baths and manually hold the jigs during process.
2. The authorisation holder shall ensure that workers perform a 'fit check' of the seal, of their respiratory protective equipment (RPE) any time before taking on relevant tasks and workers shall be trained to do this test adequately.
3. The authorisation holder shall perform a quantitative risk assessment for the environmental exposure via the oral route. This assessment shall be conducted within 12 months of the granting of an authorisation for this use.
4. The authorisation holder shall carry out and document a detailed feasibility study on:
   a) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen;
   b) the replacement of solid Cr(VI) substances by a liquid solution, or the implementation of a closed/automated system to perform the dilution of solid Cr(VI) (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions (e.g. fix-piping from the containers or mixing tanks, to the plating baths)
   c) the installation of local exhaust ventilation system and full enclosure of the turning/milling machine (Weiler C50) like the other turning/milling machines

   The feasibility study 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 further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

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

355_RR1_SD_Airbus (1 use)

Use1: *Surface treatment of metals (such as aluminium, steel, zinc, magnesium, titanium, alloys), composites and sealings of anodic films.*

Regarding the exposure to Cr(VI) associated with use of chromium trioxide, RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk for the workers.
The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.
RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk for the general population via the environment.

**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.*

RAC agreed:
Section 7: additional conditions for the authorisation

1. The authorisation holder shall immediately discontinue the activity in which the worker is required to hold manually the jigs during the Cr(VI) treatment process; this applies until the process is modified so that so that it is not necessary for workers to stay nearby the Cr(VI)-containing baths and manually hold the jigs during process.
2. The authorisation holder shall ensure that workers perform a 'fit check' of the seal, of their respiratory protective equipment (RPE) any time before taking on relevant tasks and workers shall be trained to do this test adequately.
3. The authorisation holder shall carry out and document a detailed feasibility study on:
   a) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen;
   b) the replacement of solid Cr(VI) substances by a liquid solution, or the implementation of a closed/automated system to perform the dilution of solid Cr(VI) (e.g. a glove box to transfer flakes to a mixing tank) and any subsequent (re-)filling of the baths with liquid solutions (e.g. fix-piping from the containers or mixing tanks, to the plating baths)
   c) the installation of local exhaust ventilation system and full enclosure of the turning/milling machine (Weiler C50) like the other turning/milling machines
4. The authorisation holder shall perform a quantitative risk assessment for the environmental exposure via the oral route. This assessment shall be conducted within 12 months of the granting of an authorisation for this use.

The feasibility study 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 further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

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

356_RR1_SD_AD-International (1 use)
Use1: *Use of SDC in formulation of mixtures intended for supply for authorised uses.*

RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk to workers and to the general population via the environment.

Regarding the reproductive hazards associated with the use of sodium dichromate, RAC concluded that the risk assessment presented in the review report demonstrates adequate control of risk from the use applied for, provided that the operational conditions and risk management measures described in the application are adhered to.

RAC agreed:
Section 7: additional conditions for the authorisation

Where RPE is needed to control exposure to Cr(VI), it shall be used in accordance with standard procedures for use and maintenance. Those procedures shall include

procedures for fit testing of RPE masks, applied in accordance with relevant standards, shall ensure training and medical fitness checking and supervision of the wearer and maintenance of the disposal RPE such as the half mask with P3 filter or P3 combination filter.

Section 8: monitoring arrangements for the authorisation

Section 9: recommendations for the review report.

359_RR1_CT_Circuit (1 use)

Use1: *Industrial use of chromium trioxide for the treatment of copper foil used in the manufacture of printed circuit board and Li-ion batteries.*

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 implemented and adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion.

RAC agreed:

Section 7: additional conditions for the authorisation

The authorisation holder shall replace solid CrO3 flakes by a liquid solution of CrO3 and implement a close/automated dilution station by Q1-2025 as planned. The proposed additional condition for the authorisation is expected to improve the OCs and RMMs limiting the risk for the worker.

Furthermore, the authorisation holder shall carry out and document a detailed feasibility study on:

a) the implementation of a closed/automated system to perform CrO3 solutions sampling tasks, where exposure to Cr(VI) is possible and which currently rely on the use of PPE.

The feasibility study 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 further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation with additional arrangement in point 7

7. The authorisation holder shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). The results of the biomonitoring programme can 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.

361_TEL_Trafigura (1 use)

Use1: *Blending of TEL in Avgas formulations.*

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.

RAC agreed:

Section 7: additional conditions for the authorisation

1. The applicant shall carry out and document a detailed feasibility study on the implementation of a system that controls continuously the transfer of AvGas to/from the sea vessels (trucks/tankers/railway carriages) and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the transfer) in case the loading/unloading is not functioning properly.
   The feasibility study shall be concluded within 12 months of the granting of authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to minimise the workers' exposure to TEL at as low a level as technically and practically feasible must be implemented and reviewed during the review period.

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

362_TEL_Warter-Fuels (1 use)
Use1: *FUEL FORMULATION WITH ADDED TETRAETHYL LEAD.*

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.

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

363_CT_Indestructible_Paint_Turbines (1 use)
Use1: *Treatment of components used in industrial gas turbines and associated components using slurry coating products containing chromium trioxide to enhance corrosion resistance, chemical resistance, high temperature oxidation resistance, adhesion to components which produce a smooth finish and enhance the technical performance of turbines.*

Regarding the exposure to Cr(VI) associated with use of chromium trioxide, 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 and
- are appropriate and effective in limiting the risk for the general population via the environment.

The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk for the workers, provided that they are implemented and adhered to.

RAC agreed:
Section 7: additional conditions for the authorisation
The applicant and their DUs shall implement technical improvements to the OCs/RMMs, more specifically:

1. The authorisation holder and its downstream users shall implement technical improvements to the OCs and RMMs at the slurry coating areas, followed by a measurement campaign as per the proposed monitoring arrangements mentioned in Section 8, to demonstrate their effectiveness in reducing

concentration and potential exposure to Cr(VI). The appropriate technical improvements depend on the specificity of the workplace and they can consist of automated or closed systems to perform stirring and spraying, redesign to remove loading and unloading from the treatment area, and physical segregation or removal of the workers from the treatment area.

2. Ensuring that workers involved in the manual task to apply slurry coating by brushing use appropriate RPE during these tasks with due consideration for the duration of the tasks and the comfort of the workers during their use.

These conditions 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 (e.g. reducing concentration and potential exposure).

Without prejudice to point 1 and 2 above, the applicant and its DUs shall carry out and document a detailed feasibility study on:

a) the installation of a system that continuously controls the LEV and automatically triggers an alarm, and start appropriate and effective measures to reduce the exposures to workers (e.g., immediately work stoppage), in case the local exhaust ventilation is not functioning properly.

The feasibility study 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 further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation with additional point 7

7. The authorisation holder and its DUs shall implement an annual biomonitoring programme for the workers potentially exposed to Cr(VI). This programme must consist, as a minimum, of pre and post shift urine samples (beginning of the week --> end of the week), valid existing standard methodologies are e.g. HSE, HBM4EU, etc. This annual biomonitoring program must be synchronised with the annual occupational air monitoring campaign specified in 1.a above.

Section 9: recommendations for the review report.