RAC/M/61/2022

16 June 2022

Minutes of the 61st Meeting

of the Committee for Risk Assessment

(RAC-61)

Monday 30 May, 10.00 to Thursday 2 June 2022, 17.20

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair, Tim Bowmer, welcomed the members of the Committee in person to the ECHA conference centre for the first time in two years, noting that all but three members had travelled to Helsinki and that the Agency was delighted to see such a strong turnout. He informed the Committee that the Johanna Peltola-Thies, Deputy Chair of RAC would chair some agenda items.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/61/2022**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-61 minutes.
4. Appointment of (co-)rapporteurs	

4.1 Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers, restriction dossiers and applications for authorisation and an Art 77(3)(c) request, as listed in the restricted document in the Interact collaboration tool. The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted dossiers for the above-mentioned processes.	-
5. Report from other ECHA bodies and activities	
5.1 RAC work plan for all processes The Chair presented the RAC work plan for 2022.	
6. Request under Article 77(3)(c)	
No items tabled	
7. Health based exposure limits at the workplace	
No items tabled	
8. Harmonised classification and labelling (CLH)	
8.1.1 Report from the April 2022 RAC CLH WG	
The Secretariat presented the Report of the 5th Meeting of the Committee for Risk Assessment Working Group on CLH held on 21-22 and 25-27 April 2022. The 6th Meeting of the RAC Working Group on CLH will be held on 4-5 July 2022.	
8.1.2 Update to the Framework for RAC opinion development on substances for harmonised classification and labelling	
The Secretariat presented and RAC agreed on the Framework for RAC opinion development on substances for harmonised classification and labelling.	**SECR** to upload the new Framework to ECHA website.

8.1.3 Guidance on assessing physical hazards in the CLH dossiers	
The Secretariat presented the Guidance on assessing physical hazards in the CLH dossiers. RAC considered the Guidance a helpful document in assessing the physical hazards of the CLH dossiers.	**SECR** to develop the document further for the RAC consultation and further discussion in RAC (at RAC-62 in September).
8.1.4 Addressing developmental neurotoxicity and neurotoxicity under the current CLP hazard classes	
The Secretariat presented a Note on developmental neurotoxicity and neurotoxicity under the current CLP hazard classes. RAC supported the approach proposed by ECHA in general. The intention is to provide a general line-to-take for RAC, that assessment of the data will always be on a case-by-case basis.	**SECR** to develop the document further for the RAC consultation and further discussion in RAC (at RAC-62 in September).
The expert accompanying the CropLife Regular Stakeholder Observer commented on the document.	
8.2 CLH dossiers	

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

1. 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate (EC 219-207-4; CAS 2386-87-0): *Skin sensitisation, mutagenicity, STOT RE*
2. Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl] phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl}naphthalene-2,7-disulfonate; [3] (EC 241-164-5 [1], - [2], - [3]; CAS 17095-24-8 [1], - [2], 100556-82-9 [3]): Respiratory sensitisation, skin sensitisation
3. 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (EC 438-340-0; CAS 119344-86-4): Reproductive toxicity, STOT RE, hazardous to the aquatic environment

4. Formic acid ... % (EC 200-579-1; CAS 64-18-6): Physical hazards, acute oral and inhalation toxicity, serious eye damage/eye irritation
5. Glyphosate (EC 213-997-4, CAS 1071-83-6): Physical hazards, acute toxicity via all routes, *skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE*
6. Dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid (EC 217-635-6; CAS 1918-00-9): Acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, reproductive toxicity, hazardous to the aquatic environment, hazardous to the ozone layer
7. Peracetic acid … % (EC 201-186-8; CAS 79-21-0): Flammable liquid, acute toxicity via all routes, hazardous to the aquatic environment
8. Formaldehyde … % (EC 200-001-8; CAS 50-00-0): Physical hazards, acute oral and inhalation toxicity, skin sensitisation
9. S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC -; CAS 87392-12-9): Mutagenicity, STOT RE, reproductive toxicity, hazardous to the aquatic environment
10. Silver (EC 231-131-3; CAS 7440-22-4): Carcinogenicity

2. Substances with hazard classes for agreement in plenary session

1. Glyphosate (EC 213-997-4, CAS 1071-83-6): *Mutagenicity, carcinogenicity, hazardous to the aquatic environment*
2. Dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid (EC 217-635-6; CAS 1918-00-9): *Physical hazards, carcinogenicity*
3. Peracetic acid … % (EC *201*-186-8; CAS 79-21-0): *Organic peroxide*
4. Formaldehyde … % (EC *200*-001-8; CAS 50-00-0): *Acute dermal toxicity*
5. S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-*methylphenyl*)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC -; CAS 87392-12-9): *Carcinogenicity*
6. Silver (EC 231-131-3; *CAS* 7440-22-4): *STOT RE, reproductive toxicity*

8.2.2.1 Glyphosate (EC 213-997-4, CAS 1071-83-6)	
The Chair welcomed the Dossier Submitter representative, the CropLife Europe, CEFIC and ClientEarth Regular Stakeholder Observers with their accompanying experts, the HEAL Occasional Stakeholder Observer with their accompanying expert as well as the observers from EFSA. He informed that **glyphosate** is an active substance used in PPPs to control plants, which means it is a herbicide. The substance has current Annex VI entry as Eye Dam. 1; H318 and Aquatic Chronic 2; H411. The previous opinion for this substance was adopted by RAC in March 2017. Physical hazards (solid substance), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments duri5ng the Consultation. During the opinion development some published articles which are potentially relevant to classification of glyphosate for physical hazards, respiratory sensitisation, STOT SE (respiratory irritation), germ cell mutagenicity, carcinogenicity, reproductive toxicity and hazardous to the aquatic environment were identified which were not summarised in the CLH report. A targeted consultation of these documents was therefore organised 29/03-14/04/2022. The Committee has discussed the dossier at RAC-60 plenary meeting and at RAC-61 CLH WG. The legal deadline for the adoption of an opinion is 17 March 2023.	
<u>Human Health</u> RAC evaluated the CMR properties of glyphosate in a weight of evidence assessment in comparison with the CLP criteria. This was based on the available evidence presented in the dossier prepared by Sweden, France, The Netherlands and Hungary and on the submissions received during the consultations. *Mutagenicity* RAC agreed that there is insufficient animal and human evidence to warrant classification for germ cell mutagenicity. *Carcinogenicity* RAC evaluated in detail the tumour types observed in 7 animal studies in rats and in 5 studies in mice and in doing so, considered the strength of the statistical evidence and the biological relevance of the findings. RAC also evaluated the latest epidemiological information from the ongoing cohort study (the Agricultural Health Study) as well as from available case-control studies, reviews, re-analyses and meta-analyses. RAC agreed that on balance, the findings in the many studies in rats and mice, as well as the epidemiology studies provide insufficient evidence for classification for carcinogenicity.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

Reproductive toxicity RAC concluded that the studies did not provide consistent evidence of adverse effects on fertility and agreed on no classification. RAC concluded that there is no convincing evidence of developmental effects following *in utero* exposure to glyphosate either from the studies in rats or rabbits or from epidemiological studies and agreed on no classification for developmental toxicity. RAC agreed on no classification for effects on or via lactation. <u>Hazardous to the aquatic environment</u> RAC concluded that glyphosate is not rapidly degradable and does not fulfil the criteria for bioaccumulation. Acute toxicity values for the three trophic levels are all above 1 mg/L and hence no acute classification is warranted. RAC agreed that glyphosate meets the criteria for classification as Aquatic Chronic 2 based on: • the NOEC of 1 mg/L on fish from Tavares 2000 study. The results from the fish studies of Fiorino, 2018 and Zhang, 2021 also support the proposed chronic classification; • the study on *Myriophyllum sibiricum* (Roshon, 1997) is relevant and reliable. A NOEC of 0.332 mg/L warrants Aquatic Chronic 2 classification. This conclusion is supported by the study on *Myriophyllum aquaticum* (Wenzel, 2012) based on a formulate (MON 52276). RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Eye Dam. 1; H318, Aquatic Chronic 2; H411]	

The HEAL Occasional Stakeholder Observer commented on mutagenicity and carcinogenicity. The ClientEarth Regular Stakeholder Observer as well as her accompanying expert commented on carcinogenicity.
The expert accompanying the CEFIC Regular Stakeholder Observer commented on aquatic toxicity.

8.2.2.2 Dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid (EC 217-635-6; CAS 1918-00-9)

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the CropLife Regular Stakeholder Observer. He informed that **dicamba** is a herbicide, it is used on field crops and has a systemic effect on a range of broadleaved weeds. The substance has current Annex VI entry as Acute Tox. 4*, H302, Eye Dam. 1; H318 and Aquatic Chronic 3; H412.
The DS (DN and RO) proposes to classify the dicamba as follows: Acute Tox. 4; H302 (remove the existing minimum classification and add ATE=1581 mg/kg bw), Acute Tox. 4; H332 (ATE=4.46 mg/L), Eye Dam. 1; H318, Carc. 2; H351, STOT SE 3; H335, STOT SE 3; H336, Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1) (the DS changed their proposal to Aquatic Chronic 2; H411 after the Consultation).
Selected physical hazards (explosives, flammable solids, self-heating substances or mixtures, oxidising solids), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment and hazardous for the ozone layer were the hazard classes open for comments during the Consultation.
The legal deadline for the adoption of an opinion is 13 October 2022.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Acute Tox. 4; H302 (ATE=4.0 mg/L), Acute Tox. 4; H332 (ATE=1500 mg/kg bw), Eye Dam. 1; H318, STOT SE 3; H335, STOT SE 3; H336, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 2; H411] RAC agreed on no classification for carcinogenicity due to inconclusive data. For the final opinion additional description is needed on the adequacy of the rat and mouse studies, the use of the HCD data and more detailed analysis of the findings from the Lerro (2020) study.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

8.2.2.3 Peracetic acid … % (EC 201-186-8; CAS 79-21-0)

The Deputy Chair welcomed the DS representatives and the expert accompanying the CEFIC Regular Stakeholder Observer. She informed that **peracetic acid … %** is a biocidal active substance with strong bactericidal, fungicidal, and virucidal activity. Peracetic acid is mainly used as a bactericide, fungicide or virucide. Moreover, indications of potential efficacy against

amoeboe and algae have been reported. The substance has current Annex VI entry as Flam. Liq. 3; H226, Org. Perox. D****; H242, Acute Tox. 4*; H332, Acute Tox. 4*; H312, Acute Tox. 4*; H302, Skin Corr. 1A; H314 and Aquatic Acute 1; H400.
The DS (FI) proposes to retain Org. Perox. D****; H242 and Aquatic Acute 1; H400, to add Aquatic Chronic 1; H410, to modify Acute Tox. 2; H330, Acute Tox. 2; H310, Acute Tox. 3; H301, to remove Flam. Liq. 3; H226. The DS also proposes to add inhalation ATE=0.204 mg/L (dusts and mists), dermal ATE=56.1 mg/kg bw, oral ATE=70 mg/kg bw and M=10, M=100.
Selected physical hazards (flammable liquids, organic peroxides), acute toxicity via all routes and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.
The legal deadline for the adoption of an opinion is 24 December 2022.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Org. Perox. D; H242, Acute Tox. 2; H330 (ATE=0.2 mg/L (dusts and mists)), Acute Tox. 2; H310 (ATE=60 mg/kg bw), Acute Tox. 3; H301 (ATE=80 mg/kg bw), Skin Corr. 1A; H314, STOT SE 3; H335 (C≥1%), Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=100), note T]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

8.2.2.4 Formaldehyde … % (EC 200-001-8; CAS 50-00-0):

The Chair welcomed the expert accompanying the CEFIC Regular Stakeholder Observer and informed that **formaldehyde … %** is an existing biocidal active substance approved in accordance with Regulation (EU) No 528/2012. It is used in adhesives and sealants, paints and coating products, fillers, putties, plasters, modelling clay, inks and toners, polymers, fuels, biocides (e.g. disinfectants, pest control products), polishes and waxes, washing and cleaning products, cosmetics, personal care products, machine wash liquids/detergents, automotive care products, fragrances and air fresheners, metal, wooden and plastic construction and building materials, flooring, furniture, toys, textiles (e.g. curtains, carpet, clothing), footwear, leather products, paper and cardboard products, electronic equipment. The substance has an existing Annex VI entry as Acute Tox. 3*; H331, Acute Tox. 3*; H311, Acute Tox. 3*; H301, Skin Corr. 1B; H314, Skin Sens. 1; H317, Muta. 2; H341 and Carc. 1B; H350.
The DS (DE) proposes to modify the classification to Flam. Gas 1B; H221, Acute Tox. 2; H330 (ATE=490 ppm (gases)); Acute Tox. 3; H311 (ATE=270 mg/kg bw), Acute Tox. 4; H302 (ATE=640 mg/kg bw) and Skin Sens. 1A, H317 (C ≥ 0.2 %).
Selected physical hazards (explosives, flammable gases, oxidising gases, gases under pressure, flammable liquids, self-reactive substances, pyrophoric liquids, substances which in contact with water emit flammable gases, oxidising liquids, organic peroxides, corrosive to metals), acute toxicity via all routes and skin sensitisation were the hazard classes open for comments during the Consultation.
The legal deadline for the adoption of an opinion is 29 December 2022.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

[Acute Tox. 4; H302 (ATE=500 mg/kg bw), Acute Tox. 2; H330 (ATE=100 ppmV (gases), Skin Sens. 1A; H317, EUH071, notes D and F] RAC agreed to remove the existing classification for acute dermal toxicity.	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.5 S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC -; CAS 87392-12-9)	
The Chair welcomed the DS representatives and the expert accompanying the CropLife Regular Stakeholder Observer and informed that **S-metolachlor** is a herbicide in maize and sunflower. The substance has current entry as Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The DS (DE) proposes <u>to add</u> Carc. 2; H351, Repr. 2; H361d, STOT RE 2; H373 (skin) and M=10 for both aquatic acute and chronic hazards. The DS proposes <u>to retain</u> Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. Germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation. The dossier was discussed at RAC-60 CLH WG, where it was agreed to organise a targeted consultation on the new carcinogenicity data received. The targeted consultation was organised on 21/02-07/03/2022. The legal deadline for the adoption of an opinion is 24 November 2022.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Carc. 2; H351, Aquatic Acute 1; H400 (M=10) Aquatic Chronic 1; H410 (M=10) and EUH066]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.6 Silver (EC 231-131-3; CAS 7440-22-4)	
The Chair welcomed the Dossier Submitter representatives, the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers, the Occasional Stakeholder Observer from EPMF with the accompanying expert as well as the Occasional Stakeholder Observer from CIRFS. He informed that **silver** is used in biocidal products. It is used in products categorised into the following product types: disinfectants and algaecides not intended for direct application to humans or animals, food and feed area disinfection, drinking water disinfection, preservatives for liquid-cooling and processing systems. Some of these uses may result in a	

vast range of consumer applications. Apart from biocidal use, silver is widely used by industry, professionals and consumers. Silver has no current Annex VI entry.
The DS (SE) proposes to classify silver as Skin Sens. 1; H317, Muta. 2; H341, Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 10) and Aquatic Chronic 1; H410 (M = 10). The DS proposes to classify nanosilver as Skin Sens. 1; H317, Muta. 2; H341, Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 1000) and Aquatic Chronic 1; H410 (M = 100).
Selected physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.
The Committee has discussed the dossier at RAC-58 plenary meeting, at RAC-59 CLH WG, at RAC-59 plenary meeting, at RAC-60 CLH WG, at RAC-60 plenary meeting and at RAC-61 CLH WG.
The legal deadline for the adoption of an opinion was 16 March 2022. The deadline has been extended until 30 July 2022.

STOT RE RAC concluded that there was evidence of neurotoxicity from a variety of sources including published literature studies on AgNPs and soluble silver salts in adults and juveniles within the general guidance values for category 1 and 2. The new (2022) OECD 443 EOGRTS study also supported the findings in published reports with AgNPs showing neuro-developmental toxicity with AgOAc treatment. There were also two studies showing neurotoxicity in offspring exposed to AgNPs in utero only. The observed neuronal cell loss in hippocampus is permanent and thus considered to be a significant toxicological effect. RAC agreed to classify silver as STOT RE 2; H373 (nervous system). *Reproductive toxicity* *Fertility* RAC concluded that there was evidence of concern regarding spermatogenic effects with AgNPs from the publicly available studies supported by weak evidence on sexual function and fertility with silver acetate and agreed on category 2, H361f. *Development* RAC agreed on no classification based on inconclusive data.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to organise a RAC consultation on the final ODD. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

Lactation RAC agreed on no classification for effects on or via lactation. RAC adopted by a simple majority the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. ***For Silver massive [particle diameter ≥ 1 mm]:*** [STOT RE 2; H373 (nervous system), Repr. 2; H361f] ***For Silver powder [particle diameter > 100 nm < 1 mm]:*** [STOT RE 2; H373 (nervous system), Repr. 2; H361f, Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=10)] ***For Silver nano [particle diameter > 1 nm ≤ 100 nm]*** [STOT RE 2; H373 (nervous system), Repr. 2; H361f, Aquatic Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=1000)] Two Members did not support the RAC agreement on mutagenicity and one fertility and will submit their minority positions.	
The expert accompanying the Eurometaux Regular Stakeholder Observer commented on STOT RE and reproductive toxicity. The expert accompanying the EPMF Occasional Stakeholder Observer commented on reproductive toxicity.	
9. Restrictions	
9.1 General Restriction issues	
1. Report from the May 2022 RAC REST WG	
RAC took note of the Report of the 5th meeting of the Committee for Risk Assessment Working Group on restrictions held on 5-6 May 2022. The 6th meeting of the RAC Working Group on restrictions will be held during the week of 16-18 August 2022 (exact dates to be confirmed).	
9.2 Restriction Annex XV dossiers	
9.2.1 Conformity check and key issues discussion	

1. Creosote and Creosote related substances	
The Chair, Tim Bowmer welcomed the Dossier Submitter representatives from France, the regular stakeholder observers, and their accompanying expert (Creosote Council Europe). The dossier had been submitted on 1 February 2022. The restriction proposal aims at reducing health and environmental risks associated with the reuse and second-hand use of wood treated with creosote (CAS 8001-58-9, EC 232-287-5) and creosote-related substances.	
RAC agreed that the dossier does not conform to the Annex XV requirements. RAC discussed the recommendations to the Dossier Submitter. The Chair expressed the hope that ECHA could provide the DS with some advice to reword the proposal to be more in line with recent non-threshold risk assessments and to indicate with references the links to the appropriate parts of the creosote RAR and the recent BPC opinion.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC. **SECR** to inform the Dossier Submitter on the outcome of the conformity check.
2. Terphenyl, hydrogenated	
The Deputy Chair welcomed the Dossier Submitter's representatives from Italy and the regular stakeholder observer. She informed the participants that the dossier has been submitted by Italy in April 2022 and concerns the restriction of the use of Terphenyl, hydrogenated.	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
3. N,N-dimethylacetamide and 1-ethylpyrrolidin-2-one	
The Chair, Tim Bowmer, welcomed the Dossier Submitter's representatives from the Netherlands and the occasional stakeholder observer from CIRFS. He informed the participants that the dossier has been submitted by the Netherlands in April 2022 and concerns occupational exposure to N,N-dimethylacetamide and 1-ethylpyrrolidin-2-one.	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
The occasional stakeholder observer from CIRFS supported the proposed restriction.	
9.2.2 Opinion development	
1. Per- and polyfluoroalkyl substances (PFASs) in fire-fighting foams – First draft opinion	

The Chair welcomed the Dossier Submitter's representatives from ECHA and their invited expert (WFVD), the regular stakeholder observers, and their accompanying experts (FPP4EEU, EEB, Bayer Crop Science, Daikin Chemical Europe GmbH), as well as the occasional stakeholder observers (EUROFEU, EPEE and CONCAWE) and their accompanying experts (EUROFEU). He informed the participants that the dossier has been submitted by ECHA in January 2022 and aims to restrict the formulation, placing on the market and use of PFASs for the use in fire-fighting foams.	
Based on the recommendations of the Restriction Working Group which met on 05-06 May 2022, RAC-61 provisionally agreed on the: • Scope of the restriction proposal, including the grouping of PFASs and the targeting of firefighting foam • Hazard assessment in terms of persistence combined with a variety of supporting hazards are the main hazard concerns to be addressed • Case-by-case risk assessment approach and consideration of PFASs as non-threshold substances The rapporteurs then presented and RAC briefly discussed the 1st draft opinion. RAC supported the WG recommendation to further evaluate the hazard assessment for the PFAS group and the assumptions underlying the emission modelling and overall exposure assessment.	**Rapporteurs** to prepare the second draft opinion, taking into account the discussions of RAC-61 and the RAC-61 Working Group on restrictions. **Secretariat** to table the second draft opinion for discussion at the RAC-62 Working Group on restrictions in August 2022.
The accompanying expert to the regular CropLife, EEB and CEFIC stakeholder observers commented on the hazard assessment and exposure assessment.	
2. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting – second draft opinion	
The Deputy Chair welcomed the Dossier Submitter's representatives from ECHA, the regular stakeholder observers, and their accompanying expert (Coal Chemicals Europe sector group), as well as the occasional stakeholder observer (CONCAWE). She informed the participants that the dossier has been submitted by ECHA in October 2021 and concerns on the placing on the market and use of substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting.	
Based on the recommendations of the Restriction Working Group which met on 5-6 May 2022, RAC-61 agreed on the: • Exposure assessment	**Rapporteurs** to prepare the third draft opinion, taking into account the discussions of RAC-61 and the RAC-61 Working Group on restrictions as well as the outcome of third party consultation.

• Evaluation on the estimation of releases and exposure of the environment • Qualitative approach to address human exposure • Characterization of risk • Many PAHs contained in clay targets are PBT/vPvB and genotoxic carcinogens, emissions are a suitable proxy of risks, consistent with previous similar restrictions. • Evidence that the risk management measures and operational conditions implemented and/or recommended by the manufactures and/or importers are not sufficient to control the risk • Conclusions from AfAs for use of CTPHT in clay targets apply to this restriction and analogously to all binders containing PAHs. • The aim is minimisation of releases to environment. • Evidence that the existing regulatory risk management instruments are not sufficient to control the risk • Justification that action is required on an union-wide basis • A union-wide action to address the risks associated with manufactured or imported clay targets with substances containing PAHs is needed to ensure a harmonised high level of protection of environment across the EU. • Reasons to act on a Union-wide basis is the cross-boundary environmental problem, due to the PBT and vPvB properties of PAHs containing binder materials, and due to the wide-spread use and exposure, considering also the carcinogenic PAHs • Justification that the suggested restriction is the most appropriate EU wide measure.	**Secretariat** to table the third draft opinion for discussion at the RAC-62 Working Group on restrictions in August 2022.

Furthermore, RAC provided input to the effectiveness and enforceability of different sets of PAH indicators. Regarding effectiveness, practicality and enforceability, RAC requested that the uncertainties should be clearly reflected in the opinion.	
The accompanying expert to the regular CEFIC stakeholder observer commented on the effectiveness.	
3. 2,4-dinitrotoluene – third draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA. He informed the participants that the restriction dossier had been submitted in July 2021 and concerns the placing on the market or use of 2,4 dinitrotoluene in articles for supply to the general public or to professional workers in concentrations greater than 0.1 % weight by weight. In accordance with Article 69(2) of REACH, ECHA considers that there are uses of the substance in articles for which the risks are not adequately controlled.	

Based on the recommendations of the Restriction Working group which met on 5-6 May 2022, RAC-61 agreed on:
 	
- Justification for action on an EU-wide basis;
- Justification that the suggested restriction is the most appropriate EU wide measure;
- The proposed restriction is an effective measure for addressing the identified risks assessed by the DS;
- The proposed restriction is practical, enforceable and monitorable;
- The proposed derogations.
 	
The rapporteur presented and RAC discussed the revised 3rd draft opinion:
 	
• Regarding to the scope, RAC recommended:
  • for the Commission to consider including explosives for civil uses are those defined in Directive 2014/28/EU; and pyrotechnic articles are those defined in Article 3 ((1) to (4), Directive 2013/29/EU
  • to change industrial installation by industrial site (some industrial site does not include industrial installation)
	The rapporteur, together with **SECR,** to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion.
	
	SECR to forward the adopted opinion and its supporting documentation to SEAC.

• Noting that no risk assessment has been made in the restriction proposal for these uses, RAC agreed that the effectiveness and practicability, including enforceability would have been further increased by including explosives for civilian and industrial use in the scope of the restriction. • RAC recommended that the need for a restriction of DNT (a substance containing 2,4-DNT as a constituent) could also be usefully assessed at some point in the future. RAC also concluded not to add a recommendation on the setting of a binding OEL; • Overall, RAC concluded that there are uncertainties associated with the restriction proposal, but these do not change the conclusion that there is a risk from 2,4-DNT that is not adequately controlled. Finally, RAC adopted its opinion by consensus.	
4. Lead and its compounds in outdoor shooting and fishing – fifth draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA, the SEAC rapporteurs, invited experts from UNEP/AEWA, the regular stakeholder observers, and their accompanying experts (from International Lead Association (ILA)), and University of Cambridge) as well as the occasional stakeholder observers and their accompanying experts from European Anglers Alliance (EAA), FACE, FITASC/ISSF, and AquaTerraSana. He informed the participants that the restriction dossier had been submitted in January 2021 and concerns lead in outdoor shooting and fishing.	
Based on the recommendations of the Restriction Working Group which met on 5-6 May 2022, RAC-61 agreed on (hunting and sports shooting): • Evidence that the RMMs and OCs implemented and recommended by the manufactures and/or importers are not sufficient to control the risk • Evidence that the existing regulatory risk management instruments are not sufficient to control the risk • Justification that action is required on an Union wide basis	**The rapporteur**, together with **SECR,** to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.

• Justification that the suggested restriction is the most appropriate EU wide measure
  • Targeting/scope
  • Effectiveness in reducing the risk
• Practicality, including enforceability
• Monitorability
 	
The rapporteurs then presented and RAC discussed the revised 5th draft opinion.
 	
RAC concluded that there is justification that action is required on an Union wide basis, as the use of lead in hunting and sports shooting is widespread and there is evidence on the risk to the environment and to human health that is not adequately controlled.
 	
RAC concluded that there is justification that the suggested restriction is the most appropriate EU wide measure:
 	
• for hunting, RAC agreed with the conditions of the restriction and the derogations proposed by the DS:
  ○ Derogations for seal hunting and for the use of full metal jacket bullets for Nordic bird hunting.
  ○ For copper and copper-based (brass) bullets, a concentration limit of 3% of lead w/w is proposed with a later review to determine if a concentration of less than 1 % of lead w/w can be achieved.
  ○ Several comments submitted in the consultation of the Annex XV restriction report requested also a derogation for small calibres due to the lack of alternatives with adequate precision. Instead of a derogation, RAC supported the DS proposal for a longer transition period of 5 years (with a review before entry into force).
• RAC proposed a shorter transition period than 5 years for the ban of using gunshot in hunting.
• For sports shooting with lead gunshot, RAC agreed with the conditions proposed by the DS. RAC did not support the optional derogation and considered that the enforceability of the restriction would be greatly improved if the optional derogation is not implemented. As a secondary option	

the optional derogation should be limited to shot sizes used in sports shooting, as proposed by SEAC. • For sports shooting with lead projectiles other than gunshot, RAC agreed with the conditions of the restriction and the derogation proposed by the DS, when the shooting range has been notified to the Member State and adequate risk management measures are implemented (bullet trap chambers or "best practise sand traps" with overhanging roof or a permanent cover, and a water management system), combined with a ban of any agricultural use within the site boundary and compulsory information. RAC supported the proposed labelling requirements and information requirements at the point of sale for lead ammunition. However, RAC proposed to use the limit of ≥1.0% w/w of lead to trigger the information and labelling requirements. If a derogation allowing the use of copper or copper alloys containing lead up to 3% in other projectiles not defined as gunshot is accepted, then the information and labelling requirements should be applied for these alternatives only when lead content ≥3% w/w. RAC supported labelling of individual shotgun cartridges with the statement "Contains lead: do not use for hunting." Attention should be paid also to the readability of the labelling of individual cartridges, which can be improved by introducing g a colour coding). RAC concluded that the proposed restriction is effective in reducing risks, practical, enforceable and monitorable. RAC agreed with the DS that there are significant uncertainties related to the exposure assessment due to game meat consumption, which might be underestimated. There are also uncertainties related to the enforcement of bullets for hunting due to the derogated uses or uses outside of scope and also for gunshot if the optional derogation is accepted. There are uncertainties also related to the enforcement of use which requires inspection of individuals. RAC agreed with the DS that there are significant uncertainties related to the assessment of human health risks due to	

outdoor shooting and home-casting of ammunition, and to the number of shooting ranges in vulnerable areas in which contamination of ground water may occur. Finally, RAC adopted its opinion by consensus.	
The occasional stakeholder observer FACE commented on the difficulties encountered in obtaining access to the European Food Safety Authority (EFSA) data on game meat intake. The occasional stakeholder observer FITASC/ISSF together its accompanying expert commented on risks at shooting ranges. The invited expert commented on the lead impact on wildlife and birds. The expert accompanying the regular stakeholder observer from EEB commented on risks to common bird species and to subsistence hunters. The occasional stakeholder observer from EAA commented on alternatives for certain lead sinkers (the Secretariat asked for this information to be submitted in the consultation on the SEAC draft opinion).	
10. Authorisation	
10.1 General authorisation issues	
1. Report from the May AFA Working Group	
The Secretariat presented the Report of the 11th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 10-11 May 2022. RAC took note of the Report.	
2. Update on incoming/future applications	
The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2022 and timelines. RAC took note of the information.	
3. Update of technical guidance for rapporteurs ('Lines to take')	
The ECHA Secretariat presented the Update of technical guidance for rapporteurs ("Lines to take"). RAC took note of the information.	
10.2 Authorisation applications	
10.2.1. Discussion on key issues	
1. **13 applications for authorisation (chromium trioxide and trixylyl phosphate) from the February 2022 submission window**	
RAC discussed the key issues in 13 applications for authorisation (chromium trioxide and	

trixylyl phosphate) from the February 2022 submission window The table was made available on the S-CIRCABC and on the Interact Portal.	

10.3 Agreement on draft opinions

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

1. 242_RR1_TCE_Microporous (1 use)
2. 243_RR1_TCE_DOMO (1 use)
3. 244_CT_Cromaplast (2 uses)
4. 247_OPE_Boehringer_2 (1 use)
5. 248_NPE_OCV (1 use)
6. 249_CT_Tenneco_CZ (1 use)
7. 250_CT_Tenneco_ES (1 use)
8. 251_CT_Tenneco_BE (1 use)
9. 252_CT_Tenneco_PL (1 use)

The Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 11th meeting the RAC AFA WG the 10 draft opinions have been proposed for agreement via the A-listing procedure. ECHA Secretariat presented the summary of the draft opinions.

RAC agreed by consensus the 10 draft opinions on the following Application cases.

242_RR1_TCE_Microporous (1 use) **Use1:** *Trichloroethylene used as extraction solvent in the manufacture of polyethylene separators for lead-acid 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. RAC agreed: Section 7. Proposed additional conditions for the authorisation None Section 8. Proposed monitoring arrangements for the authorisation 1. The authorisation holder shall implement a continuous monitoring of TCE workplace concentrations in the extraction units and shall continue to perform a continuous monitoring of TCE workplace concentrations in the production and finishing areas and conduct an annual monitoring programme of occupational exposure for trichloroethylene of workers, directly or	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

indirectly involved in the production of polyethylene separators for lead-acid batteries, using a sufficiently sensitive analytical method for inhalation exposure measurement and for biomonitoring. Samples for biomonitoring should be taken at the end of the last shift of the working week, as recommended by the SCOEL when establishing the BLV for TCE. The monitoring programmes shall be based on relevant standard methodologies or protocols, comprise both static and personal inhalation exposure sampling, include detailed contextual information on the tasks performed, the duration of monitoring, the OCs and RMMs in place and be representative of: a. the range of tasks undertaken within all worker contributing scenarios identified where exposure to trichloroethylene is possible, including tasks involving maintenance tasks; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed, including workers not directly using the substance. 2. The authorisation holder shall maintain the continuous TCE measurements in exhaust air using a sufficiently sensitive analytical method and the continuous measurement of exhaust air volume flow of the active carbon plant chimney, to obtain a more accurate statement about the air emission. 3. The information gathered via the measurements referred to in paragraphs 1 and 2, as well as related contextual information, shall be used by the authorisation holder to confirm the effectiveness of OCs and RMMs and to review regularly the effectiveness of OCs and RMMs in place and to introduce measures to further reduce workplace exposure, respectively air emissions of TCE, to as low a level as technically and practically feasible. 4. The information from the monitoring programmes referred to in paragraphs 1	

and 2, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 3, shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent authority, and included in any subsequent authorisation review report. 5. The authorisation holder may reduce the frequency of measurements, once he can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at the site where the use takes place shall be documented. The authorisation holder shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. Section 9. Recommendations for the review report The results of the measurements referred to in section 8, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8, should be documented and included in any subsequent review report.	
243_RR1_TCE_DOMO (1 use) **Use1:** *Industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. RAC agreed: Section 7. Proposed additional conditions for the authorisation 1. The authorisation holder shall implement the OCs and RMMs as planned, for example the extension of the vent system with integration of a vessel and a separation tube, to seal the system and prevent the TCE emissions. 2. The authorisation holder shall carry out and document a feasibility study to further limit fugitive emissions. Section 8. Proposed monitoring arrangements for the authorisation 1. The authorisation holder shall continue to conduct regular occupational exposure measurements relating to the use of TCE described in this review report. (a) Occupational inhalation exposure monitoring programmes, which shall: (i) take place at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to trichloroethylene.; (ii) be based on relevant standard methodologies or protocols; (iii) ensure a sufficiently low limit of quantification; (iv) comprise personal and/or static inhalation exposure sampling; (v) be representative of: a. the full range and duration of tasks undertaken where exposure to trichloroethylene is possible, i.e. including production and maintenance workers;	**SECR** to send the draft opinion to the applicant for commenting.

b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (vi) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the authorisation holder shall continue conducting their monitoring programme for TCE emission to air and wastewater monitoring before discharging the wastewater to the WWTP; (ii) the authorisation holder shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the authorisation holder's site. 1. The authorisation holder shall use the information gathered via the measurements referred to in Section 8.1 including the contextual information to review annually the effectiveness of the risk management measures and operational conditions and to introduce measures to reduce worker's exposure to trichloroethylene as well as emissions to the environment to as low a level as technically and practically feasible. 2. The authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The authorisation holder shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph	

1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The authorisation holders may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 6, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holder shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. 7. The authorisation holder shall continue their existing biomonitoring programme for the workers potentially exposed to trichloroethylene. Section 9. Recommendations for the review report The authorisation holder should document - in a potential further review report - the results of the monitoring programs and the	

optimisation of RMMs and OCs carried out in order to minimise the TCE emissions.	
244_CT_Cromaplast (2 uses) **Use1:** *Industrial use of CrO3 in the pre-treatment (etch) in the chrome plating process of automotive plastic components* 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. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO3 flakes by liquid CrO3 to further limit exposure b) the implementation of a closed automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths in both lines c) the implementation of an automatic system for drawing samples at the Line A1A2 d) the implementation of an automatic system to replace the manual tasks of skimming the etching baths and stirring the baths in both lines e) the coverage of the baths of the A1A2 line as in the new plating line (Line 2004). The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period Section 8. Proposed monitoring arrangements for the authorisation	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

1. The applicant shall continue their yearly monitoring programmes for Cr(VI) and considering the following: a. Occupational inhalation exposure monitoring programmes, which shall: i. be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); ii. be based on relevant standard methodologies or protocols; iii. ensure a sufficiently low limit of quantification; iv. comprise personal and / or static inhalation exposure sampling; v. be representative of: a. the full range and duration of tasks undertaken where exposure to Cr(IV) is possible, including rare maintenance activities (WCS 8) and waste and wastewater management (WCS 9). b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; vi. include contextual information about the tasks performed during sampling; b. Environmental releases: i. the applicant shall continue conducting their yearly monitoring programme for Cr(VI) emission to wastewater and air; ii. the applicant shall conduct air emission measurements more frequently following any possible changes in the process; iii. the monitoring programmes for wastewater and air emissions shall:	

a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraphs 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The authorisation holder may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed	

in the chemical safety report function appropriately 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. 7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the feasibility studies as mentioned in Section 7 and the monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report. **Use2:** *Industrial use of CrO3 in the chrome plating of automotive plastic components.* 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. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on:	

a) the substitution of solid CrO3 flakes by liquid CrO3 to further limit exposure b) the implementation of a closed automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths in both lines c) the implementation of an automatic system for drawing samples at the Line A1A2 d) the implementation of an automatic system to replace the manual tasks of skimming the etching baths and stirring the baths in both lines e) the coverage of the baths of the A1A2 line as in the new plating line (Line 2004). The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue their yearly monitoring programmes for Cr(VI) and considering the following: a. Occupational inhalation exposure monitoring programmes, which shall: i. be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); ii. be based on relevant standard methodologies or protocols; iii. ensure a sufficiently low limit of quantification; iv. comprise personal and / or static inhalation exposure sampling; v. be representative of:	

a. the full range and duration of tasks undertaken where exposure to Cr(IV) is possible, including rare maintenance activities (WCS 8) and waste and wastewater management (WCS 9). b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; vi. include contextual information about the tasks performed during sampling; b. Environmental releases: i. the applicant shall continue conducting their yearly monitoring programme for Cr(VI) emission to wastewater and air; ii. the applicant shall conduct air emission measurements more frequently following any possible changes in the process; iii. the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraphs 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.	

3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The authorisation holder may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The authorisation holders shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. 7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report	

The results of the feasibility studies as mentioned in Section 7 and the monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report.	
247_OPE_Boehringer_2 **Use1:** *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a detergent in the purification of lapidated OspA protein subsequently used for manufacturing of Lyme disease vaccine candidate.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. RAC agreed: Section 7. Proposed additional conditions for the authorisation none Section 8. Proposed monitoring arrangements for the authorisation As soon as the full-scale production commences the applicant shall monitor at least quarterly or 4 times per year (during the time of operation) 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site WWTP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The results of the monitoring programme shall be used to ensure that the effectiveness of the OCs and RMMs recorded during the small-scale production will also be achieved during the full-scale production. The results shall be documented, maintained, and made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. The results should be included in any review report, including details of sampling point, the	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

analytical method, the concentrations detected and the corresponding environmental release values. Section 9. Recommendations for the review report The information gathered via the measurements referred to in Section 8 as well as the outcome and conclusions of the review and any action taken should be included in any subsequent authorisation review report.	
248_NPE_OCV **Use1:** *Mixing by the Applicant of a 4-NPnEO-containing epoxy resin, resulting in mixtures containing < 0.1% w/w of 4-NPnEO for the manufacture of glass fibre articles for critical composite helicopter parts, that is exempt from authorisation under REACH Art. 56(6)(a)* 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 use applied for may result in 0 kg per year releases of the substance to the environment. RAC agreed: Section 7. Proposed additional conditions for the authorisation none Section 8. Proposed monitoring arrangements for the authorisation none Section 9. Recommendations for the review report none	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
249_CT_Tenneco_CZ **Use1:** *The use of Chromium Trioxide (EC 215-607-8) by Monroe Czechia s.r.o. in the functional chrome plating of shock absorber rods.* 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.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC agreed: Section 7. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 flakes by liquid CrO_3 to further limit exposure, taking into account additional RMMs such as the use of a plastic sleeve adapter on the top of solid CrO_3 container to prevent exposure of the workers to CrO_3 dust. (b) the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen 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. Relevant actions must be implemented accordingly during the review period. Until the implementation of the relevant actions according to feasibility study, the applicant shall consider additional RMMs (for example, the use of a plastic sleeve adapter on the top of solid CrO_3 container) to prevent exposure of the workers to CrO_3 dust. Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue to implement the following programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes, which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) ensure a sufficiently low limit of quantification;	

(iv) comprise personal and/or static inhalation exposure sampling, including sampling, preventative and corrective maintenance activities (WCSs 7, 8 and 10); (v) be representative of: a. the full range of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (vi) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. 3. The applicant shall use the monitoring	

results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. 6. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report	

The results of the feasibility study referred to in section 7.1 and the measurements referred to in sections 8 paragraph 1, and 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, should be documented and included in any subsequent review report.	
250_CT_Tenneco_ES **Use1:** *The use of Chromium Trioxide (EC 215-607-8) by Tenneco Automotive Ibérica S.A in the functional chrome plating of shock absorber rods.* 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. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen 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. Relevant actions must be implemented accordingly during the review period. Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue to implement the following programmes for Cr(VI): (c) Occupational inhalation exposure monitoring programmes, which shall: (vii) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

workers to Cr(VI); (viii) be based on relevant standard methodologies or protocols; (ix) ensure a sufficiently low limit of quantification (x) comprise personal and/or static inhalation exposure sampling, including corrective maintenance activities (WCS 6); (xi) be representative of: d. the full range of tasks undertaken where exposure to Cr(VI) is possible; e. the OCs and RMMs typical for each of these tasks; f. the number of workers potentially exposed; (xii) include contextual information about the tasks performed during sampling. (d) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: c. be based on relevant standard methodologies or protocols; and d. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce	

workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as	

low a level as technically and practically possible. 6. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the feasibility study referred to in section 7.1 and the measurements referred to in sections 8 paragraph 1, and 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, should be documented and included in any subsequent review report.	
251_CT_Tenneco_BE **Use1:** *The use of Chromium Trioxide (EC 215-607-8) by Tenneco Automotive Europe BVBA in the functional chrome plating of shock absorber rods* 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. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: (a) the feasibility of automated/closed decanting of solid chromium trioxide into the pre-mixing tank (for example using a closed cabinet or glove box), (b) the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. The feasibility study shall be concluded within 12 months of the granting of the authorisation for this use. Relevant actions must be implemented accordingly during the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue to implement the following programmes for Cr(VI): (e) Occupational inhalation exposure monitoring programmes, which shall: (xiii) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (xiv) be based on relevant standard methodologies or protocols; (xv) ensure a sufficiently low limit of quantification (xvi) comprise personal and/or static inhalation exposure sampling, including activities such as sampling and corrective maintenance (WCSs 7 and 9); (xvii) be representative of: g. the full range of tasks undertaken where exposure to Cr(VI) is possible; h. the OCs and RMMs typical for each of these tasks; i. the number of workers potentially exposed; (xviii) include contextual information about the tasks performed during sampling. (f) Environmental releases: a. the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; b. the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process~~;~~ c. the monitoring programmes for wastewater and air emissions shall: e. be based on relevant standard methodologies	

or protocols; and f. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicantshall also review and, if needed, update their assessment of the combined exposure for the different groups of workers *3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.* 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. *5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function*	

appropriately. *Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible.* 6. The applicant shall reimplement an annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the measurements referred to in sections 8 paragraph 1 and 4, , as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, should be documented and included in any subsequent review report.	
252_CT_Tenneco_PL **Use1:** *The use of Chromium Trioxide (EC 215-607-8) by Tenneco Automotive Eastern Europe Sp. z o.o in the functional chrome plating of shock absorber rods* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. RAC agreed: Section 7. Proposed additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period. Section 8. Proposed monitoring arrangements for the authorisation 1. The applicant shall continue to implement the following programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes, which shall: (i) be conducted quarterly (as performed currently). The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) ensure a sufficiently low limit of quantification (iv) comprise personal and/or static inhalation exposure sampling, including sampling and corrective maintenance activities (WCSs 7 and 9); (v) be representative of: a. the full range of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (vi) include contextual information about the tasks performed during sampling. (b) Environmental releases: a. the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; b. the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; c. the monitoring programmes for wastewater and air emissions	

shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report function	

appropriately. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. 6. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the feasibility study referred to in section 7.1 and the measurements referred to in sections 8 paragraph 1, and 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, should be documented and included in any subsequent review report.	
10.4 Agreement of opinions	
245_CT_Newform (1 use)	
Use1: *Electroplating of different types of substrates using Chromium Trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications* RAC discussed: Proposed additional conditions for the authorisation - RAC proposed to add condition to apply the hierarchy of control - RAC recommended to request decommissioning of the manual plating line immediately in the justification of the conditions. Proposed monitoring arrangements for the authorisation - RAC proposed to delete point 5 and point 6.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion according to the discussion at the plenary. **SECR** to send the draft opinion to the applicant for commenting.

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk.

RAC agreed:

Section 7. Proposed additional conditions for the authorisation

RAC proposes the following conditions for the authorisation:

1. The applicant shall immediately discontinue the use of the manual plating line until such time as the process is modified so that workers no longer stay nearby the Cr(VI)-containing baths and manually hold the jigs during plating and the OCs and RMMs are effective in limiting the risk.
2. The applicant shall carry out and document a detailed feasibility study:
    a. on the automation of the concentration adjustment using liquid CrO_3 within a closed system.
    b. on the automatization or a closed system to perform the bath sampling.
3. The applicant shall implement the necessary OCs and RMMs (e.g., physical segregation) to ensure that the exposure to Cr(VI) at the loading/unloading working area is as low a level as technically and practically feasible.
4. The feasibility study referred to in paragraph 2 and the implementation of the RMMs and OCs referred to in paragraph 3 shall be concluded within 12 months of the granting of authorisation for this use. Any relevant actions shall be implemented accordingly during the review period.
5. The applicant shall ensure that workers perform a 'fit check' of the seal of their RPE before taking on relevant tasks and workers shall be trained to perform this test adequately.

Section 8. Proposed monitoring arrangements for the authorisation

1. The applicant shall implement the following monitoring programmes for Cr(VI):
    a) Occupational inhalation exposure monitoring programme which shall:
        i. be conducted at least annually for the workers exposed to Cr(VI). The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI).

ii. be based on relevant standard methodologies or protocols. iii. ensure a sufficiently low limit of quantification. iv. comprise personal and/or static inhalation exposure sampling. v. be representative of: a. the full range and duration of tasks undertaken where exposure to Cr(IV) is possible. b. the OCs and RMMs typical for each of these tasks. c. the number of workers potentially exposed. vi. include contextual information about the tasks performed during sampling. b) Environmental releases: i. the applicant shall continue conducting their annual monitoring programme for Cr(VI) emission to wastewater or more frequently in the periods following any possible changes in the process. ii. the applicant shall conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process. iii. the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols. b. be representative of the OCs and RMMs used at the applicant's site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the OCs and RMMs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the studies and monitoring programmes referred to in paragraph 1, including the contextual	

information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. ~~5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the OCs and RMMs corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately.~~ ~~6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 4 any subsequent changes to the OCs or RMMs that may affect the exposure of workers and humans via environment at the site where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers and humans via environment continues to be reduced to as low a level as technically and practically possible.~~ 7. The applicant shall continue their existing annual biomonitoring programme for the workers potentially exposed to Cr(VI). Section 9. Recommendations for the review report The results of the feasibility study referred to in section 7.1 paragraph 2 and the measurements referred to in section 8.1 paragraph 1 as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent review report. RAC agreed the Draft Opinion by consensus.	
246_MOCA_Courbis (1 use)	
Use1: *Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of hot cast polyurethane products* RAC concluded that the operational conditions and risk management measures described in	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion according to the discussion at the plenary. **SECR** to send the draft opinion to the applicant for commenting.

the application are not appropriate and effective in limiting the risk. RAC agreed: Section 7. Proposed additional conditions for the authorisation 1. The applicant shall put in place, in all sites, the following RMMs: <u>Engineering measures</u> a) Glove boxes implemented for loading MOCA to all casting machines (this recommendation is for sites F and G); b) LEV in all the casting benches (this recommendation is for sites G, H and J). c) Curing shall be done in closed ovens with suitable exhaust ventilation located inside the oven. The ovens shall only be possible to open after the vapours have been completely exhausted (this recommendation is for sites B, F, J and K). d) In WCS 6 (pouring of PU mixture to moulds in partially open system) all the sites shall have LEV in place during the casting step. e) To control air emissions, suitable filters or other air abatement techniques shall be implemented in all the sites. <u>Organizational Measures</u> f) A regular cleaning and maintenance program of the glove boxes, including the structural integrity of the gloves shall be implemented to eliminate the potential for dermal exposure. g) An adequate maintenance program of all the LEV systems in place and also for the ones to be installed; h) Workers shall perform the sealing test of their RPE before taking on relevant tasks and shall be trained to perform this test adequately; i) All sites shall have a program to guarantee that all the working clothes are disposable or cleaned after a working day; j) Workers rotation to reduce biomonitoring levels shall be eliminated in all the sites. <u>Personal Protective Equipment (RPE)</u> The use of RPE shall be considered as the last resort in the hierarchy of control. Other preventive and protective measures shall be considered first, such as closed systems whenever possible, automating the process and/or by the use of engineering controls such as LEV. However, until such time as the	

engineering measures listed above are fully in place and their efficacy has been evaluated, RPE shall be considered as a provisional measure to protect workers. Therefore, workers should use RPE as follows: a) Near the casting benches until a LEV system is implemented; b) During curing or when opening the ovens after the curing process until all sites have closed ovens with suitable exhaust ventilation located inside; c) During the casting step in the sites that still do not have LEV systems are in place. The use of RPE could stop if exposure data obtained through monitoring campaigns allow the conclusion that there is no exposure (measured with a relevant standard methodologies or protocols). 2. The applicant shall carry out and document a feasibility study on substituting the semi-closed mixing chamber by a closed chamber in site D since this situation might result in workers exposure. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. Any relevant action shall be implemented accordingly during the review period. Section 8. Proposed monitoring arrangements for the authorisation 1. To have a detailed overview of the exposure to MOCA at the different sites and workplaces the applicant shall implement a complementary monitoring programme, using simultaneously different exposure assessment methods that are describe below: <u>a) Biomonitoring:</u> (i) Exposure of all workers working within the premises in which MOCA is used shall be followed by twice yearly biomonitoring programmes, in which urinary total MOCA levels are measured from urinary samples collected on the Friday afternoon after the work week. If urinary levels are repeatedly low (below LoD using sensitive biomonitoring methods) frequency of monitoring may be reduced to once per year. The applicant should also provide contextual information that allows connecting the data with each WCS, RMMs in place and changes in the process (e.g. increase of the volume used). <u>b) Air monitoring for occupational exposure:</u>	

The applicant shall continue their monitoring programmes for MOCA exposure, which shall: (i) be conducted at least annually for the workers exposed to MOCA. Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure due, for instance, to the foreseen increase of the volume used; (ii) be based on relevant standard methodologies or protocols ensuring a sufficiently low limit of quantification; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to MOCA is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. <u>c) Surface contamination monitoring:</u> (i) Surface measurements of surface contamination shall continue to be conducted at least twice per year in all sites in order to identify exposure sources and prevent exposure via the contaminated surfaces. This is especially important when biomonitoring shows measurable (above LoD) urinary MOCA levels but not limited to this criteria since the data provided should be used to take actions and prevent exposure. Surface monitoring shall be targeted to surfaces located in workplaces with highest potential for dust formation and with higher frequency for hands contact. <u>d) Environmental releases</u> (i) the applicant shall conduct air emission measurements in all the sites at least yearly, particularly if changes in the process justifies; (ii) the monitoring programmes for air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and	

RMMs used at the applicant´s sites. (iii) include contextual information about the RMMs and the process conditions in place when measurements were done. 2. The information gathered in the monitoring campaigns shall be used by the applicant to review and improve the RMMs and OCs to further reduce workers' exposure to MOCA. The outcomes and conclusions of this review, including those related to the implementation of any additional RMMs, must be documented. The results of the monitoring and of the review of the OCs and RMMs shall be maintained, be available to national enforcement authorities, and included in any subsequent authorisation review report submitted. Section 9. Recommendations for the review report The applicant should continue to conduct annual biomonitoring, air monitoring and surface monitoring programmes for the workers potentially exposed to MOCA. These monitoring programmes should be used as complementary, since all provide different information concerning exposure, and should be based on validated methodologies and protocols for MOCA exposure. In case of biomonitoring, the urinary sampling should be performed in the end of the shift and week. All these datasets should be included in future exposure assessments and included in any subsequent review report. The same principles should be followed for environmental releases monitoring. The results of the measurements referred to in sections 7 and 8 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with sections 7 and 8 paragraph 2, should be documented and included in any subsequent review report. RAC agreed the Draft Opinion by consensus.	
11. AOB	
The Chair presented information on the ECHA Executive Director Request to the Committee for Risk Assessment to set a DNEL for 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) under Article 77(3)(c).	

The Chair informed RAC that the request is to set DNELs reference value by 31st December 2022 for the applicants submitting applications in 2023. RAC took note of the request.	
12. Minutes of RAC-61	
12.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-61	
RAC adopted the final minutes by consensus at the plenary meeting.	**SECR** to upload the table with Summary Record of the Proceedings and Conclusions and Action points from RAC-61 to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-61

1. 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate (EC 219-207-4; CAS 2386-87-0)

2. Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl] phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]thyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl}naphthalene-2,7-disulfonate; [3] (EC 241-164-5 [1], - [2], - [3]; CAS 17095-24-8 [1], - [2], 100556-82-9 [3])

3. 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (EC 438-340-0; CAS 119344-86-4)

4. Formic acid ...% (EC 200-579-1; CAS 64-18-6)

5. Glyphosate (EC 213-997-4, CAS 1071-83-6)

6. Dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid (EC 217-635-6; CAS 1918-00-9)

7. Peracetic acid …% (EC 201-186-8; CAS 79-21-0)

8. Formaldehyde …% (EC 200-001-8; CAS 50-00-0)

9. S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC -; CAS 87392-12-9)

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

1. 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate (EC 219-207-4; CAS 2386-87-0)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	219-207-4	2386-87-0	Muta. 2 STOT RE 2 Skin Sens. 1	H341 H373 (nasal cavity) H317	GHS08 GHS07 Wng	H341 H373 (nasal cavity) H317			
RAC opinion	TBD	7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	219-207-4	2386-87-0	Muta. 2 STOT RE 2 Skin Sens. 1	H341 H373 (nasal cavity) H317	GHS08 GHS07 Wng	H341 H373 (nasal cavity) H317			
Resulting Annex VI entry if agreed by COM	TBD	7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	219-207-4	2386-87-0	Muta. 2 STOT RE 2 Skin Sens. 1	H341 H373 (nasal cavity) H317	GHS08 GHS07 Wng	H341 H373 (nasal cavity) H317			

2. Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl] phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl} naphthalene-2,7-disulfonate; [3] (EC 241-164-5 [1], - [2], - [3]; CAS 17095-24-8 [1], - [2], 100556-82-9 [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	607-RST-VW-Y	tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy) ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl) phenyl]diazenyl}naphthalene-2,7-disulfonate; [3]	241-164-5 [1] - [2] - [3]	17095-24-8 [1] - [2] 100556-82-9 [3]	Resp. Sens. 1A Skin Sens. 1	H334 H317	GHS08 Dgr	H334 H317			
RAC opinion	607-RST-VW-Y	tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy) ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate; [1] and	241-164-5 [1] - [2] - [3]	17095-24-8 [1] - [2] 100556-82-9 [3]	Resp. Sens. 1A Skin Sens. 1	H334 H317	GHS08 Dgr	H334 H317			

		Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl) phenyl]diazenyl}naphthalene-2,7-disulfonate; [3]									
Resulting Annex VI entry if agreed by COM	607-RST-VW-Y	tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy) ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl) phenyl]diazenyl}naphthalene-2,7-disulfonate; [3]	241-164-5 [1] - [2] - [3]	17095-24-8 [1] - [2] 100556-82-9 [3]	Resp. Sens. 1A Skin Sens. 1	H334 H317	GHS08 Dgr	H334 H317			

3. 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (EC 438-340-0; CAS 119344-86-4)

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	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	438-340-0	119344-86-4	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360FD H400 H410	GHS08 GHS09 Dgr	H360FD H410		M = 1 M = 1	
RAC opinion	TBD	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	438-340-0	119344-86-4	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360Df H400 H410	GHS08 GHS09 Dgr	H360Df H410		M = 1 M = 1	
Resulting Annex VI entry if agreed by COM	TBD	2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one	438-340-0	119344-86-4	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360Df H400 H410	GHS08 GHS09 Dgr	H360Df H410		M = 1 M = 1	

4. Formic acid ... % (EC 200-579-1; CAS 64-18-6)

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	607-001-00-0	formic acid ... %	200-579-1	64-18-6	Skin Corr. 1A	H314	GHS05 Dgr	H314		Skin Corr. 1A; H314: C ≥ 90% Skin Corr. 1B; H314: 10% ≤ C < 90% Skin Irrit. 2; H315: 2% ≤ C < 10% Eye Irrit. 2; H319: 2% ≤ C < 10%	B
Dossier submitters proposal	607-001-00-0	formic acid ... %	200-579-1	64-18-6	**Add** Flam. Liq. 3 Met. Corr. 1 Acute Tox. 3 Acute Tox. 4 Eye Dam. 1	**Add** H226 H290 H331 H302 H318	**Add** GHS02 GHS06	**Add** H226 H290 H331 H302	**Add** EUH071	**Add** Flam. Liq. 3; H226: C ≥ 99% Met. Corr. 1; H290: C ≥ 85% Eye Dam. 1; H318: C ≥ 10%	
RAC opinion	607-001-00-0	formic acid ... %	200-579-1	64-18-6	**Add** Flam. Liq. 3 Met. Corr. 1 Acute Tox. 3 Acute Tox. 4 Eye Dam. 1	**Add** H226 H290 H331 H302 H318	**Add** GHS02 GHS06	**Add** H226 H290 H331 H302	**Add** EUH071	**Add** Flam. Liq. 3; H226: C > 85% inhalation: ATE = 7.4 mg/L (vapours) oral: ATE = 500 mg/kg bw Eye Dam. 1; H318: C ≥ 10%	
Resulting Annex VI entry if agreed by COM	607-001-00-0	formic acid ... %	200-579-1	64-18-6	Flam. Liq. 3 Met. Corr. 1 Acute Tox. 3 Acute Tox. 4 Skin Corr. 1A Eye Dam. 1	H226 H290 H331 H302 H314 H318	GHS02 GHS06 GHS05 Dgr	H226 H290 H331 H302 H314	EUH071	Flam. Liq. 3; H226: C > 85% inhalation: ATE = 7.4 mg/L (vapours) oral: ATE = 500 mg/kg bw Skin Corr. 1A; H314: C ≥ 90% Skin Corr. 1B; 314: 10% ≤ C < 90% Skin Irrit. 2; H315: 2% ≤ C < 10% Eye Dam. 1; H318: C ≥ 10% Eye Irrit. 2; H319: 2% ≤ C < 10%	B

5. Glyphosate (EC 213-997-4, CAS 1071-83-6)

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	607-315-00-8	Glyphosate	213-997-4	1071-83-6	Eye Dam. 1 Aquatic Chronic 2	H318 H411	GHS05 GHS09 Dgr	H318 H411			
Dossier submitters proposal	607-315-00-8	Glyphosate	213-997-4	1071-83-6	Eye Dam. 1 Aquatic Chronic 2	H318 H411	GHS05 GHS09 Dgr	H318 H411			
RAC opinion	607-315-00-8	Glyphosate	213-997-4	1071-83-6	Eye Dam. 1 Aquatic Chronic 2	H318 H411	GHS05 GHS09 Dgr	H318 H411			
Resulting Annex VI entry if agreed by COM	607-315-00-8	Glyphosate	213-997-4	1071-83-6	Eye Dam. 1 Aquatic Chronic 2	H318 H411	GHS05 GHS09 Dgr	H318 H411			

6. Dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid (EC 217-635-6; CAS 1918-00-9)

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	607-043-00-X	dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid	217-635-6	1918-00-9	Acute Tox. 4* Eye Dam. 1 Aquatic Chronic 3	H302 H318 H412	GHS07 GHS05 Dgr	H302 H318 H412			
Dossier submitters proposal	607-043-00-X	dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid	217-635-6	1918-00-9	**Retain** Eye Dam. 1 **Add** Carc. 2 Acute Tox. 4 STOT SE 3 STOT SE 3 Aquatic Acute 1 **Modify** Acute tox. 4 Aquatic Chronic 1	**Retain** H318 **Add** H351 H332 H335 H336 H400 **Modify** H302 H410	**Retain** GHS07 GHS05 Dgr **Add** GHS08 GHS09	**Retain** H318 **Add** H351 H332 H335 H336 **Modify** H302 H410		**Add** inhalation: ATE = 4.46 mg/L oral: ATE = 1581 mg/kg bw M = 1 M = 1	
RAC opinion	607-043-00-X	dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid	217-635-6	1918-00-9	**Retain** Eye Dam. 1 **Add** Acute Tox. 4 STOT SE 3 STOT SE 3 Aquatic Acute 1 **Modify** Acute Tox. 4 Aquatic Chronic 2	**Retain** H318 **Add** H332 H335 H336 H400 **Modify** H302 H411	**Retain** GHS07 GHS05 Dgr **Add** GHS08 GHS09	**Retain** H318 **Add** H332 H335 H336 **Modify** H302 H410		**Add** inhalation: ATE = 4.0 mg/L oral: ATE = 1500 mg/kg bw M = 1	
Resulting Annex VI entry if agreed by COM	607-043-00-X	dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid	217-635-6	1918-00-9	Acute Tox. 4 Acute Tox. 4 Eye Dam. 1 STOT SE 3 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 2	H332 H302 H318 H335 H336 H400 H411	GHS07 GHS05 GHS09 Dgr	H332 H302 H318 H335 H336 H410		inhalation: ATE = 4.0 mg/L oral: ATE = 1500 mg/kg bw M = 1	

7. Peracetic acid … % (EC 201-186-8; CAS 79-21-0)

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	607-094-00-8	Peracetic acid	201-186-8	79-21-0	Flam. Liq. 3 Org. Perox. D**** Acute Tox. 4* Acute Tox. 4* Acute Tox. 4* Skin Corr. 1A Aquatic Acute 1	H226 H242 H332 H312 H302 H314 H400	GHS02 GHS07 GHS05 GHS09 Dgr	H226 H242 H332 H312 H302 H314 H400		STOT SE 3; H335: C ≥ 1 %	B, D
Dossier submitters proposal	607-094-00-8	Peracetic acid	201-186-8	79-21-0	**Retain** Org. Perox. D**** Aquatic Acute 1 **Add** Aquatic Chronic 2§ **Modify** Acute Tox. 2 Acute Tox. 2 Acute Tox. 3 **Remove** Flam. Liq. 3	**Retain** H242 H400 **Add** H411§ **Modify** H330 H310 H301 **Remove** H226	**Retain** GHS02 GHS09 **Add** GHS06 **Remove** GHS07	**Retain** H242 **Modify** H330 H310 H301 H410 **Remove** H226	**Add** EUH071	**Add** inhalation: ATE = 0,204 mg/L (dusts and mists) dermal: ATE = 56.1 mg/kg bw oral: ATE = 70 mg/kg bw M = 10	
RAC opinion	607-094-00-8	Peracetic acid	201-186-8	79-21-0	**Retain** Org. Perox. D Aquatic Acute 1 **Add** Aquatic Chronic 1 **Modify** Acute Tox. 2 Acute Tox. 2 Acute Tox. 3 **Remove** Flam. Liq. 3	**Retain** H242 H400 **Add** H410 **Modify** H330 H310 H301 **Remove** H226	**Retain** GHS02 GHS09 **Add** GHS06 **Remove** GHS07	**Retain** H242 **Modify** H330 H310 H301 H410 **Remove** H226	**Add** EUH071	**Add** inhalation: ATE = 0,2 mg/L (dusts and mists) dermal: ATE = 60 mg/kg bw oral: ATE = 80 mg/kg bw M = 10 M = 100	**Add** T
Resulting Annex VI entry if	607-094-00-8	Peracetic acid	201-186-8	79-21-0	Org. Perox. D Acute Tox. 2 Acute Tox. 2 Acute Tox. 3	H242 H330 H310 H301	GHS02 GHS06 GHS05 GHS09	H242 H330 H310 H301	EUH071	inhalation: ATE = 0,2 mg/L (dusts and mists) dermal:	B, D, T

agreed by COM					Skin Corr. 1A Aquatic Acute 1 Aquatic Chronic 1	H314 H400 H410	Dgr	H314 H410		ATE = 60 mg/kg bw oral: ATE = 80 mg/kg bw STOT SE 3; H335: C ≥ 1 % M = 10 M = 100	

§ proposal changed to Aquatic Chronic 1, M factor = 100, H410 after the commenting period

8. Formaldehyde … % (EC 200-001-8; CAS 50-00-0)

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	605-001-00-5	formaldehyde … %	200-001-8	50-00-0	Carc. 1B Muta. 2 Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* Skin Corr. 1B Skin Sens. 1	H350 H341 H331 H311 H301 H314 H317	GHS08 GHS06 GHS05 Dgr	H350 H341 H331 H311 H301 H314 H317		* STOT SE 3; H335: C ≥ 5 % Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % Skin Sens. 1; H317: C ≥ 0,2 %	B, D
Dossier submitters proposal	605-001-00-5	formaldehyde … %	200-001-8	50-00-0	**Add** Flam. Gas 1B **Modify** Acute Tox. 2 Acute Tox. 3 Acute Tox. 4 Skin Sens. 1A	**Add** H221 **Modify** H330 H311 H302 H317	**Add** GHS02	**Add** H221 **Modify** H330 H311 H302 H317	**Add** EUH071	**Add** inhalation: ATE = 490 ppm (gases) dermal: ATE = 270 mg/kg bw oral: ATE = 640 mg/kg bw **Remove** Skin Sens. 1; H317: C ≥ 0,2 %	**Remove** *, D **Add** F, T, 5
RAC opinion	605-001-00-5	formaldehyde … %	200-001-8	50-00-0	**Modify** Acute Tox. 2 Acute Tox. 4 Skin Sens. 1A **Remove** Acute Tox. 3	**Modify** H330 H302 H317 **Remove** H311		**Modify** H330 H302 H317 **Remove** H311	**Add** EUH071	**Add** inhalation: ATE = 100 ppmV (gases) oral: ATE = 500 mg/kg bw **Remove** Skin Sens. 1; H317: C ≥ 0,2 %	**Retain** D **Remove** * **Add** F
Resulting Annex VI entry if agreed by COM	605-001-00-5	formaldehyde … %	200-001-8	50-00-0	Carc. 1B Muta. 2 Acute Tox. 2 Acute Tox. 4 Skin Corr. 1B Skin Sens. 1A	H350 H341 H330 H302 H314 H317	GHS08 GHS06 GHS05 Dgr	H350 H341 H330 H302 H314 H317	EUH071	inhalation: ATE = 100 ppmV (gases) oral: ATE = 500 mg/kg bw STOT SE 3; H335: C ≥ 5 % Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 %	B, D, F

9. S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC -; CAS 87392-12-9)

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	607-432-00-4	S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide	-	87392-12-9	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410			
Dossier submitters proposal	607-432-00-4	*S*-metolachlor (ISO); 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*S*)-1-methoxypropan-2-yl]acetamide; (R_aS_a)-2-chloro-*N*-(6-ethyl-*o*-tolyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide [contains 80-100% 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*S*)-1-methoxypropan-2-yl]acetamide and 0-20% 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*R*)-1-methoxypropan-2-yl]acetamide]	-	87392-12-9	**Retain** Aquatic Acute 1 Aquatic Acute 1 **Add** Carc. 2 Repr. 2 STOT RE 2	**Retain** H400 H410 **Add** H351 H361d H373 (skin)	**Retain** GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H351 H361d H373 (skin)		**Add** M = 10 M = 10	

RAC opinion	607-432-00-4	*S*-metolachlor (ISO); 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*S*)-1-methoxypropan-2-yl]acetamide; (R_aS_a)-2-chloro-*N*-(6-ethyl-*o*-tolyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide [contains 80-100% 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*S*)-1-methoxypropan-2-yl]acetamide and 0-20% 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*R*)-1-methoxypropan-2-yl]acetamide]	-	87392-12-9	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Carc. 2	**Retain** H400 H410 **Add** H351	**Retain** GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H351	**Add** EUH066	**Add** M = 10 M = 10	
Resulting Annex VI entry if agreed by COM	607-432-00-4	*S*-metolachlor (ISO); 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*S*)-1-methoxypropan-2-yl]acetamide; (R_aS_a)-2-chloro-*N*-(6-ethyl-*o*-tolyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide [contains 80-100% 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*S*)-1-methoxypropan-2-yl]acetamide and 0-20% 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(2*R*)-1-methoxypropan-2-yl]acetamide]	-	87392-12-9	Carc. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H317 H410	EUH066	M = 10 M = 10	

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

1/3

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	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	Silver massive: [particle diameter ≥ 1 mm]	231-131-3	7440-22-4	Muta. 2 Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H341 H360FD H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H341 H360FD H317 H410		 M = 10 M = 10	
RAC opinion	TBD	Silver massive: [particle diameter ≥ 1 mm]	231-131-3	7440-22-4	Repr. 2 STOT RE 2	H361f H373 (nervous system)	GHS08 Wng	H361f H373 (nervous system)			
Resulting entry in Annex VI if agreed by COM	TBD	Silver massive: [particle diameter ≥ 1 mm]	231-131-3	7440-22-4	Repr. 2 STOT RE 2	H361f H373 (nervous system)	GHS08 Wng	H361f H373 (nervous system)			

Note - The DS originally proposed that massive and powder silver should have the same classification and therefore one entry in Annex VI to CLP (i.e., all silver > 100 nm), based on the hazards of the powder. However, RAC has concluded that massive silver warrants independent assessment for aquatic hazards and 'No Classification' is concluded for aquatic hazards of massive silver.

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	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	Silver powder: [particle diameter > 100 nm < 1 mm]	231-131-3	7440-22-4	Muta. 2 Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H341 H360FD H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H341 H360FD H317 H410		 M = 10 M = 10	
RAC opinion	TBD	Silver powder: [particle diameter > 100 nm < 1 mm]	231-131-3	7440-22-4	Repr. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H361f H373 (nervous system) H400 H410	GHS08 GHS09 Wng	H361f H373 (nervous system) H410		 M = 10 M = 10	
Resulting entry in Annex VI if agreed by COM	TBD	Silver powder: [particle diameter > 100 nm < 1 mm]	231-131-3	7440-22-4	Repr. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H361f H373 (nervous system) H400 H410	GHS08 GHS09 Wng	H361f H373 (nervous system) H410		 M = 10 M = 10	

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	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	Silver nano: [particle diameter > 1 nm ≤ 100 nm]	231-131-3	7440-22-4	Muta. 2 Repr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H341 H360FD H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H341 H360FD H317 H410		M = 1000 M = 100	
RAC opinion	TBD	Silver nano: [particle diameter > 1 nm ≤ 100 nm]	231-131-3	7440-22-4	Repr. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H361f H373 (nervous system) H400 H410	GHS08 GHS09 Wng	H361f H373 (nervous system) H410		M = 1000 M = 1000	
Resulting entry in Annex VI if agreed by COM	TBD	Silver nano: [particle diameter > 1 nm ≤ 100 nm]	231-131-3	7440-22-4	Repr. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H361f H373 (nervous system) H400 H410	GHS08 GHS09 Wng	H361f H373 (nervous system) H410		M = 1000 M = 1000	

Part III. List of Attendees of the RAC-61 meeting

Part III. List of Attendees of the RAC-61 meeting

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

RAC members (remote attendance)	
Gebel	Thomas
Leinonen	Riitta
Strumylaite	Loreta

Apologies RAC members	
Hartwig	Andrea (co-opted member)
Stahlmann	Ralf
Tsakovska	Ivanka
Xanthos	Theodore

Members' advisers (physical attendance)		
Esposito	Dania	(Pietro Paris)_CLH: Glyphosate
Saksa	Jana	(Moldov Raili)

Members' advisers (remote attendance)		
Catone	Tiziana	(Gabriele Aquilina) CLH: Paracetic Acid
Hoffmann	Frauke	(Agnes Schulte)
Huuskonen	Pasi	(Santonen Tiina)
Lindeman	Birgitte	(Christine Bjørge)_CLH: Glyphosate
Marinkovic	Marino	(Gerlienke Schuur)
Nielsen	Peter Juhl	(Lea Stine Tobiassen) Restrictions: PFAS in fire fighting foam
Pace	Emanuela	(Pietro Paris)_CLH: Glyphosate
Russo	Maria Teresa	(Gabriele Aquilina) CLH: Paracetic Acid
Stalter	Daniel	(Agnes Schulte)
Suutari	Tiina	(Riitta Leinonen)

SEAC Rapporteurs (physical attendance)		
Kiiski	Johanna	Restrictions: PFAS in firefighting foams
Thiele	Karen	Restrictions: Lead in outdoor shooting and fishing
Urban	Klaus	Restrictions: PAHs in clay targets for shooting

Invited experts (remote attendance)		Substance
August	Christina (UPFAS)	Restrictions: PFAS in firefighting foams
Beekman	Martijn (UPFAS)	Restrictions: PFAS in firefighting foams
Cromie	Ruth (AEWA Technical Committee)	Restrictions: Lead in outdoor shooting and fishing
Dannenberg	Carl (UPFAS)	Restrictions: PFAS in firefighting foams
Dereliev	Sergey (UNEP/AEWA)	Restrictions: Lead in outdoor shooting and fishing
Ivarsson	Jenny (UPFAS)	Restrictions: PFAS in firefighting foams
Peltzer	Eike (WFVD)	Restrictions: PFAS in firefighting foams
Schulze	Jona (UPFAS)	Restrictions: PFAS in firefighting foams
Stalter	Daniel (UPFAS)	Restrictions: PFAS in firefighting foams
Winther	Toke (UPFAS)	Restrictions: PFAS in firefighting foams

Dossier submitters (physical attendance)		Substance
Jongeneel	Rob (NL)	Restrictions: N,N-dimethylacetamide and NEP

Dossier submitters (remote participation)		Substance
Alivernini	Silvia (IT)	Restrictions: Terphenyl, hydrogenated
Attias	Leonello (IT)	Restrictions: Terphenyl, hydrogenated
Birgander	Pernilla (SE)	CLH: Silver
Boquist	Pernilla (SE)	CLH: Silver
Catone	Tiziana (IT)	Restrictions: Terphenyl, hydrogenated
Charron	Isabelle (FR)	Restrictions: Creosote
Gall	Andrea (DE)	CLH: S-Metolachlor
Jacobsen	Pernille (DK)	CLH: dicamba
Jomini	Stéphane (FR)	Restrictions: Creosote
Lemaître	Cécile (FR)	Restrictions: Creosote
Lundberg	Katarina (SE)	CLH: Glyphosate
Orrú	Maria Antonietta (IT)	Restrictions: Terphenyl, hydrogenated
Pasquier	Elodie (FR)	Restrictions: Creosote
Ramsden	Niall (NL)	Restrictions: PFAS
Willenbockel	Christian Tobias (DE)	CLH: S-Metolachlor

Regular stakeholder observers (physical attendance)	
De Backer	Liisi (CEFIC), replacing Steven van de Brouck
Duguy	Hélène (ClientEarth)
Fernandez	Ana (EEB)
Ruelens	Paul (CropLife Europe)
Verougstraete	Violaine (Eurometaux)
Waeterschoot	Hugo (Eurometaux): Restriction: Lead and PAHs

Regular stakeholder observers (remote attendance)	
Barry	Frank (ETUI)
Robin	Nicolas (PlasticsEurope) Restrictions: PFAS in fire fighting foams
Robinson	Jan (A.I.S.E.)
Romano	Dolores (EEB)

Occasional stakeholders (remote participation)		Substance
Alami	Anissa (EPMF)	CLH: Silver
Ballach	Jochen (CIRFS)	Restrictions: DMAC and NEP conformity check and CLH: silver
Kappel	Jan (EAA)	Restrictions: Lead in outdoor shooting and fishing
Leonhardt	Thomas (EUROFEU)	Restrictions: PFAS in firefighting foams
Lyssimachou	Angeliki (HEAL)	CLH: Glyphosate
Niemela	Helena (CONCAWE)	General administrative, general CLH, general restrictions items; CLH dossiers; restrictions: creosote, terphenyl, hydrogenated; PFAS, PAHs
Palinkas	Jean-Francois (FITASC)	Restrictions: Lead in outdoor shooting and fishing
Puustinen	Seppo (FACE)	Restrictions: Lead in outdoor shooting and fishing

Stakeholder experts (remote participation)		Substance
Aveyard	Lindsay (EPMF/ GPC Consulting CC)	CLH: Silver
Bock	Ronald (Cefic/ AGC)	Restrictions: PFAS in firefighting foams
Bothe	Kathrin (CroplifeEurope)	CLH: Hazard classes to address developmental neurotoxicity
Clausing	Peter (ClientEarth/ Pesticide Action Network – PAN Germany)	CLH: Glyphosate
Grosse Hovest	Miriam (Cefic / Ecolab Deutschland)	CLH: Peracetic acid
Hannebaum	Peter (EUROFEU)	Restrictions: PFAS in firefighting foams
Höke	Hartmut (Eurometaux/ Coal Chemicals Europe sector group)	Restrictions: Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting
Kanstrup	Niels (ClientEarth/ Aarhus University)	Restrictions: Lead in outdoor shooting and fishing
Kasakov	Konstantin (PlasticsEurope/ Daikin Chemical Europe GmbH)	Restrictions: PFAS in firefighting foams
Korner	Mads Boye (Cefic/ Creosote Council Europe)	Restrictions: Creosote and creosote related substances
Leibold	Edgar (Cefic/ Formacare BASF)	CLH: Formaldehyde
Lloyd	Sara (CropLifeEurope/ Syngenta)	CLH: S-metolachlor and Dicamba
Manson	Philip (Cefic/ Bayer company on behalf of the Glyphosate Renewal Group)	CLH: Glyphosate
Pain	Debbie (EEB/Department of Zoology, Cambridge University)	Restrictions: Lead in outdoor shooting and fishing
Pazenok	Sergii (CropLife Europe/ Bayer AG)	Restrictions: PFAS in fire fighting foams
Portier	Christopher Jude (HEAL/ Emory University)	CLH: Glyphosate
Raffray	Mark (Eurometaux/ Raffray Biosciences Ltd)	CLH: Silver
Saltmiras	David (CropLife Europe/ Bayer in behalf GRG)	CLH: Glyphosate
Seveque	Jean-Louis (FITASC/ AquaTerraSana)	Restrictions: Lead in outdoor shooting and fishing
Wietor	Jean-Luc (EEB)	Restrictions: PFAS in firefighting foams
Williams	Cris (Cefic/ILA)	Restrictions: Lead in outdoor shooting and fishing

European Commission (remote participation)		DG
Bertato	Valentina	DG ENV
Kilian	Karin	DG ENV
Lekatos	Stylianos	DG GROW
Pinte	Jérémy	DG GROW (CLP)
Roebben	Gert	DG GROW
Schutte	Katrin	DG ENV

Tzvetkov	Nikolay	DG SANTE: CLH: Glyphosate

EU Agency Observers (remote participation)		
Castoldi	Anna F	EFSA: Glyphosate
Court Marques	Danièle	EFSA
Panzarea	Martina	EFSA: CLH: Glyphosate
Parra Morte	Juan Manuel	EFSA: CLH: Glyphosate

ECHA staff (physical or remote participation)	
Ahtiainen	Heini
Blainey	Mark (DS: Restriction: DNT)
Bowmer	Tim (Chair)
Franke	Greta
Gmeinder	Michael
Hellsten	Kati
Jones	Stella
Karjalainen	Ari
Klausbruckner	Carmen
Kokkola	Leila
Lefevre	Sandrine (DS: Restrictions: Lead)
Logtmeijer	Christiaan (DS: Restrictions: Lead)
Ludborzs	Arnis
Marchetto	Flavio
Marquez-Camacho	Mercedes
Mazzolini	Anna (DS: Restrictions: Lead)
Nicot	Thierry
Nygren	Jonas
Orispää	Katja
O'Rourke	Regina
Peltola	Jukka
Peltola-Thies	Johanna (Vice-Chair)
Perazzolo	Chiara
Prevedouros	Kostas
Rheinberger	Christoph (DS: Restrictions: DNT and Lead)
Reuter	Ulrike (DS: Restriction: Lead)
Ryan	Paul
Sadam	Diana
Schakir	Yasmin
Simpson	Peter
Sosnowski	Piotr (DS: Restrictions: PFAS)
Spjuth	Linda
Thierry-Mieg	Morgane (DS: Restrictions: PAHs)
Uphill	Simon
van Haelst	Anniek
Vazquez Rodriguez	Jesus
Zeiger	Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-61 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-61 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-61 meeting

30 May 2022
RAC/A/61/2022

Final Agenda
61st meeting of the Committee for Risk Assessment
(RAC-61)

30 May-2 June 2022

Face-to-face meeting[1]

Monday 30 May starts at 10.00
Thursday 2 June ends at 17.20

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/61/2022

For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

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

For agreement

Closed session

Item 5 – Report from other ECHA bodies and activities

5.1 RAC Work Plan for all processes

For information

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

No agenda items under this heading.

[1] Members are expected to attend in person.

Item 7 –Health based exposure limits at the workplace

No agenda items under this heading.

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the April CLH WG

RAC/61/2022/01
For information

2. Update to the Framework for RAC opinion development on substances for harmonised classification and labelling

RAC/61/2022/02
For discussion/agreement

3. Guidance on assessing physical hazards in the CLH dossiers

RAC/61/2022/03
For discussion

4. Addressing developmental neurotoxicity and neurotoxicity under the current CLP hazard classes

RAC/61/2022/04
For discussion/agreement

8.2 CLH dossiers

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

1. 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate (EC 219-207-4; CAS 2386-87-0): *Skin sensitisation, mutagenicity, STOT RE*
2. Tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl] phenyl]azo]naphthalene-2,7-disulphonate; [1] and Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts; [2] and disodium 4-amino-5-hydroxy-3,6-bis{[4-(vinylsulfonyl)phenyl]diazenyl}naphthalene-2,7-disulfonate; [3] (EC 241-164-5 [1], - [2], - [3]; CAS 17095-24-8 [1], - [2], 100556-82-9 [3]): *Respiratory sensitisation, skin sensitisation*
3. 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(morpholin-4-yl)phenyl]butan-1-one (EC 438-340-0; CAS 119344-86-4): *Reproductive toxicity, STOT RE, hazardous to the aquatic environment*
4. Formic acid ...% (EC 200-579-1; CAS 64-18-6): *Physical hazards, acute oral and inhalation toxicity, serious eye damage/eye irritation*

5. Glyphosate (EC 213-997-4, CAS 1071-83-6): *Physical hazards, acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, STOT RE*

6. Dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid (EC 217-635-6; CAS 1918-00-9): *Acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, reproductive toxicity, hazardous to the aquatic environment, hazardous to the ozone layer*

7. Peracetic acid …% (EC 201-186-8; CAS 79-21-0): *Acute toxicity via all routes, hazardous to the aquatic environment*

8. Formaldehyde …% (EC 200-001-8; CAS 50-00-0): *Physical hazards, acute oral and inhalation toxicity, skin sensitisation*

9. S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC -; CAS 87392-12-9): *Mutagenicity, STOT RE, reproductive toxicity, hazardous to the aquatic environment*

10. Silver (EC 231-131-3; CAS 7440-22-4): *Carcinogenicity*

2. Hazard classes for agreement with plenary debate

1. Glyphosate (EC 213-997-4, CAS 1071-83-6): *Mutagenicity, carcinogenicity, hazardous to the aquatic environment*

2. Dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid (EC 217-635-6; CAS 1918-00-9): *Physical hazards, carcinogenicity*

3. Peracetic acid …% (EC 201-186-8; CAS 79-21-0): *Physical hazards*

4. Formaldehyde …% (EC 200-001-8; CAS 50-00-0): *Acute dermal toxicity*

5. S-metolachlor (ISO); 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide; (RaSa)-2-chloro-N-(6-ethyl-o-tolyl)-N-[(1S)-2-methoxy-1-methylethyl]acetamide [contains 80-100 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide and 0-20 % 2-chloro-N-(2-ethyl-6-methylphenyl)-N-[(2R)-1-methoxypropan-2-yl]acetamide] (EC -; CAS 87392-12-9): *Carcinogenicity*

6. Silver (EC 231-131-3; CAS 7440-22-4): *STOT RE, reproductive toxicity*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the May Restriction WG

RAC/61/2022/05
For information

2. Capacity building

For information

9.2 Restriction Annex XV dossiers

1. Conformity check and key issues discussion

    4. Creosote and Creosote related substances
    5. Terphenyl, hydrogenated
    6. *N*,*N*-dimethylacetamide and 1-ethylpyrrolidin-2-one

For discussion and agreement

2. Opinion development

    1. Per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams – First draft opinion
    2. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting – second draft opinion

For discussion

    3. 2,4-dinitrotoluene – third draft opinion
    4. Lead in outdoor shooting and fishing – fifth draft opinion

For discussion and adoption

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the May AFA Working Group

RAC/61/2022/06

2. Update on incoming/future applications
3. Update of technical guidance for rapporteurs ('Lines to take')

RAC/61/2022/07

For information/discussion

10.2 Authorisation applications

1. Discussion on key issues

1. 13 applications for authorisation (chromium trioxide and trixylyl phosphate) from February 2022 submission window

For discussion

10.3 Agreement on draft opinions

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

10. 242_RR1_TCE_Microporous (1 use)
11. 243_RR1_TCE_DOMO (1 use)
12. 244_CT_Cromaplast (2 uses)
13. 245_CT_Newform (1 use)
14. 246_MOCA_Courbis (1 use)
15. 247_OPE_Boehringer_2 (1 use)
16. 248_NPE_OCV (1 use)
17. 249_CT_Tenneco_CZ (1 use)
18. 250_CT_Tenneco_ES (1 use)
19. 251_CT_Tenneco_BE (1 use)
20. 252_CT_Tenneco_PL (1 use)

For discussion and agreement

10.4 Adoption of opinions

No agenda items under this subheading.

Item 11 – AOB

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

RAC/61/2022/08
Room document
For information

3. Interact security rules

For information

Item 12 – Minutes of RAC-61

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-61

For adoption

Annex II (RAC 61)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-61 meeting.

RAC/A/61/2022	RAC-61 final Draft Agenda
RAC/61/2022/01	Report from the April CLH WG
RAC/61/2022/02	Update to the Framework for RAC opinion development on substances for harmonised classification and labelling
RAC/61/2022/03	Guidance on assessing physical hazards in the CLH dossiers
RAC/61/2022/04	Addressing developmental neurotoxicity and neurotoxicity under the current CLP hazard classes
RAC/61/2022/05	Report from the May Restriction WG
RAC/61/2022/06	Report from the May AFA Working Group
RAC/61/2022/07	Update of technical guidance for rapporteurs ("Lines to take")
RAC/61/2022/08 *Room document*	Request to the Committee for Risk Assessment to set a DNEL for 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)

ANNEX III (RAC-61)

The following participants, including those for whom the Chairman declared the interest on their behalf, declared potential conflicts of interest with the Agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Restrictions		
Creosote, and Creosote related substances **FR**	Nathalie PRINTEMPS	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.
N,N-dimethylacetamide and NEP **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.
Terphenyl, hydrogenated **IT**	-	-
Harmonised classification & labelling		
Silver **SE**	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	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.
Glyphosate **SE**	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Glyphosate **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.
Glyphosate **HU**	Anna BIRO	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
S-metolachlor (ISO) **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Tom Gebel	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Dossier / DS	**RAC Member**	**Reason for potential CoI / Working for**
NEW DOSSIERS		
Harmonised classification & labelling		
7-oxabicyclo **IE**	Brendan MURRAY	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Formic acid ...% **BE**	Wendy RODRIGUEZ	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Peracetic acid …% **FI**	Tiina SANTONEN	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.
	Riitta LEINONEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1) **Tetrasodium** 2) **Formaldehyde …%** 3) **S-metolachlor (ISO)** **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement in no 1.
	Tom Gebel	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Butan-1-one **AT**	Manuel FACCHIN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	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. Personal involvement.
Dicamba (ISO) **DK**	Peter Hammer SORENSEN	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.
	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.
Dicamba (ISO) **RO**	Michaela PRIBU	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.