RAC/M/60/2022

Final

11 April 2022

Minutes of the 60th Meeting

of the Committee for Risk Assessment

(RAC-60)

Monday 14 March, 10.00 to Friday 18 March, 13.00

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

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

ECHA's Executive Director, Mr Bjorn Hansen, addressed the meeting. The Chair thanked Mr Hansen and wished him well for his upcoming retirement.

Glyphosate was on the meeting's agenda for information only. The Rapporteurs gave an overview of the dossier focussing on what is new Dossier Submitter, and Stakeholders and EFSA briefly presented their positions.

Finally, the Chair informed that RAC-61, starting on 30 May is planned as a one week in-person meeting.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/60/2022**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-60 minutes.
4. Appointment of (co-)rapporteurs	
4.1 Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers, restriction dossiers, applications for authorisation and OELs, as listed in the restricted document in the Interact collaboration tool. The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted dossiers for the above-mentioned processes.	-
5. Report from other ECHA bodies and activities	
5.1 RAC work plan for all processes The Chair presented the RAC work plan which is updated every quarter.	
6. Request under Article 77(3)(c)	
No items tabled	
7. Health based exposure limits at the workplace	
7.1 Opinion Development	
7.1.1 1,4-dioxane – first draft opinion	
The Chair welcomed the two observers from WPC and the three observers from DG EMPL. The Commission made a request to evaluate exposure to 1,4-dioxane to assess the option of an airborne occupational exposure limit, other limit values (BLV/BGV) and notations. 1,4-dioxane was previously classified as category 2 carcinogen, but has a new classification as 1B	

carcinogen bringing it into the scope of the Carcinogens and Mutagens Directive (CMD). 1,4-dioxane already has an IOELV under Chemical Agents Directive (CAD) and as a result of its reclassification it is necessary to review the current IOELV and to replace it with an OEL under CMD. The deadline of this request is **30 June 2022**.

The ECHA scientific report was open for comments from 27 September until 26 November 2021.

During the opinion development process, the ECHA scientific report will be transferred into an Annex to the RAC opinion.

The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for 1,4-dioxane at the workplace.

RAC supported the approach taken to set an OEL for this substance based on systemic effects.

RAC agreed with the airborne occupational exposure limit values for 1,4-dioxane, as proposed in the draft opinion:

OEL as 8-hour TWA:	7.3 mg/m^3 (2 ppm)

RAC considered that in the case of the OEL derivation based on local effects an assessment factor of 2.5 would be more appropriate than an assessment factor of 1 for interspecies differences, noting that this did not change the proposed OEL based on systemic effects. The Rapporteurs will update this in the final opinion.

RAC agreed to include an explanation in the opinion, why a dose-response relationship for carcinogenicity is not additionally presented.

RAC agreed to recommend a Short Term Exposure Limit (STEL; 15 minutes) of 73 mg/m^3 (20 ppm).

RAC agreed to propose a Biological Limit Value (BLV) of 45 mg HEAA in urine/g creatinine.

RAC agreed not to propose Biological Guidance Value (BGV), as insufficient data are available to support it. Text will be added to the opinion, that it is expected that biological background levels are markedly lower than the proposed BLV.

RAC agreed to propose a skin notation, noting that the dermal absorption studies indicate that dermal exposure is relevant.

Rapporteurs to revise the opinion in accordance with the agreed modifications in RAC-60 and to provide it to SECR.

SECR to make an editorial check of the opinion documents in consultation with the Rapporteurs and to ensure that the Annex and the RCOM are in line with the adopted opinion.

SECR to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

RAC adopted its opinion (with modifications agreed at RAC-60) by consensus.

7.1.2 Isoprene – first draft opinion

The Chair welcomed the expert accompanying the CEFIC Regular Stakeholder Observer, the CONCAWE Occasional Stakeholder Observer, the two observers from WPC and the three observers from DG EMPL.

The Commission made a request to evaluate exposure to isoprene to assess the option of an airborne occupational exposure limit, other limit values (BLV/BGV) and notations. Isoprene (2-methyl-(1,3) butadiene) is a carcinogen, classified as 1B and is a monomer used for the polymerization of elastomers. The deadline of this request is **30 September 2022**.

The ECHA scientific report was open for comments from 11 October until 10 December 2021.

During the opinion development process, the ECHA scientific report will be transferred into an Annex to the RAC opinion.

The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for isoprene at the workplace.

RAC supported the approach taken to set an OEL for this substance.

RAC agreed that the uncertainties surrounding the endogenous levels and interspecies differences should be described in more detail in the opinion.

RAC agreed with the airborne occupational exposure limit values for isoprene, as proposed in the draft opinion:

OEL as 8-hour TWA:	8.5 mg/m^3 (3 ppm)

It was agreed that no STEL is needed, neither are a BGV nor a BLV proposed. No notations are proposed.

RAC adopted its opinion (with modifications agreed at RAC-60) by consensus.

Rapporteurs to revise the opinion in accordance with the agreed modifications in RAC-60 and to provide it to SECR.

SECR to make an editorial check of the opinion documents in consultation with the Rapporteurs and to ensure that the Annex and the RCOM is in line with the adopted opinion.

SECR to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

8. Harmonised classification and labelling (CLH)

8.1.1 Report from the January 2022 RAC CLH WG

The Secretariat presented the Report of the 4th Meeting of the Committee for Risk Assessment Working Group on CLH held on 24-27 January 2022. The 5th Meeting of the RAC Working Group on CLH will be held on 20-21 and 25-27 April 2022.	

8.1.2 Renewal of Mandate of the CLH Working Group

The Secretariat presented and RAC agreed on the renewal of the mandate of the CLH Working Group.	**SECR** to publish the renewal of the Mandate of the ECHA website.

8.2 CLH dossiers

8.2.1 Key issues discussion: glyphosate

The Chair welcomed the Dossier Submitter representatives, the EEB, ClientEarth, CropLife and CEFIC Regular Stakeholder Observers with their accompanying experts, the HEAL Occasional Stakeholder Observer as well as the observers from EFSA and DG Sante. 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 during the Consultation.
The legal deadline for the adoption of an opinion is 17 March 2023.

RAC took note of the presentations made by the Dossier Submitter's representative, experts accompanying the EEB, ClientEarth, CropLife Europe and CEFIC Regular Stakeholder Observers, the HEAL Occasional Stakeholder Observer, as well as by the EFSA representative. The Rapporteurs presented and RAC discussed the key issues in relation to the glyphosate dossier, covering all hazard classes. RAC took particular note of the studies that were not included in the previous (2017) RAC assessment on this substance.	**Rapporteurs** to develop the first draft opinion on the dossier and to provide it to SECR. **SECR** to organise a written consultation in RAC on the first draft opinion and to table the dossier for further discussion in the April CLH WG. **Members** were encouraged to submit comments on the first draft opinion.

The experts accompanying the EEB, ClientEarth, CropLife and CEFIC Regular Stakeholder Observers, the HEAL Occasional Stakeholder Observer as well as the representative of EFSA made short presentations, explaining their positions/statements (published on the ECHA website).

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

8.2.2.1. Reaction mass of: N,N'-Ethane-1,2 diylbis(decanamide) 12-Hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide N,N'-Ethane-1,2-diylbis(12-hydroxyoctadecanamide)[Thixatrol plus]: *hazardous to the aquatic environment*

8.2.2.2. α-methyl-1,3-benzodioxole-5-propionaldehyde: *skin sensitisation*

8.2.2.3. 2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol [Disperse Blue 106]: *skin sensitisation*

8.2.2.4. 2,3-epoxypropyl neodecanoate: *skin sensitisation, mutagenicity*

8.2.2.5. Acetone oxime: *acute dermal toxicity, skin corrosion/skin irritation, eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity*

8.2.2.6. Propyl 3,4,5-trihydroxybenzoate: *acute toxicity, hazardous to the aquatic environment*

8.2.2.7. (3E)-dec-3-en-2-one: *physical hazards, acute toxicity, skin corrosion/ skin irritation, eye damage/ eye irritation, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, STOT SE, STOT RE, hazardous to the aquatic environment*

8.2.2.8. Benthiavalicarb-isopropyl (ISO): *acute toxicity, skin corrosion/skin irritation, eye damage/eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, hazardous to the aquatic environment*

8.2.2.9. Sulfur: *physical hazards, acute toxicity, skin corrosion/skin irritation, skin sensitisation, STOT RE, carcinogenicity, mutagenicity, reproductive toxicity*

8.2.3 Substances with hazard classes for agreement in plenary session

8.2.3.1 (3E)-dec-3-en-2-one (EC: -; CAS: 18402-84-1)

8.2.3.2 Benthiavalicarb-isopropyl (ISO); isopropyl [(S)-1-{[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate (EC: -; CAS: 177406-68-7)

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

8.2.3.4 Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T (EC: -; CAS: -)

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

8.2.3.6 Sulfur (EC: 231-722-6; CAS: 7704-34-9)

8.2.3.1. (3E)-dec-3-en-2-one (EC: -; CAS: 18402-84-1)

The Deputy Chair welcomed the Dossier Submitter representative and informed that **(3*E*)-dec-3-en-2-one** is intended to be used as plant growth regulator in potatoes during storage. The product is applied by hot fogging. The substance has no current Annex VI entry.
The DS (NL) proposes to classify (3*E*)-dec-3-en-2-one as Acute Tox. 4; H332 (ATE = 1.5 mg/L (dusts and mists)), Skin Irrit. 2; H315, Skin Sens. 1; H317, Asp. Tox. 1; H304, Aquatic Chronic 2; H411.
Physical hazards relevant for liquid substance, carcinogenicity, germ cell mutagenicity, reproductive toxicity, acute toxicity – inhalation, dermal, oral, aspiration hazard, specific target organ toxicity – single exposure, repeated exposure, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, 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 2 November 2022.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H332 (ATE = 1.5 mg/L (dusts and mists)), EUH071, Skin Irrit. 2; H315, Asp. Tox. 1; H304, Aquatic Chronic 2; H411] RAC decided not to classify the substance for skin sensitisation due to 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 forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

8.2.3.2. Benthiavalicarb-isopropyl (ISO); isopropyl [(S)-1-{[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate (EC: -; CAS: 177406-68-7)

The Deputy Chair welcomed the experts accompanying the CropLife Regular Stakeholder Observer as well as the CEFIC Regular Stakeholder Observer. She informed that **benthiavalicarb-isopropyl** is an active substance used in plant protection products as a fungicide against *Peronosporales* fungi, except *Pythium* spp and *Phytophthora infestans* in potato crops. The substance has no current Annex VI entry.
The DS (PL) proposes to classify the substance as Carc. 2; H351, Skin Sens. 1; H317 and Aquatic Chronic 2; H411.
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 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 22 July 2022.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below (pending the RAC consultation on the Physical hazards part of the opinion):	**SECR** to organise a RAC written consultation on the Physical hazards part of the draft opinion.

[Carc. 1B; H350, Repr. 2; H361fd, Skin Sens. 1; H317, Aquatic Chronic 2; H411]	**Rapporteur** 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 Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the CropLife Europe Regular Stakeholder Observer commented on carcinogenicity. The expert accompanying the CEFIC Regular Stakeholder Observer commented on reproductive toxicity.	
8.2.3.3. Hexyl salicylate (EC: 228-408-6; CAS: 6259-76-3)	
The Deputy Chair welcomed the Dossier Submitter representatives and the Occasional Stakeholder Observer from IFRA with an accompanying expert. She informed that **hexyl salicylate** is a fragrance ingredient used in many fragrance compounds. It may be found in fragrances used in decorative cosmetics, fine fragrances, shampoos, toilet soaps and other toiletries as well as in non-cosmetic products such as household cleaners and detergents. Hexyl salicylate has no current Annex VI entry. The DS (FR) proposes to classify the substance as Skin Sens. 1; H317. Selected physical hazards (explosives, flammable liquids, self-reactive substances, pyrophoric liquids, substances which in contact with water emit flammable gases, oxidising liquids, organic peroxides, corrosive to metals), skin sensitisation and reproductive toxicity were the hazard classes open for comments during the Consultation. The legal deadline for the adoption of an opinion is 8 June 2022. The dossier was discussed at RAC-59 CLH WG, where it was decided to arrange a targeted Consultation on the read across (the targeted Consultation was carried out 10 December 2021 – 18 January 2022).	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1; H317, Repr. 2; H361d] RAC agreed on no classification for fertility based on inconclusive data and to classify for development based on read across to linear and branched salicylates (Methyl salicylate, salicylic acid, sodium salicylate and ethyl hexyl salicylate).	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the IFRA Occasional Stakeholder Observer commented on reproductive toxicity.	

8.2.3.4. Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T (EC: -; CAS: -)

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the CEFIC Regular Stakeholder Observer. He informed that **MWC(N)T** is used in antistatic and electro-paintable thermoplastics, anti-fouling coatings, batteries (Li-ion), textiles, structural composites (e.g. for windmill blades and high performance sporting goods) and possibly printed electronics (conductive inks) and conductive coatings for displays and touch screens. The substance has no current Annex VI entry.
The DS (DE) proposes to classify the substances as Carc. 1B; H350i and STOT RE 1; H372 (lung).
Carcinogenicity and STOT RE were the hazard classes open for comments during the Consultation.
The legal deadline for the adoption of an opinion is 4 September 2022.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 1B; H350i, STOT RE 1; H372 (lung)(inhalation), SCL≥1% for STOT RE 1 and SCL≥0.1%-1% for STOT RE 2]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the CEFIC Regular Stakeholder Observer commented on the scope of the dossier.

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

The Chair welcomed the Dossier Submitter representative, the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers as well as the Occasional Stakeholder Observer from EPMF with the accompanying expert. He informed that **silver** is used in biocidal products. It is used in products categorised into the following product types: disinfectants and algaecides not intended for direct application to humans or animals, food and feed area disinfection, drinking water disinfection, preservatives for liquid-cooling and processing systems. Some of these uses may result in a vast range of consumer applications. Apart from biocidal use, silver is widely used by industry, professionals and consumers. Silver has no current Annex VI entry.
The DS (SE) proposes to classify silver as Skin Sens. 1; H317, Muta. 2; H341, Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 10) and Aquatic Chronic 1; H410 (M = 10). The DS proposes to classify nanosilver as Skin Sens. 1; H317, Muta. 2; H341, Repr. 1B; H360FD, Aquatic Acute 1; H400 (M = 1000) and Aquatic Chronic 1; H410 (M = 100).
Selected physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell

mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment were the hazard classes open for comments during the Consultation. The Committee has discussed the dossier at RAC-58 plenary meeting, at RAC-59 CLH WG, at RAC-59 plenary meeting and at RAC-60 CLH WG. The legal deadline for the adoption of an opinion is 16 March 2022.	
Environment RAC agreed on the following classification for silver: ***Silver massive ≥ 1 mm:*** **No classification** ***Silver powder > 100 nm < 1 mm*** **Aquatic Acute 1, H400, M = 10** **Aquatic Chronic 1, H410, M = 10** ***Silver nano ≥ 1 nm ≤ 100 nm*** **Aquatic Acute 1, H400, M = 1000** **Aquatic Chronic 1, H410, M = 1000** Human Health *STOT RE* Some Members supported the Rapporteur in recommending to classify silver as STOT RE 2; H373 (brain) based on hippocampal effects in some studies. Other Members, however, expressed concern with regards to the quality of the Charehsaz, et al. (2016) study and asked for further information from 90-day studies and human argyria cases, if available. The discussion on this hazard class will be finalised at the RAC-61 CLH WG and RAC-61. *Mutagenicity* At the Working group, the participants had requested the Rapporteur to reassess the quality of the *in-vivo* genotoxicity studies in order to allow a clearer assessment. This was presented to the Committee. RAC concluded that a split classification for this endpoint would be difficult to justify, as toxicity is dependent on exposure regardless of the source. The Chair noted that the matter of a	**Rapporteur** to revise the opinion (HH) in accordance with the discussion in RAC and to provide it to SECR. **SECR** to organise a RAC written consultation on the revised draft opinion (for Human Health) and to table it for further discussion at the RAC-61 CLH WG and RAC-61. **The hazard classes going for the RAC-61 CLH WG/RAC-61: STOT RE, carcinogenicity, reproductive toxicity.**

possible split classification could be considered in more general terms later on. RAC considered it a border line case between Muta. 2 and no classification. There were a large number of studies, both positive and negative and of varying quality. One Member expressed support for Muta. 1B classification based on their analysis of the data. RAC agreed to recommend no classification for mutagenicity due to inconclusive data. Two Members did not support and will submit their minority positions (after the adoption of the opinion in June). *Carcinogenicity* RAC agreed to provisionally recommend no classification for carcinogenicity due to inconclusive data.	
The Eurometaux Regular Stakeholder Observer commented on the possible split classification and related information. The EPMF Occasional Stakeholder Observer, the expert accompanying the Eurometaux Regular Stakeholder Observer and the expert accompanying the EPMF Occasional Stakeholder Observer commented on STOT RE. The expert accompanying the Eurometaux Regular Stakeholder Observer commented on mutagenicity.	
8.2.3.6. Sulfur (EC: 231-722-6; CAS: 7704-34-9)	
The Chair welcomed the expert accompanying the Eurometaux Regular Stakeholder Observer and the CONCAWE Occasional Stakeholder Observer. He informed that **sulfur** is a fungicide and acaricide active substance used for many years in Europe on various crop. The substance has current Annex VI entry as Skin Irrit. 2; H315. The DS (FR and SL) propose to add Eye Irrit. 2; H319 and STOT SE 3; H335 and to retain Skin Irrit. 2; H315. Selected physical hazards (explosives, flammable solids, self-reactive substances or mixtures, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, carcinogenicity, germ cell mutagenicity, reproductive toxicity, STOT SE and STOT RE were the hazard classes open for the Consultation. The legal deadline for the adoption of an opinion is 16 December 2022.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Irrit. 2; H315]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

RAC agreed on no classification for eye irritation. RAC also agreed on no classification for STOT SE due to data not sufficient for classification.	**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.
9. Restrictions	
9.1 General Restriction issues	
9.1.1. Report from the February 2022 RAC REST WG	
RAC took note of the Report of the 4th meeting of the Committee for Risk Assessment Working Group on restrictions held on 9-10 February 2022. The 5th meeting of the RAC Working Group on restrictions will be held on 5-6 May 2022.	**SECR** to publish the results of the RAC survey regarding the revisions in the opinion development process.
9.1.2. Renewal of Mandate of the Restriction Working Group	
The Secretariat presented and RAC agreed on the renewal of the mandate of the RAC Working Group.	**SECR** to publish the renewal of the Mandate of the ECHA website.
9.2 Restriction Annex XV dossiers	
9.2.1 Conformity check	
9.2.1.1 PFAS in fire-fighting foams	
The Chair, Tim Bowmer, welcomed the Dossier Submitter's representatives from ECHA, the invited expert (Werkfeuerwehrverband Deutschland e.V.) the expert (FPP4EEU), accompanying the regular CEFIC stakeholder observer, as well as the occasional stakeholder observer from EUROFEU. He informed the participants that the dossier has been submitted by ECHA in January 2022 and concerns the placing on the market, use and export of PFAS in fire-fighting foams.	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
The expert from FPP4EEU accompanying the regular CEFIC stakeholder observer and the regular EEB stakeholder commented on the link to the other REACH restriction proposals on PFHxA. The occasional stakeholder from EUROFEU commented on the scope of the proposed restriction.	
9.2.2 Opinion development	

9.2.2.1 Lead and its compounds in outdoor shooting and fishing – fourth draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA, the SEAC rapporteur, invited experts from UNEP/AEWA, the regular stakeholder observers, and their accompanying experts (from AFEMS, Arche Consulting, International Lead Association (ILA), and University of Cambridge) as well as the occasional stakeholder observers and their accompanying experts from European Anglers Alliance (EAA), 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.	
The rapporteurs presented their assessment of the comments received in the consultation of the Annex XV report (regarding scope and derogations, environmental risks, human health risks, risks of alternatives, and RMMs at shooting ranges). The rapporteurs presented the recommendations and conclusions from the RAC-60 Restriction Working Group (which met on 09-10/02/2022). Based on the recommendations of the Restriction Working Group, RAC-60 agreed on their evaluation of the proposed restriction of lead in fishing tackle as proposed by the DS (i.e. ban on placing on the market and use for fishing). The concentration limit for triggering the information requirements at the point of sale was agreed to be recommended to be 1% lead consistent with the concentration limit used for the other conditions of the restriction for fishing tackle. The rapporteurs will continue their work concerning the assessment of the comments from interested parties in the consultation on the Annex XV report and will present the final version of the opinion at the May Restriction Working Group and at RAC-61.	**Rapporteurs** to prepare the fifth draft opinion, taking into account the discussions of RAC-60 and the RAC-60 Working Group on restrictions and the outcome of the third-party consultation. **Secretariat** to table the fifth draft opinion for discussion at the RAC-61 Working Group on restrictions in May 2022.
The expert accompanying the regular stakeholder observer from EEB commented on lead exposure estimates and will forward a paper on its scientific data review. The occasional stakeholder observer from EAA commented on enforcement of home casting, of licensing system and on lead content in copper brass and on derogations. The Secretariat clarified that use of lead fishing sinkers whilst fishing is the scope of the restriction, not the home casting. The expert accompanying FITASC/ISSF commented on risks at shooting ranges.	

9.2.2.2 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo-[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene (Dechlorane Plus)– fourth draft opinion	
The Deputy Chair welcomed the Dossier Submitter's representatives from Norway. She also welcomed the regular stakeholders. She informed the participants that the restriction dossier had been submitted in April 2021 and concerns risks for human health and the environment from emissions of Dechlorane Plus.	
Based on the recommendations of the Restriction Working group which met on 09-10 February 2022, RAC-60 agreed on: – Emissions and exposure assessment – Existing regulatory risk management measures – Scope including derogations – Effectiveness of the proposed restriction in reducing the identified risks – Uncertainties RAC-60 also discussed the additional advice received from Forum (1-3-2022) regarding RO2plus and agreed on practicability, enforceability and monitorability. RAC discussed the proposed derogations under RO2plus for spare parts for marine, garden and forestry machinery and took note that for the FORUM it is not clear what exactly is included in the definition. RAC agreed not to support these derogations due to the fact that no substantive data or information on conditions of use, exposure resulting from the use and whether emissions were minimised had been received during the consultation. RAC noted that due to the unclarity of the use definition, it was not possible to make any qualitative assumptions on conditions of use and releases. RAC discussed and supported the derogations included in RO2plus for medical imaging and radiotherapy devices and their spare parts because of the limited applications in a small market sector. Low releases may be expected although there are uncertainties.	**The rapporteurs**, 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.
The Commission commented on the proposed derogations and highlighted the link to the ongoing process under the Stockholm Convention.	
9.2.2.3 Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting – first 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 9-10/02/2022, RAC-60 agreed on the: Scope and conditions: • the intended target of the restriction is substances containing PAHs in clay targets for shooting; • the general approach to the scoping of a selection of indicator PAHs and concentration limit. The group noted that the same approach (but using a narrower set of marker substances) was used in previous restrictions for PAHs (Entry 50). Hazards: • Hazard assessment based on 15 Carc, PBT, or vPvB indicator PAHs; • Presence of PAHs with non-threshold hazardous properties triggers a need to minimize releases and exposures. The rapporteurs will update these sections and continue their work concerning all the other sections in the next draft opinion.	**Rapporteurs** to prepare the second draft opinion, taking into account the discussions of RAC-60 and the RAC-60 Working Group on restrictions. **Secretariat** to table the second draft opinion for discussion at the RAC-61 Working Group on restrictions in May 2022.
The accompanying expert to the regular CEFIC stakeholder observer commented on the scope and on hazard assessment.	
10. Authorisation	
10.1 General authorisation issues	
10.1.1. Update on incoming/future applications	
The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2022 and timelines. RAC took note of the information.	
10.1.2. Update of technical guidance for rapporteurs ('Lines to take')	
The ECHA Secretariat presented the Update of technical guidance for rapporteurs ("Lines to take"). The main objective of the document is to harmonise approaches and get consistent outcomes in the RAC opinions, however, case-specific reasoning is always possible if justified	**SECR** to launch RAC consultations on the document prior to the RAC AFA WG in May 2022. **SECR** to organise a workshop on human biomonitoring in the context of Cr(VI) AfAs in June or September 2022.

by rapporteurs. It is a living document to be enriched and updated 'down the road'. The document has been distributed to the RAC members. RAC took note of the information.	
10.1.3. AfA overview table	
The ECHA Secretariat presented an overview table for Cr(VI) AFAs. The table has been distributed to the RAC members. RAC took note of the information.	
10.1.4. Report from the February AFA Working Group	
The Secretariat presented the Report of the 10th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group. RAC took note of the Report.	
10.2 Authorisation applications	
10.2.1. Discussion on key issues	
10.2.1.1 7 applications for authorisation (chromium trioxide, 4-tert-OPnEO, 4-NPnEO) from November 2021 submission window	
RAC discussed the key issues in 7 (11 uses) applications for authorisation (chromium trioxide, 4-tert-OPnEO, 4-NPnEO) from November 2021 submission window. The table was made available on the S-CIRCABC and on the Interact Portal.	
10.3 Agreement on draft opinions	
10.3.1. Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate **10.3.1.1** 236_SD_Robur (1 use) **10.3.1.2** 239_OPE_NPE_Prionics (1 use) **10.3.1.3** 240_OPE_Alexion (1 use) The Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 10th meeting the RAC AFA WG the three 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 three draft opinions on the following Application cases.	
• **236_SD_Robur (1 use)** **Use1:** *Use of sodium dichromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

to 1.05% w/w (corresponding to 0.42% w/w as Cr(VI)) in the refrigerant solution. RAC concluded that the in the opinion ES 3 should be included in the scope of the eventual authorisation since there is a possibility of Cr VI release into the working environment. *- Agreed after discussion at the RAC plenary.* 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 recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. RAC agreed: 1. additional conditions for the authorisation *Maintenance and repair tasks performed under WCS1 of ECS 3 shall be subject of the authorisation.* *- Agreed after discussion at the RAC plenary.* 2. monitoring arrangements for the authorisation 1. The applicant shall conduct annual monitoring programme of occupational exposure for Cr(VI) of workers directly or indirectly involved in ECS1 and ECS 3, using an sufficiently sensitive analytical method. Those 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: o the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance/cleaning tasks; o the OCs and RMMs typical for each of these tasks; o the number of workers potentially exposed, including workers not directly using the substance. 2. The authorisation holder shall continue to conduct at least annual Cr(VI) measurements in exhaust air using a sufficiently sensitive analytical method. 3. The information gathered via the measurements referred to in paragraph	**SECR** to send the draft opinion to the applicant for commenting.

1 and 2 related contextual information shall be used by the applicant to confirm the effectiveness of OCs and RMMs as well as to review regularly the effectiveness of OCs and RMMs in place and to introduce measures to further reduce workplace exposure respectively air emissions to Cr(VI) to as low a level as technically and practically feasible. 4. The information from the monitoring programmes referred to in paragraph 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 applicant, upon request, to the competent authority, and included in any subsequent authorisation review report 3. 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.	
10.3.1.1. 239_OPE_NPE_Prionics (1 use) **Use1:** *Use as component of buffer solutions to produce antigens (Cell extraction, cell lysis, coating of biological antigens onto articles, inactivation of microorganisms that produce targeted antigen and solvent exchange) and in-process and final Quality Control of antigens intended for use as veterinary and human health laboratory reagents in Scientific Research and Development and In Vitro Diagnostic applications.* 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 approximately 0 kg per year releases of the substances to the environment. RAC agreed: 1. No additional conditions 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.

2. No monitoring arrangements for the authorisation 3. No recommendations for the review report	
10.3.1.2. 240_OPE_Alexion (1 use) **Use1:** *Industrial use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated for virus inactivation in the manufacture of Andexanet alfa for treatment of adult patients treated with a direct factor Xa (FXa) inhibitor when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.* RAC concluded that the operational conditions and risk management measures described in the application are not expected to be appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in releases during the review period. This information should also be included in a possible review report. RAC agreed: 1. additional conditions for the authorisation As soon as the new process becomes operational, the applicant shall carry out a mass balance analysis based on measurements as indicated in section 8 below. Based on the results, the applicant shall assess if and how the operational conditions and risk management measures can be optimised in such a way that the releases of 4-tert-OPnEO to the environment can be effectively minimised taking into account the outcomes of the measurement programme. 2. monitoring arrangements for the authorisation As soon as the new process becomes operational, the applicant shall undertake a monitoring programme, measuring the concentration of 4-tert-OPnEO in individual waste streams prior to release to the municipal STP. The initial sampling	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion including relevant standard wording for the future use cases. **SECR** to send the draft opinion to the applicant for commenting.

frequency should be sufficient to account for daily fluctuations. Once established, RAC recommends that the applicant should monitor at least quarterly / 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 municipal STP, using an analytical method capable of adequately characterising the substance and its degradation products in water and at an appropriately low level of detection. The results of the monitoring programme 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. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. 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.	
10.3.2 Draft opinions for agreement with plenary debate	
10.3.2.1. 237_CT_Nobili (1 use)	
Use1: *Use at industrial site electroplating of different types of substrates to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management	**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.

measures implemented as a result of additional conditions and on associated trends in exposure during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. RAC agreed: 1. additional conditions for the authorisation RAC acknowledges that the applicant has already evaluated the automation of tasks at the site. However, the Committee stresses the importance of such automation for the protection of workers and proposes the following conditions for the authorisation: 1. The applicant shall carry out and document a detailed feasibility study on (a) the substitution of solid CrO_3 flakes by liquid CrO_3. (b) the implementation of an automated system to replace the manual bath adjustments and the implementation of a closed/automatic system to replace the manual bath sampling tasks where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. The feasibility study must be concluded within 12 months of the granting of an authorisation for this use. Relevant actions must be implemented accordingly during the review period. 2. The applicant shall ensure that: (a) workers perform the sealing test of their respiratory protective equipment (RPE) before taking on relevant tasks (b) workers are trained to perform this test adequately (c) workers involved in WCS 7 use RPE even if not involved directly in the tasks being performed (supervision of the tasks external workers perform when collecting hazardous waste and cleaning the plating tanks (removal of sludge). 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. monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes for Cr(VI),	

which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and/or static sampling for workers for all the WCS, including WCS 7 (emphasis to be added regarding personal sampling); (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling. (b) Environmental releases: (i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission to air; (ii) the applicant shall conduct air emission measurements at least yearly or more frequently if changes in the process take place; (iii) 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 site. 2. The applicant shall use the information gathered via the measurements referred to in paragraph 1 and related contextual information to review 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. This review shall be conducted annually. 3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurement as well as the outcome and conclusions of the review and any action taken in	

accordance with 7.1 paragraph 3, 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. 4. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). 3. recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1 and paragraph 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent review report. RAC agreed the Draft Opinion by consensus.	
10.3.2.2. 238_CT_Hueck (1 use)	
Use1: *Functional chrome plating of high-quality stainless-steel press plates for the premium wood-based materials industry.* RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented and on associated trends in exposure during the review period. This information should also be included in a possible review report. The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently. RAC agreed: 1. additional conditions for the authorisation The applicant shall 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 b) the implementation of an automated system to perform the bath adjustment and the implementation of a closed/automatic system to perform the bath sampling tasks where exposure to	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion Request the applicant for clarification on their conservative approach to the risk assessment for the general population. Request the applicant for clarification on the significant and scale of the dechroming process. **SECR** to send the draft opinion to the applicant for commenting.

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. 2. monitoring arrangements for the authorisation 1. The applicant shall continue to monitor by implementing the following programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes, which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) comprise personal sampling for the workers involved in plating, sampling, concentration adjustment and maintenance activities (WCSs 2, 3, 4, 5 and 6); (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 annually, to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. 3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 4. The applicant shall continue to conduct their annual biomonitoring programme for the workers potentially exposed to Cr(VI). 3. recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 paragraph 1, and paragraph 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report. RAC agreed the Draft Opinion by consensus.	
10.3.2.3. 241_CT_Gessi (1 use)	
Use1: *Use of chromium trioxide for electroplating of metal substrates with the purpose of creating a long-lasting high durability surface with bright look for kitchen and bathroom sanitaryware (functional plating with decorative character).* RAC concluded that the operational conditions and risk management measures described in the application **<u>are</u>** appropriate and effective in limiting the risk **at the Gessi site**, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion. RAC concluded that the operational conditions and risk management measures described in the application are **<u>not</u>** appropriate and effective in limiting the risk **at the San Marco site**. The proposed additional conditions for the authorisation are expected to result 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.

operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.
The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure and releases during the review period. This information should also be included in a possible review report.

RAC agreed:

1. additional conditions for the authorisation
   RAC acknowledges that the applicant has already evaluated the automation of tasks at both sites. However, the Committee stresses the importance of such automation for the protection of workers and proposes the following conditions for the authorisation:
   1. Gessi site
      a. The applicant shall carry out and document a detailed feasibility study on:
         i. the substitution of solid CrO_3 flakes by liquid CrO_3.
         ii. the implementation of an automated system to perform the manual bath adjustments and the implementation of a closed/automatic system to perform the manual bath sampling tasks where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.
      b. 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.
   2. San Marco site
      a. Without prejudice to point 1 above, the applicant shall modify the RMMs at the site to ensure that they are in line with those in place at the Gessi site. The outcome of the feasibility study referred to in paragraph 1.a.ii shall also be taken into consideration. The changes must be implemented during the review period.

2. monitoring arrangements for the authorisation
   1. The applicant shall continue to perform the following monitoring programmes for Cr(VI):

(a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (vii) 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) (e.g. due to the increase of the substance use expected for San Marco site); (viii) be based on relevant standard methodologies or protocols; (ix) comprise personal and/or static sampling for workers for WCS that might imply exposure, including WCS 7; (x) be representative of: a. the range of tasks undertaken where exposure to Cr(VI) is possible, particularly the short duration tasks that might imply higher exposure moments (e.g. baths sampling, dipping of jigs); b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (xi) 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 air and water. (ii) the applicant shall conduct air emission measurements more frequently (at least yearly), particularly if changes in the process justifies such as the expected increase of volume; (iii) the monitoring programmes for air and water emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant´s site. 2. The applicant shall use the information gathered via the measurements referred to in paragraph 1 and related contextual information to review 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. This review shall be conducted annually.	

3. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 4. The applicant shall continue to conduct annual biomonitoring programme for the workers potentially exposed to Cr(VI). 3. recommendations for the review report The results of the feasibility study as mentioned in section 7 and the measurements referred to in section8.1 paragraph 1 and paragraph 4, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent review report. RAC agreed the Draft Opinion by consensus.	
10.4 Adoption of final opinions	
10.4.1 224_RR1_EDC_Eurenco (1 use)	
Use1: *Industrial use of 1,2-Dichloroethane as a solvent for the synthesis of Polyepichlorohydrin used as a precursor in the production of Glycidyl Azide Polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.* RAC agreed for no changes in the RAC draft opinion after the authorisation holder comments. RAC adopted the Final Opinion by consensus.	**SECR** to send the final opinion to the EC, MSs and the Applicant.
11. AOB	
No items were tabled.	
12. Minutes of RAC-60	
12.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-60	

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-60 to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-60

CLH opinions at RAC-60

1. Reaction mass of: N,N'-Ethane-1,2 diylbis(decanamide) 12-Hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide N,N'-Ethane-1,2-diylbis(12-hydroxyoctadecanamide)[Thixatrol plus]
2. α-methyl-1,3-benzodioxole-5-propionaldehyde
3. 2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol [Disperse Blue 106]
4. 2,3-epoxypropyl neodecanoate
5. Acetone oxime
6. Propyl 3,4,5-trihydroxybenzoate
7. (3E)-dec-3-en-2-one
8. Benthiavalicarb-isopropyl (ISO)
9. Sulfur
10. Hexyl salicylate
11. Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T

Reaction mass of: N,N'-Ethane-1,2 diylbis(decanamide) 12-Hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide N,N'-Ethane-1,2-diylbis(12-hydroxyoctadecanamide)[Thixatrol plus]

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	616-127-00-5	reaction mass of N,N'-ethane-1,2-diylbis(decanamide); 12-hydroxy-N-[2-[(1-oxodecyl)amino]ethyl] octadecanamide; N,N'-ethane-1,2-diylbis(12-hydroxyoctadecanamide)	430-050-2	-	Skin Sens. 1 Aquatic Chronic 2	H317 H411	GHS07 GHS09 Wng	H317 H411			
Dossier submitters proposal	616-127-00-5	Reaction mass of *N,N'*-ethane-1,2-diylbis(decanamide) and 12-hydroxy-*N*-[2-[(1-oxodecyl)amino]ethyl] octadecanamide and *N,N'*-ethane-1,2-diylbis(12-hydroxyoctadecanamide);[1] Reaction mass of *N,N'*-ethane-1,2-diylbis(decanamide) and 12-hydroxy-*N*-[2-[(1-oxodecyl)amino]ethyl] octadecanamide; [2]	430-050-2 [1] - [2]	- [1] - [2]	**Add** Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H400 **Modify** H410	**Retain** GHS09 Wng	**Modify** H410		**Add** M = 100 M = 10	
RAC opinion	616-127-00-5	Reaction mass of *N,N'*-ethane-1,2-diylbis(decanamide) and 12-hydroxy-*N*-[2-[(1-oxodecyl)amino]ethyl] octadecanamide and *N,N'*-ethane-1,2-diylbis(12-	430-050-2 [1]	- [1]	**Add** Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H400 **Modify** H410	**Retain** GHS09 Wng	**Modify** H410		**Add** M = 100 M = 10	

		hydroxyoctadecanamide);[1] Reaction mass of *N,N*'-ethane-1,2-diylbis(decanamide) and 12-hydroxy-*N*-[2-[(1-oxodecyl)amino]ethyl] octadecanamide; [2]	- [2]	- [2]							
Resulting Annex VI entry if agreed by COM	616-127-00-5	Reaction mass of *N,N*'-ethane-1,2-diylbis(decanamide) and 12-hydroxy-*N*-[2-[(1-oxodecyl)amino]ethyl] octadecanamide and *N,N*'-ethane-1,2-diylbis(12-hydroxyoctadecanamide);[1] Reaction mass of *N,N*'-ethane-1,2-diylbis(decanamide) and 12-hydroxy-*N*-[2-[(1-oxodecyl)amino]ethyl] octadecanamide; [2]	430-050-2 [1] - [2]	- [1] - [2]	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410		M = 100 M = 10	

α-methyl-1,3-benzodioxole-5-propionaldehyde

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	α-methyl-1,3-benzodioxole-5-propionaldehyde [1] (*S*)-α-methyl-1,3-benzodioxole-5-propionaldehyde; (2*S*)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [2] (*R*)-α-methyl-1,3-benzodioxole-5-propionaldehyde; (2*R*)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [3]	214-881-6 [1]	1205-17-0 [1] 737776-68-0 [2] 737776-59-9 [3]	Skin Sens. 1B	H317	GHS07 Wng	H317			
RAC opinion	TBD	α-methyl-1,3-benzodioxole-5-propionaldehyde [1] (*S*)-α-methyl-1,3-benzodioxole-5-propionaldehyde; (2*S*)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [2] (*R*)-α-methyl-1,3-benzodioxole-5-propionaldehyde; (2*R*)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [3]	214-881-6 [1]	1205-17-0 [1] 737776-68-0 [2] 737776-59-9 [3]	Skin Sens. 1B	H317	GHS07 Wng	H317			

Resulting Annex VI entry if agreed by COM	TBD	α-methyl-1,3-benzodioxole-5-propionaldehyde [1] (*S*)-α-methyl-1,3-benzodioxole-5-propionaldehyde; (2*S*)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [2] (*R*)-α-methyl-1,3-benzodioxole-5-propionaldehyde; (2*R*)-3-(1,3-benzodioxol-5-yl)-2-methylpropanal [3]	214-881-6 [1]	1205-17-0 [1] 737776-68-0 [2] 737776-59-9 [3]	Skin Sens. 1B	H317	GHS07 Wng	H317			

2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol [Disperse Blue 106]

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-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol	271-183-4	68516-81-4	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1A; H317: C ≥ 0,001%	
RAC opinion	TBD	2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol	271-183-4	68516-81-4	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1A; H317: C ≥ 0,001%	
Resulting Annex VI entry if agreed by COM	TBD	2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol	271-183-4	68516-81-4	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1A; H317: C ≥ 0,001%	

2,3-epoxypropyl neodecanoate

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	2,3-epoxypropyl neodecanoate	247-979-2	26761-45-5	Muta. 2 Skin Sens. 1A	H341 H317	GHS08 GHS07 Wng	H341 H317		Skin Sens. 1A; H317: C ≥ 0,001%	
RAC opinion	TBD	2,3-epoxypropyl neodecanoate	247-979-2	26761-45-5	Muta. 2 Skin Sens. 1A	H341 H317	GHS08 GHS07 Wng	H341 H317		Skin Sens. 1A; H317: C ≥ 0,001%	
Resulting Annex VI entry if agreed by COM	TBD	2,3-epoxypropyl neodecanoate	247-979-2	26761-45-5	Muta. 2 Skin Sens. 1A	H341 H317	GHS08 GHS07 Wng	H341 H317		Skin Sens. 1A; H317: C ≥ 0,001%	

Acetone oxime

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	Acetone oxime	204-820-1	127-06-0	Carc. 1B Acute Tox. 4 STOT SE 3 STOT RE 2 Eye Dam. 1 Skin Sens. 1B	H350 H312 H336 H373 (blood system) H318 H317	GHS08 GHS07 GHS05 Dgr	H350 H312 H336 H373 (blood system) H318 H317		dermal: ATE = 1100 mg/kg bw	
RAC opinion	TBD	Acetone oxime	204-820-1	127-06-0	Carc. 1B Acute Tox. 4 STOT SE 3 STOT RE 2 Eye Dam. 1 Skin Sens. 1B	H350 H312 H336 H373 (blood system) H318 H317	GHS08 GHS07 GHS05 Dgr	H350 H312 H336 H373 (blood system) H318 H317		dermal: ATE = 1100 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	Acetone oxime	204-820-1	127-06-0	Carc. 1B Acute Tox. 4 STOT SE 3 STOT RE 2 Eye Dam. 1 Skin Sens. 1B	H350 H312 H336 H373 (blood system) H318 H317	GHS08 GHS07 GHS05 Dgr	H350 H312 H336 H373 (blood system) H318 H317		dermal: ATE = 1100 mg/kg bw	

Propyl 3,4,5-trihydroxybenzoate

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	607-198-00-3	propyl 3,4,5-trihydroxybenzoate	204-498-2	121-79-9	Acute Tox. 4* Skin Sens. 1	H302 H317	GHS07 Wng	H302 H317			
Dossier submitters proposal	607-198-00-3	propyl 3,4,5-trihydroxybenzoate	204-498-2	121-79-9	**Modify** Acute Tox. 4 **Add** Aquatic Acute 1 Aquatic Chronic 2§	**Retain** H302 **Add** H400 H411	**Retain** GHS07 Wng **Add** GHS09	**Retain** H302 **Add** H410		**Add** oral: ATE = 1000 mg/kg bwΩ M = 1	
RAC opinion	607-198-00-3	propyl 3,4,5-trihydroxybenzoate	204-498-2	121-79-9	**Modify** Acute Tox. 4 **Add** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H302 **Add** H400 H410	**Retain** GHS07 Wng **Add** GHS09	**Retain** H302 **Add** H410		**Add** oral: ATE = 1700 mg/kg bw M = 1 M = 1	
Resulting Annex VI entry if agreed by COM	607-198-00-3	propyl 3,4,5-trihydroxybenzoate	204-498-2	121-79-9	Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H317 H400 H410	GHS07 GHS09 Wng	H302 H317 H410		oral: ATE = 1700 mg/kg bw M = 1 M = 1	

§ proposal changed to Aquatic Chronic 1, M factor = 1 after the commenting period
Ω proposal changed to ATE = 1700 mg/kg bw after the commenting period

(3*E*)-dec-3-en-2-one

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	(3*E*)-dec-3-en-2-one	-	18402-84-1	Acute Tox. 4 Asp. Tox. 1 Skin Irrit. 2 Skin Sens. 1 Aquatic Chronic 2	H332 H304 H315 H317 H411	GHS07 GHS08 GHS09 Dgr	H332 H304 H315 H317 H411	EUH071	inhalation: ATE = 1,5 mg/L (dusts or mists)	
RAC opinion	TBD	(3*E*)-dec-3-en-2-one	-	18402-84-1	Acute Tox. 4 Asp. Tox. 1 Skin Irrit. 2 Aquatic Chronic 2	H332 H304 H315 H411	GHS07 GHS08 GHS09 Dgr	H332 H304 H315 H411	EUH071	inhalation: ATE = 1,5 mg/L (dusts or mists)	
Resulting Annex VI entry if agreed by COM	TBD	(3*E*)-dec-3-en-2-one	-	18402-84-1	Acute Tox. 4 Asp. Tox. 1 Skin Irrit. 2 Aquatic Chronic 2	H332 H304 H315 H411	GHS07 GHS08 GHS09 Dgr	H332 H304 H315 H411	EUH071	inhalation: ATE = 1,5 mg/L (dusts or mists)	

Benthiavalicarb-isopropyl (ISO)

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	benthiavalicarb-isopropyl (ISO); isopropyl [(*S*)-1-{[(*R*)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate		177406-68-7	Carc. 2 Skin Sens. 1 Aquatic Chronic 2	H351 H317 H411	GHS08 GHS07 GHS09 Wng	H351 H317 H411			
RAC opinion	TBD	benthiavalicarb-isopropyl (ISO); isopropyl [(*S*)-1-{[(*R*)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate		177406-68-7	Carc. 1B Repr. 2 Skin Sens. 1 Aquatic Chronic 2	H350 H361fd H317 H411	GHS08 GHS07 GHS09 Dgr	H350 H361fd H317 H411			
Resulting Annex VI entry if agreed by COM	TBD	benthiavalicarb-isopropyl (ISO); isopropyl [(*S*)-1-{[(*R*)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate		177406-68-7	Carc. 1B Repr. 2 Skin Sens. 1 Aquatic Chronic 2	H350 H361fd H317 H411	GHS08 GHS07 GHS09 Dgr	H350 H361fd H317 H411			

Sulfur

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	016-094-00-1	Sulfur	231-722-6	7704-34-9	Skin Irrit. 2	H315	GHS07 Wng	H315			
Dossier submitters proposal	016-094-00-1	Sulfur	231-722-6	7704-34-9	**Retain** Skin Irrit. 2 **Add** Eye Irrit. 2 STOT SE 3	**Retain** H315 **Add** H319 H335	**Retain** GHS07 Wng	**Retain** H315 **Add** H319 H335			
RAC opinion	016-094-00-1	Sulfur	231-722-6	7704-34-9	**Retain** Skin Irrit. 2	**Retain** H315	**Retain** GHS07 Wng	**Retain** H315			
Resulting Annex VI entry if agreed by COM	016-094-00-1	Sulfur	231-722-6	7704-34-9	Skin Irrit. 2	H315	GHS07 Wng	H315			

Hexyl salicylate

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	Hexyl salicylate	228-408-6	6259-76-3	Repr. 2 Skin Sens. 1	H361d H317	GHS08 GHS07 Wng	H361d H317			
RAC opinion	TBD	Hexyl salicylate	228-408-6	6259-76-3	Repr. 2 Skin Sens. 1	H361d H317	GHS08 GHS07 Wng	H361d H317			
Resulting Annex VI entry if agreed by COM	TBD	Hexyl salicylate	228-408-6	6259-76-3	Repr. 2 Skin Sens. 1	H361d H317	GHS08 GHS07 Wng	H361d H317			

Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T

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	Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T	-	-	Carc. 1B STOT RE 1	H350i H372 (lung)	GHS08 Dgr	H350i H372 (lung)			
RAC opinion	TBD	Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T	-	-	Carc. 1B STOT RE 1	H350i H372 (lung)(inhalation)	GHS08 Dgr	H350i H372 (lung)(inhalation)		STOT RE 1; H372 (lung): C ≥ 1 %; STOT RE 2; H373 (lung): 0,1 % ≤ C < 1 %	
Resulting Annex VI entry if agreed by COM	TBD	Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T	-	-	Carc. 1B STOT RE 1	H350i H372 (lung)(inhalation)	GHS08 Dgr	H350i H372 (lung)(inhalation)		STOT RE 1; H372 (lung): C ≥ 1 %; STOT RE 2; H373 (lung): 0,1 % ≤ C < 1 %	

Part III. List of Attendees of the RAC-60 meeting

RAC members	
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
Gebel	Thomas
Geoffroy	Laure
Ginnity	Bridget (co-opted member)
Hakkert	Betty
Hartwig	Andrea (co-opted member)
Kadikis	Normunds
Karadjova	Irina
Leinonen	Riitta
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
Tsakovska	Ivanka
Tsitsimpikou	Christina
Uzomeckas	Žilvinas

van der Haar	Rudolf (co-opted member)
Varnai	Veda
Viegas	Susana

Apologies members	
Stahlmann	Ralf
Xanthos	Theodore

Members' advisers		
Algharably	Engi	(Ralf Stahlmann)
Bauer	Kevin	(Michael Neumann)_Restriction: PAHs, PFAS, Lead
Catone	Tiziana	(Gabriele Aquilina)
Esposito	Dania	(Pietro Paris)_CLH: Glyphosate
Hoffmann	Frauke	(Agnes Schulte)
Häschke	Denise	(Ralf Stahlmann)
Lindeman	Birgitte	(Christine Bjørge)_CLH: Glyphosate
Marinkovic	Marino	(Gerlienke Schuur)
Nielsen	Peter Juhl	(Lea Stine Tobiassen)
Pace	Emanuela	(Pietro Paris)_CLH: Glyphosate
Partosch	Falko	(Ralf Stahlmann)_CLH: Hexyl salicylate
Russo	Maria Teresa	(Gabriele Aquilina)
Sachno	Dmitrij	(Ralf Stahlmann)_CH: Glyphosate
Seba	Julie	(Wendy Rodriguez)
Sonnenburg	Anna	(Ralf Stahlmann)_CLH: Hexyl salicylate
Stalter	Daniel	(Agnes Schulte)
Suutari	Tiina	(Riitta Leinonen)
van Herwijnen	Rene	(Betty Hakkert)
Winther	Toke	(Lea Stine Tobiassen)_Restrictions: PFAS in firefighting foams
Wolff	Henrik	(Tiina Santonen)_CLH: MWC(N)T

SEAC Rapporteurs		
Alexandre	João	Restrictions: Dechlorane Plus
Bücker	Michael	(adviser to Klaus Urban) Restrictions: PFAS in firefighting foams
Hard	Sebastiana	(adviser to Silke Gabbert) Restrictions: PFAS in firefighting foams
Gabbert	Silke	Restrictions: PFAS in firefighting foams
Kiiski	Johanna	Restrictions: PFAS in firefighting foams
Svostrup Petersen	Ida	Restrictions: Dechlorane Plus
Thiele	Karen	Restrictions: Lead in outdoor shooting and fishing
Urban	Klaus	Restrictions: PAHs in clay targets for shooting

Invited experts		**Substance**
August	Christina (UPFAS)	Restrictions: PFAS in firefighting foams
Averbeck	Frauke (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
Drost	Wiebke (UPFAS)	Restrictions: PFAS in firefighting foams
Levy	Patrick (WPC)	OEL: isoprene/1,4 dioxane
Saarikoski	Sirkku (WPC)	OEL: 1,4-Dioxane, Isoprene

Dossier submitters		**Substance**
Birgander	Pernilla (SE)	CLH - Silver
Boquist	Pernilla (SE)	CLH - Silver
Fotland	Tor Øystein (NO)	Restrictions: Dechlorane Plus
Gadermann	Angelina (DE)	CLH: MWC(N)T
Groothuis	Floris	CLH: (3E)-dec-3-en-2-one
Herzberg	Frank	CLH: MWC(N)T
Kerkhof	Odile Kerkhof	CLH: Hexyl salicylate
Lundberg	Katarina (SE)	CLH: Glyphosate
Michel	Cecile (FR)	CLH: Hexyl salicylate
Olsen	Christel M. (NO)	Restrictions: Dechlorane Plus
van Duijn	Luuk (NL)	CLH: Glyphosate

Regular stakeholder observers	
Barry	Frank (ETUC)
Cassart	Michel (PlasticsEurope)
De Backer	Liisi (CEFIC)
Duguy	Hélène (ClientEarth)
Evans	Benedict (MedTech Europe)
Robinson	Jan (A.I.S.E.)
Romano	Dolores (EEB)
Ruelens	Paul (CropLife Europe)
Verougstraete	Violaine (Eurometaux)
Waeterschoot	Hugo (Eurometaux): Restriction Lead

Apologies Regular stakeholder observers	
Van de Broeck	Steven (CEFIC)

Occasional stakeholders		**Substance**
Alami	Anissa (EPMF)	CLH: Silver
Arregui	Cristina (IFRA)	CLH: Hexyl salicylate
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)	All open general discussions; PAHs, Isoprene, Glyfosate, Sulfur and Minutes
Palinkas	Jean-Francois (FITASC)	Restrictions: Lead in outdoor shooting and fishing

Stakeholder experts		Substance
Ata	Masafumi (Cefic/Zeon Corporation)	CLH: MWC(N)T
Aveyard	Lindsay (EPMF/ GPC Consulting CC)	CLH: Silver
Battersby	Rodger V. (Eurometaux/ EBRC Consulting GmbH)	CLH: Sulphur
Bock	Ronald (Cefic/ FPP4EU)	Restrictions: PFAS in firefighting foams
Clausing	Peter (ClientEarth/ Pesticide Action Network – PAN Germany)	CLH: Glyphosate
Cohen	Samuel (CropLife Europe/ University Nebraska Medical Center on behalf of Kumiai company)	CLH: Benthiavalicarb-isopropyl
Green	Rhys (ClientEarth/ University of Cambridge)	Restrictions: Lead in outdoor shooting and fishing)
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
Manson	Philip (Cefic/ Bayer company on behalf of the Glyphosate Renewal Group)	CLH: Glyphosate
Mertens	Jelle (Cefic/EPMF)	CLH: Silver
Neely	Theresa (IFRA/Dr Knoell Consult Ltd)	CLH: Hexyl salicylate
Pain	Debbie (EEB/Department of Zoology, Cambridge University)	Restrictions: Lead in outdoor shooting and fishing
Portier	Christopher Jude (HEAL/ Emory University)	CLH: Glyphosate
Raffray	Mark (Eurometaux/ Raffray Biosciences Ltd)	CLH: Silver
Saltmiras	David (CropLife Europe/	CLH: Glyphosate
Sebastiani	Giuliana (Eurometaux/AFEMS	Restrictions: Lead in outdoor shooting and fishing
Segal	Lawrence (Cefic/ LOA Reach Consortium)	OEL: Isoprene
Seveque	Jean-Louis (FITASC/ AquaTerraSana)	Restrictions: Lead in outdoor shooting and fishing
Van Cruchten	Steven (Cefic/ University of Antwerp on behalf of K-I Chemical Europe company)	CLH: Benthiavalicarb-isopropyl
Wietor	Jean-Luc (EEB)	Restrictions: PFAS in firefighting foams
Williams	Cris (Cefic/ILA)	Restrictions: Lead in outdoor shooting

		and fishing

European Commission		**DG**
Bertato	Valentina	DG ENV
Dunauskiene	Lina	DG GROW
Fabbri	Marco	DG GROW
Kilian	Karin	DG ENV
Lekatos	Stylianos	DG GROW
Morris	Alick	DG EMPL: OEL: Isoprene and 1,4-dioxane
Pinte	Jérémy	DG GROW
Pirselova	Katarina	DG ENV
Podniece	Zinta	DG EMPL: OEL: Isoprene and 1,4-dioxane
Roebben	Gert	DG GROW
Schutte	Katrin	DG ENV
Tailler	William	DG EMPL: OEL: Isoprene and 1,4-dioxane
Tzvetkov	Nikolay	DG SANTE: CLH: Glyphosate

EU Agency Observers		
Court Marques	Danièle	EFSA
Binaglia	Marco	EFSA: CHL: Glyphosate
Lanzoni	Anna	EFSA: CLH: Glyphosate
Mangas	Iris	EFSA: CLH: Glyphosate
Panzarea	Martina	EFSA: CLH: Glyphosate
Parra Morte	Juan Manuel	EFSA: CLH: Glyphosate
Rincon	Anna	EFSA
Terron	Andrea	EFSA: CLH: Glyphosate

ECHA staff	
Bowmer	Tim (Chair)
Doyle	Simone
Franke	Greta
Jones	Stella
Karjalainen	Ari
Kokkola	Leila
Lazic	Nina
Lefevre-Brevart	Sandrine
Logtmeijer	Christiaan
Ludborzs	Arnis
Marquez-Camacho	Mercedes
Mattiuzzo	Marco
Mazzolini	Anna
Orispää	Katja
O'Rourke	Regina
Peltola	Jukka
Peltola-Thies	Johanna
Perazzolo	Chiara
Pillet	Monique
Prevedouros	Kostas

Rahkonen	Olli
Rheinberger	Christoph
Regil	Pablo
Reuter	Ulrike
Ryan	Paul
Sadam	Diana
Schakir	Yasmin
Simoes	Ricardo
Simpson	Peter
Sosnowski	Piotr
Spjuth	Linda
Stockmann-Juvala	Helene
Uphill	Simon
van Haelst	Anniek
Vazquez Rodriguez	Jesus
Wilk	Mateusz
Zeiger	Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-60 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-60 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-60 meeting

14 March 2022
RAC/A/60/2022

Final Agenda

60th meeting of the Committee for Risk Assessment

14-18 March 2022

Virtual meeting

14 March starts at 10.00
18 March ends at 13.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/60/2022

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)

n/a

Item 7 –Health based exposure limits at the workplace

7.1 OEL dossiers

1. Opinion development

1. 1,4-Dioxane
2. Isoprene

For discussion and agreement

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CHL issues

1. Report from the January CLH WG

RAC/60/2022/01
For information

2. Renewal of Mandate of the CLH Working Group

RAC/60/2022/02
For agreement

8.2 CLH dossiers

1. Key issues discussion

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

For information only

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

8.2.2.10. Reaction mass of: N,N'-Ethane-1,2 diylbis(decanamide) 12-Hydroxy-N-[2-[1-oxydecyl)amino]ethyl]octadecanamide N,N'-Ethane-1,2-diylbis(12-hydroxyoctadecanamide)[Thixatrol plus]: *hazardous to the aquatic environment*

8.2.2.11. α-methyl-1,3-benzodioxole-5-propionaldehyde: *skin sensitisation*

8.2.2.12. 2-[ethyl[3-methyl-4-[(5-nitrothiazol-2-yl)azo]phenyl]amino]ethanol [Disperse Blue 106]: *skin sensitisation*

8.2.2.13. 2,3-epoxypropyl neodecanoate: *skin sensitisation, mutagenicity*

8.2.2.14. Acetone oxime: *acute dermal toxicity, skin irritation, eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity*

8.2.2.15. Propyl 3,4,5-trihydroxybenzoate: *acute toxicity, hazardous to the aquatic environment*

8.2.2.16. (3E)-dec-3-en-2-one: *physical hazards, acute toxicity, skin irritation, eye irritation, mutagenicity, carcinogenicity, reproductive toxicity, aspiration hazard, STOT SE, STOT RE, hazardous to the aquatic environment*

8.2.2.17. Benthiavalicarb-isopropyl (ISO): *acute toxicity, skin irritation, eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, hazardous to the aquatic environment*

8.2.2.18. Sulfur: *physical hazards, acute toxicity, skin irritation, skin sensitisation, STOT RE, carcinogenicity, mutagenicity, reproductive toxicity*

3. Hazard classes for agreement [with plenary debate]

1. (3*E*)-dec-3-en-2-one (EC: -; CAS: 18402-84-1): *skin sensitisation*
2. Benthiavalicarb-isopropyl (ISO); isopropyl [(S)-1-{[(R)-1-(6-fluoro-1,3-benzothiazol-2-yl)ethyl]carbamoyl}-2-methylpropyl]carbamate (EC: -; CAS: 177406-68-7): *physical hazards, carinogenicity, reproductive toxicity*
3. Hexyl salicylate (EC: 228-408-6; CAS: 6259-76-3): *reproductive toxicity*
4. Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio > 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T (EC: -; CAS: -): *STOT RE, carcinogenicity*
5. Silver (EC: 231-131-3; CAS: 7440-22-4): *STOT RE, mutagenicity, carcinogenicity, hazardous to the aquatic environmen*t
6. Sulfur (EC: 231-722-6; CAS: 7704-34-9): *eye irritation, STOT SE*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the February Restriction WG

RAC/60/2022/03
For information

2. Renewal of Mandate of the Restriction Working Group

RAC/60/2022/04
For agreement

9.2 Restriction Annex XV dossiers

1. Conformity check and key issues discussion

    1. PFAS in fire fighting foams

For discussion and agreement

2. Opinion development

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

For discussion

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

For discussion and adoption

    3. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting – first draft opinion

For discussion

    4. 2,4-dinitrotoluene – **not** for discussion at RAC-60

Item 10 – Authorisation

10.1 General authorisation issues

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

RAC/60/2022/05
Room document
Confidential
For information/discussion

3. AfA Overview table
4. Report from the February AFA Working Group

RAC/60/2022/06
For information/discussion

10.2 Authorisation applications

1. Discussion on key issues

1. 13 applications for authorisation (chromium trioxide, 4-tert-OPnEO, 4-NPnEO) from November 2021 submission window

For discussion

10.3 Agreement on draft opinions

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

1. 236_SD_Robur (1 use)
2. 239_OPE_NPE_Prionics (1 use)
3. 240_OPE_Alexion (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 237_CT_Nobili (1 use)
2. 238_CT_Hueck (1 use)
3. 241_CT_Gessi (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 224_RR1_EDC_Eurenco (1 use)

For discussion and adoption

Item 11 – AOB

Item 12 – Minutes of RAC-60

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-60

For adoption

Annex II (RAC 60)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-60 meeting.

Document number	Title
RAC/A/60/2022	Final Draft Agenda
RAC/60/2022/01	Report from the January 2022 CLH WG
RAC/60/2022/02	Renewal of Mandate of the CLH Working Group
RAC/60/2022/03	Report from the February Restriction WG
RAC/60/2022/04	Renewal of Mandate of the Restriction Working Group
RAC/60/2022/05 Restricted Room document	Update of technical guidance for rapporteurs ('Lines to take')
RAC/60/2022/06	Report from the October AFA Working Group and the Capacity Building Seminar on Assessment of human biomonitoring data

ANNEX III (RAC-60)

The following participants, including those for whom the Chair 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 Chair.
Restrictions		
Dechlorane Plus **NO**	Christine BJØRGE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Harmonised classification & labelling		
Silver **SE**	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Hexyl salicylate **FR**	Nathalie PRINTEMPS	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied. No personal involvement.
	Laure GEOFFROY	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.
Health based exposure limits at the workplace		
1,4-dioxane **ECHA**		
Isoprene **ECHA**		
Article 77.3(c)		
None		

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Harmonised classification & labelling		
Benthiavalicarb-isopropyl (ISO) **PL**	Boguslaw BARANSKI	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Beata PECZKOWSKA	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
1) **Sulfur** 2) **Glyphosate** **FR**	Nathalie PRINTEMPS	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.
	Laure GEOFFROY	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.
Thixatrol Plus **ES**	Ignacio de la FLOR TEJERO	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Miguel SOGORB	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
1) **Disperse Blue 106;** 2) **S-metolachlor (ISO);** 3) **Propyl 3,4,5-trihydroxybenzoate;** 4) **Multi-Walled Carbon Tubes** **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, 3 and 4.
	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.
	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. Personal involvement in no 4.
	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.
Acetone oxime **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. No personal involvement.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
	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.
1) **α-methyl-1,3-benzodioxole-5-propionaldehyde;** 2) **2,3-epoxypropyl neodecanoate** **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. Personal involvement in no 2.
	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. Personal involvement in no 2.
1) **(3*E*)-dec-3-en-2-one** 2) **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 **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.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
	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 **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.