RAC/M/55/2020

Final

17 December 2020

Minutes of the 55th Meeting

of the Committee for Risk Assessment

(RAC-55)

Monday 30 November, 14.00 to Thursday 3 December, 18.00
and
Monday 7 December, 14.00 to Thursday 10 December, 15.30

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair, Tim Bowmer, reflected on the following topics in his opening address:

- With the conclusion of the agenda for this plenary, RAC would be able to complete its 2020 work programme as planned. The Chair thanked members for their extra efforts last month when the 10 delayed CLH dossiers from the first lockdown in March were completed by the Committee

- As the participants survey on virtual meeting experience was last performed in June of this year, an end-of-year survey will be carried out right after the RAC-55 plenary meeting.

- ECHA staff have returned to full teleworking due to the Covid-19 situation in Finland and according to the latest decision, there will be no face-to-face external meetings at ECHA before 30 June 2021. RAC meetings will remain virtual until then.

- The Secretariat is still investigating alternative meeting software, which will be tested further with smaller meetings (e.g. the AfA WG in February) before making any changes in RAC. Until then, the meeting software will stay the same.

The Chair informed the Committee that Ms Stephka Chankova-Petrova resigned from her position as a RAC Member on 27 November 2020. He also noted that Ms Annamarie Losert and Mr Daniel Borg were attending their last meeting of RAC and thanked all three members for their significant contributions to the work of the Committee.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/55/2020**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-54 minutes.
4. Appointment of (co-)rapporteurs	

a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers, restriction dossiers and applications for authorisation, as listed in the restricted documents in the Interact collaboration tool. The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted CLH dossiers, as well as to the pool of volunteers for the applications for authorisation and for the restriction dossier.	**-**

5. Report from other ECHA bodies and activities

a) RAC work plan for all processes The Chair presented the RAC work plan for 2021.	
b) ECHA administrative improvement proposals	The secretariat informed the Committee about the administrative improvements related to members´ annual review of Declaration of Interest, and the stakeholder participation.

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

1) DNEL development for trixylyl phosphate

The Rapporteurs presented the RAC draft note on the ECHA report on DNEL setting for reprotoxic properties of trixylyl phosphate. RAC adopted the note by consensus.	**Rapporteurs** to make final editorial changes in the adopted note. **SECR** to publish the RAC note on the ECHA website.

2) Revision of derogations from proposed restrictions on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances; C9-C14 perfluorocarboxylic acids (C9-C14 PFCA), their salts and C9-C14 PFCA-related substances

RAC rapporteur presented and RAC discussed the draft opinion on the Article 77(3)(c) request on revision of derogations from proposed restriction on PFOA/PFCAs. RAC supported the rapporteur's conclusions to keep 2000 ppb, but to add 'any' perfluoroalkoxy group, and to require decreasing the concentration to 100 ppb within 3 years for derogation #1. RAC supported 1000 ppb PFOA and a specific end date in July 2022 for derogation #2.	**Rapporteur** to make final editorial changes in the adopted opinion. **SECR** to prepare the compiled RAC and SEAC opinion package and send it to COM.

RAC did not support the derogation for C9-C14 PFCAS (derogation #3). RAC supported 10 ppm and proposes a review in July 2022, or at the latest two years after the entry into force of the restriction (derogation #4). The first part of derogation #5 concerns the use of PFOA (until 2023) as a polymerisation aid in the production of fluoropolymers. There is no use of PFOA (or C9-C14 PFCAs) as polymerisation aid in the EU, so the derogation is not needed. It is outside the scope of ECHA/RAC to propose a deletion of §5 from the PFOA regulation, so to obtain an alignment, inclusion of this unnecessary derogation is proposed for C9-C14 PFCAs in the ECHA analysis. RAC agreed to this. RAC noted that the second derogation, for use in fire-fighting foams (#6), is already aligned, as both restrictions contain the same derogation. RAC adopted the opinion by consensus.	
The expert accompanying occasional stakeholder (PlasticsEurope) questioned the move from 400 ppb to 100ppb and asked clarifying questions regarding the alignment of derogation 5. The expert accompanying the regular CEFIC stakeholder asked for alignment with the EU POP regulation. The regular EEB stakeholder also asked clarifying questions.	
3) Classification for acute inhalation toxicity of EGBE	
The Chair welcomed the ECETOC Occasional Stakeholder Observer, with an accompanying expert, and the expert accompanying the CEFIC Regular Stakeholder Observer. He reminded that on 14 September 2018, RAC had adopted an opinion on the harmonised classification and labelling of EGBE, which concluded that regarding acute inhalation toxicity this substance should be classified as Acute Tox. 3; H331. New information had been provided by Industry addressing the adopted classification for acute inhalation toxicity and RAC was requested, based on Article 77(3)(c), to review its opinion of 14 September 2018 in relation to the classification for acute inhalation toxicity. The *ad hoc* consultation was carried out prior to RAC-55. Legal deadline for the adoption of an opinion is 13 May 2021.	
RAC took note of the new information, including a new acute inhalation study but concluded that the classification agreed by the Committee in 2018 (Acute Tox. 3; H331 (ATE=3 mg/L/4h)) is still warranted.	**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 CEFIC Regular Stakeholder Observer and the expert accompanying the ECETOC Occasional Stakeholder Observer commented extensively on acute inhalation toxicity.	
4) Classification for environmental toxicity of lead	
The Chair welcomed the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers and reminded that on 30 November 2018, RAC had adopted an opinion on the harmonised classification and labelling of lead, which concluded that for both the massive and the powder forms, it should be classified as Aquatic Acute 1 (M = 1) and Aquatic Chronic 1 (M = 10). New information had been provided by Industry on the chronic toxicity of lead in the pond snail *Lymnea stagnalis* (OECD TG 243) and RAC was requested, based on Article 77(3)(c), to review its opinion of 30 November 2018 as regards to the environmental classification of lead. The *ad hoc* consultation was carried out prior to RAC-55. The Commission's deadline for the adoption of an opinion is 13 May 2021.	
RAC discussed the first draft opinion. Some members expressed support for the rapporteur's initial analysis, pointing towards one entry on Annex VI. The Chairman noted that more information was required before the Committee could conclude with a robust justification. The following points were discussed and/or agreed: • It was agreed to review and consider previous metal classifications under DSD, including the ATP entries. • The Commission is kindly requested to clarify what was meant with CLP Annex 1 section 1.3.4 and section 1.2.3.3 of the CLP guidance. • It was agreed that Industry will provide data on the proportion of powder and massive lead. • Stakeholders and MSs, including DK (the previous DS), are kindly requested to provide any original supporting documents which could explain the meaning of the term "special process". • Industry agreed to provide further details of the source material used in the atomisation production technique for lead powder.	**Rapporteurs**, with the support from the *ad hoc* group, to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to table the revised draft opinion for another RAC discussion at RAC-56 in March 2021.
The COM observer commented on some of the legal interpretations of the CLP regulation and the guidance made by the Rapporteurs and promised to help clarify these issues after RAC-55. The Eurometaux Regular Stakeholder Observer and the expert accompanying the CEFIC Regular Stakeholder Observer also commented on the interpretation made by the Rapporteurs of section IV.5.5 of the CLP guidance and on several aspects of the RAC draft opinion.	

7. Health based exposure limits at the workplace

a) Opinion development

1. Cadmium and its inorganic compounds – first draft opinion

The Chairman welcomed the experts accompanying the regular Eurometaux stakeholder observers, one occasional stakeholder as well as the three observers from the DG-EMPL, Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC).

Directive (EU) 2019/37/EC, the third amendment of the Carcinogens and Mutagens Directive (Dir 2004/37/EC) was published on 5 June 2019, and included cadmium and its inorganic compounds in Annex III. However in Recital (17) it stated that " *….the Commission should, no later than three years after the date of entry into force of this Directive, assess the option of amending Directive 2004/37/EC by adding provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds".* Therefore, the Commission made a request on 08/01/2020, with a deadline of 18 months, to ECHA to evaluate the following chemical agents: **Cadmium and its inorganic compounds,** in particular "*to assess the option of an airborne occupational exposure limit (OEL) and/or a combination of an airborne occupational exposure limit and a biological monitoring value for cadmium and its inorganic compounds based on their possible equal effectiveness in protecting the health of workers".*

A call for evidence in the preparatory phase inviting interested parties to submit comments and evidence on the subject took place from 2 March 2020 to 2 June 2020. The ECHA scientific report was open for a two month consultation from 14 September to 12 November 2020.

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

RAC discussed the first draft opinion and the Scientific Report on the scientific evaluation of limit values for Cadmium and its inorganic compounds. The following points were discussed and/or agreed: • It was agreed that a combination of an 8 h air limit value (OEL) and a biological limit value (BLV) would be more effective in protecting the health of workers than either of them alone. A robust justification would need to be included in the final opinion. • It was supported that in this specific case, data from the general population needs to be considered when discussing the occupational limit values for cadmium. Taking the cumulative cadmium exposure from all sources (inhalation, food, hand to mouth, dermal) into account would protect workers, also after their occupational career.	Rapporteurs to prepare the draft final opinion taking into account RAC-55 discussions.

• RAC discussed uncertainties concerning setting an air limit value but supported as a starting point the value of 0.001 mg/m^3 (inhalable fraction), currently set in the Carcinogens and Mutagens Directive. More justification on the air limit value would need to be inserted in the final opinion. Further discussion and agreement on the values (OEL and BLV) is foreseen at RAC-56.	

The expert accompanying the regular Eurometaux stakeholder observer commented on the relevance of human lung cancer data to consider in the derivation of the air limit value and on the uncertainties associated with the data from the general population at very low exposure levels, if used to derive occupational exposure limit values for cadmium. The observer from the Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC), representing the Employers Interest Group, commented on the approach in general to consider data from the general population when discussing occupational exposure limits.

8. Harmonised classification and labelling (CLH)

8.1 CLH dossiers

A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate

- C. I. Disperse Blue 124: skin sensitisation
- Bentazone (ISO): acute oral toxicity, skin sensitisation, acute aquatic hazards, chronic aquatic hazards
- Margosa ext.: physical hazards (explosives, flammable gases, flammable aerosols, oxidising gases, gases under pressure, flammable liquids, flammable solids, self-reactive substances and mixtures, pyrophoric liquids, pyrophoric solids, substances and mixtures which in contact with water emit flammable gases, oxidising liquids, oxidising solids, organic peroxides, substances and mixtures corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, STOT RE, acute aquatic hazards, chronic aquatic hazards
- Benfluralin (ISO): physical hazards, acute aquatic hazards, chronic aquatic hazards, hazardous to the ozone layer
- Melamine: germ cell mutagenicity
- Valifenalate: physical hazards (explosives, flammable solids, self-heating substances, oxidising solids), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, STOT SE, STOT RE, chronic aquatic hazards, hazardous to the ozone layer
- Isopyrazam: physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance which in contact with water emit flammable gases, oxidising solid, corrosive to metals), acute dermal and

inhalation toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, STOT RE, acute aquatic hazards, chronic aquatic hazards

- 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta-PSCA Na-TEA): STOT RE

- 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA): STOT RE

- 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA): STOT RE

B. Substances with hazard classes for agreement in plenary session

1) Bentazone (ISO) (EC: 246-585-8; CAS: 25057-89-0)
2) Margosa ext. (EC: 283-644-7; CAS: 84696-25-3)
3) Perfluroheptanoic acid (PFHpA) (EC: 206-798-9; CAS: 375-85-9)
4) Bisphenol S (EC: 201-250-5; CAS: 80-09-1)
5) Melamine (EC: 203-615-4; CAS: 108-78-1)
6) Valifenalate (EC: -; CAS: 283159-90-0)
7) Isopyrazam (EC: -; CAS: 881685-58-1)
8) 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta-PSCA Na TEA) (EC: 701-271-4; CAS: -)
9) 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA) (EC: 206-798-9; CAS: 375-85-9)
10) 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA) (EC: 701-162-1; CAS: -)
11) Divanadium pentaoxide

1. Bentazone (ISO) (EC: 246-585-8; CAS: 25057-89-0)

The Chair welcomed the Dossier Submitter representative and the expert accompanying the ECPA Regular Stakeholder Observer. He explained that bentazone (ISO) acts as a selective post-emergent herbicide against broadleaved weeds in a broad range of crops, including cereals, maize, legume vegetables (pulses), bulb vegetables and forage crops (alfalfa, clover). The substance has an existing Annex VI entry as Acute Tox. 4*; H302, Eye Irrit. 2; H319, Skin Sens. 1; H317 and Aquatic Chronic 3; H412. Legal deadline for the adoption of an opinion is 2 April 2021.
The DS (NL) proposes to modify Acute Tox. 4; H302 (ATE=1640 mg/kg bw), to retain Skin Sens. 1; H317, to add Repr. 2; H361d and to remove Aquatic Chronic 3; H412.

Acute oral toxicity, skin sensitisation, reproductive toxicity and hazardous to the aquatic environment were open for comments during the Consultation.

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

[Acute Tox. 4; H302 (ATE=1600 mg/kg bw, Skin Sens. 1; H317, Repr. 2; H361d] RAC agreed on no classification for fertility, acute and chronic aquatic toxicity.	**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.

2. Margosa ext. (EC: 283-644-7; CAS: 84696-25-3)

The Chair welcomed the Dossier Submitter representative and the expert accompanying the ECPA Regular Stakeholder Observer. He explained that margosa, ext. [from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents] is an active substance in the meaning of Regulation (EU) No 528/2012. The substance has no current Annex VI entry. Legal deadline for the adoption of an opinion is 1 May 2021.

The DS (DE) proposes to classify the substance as Repr. 2; H361d, Skin Sens. 1; H317 and Aquatic Chronic 1; H410 (M=10).

Physical hazards (explosives, flammable gases, flammable aerosols, oxidising gases, gases under pressure, flammable liquids, flammable solids, self-reactive substances and mixtures, pyrophoric liquids, pyrophoric solids, substances and mixtures which in contact with water emit flammable gases, oxidising liquids, oxidising solids, organic peroxides, substances and mixtures corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and hazardous to the aquatic environment were open for comments during the Consultation.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1; H317, Repr. 2; H361d, Aquatic Chronic 1; H410 (M=10)] RAC agreed on no classification for the other hazard classes considered.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the ECPA Regular Stakeholder Observer commented on developmental toxicity.

3. Perfluroheptanoic acid (PFHpA) (EC: 206-798-9; CAS: 375-85-9)

The Chair informed that perfluoroheptanoic acid is a degradation product from C8 per- and polyfluorinated substances. It has no current Annex VI entry. Legal deadline for the adoption of an opinion is 24 April 2021.
The DS (BE) proposes to classify the substance as Repr. 1B; H360D and STOT RE 1; H372 (liver).

Reproductive toxicity and STOT RE were open for comments during the Consultation.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1; H360D, STOT RE 1; H372 (liver)] RAC agreed on no classification for sexual function and fertility based on conclusive data and for effects on or via lactation based on inconclusive data.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
4. Bisphenol S (EC: 201-250-5; CAS: 80-09-1)	
The Chair welcomed the Occasional Stakeholder Observer from PlasticsEurope and the experts accompanying the CEFIC Regular Stakeholder Observer and the PlasticsEurope Occasional Stakeholder Observer. Bisphenol S is used in articles, by professional workers, in formulation, or re-packaging at industrial sites and in manufacturing. It has no current Annex VI entry. Legal deadline for the adoption of an opinion is 10 April 2021. The DS (BE) proposes to classify the substance as Repr. 1B; H360FD. Reproductive toxicity was the only hazard class open for comments during the Consultation.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360FD]	**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 CEFIC Regular Stakeholder Observer commented on sexual function and fertility and on developmental toxicity. The expert accompanying the PlasticsEurope Occasional Stakeholder Observer commented on developmental toxicity.	
5. Melamine (EC: 203-615-4; CAS: 108-78-1)	
The Chair welcomed the Dossier Submitter representative and the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers. He explained that melamine is used in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. It has no current Annex VI entry. Legal deadline for the adoption of an opinion is 15 May 2021. The DS (DE) proposes to classify the substance as Carc. 2 and STOT RE 1; H372 (urinary tract).	

Germ cell mutagenicity, carcinogenicity and STOT RE were open for comments during the Consultation.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, STOT RE 2; H373 (urinary tract)] RAC agreed on no classification for germ cell mutagenicity.	**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 STOT RE and carcinogenicity.	
6. Valifenalate (EC: -; CAS: 283159-90-0)	
The Chair welcomed the expert accompanying the ECPA Regular Stakeholder Observer. Valifenalate is an active substance in the meaning of Regulation (EU) No 1107/2009. It has no current Annex VI entry. Legal deadline for the adoption of an opinion is 15 May 2021. The DS (HU) proposes to classify the substance as Aquatic Chronic 2; H411. Physical hazards (explosive, flammable solid, self-heating substance, oxidising solid), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment and hazardous to the ozone layer were open for comments during the Consultation.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Aquatic Chronic 2; H411] RAC agreed on no classification for the other hazard classes considered.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the ECPA Regular Stakeholder Observer commented on sexual function and fertility.	
7. Isopyrazam (EC: -; CAS: 881685-58-1)	
The Chair welcomed the expert accompanying the ECPA Regular Stakeholder Observer and informed that isopyrazam is an active substance in the scope of Regulation (EC) 1107/2009. It	

is a broad spectrum foliar fungicide. The substance has no current Annex VI entry. Legal deadline for the adoption of an opinion is 30 January 2021.

The DS (NO) proposes to classify the substance as Repr. 1B; H360D, Skin Sens. 1B; H317, Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=10).

Physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance which in contact with water emit flammable gases, oxidising solid, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and hazardous to the aquatic environment were open for comments during the Consultation.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Repr. 1B; H360D (SCL ≥ 3%), Skin Sens. 1B; H317, Aquatic Acute 1; H400 (M=10), Aquatic Chronic 2; H411 (M=10)] RAC agreed on no classification for the other hazard classes considered.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC (specifically related to the mode-of-action for liver and uterine tumours) 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 ECPA Regular Stakeholder Observer commented on acute oral toxicity and on carcinogenicity.

8. 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta-PSCA Na TEA) (EC: 701-271-4; CAS: -)

The Chair informed that Penta-PSCA Na TEA is used in lubricants, grease and metal working fluids. It has no current Annex VI entry. Legal deadline for the adoption of an opinion is 10 July 2021.

The DS (AT) proposes to classify the substance as Repr. 1B; H360FD and Eye Irrit. 2; H319.

Skin corrosion/irritation, serous eye damage/eye irritation, reproductive toxicity and STOT RE were open for comments during the Consultation.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360FD, Eye Irrit. 2; H319] RAC agreed on no classification for skin corrosion/irritation and STOT RE.	**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.
9. 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA) (EC: 206-798-9; CAS: 375-85-9)	
The Chair informed Tetra-PSCA is used in lubricants, grease and metal working fluids. It has no current Annex VI entry. Legal deadline for the adoption of an opinion is 10 July 2021. The DS (AT) proposes to classify the substance as Repr. 1B; H360FD (H360D: SCL ≥ 0.03%) and Eye Irrit. 2; H319. Skin corrosion/irritation, serous eye damage/eye irritation, reproductive toxicity and STOT RE were open for comments during the Consultation.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360FD, Eye Irrit. 2; H319] RAC agreed on no classification for skin corrosion/irritation and STOT RE.	**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.
10. 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA) (EC: 701-162-1; CAS: -)	
The Chair informed that Penta-PSCA is used in lubricants, grease and metal working fluids. It has no current Annex VI entry. Legal deadline for the adoption of an opinion is 10 July 2021. The DS (AT) proposes to classify the substance as Repr. 1B; H360FD (H360D: SCL ≥ 0.03%). Skin corrosion/irritation, serous eye damage/eye irritation, reproductive toxicity and STOT RE were open for comments during the Consultation.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360FD] RAC agreed on no classification for skin corrosion/irritation, serious eye damage/eye irritation and STOT RE.	**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.
11. Divanadium pentaoxide	

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the Eurometaux Regular Stakeholder Observer. The Chair reminded that RAC had adopted its opinion on the divanadium pentaoxide dossier at RAC-54 in September 2020. However, after the meeting and prior to completion of the final text, the Rapporteur brought to the attention of the Chair new information regarding the interpretation of the OECD TG 436 for acute inhalation toxicity that would further support Cat. 2. In parallel, the Rapporteur also addressed Industry's representatives' comments regarding the reported tissue burden levels of Vanadium in the NTP (2002) inhalation study and the discussion that followed during the RAC-54 meeting. The issues raised by the Rapporteur, although not implying a change in the classification agreed, were more substantial than editorial changes. Therefore, exceptionally and in the interests of accuracy and transparency, the Chair decided to take the opinion back to RAC to give Members another opportunity to discuss these specific points before it is finalised and sent to the Commission.	
RAC took note of the new information related to acute inhalation toxicity and carcinogenicity but did not change its earlier classification conclusion (Acute Tox. 2; H330 (ATE=0.05 mg/L (dusts or mists) and Carc. 1B; H350) as a result of the new information.	**Rapporteur** to make the final amendments to the RAC opinion and to provide it to SECR. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The Eurometaux Regular Stakeholder Observer as well as the expert accompanying the Eurometaux Regular Stakeholder Observer commented on carcinogenicity.	
9. Restrictions	
9.1 General restriction issues	
a) Updated Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals	
RAC took note of the presentation by the Secretariat on its plans to update the Framework paper for restrictions.	**SECR** to arrange a RAC written consultation of the updated version. **SECR** to arrange a specific capacity building training for RAC members in spring 2021.
9.2 Restriction Annex XV dossiers	
a) Conformity check	
1. Substances in single-use diapers	
The Chair welcomed the Dossier Submitter's representatives from France, the occasional stakeholder observers from EDANA as well as EURATEX and their accompanying expert from the Bavarian Textile and Apparel Association. He informed the participants that the restriction dossier had been submitted in October 2020 and concerns substances in single-use baby diapers.	

RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
The occasional stakeholder observer from EDANA commented on various aspects mentioned in the dossier.	
b) Opinion development	
1. Perflurohexanoic acid (PFHxA) - third draft opinion	
The Chair welcomed the Dossier Submitter's representatives from Germany, regular stakeholder observers with their accompanying experts (to CEFIC, ClientEarth and EEB), the occasional stakeholder observers from PlasticsEurope, EDANA, EURATEX, EUROFEU, together with their accompanying experts. He informed the participants that the restriction dossier had been submitted in December 2019 and concerns the manufacture, use and placing on the market of perfluorohexanoic acid (PFHxA), its salts and the related substances.	
The rapporteurs presented and RAC discussed the third draft opinion. RAC reconfirmed (as already agreed at RAC-54), the revised degradation factors of – 7% for low molecular weight precursors using 6:2 FTOH as surrogate – 1% for SFPs using read-across to the same factor as used in the restriction for PFOA, its salts and related substances. RAC provisionally agreed on the approach and/or conclusions concerning emissions from the main use sectors, subject to further clarifications of the methodology and refinement of the descriptions of uncertainties in the Dossier Submitter's final update of the Background Document planned for 8 January 2021. Furthermore, RAC noted that – Emission estimates are uncertain due to data gaps on uses, use volumes, operational conditions and release factors – Emission estimates could not be calculated for all uses, e.g. cosmetics, building materials, consumer products and the semiconductor industry – However, RAC considered that there is sufficient information available for key sectors to allow the calculation of ranges of potential emissions of PFHxA to the environment. – For two of the main sectors, greaseproof paper and textiles (including imported textile), RAC concluded that the Dossier Submitter's assumptions represent an	**Rapporteurs** to prepare the fourth draft opinion, taking into account RAC-55 discussions and the timely provision of missing information by the Dossier Submitter, by early/mid February 2021. **Rapporteurs** to take into account the study on the degradation factor for SFP mentioned by stakeholders during plenary (see reply 3030 to the consultation). **Rapporteurs**, to further refine elements of the evaluation of the emissions assessment, including: • how much weight to put on the data for low molecular weight related substances in the emissions assessment for greaseproof paper/board; • the uncertainties introduced by reliance on aggregated volume information for fluoropolymers and C6-SFPs; • the implications of information submitted in the consultation on (i) emissions from fire-fighting foams (e.g. average fluorine content of 2% by weight) and (ii) emissions of PFHxA arising from manufacture and use of fluoropolymers / fluoroelastomers.

unrealistic worst-case and releases are likely to be significantly lower. – Nevertheless, paper, textile and firefighting foams remain the main emission sources of PFHxA. Specifically: RAC agreed with the rapporteurs' approach for the evaluation of the emissions assessment for greaseproof paper/board used as food contact material. RAC noted that there are large uncertainties in the assessment, particularly for the low molecular weight related substances. RAC concluded that an assumption that 25% of greaseproof paper/board is treated with PFHxA related substance would be a more realistic than the 100% assumed by the Dossier Submitter. RAC agreed with the rapporteurs' approach for the evaluation of the emissions assessment for textiles. RAC concluded that emissions are likely to be overestimated and that an assumption that 50% of clothing is treated with PFHxA related substances would be appropriate, compared to the 100% assumed by the Dossier Submitter. RAC agreed with the rapporteurs' approach for the evaluation of the emissions assessment for firefighting foams, but noted some uncertainties to be addressed. RAC agreed with the Dossier Submitter's approach for inks and photographic uses, for chrome plating and for the manufacture of SFPs. For the manufacture and use of fluoroelastomers, RAC considered, pending updates to the Background Document, whether releases could be in the order of tonnes, rather than kilograms. Regarding definitions, RAC acknowledged that fluoroelastomers are not, themselves, within the scope of the proposed restriction. RAC agreed that the proposed restriction with targeted derogations and transitional periods is the most appropriate and effective EU wide measure to reduce the emissions and the risks of PFHxA, its salts and related substances. Furthermore, RAC agreed that reduced emissions and reduced cumulative	**Rapporteurs**, to review consistent use of terminology in the opinion, specifically in relation to fluoropolymers and fluoroelastomers. **Dossier Submitter** to clarify the emission assumptions in the Background Document by 8 January 2021. **SECR** to arrange an open ad hoc Webex meeting on emissions in early 2021 prior to RAC-56.

emissions are the most appropriate measures of the effectiveness of the restriction. RAC concluded that the length of transitional periods has an impact on the increase of the environmental pollution stock PFHxA, i.e. that due to its persistence all emitted PFHxA, its salts or related substances will contribute to stocks. From a risk perspective, RAC concluded that the transitional period should be as short as practically possible - a shorter transitional period will result in a lower increase in risk. RAC agreed to derogate articles and mixtures placed on the market before entry into force of the restriction (incl. second-hand articles) for practical reasons (identification and destruction) and difficulties related to enforcement. Also, using an item as long as possible is a sustainable use of resources. RAC supported the inclusion of recycled materials within the scope of the restriction (i.e. with the same concentration limits of virgin materials), consistent with previous PFAS-restrictions. Due to the extreme persistence PFHxA, it will likely remain in articles over successive life cycles. RAC provisionally concluded (pending completion of the review of consultation comments) that none of the derogations have been supported with sufficient information to provide a clear view of the emissions under the conditions of the proposed restriction, nor described to what extent emissions have been/will be minimised or any conditions to do so. RAC provisionally concluded that the proposed restriction will be effective – From a qualitative perspective the scope is effective, i.e. broad, covering all sectors, with targeted derogations (time-limited or unlimited in time) – The restriction will achieve approximately 50% emissions reduction over the 20 year assessment period following entry into force. However 80% of the remaining emissions are estimated to occur from deposited products and articles which is principally unavoidable	

– A complete ban on all uses in all sectors (no derogations) would further decrease emissions and increase the effectiveness – The effectiveness will increase over time (> 20 years) due to the expiration of time-limited derogations and as articles with long service lives are replaced. With regard to possible impact on human health and the environment, RAC noted that impacts are difficult to quantify: – Current data show a gap between general human and environmental exposure levels and those levels that would cause adverse effects. Without any new data, no quantitative risk is anticipated at present and in the short-term future – However, based on the persistency of PFHxA, the ongoing use of the PFHxA, its salts and related substances will lead to increasing environmental stocks over time, which could lead to irreversible adverse effects in the in future. Impact of derogations to be discussed in more detail at RAC-56. Finally, RAC concluded provisionally, pending further discussion, that the proposed restriction is practical, enforceable and monitorable. Overall, RAC noted that there are uncertainties associated with the restriction proposal, but that the uncertainties do not change the conclusion that there is a risk from PFHxA, its salts and related substances that is not adequately controlled.	
The accompanying expert to regular observer (EEB) asked for clarifications on degradation estimates and whether the use of degradation factors (to express releases in terms of PFHxA) resulted in a general underestimation of emissions. The expert accompanying the occasional stakeholder observer (PlasticsEurope) and the regular stakeholders (CEFIC) referred to the study submitted in the consultation on the degradation rate of a specific SFP. The occasional stakeholder observer (EUROFEU) commented on emissions for firefighting foams. The experts accompanying the regular stakeholders (CEFIC) commented on analytical methods and derogations. The occasional stakeholder observer (EURATEX) commented on overestimation of emission estimates as well as on derogations. The expert accompanying the occasional stakeholder observer (PlasticsEurope) restated their comment on the terminology used for fluorinated polymers and commented on alternatives and analytical methods.	
10. Authorisation	

10.1 General authorisation issues

a) Update on incoming/future applications

The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2020/2021 and timelines. The ECHA Secretariat presented the information on horizontal issues related to the AFA process. 1. Conditions for IVDs used by hospitals 2. Measurements (frequency, biomonitoring…) 3. Excess Lifetime Risk RAC discussed and took note of the information.	**RAC** to use overview table presented by the SECR as a guide to harmonise opinions on DUs use of IVD kits. **SECR** to consider organising a workshop to discuss presented horizonal issues related to the AFA process.

b) OPE/NPE ED properties - Adoption of approach

RAC discussed and agreed the approach to ED properties in the AFA on OPE/NPE. RAC concludes that the current state of knowledge of the endocrine disrupting properties, mode(s) of action and effects of 4-tert-OP and 4-NPnEO in the environment as presented by the applicants is insufficient to determine a threshold.	**Rapporteurs** together with **SECR** to apply agreed approach in relevant draft opinions.

c) Report from RAC WG on AfAs during October 2020 meeting

The 6th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation took place on 27-29 October 2020.
Participants: 20 RAC members, 5 Members' advisers, 2 Regular stakeholder observers, 1 Commission observer, ECHA.
The working group recommended that the following draft opinions were suitable for consideration via the A-listing procedure.

- 202_OPE_Merckle (1 use)
- 198_OPE_Zoetis (uses 1 and 2)
- 199_OPE_Biokit (use 2)
- 197_OPE_NPE_Phadia (2 uses)

The working group recommended that the following draft opinions were suitable for general agreement at the RAC plenary:

- 196_OPE_Becton (1 use)
- 198_OPE_Zoetis (uses 3 and 4)
- 208_RR1_TCE_BlueCube (1 use)
- 209_CT_Safran (1 use)
- 210_CT_SD_TataSteel (1 use)
- 211_CT_Hubner (3 uses)

The working group recommended that the following draft opinions required full discussion or discussion on specific points at the RAC plenary:

- 199_OPE_Biokit (use 1)
- 207_NPE_Chemetall (2 uses)

• 193_OPE_PPG (2 uses)	
The Secretariat presented the Report of the 6th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. RAC took note of the Report.	
10.2 Authorisation applications	
1. Discussion on key issues	
1) 9 applications for authorisation (EDC, Cr(VI), MOCA, 4-tert-OPnEO) from August 2020 submission window	
RAC discussed the key issues in 6 AfAs and 3 RRs / 12 uses	-
10.3 Agreement on draft opinions	
A. Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate 1. 197_OPE_NPE_Phadia (2 uses) 2. 198_OPE_Zoetis (uses 1 and 2) 3. 199_OPE_Biokit (use 2) 4. 202_OPE_Merckle (1 use) The Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 6th meeting the RAC AFA WG on the 6 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 6 draft opinions on the following AFA cases.	
1. 197_OPE_NPE_Phadia (2 uses) **Use1:** *Use as component of buffer solutions for the production of purified proteins (cell extraction, chromatographic purification and solvent exchange) and in-process and final Quality Control testing; intended for use as 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 implemented and adhered to. The use applied for may result in 0 kg/year of releases of the substance 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.	
Use2: *Coating Thyroid Stimulating Hormone Receptor onto articles used as components of IVD reagent systems*. 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 implemented and adhered to. The use applied for may result in 0 kg/year of releases of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report.	**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. 198_OPE_Zoetis (uses 1 and 2) **Use1:** *Industrial use as a surfactant in a lysis buffer for the release of proteins and antigens from biological material used in the manufacture of three SERELISA veterinary In Vitro Diagnostic devices (IVDs) for detecting infectious disease in farm animals*. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in 0 kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
Use2: *Industrial use in formulation of kits, kit reagents and buffer solutions in two WITNESS and three SERELISA veterinary In Vitro Diagnostic devices (IVDs) used for detecting certain diseases in pets and farm animals*.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in 0 kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report.	
3. 199_OPE_Biokit (use 2) **Use2:** *Professional use of 4-tert-OPnEO as a detergent during the final use of latex-based, ELISA and CLIA In-Vitro-Diagnostic kits* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the environment. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk to the environment. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 22 kg/year of the substance to the environment for a total of 500 – 3 000 downstream users' sites (i.e. an average per site up to 7 - 44 g/year). RAC agreed: 1. additional conditions for the authorisation All solid and liquid waste containing 4-tert-OPnEO shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Disposal of solid waste as common waste is not adequate treatment. Release of liquid waste into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users about their efforts to	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

collect all solid and liquid waste for adequate treatment, and which treatment methods are applied (e.g., incineration).	
4. 202_OPE_Merckle (1 use) **Use1:** *The use of 4-OPnEO as an emulsifier in a silicone oil emulsion for siliconization of pre-filled syringes in a medicinal product.* 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. The use applied for may result in emissions of up to 15 g per year of the substance to the environment in waste water. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid waste contaminated with 4-tert-OPnEO for adequate treatment, and act on the outcome of the feasibility study. RAC recommends the applicant to monitor at least quarterly / 4 times per year (during the time of operation) 4-tert-OPnEO and its principal degradation products in the waste water from the washing/siliconization machine prior to release to the off-site STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
B. Agreement on draft opinions on AFA in plenary session	
1. 193_OPE_PPG (2 uses)	

Use 1: *The formulation of a hardener component containing OPE in Aerospace and Defence (A&D) two-part polysulphide sealants.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in 0 kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
Use 2: *Mixing, by Aerospace and Defence Companies, and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1% w/w of OPE for Aerospace and Defence uses that are exempt from authorisation under REACH Art. 56(6)(a).* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in up to 2.5 kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. RAC agreed on the draft opinion by consensus.	**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. 196_OPE_Becton (1 use)	
Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) as a processing aid in imported diagnostics.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The recommendations for the review report are designed to allow RAC to evaluate any potential review report efficiently. The use applied for may result in up to 18-30 kg per year (approximately 0.03 kg per year per downstream user site) emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation All solid and liquid waste shall be collected for an adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not considered by RAC to be an adequate treatment. Downstream users should be instructed to collect all solid and liquid waste for an adequate treatment and should not discharge liquid waste containing residues of 4-tert-OPnEO down the drain. 2. no monitoring arrangements 3. recommendations for the review report In case a review report is submitted, the applicant needs to conduct and report on a representative survey of their EEA downstream users (in terms of number of users and volume of diagnostics used) about the treatment methods that are applied at that point in time (e.g. incineration) following from the requirement to collect all solid and liquid waste containing 4-tert-OPnEO for an adequate treatment. RAC agreed on the draft opinion by consensus.	
3. 198_OPE_Zoetis (uses 3 and 4)	
Use 3: *Professional use as a surfactant in kits, kit reagents and buffer solutions in 18 veterinary In Vitro Diagnostic devices (IVDs) including one SERELISA, six ProFLOK, six WITNESS and five VetScan. The use is carried out by professional users in diagnostic laboratories and veterinary clinics to detect certain diseases in pets and farm animals.*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The use applied for may result in approximately 1.79 kg/year (worst case) or 0.33 kg/year (realistic reasonable case) per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation All the liquid and solid waste shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not considered to constitute adequate treatment 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a representative survey of their EU downstream users about the treatment methods that are applied at that point in time (e.g. incineration) following from the requirement to collect all the solid and liquid waste containing 4-tert-OPnEO for adequate treatment. RAC agreed on the draft opinion by consensus.	
Use 4: *Industrial use as a viral inactivating agent in the manufacture of two veterinary biologic drugs for treatment of osteoarthritis in cats and dogs.* 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. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

the authorisation period. This information should also be included in the review report. The use applied for may result in approximately 10-20 kg/year (worst case), 1-10 kg/year (2.07 kg/year realistic case) kg per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation All liquid waste releases which will occur during the remaining filtration and chromatography steps (stream C) shall be collected and disposed of for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not considered as adequate treatment. As soon as the first measurements obtained through monitoring (as described in section 8) are available, the applicant shall carry out a mass balance analysis that takes those measurements into account. Based on the results, the applicant shall assess how the operational conditions and risk management measures can be optimized in such a way that the releases of 4-tert-OPnEO to the environment can be further minimised taking into account the outcomes of the monitoring programme and act on the outcome of the assessment. 2. monitoring arrangements for the authorisation As soon as full production takes place, the applicant shall undertake a monitoring programme to measure the concentration of 4-tert-OPnEO in individual waste streams prior to release to the municipal STP. The initial sampling frequency shall be sufficient to take account of daily fluctuations and to demonstrate the effectiveness of the new RMMs that will be implemented. Once the appropriate frequency has been established, the applicant shall monitor [at least quarterly] or [at least 4 times per year] 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 principal degradation products at an appropriately low level of	

quantification. 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 results of the monitoring program, as well as the mass balance and the outcome and conclusions of the actions taken with regards to minimising emissions, should be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
4. 199_OPE_Biokit (use 1)	
Use 1: *Industrial use of 4-tert-OPnEO as a detergent in the preparation of reagents for incorporation into latex-based, ELISA and CLIA In-Vitro-Diagnostic kits.* 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. The use applied for may result in 539 g per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends that the applicant should monitor at least quarterly or 4 times per year (during the time of operation) 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the off-site WWTP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The applicant may reduce the frequency of measurements to one measurement per year after it is shown in four consecutive measurements that the releases are zero. The results should be included in any review report, including details of sampling point, the	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

analytical method, the concentrations detected and the corresponding environmental release values. RAC agreed on the draft opinion by consensus.	
5. 203_OPE_NPE_Qiagen (4 uses)	
Use 1: *Formulation and filling of buffer solutions containing 4-tert-OPnEO/4-NPnEO for the manufacturing of and use in in-vitro Diagnostic and Life Sciences kits of the product groups sample preparation, PCR and sequencing.* 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. The use applied for may result in emissions of 4-tert-OPnEO to the environment of up to 57.03 g per year and in emissions of 4-NPnEO to the environment of up to 52.95 g per year. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends that the applicants should monitor at the Hilden site at least quarterly/four times per year (when the processes are operating and the substances are used at maximum daily amounts) 4-tert-OPnEO and 4-NPnEO and their principal degradation products in the wastewater prior to release to the public sewage system using an analytical method capable of adequately characterising the substances and their degradation products in water and at an appropriately low level of quantification. 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. RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion with proper justification for placing the monitoring recommendation in section 9 rather than in section 8 of the opinion. **SECR** to send the draft opinion to the applicant for commenting.

Use 2: *Industrial use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for the use in in-vitro Diagnostic and Life Sciences kits of the product groups sample preparation, PCR and sequencing.* 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. The use applied for may result in emissions of 4-tert-OPnEO to the environment of up to 1.09 g per year and in emissions of 4-NPnEO to the environment of up to 78 g per year. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends that the applicant should monitor at least quarterly/four times per year (when the processes are operating and the substances are used at maximum daily amounts) 4-tert-OPnEO and 4-NPnEO and their principal degradation products in the wastewater prior to release to the public sewage system using an analytical method capable of adequately characterising the substances and their degradation products in water and at an appropriately low level of quantification. 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. RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion with proper justification for placing the monitoring recommendation in section 9 rather than in section 8 of the opinion. **SECR** to send the draft opinion to the applicant for commenting.
Use 3: *Professional downstream use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for the use in in-vitro Diagnostic and Life Sciences kits with regulatory impact of the product groups sample preparation, PCR, sequencing (and immunoassay for 4-tert-OPnEO only).*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 4-tert-OPnEO to the environment of up to 390 kg per year (average per site: 1.95-7.8 g) and in emissions of 4-NPnEO to the environment of 0 kg per year. RAC agreed: 1. additional conditions for the authorisation In addition to the solid waste containing 4-tert-OPnEO, all liquid waste containing 4-tert-OPnEO generated from the use applied for shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicants shall report on a representative survey of their downstream users about the treatment methods that are applied (e.g. incineration) following from the requirement to collect all liquid waste for adequate treatment. RAC agreed on the draft opinion by consensus.	
Use 4: *Professional downstream use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for Life Sciences kits without regulatory impact of the product groups sample preparation, PCR and sequencing.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

operational conditions and risk management measures that are appropriate and effective in limiting the risk. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 4-tert-OPnEO to the environment of up to 22.4 kg per year (average per site: 0.112-0.448 g) and in emissions of 4-NPnEO to the environment of 0 kg per year. RAC agreed: 1. additional conditions for the authorisation In addition to the solid waste containing 4-tert-OPnEO, all liquid waste containing 4-tert-OPnEO generated from the use applied for shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicants shall report on a representative survey of their downstream users about the treatment methods that are applied (e.g. incineration) following from the requirement to collect all liquid waste for adequate treatment. RAC agreed on the draft opinion by consensus.	
6. 207_NPE_Chemetall (2 uses)	
Use 1: *The formulation of a hardener component containing NPE in Aerospace two-part polysulphide sealants.* 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 emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC agreed on the draft opinion by consensus.	
Use 2: *Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1 % w/w of NPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a).* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in up to 1.75 kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
7. 208_RR1_TCE_BlueCube (1 use)	
Use 1: *RR1_TCE_BlueCube__1 use: Industrial use of trichloroethylene as process chemical (enclosed systems) in Alcantara Material production.* RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are adhered to. A small monitoring database was submitted by the downstream user of the authorisation holder that reflects the exposure levels of 2019 and 2020 provides some reassurance. The monitoring arrangements for the authorisation are expected to provide information on the trends in exposure over the authorisation period. Given the rather short time that was available after the COM decision, the available database is still limited. Therefore, the monitoring arrangements for the authorisation shall remain unchanged in order to further reduce uncertainty and increase the representativeness of the exposure scenarios. This information should also be included in the review report.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

The exposure to workers was estimated to be 3.0735 mg/m³ (inhalation) and 2.7867 mg/kg bw (dermal) per 8h adjusted TWA without the effect of the operational conditions and risk management measures. For reference, the current binding Occupational Exposure Limit (BOEL) for this substance is 54.7 mg/m³. The exposure of the general population was estimated to be 0.00357 mg/m³ (inhalation) and 4.19 $x10^{-5}$ mg/kg bw/d (dermal) for 24 hours exposure to trichloroethylene for 70 years without the effect of the conditions. Bearing in mind that the route of exposure for the general population may be different from the one relevant for workers. The excess lifetime cancer risk for workers is estimated to be 2.72 x 10^{-4} per mg/m^3 for 8h TWA exposure for 40 years, per year, for the review period without the effect of the conditions, and 2.47× 10^{-7} per mg/m^3 for 24h exposure for 70 years, per year, for the review period without the effect of the conditions for the general population. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation (a) the downstream user of the authorisation holder and/or his downstream users shall continue to conduct regular occupational exposure measurements of trichloroethylene. Those measurements shall: (i) take place at least annually; (ii) be based on relevant standard methodologies or protocols; (iii) comprise both personal inhalation exposure sampling and static inhalation exposure sampling and biomonitoring (consisting of measurement of the trichloroethylene metabolite trichloroacetic acid in urine). All these exposure assessment methods should be representative of the range of tasks undertaken and of the total number of workers that are potentially exposed (including process, maintenance and other types of workers involved); (b) the downstream user of the authorisation holder and his downstream users shall use the information gathered via the measurements referred to in point (a) including the contextual information to regularly review the	

effectiveness of the risk management measures and operational conditions and to introduce measures to reduce worker's exposure to trichloroethylene, the downstream user of the authorisation holder should reconsidered if PPE is overused in specific situations; (c) the results of the measurements referred to in point (a), as well as the outcome and conclusions of the review and any actions taken in accordance with point (b), shall be documented and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place; (d) the downstream user of the authorisation holder's downstream users shall make available the information from the measurements referred to in point (a) and the conclusions and outcomes of the review pursuant to point (b) to the European Chemicals Agency, for transmission to the downstream user of the authorisation holder for the purpose of the review report referred to in Article 61(1) of that Regulation; (e) the information collected in accordance with point (d) shall be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006. 3. recommendations for the review report The review report shall document the results of the monitoring programs and the optimisation of RMMs and OCs carried out by the applicant in order to minimise exposure and fugitive emissions. As part of the review of the OCs and RMMs, the downstream user of the authorisation holder should reconsider if PPE is overused in specific situations. RAC agreed on the draft opinion by consensus.	
8. 209_CT_Safran (1 use)	
Use 1: *Industrial use of chromium trioxide-based mixtures for the surface treatment of legacy spare parts of military aircraft engines, including safety-critical parts whose failure endangers airworthiness.* RAC concluded that the operational conditions and risk management measures described in the	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

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. The exposure to workers was estimated to be 8.1 x 10^{-3} µg Cr(VI)/m^3 (average exposure value for one worker corrected for RPE, duration and frequency). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to the general population via inhalation at the local scale was estimated to be 1.61 x 10^{-4} µg/m^3, while via the oral route it was estimated to be 2.05 x 10^{-4} µg/kg bw/d. At the regional scale, the exposure via inhalation was estimated to be 1.98 x 10^{-13} µg/m^3 and 6.72 x 10^{-7} µg/kg bw/d via the oral route. Based on the above exposures, the excess lifetime cancer risk for workers (inhalation route) is estimated to be 3.21 x 10^{-5} over 40 years per worker, and, for the general population: 4.83 x 10^{-6} at local scale and 5.38 x 10^{-10} at the regional level (inhalation and oral route combined). RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation a) The applicant shall continue to conduct annual monitoring programmes for Cr(VI) emissions to air in the environment at least annually. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicant´s site. b) The information gathered via the measurements referred to in point (a) and related contextual information shall be used by the applicant to evaluate the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce Cr(VI) emissions to air to as low a level as technically and practically feasible. c) The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. d) The information from the monitoring programmes referred to in point (a), including the contextual information associated with each of the measurements as well as the outcome	

and conclusions of the review and any action taken in accordance with point (b) shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report RAC recommends to conduct an annual occupational exposure monitoring programme for Cr(VI). RAC recommends that the information gathered via the measurements referred to in section 8 point (a) as well as the outcome and conclusions of the review and any action taken in accordance with point (b) should be included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
9. 210_CT_SD_TataSteel (1 use)	
Use 1: *Use of Chromium Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The monitoring arrangements for the authorisation are expected to provide information on the trends in exposure over the authorisation period. The information should also be included in the review report. The exposure to workers was estimated to be at maximum: - inhalation (µg/m^3): max. 0.220 (Trostre and IJmuiden) - dermal (µg/kg bw/d): 25.4 (Trostre), 28.0 (IJmuiden). The exposure to the general population was estimated to be: - inhalation, local (µg/m^3): 8.12 x 10^{-4} (Trostre), 6.61 x 10^{-3} (IJmuiden) - oral: local (µg/kg bw/d): 1.50 x 10^{-4} (Trostre), 1.12 x 10^{-3} (IJmuiden). The excess lifetime cancer risk - for directly exposed workers is estimated to be at maximum:	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

○ inhalation: 8.8 x 10^{-4} (Trostre and IJmuiden) ○ RCR dermal (reproductive toxicity): 0.59 (Trostre), 0.652 (IJmuiden), - for indirectly exposed workers is estimated to be at maximum: ○ inhalation : 3.25 x 10^{-6} (Trostre), 2.92 x 10^{-5} (IJmuiden) ○ oral: 3 x 10^{-8} (Trostre), 2.24 x 10^{-7} (IJmuiden). The excess lifetime cancer risk for the general population is calculated to be: - inhalation: 2.35 x 10^{-5} (Trostre), 1.92 x 10^{-4} (IJmuiden), - oral: 1.2 x 10^{-7} (Trostre), 8.96 x 10^{-7} (IJmuiden) - combined: 2.36 x 10^{-5} (Trostre), 1.93 x 10^{-4} (IJmuiden). RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation (a) The applicants shall continue to implement and conduct an annual exposure monitoring programmes for Cr(VI) for both sites. Those programmes shall be based on relevant standard methodologies or protocols, comprise both static and/or personal inhalation exposure sampling and be representative of: (i) the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance workers; (ii) the OCs and RMMs typical for each of these tasks; (iii) the number of workers potentially exposed. (iv) In case WCS 8 is implemented, the applicants shall conduct static control measurements immediately after the establishment of this scenario and include this scenario in their regular occupational exposure monitoring programmes. (b) The applicants shall continue conducting monitoring programmes for Cr(VI) emissions to air at least annually for both sites. Those programmes shall be based on relevant standard methodologies or protocols and be	

representative of the OCs and RMMs used at the applicants´ site. (c) The information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicants to evaluate the effectiveness of the RMM and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to a level as low as technically and practically feasible. (d) The applicants shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles (e.g. use powered respirators instead of non-powered full face masks at the Trostre site); (e) The information from the monitoring programmes referred to in points (a) and (b), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the applicants, upon request, to the national competent authority of the Member State where the authorised use will take place; (f) The applicants may reduce the frequency of measurements, once the applicants can clearly demonstrate to the national competent authority of the Member State where the use takes place, that exposure to humans and releases to the environment have been reduced to a level as low as technically and practically possible and that the RMMs and OCs function appropriately. 3. recommendations for the review report The information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
10. 211_CT_Hubner (3 uses)	
Use 1: *Use 1: Etching of single-component (1K) plastic articles.* **Use 2:** *Etching of multi-component (2K/3K) plastic articles*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

Use 3: *The use of chromium trioxide in the functional electroplating of single-component (1K) and multi-component (2K/3K) plastic articles with the specific aim of obtaining a final Cr(0) coating with high durability and chemical resistance while preserving the lightweight nature of the plastic component* 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 monitoring arrangements for the authorisation and recommendations for the review report, are expected to address RAC's minor concerns related to the assessment of the workers' exposure and indirect exposure of humans. The exposure to workers was estimated to be (inhalation) 0.88 µg Cr(VI)/m^3 per 8h adjusted TWA (highest value). The exposure to the general population was estimated to be (inhalation, local) $3.74*10^{-4}$ µg Cr(VI)/m^3 per 8h TWA and (oral, regional) $1.53*10^{-9}$ µg Cr(VI)/kg bw/d. The excess lifetime cancer risk for workers is estimated to be (inhalation) $3.52*10^{-3}$ per µg/m^3 (for 8h TWA exposure for 40 years), per year, for the review period without the effect of the conditions, and (inhalation, local) $1.08*10^{-5}$ per µg/m^3 for 24h exposure for 70 years, per year, for the review period without the effect of the conditions for the general population. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programmes for chromium (VI): (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (i) be conducted at least annually or more frequently if a substantial increase of CrO_3 consumption takes place on site. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) comprise personal and / or static inhalation exposure sampling; (iii) comprise personal sampling for	**SECR** to send the draft opinion to the applicant for commenting.

maintenance workers (WCS 6); (iv) be representative of: a. the range of tasks undertaken where exposure to chromium 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 quarterly monitoring programme for Cr(VI) emission to wastewater; (ii) the applicant shall at least conduct annual air emission measurements or more frequently to following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant´s site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. 3. The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be	

documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report The results of the measurements referred to in section 8 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, shall be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinions by consensus.	

10.4 Adoption of final opinions

The Applicants submitted comments on the following draft opinions agreed at RAC 52 and RAC 53.

1. 143_OPE_bioMerieux (3 uses)
2. 147_CTPht_Bilbaina (1 use)
3. 148_CTPht_DEZA (1 use)
4. 149_CTPht_Nalon (1 use)
5. 150_CTPht_AO_Koppers (1 use)
6. 153_CTPht_AO_Bilbaina (1 use)
7. 162_OPE_LFB (1 use)
8. 176_OPE_Abbott_1 (5 uses)
9. 184_OPE_Lilly (1 use)
10. 186_OPE_NPE_Beckman (5 uses)
11. 187_OPE_AGC (2 uses)
12. 188_OPE_Wallac_2 (2 uses)

1. 143_OPE_bioMerieux (3 uses)

Use 1: *Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in the formulation of reagents for molecular in vitro preparative and testing applications* The RAC consultations on the draft Final Opinion has been held 04-10 November 2020. 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. The use applied for may result in emissions of 2.08 kg/year of the substance to the environment. (monitoring data)	**SECR** to send the final opinion to the EC, MSs and the Applicant.

RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends that the applicant should continue quarterly / 4 times/year monitoring of 4-tert-OPnEO (parent substance and its main degradation products) in the waste water prior to release to the local STP using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. 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. RAC recommends the applicant to further assess in any review report the feasibility to collect the liquid wastes from washing the glassware and put it in practice if the outcome of the feasibility study is favourable. RAC adopted the final opinion by consensus with changes made to the draft opinion.	
2. 147_CTPht_Bilbaina (1 use)	
Use 1: *Use of CTPHT as a binder in the manufacture of clay targets.* The RAC consultations on the draft Final Opinion has been held 30 October - 6 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. RAC concluded that alternative(s) presented by the applicant, taking into consideration the input of the third parties submitted in the public consultation, if implemented, would reduce the overall risks. The exposure of workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3. Since CTPHT has PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

The use applied for may result in approximately 70-700 tonnes per year of emissions to the environment of PAHs with PBT, vPvB and carcinogenic properties. RAC was unable to propose additional authorisation conditions that could make the operational conditions and risk management measures appropriate and effective in limiting the risk for the environment and humans via the environment. RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
3. 148_CTPht_DEZA (1 use)	
Use 1: *Use of CTPht as a binder in the manufacture of clay targets.* The RAC consultations on the draft Final Opinion has been held 04-11 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. RAC concluded that alternative(s) presented by the applicant, taking into consideration the input of the third parties submitted in the public consultation, if implemented, would reduce the overall risks. The exposure of workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3. Since CTPHT has PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 70-700 tonnes per year of emissions to the environment of PAHs with PBT, vPvB and carcinogenic properties. RAC was unable to propose additional authorisation conditions that could make the operational conditions and risk management measures appropriate and effective in limiting the risk for the environment and humans via the environment. RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

4. 149_CTPht_Nalon (1 use)	
Use 1: *Use of CTPht for manufacture of formulations for various industrial uses* The RAC consultations on the draft Final Opinion has been held 09-13 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report The exposure to workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3 of the justification to this opinion. Since CTPHT has PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 0.297 kg per year of emissions to the environment of indicator PAHs with PBT, vPvB and carcinogenic properties. RAC agreed for: 1. additional conditions for the authorisation RAC proposes as a condition for the authorisation that the applicant shall at the latest 3 years after the authorisation has been granted for this use implement further treatment of the exhaust air from the scrubbers by e.g. incineration or active carbon filters. 2. monitoring arrangements for the authorisation To improve the exposure assessment and facilitate further minimisation of the workers' exposure to CTPHT, RAC proposes that the	**SECR** to send the final opinion to the EC, MSs and the Applicant.

applicant shall implement at least annual programmes of inhalation exposure monitoring through personal sampling in combination with post-shift urinary biomonitoring, representative of the number of workers potentially exposed and the range of tasks undertaken where exposure to CTPHT is possible. This information from the monitoring programmes including the contextual information associated with each set of measurements and any action taken should also be included in the review report, if submitted. RAC proposes for the authorisation that the applicant shall implement at least quarterly programmes of measurement of emissions of PAHs to air. This information should also be included in the review report, if submitted. 3. no recommendations for the review report The applicant should revise the potential exposure assessment for the maintenance operations and provide a quantitative assessment. The applicant should act upon the outcome of this review without delay. The outcome of this action should be made available to the national authorities and documented in the review report, if submitted. The applicant should review the suitability of the personal protective equipment used to protect workers against dermal exposure to products containing CTPHT and should revise the dermal exposure assessment. The applicant should act upon the outcome of this review without delay. The outcome of this action should be documented in the review report, if submitted. The applicant stated that the PAH-concentrations in the combined wastewater stream were measured at the release point at least once per year and monthly from September 2017 onwards. It is not fully clear whether this is a requirement in the environmental permit. RAC recommends to continue the monthly monitoring of the indicator PAHs in water. RAC recommends that the applicant includes the measurement data in any review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.	

The monitoring data referred to in section 8.1 of the justification to this opinion shall be included in the review report, if submitted. RAC adopted the final opinion by consensus with changes made to the draft opinion.	
5. 150_CTPht_AO_Koppers (1 use)	
Use 1: *Use of CTPht for manufacture of formulations for various industrial uses* *Use of AO for manufacture of formulations for various industrial uses* The RAC consultations on the draft Final Opinion has been held 09-13 November 2020. RAC concluded that the operational conditions and risk management measures described in the application for the use of Anthracene oil (AO) are appropriate and effective in limiting the risk, provided that they are adhered to. RAC concluded that the operational conditions and risk management measures described in the application for Pitch, coal tar, high temp. (CTPHT) are expected to be 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 information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The exposure to workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3 of the justification to this opinion. Since CTPHT and AO have PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 6.17 $\times$ 10^{-3} kg per year of emissions to the environment of indicator PAHs with PBT, vPvB and carcinogenic properties.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

RAC agreed for: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation To improve the exposure assessment and facilitate further minimisation of the workers' exposure to CTPHT, RAC proposes that the applicant shall implement at least annual programmes of inhalation exposure monitoring through personal sampling in combination with post-shift urinary biomonitoring, representative of the number of workers potentially exposed and the range of tasks undertaken where exposure to CTPHT is possible. This information from the monitoring programmes including the contextual information associated with each set of measurements and any action taken should also be made available to Competent Authorities upon request and be included in the review report, if submitted. RAC proposes for the authorisation that the applicant shall implement at least annual programmes of measurement of emissions of PAHs to air from the incinerator. This information should also be included in the review report, if submitted. 3. recommendations for the review report The applicant should review the suitability of the personal protective equipment used to protect workers against dermal exposure to products containing CTPHT and should revise the dermal exposure assessment. The applicant should act upon the outcome of this review without delay. The outcome of this action should be made available to the national authorities and documented in the review report, if submitted. The applicant notes that the concentrations of individual PAHs in the effluent of the active carbon filtered rainwater are measured at least once per month as required according to the environmental permit. RAC recommends that the applicant includes the measurement data in any review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. The monitoring data referred to in section 8.1 of the justification to this opinion shall be included in the review report, if submitted.	

RAC adopted the final opinion by consensus with ~~editorial~~ changes made to the draft opinion.	
6. 153_CTPht_AO_Bilbaina (1 use)	
Use 1: *Use of CTPht for manufacture of formulations for various industrial uses* *Use of AO for manufacture of formulations for various industrial uses* The RAC consultations on the draft Final Opinion has been held 09-13 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The exposure to workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3. Since CTPHT and AO have PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 0.8 kg per year of emissions to the environment of indicator PAHs with PBT, vPvB and carcinogenic properties. RAC agreed for: 1. additional conditions for the authorisation RAC proposes that as a condition for the authorisation the applicant shall implement state of the art technical RMMs following the hierarchy of control for the drum filling station and for the pump repair shop. 2. monitoring arrangements for the authorisation To improve the exposure assessment and facilitate further minimisation of the workers'	**Rapporteurs** together with **SECR** to do the final editing of the final opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.

exposure to CTPHT, RAC proposes that the applicant shall implement: OPTION 1. annual programmes of inhalation exposure monitoring through personal sampling in combination with post-shift urinary biomonitoring, representative of the number of workers potentially exposed and the range of tasks undertaken where exposure to CTPHT is possible. This information from the monitoring programmes, including the contextual information associated with each set of measurements and any action taken, should be included in the review report, if submitted. RAC proposes for the authorisation that the applicant shall implement at least quarterly monitoring of PAHs in the wastewater prior to release to the external STP. The results should be included in the review report, if submitted, including the details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC proposes for the authorisation that the applicant shall implement at least annual programmes of measurement of emissions of PAHs to air. This information should also be included in the review report, if submitted. 3. recommendations for the review report The applicant should review the suitability of the personal protective equipment used to protect workers against dermal exposure to products containing CTPHT and should revise the dermal exposure assessment. The applicant should act upon the outcome of this review without delay. The outcome of this action should be made available to the national authorities and documented in the review report, if submitted. The monitoring data referred to in section 8.1 as well as a description of the risk management measures implemented in accordance with section 7.1 and their appropriateness and effectiveness, shall be included in the review report, if submitted. The applicant shall revise the exposure scenario for the maintenance operations and include the update in the review report, if submitted.	

RAC adopted the final opinion by consensus with changes made to the draft opinion as presented by the Rapporteurs.	
7. 162_OPE_LFB (1 use)	
Use 1: *Use as virus inactivation into the manufacture process of plasma-derived immunoglobulins.* The RAC consultations on the draft Final Opinion has been held 04-10 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in up to 10 kg per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation As soon as the first measurements obtained through monitoring are available, the applicant shall carry out a mass balance analysis based on measurements as indicated in section 8 of the justification to the opinion. Based on the results, the applicant shall assess how the operational conditions and risk management measures (OCs and RMM) can be optimised in such a way that the releases of 4-tert-OPnEO to the environment can be further minimised taking into account the outcomes of the measurement programme. Such optimisation may include the collection of the waste streams following the ultrafiltration step and the cleaning-in-place step. The applicant shall act upon the outcome of this assessment. 2. monitoring arrangements for the authorisation As soon as the new RMMs are operational, the applicant shall start undertaking a monitoring programme, measuring the concentration of 4-	**SECR** to send the final opinion to the EC, MSs and the Applicant.

tert-OPnEO in individual waste streams prior to release to the municipal STP. The initial sampling frequency should be sufficient to take account of daily fluctuations. Once established, RAC recommends that the applicant should continue with the quarterly / four times per year monitoring of 4-tert-OPnEO and its principal degradation products in the waste water 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 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 As described in section 7 of the justification to the opinion, after implementation of the new RMMs, the applicant shall perform a new mass balance analysis in order to confirm the predicted effectiveness of the implemented RMMs and report the results in any review report, including details of the calculations carried out, the assumptions made, if any, and the corresponding environmental release values. Cleaning-in-place should be included in the mass balance analysis. The results of the monitoring programme, as well as the mass balance and the outcome and conclusions of the actions taken with regards to minimising emissions, shall be documented and included in any subsequent authorisation review report. The new mass balance analysis and measurement results should allow the evaluation of the effectiveness of the OCs and RMMs in place and to confirm that emissions are reduced to as low a level as is technically and practically possible. The information gathered via the measurement programme as well as the outcome and conclusions of the review and any action taken, shall be included in any subsequent authorisation review report. It was noted by RAC that there will be an excess solution of 4-tert-OPnEO per batch prepared and only parts of the solution will be	

required for the virus inactivation step. The applicant is invited to further assess in a review report the feasibility for the batch quantity management. RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
8. 176_OPE_Abbott_1 (uses 1 and 2)	
Use 1: *Industrial use as a surfactant in the formulation of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.* The RAC consultations on the draft Final Opinion has been held 09-13 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional authorisation conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The use applied for may result in approximately 116.16 kg (from that 37.27 kg Sligo, 30.65 kg/year Longford, 48.24 kg/year in Wiesbaden) per year emission of 4-tert-OPnEO to the environment. RAC agreed for: 1. additional conditions for the authorisation Liquid waste All liquid waste releases containing the substance shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the public sewer system is not considered to be adequate treatment. 2. monitoring arrangements for the authorisation RAC recommends that the applicant should monitor at least 4 times per year / quarterly 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the off-site WWTP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level	**SECR** to send the final opinion to the EC, MSs and the Applicant.

of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values." 3. no recommendations for the review report. RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
Use 2: *Professional use as a surfactant in the final use of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.* The RAC consultations on the draft Final Opinion has been held 09-13 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional authorisation conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. Per year the use applied for may result in 4-tert-OPnEO emissions to the environment of approximately 514 kg in wastewater and 13 kg in solid waste. This amounts to a maximum average release of 27.6 g/day/site. RAC agreed for: 1. additional conditions for the authorisation All liquid and solid waste containing the substance shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report. In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users about their efforts to collect all liquid waste for adequate treatment,	**SECR** to send the final opinion to the EC, MSs and the Applicant.

and which treatment methods are applied (e.g., incineration). RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
9. 184_OPE_Lilly (1 use)	
Use 1: *Industrial formulation (dilution) of) of a silicone solution containing 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and its subsequent use as a lubricant in the manufacture of medicinal product delivery devices* The RAC consultations on the draft Final Opinion has been held 09-13 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the environment. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report. The recommendations defined for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in up to 29.6 kg and 10.3 kg per year emissions of the substance 4-tert-OPnEO to the environment at Fegersheim and Sesto Fiorentino site, respectively. RAC agreed for: 1. additional conditions for the authorisation All relevant wastewater containing 4-tert-OPnEO shall be collected and subject to adequate treatment with the view of minimisation of releases to the environment at both sites. After implementation of new OCs and RMMs, the applicants should perform a mass balance analysis in order to confirm the predicted effectiveness of implemented RMMs and report the results in any review report. The validation	**Rapporteurs** together with **SECR** to do the final editing of the final opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.

data should be available to the enforcement authorities upon request. 2. monitoring arrangements for the authorisation The applicants shall continue to monitor at least quarterly/four times per year the concentration of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site STP using an analytical method capable of adequately characterising the parent substance and its principal degradation products in water at an appropriately low level of quantification. 3. recommendations for the review report The information on the implemented OCs and RMMs, the mass balance and the results of the monitoring campaigns should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC adopted the final opinion by consensus with changes made to the draft opinion.	
10. 186_OPE_NPE_Beckman (uses 1 and 3)	
Use 1: *Formulation of NPnEO and OPnEO solutions in European sites for use as laboratory products. Laboratory products are used as intermediate solutions for preparation of finished laboratory products (finished goods) or in-process use.* The RAC consultations on the draft Final Opinion has been held 04-10 November 2020. 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 zero kg per year emissions of the substance to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. RAC adopted the final opinion by consensus with changes made to the draft opinion.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

Use 3: *Downstream use of OPnEO- or NPnEO-containing clinical laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, hematology and flow cytometry laboratory instruments and assays* The RAC consultations on the draft Final Opinion has been held 04-10 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. This information should also be included in the review report. The use applied for may result in up to 305 kg 4-tert-OPnEO and 1 740 kg 4-NPnEO] per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation All solid waste containing of OPnEO and NPnEO shall be collected for adequate treatment. The treatment shall minimize releases to environmental compartments as far as technically and practically possible. The collection of contaminated liquid wastes for adequate treatment shall continue at the sites where it is already implemented. The applicant shall follow the reformulation strategy described in their comments to the draft opinion. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users about their efforts to collect all solid waste for adequate treatment, and which treatment methods are applied. In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users about their implemented system to collect liquid waste for	**Rapporteurs** together with **SECR** to do the final editing of the final opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.

adequate treatment, and which treatment methods are applied. RAC adopted the final opinion by consensus with changes made to the draft opinion.	
11. 187_OPE_AGC (2 uses)	
Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as detergent for the inactivation of viruses in the production of therapeutic proteins using mammalian cell hosts* The RAC consultations on the draft Final Opinion has been held 09-13 November 2020. 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 monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in approximately 0.00778 kg per year emissions of the substance to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation As soon as the new RMMs are operational (collection of the second wash water), the applicants shall start undertaking a monitoring programme, measuring the concentration of 4-tert-OPnEO and its principal degradation products prior to release to the municipal STP. The initial sampling frequency should be sufficient to take account of daily fluctuations. Once established, RAC recommends that the applicants should continue with the quarterly monitoring of 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the municipal STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point,	**SECR** to send the final opinion to the EC, MSs and the Applicant.

the analytical method, the concentrations detected and the corresponding environmental release values. A mass balance report should also be included when the use is increased and/or the new facility is operating. 3. recommendations for the review report RAC recommends that the applicants should, after implementation of the new RMMs (collection of the second wash water of the chromatographic column) and the results of the monitoring data, perform a new mass balance analysis in order to confirm the predicted effectiveness of the implemented RMMs in the current and future building. The information gathered via the measurement program as well as the outcome and conclusions of the review and any action taken, shall be included in any subsequent authorisation review report. RAC recommends the applicants to further assess in any review report the feasibility of implementing an appropriate treatment of the residual waste water not collected and act on the outcome of the feasibility study. RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
Use 2: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a detergent during the purification process of recombinant biopharmaceuticals derived from microbial expression hosts in projects where processes have been approved by ther authorities (GMP compliant)* The RAC consultations on the draft Final Opinion has been held 09-13 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

The use applied for may result in approximately 8.2 kg per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation In the Heidelberg and Copenhagen sites, all liquid waste releases, which occur during the cleaning of premises (second wash of the chromatographic columns, clean in place rinse of the stainless steel tanks and centrifuge), shall be collected and disposed for adequate treatment. The applicants shall, after implementation of the new RMMs and the results of the monitoring data, perform a new mass balance analysis in order to confirm the predicted effectiveness of the implemented RMMs in the current Heidelberg site and in the in the Copenhagen site. The new validation data should be available to the enforcement authorities upon request. 2. monitoring arrangements for the authorisation In the current Heildelberg site, as soon as the new RMMs are operational (collection of the waste water from the rinse of the tanks/centrifuge and the second wash of the chromatographic column), the applicants shall start undertaking a monitoring programme, measuring the concentration of 4-tert-OPnEO and its principal degradation products prior to release to the municipal sewage treatment plant (STP). In Copenhagen, the applicants shall start undertaking, after the production lines will become operational, a monitoring programme, measuring the concentration of 4-tert-OPnEO and its principal degradation products prior to release to the municipal STP. In both sites the initial sampling frequency should be sufficient to take account of daily fluctuations. Once established, RAC recommends that the applicants should continue with the quarterly monitoring of 4-tert-OPnEO and its principal degradation products in the waste water 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 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 applicants are required to include a detailed description of the OCs and RMMs and the results of the monitoring data and mass balance analysis in any subsequent review report in order to corroborate the appropriateness and effectiveness of the RMMs and OCs in place in the increase use scenario in Heidelberg and in the in Copenhagen site. RAC recommends the applicants to further assess in any review report the feasibility of implementing an appropriate treatment of the residual waste water not collected and act on the outcome of the feasibility study. RAC recommends the applicants to further assess in any review report the feasibility of implementing an appropriate treatment of the residual waste water not collected and act on the outcome of the feasibility study. RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
12. 188_OPE_Wallac_2 (2 uses)	
Use 1: *Formulation of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (as Triton X-100) for use in the assay buffer for the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity* The RAC consultations on the draft Final Opinion has been held 04-10 November 2020. Therefore, RAC did not evaluate the potential risk of alternatives. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

The use applied for may result in approximately 0.0006 kg per year of emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation All liquid waste releases which occur during QC control of IVD kits and R&D processes shall be collected and disposed of for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. monitoring arrangements for the authorisation The applicant shall continue to monitor at least four times per year the concentration of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site WWTP, using an analytical method capable of adequately characterising the substance and its principal degradation products in water and at an appropriately low level of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. no recommendations for the review report RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
Use 2: *Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in the assay buffer of the GSP®Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity.* The RAC consultations on the draft Final Opinion has been held 04-10 November 2020. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

The use applied for may result in approximately 0.135 kg per year of emissions of the substance to the environment for a total number of 7 sites. RAC agreed for: 1. additional conditions for the authorisation In addition to the solid waste containing traces of 4-tert-OPnEO generated from the use applied for, all liquid waste containing of 4-tert-OPnEO generated from the use applied for shall be collected by the downstream users for adequate treatment (e.g. incineration). The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users on the measures they have in place to collect for adequate treatment all liquid and solid waste containing 4-tert-OPnEO resulting from the use applied for, and which treatment methods are applied (e.g., incineration). RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
11. AOB	
12. Minutes of RAC-55	
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-55 to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-55B

1. **C. I. Disperse Blue 124**
2. **Bentazone (ISO)**
3.

Margosa, ext.

4. Perfluroheptanoic acid (PFHpA)

5. Bisphenol S

6. Melamine

7. Valifenalate

8. Isopyrazam

9. 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta-PSCA Na TEA)

10. 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA)

11. 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA)

12. EGBE (Art 77-3c request)

Table 1

1. C. I. Disperse Blue 124

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-[N-ethyl-4-[(5-nitrothiazol-2-yl)azo]-m-toluidino]ethyl acetate; C.I. Disperse Blue 124	239-203-6	15141-18-1	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1A; H317: C ≥ 0,001%	
RAC opinion	TBD	2-[N-ethyl-4-[(5-nitrothiazol-2-yl)azo]-m-toluidino]ethyl acetate; C.I. Disperse Blue 124	239-203-6	15141-18-1	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1A; H317: C ≥ 0,001%	
Resulting Annex VI entry if agreed by COM	TBD	2-[N-ethyl-4-[(5-nitrothiazol-2-yl)azo]-m-toluidino]ethyl acetate; C.I. Disperse Blue 124	239-203-6	15141-18-1	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1A; H317: C ≥ 0,001%	

2. Bentazone (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	613-012-00-1	bentazone (ISO); 3-isopropyl-2,1,3-benzothiadiazine-4-one-2,2-dioxide	246-585-8	25057-89-0	Acute Tox. 4* Eye Irrit. 2 Skin Sens. 1 Aquatic Chronic 3	H302 H319 H317 H412	GHS07 Wng	H302 H319 H317 H412			
Dossier submitters proposal	613-012-00-1	bentazone (ISO); 3-isopropyl-2,1,3-benzothiadiazine-4-one-2,2-dioxide	246-585-8	25057-89-0	**Retain** Skin Sens. 1 **Add** Repr. 2 **Modify** Acute Tox. 4 **Remove** Aquatic Chronic 3	**Retain** H317 **Add** H361d **Modify** H302 **Remove** H412	**Retain** GHS07 Wng **Add** GHS08	**Retain** H317 **Add** H361d **Modify** H302 **Remove** H412		**Add** oral: ATE = 1640 mg/kg bw	
RAC opinion	613-012-00-1	bentazone (ISO); 3-isopropyl-2,1,3-benzothiadiazine-4-one-2,2-dioxide	246-585-8	25057-89-0	Repr. 2 Acute Tox. 4 Skin Sens. 1	H361d H302 H317	GHS08 GHS07 Wng	H361d H302 H317		oral: ATE = 1600 mg/kg bw	
Resulting Annex VI entry if agreed by COM	613-012-00-1	bentazone (ISO); 3-isopropyl-2,1,3-benzothiadiazine-4-one-2,2-dioxide	246-585-8	25057-89-0	Repr. 2 Acute Tox. 4 Eye Irrit. 2 Skin Sens. 1	H361d H302 H319 H317	GHS08 GHS07 Wng	H361d H302 H319 H317		oral: ATE = 1600 mg/kg bw	

3. Margosa, ext.

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	Margosa, ext. [from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents]	283-644-7	84696-25-3	Repr. 2 Skin Sens. 1 Aquatic Chronic 1	H361d H317 H410	GHS08 GHS07 GHS09 Wng	H361d H317 H410		M = 10	
RAC opinion	TBD	Margosa, ext. [from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents]	283-644-7	84696-25-3	Repr. 2 Skin Sens. 1 Aquatic Chronic 1	H361d H317 H410	GHS08 GHS07 GHS09 Wng	H361d H317 H410		M = 10	
Resulting Annex VI entry if agreed by COM	TBD	Margosa, ext. [from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents]	283-644-7	84696-25-3	Repr. 2 Skin Sens. 1 Aquatic Chronic 1	H361d H317 H410	GHS08 GHS07 GHS09 Wng	H361d H317 H410		M = 10	

4. Perfluroheptanoic acid (PFHpA)

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	Perfluoroheptanoic acid; tridecafluoroheptanoic acid	206-798-9	375-85-9	Repr. 1B STOT RE 1	H360D H372 (liver)	GHS08 Dgr	H360D H372 (liver)			
RAC opinion	TBD	Perfluoroheptanoic acid; tridecafluoroheptanoic acid	206-798-9	375-85-9	Repr. 1B STOT RE 1	H360D H372 (liver)	GHS08 Dgr	H360D H372 (liver)			
Resulting Annex VI entry if agreed by COM	TBD	Perfluoroheptanoic acid; tridecafluoroheptanoic acid	206-798-9	375-85-9	Repr. 1B STOT RE 1	H360D H372 (liver)	GHS08 Dgr	H360D H372 (liver)			

5. Bisphenol S

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	4,4'-sulphonyldiphenol; bisphenol S	201-250-5	80-09-1	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
RAC opinion	TBD	4,4'-sulphonyldiphenol; bisphenol S	201-250-5	80-09-1	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
Resulting Annex VI entry if agreed by COM	TBD	4,4'-sulphonyldiphenol; bisphenol S	201-250-5	80-09-1	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

6. Melamine

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	Melamine	203-615-4	108-78-1	Carc. 2 STOT RE 1	H351 H372 (urinary tract)	GHS08 Dgr	H351 H372 (urinary tract)			
RAC opinion	TBD	Melamine	203-615-4	108-78-1	Carc. 2 STOT RE 2	H351 H373 (urinary tract)	GHS08 Wng	H351 H373 (urinary tract)			
Resulting Annex VI entry if agreed by COM	TBD	Melamine	203-615-4	108-78-1	Carc. 2 STOT RE 2	H351 H373 (urinary tract)	GHS08 Wng	H351 H373 (urinary tract)			

7. Valifenalate

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	methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)-β-alaninate; valifenalate		283159-90-0	Aquatic Chronic 2	H411	GHS09	H411			
RAC opinion	TBD	methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)-β-alaninate; valifenalate		283159-90-0	Carc. 2 Aquatic Chronic 2	H351 H411	GHS08 GHS09 Wng	H351 H411			
Resulting Annex VI entry if agreed by COM	TBD	methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)-β-alaninate; valifenalate		283159-90-0	Carc. 2 Aquatic Chronic 2	H351 H411	GHS08 GHS09 Wng	H351 H411			

8. Isopyrazam

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	Reaction mass of 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9RS)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide and 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide [≥78% syn isomers ≤15% anti isomers relative content]; isopyrazam	-	881685-58-1	Repr. 1B Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360D H317 H410		M = 10 M = 10	
RAC opinion	TBD	Reaction mass of 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9RS)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide and 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-	-	881685-58-1	Carc. 2 Repr. 1B Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H351 H360D H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H351 H360D H317 H410		Repr. 1B; H360D: C ≥ 3% M = 10 M = 10	

		5-yl]pyrazole-4-carboxamide [≥78% syn isomers ≤15% anti isomers relative content]; isopyrazam									
Resulting Annex VI entry if agreed by COM	TBD	Reaction mass of 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9RS)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide and 3-(difluoromethyl)-1-methyl-N-[(1RS,4SR,9SR)-1,2,3,4-tetrahydro-9-isopropyl-1,4-methanonaphthalen-5-yl]pyrazole-4-carboxamide [≥78% syn isomers ≤15% anti isomers relative content]; isopyrazam	-	881685-58-1	Carc. 2 Repr. 1B Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H351 H360D H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H351 H360D H317 H410		Repr. 1B; H360D: C ≥ 3% M = 10 M = 10	

9. 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta-PSCA Na TEA)

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	6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts	701-271-4	-	Repr. 1B Eye Irrit. 2	H360FD H319	GHS08 GHS07 Dgr	H360FD H319			
RAC opinion	TBD	6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts	701-271-4	-	Repr. 1B Eye Irrit. 2	H360FD H319	GHS08 GHS07 Dgr	H360FD H319			
Resulting Annex VI entry if agreed by COM	TBD	6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts	701-271-4	-	Repr. 1B Eye Irrit. 2	H360FD H319	GHS08 GHS07 Dgr	H360FD H319			

10. 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA)

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	6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	701-118-1	2156592-54-8	Repr. 1B Eye Irrit. 2	H360FD H319	GHS08 GHS07 Dgr	H360FD H319		Repr. 1B; H360FD: C ≥ 0,03 %	
RAC opinion	TBD	6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	701-118-1	2156592-54-8	Repr. 1B Eye Irrit. 2	H360FD H319	GHS08 GHS07 Dgr	H360FD H319			
Resulting Annex VI entry if agreed by COM	TBD	6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	701-118-1	2156592-54-8	Repr. 1B Eye Irrit. 2	H360FD H319	GHS08 GHS07 Dgr	H360FD H319			

11. 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA)

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	6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	701-162-1	-	Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD: C ≥ 0,03 %	
RAC opinion	TBD	6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	701-162-1	-	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
Resulting Annex VI entry if agreed by COM	TBD	6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid	701-162-1	-	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

12. EGBE (Art 77-3c request)

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

	Index No	International Chemical Identification	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)		
First RAC opinion	603-014-00-0	2-butoxyethanol; ethylene glycol monobutyl ether	203-905-0	111-76-2	Acute Tox. 3 Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2	H331 H302 H315 H319	GHS06 Dgr	H331 H302 H315 H319		inhalation: ATE =3 mg/L oral: ATE = 1200 mg/kgbw	
For RAC discussion following Art 77(3)c request	603-014-00-0	2-butoxyethanol; ethylene glycol monobutyl ether	203-905-0	111-76-2	Acute Tox. 3	H331	GHS06 Dgr	H331		inhalation: ATE = 3 mg/L	
RAC opinion following Art 77(3)c request	603-014-00-0	2-butoxyethanol; ethylene glycol monobutyl ether	203-905-0	111-76-2	Acute Tox. 3	H331	GHS06 Dgr	H331		inhalation: ATE = 3 mg/L	
Resulting Annex VI entry if agreed by COM	603-014-00-0	2-butoxyethanol; ethylene glycol monobutyl ether	203-905-0	111-76-2	Acute Tox. 3 Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2	H331 H302 H315 H319	GHS06 Dgr	H331 H302 H315 H319		inhalation: ATE = 3 mg/L oral: ATE = 1200 mg/kg bw	

Part III. List of Attendees of the RAC-55 meeting

RAC Members
Aquilina Gabriele
Barański Bogusław
Biró Anna
Bjørge Christine
Borg Daniel
Branisteanu Radu (co-opted member)
Carvalho João
Chiurtu Elena (co-opted member)
de la Flor Tejero Ignacio
Doak Malcolm
Docea Anca Oana
Dobrev Ivan
Geoffroy Laure
Hakkert Betty
Hartwig Andrea (co-opted member)
Husa Stine
Kadiķis Normunds
Kapelari Sonja
Karadjova Irina
Leinonen Riitta
Losert Annemarie
Lund Bert-Ove
Martínek Michal
Menard Srpčič Anja
Moeller Ruth
Moldov Raili
Murray Brendan

Neumann Michael
Paris Pietro
Peczkowska Beata
Pribu Mihaela
Printemps Nathalie
Rodriguez Wendy
Rucki Marian
Santonen Tiina
Schlüter Urs
Schulte Agnes
Schuur Gerlienke
Séba Julie
Sørensen Hammer Peter
Sogorb Miguel A.
Spetseris Nikolaos
Stahlmann Ralf
Tobiassen Lea Stine
Tsitsimpikou Christina
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted member)
Varnai Veda
Xanthos Theodore
Apologies, Members
Brovkina Julija
Heederik Dick (co-opted member)
Zeljezic Davor
SEAC rapporteurs
Fankhauser Simone (restriction: PFHxA)
Kiiski Johanna (restriction: PFHxA, Art 77(3)c: PFOA)

Members' advisers
Boel Els (Julie Seba)
Catone Tiziana (Pietro Paris)
Clausen Henning (Peter Hammer Soerensen)
Esposito Dania (Pietro Paris)
Gabbert Silke (Betty Hakkert)
Henriksson Jörgen (Daniel Borg)
Hoffmann Frauke (Agnes Schulte)
Mahiout Selma (Tiina Santonen)
Martin Theresa (Ralf Stahlmann)
Munch Pernille (Lea Tobiassen)
Paludan Ditte Secher (Lea Tobiassen)
Partosch Falko (Ralf Stahlmann)
Seba Julie (Wendy Rodriguez-Gonzalez)
Rother Dag (Urs Schlueter)
Romoli Debora (Pietro Paris)
Russo Maria Teresa (Pietro Paris)
Sonnenburg Anna (Ralf Stahlmann)
Suutari Tiina (Riitta Leinonen)
Viegas Susana (Joao Carvalho)
Invited experts
Facchin Manuel (Annemarie Losert)
Levy Patrick (OEL: cadmium)
Musu Tony (OEL: cadmium)
Saarikoski Sirkku (OEL: cadmium)

Dossier submitters
Affourtit Femke (NL)_bentazone
August Christina (DE)_PFHxA
Averbeck Frauke (DE)_PFHxA
Beausoleil Claire (FR)_divanadium pentaoxide
Charles Sandrine (FR)_V205
Drost Wiebke (DE)_PFHxA
Dubois Celine (FR)_single use nappies
Erdmann Christian (DE)_PFHxA
Fiore Karine (FR)_single use nappies
Henkler-Stephani Frank (DE)_PFHxA
Kacan Stefan (DE)_PFHxA
Mathieu-Huart Aurélie (FR)_single use nappies
Meys Catherine (BE)_Bisphenol S
Peiser Matthias (DE)_margosa
Schmeisser Sebastian (DE)_melamine
Regular stakeholder observers
Barry Frank (ETUC)
Comini Andrea (EuCheMS)
De Backer Liisi (CEFIC)
Duguy Hélène (ClientEarth)
Robinson Jan (A.I.S.E)
Romano Mozo Dolores (EEB)
Ruelens Paul (ECPA)
Van de Broeck Steve (CEFIC)
Verougstraete Violaine (Eurometaux)
Waeterschoot Hugo (Eurometaux)

Occasional stakeholders
Barbu Luminita (EDANA)_Restriction : PFHxA, single use nappies, general restrictions
Cassart Michael (PlasticsEurope)_CLH : Bisphenol S
Leonhardt Thomas (EUROFEU)_Restriction: PFHxA, Art 77(3)c: PFOA
De Matos Olivier (ECETOC)_Art 77(3)c : EGBE
Niemelä Helena (CONCAWE)_Art (77)3 c : PFOA, DNEL trixylyl, OEL : cadmium
Robin Nicolas (PlasticsEurope)_ Restriction : PFHxA, Art 77(3)c : PFOA
Scalia Mauro (Euratex)_Restriction : PFHxA, single use nappies, general restrictions
Stakeholder experts
Battersby Rodgers (Eurometaux/EBRC consulting)_Art 77(3)c : lead
Binks Steve (CEFIC/Downstream users of lead and compounds of the Pb Reach consortium)_Art 77(3)c : lead
Bock Ronald (PlasticsEurope/Fluoropolymer)_Restriction: PFHxA, Art 77(3)c PFOA
Bomann Werner (ECPA/Belchim)_CLH : valifenalate
Chowdhury Jasim (Eurometaux/ILA)_Art 77(3)c :lead
da Cunha Vicente Golin (Eurometaux/REACH melamine consortium)_CLH : melamine
Gelbke Heinz-Peter (CEFIC/PASG)_CLH : melamine
Grant Claire (PlasticsEurope/Regulatory Science Associates)_CLH : bisphenol S
Hannebaum Peter (EUROFEU/Tyco Fire Protection Products)_Restriction :PFHxA, Article 77(3)c : PFOA

Kelsey Jeff (CEFIC/OSPA)_Art 77(3)c : EGBE
Kemeny Monika (ECPA/BASF)_CLH : bentazone
Krug Isabel (CEFIC/BASF)_CLH : bisphenol S
Lloyd Sara (ECPA/Syngenta)_CLH : isopyrazam
Lombaert Noömi (Eurometaux/ICdA)_OEL :cadmium
Otter Rainer (ECETOC/BASF)_Art 77(3)c: EGBE
Pfau Wolfgang (ECPA/Trifolio)_CLH : margosa
Thumm Stefan (Euratex/Bavarian Textile and Apparel Association)_Restriction : PFHxA, single-use nappies, general restrictions
Wietor Jean-Luc (EEB/EEB)_Restriction : PFHxA, Art 77(3)c : PFOA
Yada Makiko (CEFIC/Daikin)_Restriction: PFHxA, Article 77(3)c: PFOA

Commission
Baricic Peter (DG GROW)
Bertato Valentina (DG ENV)
Bintein Sylvain (DG ENV)
Blass-Rico Ana Maria (DG GROW)
Gutierrez-Medina Miriam (DG GROW)
Jezso Veronika (DG GROW)
Kilian Karin (DG ENV)
Kusendila Christophe (DG SANTE)
Lekatos Stylianos (DG GROW)
Morris Alick (DG EMPL)
Pirselova Katarina (DG ENV)
Podniece Zinta (DG EMPL)
Reixeira Carla (DG EMPL)
Roebben Gert (JRC)
Rozwadowski Jacek (DG GROW)
Tailler William (DG EMPL)
Tosetti Patricia (DG SANTE)
Zorgno Riccardo (DG GROW)
ECHA staff
Blainey Mark
Bowmer Tim, Chair
Broeckaert Fabrice
Doyle Simone
Gmeinder Michael
Henrichson Sanna
Karjalainen Ari
Kivelä Kalle
Kokkola Leila
Koskinen Marjo
Lapenna Silvia
Lazic Nina

Ludborzs Arnis
Majoros Laszlo
Marques-Camacho Mercedes
Matthes Jochen
Mottet Denis
Myöhänen Kirsi
Nicot Thierry
Nurmi Väinö
Nygren Jonas
Orispää Katja
O´Rourke Regina
Ottati Maria
Peltola Jukka
Perazzolo Chiara
Pillet Monique
Prevedouros Konstantinos
Regil Pablo
Roggeman Maarten
Rossi Ludovica
Sadam Diana
Sihvonen Kirsi
Simoes Ricardo
Simpson Peter
Smilovici Simona
Sosnowski Piotr
Spjuth Linda
Stasko Jolanta
Unamuno Virginia
Uphill Simon
Vainio Matti
Van Haelst Anniek
Zeiger Bastian

Part II. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-55 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-55 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-55 meeting

30 November 2020
RAC/A/55/2020
Final

Final Agenda

55th meeting of the Committee for Risk Assessment

30 November – 3 December
and
7-10 December 2020

Virtual meeting

Monday 30 November starts at 14.00
Thursday 3 December breaks at 18.00
Monday 7 December resumes at 14.00
Thursday 10 December ends at 15.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/55/2020
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

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

For agreement

Item 5 – Report from other ECHA bodies and activities

a) RAC Work Plan for all processes

For information

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

1) DNEL development for trixylyl phosphate

For discussion and adoption

2) Revision of derogations from proposed restrictions on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances; C9-C14 perfluorocarboxylic acids (C9-C14 PFCA), their salts and C9-C14 PFCA-related substances

For discussion and adoption

3) Classification for acute inhalation toxicity of EGBE

For discussion and adoption

4) Classification for environmental toxicity of lead

For discussion

Item 7 –Health based exposure limits at the workplace

a) Opinion development

1) Cadmium and its inorganic compounds – first draft opinion

For discussion and agreement

Item 8 – Harmonised classification and labelling (CLH)

8.1 CLH dossiers

A. Hazard classes for agreement without plenary debate (fast-track)

- C. I. Disperse Blue 124: skin sensitisation
- Bentazone (ISO): acute oral toxicity, skin sensitisation, acute aquatic hazards, chronic aquatic hazards
- Margosa ext.: physical hazards (explosives, flammable gases, flammable aerosols, oxidising gases, gases under pressure, flammable liquids, flammable solids, self-reactive substances and mixtures, pyrophoric liquids, pyrophoric solids, substances and mixtures which in contact with water emit flammable gases, oxidising liquids, oxidising solids, organic peroxides, substances and mixtures corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, STOT RE, acute aquatic hazards, chronic aquatic hazards
- Benfluralin (ISO): physical hazards, acute aquatic hazards, chronic aquatic hazards
- Melamine: germ cell mutagenicity
- Valifenalate: physical hazards (explosives, flammable solids, self-heating substances, oxidising solids), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, STOT SE, STOT RE, chronic aquatic hazards, hazardous to the ozone layer

- Isopyrazam: physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance which in contact with water emit flammable gases, oxidising solid, corrosive to metals), acute dermal and inhalation toxicity, skin

corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, STOT RE, acute aquatic hazards, chronic aquatic hazards

- 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta-PSCA Na-TEA): STOT RE

- 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA): STOT RE

- 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA): STOT RE

For agreement

B. **Hazard classes for agreement with plenary debate**

1. Bentazone (ISO) (EC: 246-585-8; CAS: 25057-89-0)
2. Margosa ext. (EC: 283-644-7; CAS: 84696-25-3)
3. Perfluroheptanoic acid (PFHpA) (EC: 206-798-9; CAS: 375-85-9)
4. Bisphenol S (EC: 201-250-5; CAS: 80-09-1)
5. Melamine (EC: 203-615-4; CAS: 108-78-1)
6. Valifenalate (EC: -; CAS: 283159-90-0)
7. Isopyrazam (EC: -; CAS: 881685-58-1)

10) 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta_PSCA Na TEA) (EC: -; CAS: -)

11) 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA) (EC: -; CAS: 2156592-54-8)

12) 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid

(Penta-PSCA) (EC: -; CAS: -)

13) Divanadium pentaoxide

For discussion and agreement

Item 9 – Restrictions

9.1 General restriction issues

a) Updated Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals

9.2 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Substances in single-use nappies

For discussion and agreement

b) Opinion development

1) Undecafluorohexanoic acid (PFHxA), its salts and related substances –third draft opinion

For discussion and provisional agreement

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications
b) Substitution Plans
c) Report from RAC WG on AfAs during October 2020 meeting

RAC/55/2020/01
For information/discussion

10.2 Authorisation applications

1. Discussion on key issues
1) 9 applications for authorisation (EDC, Cr(VI), MOCA, 4-tert-OPnEO) from August 2020 submission window

For discussion

10.3 Agreement on draft opinions

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

1. 197_OPE_NPE_Phadia (2 uses)
2. 198_OPE_Zoetis (uses 1 and 2)
3. 199_OPE_Biokit (use 2)
4. 202_OPE_Merckle (1 use)

B. Draft opinions for agreement with plenary debate

1. 193_OPE_PPG (2 uses)
2. 196_OPE_Becton (1 use)
3. 198_OPE_Zoetis (uses 3 and 4)
4. 199_OPE_Biokit (use 1)
5. 203_OPE_NPE_Qiagen (4 uses)
6. 207_NPE_Chemetall (2 uses)
7. 208_RR1_TCE_BlueCube (1 use)
8. 209_CT_Safran (1 use)
9. 210_CT_SD_TataSteel (1 use)
10. 211_CT_Hubner (3 uses)

For discussion and agreement

10.4 Adoption on opinions

10.4.1.1 143_OPE_bioMerieux (use 1)
10.4.1.2 147_CTPht_Bilbaina (1 use)
10.4.1.3 148_CTPht_DEZA (1 use)
10.4.1.4 149_CTPht_Nalon (1 use)
10.4.1.5 150_CTPht_AO_Koppers (1 use)
10.4.1.6 153_CTPht_AO_Bilbaina (1 use)
10.4.1.7 162_OPE_LFB (1 use)
10.4.1.8 176_OPE_Abbott_1 (uses 1 and 2)
10.4.1.9 184_OPE_Lilly (1 use)
10.4.1.10 186_OPE_NPE_Beckman (uses 1 and 3)
10.4.1.11 187_OPE_AGC (2 uses)
10.4.1.12 188_OPE_Wallac_2 (2 uses)

For discussion and adoption

Item 11 – AOB

a) ECHA administrative improvement proposals

Item 12 – Minutes of RAC-55

a) Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-55

For adoption

Annex II (RAC 55)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 55 meeting.

Document number	Title
RAC/A/55/2020	Final Draft Agenda
RAC/55/2020/01	Report from RAC WG on AFAs during October 2020 meeting

Annex III (RAC-55)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Restrictions		
NEW Diapers (FR)	Nathalie PRINTEMPS	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
Perfluorohexanoic acid – PFHxA (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.
	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.
	Ivan DOBREV	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		
Divanadium pentaoxide	Laure GEOFFROY	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
FR		substance - no other mitigation measures applied. No personal involvement.
	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.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Health based exposure limits at the workplace		
Cadmium and its inorganic compounds		
Harmonised classification & labelling		
Bentazone (ISO) **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.
1. Perfluroheptanoic acid (PFHpA) **2. Bisphenol S** **BE**	Wendy RODRIGUEZ	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1. C. I. Disperse Blue 124 **2. Margosa ext.** **3. Melamine** **DE**	Agnes SCHULTE	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on these substances - no other mitigation measures applied. Personal involvement in dossiers 1 and 3. No personal involvement in dossier 2.
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ivan DOBREV	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
		measures applied. Personal involvement.
Valifenalate **HU**	Anna BIRO	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1. Isopyrazam **2. Benfluralin (ISO)** **NO**	Christine BJORGE	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.
	Stine HUSA	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1. Penta-PSCA Na TEA **2. Penta-PSCA** **3. Tetra-PSCA** **AT**	Annemarie LOSERT	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.
Article 77.3(c)		
Classification for acute inhalation toxicity of EGBE	-	-

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Classification for environmental toxicity of lead	-	-