RAC/M/54/2020

Final

7 October 2020

Minutes of the 54th Meeting

of the Committee for Risk Assessment

(RAC-54)

Tuesday 8 September, 14.00 to Wednesday 9 September, 18.30
and
Monday 14 September, 14.00 to Thursday 17 September, 17.00

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:

- The opportunity provided by the Chair's interviews with the members and occasional stakeholders especially to focus on the current working conditions due to Covid-19 situation.
- Members were informed that the meeting schedule would remain the same for 2020 and 2021 but there will be no face-to-face external meetings before 31 March 2021.
- The Chair thanked participants for the very high response rate to the Webropol surveys after RAC 52B Part 1 in May and RAC 53 in June.
- Members were informed that ECHA is reviewing the first six months of remote meeting experience right across the Agency with an eye to making improvements. That includes experimenting with different meeting formats, start times, breaks, and duration per day versus length of the overall meeting. Ways of creating opportunities for informal discussions in the margins of the meetings are also under discussion.

He informed the Committee that the Deputy Chair Johanna Peltola-Thies would chair sections of RAC-54.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/54/2020**) 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 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.	-

5. Report from other ECHA bodies and activities

a) RAC work plan for all processes The Chair presented the RAC work plan for 2020 and the first quarter of 2021.	
b) Annual update of RAC accredited stakeholders' list	Following the decision of the Committee, the **Secretariat** to editorially finalise and publish the list on ECHA´s webpage, and inform the stakeholders in question about the decision.

RAC agreed in closed session to add the following organisations to the list of **regular** stakeholders accredited to RAC:

- International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.)
- MedTech Europe representing medical technologies.

The Committee also agreed to add the following organisations to the list of **occasional** stakeholders accredited to RAC:

- Eurocolour
- European Professional Beekeepers Association
- International Association of Oil & Gas producers (IOGP)

The Chairman informed the Committee of his intent to examine the balance of representation in the Committee over the next year, including the procedural limits set in the general approach on the admission of observers to the work of RAC[1]

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 supported the Rapporteurs proposal to use: Absorption percentages – 10% for dermal absorption – 50% for oral absorption	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to launch the RAC consultations on the draft note.

[1] http://echa.europa.eu/documents/10162/13580/admission_of_stakeholder_organisations_as_observers_en.pdf

– 100% for inhalation absorption	**SECR** and to table the draft note for discussion and adoption at RAC-55.
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 took note of the introduction presentation on the Article 77(3)(c) request on revision of derogations from proposed restriction on PFOA/PFCAs and the planned timelines for the opinion development.	**Rapporteur** to provide the draft opinion to SECR by 12 October. **SECR** to launch the RAC consultations on the technical analysis prepared by ECHA and the draft opinion prepared by RAC rapporteur prior to RAC-55 and to table the draft opinion for discussion and adoption at RAC-55.
The accompanying expert to regular CEFIC stakeholder and the expert accompanying occasional stakeholder (PlasticsEurope) asked for clarifications on how the additional requests for the derogations provided in the call for evidence would be taken into account in the process.	

7. Health based exposure limits at the workplace

No items were discussed at this meeting.

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

- 4,4'-oxydi(benzenesulphonohydrazide): explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides, acute aquatic hazards, chronic aquatic hazards
- Toluene-4-sulphonohydrazide: explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides
- N-(2-nitrophenyl)phosphoric triamide: STOT RE
- 1,3-bis(1-isocyanato-1-methylethyl)benzene: respiratory sensitisation, skin sensitisation
- 1,3-bis(isocyanatomethyl)benzene: respiratory sensitisation, skin sensitisation
- 2,4,6-triisopropyl-m-phenylene diisocyanate: respiratory sensitisation, skin sensitisation
- 1,5-naphthylene diisocyanate: skin sensitisation
- Cumene: reproductive toxicity
- Divanadium pentaoxide; vanadium pentoxide: acute oral toxicity, respiratory sensitisation, STOT RE
- Barium diboron tetraoxide: acute dermal toxicity

- Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone: physical hazards, acute toxicity (via all routes), STOT SE, skin corrosion/irritation, serious eye damage/irritation, skin sensitisation, germ cell mutagenicity

B. Substances with hazard classes for agreement in plenary session

1) Trimethylolpropane triacrylate
2) N-(2-nitrophenyl)phosphoric triamide
3) 1,5-naphthylene diisocyanate
4) Cumene
5) Divanadium pentaoxide; vanadium pentoxide
6) Theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione
7) Barium diboron tetraoxide
8) Dibutyltin bis(2-ethylhexanoate)
9) Dibutyltin di(acetate)
10) Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone

1. Trimethylolpropane triacrylate

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the CEFIC Regular Stakeholder Observer. Trimethylolpropane triacrylate (TMPTA) is used in industrial applications of coatings and inks in dry process and in polymerisation in the polymer industry. TMPTA is also used by professionals for indoor printing with ink cartridges in dry process. The substance has an existing Annex VI entry as Skin Irrit. 2; H315, Eye Irrit. 2; H319 and Skin Sens. 1; H317. Legal deadline for the adoption of an opinion is 27 December 2020.

The DS (FR) proposes to add Carc. 2; H351, Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1).
Germ cell mutagenicity, carcinogenicity 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. [Carc. 2; H351, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=1)] 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 carcinogenicity, in particular the low study quality and lack of relevance to humans of some of the observed tumours and on reproductive toxicity.

2. N-(2-nitrophenyl)phosphoric triamide

The Chair welcomed the Dossier Submitter representatives. N-(2-nitrophenyl)phosphoric triamide is used by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance is an additive for urea based fertilizers.

The substance has no current Annex VI entry. Legal deadline for the adoption of an opinion is 7 January 2021. The DS (AT) proposes to classify the substance as Repr. 1B; H360FD, STOT RE 2; H373 (kidney) and Aquatic Chronic 3; H412. Reproductive toxicity, 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. [Repr. 1B; H360Fd, STOT RE 2; H373 (kidneys)] RAC agreed on no classification for effects on or via lactation due to inconclusive data. RAC agreed on no classification for acute and chronic aquatic toxicity.	**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.
3. 1,5-naphthylene diisocyanate	
The Deputy Chair welcomed the Dossier Submitter representatives and the expert accompanying the CEFIC Regular Stakeholder Observer. She explained that NDI is used as polyurethane enhancer. The substance has an existing Annex VI entry as Acute Tox. 4*; H332, Skin Irrit. 2; H315, Eye Irrit. 2; H319, Resp. Sens. 1; H334, STOT SE 3; H335 and Aquatic Chronic 3; H412. The legal deadline for the adoption of an opinion is 18 December 2020. The DS (DE) proposes to split the entry between 1,5-naphthylene diisocyanate [containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] (split-entry 1) and 1,5-naphthylene diisocyanate [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm] (split-entry 2). For the split-entry 1, the DS proposes <u>to add</u> Skin Sens. 1A; H317, <u>to retain</u> Skin Irrit. 2; H315, Eye Irrit. 2; H319, Resp. Sens. 1; H334, STOT SE 3; H335 and Aquatic Chronic 3; H412, and <u>to delete</u> Acute Tox. 4*; H332. For the split-entry 2, the DS proposes <u>to add</u> Skin Sens. 1A; H317, <u>to retain</u> Skin Irrit. 2; H315, Eye Irrit. 2; H319, Resp. Sens. 1; H334, STOT SE 3; H335 and Aquatic Chronic 3; H412, and <u>to modify</u> Acute Tox. 2; H330 (with ATE (inhalation)=0.27 mg/L (dusts or mists)). Acute inhalation toxicity and skin sensitisation 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. For 1,5-naphthylene diisocyanate, [containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]: [Skin Sens. 1A; H317] For 1,5-naphthylene diisocyanate, [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]: [Skin Sens. 1A; H317, Acute Tox. 2; H330, ATE = 0,27 mg/L (dusts or mists)]	**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 acute inhalation toxicity.

4. Cumene

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the CEFIC Regular Stakeholder Observer. He explained that cumene is mainly used as an intermediate (approximately 95%) for the production of phenol and acetone. In addition, the substance is a minor constituent of gasolines and solvents. The substance has an existing Annex VI entry as Flam. Liq. 3; H226, Asp. Tox. 1; H304, STOT SE 3; H335 and Aquatic Chronic 2; H411. The legal deadline for the adoption of an opinion is 13 February 2021.
The DS (DK) proposes to add Carc. 2; H351 to the existing entry.
Germ cell mutagenicity, carcinogenicity and reproductive toxicity 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. 1B; H350] 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 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 carcinogenicity.

5. Divanadium pentaoxide; vanadium pentoxide

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the Eurometaux Regular Stakeholder Observer and explained the divanadium pentaoxide is used for the production of vanadium compounds and as an intermediate in the production of vanadium and steel alloys. Besides it is used as a catalyst e.g. in developing solutions or for the oxidation of sulfide to sulfate. The substance has a current Annex VI entry as Muta. 2; H341, Repr. 2; H361d***, Acute Tox. 4 *; H332, Acute Tox. 4 *; H302, STOT SE 3; H335, STOT RE 1; H372** and Aquatic Chronic 2; H411. The legal deadline for the adoption of an opinion is 5 February 2021.
The DS (FR) proposes to add Carc. 1B; H350 and Lact.; H362 and to modify Muta. 1B; H340, Repr. 1B; H360Fd, Acute Tox. 1; H330, Acute Tox. 3; H301 and STOT RE 1; H372 (respiratory tract, inhalation). The DS also proposes the following ATEs: inhalation: 0.005 mg/L (dusts or mists); oral: 100 mg/kg bw.
Acute toxicity via all routes, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity and STOT RE were open for comments during the Consultation.

RAC adopted by simple majority* the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3; H301 (ATE = 220 mg/kg bw), Acute Tox. 2; H330 (ATE = 0,05 mg/L (dusts or mists)), Muta. 2; H341, Carc. 1B; H350, Repr. 2; H361fd, Lact.; H362, STOT RE 1; H372 (respiratory tract, inhalation)] RAC agreed on no classification for respiratory sensitisation. *pending a minority opinion by one RAC Member on Muta. 2; H341 classification.	**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 Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the Eurometaux Regular Stakeholder Observer commented on carcinogenicity and on lactation.	

6. Theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione

The Chair welcomed the Dossier Submitter representatives and explained that theophylline is a naturally occurring substance in certain plants, e.g. black tea, coffee and cocoa. It is a substance with wide dispersive use, predominantly used as an anti-asthmatic drug in the pharma sector (99%). 1% is used in cosmetic applications. The substance has no current Annex VI entry. The legal deadline for the adoption of an opinion is 14 January 2021. The DS (NL) proposes to classify the substance as Repr. 1B; H360D. Reproductive toxicity was the only hazard class 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. [Repr. 1B; H360D] RAC agreed on no classification for sexual function and fertility based on conclusive data. RAC agreed on no classification 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 Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

7. Barium diboron tetraoxide

The Deputy Chair welcomed the Dossier Submitter representatives and explained that barium diboron tetraoxide is used for manufacturing of coatings and paints, thinners and paint removers in the industry, and by professional workers and consumers. The substance has an existing Annex VI entry as Acute Tox. 4*; H302 and Acute Tox. 4*; H332. The legal deadline for the adoption of an opinion is 7 February 2021. The DS (SE) proposes to modify Acute Tox. 4; H302 (with ATE (oral) = 530 mg/kg bw), to add Repr. 1B; H360FD and to remove Acute Tox. 4*; H332. Acute toxicity via all routes and reproductive toxicity 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, Acute Tox. 3; H301 (ATE = 100 mg/kg bw), Acute Tox. 4; H332 (ATE = 1,5 mg/L (dusts or mists))] RAC agreed on no classification for acute dermal toxicity. RAC agreed on no classification for effects on or via lactation.	**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 Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8. Dibutyltin bis(2-ethylhexanoate)	
The Deputy Chair welcomed the Dossier Submitter representatives and explained that dibutyltin bis(2-ethylhexanoate) is used in articles, formulations and in manufacturing. The technical function of the substance during formulation is as a stabiliser. The substance has no current Annex VI entry. The legal deadline for the adoption of an opinion is 25 February 2021. The DS (NO) proposes to classify the substances as Muta. 2; H341, Repr. 1B; H360FD and STOT RE 1; H372 (immune system). Germ cell mutagenicity, 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. [Muta. 2; H341, Repr. 1B; H360FD, STOT RE 1; H372 (immune system)]	**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.
9. Dibutyltin di(acetate)	
The Deputy Chair welcomed the Dossier Submitter representatives and explained that dibutyltin di(acetate) is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing. The substance has no current Annex VI entry. The legal deadline for the adoption of an opinion is 28 February 2021. The DS (NO) proposes to classify the substances as Muta 2; H341, Repr. 1B; H360FD and STOT RE 1; H372 (immune system). Germ cell mutagenicity, 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.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

[Muta. 2; H341, Repr. 1B; H360FD, STOT RE 1; H372 (immune system)]	**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.

10. Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone

The Chair explained that quinoclamine is an active substance used in plant protection products which is being currently re-evaluated under Regulation 1107/2009. The substance has no current Annex VI entry. The legal deadline for the adoption of an opinion is 13 November 2020. The DS (SE and DE) propose to classify the substance as Carc. 2; H351, Repr. 2; H361d; Acute Tox. 4 (ATE = 500 mg/kg bw); H302, Eye Irrit. 2; H319, Skin Sens. 1A; H317, STOT RE 2; H373 (blood system, kidneys), Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 (M-factor = 10 for both).
Selected physical hazards (explosives, flammable solids, pyrophoric solids, substances which in contact with water emit flammable gases), 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. [Carc. 2; H351, Repr. 2; H361d, Acute Tox. 4; H302 (ATE = 500 mg/kg bw), Eye Irrit. 2; H319, Skin Sens. 1A; H317, STOT RE 2; H373 (blood system, kidneys), Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=10)] RAC agreed on no classification for physical hazards, acute dermal and inhalation toxicity, skin corrosion/irritation, STOT SE and germ cell mutagenicity. RAC agreed on no classification for reproductive toxicity for fertility based on inconclusive data. RAC agreed on no classification 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 Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The ECPA Regular Stakeholder Observer commented on reproductive toxicity.

9. Restrictions

9.1 Restriction Annex XV dossiers

a) Opinion development

1. Perflurohexanoic acid (PFHxA) Second 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 second draft opinion. RAC took note and supported 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. The emission estimates are subject of further clarifications by the Dossier Submitter in order to finalise the conclusions on them and RAC took note of the oral clarifications of the Dossier Submitter on this matter. The Chairman noted that a consolidated dataset would be required very shortly after RAC-54. RAC agreed with the rapporteurs' conclusion that the measured data on primarily PFHxA is sufficient to provide a consistent picture of wide ongoing environmental exposure at all levels of the food chain as well as widespread human exposure. RAC supported the proposed approach for environmental stock estimation used by the Dossier Submitter, resulting in a current estimated existing environmental stock of 17,350 tonnes of PFHxA. RAC concluded that there is evidence that risk management measures/operational conditions implemented and recommended by the manufacturers and/or importers are not sufficient to control the risks. Furthermore, RAC agreed that based on the environmental/human monitoring data provided, there is evidence that the existing regulatory risk management instruments are not sufficient. RAC concluded that action is required on an Union-wide basis to reduce the emissions of PFHxA, its salts and related substances from their manufacturing,	**Rapporteurs** to prepare the third draft opinion, taking into account RAC-54 discussions, further clarifications on emission estimates by the Dossier Submitter and the outcome of the consultation, by end of October 2020. **SECR,** together with **Dossier Submitter and rapporteurs** to check the new study submitted in the consultation on the degradation rate of a specific SFP. The confidentiality status of the submitted study to be scrutinised by ECHA. **SECR** to consider arranging an open ad hoc Webex meeting on emissions in autumn prior to RAC-55.

use and placing on the market in the EU, including articles imported from outside the EU. RAC held an initial discussion on whether the proposed restriction is the most appropriate EU-wide measure, including the proposed targeted derogations and transitional periods to reduce the risks of PFHxA, its salts and related substances (subject to outcome of the consultation and further clarifications on emission and effectiveness calculations for the derogations by the Dossier Submitter). The Committee will return to this discussion at the next meeting.	

The accompanying expert to regular observer (EEB) asked for clarifications on emissions assumptions on textiles/clothing and firefighting foams as well as transitional periods. The expert accompanying the occasional stakeholder observer (PlasticsEurope) commented on the terminology used for fluorinated polymers. The occasional stakeholder observer (EUROFEU) commented on emissions for firefighting foams and type of testing. The experts accompanying the regular stakeholders (CEFIC) and (ClientEarth) commented on the degradation factors (i.e. confidential study) and the emission control in place.

10. Authorisation

10.1 General authorisation issues

a) New AfAs and review reports (RRs) submitted in the August 2020 submission window

b) Upcoming AfAs, RRs and Substitution Plans

The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2020/2021 and timelines.

a) Report from RAC WG on AfAs during July 2020 meeting

The 5th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation took place on 7-8 July 2020.
Participants: 13 RAC members, 3 Members' advisers, 0 Regular stakeholder observers, 0 Invited expert, ECHA.
The working group recommended that the following draft opinions were suitable for consideration via the A-listing procedure.

- 201_OPE_Vetter_2 (1 use)
- 194_OPE_Yposkesi (1 use)
- 205_OPE_Pfizer (2 uses)
- 204_OPE_Merck_3 (use 1)
- 206_OPE_Sanquin (1 use)
- 195_OPE_IL (1 use)

• 164_OPE_Baxter (1 use) - second discussion The working group recommended that the following draft opinions were suitable for general agreement at the RAC plenary: • 200_OPE_RSI (1 use) • 204_OPE_Merck_3 (use 2)	
The Secretariat presented the Report of the 5th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. RAC took note of the Report.	**-**
10.2 Authorisation applications	
a) Discussion on key issues	
1) 6 applications for authorisation from May 2020 submission window (Cr(VI), diglyme)	
RAC discussed the key issues in the 6 applications for authorisation - 11 uses.	-
b) Agreement on draft opinions	
A. Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate 1. 164_OPE_Baxter (1 use) 2. 194_OPE_Yposkesi (1 use) 3. 195_OPE_IL (1 use) 4. 201_OPE_Vetter_2 (1 use) 5. 204_OPE_Merck_3 (use 1) 6. 205_OPE_Pfizer (2 uses) 7. 206_OPE_Sanquin (1 use) The Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 5th meeting the RAC AFA WG on the 8 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 8 draft opinions on the following AFA cases.	
164_OPE_Baxter (1 use) **Use1:** *Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (as a detergent) for virus inactivation via S/D (Solvent/Detergent) treatment in recombinant and plasma-derived medicinal products*. This draft opinion has already been preliminary agreed by RAC during RAC-53. RAC agreed updated version which includes the additional information to cover the future	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

manufacturing of COVID-19 medication by the applicant. 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 up to 31.67 kg per year of emissions of the substance to the environment across four sites in the EU. RAC agreed: 1. additional conditions for the authorisation At the Vienna#1 site, the applicants shall further assess the feasibility to implement additional OCs and RMMs and act on the outcome of the feasibility study. Such action may encompass, e.g., if found feasible, collection of the remaining liquid waste for adequate treatment. In addition, the applicants should demonstrate in the review report that all measures were periodically re-assessed and considered, to show that the release was all the time at the lowest possible level. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report The applicants should undertake a monitoring programme of the wastewater. At Vienna#1 site, the monitoring should be done prior to release to the municipal STP; and at Lessines, the monitoring should be done prior and after the on-site STP. The initial sampling frequency should be sufficient to demonstrate daily fluctuations. Once established, RAC recommends that thereafter the applicants should continue with the quarterly / four times per year monitoring of 4-tert-OPnEO and its principal degradation products in the wastewater prior or after to release to the municipal or on-site 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. The applicants shall use the monitoring data to review the release estimates and confirm the effectiveness of the OCs and RMMs in place and act upon the outcome of this evaluation. The outcome and conclusions of the review and any action taken shall be included in any subsequent authorisation review report. In Lessines, the applicants should further assess the feasibility to implement additional OCs and RMMs and act on the outcome of the feasibility study. Such action may encompass, e.g., if found feasible, collection of the remaining liquid waste for adequate treatment. The applicants should demonstrate in the review report that all measures were periodically re-assessed and considered, to show that the release was all the time at the lowest possible level.	
194_OPE_Yposkesi (1 use) **Use1:** *Use of 4-tert-OPnEO for its non-ionic detergent properties for the cell membrane lysis and viral clearance during the development and manufacturing of viral vectors in medicinal products dedicated to human use (Investigational and Authorized Advanced Therapy 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 use applied for may result in 0.0 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.
195_OPE_IL (1 use) **Use1:** *The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a lysing agent for red blood cells in blood analysis diagnostic device.* 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 use applied for results 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. recommendations for the review report RAC recommends the applicant to provide all downstream users of cartridges containing 4-tert-OPnEO with instructions on how unused cartridges should be disposed of due to the endocrine disrupting properties of 4-tert-OPnEO and to assess in any review report whether this recommendation on waste handling and treatment has been followed. In case a review report is submitted, the applicant shall report on a representative survey of their downstream users about the collection and treatment methods that are applied (e.g. incineration) to all waste.	
201_OPE_Vetter_2 (1 use) **Use1:** *Use of Octylphenolethoxylates as emulsifier in the siliconisation of glass containers (syringes and cartridges) used as primary packaging material for 44 medicinal products of several pharmaceutical companies listed in the confidential Appendix 1 to the AoA. These products cover several therapeutic areas, and approx. 40 % of them are listed on the WHO Model List of Essential Medicines (EML)*. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risks, 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 up to 26.44 g per year total emissions of the substance to the environment across three sites in the EU. 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 perform at least quarterly / four times per year	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

(during the time of operation) monitoring of 4-tert-OPnEO in the wastewater prior to release to the local STP at all three sites using an analytical method capable of adequately characterising the substance and its 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.	
204_OPE_Merck_3 (use 1) **Use1:** *Industrial use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a surface-active ingredient for the production of two types of mixed cellulose ester membranes (lateral flow and microfiltration membranes).* 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 approximately 0.145 kg per year emissions of 4-tert-OPnEO 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 perform quarterly or four times per year monitoring of 4-tert-OPnEO (parent substance and its primary 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.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

205_OPE_Pfizer (use 1) **Use1:** *The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) (Triton X-100) as a surfactant in the manufacture of biopharmaceuticals* *- Viral Inactivation and Associated Processes* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emission to waste water over the authorisation period. This information should also be included in the review report. The use applied for may result in max. 0.152 kg/year emissions of 4-tert-OPnEO to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation The applicant should establish and implement a monitoring programme of 4-tert-OPnEO and its principal degradation products in the relevant waste stream from the production prior to release to the municipal 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 monitoring should be performed at least quarterly/four times per year during the time of operation). 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. The information from the monitoring programmes including contextual information associated with each set of measurements as well as the outcome and conclusion of the review and any action taken - if needed to further reduce emissions of 4-tert-OPnEO - shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent authority. 3. recommendations for the review report RAC recommends that the results of the monitoring programme according to point 8	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.	
205_OPE_Pfizer (use 2) **Use1:** *The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) (Triton X-100) as a surfactant in the manufacture of biopharmaceuticals - Post Production Cleaning* 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 is expected to result in 0 kg per year of emissions of 4-tert-OPnEO 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.
206_OPE_Sanquin (1 use) **Use1:** *Use of Triton™ X-100 (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated) in formulation of components for IVD 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 implemented and adhered to. The use applied for may result in approximately 0 kg per year of release 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.
B. Agreement on draft opinions on AFA in plenary session	
1. 200_OPE_RSI (1 use)	
Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as surfactant in in –vitro diagnostic device developer solution.*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion as agreed during the plenary including

RAC concluded that the operational conditions (OCs) and risk management measures (RMMs) described in the application - are not appropriate and effective in limiting the risk for ESC1 (consumer use): The OCs and RMMs as described in the Exposure Scenario ESC 1 do not prevent or minimise release to the environment as far as technically and practically possible - are appropriate and effective in limiting the risk for ESC 2 (professional use). 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 4-tert-OPnEO to the environment via the water compartment of 0.91 kg/year. Most of the substance used, however, will end up in waste (up to 5-10 kg/year in total, 5.13 kg/year for ECS 1). For ECS 1 a fraction of the household waste will end up as landfill, the rest will be incinerated while almost the entire amount used for ECS 2 will go for incineration as hazardous waste. RAC notes that there might be some leaching from the landfill. RAC agreed: 1. additional conditions for the authorisation The applicant shall without undue delay • implement changes to the product design that minimise releases via any relevant route from this use to any of the environmental compartments; • assess the feasibility to implement a system for the collection and further treatment of used kits following the consumer use. If found to be feasible, the system for the collection and further treatment shall be implemented without delay. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report As relevant, the applicant shall report on the return rate of the kits. An adapted sensitivity analysis should be included in any review report to gather information on the disposal of the used IVD kits.	ECHA proposal for additional conditions for the authorisation and recommendations for the review report. **SECR** to send the draft opinion to the applicant for commenting.

RAC agreed on the draft opinion by consensus.	
2. 204_OPE_Merck_3 (2 uses)	
Use 2: *Downstream use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as component of mixed cellulose ester membranes.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk for professional users, provided that they are adhered to. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk for consumer uses. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in approximately 0.495 kg per year emissions of 4-tert-OPnEO to the environment. RAC agreed: 1. additional conditions for the authorisation The applicant shall assess without undue delay • the possibilities to implement changes to the product design that minimise release to environmental compartments; • the feasibility to implement a system for the collection and further treatment of used kits following the consumer use. If found to be feasible, the system for the collection and further treatment shall be implemented without delay. Following of implementation of changes to the product design and the system for the collection and further treatment the applicant shall provide instructions to consumers for correct disposal of used kits with the aim to minimise release to environmental compartments. Specifically, for any products containing MCE membranes that can be flushed, the applicant shall provide instructions for the consumer not to flush. 2. no monitoring arrangements 3. recommendations for the review report The applicant shall report on the assessments that are required to be made under section 7	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

of the opinion. If relevant, the applicant shall also report on the return rate of the kits. RAC agreed on the draft opinion by consensus.	
C. Adoption of final opinions	
1. 155_OPE_Siemens_2 (uses 4 and 5) 2. 171_OPE_Wallac (2 uses) 3. 173_OPE_Sobi (1 use) 4. 175_OPE_Rousselot (1 use) 5. 181_OPE_NPE_Roche (Uses 2 and 4 only) The Chair informed the Committee that Applicants submitted comments on the draft opinions agreed at RAC 52.	
1. 155_OPE_Siemens_2 (uses 4 and 5)	
Use 4: *Use of IVD kit reagents on diagnostic analyser systems* The RAC consultations on the draft Final Opinion has been held 17-24 August 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 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 200-400 kg/year of the substance to the environment for a total of 1 000-10 000 downstream users' sites (i.e. an average per site up to 0.02-0.4 kg/year). RAC agreed for: 1. additional conditions for the authorisation In addition to all solid waste containing 4-tert-OPnEO, all liquid 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 municipal sewer system or to surface	**SECR** to send the final opinion to the EC, MSs and the Applicant.

waters is not considered to be 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, and which treatment methods are applied (e.g., incineration). RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
Use 5: *Use of IVD-wash solutions on diagnostic analyser systems.* The RAC consultations on the draft Final Opinion has been held 17-24 August 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 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 1 545 kg/year of the substance to the environment for a total of 1 000-10 000 downstream users' sites (i.e. an average per site up to 0.15-1.5 kg/year). RAC agreed for: 1. additional conditions for the authorisation In addition to all solid waste containing 4-tert-OPnEO, all liquid 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 to the municipal sewer system or to surface waters is not considered to be adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report	**SECR** to send the final opinion to the EC, MSs and the Applicant.

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, and which treatment methods are applied (e.g., incineration). RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
2. 171_OPE_Wallac (2 uses)	
Use 1: *Formulation of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) into enhancement solutions and DELFIA standard and maintenance solutions used in In Vitro Diagnostic assays and RUO products as well as maintenance of instruments as a critical ingredient for detection process while measuring europium (or other lanthanide) content of the assay solution.* The RAC consultations on the draft Final Opinion has been held 18-25 August 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 emissions of the substance to the environment of 0.7 to 6 kg of 4-tert-OPnEO/year. 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 considered to be adequate treatment. 2. monitoring arrangements for the authorisation	**SECR** to send the final opinion to the EC, MSs and the Applicant.

The applicant shall continue to monitor at least four times per year (during the time of operation) 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 enhancement solutions and DELFIA standard and maintenance solutions as a critical ingredient for detection process while measuring europium (or other lanthanide) content in In Vitro Diagnostic assays and RUO products or during maintenance of instruments* The RAC consultations on the draft Final Opinion has been held 18-25 August 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 use applied for is estimated to have resulted in up to 7.2 kg of 4-tert-OPnEO emissions in 2017; this is projected by the applicant to increase to 52.5 kg per year of emissions of the substance to the environment by 2047 for a total of around 190 downstream user sites (i.e. an average per site up to 0.04 kg/year in 2017 and up to 0.3 kg/year by 2047). RAC agreed for: 1. additional conditions for the authorisation In addition to all solid waste containing 4-tert-OPnEO, all liquid waste containing the	**SECR** to send the final opinion to the EC, MSs and the Applicant.

substance shall be collected by the applicant's downstream users 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 is advised to report on a representative survey of their EEA downstream users about the treatment methods that are applied at that point in time (e.g. incineration) following from the requirement to collect all liquid waste containing 4-tert-OPnEO for adequate treatment. In their review report, the applicant should describe in details the efforts made to substitute 4-tert-OPnEO in all their products by specifying the activities, procedures, resources and results made by then, and describe the next steps to be implemented to achieve a full substitution. The applicant should describe all efforts made to accelerate the substitution process, including by conducting tests/substitution implementation on several end-products simultaneously and by allocating more resources to their substitution activities. In addition, the applicant should demonstrate that it made all reasonable efforts to consider multiple relevant information sources to identify and test potential alternatives, including other technologies and through external consultations (e.g. with other biopharmaceutical companies, industry associations, universities, research centres, providers of alternatives, consultants, etc.). RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
3. 173_OPE_Sobi (1 use)	
Use 1: *The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) as a surfactant in manufacture of biopharmaceuticals by Swedish Orphan Biovitrum AB* The RAC consultations on the draft Final Opinion has been held 14-25 August 2020.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

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 approximately 1.12 kg per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation The applicant should perform a new mass balance analysis in order to confirm the predicted effectiveness of implemented RMMs. The applicant should increase the efficiency of the filter when technically and practically possible and report the results in any review report. 2. monitoring arrangements for the authorisation The applicant should establish and implement a monitoring program of 4-tert-OPnEO and its principal degradation products in the relevant waste stream from the production taking place after the carbon filter and prior to release to the on-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 monitoring should be performed at least 4 times per year during the time of operation). 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. recommendations for the review report The results of mass balance analysis and from the monitoring programme 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 editorial changes made to the draft opinion.	
4. 175_OPE_Rousselot (1 use)	
Use 1: *Use of 4-tert-OPnEO as surfactant in the manufacturing of low endotoxin gelatin* The RAC consultations on the draft Final Opinion has been held 12-19 August 2020. RAC concluded that the operational conditions (OCs) and risk management measures (RMMs) described in the application for the current small-scale installation are appropriate and effective in limiting the risk provided they are adhered to. The use applied for results in 0 kg per year of emissions of 4-tert-OPnEO to the environment in the current small scale installation. RAC is of the opinion that the described OCs & RMMs are also expected to be appropriate and effective in limiting the risk in the future large-scale installation provided the OCs, RMMs and proposed additional conditions for the authorisation are implemented and adhered to. The use applied for is expected to result in 0 kg per year of emissions of 4-tert-OPnEO to the environment in the future large-scale installation. RAC agreed for: 1. additional conditions for the authorisation All liquid and solid wastes should be collected and treated in the future large-scale installation as described for the current operation, in order to ensure that releases to the environment are prevented from the future use. If a different method, other than incineration is used for the treatment of liquid wastes in the future installation, the effectiveness of the waste treatment technology should be clearly demonstrated through an appropriate validation method immediately after the commissioning of the new plant. A mass balance report should also be included. The validation data should be available to the enforcement authorities upon request. 2. monitoring arrangements for the authorisation If a different method than incineration is used for the treatment of liquid wastes in the future installation, the applicant should carry out	**SECR** to send the final opinion to the EC, MSs and the Applicant.

quarterly/4 times per year monitoring of 4-tert-OPnEO (parent substance and its primary degradation products) in the waste water prior to release to the aquatic compartment using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. The results should include details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. A mass balance report on 4-tert-OPnEO should also be included. 3. recommendations for the review report The applicant is required to include a detailed description of the OCs & RMMs and the results of the monitoring data, including a mass balance report, in any subsequent authorisation review report in order to corroborate the appropriateness and effectiveness of the OCs & RMMs in place in the future large-scale installation. RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
5. 181_OPE_NPE_Roche (Uses 2 and 4)	
Use 2: *Use of Octyl- and Nonylphenolethoxylates in the formulation and filling of in vitro diagnostic (IVD) assays specified in Appendix 1 to the AoA* The RAC consultations on the draft Final Opinion has been held 24-27 August 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 recommendations defined for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in the worst case in emissions of 0.92 kg/year of 4-tert-OPnEO and of 2.41 kg/year of 4-NPnEO to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report	**SECR** to send the final opinion to the EC, MSs and the Applicant.

The applicant is recommended to show in the review report that, during the substitution process, all measures to further collect the remaining liquid waste were periodically re-assessed and considered, to show that the release was all the time the lowest achievable. RAC recommends that the applicant should monitor at least 4 times per year 4-tert-OPnEO and 4-NPnEO and their 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 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. RAC adopted the final opinion by consensus with editorial changes made to the draft opinion.	
Use 4: *Use of Octyl- and Nonylphenolethoxylates in the production of proteins and the conjugation of latex beads, both being used as components or for the production of components of in vitro diagnostic (IVD) assays, research or quality control products and other, e.g. analytical applications (processes specified in Appendix 1 to the AoA)* The RAC consultations on the draft Final Opinion has been held 24-27 August 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 recommendations defined for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in a realistic worst case in emissions of 0.685 kg/year 4-tert-OPnEO to the environment. The emissions to the environment of 4-NPnEO are 0 kg/year. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation	**SECR** to send the final opinion to the EC, MSs and the Applicant.

3. recommendations for the review report The applicant is recommended to show in the review report that, during the substitution process, all measures to further collect the remaining liquid waste were periodically re-assessed and considered, to show that the release was all the time the lowest possible. RAC recommends that the applicant should carry out 4 times/year monitoring of 4-tert-OPnEO (parent substance and its primary degradation products) in the waste water prior to release to the municipal WWTP at the site of Mannheim and after the on-site STP of Penzberg 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 adopted the final opinion by consensus with editorial changes made to the draft opinion.	
11.Any Other Business As preparation for an upcoming Art. 77(3)c request from the Commission on the environmental classification of lead, Industry was invited to present two short video's on the manufacture of massive and powder forms of lead. RAC briefly discussed the ability of massive lead or its alloys to produce lead-containing dust. Eurometaux was requested to provide information on minimum maximum and median particle sizes on the market, as well as to firm up on the quantities of powder imported into the EU. They also agreed to ask their downstream users for information on alloys regarding the potential for dustiness.	
12. Minutes of RAC-54	
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-54 to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-54B

Table 1: CLH opinions which were adopted at RAC-54B

1. Trimethylolpropane triacrylate

2. 4,4'-oxydi(benzenesulphonohydrazide)

3. Toluene-4-sulphonohydrazide

4. N-(2-nitrophenyl)phosphoric triamide

5. 1,3-bis(1-isocyanato-1-methylethyl)benzene

6. 1,3-Bis(isocyanatomethyl)benzene

7. 2,4,6-triisopropyl-m-phenylene diisocyanate

8. 1,5-naphthylene diisocyanate

9. Cumene

10. Divanadium pentaoxide; vanadium pentoxide

11. Theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione

12. Barium diboron tetraoxide

13. Dibutyltin bis(2-ethylhexanoate)

14. Dibutyltin di(acetate)

15. Quinoclamine (ISO)

1. Trimethylolpropane triacrylate

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-111-00-9	2,2-bis(acryloyloxymethyl) butyl acrylate; trimethylolpropane triacrylate	239-701-3	15625-89-5	Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H315 H319 H317	GHS07 Wng	H315 H319 H317			D
Dossier submitters proposal	607-111-00-9	2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate; 2,2-bis(acryloyloxymethyl) butyl acrylate; trimethylolpropane triacrylate	239-701-3	15625-89-5	**Add** Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	**Add** H351 H400 H410	**Add** GHS08 GHS09	**Add** H351 H410		**Add** M=1 M=1	
RAC opinion	607-111-00-9	2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate; 2,2-bis(acryloyloxymethyl) butyl acrylate; trimethylolpropane triacrylate	239-701-3	15625-89-5	**Add** Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	**Add** H351 H400 H410	**Add** GHS08 GHS09	**Add** H351 H410		**Add** M=1 M=1	
Resulting Annex VI entry if agreed by COM	607-111-00-9	2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate; 2,2-bis(acryloyloxymethyl) butyl acrylate; trimethylolpropane triacrylate	239-701-3	15625-89-5	Carc. 2 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351H315 H319 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H315 H319 H317 H410		M=1 M=1	D

2. 4,4'-oxydi(benzenesulphonohydrazide)

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'-oxydi(benzenesulphonohydrazide)	201-286-1	80-51-3	Self-react. D Aquatic Chronic 1	H242 H410	GHS02 GHS09 Dgr	H242 H410		M=1	
RAC opinion	TBD	4,4'-oxydi(benzenesulphonohydrazide)	201-286-1	80-51-3	Self-react. D Aquatic Acute 1 Aquatic Chronic 1	H242 H400 H410	GHS02 GHS09 Dgr	H242 H410		M=1 M=1	
Resulting Annex VI entry if agreed by COM	TBD	4,4'-oxydi(benzenesulphonohydrazide)	201-286-1	80-51-3	Self-react. D Aquatic Acute 1 Aquatic Chronic 1	H242 H400 H410	GHS02 GHS09 Dgr	H242 H410		M=1 M=1	

3. Toluene-4-sulphonohydrazide

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	toluene-4-sulphonohydrazide	216-407-3	1576-35-8	Self-react. D	H242	GHS02 Dgr	H242			
RAC opinion	TBD	toluene-4-sulphonohydrazide	216-407-3	1576-35-8	Self-react. D	H242	GHS02 Dgr	H242			
Resulting Annex VI entry if agreed by COM	TBD	toluene-4-sulphonohydrazide	216-407-3	1576-35-8	Self-react. D	H242	GHS02 Dgr	H242			

4. N-(2-nitrophenyl)phosphoric triamide

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	N-(2-nitrophenyl)phosphoric triamide	477-690-9	874819-71-3	Repr. 1B STOT RE 2 Aquatic Chronic 3	H360FD H373 (kidney) H412	GHS08 Dgr	H360FD H373 (kidney) H412			
RAC opinion	TBD	N-(2-nitrophenyl)phosphoric triamide	477-690-9	874819-71-3	Repr. 1B STOT RE 2	H360Fd H373 (kidney)	GHS08 Dgr	H360Fd H373 (kidney)			
Resulting Annex VI entry if agreed by COM	TBD	N-(2-nitrophenyl)phosphoric triamide	477-690-9	874819-71-3	Repr. 1B STOT RE 2	H360Fd H373 (kidney)	GHS08 Dgr	H360Fd H373 (kidney)			

5. 1,3-bis(1-isocyanato-1-methylethyl)benzene

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	1,3-bis(1-isocyanato-1-methylethyl)benzene	220-474-4	2778-42-9	Resp. Sens. 1 Skin Sens. 1A	H334 H317	GHS08 Dgr	H334 H317	EUH204		
RAC opinion	TBD	1,3-bis(1-isocyanato-1-methylethyl)benzene	220-474-4	2778-42-9	Resp. Sens. 1 Skin Sens. 1A	H334 H317	GHS08 Dgr	H334 H317	EUH204		
Resulting Annex VI entry if agreed by COM	TBD	1,3-bis(1-isocyanato-1-methylethyl)benzene	220-474-4	2778-42-9	Resp. Sens. 1 Skin Sens. 1A	H334 H317	GHS08 Dgr	H334 H317	EUH204		

6. 1,3-bis(isocyanatomethyl)benzene

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	1,3-bis(isocyanatomethyl) benzene	222-852-4	3634-83-1	Resp. Sens. 1 Skin Sens. 1A	H334 H317	GHS08 Dgr	H334 H317		Skin Sens. 1A; H317: C ≥ 0,001 %	
RAC opinion	TBD	1,3-bis(isocyanatomethyl) benzene	222-852-4	3634-83-1	Resp. Sens. 1 Skin Sens. 1A	H334 H317	GHS08 Dgr	H334 H317		Skin Sens. 1A; H317: C ≥ 0,001 %	
Resulting Annex VI entry if agreed by COM	TBD	1,3-bis(isocyanatomethyl) benzene	222-852-4	3634-83-1	Resp. Sens. 1 Skin Sens. 1A	H334 H317	GHS08 Dgr	H334 H317		Skin Sens. 1A; H317: C ≥ 0,001 %	

7. 2,4,6-triisopropyl-m-phenylene diisocyanate

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	2,4,6-triisopropyl-m-phenylene diisocyanate	218-485-4	2162-73-4	Resp. Sens. 1 Skin Sens. 1	H334 H317	GHS08 Dgr	H334 H317	EUH204		
RAC opinion	TBD	2,4,6-triisopropyl-m-phenylene diisocyanate	218-485-4	2162-73-4	Resp. Sens. 1 Skin Sens. 1	H334 H317	GHS08 Dgr	H334 H317	EUH204		
Resulting Annex VI entry if agreed by COM	TBD	2,4,6-triisopropyl-m-phenylene diisocyanate	218-485-4	2162-73-4	Resp. Sens. 1 Skin Sens. 1	H334 H317	GHS08 Dgr	H334 H317	EUH204		

8. 1,5-naphthylene diisocyanate

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	615-007-00-X	1,5-naphthylene diisocyanate	221-641-4	3173-72-6	Acute Tox. 4* Skin Irrit. 2 Eye Irrit. 2 Resp. Sens. 1 STOT SE 3 Aquatic Chronic 3	H332 H315 H319 H334 H335 H412	GHS08 GHS07 Dgr	H332 H315 H319 H334 H335 H412			
Dossier submitters proposal	TBD	1,5-naphthylene diisocyanate [containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	221-641-4	3173-72-6	**Add** Skin Sens. 1A **Remove** Acute Tox. 4*	**Add** H317 **Remove** H332		**Add** H317 **Remove** H332			
	TBD	1,5-naphthylene diisocyanate [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	221-641-4	3173-72-6	**Add** Skin Sens. 1A **Modify** Acute Tox. 2	**Add** H317 **Modify** H330	**Add** GHS06 **Remove** GHS07	**Add** H317 **Modify** H330		**Add** inhalation: ATE = 0,27 mg/L (dusts or mists)	
RAC opinion	TBD	1,5-naphthylene diisocyanate [containing < 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	221-641-4	3173-72-6	**Add** Skin Sens. 1A **Remove** Acute Tox. 4*	**Add** H317 **Remove** H332		**Add** H317 **Remove** H332			
	TBD	1,5-naphthylene diisocyanate [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	221-641-4	3173-72-6	**Add** Skin Sens. 1A **Modify** Acute Tox. 2	**Add** H317 **Modify** H330	**Add** GHS06 **Remove** GHS07	**Add** H317 **Modify** H330		**Add** inhalation: ATE = 0,27 mg/L (dusts or mists)	
Resulting Annex VI entry if agreed by COM	TBD	1,5-naphthylene diisocyanate [containing < 0.1 % (w/w) of particles with an aerodynamic	221-641-4	3173-72-6	STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Resp. Sens. 1 Skin Sens. 1A Aquatic Chronic 3	H335 H315 H319 H334 H317 H412	GHS07 GHS08 Dgr	H335 H315 H319 H334 H317 H412			

		diameter of below 50 µm]									
	TBD	1,5-naphthylene diisocyanate [containing ≥ 0.1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]	221-641-4	3173-72-6	Acute Tox. 2 STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Resp. Sens. 1 Skin Sens. 1A Aquatic Chronic 3	H330 H335 H315 H319 H334 H317 H412	GHS06 GHS08 Dgr	H330 H335 H315 H319 H334 H317 H412		inhalation: ATE = 0,27 mg/L (dusts or mists)	

9. Cumene

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	601-024-00-X	Cumene [1] Propylbenzene [2]	202-704-5 [1] 203-132-9 [2]	98-82-8 [1] 103-65-1 [2]	Flam. Liq. 3 STOT SE 3 Asp. Tox. 1 Aquatic Chronic 2	H226 H304 H335 H411	GHS02 GHS07 GHS08 GHS09 Dgr	H226 H304 H335 H411			C
Dossier submitters proposal	TBD	Cumene	202-704-5	98-82-8	**Add** Carc. 2	**Add** H351	**Add** H351				
RAC opinion	TBD	Cumene	202-704-5	98-82-8	**Add** Carc. 1B	**Add** H350	**Add** H350				
Resulting Annex VI entry if agreed by COM	TBD	Cumene	202-704-5	98-82-8	Flam. Liq. 3 Carc. 1B STOT SE 3 Asp. Tox. 1 Aquatic Chronic 2	H226 H350 H304 H335 H411	GHS02 GHS08 GHS07 GHS09 Dgr	H226 H350 H304 H335 H411			

10. Divanadium pentaoxide; vanadium pentaoxide

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	023-001-00-8	divanadium pentaoxide; vanadium pentoxide	215-239-8	1314-62-1	Muta. 2 Repr. 2 Acute Tox. 4 * Acute Tox. 4* STOT SE 3 STOT RE 1 Aquatic Chronic 2	H341 H361d*** H332 H302 H335 H372** H411	GHS07 GHS08 GHS09 Dgr	H341 H361d*** H332 H302 H335 H372** H411			
Dossier submitters proposal	023-001-00-8	divanadium pentaoxide; vanadium pentoxide	215-239-8	1314-62-1	**Add** Carc. 1B Lact. **Modify** Muta. 1B Repr. 1B Acute Tox. 1 Acute Tox. 3 STOT RE 1	**Add** H350 H362 **Modify** H340 H360Fd H330 H301 H372 (respiratory tract, inhalation)	**Retain** GHS08 Dgr **Remove** GHS07	**Add** H350 H362 **Modify** H340 H360Fd H330 H301 H372 (respiratory tract, inhalation		**Add** inhalation: ATE = 0.005 mg/L (dusts or mists) oral: ATE = 100 mg/kg bw	
RAC opinion	023-001-00-8	divanadium pentaoxide; vanadium pentoxide	215-239-8	1314-62-1	Acute Tox. 3 Acute Tox. 2 Muta. 2 Carc. 1B Repr. 2 Lact. STOT RE 1	H301 H330 H341 H350 H361fd H362 H372 (respiratory tract, inhalation)	GHS08 GHS09 Dgr	H301 H330 H341 H350 H361fd H362 H372 (respiratory tract, inhalation)		inhalation: ATE = 0.05 mg/L (dusts or mists) oral: ATE = 220 mg/kg bw	
Resulting Annex VI entry if agreed by COM	023-001-00-8	divanadium pentaoxide; vanadium pentoxide	215-239-8	1314-62-1	Acute Tox. 3 Acute Tox. 2 Muta. 2 Carc. 1B Repr. 2 Lact. STOT SE 3 STOT RE 1 Aquatic Chronic 2	H301 H330 H341 H350 H361fd H362 H335 H372 (respiratory tract, inhalation) H411	GHS07 GHS08 GHS09 Dgr	H301 H330 H341 H350 H361fd H362 H335 H372 (respiratory tract, inhalation) H411		inhalation: ATE = 0.05 mg/L (dusts or mists) oral: ATE = 220 mg/kg bw	

11. Theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione

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	theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione	200-385-7	58-55-9	Repr. 1B	H360D	GHS08 Dgr	H360D			
RAC opinion	TBD	theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione	200-385-7	58-55-9	Repr. 1B	H360D	GHS08 Dgr	H360D			
Resulting Annex VI entry if agreed by COM	TBD	theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione	200-385-7	58-55-9	Repr. 1B	H360D	GHS08 Dgr	H360D			

12. Barium diboron tetraoxide

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	Group entry 056-002-00-7	barium salts, with the exception of barium sulphate, salts of 1-azo-2-hydroxynaphthalenyl aryl sulphonic acid, and of salts specified elsewhere in Annex VI of 1272/2008			Acute Tox. 4* Acute Tox. 4*	H332 H302	GHS07 Wng			*	A1
Dossier submitter's proposal	TBD	barium diboron tetraoxide	237-222-4	13701-59-2	**Add** Repr. 1B **Modify** Acute Tox. 4 **Remove** Acute Tox. 4*	**Add** H360FD **Retain** H302 **Remove** H332	**Add** GHS08 **Retain** GHS07 **Modify** Dgr	**Add** H360FD **Retain** H302 **Remove** H332		**Add** oral: ATE = 530 mg/kg bw	
RAC opinion	TBD	barium diboron tetraoxide	237-222-4	13701-59-2	**Add** Repr. 1B **Modify** Acute Tox. 3 **Modify** Acute Tox. 4	**Add** H360FD **Modify** H301 **Retain** H332	**Add** GHS08 **Modify** GHS06 **Modify** Dgr	**Add** H360FD **Modify** H301 **Retain** H332		**Add** inhalation: ATE = 1.5 mg/L oral: ATE = 100 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	barium diboron tetraoxide	237-222-4	13701-59-2	Repr. 1B Acute Tox. 4 Acute Tox. 3	H360FD H332 H301	GHS08 GHS06 Dgr	H360FD H332 H301		inhalation: ATE = 1.5 mg/L oral: ATE = 100 mg/kg bw	

13. Dibutyltin bis(2-ethylhexanoate)

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	Dibutyltin bis(2-ethylhexanoate)	220-481-2	2781-10-4	Muta. 2 Repr. 1B STOT RE 1	H341 H360FD H372 (immune system)	GHS08 Dgr	H341 H360FD H372 (immune system)			
RAC opinion	TBD	Dibutyltin bis(2-ethylhexanoate)	220-481-2	2781-10-4	Muta. 2 Repr. 1B STOT RE 1	H341 H360FD H372 (immune system)	GHS08 Dgr	H341 H360FD H372 (immune system)			
Resulting Annex VI entry if agreed by COM	TBD	Dibutyltin bis(2-ethylhexanoate)	220-481-2	2781-10-4	Muta. 2 Repr. 1B STOT RE 1	H341 H360FD H372 (immune system)	GHS08 Dgr	H341 H360FD H372 (immune system)			

14. Dibutyltin di(acetate)

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	Dibutyltin di(acetate)	213-928-8	1067-33-0	Muta 2 Repr. 1B STOT RE 1	H341 H360FD H372 (immune system)	GHS08 Dgr	H341 H360FD H372 (immune system)			
RAC opinion	TBD	Dibutyltin di(acetate)	213-928-8	1067-33-0	Muta 2 Repr. 1B STOT RE 1	H341 H360FD H372 (immune system)	GHS08 Dgr	H341 H360FD H372 (immune system)			
Resulting Annex VI entry if agreed by COM	TBD	Dibutyltin di(acetate)	213-928-8	1067-33-0	Muta 2 Repr. 1B STOT RE 1	H341 H360FD H372 (immune system)	GHS08 Dgr	H341 H360FD H372 (immune system)			

15. Quinoclamine (ISO)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone	220-529-2	2797-51-5	Carc. 2 Repr. 2 Acute Tox. 4 Eye Irrit. 2 Skin Sens. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H361d H302 H319 H317 H373 (blood system, kidney) H400 H410	GHS07 GHS08 GHS09 Wng	H351 H361d H302 H319 H317 H373(blood system, kidney) H410		oral: ATE = 500 mg/kg bw M=10 M=10	
RAC opinion	TBD	quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone	220-529-2	2797-51-5	Carc. 2 Repr. 2 Acute Tox. 4 Eye Irrit. 2 Skin Sens. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H361d H302 H319 H317 H373 (blood system, kidney) H400 H410	GHS07 GHS08 GHS09 Wng	H351 H361d H302 H319 H317 H373 (blood system, kidney) H410		oral: ATE = 500 mg/kg bw M=10 M=10	
Resulting Annex VI entry if agreed by COM	TBD	quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone	220-529-2	2797-51-5	Carc. 2 Repr. 2 Acute Tox. 4 Eye Irrit. 2 Skin Sens. 1A STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H361d H302 H319 H317 H373 (blood system, kidney) H400 H410	GHS07 GHS08 GHS09 Wng	H351 H361d H302 H319 H317 H373 (blood system, kidney) H410		oral: ATE = 500 mg/kg bw M=10 M=10	

Part III. List of Attendees of the RAC-54 meeting

RAC Members
Aquilina Gabriele
Barański Bogusław
Biró Anna
Bjørge Christine
Borg Daniel
Branisteanu Radu (co-opted member)
Brovkina Julija
Carvalho João
Chiurtu Elena (co-opted member)
de la Flor Tejero Ignacio
Doak Malcolm
Docea Anca Oana
Dobrev Ivan
Geoffroy Laure
Hakkert Betty
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
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
Chankova-Petrova Stephka
Hartwig Andrea (co-opted member)
Heederik Dick (co-opted member)
Zeljezic Davor

Members' advisers
Bakker Joost (Betty Hakkert)
Boel Els (Julie Seba)
Buckley Kevin (Malcolm Doak)
Catone Tiziana (Pietro Paris)
Esposito Dania (Pietro Paris)
Gomes Contreras Jeannette (Betty Hakkert)
Hoffmann Frauke (Agnes Schulte)
Mahiout Selma (Tiina Santonen)
Martin Theresa (Ralf Stahlmann)
Müller Andre (Betty Hakkert)
Rodriguez-Gonzalez Wendy (Julie Seba)
Russo Maria Teresa (Pietro Paris)
Sonnenburg Anna (Ralf Stahlmann)
Suutari Tiina (Riitta Leinonen)
Van Herwijnen Rene (Betty Hakkert)
Woutersen Marjolojn (Betty Hakkert)
Viegas Susana (Joao Carvalho)
Invited experts
Duguy Hélène (ClientEarth)
Facchin Manuel (Annemarie Losert)
SEAC rapporteurs (Restrictions, AfAs)
Dominiak Dorota

Dossier submitters
Altmann Dominik (AT)_N-(2-nitrophenyl)phosphoric triamide)
August Christina (DE)_PFHxA
Averbeck Frauke (DE)_PFHxA
Beausoleil Claire (FR)_V205-divanadium pentaoxide, vanadium pentaoxide
Blom Cécile (NO)_Dibutyltins
Charles Sandrine (FR)_TMPTA, divanadium pentaoxide)
Drost Wiebke (DE)_PFHxA
Erdmann Christian (DE)_PFHxA
Geraets Liesbeth (NL)_Theophylline; 1,3-dimethyl-3,7dihydro-1H-purine-2,6-dione
Henkler-Stephani Frank (DE)_PFHxA
Kacan Stefan (DE)_Restriction: PFHxA
Larsen Ann Kristin (NO)_dibutyltins
Pasquier Elodie (FR)_TMPTA
Schulze Jona (DE)_PFHxA
Stalter Daniel (DE)_PFHxA
Tenie Adina (SE)_barium diboron tetraoxide
Theune Loryn (DE)_NDI
Regular stakeholder observers
Barry Frank (ETUC)
Bernard Alice (ClientEarth)
Comini Andrea (EuCheMS)
De Backer Liisi (Cefic)
Romano Mozo Dolores (EEB)
Ruelens Paul (ECPA)
Van de Broeck Steve (Cefic)
Verougstraete Violaine (Eurometaux)

Occasional stakeholders
Barbu Luminita (EDANA)_Restriction: PFHxA
Leonhardt Thomas (EUROFEU)_Restriction: PFHxA
Robin Nicolas (PlasticsEurope)_Restriction : PFHxA, Article 77(3)c : PFOA
Scalia auro (Euratex)_Restriction: PFHxA
Stakeholder experts
Allen Lisa (Eurometaux/ILA)_Article 77(3)c : Lead
Brosche Sara (ClientEarth/IPEN)_Restriction : PFHxA
Burzlaff Arne (Eurometaux/EBRC Consulting GmbH)_CLH: divanadium pentaoxide
Bock Ronald (PlasticsEurope/Fluoropolymer)_Restriction: PFHxA
Gelbke heinz-Peter (Cefic/PASG)_CLH : cumene
Hannebaum Peter (EUROFEU/Tyco Fire Protection Products)_Restriction :PFHxA
Thumm Stefan (Euratex/Bavarian Textile and Apparel Association)_Restriction : PFHxA
Warren Simon (ECPA/Exponent)_CLH: TMPA
Wietor Jean-Luc (EEB/EEB)_Restriction: PFHxA)
Yada Makiko (Cefic/Daikin)_Restriction: PFHxA, Article 77(3)c: PFOA

Commission
Bertato Valentina (DG ENV)
Blass-Rico Ana Maria (DG GROW)
Hualde-Grasa Eva Patricia (DG GROW)
Kilian Karin (DG ENV)
Kusendila Christophe (DG SANTE)
Rozwadowski Jacek (DG GROW)

ECHA staff
Blainey Mark
Bowmer Tim, Chair
Gilioli Roberto
Hellsten Kati
Karjalainen Ari
Kokkola Leila
Koskinen Marjo
Logtmeijer Christiaan
Loukou Christina
Ludborzs Arnis
Ludovica Rossi
Marques-Camacho Mercedes
Mottet Denis
Mushtaq Fesil
Nicot Thierry
Nygren Jonas
Orispää Katja
O´Rourke Regina
Peltola Jukka
Peltola-Thies Johanna, Deputy Chair
Perazzolo Chiara
Prevedouros Konstantinos
Rasikari Heidi
Regil Pablo
Reuter Ulrike
Sadam Diana
Sihvonen Kirsi
Simoes Ricardo
Simon Rupert
Simpson Peter

Smilovici Simona
Sosnowski Piotr
Spjuth Linda
Uphill Simon
Vainio Matti

Part II. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-54 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-54 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-54 meeting

8 September 2020
RAC/A/54/2020

Final Agenda

54th meeting of the Committee for Risk Assessment

8-9 September
and
14-17 September 2020

Virtual meeting

Tuesday 8 September starts at 14.00
Wednesday 9 September breaks at 18.30
Monday 14 September resumes at 14.00
Thursday 17 September ends at 17.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/54/2020
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

b) Annual update of RAC accredited stakeholders' list

The Secretariat will update you on the requests from stakeholder observers to attend RAC meetings since the last review of the RAC stakeholder's. You will be invited to agree on the updated list of the accredited stakeholder organisations to RAC for this year.

RAC/54/2020/01
Restricted
For agreement

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

1) DNEL development for trixylyl phosphate

For discussion

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 information

Item 7 –Health based exposure limits at the workplace

No items to discuss at this meeting.

Item 8 – Harmonised classification and labelling (CLH)

8.1 CLH dossiers

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

- Trimethylolpropane triacrylate: germ cell mutagenicity, acute aquatic hazards, chronic aquatic hazards
- 4,4'-oxydi(benzenesulphonohydrazide): explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides, acute aquatic hazards, chronic aquatic hazards
- Toluene-4-sulphonohydrazide: explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides
- N-(2-nitrophenyl)phosphoric triamide: STOT RE
- 1,3-bis(1-isocyanato-1-methylethyl)benzene: respiratory sensitisation, skin sensitisation
- 1,3-bis(isocyanatomethyl)benzene: respiratory sensitisation, skin sensitisation
- 2,4,6-triisopropyl-m-phenylene diisocyanate: respiratory sensitisation, skin sensitisation
- 1,5-naphthylene diisocyanate: skin sensitisation
- Cumene: reproductive toxicity
- Divanadium pentaoxide; vanadium pentoxide: acute oral toxicity, respiratory sensitisation, STOT RE
- Barium diboron tetraoxide: acute dermal toxicity
- Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone: physical hazards, acute toxicity (via all routes), STOT SE, skin corrosion/irritation, serious eye damage/irritation, skin sensitisation, germ cell mutagenicity

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

1) Trimethylolpropane triacrylate (EC: 239-701-3; CAS: 15625-89-5)
2) N-(2-nitrophenyl)phosphoric triamide (EC: 477-690-9; CAS: 874819-71-3)
3) 1,5-naphthylene diisocyanate (EC: 221-641-4; CAS: 3173-72-6)
4) Cumene (EC : 202-704-5 ; CAS : 98-82-8)
5) Divanadium pentaoxide; vanadium pentoxide (EC: 215-239-8; CAS: 58-55-9)
6) Theophylline; 1,3-dimethyl-3,7-dihydro-1H-purine-2,6-dione (EC: 200-385-7; CAS: 58-55-9)
7) Barium diboron tetraoxide (EC: 237-222-4; CAS: 13701-59-2)
8) Dibutyltin bis(2-ethylhexanoate) (EC: 220-481-2; CAS: 2781-10-4)
9) Dibutyltin di(acetate) (EC: 213-928-8; CAS: 1067-33-0)
10) Quinoclamine (ISO); 2-amino-3-chloro-1,4-naphthoquinone (EC: 220-529-2; CAS: 2797-51-5)

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

a) Opinion development
   1) Perfluorohexanoic acid – second draft opinion

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

a) New AfAs and review reports (RRs) submitted in the August 2020 submission window
b) Upcoming AfAs, RRs and Substitution Plans
c) Report from RAC WG on AfAs during July 2020 meeting

RAC/53/2020/02
For information/discussion

10.2 Authorisation applications

a) Discussion on key issues
   1) 6 applications for authorisation from May 2020 submission window (Cr(VI), diglyme)

For discussion

b) Agreement on draft opinions

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

1) 164_OPE_Baxter (1 use)
2) 194_OPE_Yposkesi (1 use)

3) 195_OPE_IL (1 use)
4) 201_OPE_Vetter_2 (1 use)
5) 204_OPE_Merck_3 (use 1)
6) 205_OPE_Pfizer (2 uses)
7) 206_OPE_Sanquin (1 use)

For agreement

B. Draft opinions for agreement with plenary debate

8) 200_OPE_RSI (1 use)
9) 204_OPE_Merck_3 (use 2)

For discussion and agreement

C. Adoption on opinions

1) 155_OPE_Siemens_2 (Uses 4 and 5)
2) 171_OPE_Wallac (2 uses)
3) 173_OPE_Sobi (1 use)
4) 175_OPE_Rousselot (1 use)
5) 181_OPE_NPE_Roche (Uses 2 and 4 only)

For discussion and adoption

Item 11 – AOB

1) COM request for RAC's view on a proposal by DE in Caracal to add a new note to the 17th ATP regarding the inclusion of all members of a group for the purpose of mixture calculations
2) Presentation/video by Industry on metal processing

Item 12 – Minutes of RAC-54

a) Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-54

For adoption

Annex II (RAC 54)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 54 meeting.

Document number	**Title**
RAC/A/54/2020	Final Draft Agenda
RAC/54/2020/01 *Restricted*	Annual update of RAC accredited stakeholders´ list
RAC/54/2020/02	Report from RAC WG on AFAs during July 2020 meeting

Annex III (RAC-54)

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.
Health based exposure limits at the workplace		
No dossiers at this meeting		
Restrictions		
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.
	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 measures applied. No personal involvement
Harmonised classification & labelling		

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
No dossiers		

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Harmonised classification & labelling		
Theophylline **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. Trimethylol-propane triacrylate **2. Divanadium pentaoxide** **FR**	Laure GEOFFROY	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	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.
1. 4,4'-oxydi(benzenesulphonohydrazide) **2. Toluene-4-sulphonohydrazide** **3. 1,3-bis(1-isocyanato-1-methylethyl)benzene** **4. Bis(isocyanatomethyl)benzene** **5. 2,4,6-triisopropyl-m-phenylene diisocyanate** **6. 1,5-naphthylene diisocyanate** **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. No personal involvement in dossiers no. 1 and 2. Personal involvement in dossiers no. 3-6.
	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

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
		substance - no other mitigation measures applied. No personal involvement in dossiers no. 1 and 2. Personal involvement in dossiers no. 3-6.
1. Barium diboron tetraoxide **2. Quinoclamine (ISO)** **SE**	Bert-Ove LUND	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Daniel BORG	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. Dibutyltin bis(2-ethylhexanoate) **2. Dibutyltin di(acetate)** **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.
N-(2-nitrophenyl)phosphoric triamide **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. Personal involvement.
1. Cumene **DK**	Peter Hammer SORENSEN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Lea Stine TOBIASSEN	Working for the CA submitting the dossiers; 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. No personal involvement.