RAC/M/53/2020

Final

26 June 2020

Minutes of the 53rd Meeting

of the Committee for Risk Assessment

(RAC-53)

Monday 1, 14.00 to Friday 5 June, 18.00
and
Monday 8, 14.00 to Thursday 11[1] June, 13.00

[1] The planned Friday 12 June back-up session in case of overruns on was not required.

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:

- Members were informed that the meeting schedule would remain the same for 2020 but all meetings would be hosted remotely from the ECHA conference centre in Helsinki until further notice.
- The Members were informed that for the remote RAC-53 plenary meeting, the Rules of Procedure would apply as normal. By way of exception the word 'present' in the phrase 'present and having the right to vote' in Art. 19 of the Rules of Procedure is being read as including 'remote presence'. The Executive Directors Decision ED-0010-01 in relation to remote participation at ECHa Committee meetings was brought to the attention of the participants.

He informed the Committee that the Chair Johanna Peltola Thies would chair sections of RAC-53.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The RAC Secretariat proposed to add the agenda points: 10.1.c) Renewal of the Mandate for RAC AfA WG 10.1.d) ECHA information about the request to set DNEL for Trixylyl phosphate (TXP) for the Authorisation process; The RAC Secretariat proposed to delete one agenda point: 10.2.b)C.4) Adoption of final opinion on OPE_bioMerieux (3 uses) due to request of the applicant which as a consequence of the COVID-19 crisis, it is currently increasing 4-tert-OPnEO consumption under Use-1/ES-1. Under any other business, (agenda item 11), the EEB regular stakeholder observer requested a discussion regarding the restriction on intentionally added	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-53 minutes.

microplastics, namely the Chair's decision at RAC 52 to reopen the derogation on biodegradation. The Agenda (**RAC/A/53/2020**) was adopted.	
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, upcoming restriction proposals, applications for authorisation, and Article 77(3)(c) requests, 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, upcoming restriction proposals, Article 77.(3).(c) 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.	**-**
6. Request under Article 77(3)(c)	
a) Classification for reproductive toxicity of DTPA- H_5, DTPA- K_5 and DTPA- Na_5.	
The Chair welcomed the experts accompanying the CEFIC and ECPA Regular Stakeholder Observers and reminded the Committee that on 9 June 2017, RAC had adopted its opinion on the harmonised classification and labelling of the above-mentioned substances, which concluded that these should be classified as Repr. 1B; H360D. Additional information had been provided by industry addressing the adopted classification for reproductive toxicity of these substances which RAC was requested to review and, if necessary, to amend its opinion of 9 June 2017. An *ad hoc* consultation was carried out prior to RAC-53. The deadline for the adoption of an opinion is 3 September 2020.	
RAC concluded that the classification agreed by the Committee in 2017 (Repr. 1B; H360D) is still warranted. RAC agreed that it is justified to add an SCL of 3% based on low potency of DTPA-H_5, DTPA-K_5 and DTPA-Na_5.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur.

	SECR to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The experts accompanying the CEFIC and the ECPA Regular Stakeholder Observers commented on and contributed to the discussion on reproductive toxicity.	
7. Health based exposure limits at the workplace	
a) Opinion development	
1. Diisocyanates – final draft opinion	
The Chair welcomed the expert accompanying the regular Cefic stakeholder observer and the three observers from the DG-EMPL Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC). The Chair reported that the request to ECHA to evaluate limit values for diisocyanates at the workplace, in accordance with Chemical Agents Directive, was submitted by DG EMPL in March 2019 via a Service Level Agreement with a deadline of 18 months (September 2020) to deliver the RAC opinion. A call for evidence in the preparatory phase inviting interested parties to submit comments and evidence on the subject took place from 17 April to 30 June 2019. The ECHA scientific report was launched for a two months consultation from 17 October to 16 December 2019. During the opinion development process, the ECHA scientific report is to be transferred into an Annex to the RAC opinion.	
The rapporteurs presented and RAC discussed the final draft opinion on the scientific evaluation of limit values for diisocyanates at the workplace. RAC agreed with the proposed estimated exposure based on point estimates from the exposure response relations, but agreed on an adjustment factor for exposure duration of 2. RAC agreed with the derivation of a value for a 15 minutes short term exposure limit (STEL) and that this should be derived from an 8-hour TWA, which is expected to be developed in the future from the above exposure-risk relationship. The STEL should be a maximum of a factor of 2 higher than the 8hr TWA and the STEL should not exceed the value of 6 ug/m3 NCO, based on the 'vandenPlas study'. RAC agreed not to derive a Biological Limit Value, with recommendation for adjustments to the justification. RAC agreed to set the Biological Guidance Value at the limits of quantification (LOQs) for relevant diisocyanate metabolites (diamines) in urine.	**Rapporteurs** to revise the opinion in accordance with the agreed modifications in RAC 53 and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs and to ensure that the Annex and the RCOM is in line with the adopted opinion. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

RAC agreed with the proposed skin notation and notations for 'skin sensitisation' and 'respiratory sensitisation' RAC agreed with recommended general reference on health surveillance as described in the draft opinion and Annex. RAC adopted its opinion (with modifications agreed at RAC-53) by consensus.	
The expert accompanying the regular Cefic stakeholder observer commented on the importance of the prevention of very short peak exposures at high levels, in order to reduce the incidence of sensitization and lung functional decrement, the justification of the–STEL based on a weight of evidence approach on relevant epidemiology and volunteer studies on TDI, MDI and HDI and on the reduction of uncertainties related to the STEL and TWA value by using a broader database.	
2. Lead and its compounds – final draft opinion	
The Chair welcomed the experts accompanying the regular Cefic and Eurometaux stakeholder observers, one expert accompanying an occasional stakeholder as well as the three observers from the DG-EMPL, Working Party on Chemicals (WPC) of the Advisory Committee for Safety and Health at Work (ACSH). - He reported that the request to ECHA to evaluate limit values for lead and its compounds at the workplace, in accordance with Chemical Agents Directive, was submitted by DG EMPL in March 2019 via a Service Level Agreement with a deadline of 18 months (September 2020) to deliver the opinion of RAC. A call for evidence in the preparatory phase inviting interested parties to submit comments and evidence on the subject took place from 17 April to 30 June 2019. The ECHA scientific report was launched for a two months consultation from 17 October to 16 December 2019. During the opinion development process the ECHA scientific report is to be transferred to an Annex to the RAC opinion.	
The rapporteurs presented and RAC discussed the final draft opinion on the scientific evaluation of limit values for lead and its compounds at the workplace. RAC agreed with the biological and air limit values for lead and its inorganic compounds, as proposed in the final draft opinion. RAC agreed on the recommendation for a Biological Guidance Value for lead and its compounds and the recommendation to avoid and minimize the exposure of fertile women to lead in the workplace. RAC agreed not to recommend any limit values for organic lead compounds, due to limited, mainly old data and a lack of any recent information, but did	**Rapporteurs** to revise the opinion in accordance with the agreed modifications in RAC 53 and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs and to ensure that the Annex and the RCOM is in line with the adopted opinion. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

agree to make a reference in the opinion to use existing European limit values. RAC adopted its opinion (with modifications agreed at RAC-53) by consensus.	

The experts accompanying the Eurometaux and Cefic regular stakeholders and an occasional stakeholder, respectively, commented on the analysis of the epidemiology studies used to define the blood-lead level associated with the neurotoxicity effects, the conservatism of the approach to both deriving the BLV and OEL, the association of the blood-lead level and clastogenicity, the composite nature of concurrent blood-lead measurements reflecting both past and recent exposure and related implementation, selected approach for the derivation of the air value, the sensitivity of analytical methods and the discrepancy between evidence required to derive values for organic and inorganic compounds.

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

- Tellurium: germ cell mutagenicity
- Tellurium dioxide: germ cell mutagenicity
- Piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether: physical hazards, acute toxicity (all routes), skin sensitisation, skin corrosion/irritation, respiratory sensitisation, germ cell mutagenicity, reproductive toxicity, acute aquatic hazards, chronic aquatic hazards
- Trichlorosilane: pyrophoric liquids, substances which in contact with water emit flammable gases, acute oral toxicity, acute inhalation toxicity, eye damage/irritation
- Clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine: physical hazards (explosive, flammable solid, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solid, corrosive to metals), acute toxicity (all routes), skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, STOT SE, STOT RE, aspiration hazard, hazardous to the aquatic environment
- Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid: physical hazards (explosive, flammable solid, self-heating substances, pyrophoric solids, substances which in contact with water emit flammable gases, oxidising solid), acute toxicity (all routes), skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, germ cell mutagenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment, hazardous to the ozone layer
- Fluopicolide: acute toxicity (all routes), skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, aspiration hazard

B. Substances with hazard classes for agreement in plenary session

1. Tellurium
2. Tellurium dioxide
3. Piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether
4. Trichlorosilane
5. Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate
6. Clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine
7. Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid
8. 2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol
9. Benzophenone
10. Fluopicolide
11. 2-Ethylhexanoic acid and its salts

1. Tellurium

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the Eurometaux Regular Stakeholder Observer. He explained that **tellurium** is used in processing of alloys, production of electronic devices, thin film production by physical vapour deposition and in coatings and photovoltaic solar cells. In addition, tellurium is an intermediate during production of tellurium compounds. It has no existing Annex VI entry. Legal deadline for the adoption of an opinion is 30 October 2020.

The Dossier Submitter (NL) proposed to classify the as Repr. 1B; H360FD.

Reproductive toxicity and germ cell mutagenicity 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, Lact; H362]	**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 Eurometaux Stakeholder Observer commented on lactation.

2. Tellurium dioxide	
The Chair welcomed the Dossier Submitter representatives and the expert accompanying the Eurometaux Regular Stakeholder Observer. He explained that **tellurium dioxide** is used in the manufacture of basic metals, including alloys and the manufacture of other non-metallic mineral products, e.g. plasters, cement. Further uses are in rubber production, and glass and ceramic industry as a colouring agent and in optical refraction applications.. It has no existing Annex VI entry. The legal deadline for the adoption of an opinion is 30 October 2020. The Dossier Submitter (NL) proposed to classify the as Repr. 1B; H360FD. Reproductive toxicity and germ cell mutagenicity 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. [Repr. 1B; H360fD, Lact; H362]	**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 Eurometaux Regular Stakeholder Observer commented on lactation.	
3. Piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether	
The Deputy Chair welcomed the Dossier Submitter's representatives and the expert accompanying the ECPA Regular Stakeholder Observer. **Piperonyl butoxide** is a synergist and a biocidal active substance in the scope of Biocidal Product Regulation. It has no existing entry in Annex VI to the CLP Regulation. Legal deadline for the adoption of an opinion is 28 November 2020. The Dossier Submitter (GR) proposed STOT SE 3; H335, Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1), EUH066. Certain physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment were 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. [Eye Irrit. 2; H319, STOT SE 3; H335, Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=1), EUH066]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs.

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

The expert accompanying the ECPA Regular Stakeholder Observer commented on STOT SE, STOT RE, eye irritation and carcinogenicity.

4. Trichlorosilane

The Deputy Chair welcomed the Dossier Submitter representatives. **Trichlorosilane** is used as an intermediate in the production of other silicon-based substances, as a monomer in the production of silicone polymers and resins, usually in combination with other chlorosilanes, in the semiconductor industry and as a laboratory reagent in research and development activities. It has the following entry in Annex VI to the CLP Regulation: Flam. Liq. 1; H224, Pyr. Liq. 1; H250, Acute Tox. 4*; H302, Acute Tox. 4*; H332 and Skin Corr. 1A; H314.
The legal deadline for the adoption of an opinion is 28 October 2020.

The Dossier Submitter (DE) proposed to retain: Flam. Liq. 1; H224, and Acute Tox. 4; H302, to remove: Pyr. Liq. 1; H250, Skin Corr. 1A; H314 and Acute Tox. 4; H332; and to add: Water-react 1; H260, Skin Corr. 1B; H314, Eye Dam. 1; H318 and Acute Tox. 3; H331.

Pyrophoric solids, substances which in contact with water emit flammable gases, acute oral toxicity, acute inhalation toxicity, skin corrosion/irritation and serious eye damage/eye irritation 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. [Flam. Liq. 1; H224, Water-react. 1; H260, Acute Tox. 4; H302, ATE (oral) = 1000 mg/kg bw, Acute Tox. 3; H331, ATE (inhalation) = 7.6 mg/L (vapour), Skin Corr. 1A; H314, Eye Dam. 1; H318; EUH071]	**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.

5. Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate

Isobornyl acrylate is an acrylic monomer that polymerises when exposed to sources of free radicals. It is used in plastic materials, also for valves, tubes lining, stoppers, sealants, coatings and inks, and also in the plastic materials used for the production of medical devices for diabetes patients. It has no existing entry in Annex VI to the CLP Regulation. Legal deadline for the adoption of an opinion is 2 December 2020.

The Dossier Submitter (DE) proposed to classify the substance as Skin Sens 1; H317.

Skin sensitisation 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. [Skin Sens. 1A; H317]	**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.

6. Clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine

The Chair welcomed the Dossier Submitter representatives and the expert accompanying the ECPA Regular Stakeholder Observer. He explained that **clofentezine (ISO)** is an active substance used as acaricide in plant protection products (PPP). It has no existing entry in Annex VI to the CLP Regulation. Legal deadline for the adoption of an opinion is 20 December 2020.

The Dossier Submitter (ES) proposed to classify the substance as Carc. 2; H351 and Aquatic Chronic 1; H410; M=1 (originally the DS had proposed M=10, but changed it after the Consultation).

Selected physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard 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. [Aquatic Chronic 1, H410 (M=1)] RAC concluded on no classification for carcinogenicity and reproductive toxicity based on inconclusive data.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The ECPA Regular Stakeholder Observer commented on carcinogenicity.

7. Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid

The Chair welcomed the expert accompanying the ECPA Regular Stakeholder Observer and explained that **daminozide** is a plant protection product and is used as a plant growth regulator. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 20 December 2020.

The Dossier Submitter (CZ and HU) proposed to classify the substance as Carc. 1B; H350 (the DS changed their opinion in the process and proposed to classify Carc. 2; H351).

Selected physical hazards, acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment and hazardous to the ozone layer were open for comments during the consultation. As new information had been submitted to ECHA in relation to carcinogenicity and mutagenicity hazard classes, an *ad hoc* consultation was carried out.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the ECPA Regular Stakeholder Observer commented on weight of evidence factors to consider for daminozide.

8. 2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol (TBNPA)

The Chair welcomed the Dossier Submitter representatives and explained that **TBNPA** is used as flame retardant, in the manufacture of polymers, plastic products and chemicals and as an intermediate. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 13 December 2020.

The Dossier Submitter (NO) proposed Muta. 1B; H340 and Carc. 1B; H350.
Germ cell mutagenicity, carcinogenicity, reproductive toxicity and STOT RE were open for comments during the consultation.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Muta. 2; H341, Carc. 1B; H350] RAC agreed on no classification for reproductive toxicity based on conclusive data for development and based on inconclusive data for fertility.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

9. Benzophenone

The Chair welcomed the Dossier Submitter representatives and explained that **benzophenone** is used in air care products, polishes and waxes, washing & cleaning products, anti-freeze

products, biocides (e.g. as a odoriferous agent in disinfectants, pest control products), inks and toners, perfumes and fragrances, pharmaceuticals and cosmetics and personal care products. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 21 November 2020.

The Dossier Submitter (DK) proposed Carc. 2; H351.

Carcinogenicity 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. [Carc. 1B; H350]	**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.

10. Fluopicolide

The Chair welcomed the expert accompanying the ECPA Regular Stakeholder Observer and explained that **fluopicolide (ISO)** is a fungicide. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 6 January 2021.

The Dossier Submitter (AT) proposed no classification for all the human health hazard classes assessed.

Acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and aspiration hazards 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. [Repr. 2; H361d] RAC agreed on no classification for respiratory sensitisation based on insufficient data. RAC agreed on no classification for STOT RE. RAC agreed on no classification for reproductive toxicity based on conclusive data for fertility.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the ECPA Regular Stakeholder Observer commented on STOT RE.

11. 2-Ethylhexanoic acid and its salts	
The Chair welcomed the Dossier Submitter representatives and explained that **2-EHA** is used in anti-freeze products, laboratory chemicals, metal working fluids, coating products, lubricants and greases. 2-EHA salts are reported to be present in coatings, inks, adhesives, sealants, elastomers, anti-freezing agents, lubricants and greases, heat transfer and hydraulic fluids. 2-EHA has an existing entry in Annex VI to the CLP Regulation as Repr. 2; H361d. The legal deadline for the adoption of an opinion is 15 October 2020. The Dossier Submitter (ES) proposed to add also the salts of 2-EHA (with the exception of those specified elsewhere in this Annex) to the existing entry on 2-EHA. 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 also agreed on no classification for effects on or via lactation.	**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. Restrictions	
9.1 Restriction Annex XV dossiers	
a) Opinion development	
1. Perflurohexanoic acid (PFHxA)	
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 first draft opinion. RAC provisionally agreed on the proposed scope, justification and reasons for the grouping. The generic molecular definition includes known and unknown precursors of PFHxA and the excluded molecular structures leave out substances outside the intended scope. Similar terminal degradation approach (”arrowhead”) as was used for previous PFAS restrictions (e.g. PFOA, C9-C14 PFCA).	**RAC members** to provide any remaining comments via the written consultation on the first draft opinion (by 3 July 2020). **Rapporteurs** to prepare the second draft opinion, taking into account RAC-53 discussions and the RAC written consultation, by early August 2020.

RAC provisionally agreed on targeting and that the rationale is clear for a broad restriction on all uses of PFHxA, its salts and related substances as well as on imported articles containing these substances (with specific derogations): • The conditions expressed will prohibit the use of PFHxA its salts and related substances; • Same targeting and thresholds as for the PFOA and PFHxS restrictions; • Targeting use and placing on the market of PFHxA, its salts and related substances will reduce current emissions of the substances. RAC supported the Rapporteurs' hazard assessment that any PFHxA emitted will add to an increasing and globally distributed environmental stock that cannot be removed (results in continuous and irreversible exposures to PFHxA of both wildlife and humans exposed via the environment). Furthermore, RAC provisionally agreed that the properties of PFHxA (mainly due to the very high persistence and mobile nature) constitute a hazard/risk. RAC provisionally concluded that threshold approaches may underestimate the risk of PFHxA to the environment and human health. RAC supported that concerns are similar to non-threshold substances and supported a case-by-case risk assessment approach where, in analogy to PBT/vPvB substances, any releases and exposures should be regarded as a proxy for an unacceptable risk to the environment and human health and that emissions should thus be minimized.	
The regular observer (EEB) and their accompanying expert asked for clarifications regarding the scope (i.e. a derogation and the status of the indicative list of substances published). The European Commission observer asked for a clarification regarding the scope. The occasional stakeholder observer from PlasticsEurope commented on the scope (definition), targeting and hazard assessment. The occasional stakeholder observer from EUROFEU commented on targeting. The experts accompanying the regular stakeholder CEFIC and ClientEarth commented on the hazard assessment (i.e. toxicity).	
2. Calcium cyanamide in fertilisers	
The Deputy Chair welcomed the Dossier Submitter's representatives from ECHA and the experts accompanying the CEFIC and ECPA regular stakeholder observers. She informed the participants that the restriction dossier had been submitted in July 2019 and concerns the placing on the market of calcium cyanamide used as a fertiliser.	

The rapporteurs presented and RAC discussed the fourth draft opinion. RAC adopted its opinion on this dossier (with modifications agreed at RAC-53) by consensus. RAC agreed that the Dossier Submitter's hazard assessment of the aquatic compartment for urea could not be supported based on a reevaluation of the *Microcystis aeruginosa* key study. The test was not considered reliable by RAC. No PNEC and risk characterisation for urea was therefore developed by RAC for the aquatic compartment. RAC agreed to the hazard assessment of the terrestrial compartment as proposed by the DS taking into account the final report of the higher tier field study on collembolans ['springtails'] submitted by AlzChem Trostberg GmbH in the Consultation. RAC took note of the Dossier Submitter's error in the sediment risk characterisation (unit error in the reported PECs) and agreed that it was not possible to conclude on risks to the sediment compartment with the data available. RAC agreed that risk management option 4 (a total ban on calcium cyanamide use) is the most effective approach to manage the risks to the aquatic and soil compartments. RAC noted that risk management option 3 (application of existing CAP measures) would reduce the risks only partially and would trigger challenges for monitorability and enforcement. RAC agreed that the opinion highlights potential difficulties with synchronised transitional periods for both placing on the market and use. RAC concluded that the restriction, as proposed by the Dossier Submitter, is effective, practical, enforceable and monitorable.	**The rapporteurs,** together with **SECR**, to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.
The experts accompanying the CEFIC and ECPA stakeholder observers commented on various parts of the hazard assessment and risk characterisation.	
3. Microplastics	
The Chair welcomed the Dossier Submitter's representatives from ECHA, the SEAC Rapporteurs and an expert accompanying each of the regular Cefic, ClientEarth, ECPA, EEB, and Eurometaux stakeholder observers, as well as thirteen occasional stakeholder observers together with eleven accompanying experts (See Annex. The Chair informed the participants that the restriction dossier had been submitted in January 2019. In addition, Sweden (KemI) collaborated with ECHA in the preparation of the dossier. The proposal aims at restricting the use of intentionally added microplastic particles in consumer or professional use products of any kind.	

The rapporteurs presented and RAC discussed the revised eighth draft opinion. RAC adopted its opinion on this dossier by consensus (with editorials agreed at RAC-53). With regard to the biodegradation scheme, RAC agreed that a pass in one of the screening tests (group 1 – ready biodegradation tests, group 2 – enhanced/modified ready biodegradation, and group 3 – inherent biodegradation) would allow derogation under paragraph 3b. RAC agreed with the evaluations of the different biodegradability schemes prepared by the members of the ad hoc working group and with the overall conclusion as presented by the Rapporteurs: - None of the schemes evaluated, including the Dossier Submitter's, address all the identified uncertainties and no ideal solution exists. - The key concern is to take into account the potential for biodegradation in different environmental compartments butthe biodegradation scheme should remain practical. Therefore, RAC agreed that the modified testing described in scheme #3 should be required to justify the derogation proposed under paragraph 3b, e.g. where group 1, group 2 or group 3 screening test pass criteria are not achieved, group 4 (ISO tests) **or** group 5 (OECD simulation tests) pass criteria should be achieved for three environmental compartments. Data confirming the degradation of polymer(s), rather than other constituents, should also be provided for group 1, 2, and 3 tests. RAC concluded that additional research on the environmental relevance of the outcomes of biodegradation testing methods for microplastics should be conducted as a priority. Furthermore, RAC concluded on the end-use specific derogations proposed by the Dossier Submitter: • 5b (permanent modification during end use) • 5c (permanent incorporated into solid matrix during end use) RAC agreed with the 'instructions for use and disposal' (IFUD) requirements proposed by the Dossier Submitter as set out in paragraph 7.	**The rapporteurs,** together with **SECR**, to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.

RAC agreed with the 'reporting requirement' proposed by the Dossier Submitter set out in paragraph 8. RAC concluded that there is evidence that the risk management measures (RMMs) and operational conditions (OCs) implemented and recommended by manufactures and/or importers are not sufficient to control the risk: • RAC concluded that some uses of intentionally added microplastics result in inevitable releases to the environment. • RAC concluded that risks from uses of intentionally added microplastics are not adequately controlled since it is not currently possible to demonstrate that they are safe and emissions are not minimised. RAC agreed with the three risk management components proposed by the Dossier Submitter (i.e. a complete ban, IFUD, and reporting). RAC agreed that the approach and the scope of the restriction, as modified by RAC, is the most appropriate EU-wide measure to address the microplastics concern. RAC agreed that the proposed restriction, as modified by RAC, is: - targeted to the risk identified, - capable of reducing this to an acceptable level within a reasonable period of time. RAC supported the Rapporteurs evaluation that: • A lower limit is not needed for the enforceability of the restriction. • The restriction is practical and enforceable if guidance on practical implementation is provided to both industry and inspectors. RAC concluded that the restriction, as modified by RAC, is effective, practical, enforceable and monitorable. RAC also concluded that the proposed restriction, as modified by RAC, is the most appropriate EU-wide measure to limit the emissions of intentionally added microplastics to the environment. RAC agreed that, despite uncertainties, there are sufficient scientific data to conclude that microplastics pose a risk to the environment.	

Finally, RAC agreed with the overall restriction proposal (as modified by RAC).	
Two regular stakeholders (ClientEarth and EEB) questioned why the biodegradability criteria was reopened after RAC-52 discussions and asked for clarifications on grounds of transparency. The Chair explained that due to the complexity of the issue he had decided to request the ad-hoc working group and the Rapporteurs to consider an alternative biodegradation scheme which might be more practical and enforceable. The Commission observer welcomed the additional work done on biodegradation. The experts accompanying occasional CIRFS and ECETOC stakeholder observers asked for clarifications on the various biodegradability schemes evaluated. The experts accompanying the regular Cefic and ClientEarth stakeholder observers, the EEB regular and CIRFS occasional stakeholders and the experts accompanying occasional EUBP and IFRA stakeholder observers commented on the biodegradability testing methods and criteria. The expert accompanying the regular EEB stakeholder observer asked for clarification regarding the paragraph 4h infill material and reporting requirements. The ClientEarth regular stakeholder observer and the expert accompanying the CEPE occasional stakeholder observers commented on the CBI with regard to instructions for use. The experts accompanying the occasional Plastics Europe and CEPE stakeholder observers and the regular CEFIC stakeholder observer had clarifying questions or comments regarding reporting requirements. The occasional Euroseeds stakeholder observer had a question about transitional periods. The expert accompanying ECPA asked clarifying question regarding monitorability (re: paragraph 7). The regular EEB stakeholder observer, together with their accompanying expert, and the experts accompanying regular Eurometaux as well as occasional EUBP and ECETOC stakeholder observers commented on uncertainties.	
10. Authorisation	
10.1 General authorisation issues	
a) Update on incoming/future applications	
The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2020/2021 and timelines. The Secretariat informed also about new information related to the Covid-19 and its possible impacts on OPE/NPE AfAs. The Committee was informed about the ECHA Secretariat and the Commission work on new format of the Substitution Plan. To make it compliant with the Court ruling and the "SAGA" concept. It should be ready for applicants requested by the Commission to submit SPs. The Secretariat informed about a strategy to ensure consistency through a check and comparison of AFA opinions: 1. The RAC conclusion "OCs/RMMs appropriate?" and the inclusion of i) additional conditions for the authorisation ii) monitoring arrangements for the	**SECR** to perform the consistency check between all draft opinions agreed at the RAC -53. **SECR** together with **Rapporteurs** to implement necessary changes in the Draft opinions to ensure the consistency.

authorisation and iii) recommendation for the review report 2. Conditions and recommendations concerning following aspects: - OCs/RMMs planned to be implemented Pre-Sunset Date or Post-Sunset Date - approach to conditions of uses foreseen for the applicants' downstream users - waste management - obligation to make validation data available to NEA upon request - frequency of measurements.	
b) Report from RAC WG on AfAs during May 2020 meeting	
The 4th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation took place on 5-8 May 2020. Participants: 29 RAC members, 6 Members' advisers, 2 Regular stakeholder observers, 1 Invited expert, ECHA. The working group recommended that the following draft opinions were suitable for consideration via the A-listing procedure. • 149_CTPht_Nalon (1 use) • 152_CTPht_AO_RainCarbon (1 use) • 150_CTPht_AO_Koppers (1 use) • 170_OPE_DiaSorin (1 use) • 172_OPE_DIAGAST (1 use) • 160_OPE_Merck_2 (1 use) • 165_OPE_bioMerieux_2 (1 use) • 182_NPE_Abbott (1 use) • 163_OPE_Rentschler (1 use) • 156_OPE_Hospira (1 use) • 186_OPE_NPE_Beckman (5 uses) • 185_OPE_NPE_Idexx (3 uses) • 190_OPE_TEVA (1 use) The working group recommended that the following draft opinions were suitable for agreement at the RAC plenary: • 164_OPE_Baxter (1 use) • 162_OPE_LFB (1 use) • 154_OPE_Siemens_1 (1 use) • 187_OPE_AGC (2 uses) • 189_OPE_Lonza (1 use) • 191_NPE_Sekisui (1 use) • 192_OPE_Pfizer_2 (1 use) The working group recommended that the Draft opinion requires full discussion or discussion on specific points at the RAC plenary: • 184_OPE_Lilly (1 use) • 180_OPE_NPE_Bio-Rad (4 uses)	
ECHA Secretariat presented the Report of the 4th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. RAC took note of the Report.	-

c) Renewal of the Mandate for RAC AfA WG	
The Deputy Chair thanked the Committee and the Management Board members in ensuring suitable expert participation to the RAC AfA WG and acknowledged that the WG has contributed to the increase of consistency across the opinions and to the efficiency of the Committee in developing opinions for authorisation applications. The WG has also reduced the workload of the Committee during the plenaries. She asked the committee to extend the Mandate of the RAC AFA WG until September 2021. RAG agreed by consensus to extend the Mandate of the RAC AFA WG until September 2021.	**SECR** to publish the revised mandate on the ECHA Website.
The regular stakeholder observer EEB thanked the Secretariat for introducing the paper to renew the working group's mandate, thus enhancing the transparency of the process.	
d) ECHA information about the request to set DNEL for Trixylyl phosphate (TXP) for the Authorisation process	
ECHA Secretariat presented information on the request to set DNEL for Trixylyl phosphate (TXP) for the Authorisation process.	**Members** to express interest to be rapporteurs.
10.2 Authorisation applications	
a) Discussion on key issues	
1) 12 applications for authorisation and a review report from February 2020 submission window (OPE/NPE, TCE, CT)	
RAC discussed the key issues in the 12 applications for authorisation.	-
b) Agreement on draft opinions	
A. A. Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate 1. 149_CTPht_Nalon (1 use) 2. 152_CTPht_AO_RainCarbon (1 use) 3. 150_CTPht_AO_Koppers (1 use) 4. 170_OPE_DiaSorin (1 use) 5. 172_OPE_DIAGAST (1 use) 6. 160_OPE_Merck_2 (1 use) 7. 165_OPE_bioMerieux_2 (1 use) 8. 182_NPE_Abbott (1 use) 9. 163_OPE_Rentschler (1 use) 10. 156_OPE_Hospira (1 use) 11. 186_OPE_NPE_Beckman (5 uses) 12. 185_OPE_NPE_Idexx (3 uses)	

13.190_OPE_TEVA (1 use)

The Deputy Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 4th meeting the RAC AFA WG on the 19 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 19 draft opinions on the 13 following AFA cases. **149_CTPht_Nalon (1 use)** **Use1:** *Use of CTPht for manufacture of formulations for various industrial uses*. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report The exposure to workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3 of the justification to this opinion. Since CTPHT has PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 0.297 kg per year of emissions to the environment of indicator PAHs with PBT, vPvB and carcinogenic properties. RAC agreed: 1. additional conditions for the authorisation RAC proposes as a condition for the authorisation that the applicant shall at the latest 3 years after the authorisation has been granted for this use implement further treatment of the exhaust air from	**Rapporteur** together with **SECR** to do the final editing of the draft opinions. **160_OPE_Merck_2 (1 use)** **Rapporteur** together with **SECR** to check whether there is need to address the implementation of the new building more in depth in the opinion. **SECR** to send the draft opinions to the applicant for commenting.

the scrubbers by e.g. incineration or active carbon filters. 2. monitoring arrangements for the authorisation To improve the exposure assessment and facilitate further minimisation of the workers' exposure to CTPHT, RAC proposes that the applicant shall implement at least annual programmes of inhalation exposure monitoring through personal sampling in combination with post-shift urinary biomonitoring, representative of the number of workers potentially exposed and the range of tasks undertaken where exposure to CTPHT is possible. This information from the monitoring programmes including the contextual information associated with each set of measurements and any action taken should also be included in the review report, if submitted. RAC proposes for the authorisation that the applicant shall implement at least quarterly programmes of measurement of emissions of PAHs to air. This information should also be included in the review report, if submitted. 3. recommendations for the review report The applicant should revise the potential exposure assessment for the maintenance operations and provide a quantitative assessment. The applicant should act upon the outcome of this review without delay. The outcome of this action should be documented in the review report, if submitted. The applicant should review the suitability of the personal protective equipment used to protect workers against dermal exposure to CTPHT (e.g. gloves shall be tested according to EN ISO 374:2016 for the principal constituents of CTPHT or well justified analogue substances) and should revise the dermal exposure assessment. The applicant should act upon the outcome of this review without delay. The outcome of this action should be documented in the review report, if submitted. The applicant stated that the PAH-concentrations in the combined wastewater stream were measured at the release point at least once per year and monthly from September 2017 onwards. It is not fully clear whether this is a requirement in the environmental permit. RAC recommends to continue the monthly monitoring of the indicator PAHs in water. RAC recommends that the applicant includes the measurement data in any review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.	

The monitoring data referred to in section 8.1 of the justification to this opinion shall be included in the review report, if submitted. **152_CTPht_AO_RainCarbon (1 use)** **Use 1:** *Use of CTPht for manufacture of formulations for various industrial uses.* *Use of AO for manufacture of formulations for various industrial uses.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The exposure to workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3 of the justification to this opinion. Since CTPHT and AO have PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 0.993 kg per year of emissions to the environment of indicator PAHs with PBT, vPvB and carcinogenic properties. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation To improve the exposure assessment and facilitate further minimisation of the workers' exposure to CTPHT, RAC proposes that the applicant shall implement at least annual programmes of inhalation exposure monitoring through personal sampling in combination with post-shift urinary biomonitoring, representative of the number of workers potentially exposed and the range of tasks undertaken where exposure to CTPHT is possible. This information from the monitoring programmes including the contextual information associated with each set of	

measurements and any action taken should also be included in the review report, if submitted. RAC proposes for the authorisation that the applicant shall implement at least quarterly programmes of measurement of emissions of PAHs to air (measurement after the carbon filters and the incinerator). This information should also be included in the review report, if submitted. 3. recommendations for the review report The applicant should review the suitability of the personal protective equipment used to protect workers against dermal exposure to CTPHT (e.g. gloves shall be tested according to EN ISO 374:2016 for the principal constituents of CTPHT or well justified analogue substances) and should revise the dermal exposure assessment. The applicant should act upon the outcome of this review without delay. The outcome of this action should be documented in the review report, if submitted. According to the conditions of use, the amount of PAHs from WWTP2 is controlled two times per week via certified methods and the measurements are externally verified. RAC recommends that the applicant includes the measured concentrations of individual PAHs in any review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. The monitoring data referred to in section 8.1 of the justification to this opinion shall be included in the review report, if submitted. **150_CTPht_AO_Koppers (1 use)** **Use 1:** *Use of CTPht for manufacture of formulations for various industrial uses.* *Use of AO for manufacture of formulations for various industrial uses.* RAC concluded that the operational conditions and risk management measures described in the application for the use of Anthracene oil are appropriate and effective in limiting the risk, provided that they are adhered to. RAC concluded that the operational conditions and risk management measures described in the application for Pitch, coal tar, high temp. are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to.	

The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The exposure to workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3 of the justification to this opinion. Since CTPHT and AO have PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 6.17 x 10^{-3} kg per year of emissions to the environment of indicator PAHs with PBT, vPvB and carcinogenic properties. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation To improve the exposure assessment and facilitate further minimisation of the workers' exposure to CTPHT, RAC proposes that the applicant shall implement at least annual programmes of inhalation exposure monitoring through personal sampling in combination with post-shift urinary biomonitoring, representative of the number of workers potentially exposed and the range of tasks undertaken where exposure to CTPHT is possible. This information from the monitoring programmes including the contextual information associated with each set of measurements and any action taken should also be made available to Competent Authorities upon request and be included in the review report, if submitted. RAC proposes for the authorisation that the applicant shall implement at least quarterly programmes of measurement of emissions of PAHs to air from the incinerator. This information should also be included in the review report, if submitted. 3. recommendations for the review report The applicant should review the suitability of the personal protective equipment used to protect workers against dermal exposure to CTPHT (e.g. gloves shall be tested according to EN ISO 374:2016 for the principal constituents of CTPHT or well	

justified analogue substances) and should revise the dermal exposure assessment. The applicant should act upon the outcome of this review without delay. The outcome of this action should be documented in the review report, if submitted. The applicant notes that the concentrations of individual PAHs in the effluent of the active carbon filtered rainwater is measured at least once per month as required according to the environmental permit. RAC recommends that the applicant includes the measurement data in any review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. The monitoring data referred to in section 8.1 of the justification to this opinion shall be included in the review report, if submitted. **170_OPE_DiaSorin (1 use)** **Use 1:** *Industrial use, as non-ionic surfactant, employed in the purification of antigens in in vitro diagnostics tests for infectious diseases, auto-immunity markers, bone metabolism, hepatitis and retrovirus, oncology and endocrinology.* 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 less than 0.9g per year emissions of 4-tert-OPnEO to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed for the authorisation 3. recommendations for the review report RAC recommends that the applicant should, during the period when buffer preparation and use takes place, perform at least quarterly / 4 times per year monitoring of 4-tert-OPnEO in the waste water prior to release to the local STP 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.	

172_OPE_DIAGAST (1 use) **Use 1:** *Industrial use of 4-tert-OPnEO for its amphiphilic, surfactant and non-haemolytic properties to create controlled hydrophilic spots on porous hydrophobic membranes (solid form) for in vitro diagnostic kits for blood testing via antigen/antibody reaction in the following product range: control cards, manual pads and automated ONYX.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in up to 0.158 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. **160_OPE_Merck_2 (1 use)** **Use 1:** *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (technical grade) as raw material for the manufacturing of GMP Triton® X-100 Emprove® Expert according to IPEC standards.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in up to approximately 307 g per year emissions of the substance to the environment in the status quo (current building, valid until 2020), or up to approximately 0.270 g per year emissions of the substance to the environment in the projected situation (new building, valid from 2021). RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report.	

165_OPE_bioMerieux_2 (1 use) **Use 1:** *Industrial use of 4-tert-OPnEO for its non-ionic detergent properties consisting in the filling of 4-tert-OPnEO-containing solutions into specific single-use ampoules to be included in clinical and industrial in vitro testing applications.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result as a worst case in 20.9 g 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 during filling operations, the applicant should monitor 4-tert-OPnEO in the waste water prior to release to the local STP, at least quarterly / 4 times per year 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. **182_NPE_Abbott (1 use)** **Use 1:** *Professional use as a surfactant in an onboard solution (Detergent B) as an accessory to In-Vitro Diagnostic Devices (IVDs) to wash the reagent probes, the mixers and the reaction cuvettes between tests to prevent interference with the test result on ARCHITECT and Alinity automated analyser systems.* 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 the risk being limited in an appropriate and effective way. Per year the use applied for may result in 4-NPnEO emissions to the environment of approximately 124.35 kg in wastewater. RAC agreed: 1. additional conditions for the authorisation The applicant shall follow the substitution activities described in the application. 2. no monitoring arrangements 3. no recommendations for the review report. **163_OPE_Rentschler (1 use)** **Use 1:** *Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated in a washing buffer applied during a purification step in the manufacture of the monoclonal antibody Dinutuximab beta.* 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 <1 g per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed for the authorisation 3. recommendations for the review report The applicant should undertake, a monitoring programme of the wastewater prior to release to the municipal STP. The initial sampling frequency should be sufficient to demonstrate daily fluctuations. Once the appropriate frequency has been established, RAC recommends that the applicant should continue with monitoring of 4-tert-OPnEO and its principal degradation products, when manufacturing occurs, in the wastewater prior to release to the municipal STP using an analytical method capable of adequately characterising the substance and its principal degradation products in	

water and at an appropriately low level of quantification. The results should be included in any review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values as well as the results of the feasibility study. **156_OPE_Hospira (1 use)** **Use 1:** *The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO))(Triton X-100) as a surfactant in the manufacture of one biopharmaceutical protein, a biosimilar product, used to prevent infection and neutropenic fevers.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in up to 0.0025 kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed for the authorisation 3. no recommendations for the review report. **186_OPE_NPE_Beckman (5 uses)** **Use 1:** *Formulation of NPnEO and OPnEO solutions in European sites for use as laboratory products. Laboratory products are used as intermediate solutions for preparation of finished laboratory products (finished goods) or in-process use.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in zero kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report.	

Use2: *In-process production use of OPnEO as a washing buffer used in the coating of in vitro diagnostic immunoassay particles* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in zero kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. **Use3:** *Downstream use of OPnEO- or NPnEO-containing clinical laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, hematology and flow cytometry laboratory instruments and assays.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. This information should also be included in the review report. The use applied for may result in up to 0.1106 kg 4-tert-OPnEO and 1740 kg 4-NPnEO per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation All solid waste as well as all liquid waste containing 4-tert-OPnEO and 4-NPnEO shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report	

In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users about their efforts to collect all liquid and solid waste for adequate treatment, and which treatment methods are applied (e.g., incineration). **Use4:** *Downstream use of OPnEO- or NPnEO-containing laboratory products designed for use in flow cytometry, genomics and particle characterization laboratory instruments and assays for quality control and research and development.* 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 the risk being limited in an appropriate and effective way. 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 0.310 kg 4-tert-OPnEO and 0.152 kg 4-NPnEO per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation The applicant shall follow the substitution activities described in the application. The collection of contaminated wastes for adequate treatment shall continue at the sites where it is already implemented. 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. **Use5:** *Phase out of OPnEO-containing laboratory products from the market due to obsolescence or next generation formulations.* 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 the risk being limited in an appropriate and effective way.	

The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. This information should also be included in the review report. The use applied for may result in up to 3.68 kg per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation The applicant shall comply with the plan to cease the use by the end of 2025. The collection of contaminated wastes for adequate treatment shall continue at the sites where it is already implemented. 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. **185_OPE_NPE_Idexx (3 uses)** **Use1:** *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as detergent in the technical manufacturing of in vitro diagnostic veterinary ELISA Plate tests (plate coating) to prevent the non-specific binding of unwanted macromolecules.* 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 period are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in up to 13 kg per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation All wastewater containing 4-tert-OPnEO shall be collected and disposed of for adequate treatment. The treatment shall prevent or minimise releases to environmental compartment as far as technically and practically possible. Release to the sewer system or	

to surface waters is not considered as adequate treatment. Additionally, RAC recommends that the applicants continue to assess the feasibility of implementing an appropriate collection and treatment of wastewater and act on the outcome of the feasibility study. After implementation of new RMMs, the applicants should perform a mass balance analysis in order to show the effectiveness of implemented RMMs and report the results in any review report. The validation data should be available to the enforcement authorities on their request. 2. monitoring arrangements for the authorisation The applicants should establish and implement a monitoring program of 4-tert-OPnEO and its principal degradation products at least quarterly / four times per year (during the time of operation) in the wastewater prior to release to the off-site STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report Any actions as new OCs and RMMs taken to minimise releases to environmental compartment and 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. **Use2:** *Formulation of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated in the manufacture of sample diluents and standard solutions used in in vitro diagnostic veterinary ELISA Plate tests used for the detection of infectious diseases in livestock and poultry.* 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 period are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in up to 2.2 kg per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation All wastewater containing 4-tert-OPnEO shall be collected and disposed of for adequate treatment. The treatment shall prevent or minimise releases to environmental compartment as far as technically and practically possible. Release to the sewer system or to surface waters is not considered as adequate treatment. Additionally, RAC recommends that the applicants continue to assess the feasibility of implementing an appropriate collection and treatment of wastewater and act on the outcome of the feasibility study. After implementation of new RMMs, the applicants should perform a mass balance analysis in order to show the effectiveness of implemented RMMs and report the results in any review report. The validation data should be available to the enforcement authorities on their request. 2. monitoring arrangements for the authorisation The applicants should establish and implement a monitoring program of 4-tert-OPnEO and its principal degradation products at least quarterly / four times per year (during the time of operation) in the wastewater prior to release to the off-site STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report Any actions as new OCs and RMMs taken to minimise releases to environmental compartment and 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.	

Use3: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and use of 4-Nonylphenol, branched and linear, ethoxylated in in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions.* 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 period are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in 68 kg of emissions of 4-tert-OPnEO and 14 kg of emissions of 4-NPnEO per year to the environment at the end of review period. This is equivalent to 0.68-68 g of 4-tert-OPnEO and 0.14-14 g of 4-NPnEO on average per each of the 1 000-100 000 of the applicant's downstream users throughout the EEA. RAC agreed: 1. additional conditions for the authorisation All solid and liquid waste shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release to the sewer system or to surface waters is not considered as adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicants shall report on a new representative survey of their EEA DUs about their efforts to collect all waste for adequate treatment, and which treatment methods are applied (e.g., incineration) following from the requirement to collect all solid and liquid waste containing 4-tert-OPnEO and 4-NPnEO for adequate treatment.	

190_OPE_TEVA (1 use) **Use1:** *The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a nonionic surfactant for microbial cells disruption and washing of inclusion bodies in Biological Drug Substance manufacturing process.* 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 results in emission of 7.7 g per year of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed for the authorisation 3. recommendations for the review report RAC recommends that the applicant should monitor at least 4 times per year (during the time of operation) 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the off-site WWTP (waste water treatment plant) 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 recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid waste contaminated with 4-tert-OPnEO for adequate treatment, and act on the outcome of the feasibility study.	
B. Agreement on draft opinions on AFA in plenary session	
1. 154_OPE_Siemens_1 (1 use)	
Use 1: *Use of OPE as detergent in the production of bead components for in-vitro diagnostic kits for an immunoassay platform.*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are implemented and 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 0.38 kg emissions of the substance to the environment in the year 2021. Due to the gradual decrease in the use of 4-tert-OPnEO, the emissions are estimated to be 0.04 kg in the year 2029 and are expected to cease thereafter because of the planned discontinuation in the use of 4-tert-OPnEO. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements are proposed (to be added by the Rapporteurs) 3. recommendations for the review report RAC recommends that after implementation of the planned additional RMMs, the applicant should conduct a new mass balance analysis in order to confirm the predicted effectiveness of the implemented RMMs. The results should be included in any review report, including details of the calculations carried out, any assumptions made and the corresponding environmental release values. RAC recommends the applicant to develop and implement an appropriate monitoring programme and to monitor at least quarterly/four times per year (during the time of operation) 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the on-site holding tanks and prior to removal of waste water to the off-site STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid wastes for adequate treatment and act on the outcome of the feasibility study.	

RAC agreed on the draft opinion by consensus.	
2. 162_OPE_LFB (1 use)	
Use 1: *Use as virus inactivation into the manufacture process of plasma-derived immunoglobulins.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in up to 10 kg per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation As soon as the first measurements obtained through monitoring are available, the applicant shall carry out a mass balance analysis based on measurements as indicated in section 8 of the justification to the draft opinion. Based on the results, the applicant shall assess how the operational conditions and risk management measures (OCs and RMM) can be optimized in such a way that the releases of 4-tert-OPnEO to the environment can be further minimised taking into account the outcomes of the measurement programme. The applicant shall act upon the outcome of this assessment. 2. monitoring arrangements proposed for the authorisation As soon as the new RMMs are operational, the applicant shall start undertaking a monitoring programme, measuring the concentration of 4-tert-OPnEO in individual waste streams prior to release to the municipal STP. The initial sampling frequency should be sufficient to take account of daily fluctuations. Once established, RAC recommends that the applicant should continue with the quarterly / four times per year monitoring of 4-tert-OPnEO and its	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

principal degradation products in the waste water prior to release to the municipal STP using an analytical method capable of adequately characterising the substance and its degradation products in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report As described in section 7 of the justification to the draft opinion, after implementation of the new RMMs, the applicant shall perform a new mass balance analysis in order to confirm the predicted effectiveness of the implemented RMMs and report the results in any review report, including details of the calculations carried out, the assumptions made, if any, and the corresponding environmental release values. Cleaning-in-place should be included in the mass balance analysis. The results of the monitoring programme, as well as the mass balance and the outcome and conclusions of the actions taken with regards to minimising emissions, shall be documented and included in any subsequent authorisation review report. The new mass balance analysis and measurement results should allow the evaluation of the effectiveness of the OCs and RMMs in place and to confirm that emissions are reduced to as low a level as is technically and practically possible. The information gathered via the measurement programme as well as the outcome and conclusions of the review and any action taken, shall be included in any subsequent authorisation review report. It was noted by RAC that there will be an excess solution of 4-tert-OPnEO per batch prepared and only parts of the solution will be required for the virus inactivation step. The applicant is invited to further assess in a review report the feasibility for the batch quantity management. RAC agreed on the draft opinion by consensus.	
3. 164_OPE_Baxter (1 use)	
Use 1: *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.*	**Rapporteurs** together with **SECR** to prepare for the discussion at the RAC AFA WG and to agreement at RAC-54 with regard to the new site not

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 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 proposed for the authorisation 3. recommendations for the review report The applicants should undertake a monitoring programme of the wastewater. At Vienna 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	addressed in DO (COVID-19 related issue).

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. RAC agreed provisionally on the draft opinion by consensus.	
4. 180_OPE_NPE_Bio-Rad (4 uses)	
Use 1: *Industrial use of 4-tert-OPnEO and 4-NPnEO for their non-ionic detergent properties in view of controlling reactions and chromatography support saturation required in the production of highly specific and sensitive in vitro immunoassays dedicated to the diagnosis of viral (HIV, HCV, Dengue) and parasitic infections.* 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 4.35 kg per year emissions of the substance to the environment as a worst case estimate based on ERC2 (2% release factor). With additional RMMs the applicant claims to reach "technical zero" release. RAC agreed: 1. additional conditions for the authorisation The applicant should implement the planned additional OCs and RMMs, in order to reduce the emissions to the environment as far as technically and practically possible. The effectiveness of the new	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **Rapporteurs** together with **SECR** to confirm using the phrase **"**technical zero" release. **SECR** to send the draft opinion to the applicant for commenting.

RMMs should be clearly demonstrated through an appropriate validation method (suitable monitoring campaign and mass balance) immediately after their implementation. The validation data should be available to the national enforcement authorities upon request. Considering the expected increase in the volumes used and released, RAC recommends that the applicant assesses the feasibility of implementing an appropriate treatment of residual waste water and acts on the outcome of the feasibility study. 2. monitoring arrangements for the authorisation The applicant should continue to monitor at least quarterly the concentration of 4-tert-OPnEO/4-NPnEO and its principal degradation products in the wastewater prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its principal degradation products in water and at an appropriately low level of quantification. The results should be included in any review report, including contextual information, details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The information gathered via the measurements referred to in sections 7 and 8 as well as the outcome and conclusions of the review of the OCs and RMMs and any action taken shall be included in any subsequent review report. RAC agreed on the draft opinion by consensus.	
Use 2: *Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in the formulation of in vitro reagents dedicated to high-performance microbiological and immunological assays supported on microplates or magnetic particles.* 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.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

The use applied for may result in up to 4.35 kg per year emissions of the substance to the environment as a worst case estimate based on ERC2 (2% release factor). With additional RMMs the applicant claims to reach "technical zero" release. RAC agreed: 1. additional conditions for the authorisation The applicant should implement the planned additional OCs and RMMs, in order to reduce the emissions to the environment as far as technically and practically possible. The effectiveness of the new RMMs should be clearly demonstrated through an appropriate validation method (suitable monitoring campaign and mass balance) immediately after their implementation. The validation data should be available to the national enforcement authorities upon request. Considering the expected increase in the volumes used and released, RAC recommends that the applicant assesses the feasibility of implementing an appropriate treatment of residual waste water and acts on the outcome of the feasibility study. 2. monitoring arrangements for the authorisation The applicant shall continue to monitor at least quarterly the concentration of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its principal degradation products in water and at an appropriately low level of quantification. The results should be included in any review report, including contextual information, details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The information gathered via the measurements referred to in section s 7 and 8 as well as the outcome and conclusions of the review of the OCs and RMMs and any action taken shall be included in any subsequent review report. RAC agreed on the draft opinion by consensus.	
Use 3: *Industrial use of 4-tert-OPnEO for its detergent properties used for extraction, viral inactivation and purification of biological material further formulated and /or coated on articles intended for IVD applications.*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The 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 0.3 kg per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation The applicant should continue to implement the planned additional OCs and RMMs, in order to reduce the emissions to the environment as far as technically and practically possible. The effectiveness of the new RMMs should be clearly demonstrated through an appropriate validation method (suitable monitoring campaign and mass balance) immediately after their implementation. The validation data should be available to the national enforcement authorities upon request. Considering the expected increase in the volumes used and released, RAC recommends that the applicant assesses the feasibility of implementing an appropriate treatment of residual waste water and acts on the outcome of the feasibility study. 2. monitoring arrangements for the authorisation The applicant shall continue to monitor at least quarterly the concentration of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its principal degradation products in water and at an appropriately low level of quantification. The monitoring should be carried out during the time of operation. The results should be included in any review report, including contextual information**,** details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The information gathered via the measurements referred to in sections 7 and 8 as well as the outcome	

and conclusions of the review of the OCs and RMMs and any action taken shall be included in any subsequent review report. RAC agreed on the draft opinion by consensus.	
Use 4: *Industrial use of raw material containing 4-tert-OPnEO for protein stabilization for veterinary in vitro diagnostic application.* 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 4.35 kg per year emissions of the substance to the environment as a worst case estimate based on ERC2 (2% release factor). With additional RMMs the applicant claims to reach "technical zero" release. RAC agreed: 1. additional conditions for the authorisation The applicant should implement the planned additional OCs and RMMs, in order to reduce the emissions to the environment as far as technically and practically possible. The effectiveness of the new RMMs should be clearly demonstrated through an appropriate validation method (suitable monitoring campaign and mass balance) immediately after their implementation. The validation data should be available to the national enforcement authorities upon request. Considering the expected increase in the volumes used and released, RAC recommends that the applicant assesses the feasibility of implementing an appropriate treatment of residual waste water and acts on the outcome of the feasibility study. 2. monitoring arrangements for the authorisation The applicant shall continue to monitor at least quarterly/four times per year the concentration of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the municipal STP, using an analytical method capable of adequately	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

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 contextual information, details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The information gathered via the measurements referred to in section 8 as well as the outcome and conclusions of the review of the OCs and RMMs and any action taken shall be included in any subsequent review report. RAC agreed on the draft opinion by consensus.	
5. 184_OPE_Lilly (1 use)	
Use1: *Industrial formulation (dilution) of a Triton™ X-100-containing silicone solution and its subsequent use as a lubricant in the manufacture of medicinal product delivery devices.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the environment. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in up to 29.6 kg and 10.3 kg per year emissions of the substance to the environment at Fegersheim and Sesto Fiorentino site, respectively. RAC agreed: 1. additional conditions for the authorisation All relevant wastewater containing to 4-tert-OPnEO, shall be collected and subject to adequate treatment with the view of minimisation of releases to the environment at both sites. After implementation of new RMMs, the applicants should perform a mass balance analysis in order to confirm the predicted effectiveness of implemented RMMs and report the results in any review report.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

The validation data should be available to the enforcement authorities upon request. 2. monitoring arrangements for the authorisation The applicants shall continue to monitor at least quarterly/four times per year the concentration of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site STP using an analytical method capable of adequately characterising the parent substance and its principal degradation products in water at an appropriately low level of quantification. 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 information on the implemented OCs and RMMs, the mass balance and the results of the monitoring campaigns should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC agreed on the draft opinion by consensus.	
6. 187_OPE_AGC (2 uses)	
Use1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as detergent for the inactivation of viruses in the production of therapeutic proteins using mammalian cell hosts.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in approximately 0.00778 kg per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

As soon as the new RMMs are operational (collection of the second wash water), the applicant shall start undertaking a monitoring programme, measuring the concentration of 4-tert-OPnEO and its principal degradation products prior to release to the municipal STP. The initial sampling frequency should be sufficient to take account of daily fluctuations. Once established, RAC recommends that the applicant should continue with the quarterly monitoring of 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the municipal STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. A mass balance report should also be included when the use is increased and/or the new facility is operating. 3. recommendations for the review report RAC recommends that the applicant should, after implementation of the new RMMs (collection of the second wash water of the chromatographic column) and the results of the monitoring data, perform a new mass balance analysis in order to confirm the predicted effectiveness of the implemented RMMs in the current and future building. The information gathered via the measurement program as well as the outcome and conclusions of the review and any action taken, shall be included in any subsequent authorisation review report. RAC recommends the applicant to further assess in any review report the feasibility of implementing an appropriate treatment of the residual waste water not collected and act on the outcome of the feasibility study. RAC agreed on the draft opinion by consensus.	
Use 2: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a detergent during the purification process of recombinant biopharmaceuticals derived from microbial expression hosts in projects where processes have been approved by their authorities (GMP compliant).*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in approximately 8.2 kg per year emissions of the substance to the environment. RAC agreed: 1. additional conditions for the authorisation In the current Heidelberg site and in the future production line in Copenhagen, all liquid waste releases, which occur during the cleaning of premises (second wash of the chromatographic columns, clean in place rinse of the stainless steel tanks and centrifuge), shall be collected and disposed for adequate treatment. The applicant shall, after implementation of the new RMMs and the results of the monitoring data, perform a new mass balance analysis in order to confirm the predicted effectiveness of the implemented RMMs in the current site and in the future production line in Copenhagen. The new validation data should be available to the enforcement authorities upon request. 2. monitoring arrangements	

In the current Heildelberg site, as soon as the new RMMs are operational (collection of the waste water from the rinse of the tanks/centrifuge and the second wash of the chromatographic column), the applicant shall start undertaking a monitoring programme, measuring the concentration of 4-tert-OPnEO and its principal degradation products prior to release to the municipal STP. In Copenhagen, the applicant shall start undertaking, after the new production line will become operational, a monitoring programme, measuring the concentration of 4-tert-OPnEO and its principal degradation products prior to release to the municipal STP. In both facilities the initial sampling frequency should be sufficient to take account of daily fluctuations. Once established, RAC recommends that the applicant should continue with the quarterly monitoring of 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the municipal STP using an analytical method capable of adequately characterising the substance and its degradation products in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The applicant is required to include a detailed description of the OCs and RMMs and the results of the monitoring data and mass balance analysis in any subsequent review report in order to corroborate the appropriateness and effectiveness of the RMMs and OCs in place in the increase use scenario in Heidelberg and in the new production line in Copenhagen. RAC recommends the applicants to further assess in any review report the feasibility of implementing an appropriate treatment of the residual waste water not collected and act on the outcome of the feasibility study. RAC agreed on the draft opinion by consensus.	
7. 189_OPE_Lonza (1 use)	
Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated for virus inactivation via solvent/detergent treatment in the manufacture of*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion including correct wording of the recommendations for the review report.

recombinant medicinal active pharmaceutical ingredients (APIs) from mammalian cell cultures. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided they are implemented and adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in up to 33kg/year (Slough site) and 39.6kg/year (Porriño site) emissions of the substance to the environment (based on a worst case assumption). RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements proposed for the authorisation The applicants shall monitor at least quarterly/four times per year the concentration of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its principal degradation products in water and at an appropriately low level of quantification. The information gathered via the measurements shall be used to review the effectiveness of the RMMs and OCs in place and to introduce measures to further reduce the emissions. The information on the action taken shall be documented together with the results of the monitoring campaigns and 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 documentation shall be made available to Competent Authorities upon request. 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, that do not result in higher releases than at the sunset date. RAC agreed on the draft opinion by consensus.	**SECR** to send the draft opinion to the applicant for commenting.

8. 191_NPE_Sekisui (1 use)	
Use 1: *Industrial use as polymer additive in the manufacture of interlayer polymer films for laminated safety glass.* RAC concluded that the operational conditions and risk management measures described in the application are not expected to be appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in 6.9 kg per year emissions of 4-NPnEO and nonylphenol releasing substances (this substance set is referred to as NPRs) to the environment. RAC agreed: 1. additional conditions for the authorisation The applicant shall within one year further assess the feasibility to implement additional OCs and RMMs (e.g.: granular activated carbon (GAC) filters, ozone treatment etc.) and subsequently to act on the outcome of the feasibility study and implement additional RMMs where appropriate. 2. monitoring arrangements proposed for the authorisation The applicant shall undertake a monitoring programme of the wastewater prior to release to the municipal STP. The initial sampling frequency should be sufficient to demonstrate daily fluctuations. Once the appropriate frequency has been established, RAC recommends that the applicant should monitor 4-NPnEO and its principal degradation products in the wastewater prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its principal degradation products 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. 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.

The information gathered via the measurements referred to in section 8 of the justification to the draft opinion as well as the outcome and conclusions of the review and any action taken shall be included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
9. 192_OPE_Pfizer_2 (1 use)	
Use 1: *The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO))(Triton X-100) as a surfactant within a lubricant used in the manufacture of pharmaceutical drug products.* 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 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 0.179 kg/year (air) and 0.077 kg/year (water) emissions of 4-tert-OPnEO to the environment (worst case). RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements proposed for the authorisation The applicant should undertake a monitoring programme of the wastewater in the influent/waste stream entering to the on-site WWTP, in the wastewater prior to release to the natural brook and if possible in the air originating from the depyrogenation tunnel. The initial sampling frequency should be sufficient to demonstrate daily fluctuations. Once the appropriate frequency has been established, RAC recommends that the applicant should monitor 4-tert-OPnEO and its principal degradation products when manufacturing occurs in the wastewater and if possible in the air as described above, using an analytical method capable of adequately characterising the substance and its principal degradation products at an appropriately low level of quantification. 3. 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.

The results of the monitoring campaigns should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC recommends the applicant to further assess in any review report the feasibility to implement additional OCs and RMMs for further reducing the emissions of 4-tert-OPnEO to air and water, and act on the outcome of the feasibility study. The applicant should demonstrate in the review report that all measures were periodically re-assessed and considered, to show that the release was all the time the lowest possible. RAC agreed on the draft opinion by consensus.	
C. Adoption of final opinions	
1. OPE_Sebia (3 uses) 2. NPE_Sebia (1 use) 3. OPE_Stago (2uses) ~~4. OPE_bioMerieux (3 uses)~~ 5. SC_Ariston (1 use) The Chair informed the Committee that Applicants submitted comments on the draft opinions agreed at RAC 51.	
1. OPE_Sebia (3 uses)	
Use 1: *Industrial use of 4-tert-OPnEO for its "wetting" detergent properties in the production of buffers, reagents and gel supports allowing the dissolution, the dilution and the good spreading of substrates and reagents, necessary to optimize the functioning and the sensitivity of gel electrophoresis in vitro diagnostic test.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 0.066 kg/year (according to monitoring data) or 4.4 kg/year (according to default release values from ERCs) of the substance to the environment.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid waste from washing the glassware at the site of Lisses (SEBIA) for adequate treatment and act on the outcome of the feasibility study. RAC recommends that the applicant should monitor at least quarterly or 4 times per year 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the off-site WWTP at the site of Lisses (SEBIA) using an analytical method capable of adequately characterising the substance and its 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. **Use 2:** *Industrial use of 4-tert-OPnEO for its detergent properties in the production of electrophoresis gels in view of ensuring the positioning of specific proteins necessary for the interpretation of results of in vitro diagnostic test based on protein separation.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 0.068 kg/year (according to monitoring data) or 4.7 kg/year (according to default release values from ERCs) of the substance 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 RAC recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid waste from washing the glassware at the site of Lisses (SEBIA) for adequate treatment and act on the outcome of the feasibility study.	

RAC recommends that the applicant should monitor at least quarterly or 4 times per year 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the off-site WWTP at the site of Lisses (SEBIA) and Rome (INTERLAB) using an analytical method capable of adequately characterising the substance and its 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. **Use 3:** *Industrial use of 4-tert-OPnEO for its detergent properties resulting in cellular lysis and protein interactions rupture and required for the production of reagents involved in the determination of proteins of interest in gel and capillary electrophoresis in vitro diagnostic test.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 0.066 kg/year (according to monitoring data) or 4.4 kg/year (according to default release values from ERCs) of the substance 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 RAC recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid waste from washing the glassware at the site of Lisses (SEBIA) for adequate treatment and act on the outcome of the feasibility study. RAC recommends that the applicant should monitor at least quarterly or 4 times per year 4-tert-OPnEO and its principal degradation products in the waste water prior to release to the off-site WWTP at the site of Lisses (SEBIA) using an analytical method capable of adequately characterising the substance and its 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 rapporteurs reviewed the applicant's comments. They decided to not change the draft opinions. RAC adopted the final opinions by consensus with no changes made to the draft opinions.	
2. NPE_Sebia (1 use)	
Use 1: *Industrial use of 4-NPnEO for its detergent properties in the production of buffers and reagents in view of ensuring the positioning of specific proteins necessary for the interpretation of gel electrophoresis in vitro diagnostic tests results based on the determination of isoenzymes.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 0.00016 kg/year (according to monitoring data) or 0.040 kg /year (according to default release values from ERCs) of the substance 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 RAC recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid waste from washing the glassware at the site of Lisses (SEBIA) for adequate treatment and act on the outcome of the feasibility study. RAC recommends that the applicant should monitor at least quarterly or 4 times per year 4-NPnEO and its principal degradation products in the waste water prior to release to the off-site WWTP at the site of Lisses (SEBIA) using an analytical method capable of adequately characterising the substance and its 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.	**SECR** to send the final opinion to the EC, MSs and the Applicant.

RAC rapporteurs reviewed the applicant's comments. They decided to not change the draft opinion. RAC adopted the final opinion by consensus with no changes made to the draft opinion.	
3. OPE_Stago (2 uses)	
Use 1: *Industrial use of 4-tert-OPnEO for its detergent properties in the process of cell lysing for the production of in-vitro diagnostic reagents (Asserachrom® HPIA, Asserachrom® HPIA–IgG and Asserachrom® PF4 and STA®-Néoplastine® R15 assays).* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the releases to the environment, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 4-tert-OPnEO to the environment in the range of 0.4-14 g per year. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends that the applicant should further assess in any review report the feasibility to collect the remaining liquid wastes from rinsing reusable equipment (e.g. glassware, plastic, glass and inox containers) at the site in Taverny and put in practice if the outcome of the feasibility study is favourable. RAC recommends that the applicant should, while the plant is operating, continue s with the quarterly monitoring of 4-tert-OPnEO in the waste water prior to release to the local 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. **Use 2:** *Industrial use of 4-tert-OPnEO in view of controlling the amount of non-specific reactions in*	**SECR** to send the final opinion to the EC, MSs and the Applicant.

the production of in-vitro diagnostic reagents (STA® - Liatest® D-Di assays). RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently The use applied for may result in emissions of 4-tert-OPnEO to the environment in the range of 4-164 g per year. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends that the applicant should further assess in any review report the feasibility to collect the remaining liquid wastes from rinsing reusable equipment (e.g. glassware, plastic, glass and inox containers) at the site in Taverny and put in practice if the outcome of the feasibility study is favourable. RAC recommends that the applicant should, while the plant is operating, continue s with the quarterly monitoring of 4-tert-OPnEO in the waste water prior to release to the local 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. RAC rapporteurs reviewed the applicant's comments. They agreed that all comments were addressed to SEAC. Therefore, RAC adopted the final opinions by consensus with no changes made to the draft opinions.	
~~**2. OPE_bioMerieux (3 uses)**~~	
4. SC_Ariston (1 use)	
Use 1: *Use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr6+) in the refrigerant solution*	**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 expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The exposure to workers was estimated to be: 9.0×10^{-3} µg/m³ (inhalation route) and 11.36 µg/kg bw/day (dermal route). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m³ (with a transitional value of 10 µg Cr(VI)/m³ until 17 January 2025). The exposure to the general population was estimated to be Inhalation: 1.07×10^{-7} µg/m³ and Oral: 1.10×10^{-8} µg/kg bw/d. The excess lifetime cancer risk for workers is estimated to be inhalation 3.54×10^{-5} per µg/m³ (for 8 h TWA exposure for 40 years), per year, for the review period, and 3.14×10^{-9} per µg/m³ (for 24 h exposure for 70 years), per year, for the review period for the general population. The RCR for reprotoxicity (arising from dermal exposure of workers) was estimated to be 0.26. RAC agreed for: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation (a) The applicant shall implement and conduct an initial measurement programme and, at least, annual exposure monitoring programmes for Cr(VI) thereafter. Those programmes shall be based on relevant standard methodologies or protocols, comprise static and/or personal inhalation exposure sampling and be representative of: (i) the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance workers; (ii) the OCs and RMMs typical for each of these tasks; (iii) the number of workers potentially exposed; (b) the applicant shall implement and conduct an initial measurement campaign and, at least, annual monitoring of Cr(VI) emissions to wastewater and air. Those programmes shall be based on relevant standard methodologies or protocols and be	

representative of the OCs and RMMs used at the applicants site. (c) the information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicant to review and confirm the effectiveness of proposed RMM and OCs and, if needed, to introduce measures to further reduce workplace exposure to sodium chromate and emissions to the environment to as low a level as technically and practically feasible; (d) the applicant shall ensure that the application of RMMs at his site is in accordance with the hierarchy of control principles (e.g. appropriateness of RPEs) and refine worker and HvE assessment if necessary; (e) the measurements referred to in points (a) and (b), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place; (f) following implementation of the RMMs and OCs proposed for the new installation, the applicant may reduce the frequency of measurements, once the applicant can clearly demonstrate to the national competent authority, of the Member State where the use takes place, that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible and that the RMMs and OCs function appropriately. 3. recommendations for the review report The information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report. RAC rapporteurs reviewed the applicant's comments. They agreed that all comments were addressed to SEAC. Therefore, RAC adopted the final opinion by consensus with no changes made to the draft opinion.	
11. AOB	
The EEB regular stakeholder observer had requested a discussion in plenary on the reopening by the Chair of the biodegradation derogation in the restriction on intentionally added microplastics. The Client Earth regular stakeholder observer then introduced the topic.	

The Chair noted that at RAC 52, the opinion on intentionally added microplastics had not been tabled for adoption, thus allowing for flexibility in its completion. He informed that his request to reopen this issue had been discussed on the last day of the RAC 52 plenary meeting which was cut short by one week due to the Covid-19 crisis. Having consulted members of the ad hoc working group, the rapporteurs and a Commission representative, he considered that the agreement reached on this topic at RAC 52 did not take account of other possibilities for demonstrating biodegradation and as such was not practicable. RAC agreed to his proposal, confirming this in their minutes which were later agreed by written procedure. This led to his request to the ad hoc working group and the rapporteurs to develop a range of alternatives for derogating on grounds of biodegradation, which they duly did, providing a broader analysis for discussion and agreement at the present meeting.
12. Minutes of RAC-53
a) **SECR** to upload the table with Summary Record of the Proceedings and Conclusions and Action points from RAC-53 to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-53B

1. **Tellurium**
2. **Tellurium dioxide**
3. **Piperonyl butoxide (ISO)**
4. **Trichlorosilane**
5. **Isobornyl acrylate**
6. **Clofentezine (ISO)**
7. **Daminozide (ISO)**
8. **TBNPA**
9. **Benzophenone**
10. **Fluopicolide**
11. **2-EHA and its salts**
12. **DTPA (Art 77-3c)**

Table 1

1. Tellurium

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	Tellurium	236-813-4	13494-80-9	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
RAC opinion	TBD	Tellurium	236-813-4	13494-80-9	Repr. 1B Lact.	H360fD H362	GHS08 Dgr	H360fD H362			
Resulting Annex VI entry if agreed by COM	TBD	Tellurium	236-813-4	13494-80-9	Repr. 1B Lact.	H360fD H362	GHS08 Dgr	H360fD H362			

2. Tellurium dioxide

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	Tellurium	231-193-1	7446-07-3	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
RAC opinion	TBD	Tellurium	231-193-1	7446-07-3	Repr. 1B Lact.	H360fD H362	GHS08 Dgr	H360fD H362			
Resulting Annex VI entry if agreed by COM	TBD	Tellurium	231-193-1	7446-07-3	Repr. 1B Lact.	H360fD H362	GHS08 Dgr	H360fD H362			

3. Piperonyl butoxide (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	piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether	200-076-7	51-03-6	STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H335 H400 H410	GHS07 GHS09 Wng	H335 H410	EUH066	M=1 M=1	
RAC opinion	TBD	piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether	200-076-7	51-03-6	Eye Irrit. 2 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H319 H335 H400 H410	GHS07 GHS09 Wng	H319 H335 H410	EUH066	M=1 M=1	
Resulting Annex VI entry if agreed by COM	TBD	piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether	200-076-7	51-03-6	Eye Irrit. 2 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H319 H335 H400 H410	GHS07 GHS09 Wng	H319 H335 H410	EUH066	M=1 M=1	

4. Trichlorosilane

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	014-001-00-9	trichlorosilane	233-042-5	10025-78-2	Flam. Liq. 1 Pyr. Liq. 1 Acute Tox. 4* Acute Tox. 4* Skin Corr. 1A	H224 H250 H302 H332 H314	Dgr GHS02 GHS05 GHS07	H224 H250 H302 H332 H314	EUH014 EUH029	STOT SE 3; H335: C ≥ 1 %	Note T
Dossier submitters proposal	014-001-00-9	trichlorosilane	233-042-5	10025-78-2	Flam. Liq. 1 Water-react 1 Acute Tox. 4 Acute Tox. 3 Skin Corr. 1B Eye Dam. 1	H224 H260 H302 H331 H314 H318	Dgr GHS02 GHS05 GHS06	H224 H260 H302 H331 H314	EUH014 EUH029 EUH071	Inhalation: ATE =7.65 mg/L (vapour) Oral: ATE = 1030 mg/kg bw	
RAC opinion	014-001-00-9	trichlorosilane	233-042-5	10025-78-2	Flam. Liq. 1 Water-react. 1 Acute Tox. 4 Acute Tox. 3 Skin Corr. 1A Eye Dam. 1	H224 H260 H302 H331 H314 H318	Dgr GHS02 GHS05 GHS06	H224 H260 H302 H331 H314	EUH014 EUH029 EUH071	Inhalation: ATE = 7.6 mg/L (vapour) Oral: ATE= 1000 mg/kg bw	
Resulting Annex VI entry if agreed by COM	014-001-00-9	trichlorosilane	233-042-5	10025-78-2	Flam. Liq. 1 Water-react. 1 Acute Tox. 4 Acute Tox. 3 Skin Corr. 1A Eye Dam. 1	H224 H260 H302 H331 H314 H318	Dgr GHS02 GHS05 GHS06	H224 H260 H302 H331 H314	EUH014 EUH029 EUH071	Inhalation: ATE = 7.6 mg/L (vapour) Oral: ATE= 1000 mg/kg bw	

5. Isobornyl acrylate

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	exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate	227-561-6	5888-33-5	Skin Sens. 1	H317	GHS07 Wng	H317			
RAC opinion	TBD	exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate	227-561-6	5888-33-5	Skin Sens. 1A	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate	227-561-6	5888-33-5	Skin Sens. 1A	H317	GHS07 Wng	H317			

6. Clofentezine (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	clofentezine (ISO); 3,6-bis(*o*-chlorophenyl)-1,2,4,5-tetrazine	277-728-2	74115-24-5	Carc. 2 Aquatic Chronic 1	H351 H410	GHS08 GHS09 Wng	H351 H410		M=1	
RAC opinion	TBD	clofentezine (ISO); 3,6-bis(*o*-chlorophenyl)-1,2,4,5-tetrazine	277-728-2	74115-24-5	Aquatic Chronic 1	H410	GHS09 Wng	H410		M=1	
Resulting Annex VI entry if agreed by COM	TBD	clofentezine (ISO); 3,6-bis(*o*-chlorophenyl)-1,2,4,5-tetrazine	277-728-2	74115-24-5	Aquatic Chronic 1	H410	GHS09 Wng	H410		M=1	

7. Daminozide (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	daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid	216-485-9	1596-84-5	Carc. 1B	H350	GHS08 Dgr	H350			
RAC opinion	TBD	daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid	216-485-9	1596-84-5	Carc. 2	H351	GHS08 Wng	H351			
Resulting Annex VI entry if agreed by COM	TBD	daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid	216-485-9	1596-84-5	Carc. 2	H351	GHS08 Wng	H351			

8. TBNPA

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	2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol	253-057-0	36483-57-5; 1522-92-5	Muta. 1B Carc. 1B	H340 H350	GHS08 Dgr	H340 H350			
RAC opinion	TBD	2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol	253-057-0	36483-57-5; 1522-92-5	Muta. 2 Carc. 1B	H341 H350	GHS08 Dgr	H341 H350			
Resulting Annex VI entry if agreed by COM	TBD	2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol	253-057-0	36483-57-5; 1522-92-5	Muta. 2 Carc. 1B	H341 H350	GHS08 Dgr	H341 H350			

9. Benzophenone

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	Benzophenone	204-337-6	119-61-9	Carc. 2	H351	GHS08 Wng	H351			
RAC opinion	TBD	Benzophenone	204-337-6	119-61-9	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	Benzophenone	204-337-6	119-61-9	Carc. 1B	H350	GHS08 Dgr	H350			

10. Fluopicolide

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	fluopicolide (ISO); 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	-	239110-15-7							
RAC opinion	TBD	fluopicolide (ISO); 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	-	239110-15-7	Repr. 2	H361d	GHS08 Wng	H361d			
Resulting Annex VI entry if agreed by COM	TBD	fluopicolide (ISO); 2,6-dichloro-N-[3-chloro-5-(trifluoromethyl)-2-pyridylmethyl]benzamide	-	239110-15-7	Repr. 2	H361d	GHS08 Wng	H361d			

11. 2-EHA and its salts

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	607-230-00-6	2-Ethylhexanoic acid	205-743-6	149-57-5	Repr. 2	H361d	GHS8 Wng	H361d			
Dossier submitters proposal	**Retain:** 607-230-00-6	**Retain:** 2-Ethylhexanoic acid **Add:** and its salts, with the exception of those specified elsewhere in this Annex	**Delete:** 205-743-6	**Delete:** 149-57-5	**Retain:** Repr. 2	**Retain:** H361d	**Retain:** GHS08 Wng	**Retain:** H361d			**Add a new note:** The classification for the hazard class(es) in this entry is based only on the hazardous properties of the part of the substance which is common to all members in the entry. The hazardous properties of any member in the entry also depends on the properties of the part of the substance which is not common to all members of the group; they must be evaluated to

	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	607-230-00-6	2-Ethylhexanoic acid	205-743-6	149-57-5	Repr. 2	H361d	GHS8 Wng	H361d			
											assess whether (a) more severe classification(s) (e.g. a higher category) or (b) a broader scope of the classification (additional differentiation, target organs and/or hazard statements) might apply for the hazard class(es) in the entry.
RAC opinion	607-230-00-6	**Retain:** 2-Ethylhexanoic acid **Add:** and its salts, with the exception of those specified elsewhere in this Annex	**Delete:** 205-743-6	**Delete:** 149-57-5	**Modify:** Repr. 1B	**Modify:** H360D	**Modify:** GHS08 Dgr	**Modify:** H360D			**Add a new note:** The classification for the hazard class(es) in this entry is based only on the hazardous properties of the part of the substance which is common to all substances in the entry. The hazardous

	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	607-230-00-6	2-Ethylhexanoic acid	205-743-6	149-57-5	Repr. 2	H361d	GHS8 Wng	H361d			
											properties of any substance in the entry also depends on the properties of the part of the substance which is not common to all substances of the group; they must be evaluated to assess whether (a) more severe classification(s) (e.g. a higher category) or [(b) a broader scope of the classification (additional differentiation, target organs and/or hazard statements) might apply for the hazard class(es) in the entry. – *or part (b) omitted*]
Resulting Annex VI entry if	607-230-00-6	2- Ethylhexanoic acid and its salts, with the exception of those			Repr. 1B	H360D	GHS08	H360D			The classification for the hazard class(es) in this

	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	607-230-00-6	2-Ethylhexanoic acid	205-743-6	149-57-5	Repr. 2	H361d	GHS8 Wng	H361d			
agreed by COM		specified elsewhere in this Annex					Dgr				entry is based only on the hazardous properties of the part of the substance which is common to all members in the entry. The hazardous properties of any member in the entry also depends on the properties of the part of the substance which is not common to all members of the group; they must be evaluated to assess whether (a) more severe classification(s) (e.g. a higher category) or (b) a broader scope of the classification (additional differentiation, target organs and/or hazard

	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	607-230-00-6	2-Ethylhexanoic acid	205-743-6	149-57-5	Repr. 2	H361d	GHS8 Wng	H361d			
											statements) might apply for the hazard class(es) in the entry.

12. DTPA (Art 77-3c request)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	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	TBD	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2	Acute Tox. 4 STOT RE 2	H332 H373 (Inhalation)	GHS08 GHS07 Wng	H332 H373		inhalation: ATE = 1,5 mg/l (dusts or mists)'	
For RAC discussion following art 77(3)c request	TBD	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2	Repr.					SCL Repr.	
RAC opinion	TBD	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2	Repr. 1B	H360D		H360D		Repro 1B; H360D: C ≥ 3 %	
Resulting Annex VI entry if agreed by COM	607-736-00-7	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2	Repr. 1B Acute Tox. 4 STOT RE 2	H360D H332 H373 (Inhalation)	GHS08 GHS07 Dgr	H360D H332 H373		Repro 1B; H360D: C ≥ 3 % inhalation: ATE = 1,5 mg/l (dusts or mists)'	

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	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	607-734-00-	Pentapotassium 2,2′,2″,2‴,2⁗-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H332 H373 (Inhalation) H319	GHS08 GHS07 Wng	H332 H373 H319		inhalation: ATE = 1,5 mg/l (dusts or mists)’	
For RAC discussion following art 77(3)c request	607-734-00-	Pentapotassium 2,2′,2″,2‴,2⁗-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr.					SCL Repr.	
RAC opinion	TBD	Pentapotassium 2,2′,2″,2‴,2⁗-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr. 1B Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H360D		H360D		Repro 1B; H360D: C ≥ 3 %	
Resulting Annex VI entry if agreed by COM	TBD	Pentapotassium 2,2′,2″,2‴,2⁗-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr. 1B Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H360D H332 H373 (Inhalation) H319	GHS08 GHS07 Dgr	H360D H332 H373 H319		Repro 1B; H360D: C ≥ 3 % inhalation: ATE = 1,5 mg/l (dusts or mists)’	

	Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Labelling**			**Specific Conc. Limits, M-factors**	**Notes**
					Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard state-ment Code(s)**	**Suppl. Hazard statement Code(s)**		
Current Annex VI entry	607-735-00-1	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H332 H373 (Inhalation) H319	GHS08 GHS07 Wng	H332 H373 H319	-	inhalation: ATE = 1,5 mg/l (dusts or mists)’-	-
For RAC discussion following art 77(3)c request	607-735-00-1	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	Repr.					SCL Repr.	-
RAC opinion	607-735-00-	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	Repr. 1B	H360D		H360D		Repro 1B; H360D: C ≥ 3 %’	

Resulting Annex VI entry if agreed by COM	607-735-00-	N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	Repr. 1B Acute Tox. 4 STOT RE 2 Eye Irrit. 2	H360D H332 H373 (Inhalation) H319	GHS08 GHS07 Dgr	H360D H332 H373 H319		Repro 1B; H360D: C ≥ 3 % inhalation: ATE = 1,5 mg/l (dusts or mists)'	

Part III. List of Attendees of the RAC-53 meeting

RAC Members
Andreou Kostas
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
Docea Anca Oana
Dobrev Ivan
Geoffroy Laure
Hakkert Betty
Hartwig Andrea (co-opted member)
Heederik Dick (co-opted member)
Husa Stine
Kadiķis Normunds
Kapelari Sonja
Karadjova Irina
Leinonen Riitta
Losert Annemarie
Lund Bert-Ove
Martínek Michal
Menard Srpčič Anja
Moeller Ruth
Moldov Raili
Murray Brendan
Neumann Michael
Paris Pietro
Peczkowska Beata
Pribu Mihaela
Printemps Nathalie
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
Apologies, Members
Chankova-Petrova Stephka
Zeljezic Davor

Members' advisers
Bakker Joost (Betty Hakkert)
Boel Els (Julie Seba)
Catone Tiziana (Pietro Paris)
Esposito Dania (Pietro Paris)
Henriksson Jörgen (Daniel Borg)
Hoffmann Frauke (Agnes Schulte)
Mahiout Selma (Tiina Santonen)
Marinkovic Marino (Betty Hakkert)
Martin Theresa (Ralf Stahlmann)
Paludan Ditte Secher (Peter Soerensen)
Partosch Falko (Ralf Stahlmann)
Rodriguez Wendy (Julie Seba)
Romoli Debora (Pietro Paris)
Russo Maria Teresa (Pietro Paris)
Sonnenburg Anna (Ralf Stahlmann)
Suutari Tiina (Riitta Leinonen
Sättler Daniel (Michael Neumann)
Viegas Susana (Joao Carvalho)
Wouters Linda (Julie Seba)
Invited experts (RAC candidates)
Doak Malcolm (IE)
Xanthos Theodore (CY)
Invited expert (Microplastics)
Guerriero Lee (UEFA)

WPC observers (OELs)
Levy Patrick (Employer´s Interest Group)
Tony Musu (Workers Interest Group)
Sirkku Saarikoski (Government Interest Group)
Dossier submitters
Arapaki Niki (GR)_CLH: Piperonyl butoxide
Eide Dag (NO)_CLH: TBNPA
Erdmann Christian (DE)_PFHxA
Fernández Sánchez Raquel (ES)_2-ethylhexanoic acid and its salts
Heltved Jette Rud (DK)_CLH: benzophenone
Hofer Tim (NO)_CLH: TBNPA
Kacan Stefan (DE)_Restriction: PFHxA
Larsen Ann Kristin (NO)_CLH:TBNPA
Nikolopoulou Dimitra (GR)_CLH: Piperonyl butoxide
Sanz Manuel (ES)_CLH: Clofentezine
Schulte Petra (DE)_CLH: trichlorosilane
Van der Hagen Marianne (NO)_CLH: TBNPA
Woutersen Marjolojn (NL)_CLH: tellurium and tellurium dioxide
SEAC rapporteurs (Restrictions, AfAs)
Thiele Karen (microplastics)

Regular stakeholder observers
Barry Frank (ETUC)
Bernard Alice (ClientEarth)
Comini Andrea (EuCheMS)
Romano Mozo Dolores (EEB)
Ruelens Paul (ECPA)
Van de Broeck Steve (Cefic)
Verougstraete Violaine (Eurometaux)
Occasional stakeholders
Almeida Filipe (CosmeticsEurope)_Restriction: microplastics
Ballach Jochen (CIRFS)_Restrcition: microplastics
Barbu Luminita (EDANA)_Restriction: microplastics, PFHxA
Buijs Nathalie (MedTech Europe)_ Restriction: microplastics, AfA: all AfAs
Capon France (EPMF)_OEL: lead
Cassart Michel (PlasticsEurope)_Restriction: microplastics_PFHxA
Drmac Dunja (Euratex)_Restriction: PFHxA
Kafka Amalia (Euroseeds)_Restriction: microplastics
Laroche Charles (IFRA)_Restriction: microplastics
Leonhardt Thomas (EUROFEU)_Restriction: microplastics
Leroy Didier (CEPE)_Restriction: microplastics

De Matos Olivier (ECETOC)_Restriction: microplastics_workplan_AP1-3
Musacchi Ettore (ETRA)_Restriction: microplastics_AP1-3,5
Papagrigoraki Anna (Cepi)_Restriction: microplastics
Robinson Jan (A.I.S.E)_Restriction: microplastics
Von Pogrell Hasso (EUBP)_Restriction: microplastics
Stakeholder experts
Berg Madeleine (EEB/FIDRA)_Restriction: microplastics
Binks Steve (Cefic/Pb REACH consortium)_OEL: lead
Bock Ronald (PlasticsEurope/Fluoropolymer)_Restriction: PFHxA
Bonifay Sebastien (ECPA/Corteva – representing ECHA PPP)_Restriction: microplastics
Collot Anne Gaelle (PlasticsEurope)_Restriction: microplastics
Brosche Sara (ClientEarth/IPEN)_Restriction : microplastics
Falcigno Pasquale (Euroseeds/Euroseeds)_Restriction : microplastics
Hannebaum Peter (EUROFEU/Tyco Fire Protection Products)_Restriction :calcium cyanamide_PFHxA_Workplan
Heitmann Kerstin (Eurometaux/Te/Te02 Consortium)_CLH : tellurium_tellurium dioxide
Hindle Stuart (Cefic/DOW)_Article 77(3)© : DTPA
Innocenti Degli Francesco (EUBP/European Bioplastics)_Restriction : microplastics
Jackson Ffion (MedTech/Siemens Healthineers)_Restriction: microplastics
Jenner Karen (IFRA/Givaudan)_Restriction: microplastics
Kayser Martin (ECETOC/BASF)_Restriction : microplastics
Klasse Hans-Jürgen (Cefic/Alzhem Trostberg GmbH)_Restriction: calcium cyanamide
Krueger Ines (Cefic/ISOPA)_OEL : diisocyanates

Little Joanne (ECPA/Bayer)_CLH : fluopicolide
Loonen Hélène (EEB/EEB)_Restriction : PFHxA
Moisio Emilia (Cepi/UPM)_Restriction : microplastics
Mortier Nike (ClientEarth/OWS)_Restriction: microplastics
Ott Wolfgang (CIRFS/Kelheim Fibres GmbH)_Restriction: microplastics
Roembke Jörg (ECPA/AlzChem)_Restriction: calcium cyanamide
Schutte Maaike (ECPA/Adama)_CLH : clofentezine
Serrano Ramon Blanca (Cefic)_Restriction: microplastics
Shulman Valerie L (ETRA/ETRA)_Restriction: microplastics
Smith Scott (EDANA/Evonik Nutrition and Care GmbH)_Restriction: microplastics
Terlingen Leon (Eurometaux/FertilizersEurope)_Restriction: microplastics
Thom Ellen (ECPA/Endura S.p.A)_CLH: piperonyl butoxide
Thumm Stefan (Euratex/Bavarian Textile and Apparel Association)
Van der Meulen Jan (CEPE/CEPE)_Restriction: microplastics
Warren Simon (ECPA/CRO Exponent)_CLH: daminozide
Wieske Martin (EPMF/metals sector)_OEL: Lead and its compounds
Williams Cris (Eurometaux/International Lead Association):OEL: lead
Wirkowska Beata (ECPA/PPC ADOB sp Poland)_Article 77(3)©: DTPA
Yada Makiko (Cefic/Daikin)_Restriction: microplastics

Commission
Bertato Valentina (DG ENV)
Gilliland Douglas (JRC)
Hualde-Grasa Eva Patricia (DG GROW)
Kilian Karis (DG ENV)
Lekatos Stylianos (DG GROW)
Luvara Giuseppina (DG ENV)
Morris Alick (DG EMPL)
Podniece Zinta (DG EMPL)
Tosetti Patrizia (DG SANTE)
EFSA
Chiusolo Arianna
Panzarea Martina
Parra Morte Juan Manuel

ECHA staff
Berges Markus
Blainey Mark
Bowmer Tim, Chair
Broeckaert Fabrice
Costas Ion
Figuiere Romain
Gmeinder Michael
Hellsten Kati
Henrichson Sanna
Karjalainen Antti
Kokkola Leila
Lapenna Silvia
Lefevre-Brevart Sandrine
Logtmeijer Christiaan
Ludborzs Arnis
Marques-Camacho Mercedes
Matthes Jochen
Mazzega Sbovata Silvia
Mottet Dennis
Mushtaq Fesil
Myöhänen Kirsi
Nicot Thierry
Nygren Jonas
Orispää Katja
O´Rourke Regina
Ottati Maria
Peltola Jukka
Peltola-Thies Johanna, deputy Chair
Perazzolo Chiara

Prevedouros Konstantinos
Regil Pablo
Rodriguez Unamuno Virginia
Roggeman Maarten
Sadam Diana
Simoes Ricardo
Simpson Peter
Smilovici Simona
Sosnowski Piotr
Stockmann-Juvala Helene
Tanarro Celia
Uphoff Andreas
Vaananen Virpi
Vainio Matti
Van Haelst Anniek

Part II. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-53 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-53 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-53 meeting

ANNEX IV Administrative issues and information items

1 June 2020
RAC/A/53/2020_REV 1

Final Agenda

53rd meeting of the Committee for Risk Assessment

1-5 June 2020
and
8-12 June 2020

Webex meeting

Monday 1 June starts at 14.00
Friday 5 June breaks at 18.00
Monday 8 June resumes at 14.00
Friday 12 June ends at 13.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/53/2020
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

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

For agreement

Item 5 – Report from other ECHA bodies and activities

a) RAC Work Plan for all processes

For information

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

a) Classification for reproductive toxicity of DTPA-H5, DTPA-K5 and DTPA-Na5

For agreement

Item 7 –Health based exposure limits at the workplace

7.1 Health based exposure limits at the workplace

a) Opinion development

1) Diisocyanates – final draft opinion

2) Lead and its compounds – final draft opinion

For discussion and adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 CLH dossiers

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

- Tellurium: germ cell mutagenicity
- Tellurium dioxide: germ cell mutagenicity
- Piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether: physical hazards, acute toxicity (all routes), skin sensitisation, skin corrosion/irritation, respiratory sensitisation, germ cell mutagenicity, reproductive toxicity, acute aquatic hazards, chronic aquatic hazards
- Trichlorosilane: pyrophoric liquids, substances which in contact with water emit flammable gases, acute oral toxicity, acute inhalation toxicity, eye damage/irritation
- Clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine: physical hazards (explosive, flammable solid, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solid, corrosive to metals), acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, hazardous to the aquatic environment
- Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid: physical hazards (explosive, flammable solid, self-heating substances, pyrophoric solids, substances which in contact with water emit flammable gases, oxidising solid), acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity,

reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment, hazardous to the ozone layer

• Fluopicolide: acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, aspiration hazard

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

1) Tellurium
2) Tellurium dioxide
3) Piperonyl butoxide (ISO); 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether
4) Trichlorosilane
5) Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate; isobornyl acrylate
6) Clofentezine (ISO); 3,6-bis(o-chlorophenyl)-1,2,4,5-tetrazine
7) Daminozide (ISO); 4-(2,2-dimethylhydrazino)-4-oxobutanoic acid; N-dimethylaminosuccinamic acid
8) 2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol
9) Benzophenone
10) Fluopicolide
11) 2-Ethylhexanoic acid and its salts

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

a) Opinion development

1) Perfluorohexanoic acid – first draft opinion

For discussion

2) Calcium cyanamide in fertilisers – final draft opinion
3) Microplastics – final draft opinion

For discussion and adoption

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications

b) Report from RAC WG on AfAs during May 2020 meeting

c) Renewal of the Mandate for RAC AfA WG

d) ECHA information about the request to set DNEL for Trixylyl phosphate (TXP) for the Authorisation process

RAC/53/2020/01

For discussion and agreement

10.2 Authorisation applications

a) Discussion on key issues

1) 12 applications for authorisation and a review report from February 2020 submission window (OPE/NPE, Cr(VI), TCE)

For discussion

b) Agreement on opinions

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

1) 149_CTPht_Nalon (1 use)
2) 152_CTPht_AO_RainCarbon (1 use)
3) 150_CTPht_AO_Koppers (1 use)
4) 170_OPE_DiaSorin (1 use)
5) 172_OPE_DIAGAST (1 use)
6) 160_OPE_Merck_2 (1 use)
7) 165_OPE_bioMerieux_2 (1 use)
8) 182_NPE_Abbott (1 use)
9) 163_OPE_Rentschler (1 use)
10) 156_OPE_Hospira (1 use)
11) 186_OPE_NPE_Beckman (5 uses)
12) 185_OPE_NPE_Idexx (3 uses)
13) 190_OPE_TEVA (1 use)

B. Draft opinions for agreement with plenary debate

1) 154_OPE_Siemens_1 (1 use)
2) 162_OPE_LFB (1 use)
3) 164_OPE_Baxter (1 use)
4) 180_OPE_NPE_Bio-Rad (4 uses)
5) 184_OPE_Lilly (1 use)
6) 187_OPE_AGC (2 uses)
7) 189_OPE_Lonza (1 use)
8) 191_NPE_Sekisui (1 use)
9) 192_OPE_Pfizer_2 (1 use)

For discussion and agreement

C. Adoption of final opinions

1) OPE_Sebia (3 uses)
2) NPE_Sebia (1 use)
3) OPE_Stago (2uses)
~~4) OPE_bioMerieux (3 uses)~~

5) SC_Ariston (1 use)

For discussion and adoption

Item 11 – AOB

Item 12 – Minutes of RAC-53

b) Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-53

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-53 – WEEK 1

Please note that this timeline is provisional. Changes can be made before and during the meeting in order to accommodate the discussions.

Monday 1 June 2020: Afternoon session

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

Item 3 – Declarations of conflicts of interest to the Agenda

Item 5 – RAC Work Plan for Restriction, Authorisation and C&L processes

Item 7 – Health based exposure limits at the workplace

Tuesday 2 June 2020: Morning session

Item 7 – Health based exposure limits at the workplace

Item 9 – Restrictions

Tuesday 2 June 2020: Afternoon session

Item 9 – Restrictions

Wednesday 3 June 2020: Morning session

Item 9 – Restrictions

Wednesday 3 June 2020: Afternoon session

Item 9 – Restrictions

Thursday 4 June 2020: Morning session

Item 9 – Restrictions

Thursday 4 June 2020: Afternoon session

Item 10 – Authorisation applications

Friday 5 June 2020: Morning session

Item 10 – Authorisation applications

Friday 5 June 2020: Afternoon session

Item 10 – Authorisation applications

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-53 – WEEK 2

Please note that this timeline is provisional. Changes can be made before and during the meeting in order to accommodate the discussions.

Monday 8 June 2020: Afternoon session

Item 1 – Welcome and Apologies

Item 3 – Declarations of conflicts of interest to the Agenda

Item 8 – CLH dossiers

Tuesday 9 June 2020: Morning session

Item 8 – CLH dossiers

Tuesday 9 June 2020: Afternoon session

Item 8 – CLH dossiers

Wednesday 10 June 2020: Morning session

Item 8 – CLH dossiers

Wednesday 10 June 2020: Afternoon session

Item 8 – CLH dossiers

Thursday 11 June 2020: Morning session

Item 8 – CLH dossiers

Thursday 11 June 2020: Afternoon session

Item 6 – Request under Article 77(3)(c)-

Item 11 – AOB

Item 4 – Appointment of rapporteurs

Item 12 – Minutes of RAC-53

Friday 12 June 2020: Morning session

Item 8 – CLH dossiers

Annex II (RAC 53)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 53 meeting.

Document number	Title
RAC/A/53/2020	Final Draft Agenda
RAC/53/2020/01	Mandate for a Working Group of the Committee for Risk Assessment (RAC) to handle Applications for Authorisation
RAC/53/2020/02	Administrative issues and information items

Annex III (RAC-53)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chair.
Article 77.3(c)		
No dossiers	-	-
Health based exposure limits at the workplace		
No declarations		
Restrictions		
Calcium cyanamide	Ruth MOELLER	Worked as consultant on human health risk assessment of cyanamide. No personal involvement
Perfluorohexanoic acid – PFHxA (DE)	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	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

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

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Article 77.3(c)		
Classification for reproductive toxicity of DTPA-H5, DTPA-K5 and DTPA-Na5	-	-
Health based exposure limits at the workplace		
No dossiers		
Restrictions		
No dossiers		
Applications for Authorisation		
No dossiers		
Harmonised classification & labelling		
1. Tellurium **2. Tellurium dioxide** **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.
Piperonyl butoxide (ISO) **GR**	Nikolaos SPETSERIS	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.
	Christina TSITSIMPIKOU	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.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
1. Trichlorosilane **2. isobornyl acrylate** **DE**	Agnes SCHULTE	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on these substances - no other mitigation measures applied. Personal involvement.
	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.
1. Clofentezine (ISO) **2. 2-Ethylhexanoic acid and its salts** **ES**	Ignacio de la FLOR TEJERO	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance – no other mitigation measures applied. No personal involvement.
Daminozide (ISO) **CZ and HU**	Michal MARTINEK	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.
	Marian RUCKI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
	Anna BIRO	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
2,2-dimethylpropan-1-ol, tribromo derivative **NO**	Christine BJORGE	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.
	Stine HUSA	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.
Fluopicolide **AT**	Annemarie LOSERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Benzophenone **DK**	Peter Hammer SORENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Lea Stine TOBIASSENl	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.

Annex IV (RAC-53)

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-52 Action Points

The RAC-52 action points due for RAC-52 are completed.

2 Outcome of written procedures & other consultations

2.1 Written procedures for adoption of RAC opinions / minutes of the meeting

Opinions / minutes adopted via written procedure	Deadline	Report on the outcome
No written procedures		

2.2 RAC consultations (status by 3 March 2020)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
Tellurium	8 May 2020	closed
Tellurium dioxide	8 May 2020	closed
2-EHA and its salts	8 May 2020	closed
Piperonyl butoxide (ISO)	12 May 2020	closed
Trichlorosilane	12 May	closed
Isobornyl acrylate	4 May 2020	closed
Clofentezine (ISO)	12 May 2020	closed
Daminozide (ISO)	11 May 2020	closed
TBNPA	8 May 2020	closed
Benzophenone	30 April 2020	closed
Fluopicolide	14 May 2020	closed
Application for Authorisation / Review Report		
149_CTPht_Nalon (1 use), 150_CTPht_AO_Koppers (1 use), 152_CTPht_AO_RainCarbon (1 use), 154_OPE_Siemens_1 (1 use), 156_OPE_Hospira (1 use),		closed

Subject / document	Deadline	Status / follow-up
160_OPE_Merck_2 (1 use), 162_OPE_LFB (1 use), 163_OPE_Rentschler (1 use), 164_OPE_Baxter (1 use), 165_OPE_bioMerieux_2 (1 use), 170_OPE_DiaSorin (1 use), 172_OPE_DIAGAST (1 use), 180_OPE_NPE_Bio-Rad (4 uses), 182_NPE_Abbott (1 use), 184_OPE_Lilly (1 use), 185_OPE_NPE_Idexx (3 uses), 186_OPE_NPE_Beckman (5 uses), 187_OPE_AGC (2 uses), 189_OPE_Lonza (1 use), 190_OPE_TEVA (1 use), 191_NPE_Sekisui (1 use), 192_OPE_Pfizer_2 (1 use) Consultations on draft opinions		
OPE_Sebia (3 uses), NPE_Sebia (1 use), OPE_Stago (2 uses), OPE_bioMerieux (3 uses), SC_Ariston (1 use) Consultations on (draft) final opinions		closed
193_OPE_PPG, 196_OPE_Becton, 197_OPE_NPE_Phadia, 198_OPE_Zoetis, 199_OPE_Biokit, 202_OPE_Merckle, 203_OPE_NPE_Qiagen, 207_OPE_Chemetall, 208_RR1_TCE_BlueCube, 209_CT_Saran, 210_CT_Hubner, 211_CT_SD_TataSteel Consultations on applications for authorisation	8 July 2020	ongoing
Restrictions		
Consultation on the eighth draft opinion on Microplastics	25 May 2020	closed
Consultation on the third version of the draft opinion on calcium cyanamide	18 May 2020	closed
Art. 77.3(c) request		
DTPAs	8 May 2020	closed

Subject / document	Deadline	Status / follow-up
Health based exposure limits at the workplace		
Consultations on the two scientific reports for evaluation of limit values for diisocyanates and 'lead and its compounds.	11 May– 22 May 2020	closed

2.3 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
Call for expression of interest in CLH dossiers	April 2020	three volunteers
Application for Authorisation		
Call for expression of interest in rapporteurship on applications for authorisation on SVHCs in 11 latest entries in Annex XIV of the REACH Regulation. Full list of the latest entries is published in Annex of the Commission Regulation (EU) 2020/171[2].		
Restriction No calls		

2.4 Written procedures for the appointment of (co-)rapporteurs

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling			
Written procedure for the appointment of (co-)rapporteurs	**2-Ethylhexanoic acid and its salts, with the exception of those specified elsewhere in this Annex** (EC n/a, CAS n/a)	10 February 2020	closed No comments were received from RAC members on the recommendation of the Chair; the RAC (co-)Rapporteurs were appointed with tacit agreement.
Article 77(3)(c)			
Written procedure for the appointment of (co-)rapporteurs	Request to RAC to review new information in relation to the harmonised	29 January 2020	closed No comments

[2] Commission Regulation (EU) 2020/171 of 6 February 2020 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
	classification and labelling of the substance N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid) (DTPA, EC Number: 200-652-8)		were received from RAC members on the recommendation of the Chair; the RAC (co-)Rapporteurs were appointed with tacit agreement.
Restrictions – no written procedures			
Applications for Authorisation– no written procedures			

2.5 Follow-up on the opinions on applications for authorisation adopted by RAC and SEAC

Opinion(s)	Sent on
Opinions sent to the European Commission, the Member States and applicants	
178_OPE_Janssen (1 opinion)	9 March 2020
OPE_Boehringer (1 opinion)	19 March 2020
CT_TES (1 opinion)	24 March 2020
OPE_BioMarin (2 opinions)	30 March 2020