RAC/M/52/2020

Final

7 April 2020

Minutes of the 52nd Meeting

of the Committee for Risk Assessment (RAC 52)

Monday 9 March - Friday 13 March 2020

Summary Record of the Proceedings, and Conclusions and action points

Chairman's opening address

The Chairman reflected on the following topics in his opening address:

- Members were provided with an update on the Covid-19 epidemic and the need to take personal hygiene measures such as regular hand washing;
- The exit of the United Kingdom from the European Union would still mean that some activities would continue during the transition period to the end of 2020, including the evaluation of applications for authorisation involving UK companies;
- Implementing legislation under the Plant Protection Products Regulation that was published in January may affect the role of CLH and thereby the involvement of RAC – the practical implications of this are being considered together with EFSA, including a possible further increase in the workload.

The Chairman informed the Committee that a Deputy Chairman would start to work for the Committee and congratulated Johanna Peltola-Thies who had been selected for this role.

Finally, the Chairman gave a short presentation on the new ECHA Conference centre and its historical location in the former Helsinki West harbour shipyard.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/52/2020**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-52 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for (co-)rapporteurships for CLH dossiers, applications for authorisation and occupational exposure limits, as listed in the restricted room documents (RAC/52/2020/03, RAC/52/2020/04 RAC/52/2020/05). The Committee agreed upon the proposed appointments of the Rapporteurs for	-

the intentions and/or newly submitted CLH dossiers, as well as to the pool of volunteers for the applications for authorisation and occupational exposure limits via written procedure.	
5. Report from other ECHA bodies and activities	
a) Report on RAC- 51 action points, written procedures and update on other ECHA bodies The Chairman informed the Committee that the action points from the previous meeting RAC-51, pending publications of some CLH opinions, were nearing completion. The summary of all substances related written procedures, calls for expression of interests in (co-)rapporteurship and written procedures for appointments of rapporteurs, and adopted opinions, is provided in the room document on administrative issues (RAC/52/2020/01) (see Annex IV). **SECR** presented document **RAC/52/2020/01.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes The Chairman presented the RAC work plan for 2020.	**-**
6. Health based exposure limits at the workplace	
a) Opinion development	
1. Diisocyanates – first draft opinion	
The Chairman welcomed the expert accompanying the regular Cefic stakeholder observer, two occasional stakeholders and the three observers from the DG-EMPL Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC). The Chairman 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.	

RAC discussed the first draft opinion and its Annex on the scientific evaluation of limit values for diisocyanates at the workplace; The following points are agreed: • onto select a non-threshold approach to derive exposure-response relationships based on the 'NCO-group' approach. Further explanations/discussions are needed on the uncertainties (for example possibly sensitive subgroups). • To focus on respiratory effects (sensitisation, irritation, occupational asthma) as the most relevant endpoints for quantitative assessment. • The need to derive a short term exposure limit (STEL) should be derived. The inter-individual variation and the possible derivation of an AF should be looked at. The discussion on further elements of the draft opinion will be held at RAC-53.	**Rapporteurs** to prepare the draft final opinion taking into account RAC-52 discussions
The expert accompanying the regular CEFIC stakeholder observer commented on the limitations of the human studies used for the exposure-response derivation and on their preference of a ceiling value over a STEL or a TWA.	
2. Lead and its compounds – first draft opinion	
The Chairman welcomed the experts accompanying the regular Cefic and Eurometaux stakeholder observers, one occasional stakeholder as well as the three observers from the DG-EMPL, Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC). The Chairman 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 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 to an Annex to the RAC opinion.	
RAC discussed the first draft opinion and its Annex on the scientific evaluation of limit values for lead and its compounds at the workplace. The following points were discussed and/or agreed:	**Rapporteurs** to prepare the draft final opinion taking into account RAC-52 discussions.

• The biological limit value for lead concentrations in blood as being the primary limit value. • The approach to set an air limit value. Additional clarification is needed on the uncertainties related to the approach. • Further discussion on the identification of Point of Departure and use of Weight of Evidence for the derivation of a limit value (BLV) is foreseen at RAC-53. • Reducing the risk for women of childbearing age at the workplace would need to be further described in the draft opinion. The option for inserting a recommendation for a possible qualitative statement in the Chemicals Agent Directive was agreed in this specific case. • For organic compounds, neither an air limit value nor a biological limit value would be proposed. Further discussion and agreement is foreseen at RAC-53. • It was discussed that skin notation could be needed for organic compounds. Further discussion is foreseen at RAC-53. • Some information on background levels of lead in blood and urine is needed to set potential Biological Guidance Values for inorganic and/or organic lead (information on country specific background levels)	
The expert accompanying the regular Eurometaux stakeholder observer commented on the approach taken for the derivation of the air limit value. The expert accompanying the regular CEFIC stakeholder observer commented on the need for further discussion on the Weight of Evidence approach for selecting the Point of Departure and on the use of skin notation for organic compounds. The Chairman agreed that this was necessary and that it would be further discussed at RAC-53.	
7. Harmonised classification and labelling (CLH) **The all Agenda points on CLH were postponed, as RAC 52B (second week) was cancelled due to Covid-19 concerns.**	
8. Restrictions	
8.1 General restriction issues	
a) Revised Working Procedure for opinion development	**RAC** took note of the Revised Working Procedure for opinion development provided by the SECR.

b) Update from Restriction Task Force	**RAC** took note of the report from the Restrictions Task Force provided by the SECR.
8.2 Restriction Annex XV dossiers	
a) Conformity check	
1. Perflurohexanoic acid (PFHxA)	
The Chairman welcomed the Dossier Submitter's representatives from Germany, occasional stakeholder observers from PlasticsEurope and from EUROFEU, both with 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.	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
The occasional stakeholder observer from PlasticsEurope commented on several aspects of the dossier.	
b) Opinion development	
1. Calcium cyanamide in fertilisers	
The Chairman welcomed the Dossier Submitter's representatives from ECHA and an expert each, accompanying both the Cefic and ECPA regular stakeholder observers. He 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 second draft opinion. RAC agreed with the hazard assessment of the aquatic and sediment compartments for cyanamide and cyanoguanidine and provisionally agreed on the hazard assessment of the aquatic compartment for urea (pending re-evaluation of the selected key study as presented by the Dossier Submitter(DS)). RAC provisionally agreed to the hazard assessment of the terrestrial compartment as proposed by the DS (pending the analysis by the DS of the final report of the higher tier field study on collembolans submitted by AlzChem Trostberg GmbH within the ongoing Consultation).	**The rapporteurs** to prepare the third draft opinion, taking into account RAC-52 discussions and the outcome of the Consultation, by end of April 2020.

RAC agreed with the hazard assessment of the groundwater compartment as proposed by the DS. RAC agreed with the exposure modelling in surface water, sediment and groundwater, as well as with the exposure modelling of the terrestrial compartment, as proposed by the DS. RAC agreed that there is a risk that needs to be addressed from the use of calcium cyanamide in fertilisers.	
The experts accompanying the CEFIC and ECPA stakeholder observers commented on hazard and exposure assessment.	
2. Formaldehyde and formaldehyde releasers	
The Chairman welcomed the Dossier Submitter's representatives from ECHA, the SEAC co-rapporteur (following via WebEx), an expert accompanying the regular Cefic stakeholder observer, as well as two occasional stakeholder observers. He informed the participants that the restriction dossier had been submitted in January 2019 and proposes to restrict the placing on the market of articles releasing formaldehyde at concentrations greater than 0.124 mg/m^3 as measured in accordance with the conditions specified in an appendix to the restriction proposal.	
The rapporteurs presented and RAC discussed the updated fourth draft opinion. RAC agreed on an <u>emission</u> limit value of 0.05 mg/m^3 for articles in building interiors measured according to the conditions in Appendix X. RAC agreed on a <u>concentration</u> limit value of 0.05 mg/m^3 applicable to whole cabin interiors of vehicles of any kind (within the scope of the restriction). RAC agreed that trucks and heavy load vehicles are included in the scope. RAC noted that all passengers in road, rail and water vehicles should have the same level of protection, but agreed to leave the decision to the Commission whether rail and water vehicles are to be included in the scope of the restriction, as robust data on exposure are lacking. RAC agreed that articles for outdoor use only are to be included in the scope. RAC agreed to advise the European Commission to apply a 24-month transition period for all articles and vehicles in the scope.	**The rapporteurs** to make final editorial changes (as discussed during RAC-52) to the adopted RAC opinion. **The rapporteurs**, together with **SECR**, 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 adopted the opinion on this restriction proposal by consensus.	
The Commission observers commented on the scope of restriction, the need for quantification of the risk reduction capacity related to both human health and the emission limit values. The expert accompanying the regular Cefic stakeholder observer commented on the emission limit value and transition time.	
3. Microplastics	
The Chairman welcomed the Dossier Submitter's representatives from ECHA, the SEAC Rapporteur (following via WebEx) and an expert accompanying each of the regular Cefic, ClientEarth, ECPA, EEB, Eurometaux, and stakeholder observers, as well as seven occasional stakeholder observers together with three accompanying experts. He informed the participants that the restriction dossier had been submitted in January 2019. In addition, Sweden (KemI) collaborated with ECHA in preparation of the dossier. The proposal aims at restricting the use of intentionally added microplastic particles to consumer or professional use products of any kind.	
The rapporteurs presented and RAC discussed the seventh draft opinion. <u>Scope of the restriction</u> Solubility derogation (paragraph 3c) - RAC agreed to derogate polymers with a solubility >2g/L according to the criteria in Appendix Y. Biodegradability derogation (paragraph 3d) - RAC supported the rapporteurs' proposal on biodegradation testing: i) OECD screening biodegradation testing (groups 1, 2 and 3); ii) 3 ISO tests (group 4) conditional on delayed (within 10 years) validation using OECD simulation tests in group 5.) iii) OECD Simulation tests (group 5) using Annex XIII P criteria as pass/fail threshold. Furthermore, RAC agreed with the Dossier Submitter's proposal on the type of material to be tested, including for polymer blends, but noted the difficulty of testing larger particle sizes in these tests. RAC agreed with the derogations proposed in paragraph 4 a to g[1]. RAC requested that the opinion should encourage further efforts to reduce loss of pre-production pellets as well as the	**The Rapporteurs** to prepare the eighth draft opinion, taking into account RAC-52 discussions, by end of April 2020. The **ad-hoc WG** on microplastics is requested together with the **Rapporteurs** to consider an alternative biodegradation scheme which might be more practical and enforceable and to report back prior to the next RAC plenary. **SECR** to table the dossier for adoption at RAC-53.

[1] a) use at industrial sites, b) medicinal products for human or veterinary use, c) fertilising products, d) food additives, e) *in vitro* diagnostics, f) sewage sludge and compost and g) food and feed.

presence of secondary microplastics in compost and sewage sludge. For paragraph 4h, RAC preferred the Dossier Submitter's option B i.e. a ban with a transition of 6 years from entry into force. Furthermore, RAC concluded on end-use specific derogations: • 5a: Substances or mixtures containing microplastics where the microplastics are contained by technical means to prevent releases to the environment during end use can be derogated. • 5c: Substances or mixtures where microplastics are permanently incorporated into a solid matrix at the point of use, pending the outcome of the discussion on 5b.	
The expert accompanying the regular Cefic stakeholder observer and the occasional AISE stakeholder observer supported the solubility criteria, while the regular EEB stakeholder observer asked for clarification on testing of soluble polymers. The expert accompanying the regular ECPA stakeholder observer commented on derogations; The expert accompanying the regular Cefic stakeholder observer commented on approach for testing (particel size) and the occasional AISE stakeholder observer asked for clarification on the testing approach. The occasional IFRA stakeholder observer, and the occasional AISE stakeholder observer and the experts accompanying the regular ClientEarth, Eurometaux and occasional EUBP stakeholder observers, commented on the biodegradation testing/derogation. The regular EEB stakeholder observer supported the rapporteurs' proposal. The expert accompanying the occasional EDANA stakeholder observer asked for clarification on testing biodegradation of polymeric components. The Commission observers commented on the delay in the opinion development, noting the need for a thorough evaluation and reflection of the uncertainties, and urged RAC to avoid policy statements. With regard to sports pitch infill material, the Commission observers, the expert accompanying the regular EEB and ClientEarth stakeholder observers had comments/questions in relation to: the growth of the infill supply industry, uncertainties in the release estimates and the availability of alternatives. The regular ClientEarth and the occasional MedTech Europe stakeholder observers commented on derogations 5a[2] and 5c[3], and the occasional EDANA and AISE stakeholder observers had clarifying	

[2] **5a:** contained throughout their service life

[3] **5c:** incorporation into a solid matrix (e.g. pigment extenders in paints, fibre reinforcement of cement and adhesives)

questions on the derogation 5b[4]. The experts accompanying the regular Cefic and ECPA stakeholder observers provided advice on derogation 5b (regarding pellets/polymers).	
4. Perfluorohexane-1-sulphhonic acid, its salts and related substances	
The Chairman welcomed the Dossier Submitter's representatives from Norway (following via WebEx), and the stakeholder observers. He informed the participants that the restriction dossier had been submitted in April 2019 and to restrict the manufacture, use and placing on the market of PFHxS, its salts and related substances as substances, constituents of other substances, mixtures and articles or parts thereof. The restriction proposal aims at reducing the emissions of PFHxS, its salts and their related substances to the environment and to human exposure to a minimum (the main potential exposure pathways are intake via food and drinking water and through exposure to house dust).	
The rapporteurs presented and RAC discussed the third draft opinion. RAC supported the Dossier Submitters' proposal for derogations for aqueous film-forming foams (AFFFs): • RAC noted that the transitional period should be as short as practically possible. A transitional period does allow import of AFFFs (available in Asia) which could result in use and emissions of significant amounts of PFHxS. • RAC also noted that when using and replacing/disposing of existing AFFFs containing PFHxS, all possible measures should be taken to properly handle and rigorously contain the substance(s) and to minimise the releases. • RAC recommended that the use of such foams for training or testing should be avoided, if possible, or if used then the releases should be collected and properly disposed of. RAC supported the proposed limit value of 25 /1000 ppb (for PFHxS and related substances respectively) as sufficient to prevent articles from being intentionally treated with PFHxS and placed on the market and is favorable from an enforcement perspective. RAC concluded that the proposed restriction is practical and enforceable, as well as monitorable. RAC noted specific added descriptions on uncertainties in the underlying estimations and	**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.

[4] **5b:** permanent modification of microplastic phys. properties

assumptions. These are primarily related to uses and emissions, affecting the magnitude of the risk and the suggested risk reduction measures. They do not change the conclusion that there is an uncontrolled risk from PFHxS, its salts and related substances that needs to be addressed. RAC adopted its opinion on this dossier by consensus.	
The regular EEB observer commented on the derogations for AFFFs and the limit values. The Commission observer did not support to add a non-exhaustive list of CAS-numbers in the conditions of the restriction as mentioned in the presentation as this could be viewed as a complete list.	
5. Skin sensitisers in textiles	
The Chairman welcomed the Dossier Submitter's representatives from France and Sweden, an occasional stakeholder observers from EDANA and Euratex, each with an accompanying expert. He informed the participants that the restriction dossier had been submitted in April 2019 and proposes to restrict skin sensitising substances in finished textile, leather, hide and fur articles.	
The Rapporteurs presented and RAC discussed the fifth draft opinion. RAC agreed not to support a dynamic link between this restriction and CPR due to the absence of specific data on sensitization. RAC agreed on a surface weight value of 1.5 kg/m² for leather. This is to be applied in the exposure assessment of skin sensitisers in leather. RAC agreed on migration factors of 5% for disperse dyes in leather and textile and 30% for Cr (VI) in leather and textile, to be used in the exposure assessment RAC recommended 1 mg/kg as a practical concentration limit for Cr(VI) in leather, expecting that technological advances in test methods will lead to a limit of quantification (LoQ) of sufficient sensitivity to enforce said concentration limit. RAC agreed to support a concentration limit of 30 mg/kg for formaldehyde in textile and leather. RAC agreed with the derogations proposed by the Dossier Submitter on active ingredients in biocide products, second hand articles and medical devices, however RAC did not support the proposal of the Dossier Submitter to derogate personal protective equipment articles from the present restriction proposal.	**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

RAC agreed on a 36 months transition period from entry into force of the restriction. RAC noted that, although some obstacles still have to be overcome (for example regarding test methods), the proposed restriction would be practical and monitorable after the transitional period. RAC supported the Dossier Submitter`s proposal for including substances classified in future as skin sensitisers within the group of other substances (concentration limits of 130 and 40 mg/kg; respectively for textile and leather). RAC agreed that the restriction would be monitorable. RAC noted that the risk assessment is conservative and that uncertainty tends towards an overestimation of the risk and not towards underestimation. RAC adopted its opinion on this dossier by consensus.	
The Commission observer commented on risk characterisation. The expert accompanying the EDANA stakeholder observer commented on multi-layered articles.	
9. Authorisation	
9.1 General authorisation issues	
a) Update on incoming/future applications	
ECHA Secretariat presented the information on incoming/future applications, expected workload in 2020/2021 and timelines. The secretariat informed also about OPE/NPE AfAs: approach to the confidentiality claims and consistency check. The Committee was informed about upcoming plans for the AfA Task Force; RAC members who had previously participated in the work of the Task Force expressed the hope that they would again be invited.	
b) Report from RAC WG on AfAs during February 2020 meeting	

The meeting of the 3rd Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation took place on 4-7 February 2020.

Participants: 18 RAC members, 4 Members' advisers, 2 Regular stakeholder observers, 1 commission observer, ECHA.

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

- 176_OPE_Abbott_1 (5 uses)
- 181_OPE_NPE_Roche (uses 2 and 4)
- 171_OPE_Wallac (2 uses)
- 188_OPE_Wallac_2 (use 2)
- 155_OPE_Siemens_2 (5 uses)
- 183_NPE_GEHC_Bio-Sciences (1 use)
- 179_OPE_Octapharma (use 1)
- 157_OPE_Kedrion (1 use)
- 168_OPE_Vetter (1 use)
- 167_OPE_Roche (1 use)
- 169_OPE_Nordisk (1 use)
- 158_OPE_Sanofi (1 use)
- 161_OPE_Swords (1 use)
- 173_OPE_Sobi (1 use)

The working group recommended that the Draft opinion requires full discussion or discussion on specific points at the RAC plenary:

- 148_CTPht_DEZA (1 use)
- 147_CTPht_Bilbaina (1 use)
- 153_CTPht_AO_Bilbaina (1 use)
- 151_CTPht_AO_Rutgers (1 use)
- 175_OPE_Rousselot (1 use)
- 181_OPE_NPE_Roche (use 3)
- 188_OPE_Wallac_2 (use 1)
- 179_OPE_Octapharma (2 uses)
- 174_OPE_Eli_Lilly (1 use)

The working group recommended that the following draft opinions ware suitable for consideration via the A-listing procedure.

- 146_CT_TataSteel (1 use)
- 177_OPE_Abbott_2 (1 use)
- 179_OPE_Octapharma (use 2)
- 166_OPE_Ompi (1 use)
- 159_OPE_Merck (1 use)

ECHA Secretariat presented the Report of the 3rd Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. RAC took note of the Report.	-

9.2 Authorisation applications

a) Discussion on key issues

1. 10 applications for authorisation from November 2020 submission window (OPE/NPE)

RAC discussed the key issues in the ten applications for authorisation.	-

b) Agreement on draft opinions

A. Agreement on draft opinions on AFA by A-listing following the adequate scrutiny (see below) but without plenary debate

1. 146_CT_TataSteel (1 use)
2. 177_OPE_Abbott_2 (1 use)
3. 179_OPE_Octapharma (use 2)
4. 166_OPE_Ompi (1 use)
5. 159_OPE_Merck (1 use)

The Chairman informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 3rd meeting the RAC AFA WG the draft opinions on the five AFA cases have been proposed for agreement via the A-listing procedure. ECHA Secretariat presented the summary of the draft opinions.

RAC agreed by consensus the draft opinions on the five following AFA cases. **146_CT_TataSteel (1 use)** **Use1:** *The use of Chromium (VI) for the manufacture of Electrolytic Chromium/Chromium oxide Coated Steel (ECCS).* 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 this efficiently. The maximum combined inhalation exposure to workers at the site was estimated to be 0.0102 µg Cr(VI)/m^3. The exposure to the general population via inhalation was estimated to be 3.0E-3 µg Cr(VI)/m^3, while via the oral route it was estimated to be 6.46E-3 µg Cr(VI)/kg bw/d. The excess lifetime cancer risk for workers (inhalation route) at both sites is estimated to be 4.1E-5 over 40 years, and for the general	**Rapporteur** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.

population (inhalation and oral route combined) 9.22E-5 over 70 years. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation (a) The applicant shall continue conducting at least annual exposure monitoring programmes for Cr(VI based on relevant standard methodologies or protocols, comprise both static and/or personal inhalation exposure sampling and be representative of: (i) the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance workers; (ii) the OCs and RMMs typical for each of these tasks; (iii) the number of workers potentially exposed; (b) the applicant shall continue conducting monitoring programmes for Cr(VI) emissions to wastewater and air from local exhaust ventilation at least annually. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicant´s site. (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 evaluate the effectiveness of the RMM and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible (closed loading system for the substance and use of powered respirators instead of non-powered full face masks). (d) the applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. (e) the information from the monitoring programmes referred to in points (a) and (b), including the contextual information associated	

with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place; 3. recommendations for the review report Although this is a bridging application, 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. **177_OPE_Abbott_2 (1 use)** **Use 1:** *Professional use as a surfactant, in wash buffer components used in conjunction with Fluorescence In Situ Hybridisation (FISH) test kits and/or their Laboratory Developed Test (LDT) equivalents, in clinical diagnostic use for medical analysis of human tissue and blood samples to identify characteristic genetic abnormalities related to specific disease conditions.* 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 100 kg per year emissions of the substance to the environment across 100-1000 sites in the EU (release factor 100%). RAC agreed: 1. additional conditions for the authorisation All the liquid and solid waste shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment.	

2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a representative survey of their downstream users about the collection and treatment methods that are applied (e.g. incineration) for the liquid and solid waste following from the requirement to collect all liquid and solid waste for adequate treatment. **179_OPE_Octapharma (use 2)** **Use 2:** *Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as component of a chromatography column regeneration solution during the manufacture of a recombinant-derived Factor VIII.* 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 30 kg per year emissions of the substance to the environment. This figure reflects the combined releases from Use 1 and Use 2. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements 3. recommendations for the review report An analysis of possible additional risk management solution with the aim of reducing emission of 4-tert-OPnEO containing effluent to water, with focus on rinsing procedures, should be conducted by the applicant. The result of this analysis should be included in a possible review report, and the inclusion RMM(s) in the process, if identified, included in that report. **166_OPE_Ompi (1 use)** **Use 1:** *Use of octylphenolethoxylates as emulsifier in the siliconisation of glass containers used as primary packaging for one specific medicinal product (NeoRecormon®) of one pharmaceutical company.*	

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. The use applied for results in 0 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. no recommendations for the review report. **159_OPE_Merck (1 use)** **Use 2:** *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a detergent in the purification process of G-CSF (Granulocyte Colony Stimulating Factor) inclusion bodies.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk at Martillac, provided that they are adhered to. For the future site at Billingham, they are expected to be 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 this efficiently. The use applied for may result in up to approximately 0.002 g of emissions of 4-tert-OPnEO per year (calculated residual amounts on equipment picked up during cleaning) of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed for the review report 3. recommendations for the review report The applicant shall undertake, a monitoring programme of the waste water prior to release to the local STP at the Billingham (UK) site. The initial sampling frequency should be sufficient to demonstrate daily fluctuations. Once established, RAC	

recommends that thereafter the applicant should continue with the quarterly / 4 times per year monitoring of 4-tert-OPnEO and its principal degradation products 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.	
B. Agreement on draft opinions on AFA in plenary session	
1. 151_CTPht_AO_Rutgers (1 use)	
Use 1: *4 Use of CTPht/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. Since CTPHT and AO have vPvB and PBT 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 1.9 kg per year emissions of indicator PAHs with PBT, vPvB and carcinogenic properties to the environment. RAC agreed for: 1. no additional conditions for the authorisation	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

2. monitoring arrangements proposed for the review report To further assess, validate and minimise 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. 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 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 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 on-site biological WWTP is measured at least once per month as required according to the release 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. RAC recommends the applicant report the amount solid waste going to the incinerator and the sludge from the on-site WWTP that is delivered to the external STP.	

RAC agreed on the draft opinion by consensus.	
4. 153_CTPht_AO_Bilbaina (1 use)	
Use 1: *Use of CTPht/AO 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. Since CTPHT and AO have vPvB and PBT properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 0.8 kg per year emissions of indicator PAHs with PBT, vPvB and carcinogenic properties to the environment. RAC agreed for: 1. additional conditions for the authorisation RAC proposes that as a condition for the authorisation the applicant shall implement state of the art technical RMMs following the hierarchy of control for the drum filling station and for the pump repair shop. 2. monitoring arrangements proposed for the review report To further assess, validate and minimise 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	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

biomonitoring. 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 monthly monitoring of PAHs in the waste water prior to release to the external STP. The results should be included in the review report, if submitted, including the details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC proposes for the authorisation that the applicant shall implement at least 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 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 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 reconsider the dermal exposure assessment and the outcome should be included in the review report, if submitted. RAC agreed on the draft opinion by consensus.	
4. 147_CTPht_Bilbaina (1 use)	
Use 1: *Use of CTPht as a binder in the manufacture of clay targets.* RAC concluded that alternative(s) presented by the applicant(s), taking into consideration the input of the third parties submitted in the public	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

consultation, if implemented, would reduce the overall risks. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. RAC was unable to propose additional authorisation conditions that would make operational conditions and risk management measures appropriate and effective in limiting the risk for the environment and humans via environment. The exposure to workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3. Since CTPHT has PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 70 – 700 tonnes per year emissions of indicator PAHs with PBT, vPvB and carcinogenic properties to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed for the review report 3. no recommendations for the review report. RAC agreed on the draft opinion by consensus.	
4. 148_CTPht_DEZA (1 use)	
Use 1: *Use of CTPht as a binder in the manufacture of clay targets.* RAC concluded that alternative(s) presented by the applicant(s), taking into consideration the input of the third parties submitted in the public consultation, if implemented, would reduce the overall risks. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. RAC was unable to propose additional authorisation conditions that would make operational conditions and risk	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

management measures appropriate and effective in limiting the risk for the environment and humans via environment. The exposure to workers to CTPHT was estimated to be as described in section 2 of the justification to this opinion. The excess lifetime cancer risk for workers from exposure to CTPHT is estimated to be as described in section 3. Since CTPHT has PBT and vPvB properties, RAC does not support a quantitative risk assessment for the environment or for humans exposed via the environment. The use applied for may result in approximately 70 – 700 tonnes per year emissions of indicator PAHs with PBT, vPvB and carcinogenic properties to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed for the review report 3. no recommendations for the review report. RAC agreed on the draft opinion by consensus.	
5. 171_OPE_Wallac (2 uses)	
Use 1: *Formulation of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) into enhancement solutions and DELFIA standard and maintenance solutions used in In Vitro Diagnostic assays and RUO products as well as maintenance of instruments as a critical ingredient for detection process while measuring europium (or other lanthanide) content of the assay solution.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional authorisation conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The use applied for may result in emissions of the substance to the environment of 0.7 to 6 kg of 4-tert-OPnEO/year (release factor 1.19%). RAC agreed for:	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

1. additional conditions for the authorisation All liquid waste releases which occur during QC control of IVD kits and R&D processes shall be collected and disposed of for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. monitoring arrangements for the authorisation The applicant shall continue to monitor at least 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 results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. no recommendations for the review report. RAC agreed on the draft opinion by written procedure.	
Use 2: *Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in enhancement solutions and DELFIA standard and maintenance solutions as a critical ingredient for detection process while measuring europium (or other lanthanide) content in In Vitro Diagnostic assays and RUO products or during maintenance of instruments.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. The proposed additional authorisation conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The use applied for is estimated to have resulted in up to 7.2 kg of 4-tert-OPnEO emissions in 2017; this is projected by the applicant to increase to 52.5 kg per year of emissions of the substance to	**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 environment by 2047 for a total of around 190 downstream user sites (i.e. an average per site up to 0.04 kg/year in 2017 and up to 0.3 kg/year by 2047). RAC agreed for: 1. additional conditions for the authorisation In addition to all solid waste containing 4-tert-OPnEO, all liquid waste containing the substance shall be collected by the applicant's downstream users for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant is advised to report on a representative survey of their EEA downstream users about the treatment methods that are applied at that point in time (e.g. incineration) following from the requirement to collect all liquid waste containing 4-tert-OPnEO for adequate treatment. RAC agreed on the draft opinion by written procedure.	
6. 188_OPE_Wallac_2 (1 use)	
Use 1: *Formulation of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (as Triton X-100) for use in the assay buffer for the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity.* 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.	**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 approximately 0.0006 kg per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation All liquid waste releases which occur during QC control of IVD kits and R&D processes shall be collected and disposed of for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. monitoring arrangements for the authorisation The applicant shall continue to monitor at least 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 results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. no recommendations for the review report. RAC agreed on the draft opinion by written procedure.	
Use 2: *Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in the assay buffer of the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity.* 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.	**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 approximately 0.135 kg per year emissions of the substance to the environment for a total number of 7 sites. RAC agreed for: 1. additional conditions for the authorisation In addition to the solid waste containing traces of 4-tert-OPnEO generated from the use applied for, all liquid waste containing of 4-tert-OPnEO generated from the use applied for shall be collected by the downstream users for adequate treatment (e.g. incineration). The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users on the measures they have in place to collect for adequate treatment all liquid and solid waste containing 4-tert-OPnEO resulting from the use applied for, and which treatment methods are applied (e.g., incineration). RAC agreed on the draft opinion by written procedure.	
4. 179_OPE_Octapharma (Use 1 only)	
Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as detergent for a virus inactivation step (solvent/detergent treatment) during the manufacture of plasma-derived and recombinant medicinal products.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk for Stockholm site. The planned additional operational conditions and risk management measures described in the application are expected to be appropriate and effective in limiting the risk for the Vienna,	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

Lingolsheim, and Springe sites, provided that they are implemented and 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 up to approximately 225 kg per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation The applicants should continue to implement the planned additional OCs and RMMs for the Vienna and Lingolsheim sites by the Sunset date, in order to reduce the emissions to the environment as far as technically and practically possible. 2. monitoring arrangements for the authorisation The applicants should continue to monitor 4-tert-OPnEO and its principal degradation products at least quarterly / four times per year 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 (except for Stockholm site). 3. recommendations for the review report The information on the implemented OCs and RMMs 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. For the Stockholm site, an analysis of possible additional risk management solution with the aim of reducing emission of 4-tert-OPnEO containing effluent to water, with focus on rinsing procedures, should be conducted by the applicant. The result of this analysis should be included in a possible review report, and the inclusion RMM(s) in the process, if identified, included in that report.	

RAC agreed on the draft opinion by written procedure.	
5. 157_OPE_Kedrion (1 use)	
Use 1: *Use of 4-tert-OPnEO as Triton X-100 as detergent for virus inactivation in the manufacturing process of the human plasma-derived medicinal products Plasmagrade /Plasmasafe and Resusix, as well as Plasminogen (pre-commercialization name) and any subsequent commercialization brand.* 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 this efficiently. The use applied for may result in emissions of the substance to the environment of up to 2.5 kg per year in 2021 with a maximum expected release of 5 kg per year in 2035. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed 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 wastes for adequate treatment and act on the outcome of the feasibility study. RAC recommends that the applicant should, after implementation of all new RMMs, 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. RAC recommends also that the applicant should monitor at least quarterly / four times per year times per year (during the time of operation) 4-tert-OPnEO and its principal degradation products in the waste water after on-site treatment and prior to release to the municipal STP using an analytical method capable of adequately characterising the substance 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 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 agreed on the draft opinion by written procedure.	
6. 168_OPE_Vetter (1 use)	
Use 1: *Use of Octylphenolethoxylates as emulsifier in the siliconisation of glass containers used as primary packaging for two specific medicinal products (NutropinAq® and Lucentis®) of one pharmaceutical company.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risks, provided that they are adhered to. The use applied for may result in up to approximately 1.0 g (0.932 g) per year emissions of the substance to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements proposed for the authorisation 3. no recommendations for the review report. RAC agreed on the draft opinion by written procedure.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
7. 169_OPE_Nordisk (1 use)	
Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a solvent/detergent agent for virus inactivation in the manufacture of pharmaceutical products used in the treatment of rare bleeding disorders.* 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	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

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 less than 2.1 kg per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation The applicant shall assess within a period of two years after the sunset date how the OCs and RMMs can be optimized at the Hillerød site in such a way that the releases of 4-tert-OPnEO to the environment can be further minimized taking into account the outcomes of the measurement programme (see section 8). Detailed summaries of the results with the necessary contextual information shall be included in any subsequent authorisation review report submitted. 2. monitoring arrangements proposed for the authorisation The applicant shall at both sites perform an adequate measurement programme whose results will ensure a representative release estimate within 1 year after sunset date. These results will also be used to define the subsequent monitoring programme (see also section 9). Detailed summaries of the results with the necessary contextual information shall be included in any subsequent authorisation review report submitted. 3. recommendations for the review report Once a monitoring programme can be defined based on the outcomes of the measurement programme and the study about optimizing the OCs and RMMs has been performed RAC recommends that the applicant should, while the plant is in operation, monitor at least quarterly / four times per year 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site municipal STP at both sites 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 agreed on the draft opinion by written procedure.	
8. 167_OPE_Roche (1 use)	
Use 1: *Use of Octylphenolethoxylates as emulsifier in the siliconisation of glass containers used as primary packaging for medicinal products (NeoRecormon® and MIRCERA®).* 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 8.4 g per year emissions of the substance to the environment. The recommendations for the review report are expected to allow RAC to evaluate this efficiently. RAC agreed for: 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, while the plant is in operation, perform at least quarterly / four 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.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC agreed on the draft opinion by written procedure.	
9. 158_OPE_Sanofi (1 use)	
Use 1: *Use of Octoxynol-9 for virus splitting and inactivation step in the manufacturing of influenza vaccines.* 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 recommendations for the review report are expected to allow RAC to evaluate this efficiently. The use applied for may result in emissions of the substance to the environment of up to 10-20 kg/year in the current facility. Emissions of the substance to the environment are expected to decrease to 0.1-0.4 kg/year in the new facility. RAC agreed for: 1. additional conditions for the authorisation *<u>Current facility (BX)</u>* None *<u>New facility (BW)</u>* As soon as the new facility becomes operational, the applicant should carry out a mass balance analysis by measuring the concentration of 4-tert-OPnEO in relevant individual waste streams and comparing this with previous estimations. 2. monitoring arrangements proposed for the authorisation *<u>Current facility (BX)</u>* The applicant should continue to monitor at least quarterly / four times per year (during the time of operation) 4-tert-OPnEO and its principal degradation products in the relevant waste streams prior to release to the on-site holding tanks	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

and prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. *New facility (BW)* The applicant should establish and, after the new facility will become operational, implement a monitoring programme of 4-tert-OPnEO and its principal degradation products in the relevant waste streams from the production prior to release to the on-site holding tanks and prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification (the monitoring should be performed at least quarterly / four times per year during the time of operation). The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report *Current facility (BX)* None *New facility (BW)* 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. The results of the monitoring program, as well as the mass balance and the outcome should be reported. RAC agreed on the draft opinion by written procedure.	
10.161_OPE_Swords (1 use)	
Use 1: *Industrial use of the substance as a surfactant in the purification of the biopharmaceutical drug Orencia, used for the treatment of Rheumatoid Arthritis, Juvenile Idiopathic Arthritis and Adult Psoriatic Arthritis.*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

RAC concluded that the operational conditions and risk management measures described in the application are not expected to be appropriate and effective in limiting the risk. The proposed monitoring arrangements and additional conditions for the authorisation are expected to allow a mass balance analysis and to assess how the operational conditions and risk management measures can be optimized in such a way that the releases of 4-tert-OPnEO to the environment can be further minimized. Monitoring will also provide information on the trends in emissions over the authorisation period. This information should be included in a possible review report. The use applied for may result in 10-50 kg per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation As soon as enough of the measurements obtained through monitoring (as described in section 8) are available, the applicant should carry out a mass balance analysis which takes those measurements into account. Based on the results, the applicant shall assess how the operational conditions and risk management measures can be optimized in such a way that the releases of 4-tert-OPnEO to the environment can be further minimized taking into account the outcomes of the measurement programme. 2. monitoring arrangements proposed for the authorisation As soon as the new facility becomes operational, the applicant should 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 demonstrate daily fluctuations. Once established, RAC recommends that thereafter the applicant should continue with the quarterly / four times per year monitoring of 4-tert-OPnEO and its principal degradation products in the waste	**SECR** to send the draft opinion to the applicant for commenting.

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 information gathered via the measurements referred to in Section 8 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 written procedure.	
11.173_OPE_Sobi (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 manufacture of biopharmaceuticals by Swedish Orphan Biovitrum AB.* 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 approximately 1.12 kg per year emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation After implementation of new carbon filter system, the applicant should perform a new mass balance analysis in order to confirm the predicted effectiveness of implemented RMMs, act on the outcome of the analysis and report the results in any review report. 2. monitoring arrangements proposed for the authorisation The applicant should establish and implement monitoring program of 4-tert-OPnEO and its principal degradation products in the relevant waste stream from the production prior to release to the on-site STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification (the monitoring should be performed at least quarterly / four times per year during the time of operation). The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The results of mass balance analysis and from the monitoring programme should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC agreed on the draft opinion by written procedure.	
12.155_OPE_Siemens_2 (5 uses)	
Use 1: *Use at industrial sites – Use of OPE in isolation of protein from recombinant cell cultures*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

for the production of IVD kits (protein cell extraction). RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in 0.01-0.1 kg per year (exact figure claimed confidential, but known to RAC) emissions of the substance to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements are proposed 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 wastes for adequate treatment and put it in practice if the outcome of the feasibility study is favourable. RAC recommends that the applicant should 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 municipal STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The 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 that the applicant should conduct the mass balance calculation annually. The results should be included in any review report, including details of the calculations carried out, the assumptions made if any, and the corresponding environmental release values. RAC agreed on the draft opinion by consensus.	**SECR** to send the draft opinion to the applicant for commenting.

Use 2: *Use of OPE in formulation of IVD-kit reagents.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The use applied for may result in 0.1 - 1 g per year (exact figure claimed confidential, but known to RAC) emissions of the substance to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements are proposed 3. recommendations for the review report RAC recommends the applicant to further assess in any review report the feasibility to collect the remaining liquid wastes for adequate treatment and put it in practice if the outcome of the feasibility study is favourable. RAC recommends that the applicant should 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 municipal STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The 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 that the applicant should conduct the mass balance calculation annually. The results should be included in any review report, including details of the calculations carried out, the assumptions made, if any, and the corresponding environmental release values. RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

Use 3: *Use of OPE in formulation of IVD- wash 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 report are expected to allow RAC to evaluate this efficiently. The use applied for may result in emissions of 1-5 kg/year (exact figure claimed confidential, but known to RAC) of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation All emissions of 4-tert-OPnEO to the environment, due to 4-tert-OPnEO in the waste water from the cleaning of equipment after formulation and filling processes, shall be subject to adequate treatment with a view to the minimisation of releases to the environment. The applicant shall conduct a mass balance calculation annually. The results shall include details of the calculations carried out, the assumptions made, and the corresponding environmental release values. 2. proposed monitoring arrangements The applicant should 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 municipal 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.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

3. recommendations for the review report The results of the monitoring program referred to in section 8.1, as well as the mass balance and the outcome and conclusions of the actions taken, following the conditions in section 7.1, shall be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
Use 4: *Use of IVD kit reagents on diagnostic 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 to the environment. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk to the environment. The recommendations for the review report are expected to allow RAC to evaluate this efficiently. The use applied for may result in emissions of 100-1,000 kg/year (exact figure claimed confidential, but known to RAC) of the substance to the environment for a total of 1,000-10,000 (exact figure claimed confidential, but known to RAC) downstream users' sites (i.e. an average per site up to 0.1 kg/year). RAC agreed for: 1. additional conditions for the authorisation In addition to all solid waste containing 4-tert-OPnEO, all liquid waste containing the substance shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements are proposed 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users about their efforts to collect all liquid waste for adequate treatment, and which	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

treatment methods are applied (e.g., incineration). RAC agreed on the draft opinion by consensus.	
Use 5: *Use of IVD wash solutions on diagnostic 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 to the environment. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk to the environment. The recommendations for the review report are expected to allow RAC to evaluate this efficiently. The use applied for may result in emissions of 1,000-10,000 kg/year (exact figure claimed confidential, but known to RAC) of the substance to the environment for a total of 1,000-10,000 (exact figure claimed confidential, but known to RAC) downstream users' sites (i.e. an average per site up to 1 kg/year). RAC agreed for: 1. additional conditions for the authorisation In addition to all solid waste containing 4-tert-OPnEO, all liquid waste containing the substance shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release to the sewage system or to surface waters is not considered to be adequate treatment. 2. no monitoring arrangements 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users about their efforts to collect all liquid waste for adequate treatment, and which treatment methods are applied (e.g., incineration). RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

13.175_OPE_Rousselot (1 use)	
Use 1: *Use as surfactant in the manufacturing of low endotoxin gelatin.* RAC concluded that the operational conditions (OCs) and risk management measures (RMMs) described in the application for the current small-scale installation are appropriate and effective in limiting the risk provided they are adhered to. The use applied for results in 0 kg per year of emissions of 4-tert-OPnEO to the environment in the current small scale installation. RAC is of the opinion that the described OCs & RMMs are also expected to be appropriate and effective in limiting the risk in the future large-scale installation provided the OCs, RMMs and proposed additional conditions for the authorisation are implemented and adhered to. The use applied for is expected to result in 0 kg per year of emissions of 4-tert-OPnEO to the environment in the future large-scale installation. RAC agreed for: 1. additional conditions for the authorisation All liquid and solid wastes should be collected and treated in the future large-scale installation as described for the current operation, in order to ensure that releases to the environment are prevented from the future use. If a different method, other than incineration is used for the treatment of liquid wastes in the future installation, the effectiveness of the waste treatment technology should be clearly demonstrated through an appropriate validation method immediately after the commissioning of the new plant. A mass balance report should also be included. The validation data should be available to the enforcement authorities upon request. 2. monitoring arrangements for the authorisation If a different method than incineration is used for the treatment of liquid wastes in the future installation, the applicant should carry out quarterly / four times per year monitoring of 4-tert-OPnEO (parent substance and its primary degradation products) in the waste water prior to	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

release to the aquatic compartment using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. The results should include details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. A mass balance study on 4-tert-OPnEO should also be included to confirm zero releases once the plant is operational. 3. recommendations for the review report The applicant is required to include a detailed description of the OCs & RMMs and the results of the monitoring data, including a mass balance report, in any subsequent authorisation review report in order to corroborate the appropriateness and effectiveness of the OCs & RMMs in place in the future large-scale installation. RAC agreed on the draft opinion by consensus.	
14.174_OPE_Eli_Lilly (1 use)	
Use 1: *Industrial use of a 4-tert-octylphenol ethoxylate compound as a patient safety viral inactivation reagent in the manufacture of human medicines produced from biological systems.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The used applied for may result in maximum emissions up to 5.0 kg/year of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation, The applicant shall continue their efforts to reduce emissions to the environment through the improvement of the on-site biological wastewater treatment plant. 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	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

water other than incineration and acts on the outcome of the feasibility study. 2. no monitoring arrangements proposed for the authorisation 3. recommendations for the review report RAC recommends that the applicant should continue to monitor at least quarterly / four times per year 4-tert-OPnEO and its principal degradation products in the waste water after release from the on-site WWTP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC agreed on the draft opinion by written procedure.	
15.183_NPE_GEHC_Bio-Sciences (1 use)	
Use 1: *Industrial use of emulsifiers containing nonylphenols ethoxylated for the manufacture of chromatography resins used by the biopharmaceutical industry, food & beverage sector and academia.* 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 recommendations for the review report are expected to allow RAC to evaluate this efficiently. The use applied for may result in emissions of the substance to the environment of up to 4.17-16.67 kg/year (yearly average over the requested 12-year review period).	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC agreed for: 1. additional conditions for the authorisation All emissions of 4-NPnEO to the environment shall be subject to adequate treatment. RAC recommends that the applicant should conduct the mass balance calculation annually. The results should be included in any review report, including details of the calculations carried out, the assumptions made if any, and the corresponding environmental release values. 2. monitoring arrangements for the authorisation The applicant should continue to monitor at least quarterly / four times per year (during the time of operation) the concentration and total amount of 4-NPnEO and its principal degradation products in the waste water prior to release to the off-site municipal STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The results of the monitoring programme referred to in section 8.1, as well as the outcome and conclusions of the actions taken, following the condition in section 7.1, shall be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
16.176_OPE_Abbott_1 (5 uses)	
Use 1: *Industrial use as a surfactant in the formulation of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.* RAC concluded that the operational conditions and risk management measures described in the	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

application are not appropriate and effective in limiting the risk. The proposed additional authorisation conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The use applied for may result in approximately 116.16 kg (from that 37.27 kg Sligo, 30.65 kg/year Longford, 48.24 kg/year in Wiesbaden) per year emission of 4-tert-OPnEO to the environment. RAC agreed for: 1. additional conditions for the authorisation All liquid waste releases shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the public sewer system is not considered to be adequate treatment. 2. monitoring arrangements for the authorisation RAC recommends that the applicant should monitor at least quarterly /four times per year 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 at an appropriately low level of quantification. The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. no recommendations for the review report. RAC agreed on the draft opinion by written procedure.	
Use 2: *: Professional use as a surfactant in the final use of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.* RAC concluded that the operational conditions and risk management measures described in the	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

application are not appropriate and effective in limiting the risk. The proposed additional authorisation conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. Per year the use applied for may result in 4-tert-OPnEO emissions to the environment of approximately 514 kg in wastewater and 13 kg in solid waste. RAC agreed for: 1. additional conditions for the authorisation All liquid and solid waste shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters in not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a new representative survey of their downstream users about their efforts to collect all liquid waste for adequate treatment, and which treatment methods are applied (e.g., incineration). RAC agreed on the draft opinion by written procedure.	
Use 3: *Industrial use as a surfactant in the formulation of system solutions (Pre-Trigger and Trigger), for use with In-Vitro Diagnostic Devices (IVDs) 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 to the environment. Per year the use applied for may result in 4-tert-OPnEO emissions to the environment of approximately 53.12 kg from the Sligo plant. RAC agreed for:	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

1. additional conditions for the authorisation The applicant should follow the substitution activities described in the application. 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. RAC agreed on the draft opinion by written procedure.	
Use 4: *Professional use of system solutions (Pre-Trigger and Trigger) in the final use of the In-Vitro Diagnostic Devices (IVDs) 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 authorisation conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. Per year the use applied for may result in 4-tert-OPnEO emissions to the environment of approximately 4,680 kg in wastewater and 25.40 kg of 4-tert-OPnEO in solid waste. RAC agreed for: 1. additional conditions for the authorisation The applicant should follow the substitution activities described in the application. 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. RAC agreed on the draft opinion by written procedure.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
Use 5: *Industrial use as a surfactant in the extraction and purification of antigens for incorporation into In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

Per year the use applied for may result in 4-tert-OPnEO emissions to the environment of approximately 0.03 kg. 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 wastes for adequate treatment and put it in practice if the outcome of the feasibility study is favourable. RAC agreed on the draft opinion by written procedure	
17.181_OPE_NPE_Roche (3 uses)	
Use 2: *Use of Octyl- and Nonylphenolethoxylates in the formulation and filling of in vitro diagnostic (IVD) assays specified in Appendix 1 to the AoA.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the environment. The recommendations defined for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 0.92 kg/year of 4-tert-OPnEO and of 1.26 kg/year of 4-NPnEO to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report The applicant to show in the review report that, during the substitution process, all measures to further collect the remaining liquid waste were periodically re-assessed and considered, to show that the release was all the time the lowest possible. RAC recommends that the applicant should monitor at least quarterly / four times per year 4-tert-OPnEO and 4-NPnEO and their	**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 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 agreed on the draft opinion by written procedure.	
Use 3: *Use of Octyl- and Nonylphenolethoxylates in in vitro diagnostic (IVD) assays specified in Appendix 1 to the AoA.* 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 use applied for may result in up to approximately 524 kg of 4-tert-OPnEO and 32 kg of 4-NPnEO per year of emissions of the substances to the environment. This is equivalent to less than 52g of 4-tert-OPnEO and less than 3g of 4-NPnEO on average per each of the more than 10 000 of the applicant's analysers installed throughout the EEA. RAC agreed for: 1. additional conditions for the authorisation The applicant should follow the substitution activities described in the application. 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report. RAC agreed on the draft opinion by written procedure.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
Use 4: *Use of Octyl- and Nonylphenolethoxylates in the production of proteins and the conjugation of latex beads, both being used as components or*	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

for the production of components of in vitro diagnostic (IVD) assays, research or quality control products and other, e.g. analytical applications (processes specified in Appendix 1 to the AoA). RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the environment. The recommendations defined for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 0.73 kg/year 4-tert-OPnEO 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 The applicant to show in the review report that, during the substitution process, all measures to further collect the remaining liquid waste were periodically re-assessed and considered, to show that the release was all the time the lowest possible. RAC recommends that the applicant should carry out quarterly / four times/year monitoring of 4-tert-4-tert-OPnEO (parent substance and its primary degradation products) in the waste water prior to release to the municipal STP at the site of Mannheim and after the on-site STP of Penzberg using an analytical method capable of adequately characterising the substance in water and at an appropriately low level of detection. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC agreed on the draft opinion by written procedure.	**SECR** to send the draft opinion to the applicant for commenting.
c) Adoption on opinions	

1. 135_CT_TES (1 use)
2. 138_OPE_Boehringer (1 use)

The Chairman informed the Committee that both Applicants submitted comments on the draft opinions agreed at RAC 50 (CT_TES on 13/01/2020 and OPE_Boehringer on 16/01/2020).

1. 135_CT_TES (1 use)

Use 1: *Use: Surface treatment for the manufacture of grain-oriented electrical steel used in magnetic circuits of electric devices, in particular magnetic cores of high-performance transformers.* 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 this efficiently. The maximum combined inhalation exposure to workers at both sites was estimated to be 0.39 µg Cr(VI)/m3. 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 via inhalation was estimated to be 9.44E-08 mg Cr(VI)/m^3 for Gelsenkirchen and 1.43E-07 mg Cr(VI)/m^3 for Isbergues, while via the oral route it was estimated to be 3.20E-10 mg Cr(VI)/kg bw/d for Gelsenkirchen and 1.55E-07 mg Cr(VI)/kg bw/d for Isbergues. The excess lifetime cancer risk for workers at both sites is estimated to be 1.56E-03 over 40 years, and for the general population 2.74E-06 over 70 years for Gelsenkirchen, and 4.27E-06 over 70 years for Isbergues. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report For any subsequent authorisation review report, the applicants should provide occupational exposure measurements representative for all tasks with a potential	**SECR** to send the final opinion to the EC, MSs and the Applicant.

for exposure to Cr(VI), including maintenance tasks, and for the number of workers that are potentially exposed, in order to demonstrate that the RMMs and OCs implemented are appropriate and effective in limiting the risks. The applicants should further refine the assessment of releases to the environment and associated exposure to the general population, by presenting separate environmental contributing scenarios for each site, to better represent the specificities of the sites the application covers. RAC rapporteurs reviewed the applicant's comments. RAC adopted the final opinion by consensus with only editorial changes made to the draft opinion.	
4. 138_OPE_Boehringer (1 use)	
Use 1: *Use of 4-tert-OPnEO in a washing buffer to purify biological APIs (active pharmaceutical ingredients) during the production of Palivizumab and Moxetumomab pasudotox-tdfk* 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 45 mg per year emissions of the substance to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report RAC rapporteurs reviewed the applicant's comments. RAC adopted the final opinion by consensus with only editorial changes made to the draft opinion for clarification.	**SECR** to send the final opinion to the EC, MSs and the Applicant.
d) Status update	

1. 149_CTPht_Nalon (1 use)
2. 150_CTPht_AO_Koppers (1 use)
3. 152_CTPht_AO_RainCarbon (1 use)

The Chairman informed the Committee that the initial discussion on the remaining three CTPht formulation **149_CTPht_Nalon, 150_CTPht_AO_Koppers and 152_CTPht_AO_RainCarbon** took place at the February meeting of the RAC AFA WG. It was based on the presentation without DOs.

Due to limitation of resources on the site of the ECHA Secretariat the discussion on those 3 cases has been postponed until the May meeting of the RAC AFA WG. The DOs on **149_CTPht_Nalon, 150_CTPht_AO_Koppers and 152_CTPht_AO_RainCarbon** will be scheduled for agreement at RAC 53.

10. AOB

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11. Action points and main conclusions of RAC-52

SECR to upload the adopted action points to CIRCA BC.

Part III. List of Attendees of the RAC-52 meeting

RAC Members
Andreou Kostas
Barański Bogusław
Biró Anna
Bjørge Christine
Borg Daniel
Branisteanu Radu (co-opted member)
Brovkina Julija
Chiurtu Elena (co-opted member)
de la Flor Tejero Ignacio
Dobrev Ivan
Dunauskienė Lina
Hakkert Betty
Heederik Dick (co-opted member)
Husa Stine
Kadiķis Normunds
Kapelari Sonja
Karadjova Irina
Leinonen Riitta
Lund Bert-Ove
Martínek Michal
Menard Srpčič Anja
Moeller Ruth
Moldov Raili
Murray Brendan
Neumann Michael
Peczkowska Beata
Rucki Marian
Santonen Tiina
Schlüter Urs
Schulte Agnes
Schuur Gerlienke
Sørensen Hammer Peter
Sogorb Miguel A.
Spetseris Nikolaos
Stahlmann Ralf
Tobiassen Lea Stine
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted member)
Varnai Veda
Apologies, Members
Agapiou Agapios
Aquilina Gabriele
Carvalho João
Chankova-Petrova Stephka
Geoffroy Laure
Hartwig Andrea (co-opted member)
Losert Annemarie
Paris Pietro
Pribu Mihaela
Printemps Nathalie
Séba Julie
Tsitsimpikou Christina
Zeljezic Davor

Members' advisers
Hoffmann Frauke (Agnes Schulte)_formaldehyde
Commission
Podniece Zinta (DG EMPL)
Tosetti Patricia (DG EMP)
WPC observers (OELs)
Levy Patrick (Employer´s Interest Group)
Tony Musu (Workers Interest Group)
Sirkku Saarikoski (Government Interest Group)
Invited experts
Guerriero Lee (UEFA)
Rodriguez Wendy (replacing RAC member Julie Seba)
Viegas Susana (replacing RAC Member Joao Carvalho)
Dossier Submitter
Kacan Stefan (DE)_PFHxA
Regular stakeholder observers
Bernard Alice (ClientEarth)
Van de Broeck Steven (Cefic)
Romano Mozo Dolores (EEB)
Rowe Rocky (ECPA)
Verougstraete Violaine (Eurometaux)

Occasional stakeholders
Angiulli Francesca (A.I.S.E)_Restriction: microplastics
Barbu Luminita (EDANA)_Restriction: microplastics, Skin sensitisers
Buijs Nathalie (MedTech Europe)_OEL: lead and diisocyanates; Restriction: microplastics, AfA: all AfAs
Cassart Michel (PlasticsEurope)_Restriction: formaldehyde
Laroche Charles (IFRA)_Restriction: microplastics
Luleva Parvoleta (ETRMA)_Restriction: formaldehyde_OEL: diisocyanates
Von Pogrell Hasso (EUBP)_Restriction: microplastics
Stakeholder experts
Berg Madeleine (EEB/FIDRA)_Restriction: microplastics
Binks Steve (Eurometaux/European Association of the metals Industry)_OEL: lead
Bock Ronald (PlasticsEurope/Fluoropolymer)_Restriction: PFHxA
Bonifay Sebastien (ECPA/Corteva – representing ECHA PPP)_Restriction: microplastics
Dobe Christopher (ECPA/Syngenta representing ECPA PPP)_Restriction: microplastics
Jackson Ffion (MedTech/Siemens Healthineers)_Restriction: microplastics
Jenner Karen (IFRA/Givaudan)_Restriction: microplastics
Klasse Hans-Jürgen (ECPA/Alzhem Trostberg GmbH)_Restriction: calcium cyanamide
Mortier Nike (ClientEarth/OWS)_Restriction: microplastics

Ott Wolfgang (EDANA/Kelheim Fibres GmbH)_Restriction: microplastics, skin sensitisers
Rahbaran Shayda (EDANA/Nonwovens Lenzing AG)_Restriction: skin sensitisers
Salthammer Tunga (Cefic/Fraunhofer WKI)_Restriction: formaldehyde
Sendor Thomas (Cefic/Alzchem Trostberg GmbH)_Restriction: calcium cyanamide
Serrano Ramon Blanca (Cefic)_Restriction: microplastics
Strauss Markus (Euratex/IVGT)_Restriction: skin senstitisers
Terlingen Leon (Eurometaux/FertilizersEurope)_Restriction: microplastics
Unterberger-Henig Elif (Cefic/ISOPA/ALIPA)_OEL: diisocyanates
Williams Cris (Eurometaux/International Lead Association):OEL: lead
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Urban Klaus (formaldehyde)
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Pillet Monique
Regil Pablo
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Roggeman Maarten
Sadam Diana
Sihvonen Kirsi
Simon Rupert
Simpson Peter
Smilovici Simona
Sosnowski Piotr
Stasko Jolanta
Stockmann-Juvala Helene
Tanarro Celia
Uphill Simon
Vaananen Virpi
Vainio Matti
Van Haelst Anniek

Part II. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-52 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-52 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-51 meeting

ANNEX IV Administrative issues and information items

12 March 2020
RAC/A/52/2020
DRAFT

Final Agenda
52nd meeting of the Committee for Risk Assessment

9 - 13 March 2020
and
~~17 – 20 March 2020~~ CANCELLED

ECHA Conference Centre (Telakkakatu 6, Helsinki)

Monday 9 March starts at 09.00
Friday 13 March breaks at 13.00
~~Tuesday 17 March resumes at 14.00~~
~~Friday 20 March ends at 13.00~~

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/52/2020
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) Report on RAC-51 action points, written procedures and update on other ECHA bodies

RAC/52/2020/01
Room document
For information

b) RAC Work Plan for all processes

For information

Item 6 –Health based exposure limits at the workplace

6.1 Health based exposure limits at the workplace

a) Opinion development
   1) Diisocyanates – first draft opinion
   2) Lead and its compounds – first draft opinion

For discussion

~~Item 7 – Harmonised classification and labelling (CLH)~~

~~7.1 CLH dossiers~~

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

- Acetamiprid (ISO): acute toxicity (oral)
- Isoflucypram: physical hazards, acute toxicity, STOT SE, skin corrosion / irritation, serious eye damage / eye irritation, respiratory and skin sensitisation, germ cell mutagenicity, aspiration hazards, hazards to the aquatic environment

Gilliland Douglas

- nium bromide: acute toxicity (dermal and oral), STOT SE, serious eye damage /eye irritation, skin corrosion / irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity
- Dimoxystrobin (ISO): acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, hazards to the aquatic environment
- Cyfluthrin (ISO): physical hazards, acute toxicity (dermal), skin corrosion / irritation, serious eye damage / eye irritation
- Beta-cyfluthrin (ISO): physical hazards, acute toxicity (dermal), skin corrosion / irritation, serious eye damage / eye irritation
- 2,4,6-tri-tert-butylphenol: acute toxicity (oral, dermal), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE
- Sodium pyrithione: physical hazards, acute toxicity, skin corrosion/ irritation, serious eye damage / eye irritation, STOT SE, germ cell mutagenicity, carcinogenicity, hazards to the aquatic environment
- Pendimethalin (ISO): hazards to the aquatic environment
- Pyridalyl (ISO): physical hazards (except explosives and self-reactive substance), acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, skin

sensitisation, germ cell mutagenicity, carcinogenicity, STOT RE, STOT SE, hazards to the aquatic environment

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

~~1. acetamiprid (ISO)~~
~~2. isoflucypram~~
~~3. ammonium bromide~~
~~4. dimoxystrobin (ISO)~~
~~5. cyfluthrin (ISO)~~
~~6. beta-cyfluthrin (ISO)~~
~~7. diethylene glycol monomethyl ether (2-(2-methoxyethoxy ethanol) (DEGME)~~
~~8. 2,4,6-tri-tert-butylphenol~~
~~9. sodium pyrithione~~
~~10. bisphenol A~~
~~11. pendimethalin (ISO)~~
~~12. pyridalyl (ISO)~~
~~13. methyl methacrylate~~

For discussion and adoption

Item 8 – Restrictions

8.1 **General restriction issues**

a) Revised Working Procedure for opinion development

RAC/52/2020/02
For information

b) Update from Restriction Task Force

For information

8.2 Restriction Annex XV dossiers

a) Conformity check
   1) Perfluorohexanoic acid (PFHxA)

For discussion and agreement

b) Opinion development
   1) Calcium cyanamide in fertilisers – second draft opinion

For discussion

   2) Formaldehyde and formaldehyde releasers – final draft opinion
   3) Microplastics – sixth draft opinion / final draft opinion
   4) Perfluorohexane-1-sulphhonic acid, its salts and related substances – final draft opinion (PFHxS)
   5) Skin sensitisers in textile – final draft opinion

For discussion and adoption

Item 9 – Authorisation

9.1 General authorisation issues

a) Update on incoming/future applications
b) Report from RAC WG on AfAs during February 2020 meeting

For information/discussion

9.2 Authorisation applications

a) Discussion on key issues
   1) 10 applications for authorisation from November 2020 submission window (OPE/NPE)

For discussion

b) Agreement on draft opinions

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

1) 159_OPE_Merck (1 use)
2) 146_CT_TataSteel (1 use)
3) 179_OPE_Octapharma (Use 2 only)
4) 166_OPE_Ompi (1 use)
5) 177_OPE_Abbott_2 (1 use)

B. Hazard classes for agreement with plenary debate

1) 151_CTPht_AO_Rutgers (1 use)
2) 153_CTPht_AO_Bilbaina (1 use)
3) 147_CTPht_Bilbaina (1 use)
4) 148_CTPht_DEZA (1 use)
5) 171_OPE_Wallac (2 uses)
6) 188_OPE_Wallac_2 (1 use)
7) 179_OPE_Octapharma (Use 1 only)
8) 157_OPE_Kedrion (1 use)
9) 168_OPE_Vetter (1 use)
10) 169_OPE_Nordisk (1 use)
11) 167_OPE_Roche (1 use)
12) 158_OPE_Sanofi (1 use)
13) 161_OPE_Swords (1 use)
14) 173_OPE_Sobi (1 use)
15) 155_OPE_Siemens_2 (5 uses)
16) 175_OPE_Rousselot (1 use)
17) 174_OPE_Eli_Lilly (1 use)
18) 183_NPE_GEHC_Bio-Sciences (1 use)
19) 176_OPE_Abbott_1 (5 uses)
20) 181_OPE_NPE_Roche (3 uses)

For discussion and agreement

c) Adoption on opinions
   1) 135_CT_TES (1 use)
   2) 138_OPE_Boehringer (1 use)

For discussion and adoption

d) Status update
   1) 149_CTPht_Nalon (1 use)
   2) 150_CTPht_AO_Koppers (1 use)
   3) 152_CTPht_AO_RainCarbon (1 use)

For information

Item 10 – AOB

Item 11 – Minutes of RAC-52

Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-52

For adoption

PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-52 – 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 9 March 2020: Morning 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 8 – Restrictions

Monday 9 March 2020: Afternoon session

Item 8 – Restrictions

Tuesday 10 March 2020: Morning session

Item 6 – Health based exposure limits at the workplace

Tuesday 10 March 2020: Afternoon session

Item 6 – Health based exposure limits at the workplace
Item 8 – Restrictions

Wednesday 11 March 2020: Morning session

Item 8 – Restrictions

Wednesday 11 March 2020: Afternoon session

Item 8 – Restrictions

Thursday 12 March 2020: Morning session

Item 8 – Restrictions
Item 9 – Authorisation applications

Thursday 12 March 2020: Afternoon session

Item 9 – Authorisation applications

Friday 13 March 2020: Morning session

Item 9 – Authorisation applications
Item 11 – Minutes of RAC-52

Annex II (RAC 52)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 52 meeting.

Document number	Title
RAC/A/52/2020	Final Draft Agenda
RAC/52/2020/01 Room document	Administrative issues and information items
RAC/52/2020/02	Revised Working Procedure for opinion development

ANNEX III (RAC-52)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
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
Perfluorohexane-1-sulphhonic acid, its salts and related substances	Christine BJORGE	Working for the CA submitting the dossier. No personal involvement.
	Stine HUSA	Working for the CA submitting the dossier. No personal involvement.
Skin sensitisers in textile	Daniel BORG	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.
	Bert-Ove LUND	Working for the CA submitting the dossier; personal involvement. Asked to refrain from voting in the event of a vote on this substance.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Article 77.3(c)		
no dossiers	-	-
Health based exposure limits at the workplace		
No declarations		
Restrictions		
Perfluorohexanoic acid – PFHxA (DE)	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ivan DOBREV	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
Applications for Authorisation		

Annex IV (RAC-52)

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-51 Action Points

The RAC-51 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
Written procedure for adoption of the minutes of RAC-51	31 January 2020	closed
Written procedure for adoption of RAC opinion on Cobalt salts	14 February 2020 (extended for 48 hours afterwards)	closed

2.2 RAC consultations (status by 3 March 2020)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
cyfluthrin (ISO)	14 February 2020	closed
beta-cyfluthrin (ISO)	14 February 2020	closed
pyridalyl (ISO)	14 February 2020	closed
2,4,6-tri-tert-butylphenol	11 February 2020	closed
pendimethalin (ISO)	14 February 2020 *(ENV only)* 21 February 2020 *(HH only)*	closed closed
ammonium bromide	14 February 2020	closed
methyl methacrylate	5 February 2020	closed
sodium pyrithione	14 February 2020	closed
isoflucypram	13 February 2020	closed
diethylene glycol monomethyl ether	30 January 2020	closed
bisphenol A	14 February 2020	closed
dimoxystrobin (ISO)	13 February 2020	closed
acetamiprid (ISO)	14 February 2020	closed
Application for Authorisation / Review Report		

Subject / document	Deadline	Status / follow-up
154_OPE_Siemens_1, 156_OPE_Hospira, 160_OPE_Merck_2, 162_OPE_LFB, 163_OPE_Rentschler, 164_OPE_Baxter, 165_OPE_bioMerieux_2, 170_OPE_Diasorin, 172_OPE_DIAGAST, 180_OPE_NPE_Bio-Rad, 182_NPE_Abbott, 184_OPE_Lilly, 185_OPE_NPE_Idexx, 186_OPE_NPE_Beckman, 187_OPE_AGC, 188_OPE_Wallac_2, 189_OPE_Lonza, 190_OPE_TEVA, 191_NPE_Sekisui Consultations on applications for authorisation	8 January 2020	closed
192_OPE_Pfizer_2, 194_OPE_Yposkesi, 195_OPE_IL, 200_OPE_RSI, 201_OPE_Vetter_2, 204_OPE_Merck_3, 205_OPE_Pfizer, 206_OPE_Sanquin Consultations on applications for authorisation	8 April 2020	ongoing
Restrictions		
Consultations on the fourth draft opinion on formaldehyde and formaldehyde releasers, and on the sixth draft opinion on Microplastics	25 February 2020 24 February 2020	closed
Consultations on the third and fourth versions of the draft opinions on PFHxS and on skin sensitisers, on the second version of the draft opinion on calcium cyanamide	21 February 2020 25 February 2020	closed
Art. 77.3(c) request		
no consultations		
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.	19 February – 4 March 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	21-28 January 2020	one volunteer
Article 77 (3)(c) requests		
Call for expression of interest → request to RAC to review new information in relation to the harmonised classification and labelling of the substance N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid) (DTPA, EC Number: 200-652-8)	15-22 January 2020	one volunteer
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[5].		
Restriction No calls		
Health based exposure limits at the workplace Call for expression of interest co-rapporteur asbestos	20 February - 4 March 2020	four volunteers

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 Chairman; 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 classification and labelling of the substance N-carboxymethyliminobis (ethylenenitrilo)tetra(acetic acid) (DTPA, EC Number: 200-652-8)	29 January 2020	closed No comments were received from RAC members on the recommendation of the Chairman; the RAC (co-)Rapporteurs were appointed with tacit agreement.
Restrictions – no written procedures			
Applications for Authorisation– no written procedures			

[5] 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)

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	
CTPht_Ariane (1 opinion)	7 January 2020
SD_Bussi (1 opinion)	25 February 2020
-	-