

Helsinki, 16 November 2022  
**RAC/63/2022/02**

**63<sup>RD</sup> MEETING OF THE COMMITTEE FOR RISK ASSESSMENT**

**Concerns:** Report from the November Restriction WG  
**Agenda Point:** 9.1.1.  
**Action requested:** For information

**RAC WG/REST/R/7/2022**

**9 November 2022**

**RAC/63/2022/02**

**Report  
of the Meeting of the Committee for Risk Assessment  
Restrictions Working Group (RAC REST WG)  
reporting to RAC-62**

**ECHA Conference Centre  
(Telakkakatu 6, Helsinki)  
via Webex**

**Tuesday 8 November 2022 at 14.00  
to  
Wednesday 9 November 2022 at 17.30**

**Summary Record of the Proceedings**

**1. Welcome and apologies**

The Chair of RAC, Tim Bowmer, welcomed the participants of the 7<sup>th</sup> meeting of the RAC Working Group on restrictions. He noted that Mercedes Marquez-Camacho, Christiaan Logtmeijer and Peter Simpson would chair sections of the meeting and informed the group that consultations had been organised on the three restriction agenda items prior to the meeting; the fourth item (PFASs in firefighting foams) was for information only.

**2. Adoption of the Agenda**

The Chair reviewed the agenda for the meeting (RAC WG/REST/7/2022), which was adopted with minor amendments and is attached to this Report as Annex I.

**3. Declarations of conflicts of interests to the Agenda**

The Chair requested all participants to declare any potential conflicts of interest to any of the agenda items. One participant of the meeting declared a potential conflict of interest on cases scheduled for the discussion as presented in Annex III to this

Report. The four WG Chairs, all declared that they had no potential interests related to any of the agenda points for the meeting.

#### 4. Restriction proposals

<b>1. Per- and polyfluoroalkyl substances (PFASs) in firefighting foams – status update</b>	
<p>The WG Chair Mercedes Marquez-Camacho welcomed the Dossier Submitter's representatives from ECHA and their invited experts. The WG Chair also welcomed the regular stakeholders from CropLife Europe and Cefic including their accompanying experts. She also welcomed the occasional stakeholder from Eurofeu. She informed the participants that the restriction dossier had been submitted in January 2022 and concerns PFASs in firefighting foams.</p>	
<p>The Working Group discussed the rapporteurs' assessment of the <b>comments received in the consultation on the Annex XV report</b>, focusing on the following items:</p> <ul style="list-style-type: none"> <li>• Persistence of PFASs</li> <li>• Pollution hot spots at firefighting training sites</li> <li>• Feasibility of meeting the concentration limit value in contaminated equipment</li> <li>• Potential emissions related to the concentration limit value proposed</li> <li>• Portable fire extinguishers</li> <li>• PFAS-foam management plans</li> <li>• Climate impact of fire water incineration</li> </ul>	<p>No discussion or report back is expected at RAC-63.</p> <p><b>SECR</b> to table the 3<sup>rd</sup> draft opinion for discussion at RAC-64 REST WG in February 2023.</p> <p><b>Rapporteurs</b> to take the WG discussions into account for the next version of the opinion by January 2023 prior to the February RAC-64 Restriction Working Group. The RAC opinion deadline has been extended until March 2023 due to the significance of the third-party comments on the Annex XV report received.</p>
<p>The occasional stakeholder observer from Eurofeu commented on exposure assessment assumptions, portable fire extinguishers, foam management plans and analytical methods. The Dossier Submitter provided clarifications regarding the comments received during the consultation, waste disposal issues and analytical methods.</p>	
<b>2. DMAC/NEP – second draft opinion</b>	
<p>The RAC Chair Tim Bowmer welcomed the Dossier Submitter's representative from the Netherlands. He also welcomed the regular CEFIC stakeholder, and the occasional stakeholder from the European Man-Made Fibres Association (CIRFS), including their accompanying experts. The chair informed the participants that the restriction dossier had been submitted in April 2022 and concerns occupational exposure to DMAC and NEP and proposed harmonised worker DNELs.</p>	
<p><b>No further discussion recommended</b></p>	<p><b>RAC members</b> to provide the remaining written comments on the</p>

*The WG discussed and recommended that the following could be agreed without further discussion at RAC-63:*

Hazard:

- DMAC: Systemic long-term dermal DNEL of 1.8 mg/kg bw/day based on a developmental toxicity study in rats that resulted in the lowest DNEL.

- DMAC: Biomarker DNEL of 15 mg NMAC/g creatinine, corresponding approximately to 20 mg NMAC/L urine with sampling post-shift at the end of the work week.

- NEP: Local acute inhalation DNEL (4.6 mg/m<sup>3</sup>) is not supported by the available data and therefore not proposed. The foreseen long-term Inhalation DNEL of 4 mg/m<sup>3</sup> also protects from local nasal effects.

- NEP: Biomarker DNEL of 20 mg 5-HNEP+2-HESI/L urine with sampling pre-shift the day following exposure and at the end of the working week confirmed; additional values for 5-HNEP (10 mg/L = 7 mg/g creatinine; sampled post-shift, especially in case of inhalation exposure) and 2-HESI (8 mg/L = 6 mg/g creatinine sampled next morning).

Exposure:

- Exposure estimates (tier 1 modelling) presented by the DS can be used as a conservative basis for the risk characterisation.

- The measured data already provided for some uses is missing (some) contextual information and their representativeness for all uses is uncertain. Further monitoring data and/or further contextual information might still be received during the consultation on the Annex XV report and could still be considered.

second draft opinion by 11 November 2022 via the written commenting round.

**Rapporteurs** to prepare a short presentation to RAC-63 to report the recommendations of the group, in particular in relation to the DNELs.

**Rapporteurs** to take the WG discussions (and outcome of RAC-63 and the consultation on the Annex XV report) into account for the next version of the opinion by January 2023 prior to the February RAC-64 Working Group on restrictions.

**Secretariat** to table this item for discussion at RAC-63 in November/December and RAC-64 REST WG in February 2023.

**Secretariat** to consider updating the existing guidance on the NMP restriction for DMAC and NEP.

**Stakeholders** are invited to provide additional exposure information, including contextual information (or contextual information for exposure data submitted in the Annex XV report consultation) for measurements and number of workplaces using DMAC and NEP in the Annex XV consultation.

Risk Characterisation:

- DNELs for workers are justified.
- Risks for workers cannot be excluded for all uses and are not sufficiently controlled. This can be concluded despite the underlying uncertainties in the exposure assessment.
- The uncertainties lead to conservatism in the risk characterisation.
- For some uses RMMs and OCs seem insufficient to control the risks as RCRs are above 1.

Existing RMMs and OCs:

- It is not possible to evaluate the existing OCs and RMMs as they are diverse and use-specific and data is mainly lacking.
- For some uses RMMs and OCs seem insufficient to control the risk as RCRs are above 1.

Action required at an EU-wide basis

- Action at EU level is needed to ensure the same protection across the EU.

Risks of alternatives

- As the intention of the restriction is to limit workplace exposure rather than require substitution, no further detailed analysis on the risks of alternatives is needed.

Other regulatory RMOs

- Some arguments favour a restriction over setting a binding OEL under CMDR (similar restrictions for aprotic solvents already apply for which guidance has been developed).

**Further work required**

*The WG recommended that the rapporteurs continue their work on these elements and present the next version of the opinion at the RAC-64 REST WG:*

<ul style="list-style-type: none"> <li>- Further monitoring data and contextual information to be reviewed if received as part of the consultation on the Annex XV report.</li> <li>- Uncertainties, effectiveness, practicality and monitorability of the proposed restriction options.</li> </ul>	
<p>The occasional stakeholder observer from CIRFS and their expert commented on the hazard assessment, exposure assessment, risk characterisation and justification for action required on a Union-wide basis. The Dossier Submitter provided clarifications regarding the hazard assessment. The expert accompanying the regular stakeholder observer from CEFIC commented on the hazard assessment and exposure assessment.</p>	
<p><b>3. Terphenyl, hydrogenated – second draft opinion</b></p>	
<p>The WG Chair Peter Simpson welcomed the Dossier Submitter's representatives from Italy and the regular stakeholders.</p> <p>The participants were informed that the restriction dossier had been submitted in April 2022 by Italy and concerns terphenyl, hydrogenated.</p>	
<p><b>No further discussion recommended</b></p> <p><i>The WG discussed and recommended that the following could be agreed without further discussion at RAC-63:</i></p> <ul style="list-style-type: none"> <li>- The group does not support the assumption of the DS that the <b>emissions</b> for the uses of terphenyl, hydrogenated are realistically covered by the proposed assessment.</li> <li>- The group agreed that, in line with REACH Annex I, based on the vPvB properties of the substance a quantitative <b>risk characterisation</b> is not appropriate and the emission estimates should be used as a proxy for risk. The group agreed that despite of the uncertainties in the emission estimates, releases and exposures from current uses take</li> </ul>	<p><b>RAC members</b> to provide the remaining written comments on the second draft opinion by 11 November 2022.</p> <p><b>Rapporteurs</b> to prepare a short presentation to RAC-63 to report back and to address the topics for plenary.</p> <p><b>Rapporteurs</b> to take the WG discussions (and outcome of the third-party consultation) into account for the next version of the opinion by January 2023 prior to the RAC-64 Working Group on restrictions.</p> <p><b>Dossier submitter</b> is requested to provide information on the following aspects:</p> <ul style="list-style-type: none"> <li>- Approach used to estimate emissions – redistribution in STP</li> <li>- Clarification for the use of the fate properties: Are they used for release estimations or for PEC estimations?</li> </ul>

<p>place and there is hence a risk to address.</p> <ul style="list-style-type: none"> <li>- The WG agreed that the current <b>operational conditions and risk management measures</b> are not effective to control the risks from terphenyl, hydrogenated.</li> <li>- The WG agreed that there is an EU-wide risk that needs to be addressed.</li> </ul> <p><b>Additional discussion recommended</b> <i>The WG discussed and recommended that RAC-63 further discuss the following:</i></p> <ul style="list-style-type: none"> <li>- based on the uncertainty of the quantitative data on emissions, and whilst it was agreed that there is a risk to be addressed, that a qualitative approach to the evaluation could be explored.</li> </ul> <p><b>Further work required</b> <i>The WG recommended that rapporteurs continue their work on the following elements and present the next version of the opinion at RAC-64 REST WG:</i></p> <p>The RAC WG had an initial discussion on effectiveness of the restriction and noted several important uncertainties related to the assessment of emissions and exposure.</p> <ul style="list-style-type: none"> <li>- A further evaluation of the most appropriate regulatory risk management option would be needed.</li> <li>- It was noted that alternatives appear to be available, but that many of them may pose hazards similar to terphenyl, hydrogenated. RAC's analysis is limited to the alternatives explored by the DS but further</li> </ul>	<ul style="list-style-type: none"> <li>- Provide guidance on SCC as part of the BD update</li> <li>- Justification for the tonnage used of one site for the HTF scenarios</li> <li>- Justification that HTF is not formulated in the EU</li> <li>- Assessment of the HTF in articles use scenario</li> </ul> <p><b>Secretariat</b> to table this item for discussion at RAC-63 and RAC-64 WG in January/February 2023 and to provide contextual information on SCIP data to the members.</p>
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<p>alternatives may exist, in particular for plasticisers.</p>	
<p>The expert accompanying CEFIC intervened and provided contextual information on the monitoring campaign and the alternatives for the HTF use.</p>	
<p><b>4. Chloroalkanes, C14-C17 (MCCP) – first draft opinion</b></p>	
<p>The WG Chair Christiaan Logtmeijer welcomed the Dossier Submitter's representatives from ECHA and the regular stakeholders, including the accompanying expert to the regular CEFIC stakeholder.</p>	
<p>The participants were informed that the restriction dossier had been submitted in July 2022 and concerns the manufacture, use and placing on the market of substances, mixtures and articles containing medium-chain chlorinated paraffins (MCCP) as well as other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 with PBT- and/or vPvB-properties.</p>	
<p><b>No further discussion recommended</b>  <i>The WG discussed and recommended that the following could be agreed without further discussion at RAC-63:</i></p> <p>Scope of the <u>risk assessment</u>:</p> <ul style="list-style-type: none"> <li>The scope of the <u>risk assessment</u> is clear and is justified in sufficient detail.</li> </ul> <p>Hazard(s):</p> <ul style="list-style-type: none"> <li>The hazard of the congeners (CA:C14-17) identified with PBT and/or vPvB properties (C14H30-yCly where y = 3 to 11, C15H32-yCly where y = 3 to 8, C16H34-yCly where y = 3 to 8, C17H36-yCly where y = 6 to 9) is well described and is based on MSC conclusions.</li> <li>RAC WG takes note of the MSC conclusion that any substances containing these CA:C14-17 <math>\geq</math> 0.1 % (w/w) would fulfil PBT and/or vPvB criteria</li> <li>The other congeners (CA:C14-17) with vP properties (C14Cl12-14, C15Cl9-15, C16Cl9-16, C17Cl3-5 and C17Cl10-17') as agreed by MSC, may pose an intrinsic hazard similar to PBT/vPvB due to their structural</li> </ul>	<p><b>RAC members</b> to provide the remaining written comments on the first draft opinion by 11 November 2022.</p> <p><b>Rapporteurs</b> to prepare a short presentation to RAC-63 to report back.</p> <p><b>Rapporteurs</b> to take the WG discussions (and RAC written comments received) into account for the next version of the opinion by January 2023 prior to the February RAC-64 Working Group on restrictions.</p> <p><b>Secretariat</b> to table this item for discussion at RAC-64 WG in February 2023.</p> <p><b>Stakeholders</b> to submit additional information via the third-party consultation on the Annex XV dossier.</p>



similarities based on case-by-case assessment.

#### Evaluation of emissions

- The methodology and assumptions for the emissions assessment are well described and reasonable.
- The estimated emissions are plausible.

#### Existing OCs and RMMs

- Based on the wide dispersive nature of the uses, and the estimated releases during the whole life cycle (manufacture, use and waste stage), the currently recommended and implemented operational conditions (OCs) and risk management measures (RMMs) are not sufficient and effective to control the risk.

#### Risk characterisation

- Releases of PBT, and/or vPvB congeners can be used as proxy for risk.
- As supported by the case-by-case approach, the congeners concluded by the MSC as vP ('other vP congeners'), substances containing CA:C14-17 should be treated as non-threshold substances for the purpose of risk assessment in a similar manner to PBT/vPvB substances.
- As the current uses cause releases, there is a risk that needs to be addressed at the EU level.

#### **Further work required**

*The WG recommended that rapporteurs continue their work on these elements*

*and present the next version of the opinion at RAC-64 REST WG:*

- Conclude evaluation that action is required on an EU-wide basis
- Initial evaluation of the risks of alternatives
- Initial evaluation that the proposed restriction is the most appropriate EU-wide measure (effectiveness, other RMOs, practicality and monitorability)

The expert accompanying the regular CEFIC stakeholder observer commented on the presence of CA:C14-C17 congeners present in commercial substances (including long-chain chloroalkanes) and articles, handling of substance and emission estimations and on the available study on the inherent biodegradability. The Commission observer asked for clarifications for the case-by-case assessment approach concluded by the DS.

## **5. REST horizontal issues**

The Secretariat presented the capacity building presentation on designating substances, groups of substances and mixtures in a restriction. Furthermore, the recent changes on the template for the opinion development was presented to the participants.

## **6. Adoption of the report from the RAC REST working group**

Before the Chair thanked the participants and closed the meeting, the WG adopted its report of the 7<sup>th</sup> Meeting.

### **LIST OF ANNEXES**

**Annex I Final Agenda of the of the 7th Meeting of the Committee for Risk Assessment Working Group on Restrictions**

**Annex II List of participants**

**Annex III Declarations of potential conflicts of interest**

## Annex I

17 November 2022  
RAC WG/A/REST63/2022  
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### **Final Agenda** **Meeting of the Committee for Risk Assessment Restrictions** **Working Group (RAC REST WG) reporting to RAC-63**

**8-9 November 2022**

**WebEx meeting**

**8 November starts at 14.00**  
**9 November ends at 17.30**

***Times are Helsinki times***

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***RAC WG/A/REST63/2022***  
***For adoption***

**Item 3 – Declarations of conflicts of interest to the Agenda**

**Item 4 – Restriction proposals**

1. PFASs in firefighting foams – status update
2. DMAC/NEP – second draft opinion
3. Terphenyl, hydrogenated – second draft opinion
4. Chloroalkanes, C14-C17 – first draft opinion

***For discussion***

**Item 5 – Horizontal issues**

Capacity building - Designating substances, groups of substances and mixtures in a restriction

**Item 6 – Adoption of the Report from the WG**

***For discussion and agreement***

## Annex II

### List of participants

<b>RAC Members</b>	
<b>Surname</b>	<b>Name</b>
<b>Angeli</b>	Karine
<b>Deviller</b>	Genevieve
<b>Docea</b>	Anca
<b>Doak</b>	Malcolm
<b>Facchin</b>	Manuel
<b>Geoffroy</b>	Laure
<b>Ginnity</b>	Bridget
<b>Hakkert</b>	Betty
<b>Ifthekhar</b>	Mohammed
<b>Karadjova</b>	Irina
<b>Leinonen</b>	Riitta
<b>Losert</b>	Annemarie
<b>Lund</b>	Bert-Ove
<b>Moeller</b>	Ruth
<b>Mohammed</b>	Ifthekhar Ali
<b>Moldov</b>	Raili
<b>Paris</b>	Pietro
<b>Pribu</b>	Mihaela
<b>Rakkestad</b>	Kirsten Eline
<b>Rodriguez</b>	Wendy
<b>Santonen</b>	Tiina
<b>Schlüter</b>	Urs
<b>Schulte</b>	Agnes
<b>Schuur</b>	Gerlienke
<b>Sørensen</b>	Peter Hammer
<b>Tekpli</b>	Nina
<b>Tobiassen</b>	Lea Stine
<b>Tsitsimpikou</b>	Christina

<b>RAC Members' advisers</b>		
<b>Surname</b>	<b>Name</b>	<b>Nominated by</b>
<b>Catone</b>	Tiziana	Gabriele Aquilina
<b>De Groot</b>	Stan	Gerlienke Schuur
<b>Dubois</b>	Celine	Karine Angeli
<b>Dumke</b>	Carolin	Urs Schuelte
<b>Hoffmann</b>	Frauke	Agnes Schulte
<b>Huuskonen</b>	Pasi	Tiina Santonen
<b>Marinkovic</b>	Marino	Gerlienke Schuur
<b>Moilanen</b>	Marianne	Riitta Leinonen
<b>Nielsen</b>	Peter Juhl	Lea Stine Tobiassen
<b>Rehrl</b>	Anna-Lena	Facchin Manuel
<b>Russo</b>	Maria Teresa	Gabriele Aquilina
<b>Seba</b>	Julie	Wendy Rodriguez
<b>Silvestri</b>	Federico	Pietro Paris
<b>Stalter</b>	Daniel	Agnes Schulte

<b>Invited experts</b>		
<b>Surname</b>	<b>Name</b>	<b>Substance</b>
<b>Averbeck</b>	Frauke	PFAS in firefighting foams
<b>Dannenberg</b>	Carl	PFAS in firefighting foams
<b>Ivarsson</b>	Jenny	PFAS in firefighting foams
<b>Ramsden</b>	Niall	PFAS in firefighting foams
<b>Wiebke</b>	Drost	PFAS in firefighting foams
<b>Winther</b>	Toke	PFAS in firefighting foams

<b>SEAC Rapporteurs</b>		
<b>Surname</b>	<b>Name</b>	<b>Substance</b>
<b>Kiiski</b>	Johanna	PFAS in firefighting foams

<b>Dossier Submitters</b>			
<b>Surname</b>	<b>Name</b>	<b>Authority</b>	<b>Substance</b>
<b>Jongeneel</b>	Rob	RIVM	DMAC/NEP
<b>Castelli</b>	Stefano	ISS	Terphenyl, hydrogenated
<b>Catone</b>	Tiziana	ISS	Terphenyl, hydrogenated
<b>Alivernini</b>	Silvia	ISS	Terphenyl, hydrogenated
<b>Attias</b>	Leonello	ISS	Terphenyl, hydrogenated
<b>Orru</b>	Maria Antonietta	ISS	Terphenyl, hydrogenated

<b>Regular Stakeholder Observers</b>		
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>
<b>Romano</b>	Dolores	EEB
<b>Janosi</b>	Amaya	Cefic (replacing Liisi de Backer, as approved by the RAC chair)
<b>Robin</b>	Nicolas	PlasticsEurope
<b>Ruelens</b>	Paul	CropLife Europe

<b>Occasional Stakeholder Observers</b>			
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>	<b>Substance</b>
<b>Ballach</b>	Jochen	CIRFS	DMAC/NEP
<b>Hannebaum</b>	Peter	EUROFEU	PFAS in firefighting foams

<b>Stakeholder Experts</b>			
<b>Surname</b>	<b>Name</b>	<b>Nominated by</b>	<b>Substance</b>
<b>Barber</b>	David	CropLife	PFAs in firefighting foams
<b>Schnöder</b>	Frank	CIRFS	DMAC/NEP
<b>Schrage</b>	Arnhild	Cefic	DMAC/NEP
<b>Howick</b>	Chris	Cefic	MCCP, chloroalkenens
<b>Schuller</b>	Jan	Cefic	Terphenyl, hydrogenated

<b>European Commission</b>	
<b>Surname</b>	<b>Name</b>
<b>Beekman</b>	Martijn
<b>Bertato</b>	Valentina
<b>Fabbri</b>	Marco
<b>Schutte</b>	Katrin
<b>Streck</b>	Georg

<b>ECHA Staff</b>	
<b>Surname</b>	<b>Name</b>
<b>Alami-Eerikiharju</b>	Wafa
<b>Anagnostakis</b>	Konstantinos
<b>Barnewitz</b>	Greta
<b>Bin</b>	Essi
<b>Bowmer</b>	Tim, Chairman
<b>Demattio</b>	Silvia
<b>Klausbruckner</b>	Carmen
<b>Lazic</b>	Nina
<b>Lefevre</b>	Sandrine
<b>Lisboa</b>	Patricia
<b>Logtmeijer</b>	Christiaan, co-chair
<b>Marquez-Camacho</b>	Mercedes, co-chair

<b>Nyman</b>	Anna-Maija
<b>Nygård</b>	Daniel
<b>Orispää</b>	Katja
<b>Peltola-Thies</b>	Johanna, Deputy Chair
<b>Peltola</b>	Jukka
<b>Reuter</b>	Ulrike
<b>Simpson</b>	Peter, Co- chair
<b>Sosnowski</b>	Piotr
<b>Thierry-Mieg</b>	Morgane
<b>van Haelst</b>	Anniek
<b>Zeiger</b>	Bastian



### ANNEX III

#### Declarations of potential conflicts of interest

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
<b>ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)</b>		
<b>Restrictions</b>		
DMAC/NEP	Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement