

Helsinki, 24 August 2023  
**RAC working group/R/9/2023**

**Report  
of the Meeting of the Committee for Risk Assessment  
Restrictions Working Group (RAC REST WG)  
reporting to RAC-66**

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

**Wednesday 23 August 2023 at 10:00  
to  
Thursday 24 August 2023 at 16:30**

**Summary Record of the Proceedings**

**1. Welcome and apologies**

The Chair of RAC, Roberto Scazzola, welcomed the participants of the 9<sup>th</sup> meeting of the RAC Working Group on restrictions. He noted that Christiaan Logtmeijer and Piotr Sosnowski would chair sections of the meeting and informed the group that consultations had been organised on the two restriction opinions prior to the meeting.

**2. Adoption of the Agenda**

The Chair reviewed the agenda for the meeting (RAC WG/A/REST66/2023), which was adopted without amendments and is attached to this Report as Annex I. The Chair informed that the next November Working group might be cancelled, more information will follow in the September plenary.

### 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. Five participants of the meeting declared a potential conflict of interest on cases scheduled for the discussion as presented in Annex III to this Report. The WG Chairs declared that they had no potential interests related to any of the agenda points for the meeting.

### 4. Restriction proposals

#### **1. Universal per- and polyfluoroalkyl substances (U-PFAS) – first draft opinion on food contact materials and packaging, and hazards**

The WG Chair Christiaan Logtmeijer introduced himself and welcomed the Dossier Submitter representatives from Denmark, Germany, the Netherlands, Norway and Sweden, as well as the occasional stakeholder observers from CHEM Trust, EDANA, EuChemS, EuPC, and FEC and the regular stakeholder observers together with their accompanying experts to Cefic, ClientEarth, EEB, PlasticsEurope, Eurometaux, CropLife Europe and MedTech Europe. The dossier was submitted in January 2023 and proposes to restrict the manufacture, placing on the market and use of PFAS, i.e. universal PFAS (UPFAS). All uses of PFASs are covered by this restriction proposal except for the use of PFASs in fire-fighting foams, which is assessed in a separate restriction proposal.

The following observers intervened as follows: EEB expert and EuChemS and EuPC commented on the substance scope. The expert accompanying ClientEarth, FEC and EEB, EuPC, FEC, CHEMTRUST and EUChemS commented on the hazard assessment. PlasticsEurope expert provided clarifications regarding the hazard assessment.

The EEB observer, and FEC and their accompanying expert as well as the observers from EuPC and CHEMTRUST commented on the exposure assessment. The observer from PlasticsEurope asked for clarifications regarding release estimates.

The EEB expert and the observers from EuChemS, EuPC and the accompanying expert from FEC commented on the risk characterisation as well as on risk of alternatives, and on derogations. The PlasticsEurope expert commented on restriction as the most appropriate EU wide measure.

The Commission observer commented on the hazards.

The Working Group discussed the first draft opinion and reached provisional conclusions on hazards, scope and on food contact materials and packaging.

**Further work required**

*The WG reached provisional conclusions and recommended that rapporteurs continue their work on these elements and present the next version of the opinion for discussion at a working group meeting:*

Scope

- that the scope of the restriction proposal is supported.
- that RAC agrees with the Dossier Submitter on the grouping approach focusing on the high persistence, which is a common property of all PFAS in the scope due to the high stability of the C-F bond.
- Regarding the exclusion of certain groups of PFAS from the scope:
  - that, based on the evaluation made so far, it is not possible to firmly conclude that some groups of PFAS proposed to be excluded are not persistent.
  - that rapporteurs will continue their evaluation, considering any new information from the third-party consultation.

Hazard assessment:

- that persistence is a concern common to all PFAS, including their increasing stock pollution.
- that due to the very large number of PFAS, the hazards are not homogeneous and there will always be some uncertainty regarding the hazards of the entire group.
- that high persistence of PFAS in combination with other hazards present grounds for significant concern.
- that, in case of continued releases, a long time is needed for PFAS to reach a steady state in the environment. High levels in biota even with PFAS having less or no bio-accumulative properties have been shown by

**Rapporteurs** to prepare a short presentation to RAC-66 to report back.

**Rapporteurs** to take into account the WG discussions and the outcome of the third-party consultation in the revised draft opinion to be tabled for discussion at a future working group.

**Stakeholder observers** to submit information via the ongoing third-party consultation which will end on 25 September 2023.

monitoring data and can be anticipated with continuing releases.

- that, since it is practically impossible to remove PFAS from the environment, the growing environmental stock may eventually result in increasing likelihood of adverse human health or environmental effects.
- that, despite uncertainties in the hazards and risks of PFAS, there is however sufficient evidence to conclude on the intrinsic hazard of PFAS because of their long-term persistence in the environment, mobility, growing environmental stock and a potential to cause a range of adverse effects.

Regarding polymeric PFAS in particular:

- that polymeric PFAS are very persistent.
- that there are limited data on the hazards of polymeric PFAS *per se*.
- that in case of polymeric PFAS, whole life-cycle emissions need to be considered.
- That, overall and in accordance with the DS assessment, there is a concern regarding polymeric PFAS.

Emission and exposure estimates for food contact materials (FCM) and packaging:

*Volumes*

- that FCM and packaging are among the highest uses of PFAAs/PFAA precursors and polymeric PFAS.
- that there are uncertainties in volumes estimations and more specific data for different sub-uses would allow a more accurate analysis.
- that the uses are adequately identified and volume estimates to be sufficiently robust for the assessment.
- that the use of fluorine to treat plastic containers appears to form PFCAs as reaction by-products which could be an important source of PFAS releases to the environment.

*Emissions*

- that the emission estimates and underlying assumptions are supported by RAC but will be subject for updating if relevant information appears from the third-party consultation.
- that currently the Dossier Submitter only includes manufacturing and service life emissions in the total sector emissions, pending further information from the consultation.
- Manufacturing stage:
  - That emissions of PFAS mainly constitute releases of telomers and polymers with side-chain telomers used for paper and board packaging manufacturing.
- Service life:
  - that the approach used for the estimation of releases is appropriate in the absence of further data.
  - that emissions may be overestimated as a result of the approach..
- End-of-life:
  - that end-of-life emissions may be significant.
  - that fluoropolymers constitute the majority of PFAS entering the waste stage.
  - that end-of-life emissions are currently highly uncertain.

*Monitoring data*

- that monitoring data is currently not available on a sector-by-sector level.
- that PFAS are ubiquitously found in European environments, biota and in humans, demonstrating world-wide exposure to a wide range of PFAS.

*Existing OCs and RMMs*

- that there are uncertainties associated with the lack of information related to the OCs and RMMs in place and the lack of monitoring data for a vast majority of PFAS, in general and also in this particular sector.

*Regulative risk management instruments in place*

- that existing regulations already in place are not sufficient to control

emissions of PFAS from FCM and packaging and hence the associated risk.

- that emissions related to the use of PFAAs and PFAA precursors (including side-chain polymers and telomers) can be considered significant and their releases may present a risk to humans and the environment that increases with continued use due to their persistence leading to environmental stocks over time.
- that fluoropolymers may be released to the environment in substantial amounts.
- that the life-cycle of fluoropolymers resulted in emissions of monomers (or short, bioavailable oligomers, including F-gases) but RAC was not able to quantify these emissions due to the lack of data.
- that prevention techniques are not enough to control the risk to health and environment associated with PFAS.

The above conclusions are subject to further information submitted in the third-party consultation.

*Sector-by-sector approach to evaluation*

- that the rapporteurs' approach to evaluate the proposal sector-by-sector is an appropriate method to organise the work.

Risk characterisation (FCM and packaging)

- that emissions of PFAS in FCM and packaging can be considered significant, and
- that their releases may present a risk to humans and the environment and that the risk increases with continued use due to their persistence and the consequent increase in environmental stocks over time.
- Furthermore, it was noted that :
  - The life-cycle of fluoropolymers additionally results in the emissions of monomers or

<p>short bioavailable oligomers, including F-gases, the amounts of which may be significant.</p> <ul style="list-style-type: none"> <li>○ The emissions related specifically for fluoropolymers used in FCM and packaging sector cannot be quantified due to the lack of specific data.</li> </ul> <p><u>Need for EU-wide action (FCM and packaging):</u></p> <ul style="list-style-type: none"> <li>→ that EU-wide measures are needed to control releases of PFAS used in FCM and packaging across different lifecycle stages including in particular the end-of-life stage.</li> </ul> <p><u>Risks of alternatives (FCM and packaging):</u></p> <ul style="list-style-type: none"> <li>→ that the approach used by the Dossier Submitter for the analysis of alternatives is acceptable.</li> <li>→ that several alternatives identified for uses in food contact packaging, consumer cookware and industrial food and feed applications can be considered to cause low concern for human health or environment.</li> <li>→ Further information to enhance and expand the analysis of alternatives is expected to be submitted in the third-party consultation.</li> </ul> <p><u>Restriction as the most appropriate EU-wide measure (FCM and packaging):</u></p> <ul style="list-style-type: none"> <li>→ that the group restriction based on structural similarity and equivalent hazard is the most effective RMO</li> <li>→ that RO1 is considered as an effective measure to eliminate the risks caused by PFAS.</li> <li>→ that final conclusion on RO2 can be made only after full evaluation of the dossier and</li> <li>→ that the current initial evaluation has been made considering only the derogations related to FCM and packaging sector</li> <li>→ that it is not possible for RAC to estimate the impact of the proposed time-limited derogations to the emissions of PFAS due to lack of data.</li> <li>→ that emissions of PFAS related to the proposed derogations may be significant.</li> </ul>	
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<p>→ that based on the available information for many of those uses covered under these derogations there are alternatives, which do not pose any significant concerns for human health or environment.</p> <p>Above conclusions for FCM and packaging are subject to change pending further information from the third-party consultation.</p>	
<p><b>2. Creosote, and creosote related substances – third draft opinion</b></p>	
<p>The WG Chair Piotr Sosnowski welcomed the Dossier Submitter's representatives from France 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 October 2022 and concerns the placing on the market, re-use and secondary use of wood treated with creosote or related substances.</p> <p>The CEFIC expert commented on practicality and enforceability related with the inclusion in the scope of creosote related substances(PIC notifications).</p> <p>The Working Group discussed the third draft opinion and reached the following conclusions.</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-66:</i></p> <p><u>Risk of alternatives</u></p> <p>→ There are different alternatives for different uses, but the most effective use is still generally considered to be newly creosote-treated wood. As the content of creosote (i.e., PAHs) in the wood decreases with time (e.g., due to leakage), the potential risk from newly treated wood is generally higher than from old wood treated with creosote.</p> <p>→ Assessing risk of alternatives has not been conducted in this restriction proposal.</p> <p><u>Other regulatory risk management options</u></p>	<p><b>Rapporteurs</b> to prepare the revised 3<sup>rd</sup> draft opinion by 28 August 2023 for adoption at RAC-66 taking into account the WG discussions.</p> <p><b>Rapporteurs</b> to prepare a short presentation to RAC-66 to report back.</p> <p><b>SECR</b> to table the revised 3<sup>rd</sup> draft opinion for adoption at RAC-66.</p>

- There are no other regulatory risk management options that would effectively address the risk.

#### Effectiveness in reducing the identified risks

- That the restriction option 2 effectively addresses the identified risk.
- The restriction option 3 introduced by SEAC will be further assessed by RAC to determine whether it can be more effective taking into account the associated risk of the newly treated wood
- that if reuse by other actors will be allowed, a permanent labelling should be introduced (e.g., in the form of engraved steel plates).
- that a transition period of 6 or 12 months is justified for the restriction proposal.

#### Practicality, incl. Enforceability

- that the proposed restriction option 2 is practical in terms of implementability and manageability.
- Overall, the restriction proposal can be considered enforceable as it can be expected that the authorities are capable of setting up efficient supervision mechanisms to monitor compliance with the proposed restriction.

#### Monitorability

- that the restriction option 2 is monitorable.

#### Restriction as the most appropriate EU-wide measure

- that restriction option 2 is an appropriate risk management measure to control the risks related to the secondary use and reuse of creosote treated wood. It updates and clarifies

<p>the current Entry 31 of the REACH Regulation.</p> <ul style="list-style-type: none"> <li>→ that the restriction is effective in addressing the risk.</li> <li>that the restriction is practical and enforceable .</li> </ul> <p><u>Uncertainties</u></p> <ul style="list-style-type: none"> <li>→ Exposure to creosote during secondary use is very likely but there is limited data available to allow a quantitative exposure assessment. However, RAC supports that sufficient information is available to justify the need to minimise exposure from reuse and secondary use of wood treated with creosote or creosote-like substances.</li> </ul> <p><b>Additional discussion recommended</b> <i>The WG discussed and recommended that RAC -66 further discuss the following:</i></p> <ul style="list-style-type: none"> <li>→ Restriction option 3 as introduced by SEAC</li> <li>→ Revised version of the restriction proposal</li> </ul> <p><b>Recommendation to adopt</b> <i>The WG recommended that RAC-66 could adopt the opinion, after discussion of the outstanding points and with the details discussed at the RAC-66 REST WG.</i></p>	

## 5. REST horizontal issues

No discussion.

## 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 9<sup>th</sup> Meeting.

**LIST OF ANNEXES**

**Annex I**      **Final Agenda of the of the 9th 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**

13 September 2023  
RAC WG/A/REST66/2023  
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**Final Agenda**  
**Meeting of the Committee for Risk Assessment Restrictions**  
**Working Group (RAC REST WG) reporting to RAC-66**

**23-24 August 2023**  
**WebEx meeting**

**23 August starts at 10.00**  
**24 August ends at 16.30**

***Times are Helsinki times***

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***RAC WG/A/REST66/2023***

***For adoption***

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

**Item 4 – Restriction proposals**

1. Universal per- and polyfluoroalkyl substances (U-PFAS) – first draft Opinion.
2. Creosote, and creosote related substances – third draft opinion

***For discussion***

**Item 5 – Horizontal issues**

**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>Esposito</b>	Dania
<b>Facchin</b>	Manuel
<b>Geoffroy</b>	Laure
<b>Hakkert</b>	Betty
<b>Hammer Sorensen</b>	Peter
<b>Leinonen</b>	Riitta
<b>Losert</b>	Annemarie
<b>Lund</b>	Bert-Ove
<b>Martinek</b>	Michal
<b>Menard</b>	Srpčič Anja
<b>Moeller</b>	Ruth
<b>Mohammed</b>	Ifthekhar Ali
<b>Moldov</b>	Raili
<b>Neumann</b>	Michael
<b>Piña</b>	Benjamin
<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>Tekpli</b>	Nina Landvik
<b>Tsitsimpikou</b>	Christina

<b>RAC Members' advisers</b>		
<b>Surname</b>	<b>Name</b>	<b>Nominated by</b>
<b>Dubois</b>	Celine	Karine Angeli
<b>Dumke</b>	Carolin	Urs Schlüter
<b>Granato</b>	Giuseppe	Dania Esposito
<b>Hoffmann</b>	Frauke	Agnes Schulte
<b>Marinkovic</b>	Marino	Gerlienke Schuur
<b>Moilanen</b>	Marianne	Riitta Leinonen
<b>Panieri</b>	Emiliano	Dania Esposito
<b>Rehrl</b>	Anna-Lena	Manuel Facchin
<b>Stalter</b>	Daniel	Agnes Schulte
<b>Schwanemann</b>	Torsten	Michael Neumann

<b>Invited experts</b>		
<b>Surname</b>	<b>Name</b>	<b>Substance</b>

<b>SEAC Rapporteurs</b>		
<b>Surname</b>	<b>Name</b>	<b>Substance</b>
<b>Castan</b>	Stephanie (advisor)	UPFAS
<b>Cogen</b>	Simon	UPFAS
<b>De Blaiej</b>	Arianne (advisor)	Creosote
<b>Fankhauser</b>	Simone	UPFAS
<b>Janssen</b>	Martien	Creosote

<b>Dossier Submitters</b>			
<b>Surname</b>	<b>Name</b>	<b>Authority</b>	<b>Substance</b>
<b>Averbeck</b>	Frauke	BauA (DE)	UPFAS
<b>Baumbusch</b>	Angelika	Norwegian Environmental Agency (NO)	UPFAS
<b>Borg</b>	Daniel	Kemi (SE)	UPFAS

<b>Carlsson Feng</b>	Mattias	Kemi (SE)	UPFAS
<b>Dannenberg</b>	Carl	BauA (DE)	UPFAS
<b>De Blaiej</b>	Arianne	RIVM (NL)	UPFAS
<b>De Kort</b>	Thijs	RIVM (NL)	UPFAS
<b>Drost</b>	Wiebke	Uba (DE)	UPFAS
<b>Heggelund</b>	Audun	Norwegian Environmental Agency (NO)	UPFAS
<b>Ivarsson</b>	Jenny	Kemi (SE)	UPFAS
<b>Johansson</b>	Tommy	Kemi (SE)	UPFAS
<b>Khalaf</b>	Sebhar	MST (DK)	UPFAS
<b>Kupprat</b>	Franziska	BfA (DE)	UPFAS
<b>Larsson</b>	Kristin	Kemi (SE)	UPFAS
<b>Nielsen</b>	Peter Juhl	MST (DK)	UPFAS
<b>Sanders</b>	Marion	RIVM (NL)	UPFAS
<b>Drissi-Amraoui</b>	Sammy	French Government	Creosote
<b>Jomini</b>	Stephane	ANSES	Creosote
<b>Pasquier</b>	Elodie	ANSES	Creosote

<b>Regular Stakeholder Observers</b>		
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>
<b>De Backer</b>	Liisi	Cefic
<b>Duguy</b>	Helene	ClientEarth
<b>Hermann</b>	Christine	EEB
<b>Lemetayer</b>	Lorelei	MedTech Europe
<b>Muller</b>	Patrik	PlasticsEurope
<b>Romano</b>	Dolores	EEB
<b>Ruelens</b>	Paul	CropLife Europe
<b>Verougstraete</b>	Violaine	Eurometaux

<b>Occasional Stakeholder Observers</b>			
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>	<b>Substance</b>
<b>Dainelli</b>	Dario	FEC	UPFAS
<b>Gluge</b>	Juliane	EUChemS	UPFAS
<b>Heusch</b>	Alexander	EDANA	UPFAS
<b>Schneider</b>	Julie	CHEMTrust	UPFAS
<b>Tillieux</b>	Geoffroy	EuPC	UPFAS

<b>Stakeholder Experts</b>			
<b>Surname</b>	<b>Name</b>	<b>Nominated by</b>	<b>Substance</b>
<b>Barber</b>	David	CropLife	UPFAS
<b>Bock</b>	Ronald	PlasticsEurope	UPFAS
<b>Candido</b>	Angelica	Cefic	UPFAS Slot I
<b>Consoli</b>	Elisa	Eurometaux	UPFAS
<b>DeWitt</b>	Jamie	ClientEarth	UPFAS
<b>Hedfors</b>	Cecilia	CHEMTrust	UPFAS
<b>Henry</b>	Barbara J	MedTechEurope	UPFAS
<b>Korner</b>	Mads	Cefic	Creosote
<b>Strehl</b>	Gernot	FEC	UPFAS
<b>Trier</b>	Xenia	EEB	UPFAS
<b>Vromman</b>	Thierry	Cefic	UPFAS Slot II and III

<b>European Commission</b>		
<b>Surname</b>	<b>Name</b>	<b>DG</b>
<b>Beekman</b>	Martijn	GROW
<b>Dunauskiene</b>	Lina	GROW

<b>ECHA Staff</b>	
<b>Surname</b>	<b>Name</b>
<b>Anagnostakis</b>	Konstantinos
<b>Barnewitz</b>	Greta
<b>Bin</b>	Essi
<b>Bowmer</b>	Tim
<b>Gmeinder</b>	Michael
<b>Hammer</b>	Jort
<b>Henrichson</b>	Sanna
<b>Lazic</b>	Nina
<b>Lefevre</b>	Sandrine
<b>Logtmeijer</b>	Christiaan, co-chair
<b>Marquez-Camacho</b>	Mercedes
<b>Mushtaq</b>	Fesil
<b>Nicolas</b>	Ronan
<b>Nogueroles</b>	Marta
<b>Nygård</b>	Daniel
<b>Nyman</b>	Anna-Maija
<b>Orispää</b>	Katja
<b>Salo</b>	Marta
<b>Scazzola</b>	Roberto, Chair
<b>Sosnowski</b>	Piotr, co- chair
<b>Virtanen</b>	Ville-Waltteri
<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>		
<b>Universal PFAS DE</b>	Michael NEUMANN Urs SCHLUETER	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.
<b>DE</b>	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.
<b>DK</b>	Peter Hammer SOERENSEN	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.
<b>NL</b>	Betty HAKKERT 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.
<b>NO</b>	Kirsten Eline RAKKESTAD Nina TEKPLI	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
<b>SE</b>	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied. No personal involvement.
<b>Creosote, and Creosote related substances</b> <b>FR</b>	Karine ANGELI Laure GEOFFROY	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.