

Helsinki, 29 August 2022
RAC/62/2022/06

62ND MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

Concerns: Report from the August Restriction WG

Agenda Point: 9.1.1.

Action requested: For information

RAC WG/REST/R/6/2022

29 August 2022

RAC/62/2022/06

**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**

**Wednesday 17 August 2022 at 10.00
to
Thursday 18 August 2022 at 16.30**

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Tim Bowmer, welcomed the participants of the 6th meeting of the RAC Working Group on restrictions and reminded them that the Committee had renewed its mandate as a standing working group at RAC-60 in March 2022. He noted that Mercedes Marquez-Camacho, Christiaan Logtmeijer, Sandrine Lefevre-Brevart and Peter Simpson would chair sections of the meeting (WG Chairs) and informed the group that consultations had been organised on the four restriction agenda items prior to the meeting.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/REST/6/2022), 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. Two 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 four WG Chairs, all declared that they had no potential interests related to any of the agenda points for the meeting.

4. Restriction proposals

1. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting – third draft opinion	
<p>The WG Chair Christiaan Logtmeijer welcomed the Dossier Submitter's representatives from ECHA, the regular stakeholders, as well as the expert accompanying CEFIC. He informed the participants that the restriction dossier had been submitted in October 2021 and concerns the placing on the market and use of substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting.</p>	
<p>No further discussion recommended</p> <p><i>The WG discussed and recommended that the following could be agreed without further discussion at RAC-62:</i></p> <p><u>Effectiveness in reducing the identified risks:</u></p> <ul style="list-style-type: none"> • that the proposed restriction (RO3) is effective in reducing the risks. • to reflect that there is some uncertainty in the risk reduction capacity for the compliant binders remaining on the market in relation to the potential presence of other (non-marker) PAH above the concentration limit value. <p><u>Practicality, including enforceability:</u></p> <ul style="list-style-type: none"> • that the proposed restriction (RO3) is practical and enforceable. • that it is not necessary to specify a particular analytical method. <p><u>Monitorability:</u></p>	<p>RAC members to provide remaining written comments on the third draft opinion by 19 August.</p> <p>Rapporteurs to prepare the revised 3rd draft opinion by 24 August for adoption at RAC-62 with the following editorial changes:</p> <ul style="list-style-type: none"> • The rapporteurs should remove the references to a 'dynamic link' between PAHs with harmonised classification and the scope of the proposed restriction throughout the opinion. • The rapporteurs should further clarify that the proposed restriction option (RO3) is effective, practical and monitorable. • The rapporteurs should further reflect the working group discussions on uncertainties (i.e. mixture effects, group assessment and overall significance). • The rapporteurs should consider if the bullet points currently listed in Section 1.1 should be retained or only mentioned later in the opinion.

<ul style="list-style-type: none"> • that the proposed restriction (RO3) is monitorable. <p><u>Uncertainties:</u></p> <ul style="list-style-type: none"> • that the overall uncertainties are minor and would not affect the conclusions on the effectiveness, practicality and the monitorability of the restriction. • that although the dossier submitter did not assess PAHs as a group, focusing on the CMR and PBT/vPvB properties of the indicator PAHs, it may be assumed that the same concerns apply to all PAHs given the inconsistent level of testing and/or lack of authority assessments. • that another uncertainty which could increase concern is the potential for mixture effects of PAHs. <p><u>Overall RAC conclusions:</u></p> <ul style="list-style-type: none"> • that the proposed restriction is effective, practical and monitorable. • That the newly classified (Carc. 1B) PAHs should not be proposed as indicators. <p>Recommendation to adopt <i>The WG recommended that RAC-62 could adopt the opinion, with the changes agreed at the RAC-62 REST WG.</i></p>	<p>Rapporteurs to prepare a short presentation to RAC-62 to report back.</p> <p>SECR to table the revised 3rd draft opinion for adoption at RAC-62.</p>
<p>No interventions made by the stakeholder observers or their experts.</p>	
<p>2. Per- and polyfluoroalkyl substances (PFASs) in firefighting foams – second draft opinion</p>	
<p>The WG Chair Mercedes Marquez-Camacho introduced herself and welcomed the Dossier Submitter's representatives from ECHA. The WG Chair also welcomed the regular stakeholders from CropLife Europe, Cefic and EEB including their</p>	

accompanying experts. She informed the participants that the restriction dossier had been submitted in January 2022 and concerns PFASs in firefighting foams.

No further discussion recommended

The WG discussed and recommended that the following could be agreed without further discussion at RAC-62:

Scope:

- that the reworded **scope** of the restriction proposal clarified the issues raised in the previous cycle (i.e. restriction of export; restriction of PFAS substance manufacture). A possible exclusion of PFASs that are proven not to be persistent nor to degrade to persistent PFASs was discussed, but no conclusion was reached pending the outcome of the consultation on the Annex XV report. The rapporteurs were asked to revise this aspect at the appropriate time.

Hazard assessment:

- that the revised evaluation of the hazard assessment, which went into greater depth regarding persistence and mobility, is appropriate.

Exposure assessment:

- that the estimated annual emissions of 470 tonnes of PFAS from the use in fire-fighting foams can be used as basis for the risk characterisation.

Characterisation of risk:

- that the underlying uncertainties do not prevent the Committee from reaching a robust conclusion on the assessment of the risk.

RAC members to provide remaining written comments on the second draft opinion by 23 August.

Rapporteurs to prepare a short presentation to RAC-62 to report back.

SECR to table the 2nd draft opinion for discussion at RAC-62.

Dossier Submitter to further investigate appropriate disposal options including incineration effectiveness regarding PFAS and clarify provisions regarding water treatment techniques.

Rapporteurs to take the WG discussions (and outcome of the third-party consultation) into account for the next version of the opinion by October 2022 prior to the November RAC-63 Restriction Working Group.

- that the existing RMMs and OCs are not sufficient to address the identified risk; effective control of environmental releases (including waste-water treatment) was considered to be highly unlikely.
- that releases of PFASs are not adequately controlled and should be minimised.

Action required on a Union-wide basis:

- that EU-wide action is required to reduce the risks of using PFASs in firefighting foams.

Further work required

The WG recommended that rapporteurs continue their work on these elements and present the next version of the opinion at RAC-63 REST WG:

Effectiveness to reduce risk:

- a comparative evaluation of the effectiveness of the restriction options when considered over a shorter timeframe (e.g., 10 years) .
- an evaluation of the significance of different disposal options for expired or used foams on the effectiveness of the restriction, particularly incineration.
- Introducing a rapid ban on placing on the market for handheld devices

The regular stakeholder observer from CropLife Europe and their accompanying expert commented on the scope of the restriction proposal. The regular stakeholder observer from Cefic and Plastics Europe, their accompanying expert, the accompanying expert to the regular stakeholder observer from EEB as well as the invited expert from EP Fire commented on the hazard assessment. The accompanying experts to Cefic, Plastics Europe and EEB commented on the exposure assessment. The accompanying expert to Cefic and Plastics Europe

commented on existing risk management measures. The accompanying expert to EEB commented on effectiveness in reducing the risk.

3. DMAC/NEP – first draft opinion

The WG Chair Sandrine LEFÈVRE-BRÉVART introduced herself and welcomed the Dossier Submitter's representatives from the Netherlands. The Chair also welcomed the regular CEFIC stakeholder, and the stakeholder from the European Man-Made Fibres Association (CIRFS), including their accompanying experts. The WG chair informed the participants that the restriction dossier had been submitted in April 2022 and concerns occupational exposure to DMAC and NEP.

No further discussion recommended

The WG discussed and recommended that the following could be agreed without further discussion at RAC-62:

Scope:

- That the **scope of the restriction proposal** is clear, targeted to two aprotic solvents (DMAC and NEP) that have repro-toxicity properties (cat. 1B) and that are used in industrial settings and by professionals.

Hazard:

- **DMAC: Systemic long-term inhalation DNEL of 13 mg/m³** based on development toxicity in rabbits.

- **NEP: Systemic long-term inhalation DNEL of 4 mg/m³** based on NOAEC (liver effect).

- **NEP: Systemic long-term dermal DNEL of 2.4 mg/kg bw/day** based on liver effects in rats.

- **NEP: Biomarker DNEL of 20 mg /L for combined urinary excretion of 5-HNEP plus 2-HESI.** Uncertainty with regards to peak exposure is to be further described by the rapporteurs in the next draft opinion.

Further work required

RAC members to provide the remaining written comments on the first draft opinion and the additional issues identified in the WG (systemic long-term dermal DNEL for DMAC and acute inhalation DNEL for NEP, exposure assessment) by 22 August 2022 via the written commenting round.

Rapporteurs to prepare a short presentation to RAC-62 to report back.

Rapporteurs to take the WG discussions (and outcome of the RAC and third-party consultation) into account for the next version of the opinion by October 2022 prior to the November RAC-63 Working Group on restrictions.

Secretariat to table this item for discussion at RAC-62 in September and RAC-63 RESTWG in November.

Stakeholders are invited to provide additional exposure information, including contextual information for measurements and number of workplaces using DMAC and NEP in the Annex XV consultation.

The WG recommended that the rapporteurs continue their work on these elements and present the next version of the opinion at the RAC-63 REST WG:

Hazard:

- **DMAC: Systemic long-term dermal DNEL for DMAC of 1.8 mg/kg bw/day** based on development toxicity in rats as proposed by the rapporteurs instead of 0.53 mg/kg bw/day based on liver effects as proposed by the DS. Rapporteurs to amend the DO accordingly and to provide information on all studies available including the dermal dog study.

- **DMAC: Biomarker DNEL of 15 mg NMAC/g creatinine**

The WG supported the approach from the DS to correlate the biomarker DNEL to the inhalation DNEL of 13 mg/m³. Rapporteurs to report values based on urinary volume and creatinine and to take into account if values are mean or 90 percentiles.

- **NEP: Acute inhalation DNEL.** The rapporteurs to consider the basis, need for and derivation of such a DNEL.

- Additional justification to support the use of **AF of 5** for developmental effects in line with NMP/DMF opinion.

Exposure:

- Evaluation of the exposure data. In case available information is insufficient for Tier 2 modelling, the WG supports the available exposure modelling and its use for the risk assessment as proposed by the DS.

The occasional stakeholder observer from CIRFS commented on the scope, hazard assessment and exposure assessment. Their accompanying expert commented on the hazard assessment. The Dossier Submitter provided clarifications regarding the hazard assessment. The expert accompanying the regular stakeholder observer from CEFIC commented on the hazard assessment.

4. Terphenyl, hydrogenated – first draft opinion

The WG Chair Peter Simpson welcomed the Dossier Submitter's representatives from Italy and the regular stakeholders.

The participants were informed that the restriction dossier had been submitted in April 2022 by Italy and concerns terphenyl, hydrogenated.

No further discussion recommended

The WG discussed and recommended that the following could be agreed without further discussion at RAC-62:

Scope:

- That the substance scope and the overall scope of the restriction are clear and well defined and supported the general approach of setting a concentration limit in articles.

Hazard assessment:

- that a hazard has already been established by the MSC and no further evaluation is needed.

Further work required

The WG recommended that rapporteurs continue their work on these elements and present the next version of the opinion at RAC-63 REST WG:

- That the implications of the scope will be revisited during the discussion on effectiveness, practicability and monitorability.

Risk characterisation:

RAC members to provide the remaining written comments on the first draft opinion by 19 August 2022.

Rapporteurs to prepare a short presentation to RAC-62 to report back.

Rapporteurs to take the WG discussions (and outcome of the third-party consultation) into account for the next version of the opinion by October 2022 prior to the November RAC-63 Working Group on restrictions.

Dossier submitter to provide details of the HTF site monitoring programme.

Secretariat to table this item for discussion at RAC-63 WG in November.

<ul style="list-style-type: none"> • That emission estimates can be used as a proxy for risk. • Release and exposure data provided by the DS provides evidence of ongoing exposure and thus the presence of a risk that should be controlled. <p><u>Exposure assessment:</u></p> <p>The RAC WG had an initial discussion on exposure and releases and noted several important uncertainties related to the assessment of emissions and exposure.</p> <ul style="list-style-type: none"> • The emission and exposure assessment of terphenyl, hydrogenated used as HTF was considered uncertain and underestimated and will be further evaluated. • The monitoring data available for industrial sites using terphenyl, hydrogenated as HTF were not considered reliable or representative and will be further evaluated. • The emissions and exposures assessment for the service life scenarios of articles were not supported by sufficient evidence on the types of articles considered, their concentration ranges in terphenyl, hydrogenated and the lack of information on potential for consumer use. 	
<p>No interventions made by the stakeholder observers.</p>	

5. AOB: REST horizontal issues

The item was removed from the agenda due to time constraints.

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 6th Meeting, requesting the Secretariat to make any necessary editorial changes.

LIST OF ANNEXES

- Annex I** **Final Agenda of the of the 6th 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 August 2022
RAC WG/A/REST2/2022
FINAL

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

17-18 August 2022

WebEx meeting

17 August starts at 10.00
18 August ends at 16.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/REST2/2021
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Restriction proposals

1. PAHs in clay targets for shooting – third draft opinion
2. PFASs in firefighting foams – second draft opinion
3. DMAC/NEP – first draft opinion
4. Terphenyl, hydrogenated – first draft opinion

For discussion

Item 5 – Horizontal issues

Updates regarding the opinion template changes

For information

Item 6 – Adoption of the Report from the WG

For discussion and agreement

Annex II

List of participants

RAC Members	
Surname	Name
Bjørge	Christine
Deviller	Genevieve
Doak	Malcolm
Facchin	Manuel
Geoffroy	Laure
Ginnity	Bridget
Hakkert	Betty
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Neumann	Michael
Paris	Pietro
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Varnai	Veda Marija

RAC Members' advisers		
Surname	Name	Nominated by
Catone	Tiziana	Gabriele Aquilina
Dumke	Carolin	Urs Schuelte
Hoffmann	Frauke	Agnes Schulte

Huuskonen	Pasi	Tiina Santonen
Smith	Jenny	Malcom Doak
Stalter	Daniel	Agnes Schulte

Invited experts		
Surname	Name	Substance
August	Christina	PFAS in firefighting foams
Averbeck	Frauke	PFAS in firefighting foams
Dannenberg	Carl	PFAS in firefighting foams
Borg	Daniel	PFAS in firefighting foams
Kupprat	Franziska	PFAS in firefighting foams
Peltzer	Eike	PFAS in firefighting foams
Wiebke	Drost	PFAS in firefighting foams
Winther	Toke	PFAS in firefighting foams
Ramsden	Niall	PFAS in firefighting foams

SEAC Rapporteurs		
Surname	Name	Substance
Urban	Klaus	PAHs in clay targets
Hard	Sebastiana (replacing Silke Gabbert)	PAHs in clay targets
Brignon	Jean-Marc	DMAC/NEP
Kiiski	Johanna	PFAS in firefighting foams
Bucker	Michael (adviser to Klaus Urban)	PAHs in clay targets

Dossier Submitters			
Surname	Name	Authority	Substance
Jongeneel	Rob	RIVM	DMAC/NEP

Catone	Tiziana	ISS	Terphenyl, hydrogenated
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Regular Stakeholder Observers		
Surname	Name	Organisation
Barry	Frank	ETUI
Fernandez Agudo	Ana	EEB
Evans	Benedict	Medtech Europe
Van der Broeck	Steven	Cefic
Robin	Nicolas	PlasticsEurope
Robinson	Jan	AISE
Ruelens	Paul	CropLife Europe
Waeterschoot	Hugo	Eurometaux

Occasional Stakeholder Observers			
Surname	Name	Organisation	Substance
Ballach	Jochen	CIRFS	DMAC/NEP

Stakeholder Experts			
Surname	Name	Nominated by	Substance
Barber	David	CropLife	PFAs in firefighting foams
Bock	Ronald	Cefic	PFAs in firefighting foams
Ferrara	Kevin	EEB	PFAs in firefighting foams
O'Connor	John	CIRFS	DMAC/NEP
Schrage	Arnhild	Cefic	DMAC/NEP

European Commission	
Surname	Name
Tosetti	Patrizia

ECHA Staff	
Surname	Name
Bin	Essi
Bowmer	Tim, Chairman of RAC
Dede	Yasemin
Klausbruckner	Carmen
Lefevre	Sandrine, co-chair
Logtmeijer	Christiaan, co-chair
Marquez-Camacho	Mercedes, co-chair
Nurmi	Väinö
Orispää	Katja
Peltola-Thies	Johanna, co-Chair
Peltola	Jukka
Reuter	Ulrike
Salo	Marta
Simpson	Peter, Co-chair
Sosnowski	Piotr
Thierry-Mieg	Morgane
van Haelst	Anniek
Zeiger	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
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Restrictions		
DMAC/NEP	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
	Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement