

**RAC WG/REST/R/4/2022**

**10 February 2022**

**Report  
of the Meeting of the Committee for Risk Assessment  
Restrictions Working Group (RAC REST WG)  
reporting to RAC-60**

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

**Wednesday 9 February 2022 at 10.00  
to  
Thursday 10 February 2022 at 17.30**

**Summary Record of the Proceedings**

**1. Welcome and apologies**

The Chair, Tim Bowmer, welcomed the participants of the 4<sup>th</sup> meeting of the RAC Working Group on restrictions and reminded that the Committee had agreed on its establishment as a standing working group at RAC-56 in March 2021. He noted that Johanna Peltola Thies, Deputy Chair of RAC 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.

**2. Adoption of the Agenda**

The Chair reviewed the agenda for the meeting (RAC WG/REST/4/2022), which was adopted without further 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 two Chairs, all declared that they are no potential interests related to any of the agenda points for the meeting.

#### 4. Restriction proposals

<b>1. PAHs in clay targets for shooting – first draft opinion</b>	
<p>The Chair Johanna Peltola-Thies welcomed the Dossier Submitter's representatives from ECHA, the regular stakeholders, the occasional stakeholder observer from CONCAWE as well as the expert accompanying CEFIC Coal Chemicals Europe. She 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><b><u>No further discussion recommended at RAC-60:</u></b></p> <p>The working group discussed and recommended that the following could be agreed without further discussion at RAC-60:</p> <ul style="list-style-type: none"> <li>- Regarding <b>scope</b>,</li> </ul> <p>The working group recognised that the intended target of the restriction is PAHs in general in clay targets. The working group supported the proposed general approach to the scoping (a selection of indicator PAHs and concentration limits) and noted that the same approach is used in previous restrictions for PAHs (Entry 50).</p> <ul style="list-style-type: none"> <li>- <b>Hazard evaluation;</b></li> </ul> <p>The working group supported the rapporteurs' conclusions on hazard and concluded that due to the hazardous properties of PAHs in general, release and exposure should be minimized.</p> <p><b><u>Further work required:</u></b></p> <p>The working group recommended that the rapporteurs continue their work on these elements and present the next version of the opinion at RAC-61 REST WG in May 2022:</p> <ul style="list-style-type: none"> <li>- potential and relevance of human exposure, particularly dermal exposure,</li> </ul>	<p><b>Rapporteurs</b> to prepare a short presentation to RAC-60 to report back.</p> <p><b>RAC members</b> to provide any remaining written comments on the 1<sup>st</sup> draft opinion via the ongoing SCIRCABC Newsgroup by 14 February 2022.</p> <p><b>Rapporteurs</b> to take the discussions (as well as written comments) into account for the next version of the opinion.</p> <p><b>Dossier Submitter</b> agreed to clarify the rationale for the proposed scope (e.g. DS summaries in the opinion and the BD).</p>

<p>to the conclusions of the risk assessment</p> <ul style="list-style-type: none"> <li>- evaluation of whether the proposed or alternative suites of indicator PAHs (including an option for a dynamic link to CLP or the Candidate List) are most effective with regard to the minimisation of PAH releases, human exposures and risk, and with regard to practicability and monitorability</li> <li>- Uncertainties.</li> </ul>	
<p>The expert accompanying CEFIC commented on the scope, the hazard and risk assessment.</p>	
<p><b>3. Dechlorane Plus - third draft opinion</b></p>	
<p>The Chair Johanna Peltola-Thies welcomed the Dossier Submitter's representatives from Norway. The Chair also welcomed the regular stakeholders, the occasional stakeholder observers from EDANA and CONCAWE. She informed the participants that the restriction dossier had been submitted in April 2021 and concerns risks for human health and the environment from emissions of Dechlorane Plus.</p>	
<p><b>No further discussion recommended</b></p> <p>The WG discussed and recommended that the following could be agreed without further discussion at RAC-60:</p> <ul style="list-style-type: none"> <li>• <b>Emissions and exposure.</b> Minor revisions to the opinion on this section were made to address comments received during the consultation.</li> <li>• <b>Existing regulatory risk management measures</b> are not sufficient to address the risk.</li> <li>• Justification that the proposed restriction (RO2plus) is the <b>most appropriate EU-wide measure</b>.</li> <li>• Taking into account the derogations in the revised preferred restriction option (RO2plus), the proposed restriction is <b>effective in reducing the identified risks</b>. Differences in emission reductions between this and the strictest restriction option without any derogations (RO1) were found not to be significant (in the margin of emission estimation</li> </ul>	<p><b>RAC members</b> to provide written comments on the third draft opinion by 11 February.</p> <p><b>Rapporteurs</b> to prepare the 4<sup>th</sup> draft opinion for adoption at RAC-60 with the following editorial changes:</p> <ul style="list-style-type: none"> <li>• to more clearly conclude on the reliability of the monitoring data in the exposure assessment.</li> <li>• with the support of the Secretariat o further reflect on the definitions of the automotive and aerospace industry.</li> <li>• with the support of the Secretariat to clarify the scope and implications of the proposed derogations for spare parts i.e. that as proposed, they allow the repair of articles produced</li> </ul>

<p>uncertainty). RO2plus is considered to be an effective option to address the identified risks.</p> <ul style="list-style-type: none"> <li>• The restriction is generally <b>practicable, enforceable and monitorable</b>.</li> <li>• The <b>uncertainties</b> are in line with those identified by the dossier submitter and do not change the overall conclusion that the proposed restriction is effective to address the identified risk from Dechlorane Plus.</li> </ul> <p><b><u>Additional discussion recommended</u></b></p> <p>The WG discussed and recommended that RAC-60 further discuss the following:</p> <ul style="list-style-type: none"> <li>• The <b>practicability, enforceability and monitorability</b> of the preferred restriction option RO2plus was agreed by the working group but may need to be revisited pending additional advice from the Forum.</li> </ul> <p><b><u>Recommendation to adopt</u></b></p> <p>The WG recommended that RAC-60 adopt the opinion, with the changes agreed at the RAC-60 WG.</p>	<p>prior to the entry into force of the restriction in perpetuity until the end of their service lives.</p> <ul style="list-style-type: none"> <li>• to highlight as an uncertainty the amount of Dechlorane Plus imported in articles and the ceasing of bulk imports into the EU. The future expected reduction of the volumes imported can be followed closely.</li> <li>• to reflect on the monitorability of the restriction proposal vis-a-vis environmental monitoring and the very persistent nature of Dechlorane Plus and the ongoing emissions from waste stage (e.g. landfill sites).</li> </ul> <p><b>Rapporteurs</b> to prepare a short presentation to RAC-60 to report back.</p> <p><b>SECR</b> to table the 4<sup>th</sup> draft opinion for adoption at RAC-60.</p>
<p>The Commission and the Dossier Submitter commented on the estimated emissions. The Commission commented on the links between the restriction process and the EU negotiating position under the Stockholm Convention on persistent organic pollutants. Both also commented on the definitions of derogated sectors and the derogations for spare parts. No interventions from stakeholders were noted.</p>	
<p><b>4. Lead in outdoor shooting and fishing – fourth draft opinion (fishing sector only)</b></p>	
<p>The Chair, <u>Tim Bowmer</u> welcomed the Dossier Submitter's representatives from ECHA, invited experts from UNEP/AEWA, as well as the regular and occasional stakeholder observers from CEFIC, CONCAWE, EUROMETAUX, EAA, EEB, FACE, FITASC, and their accompanying experts (see participants list). He informed the participants that the restriction dossier had been submitted in January 2021 and concerns lead in outdoor shooting and fishing.</p>	
<p>The Working Group discussed the rapporteurs' assessment of the <b>comments received in the</b></p>	<p><b>Rapporteurs</b> to prepare a short presentation to RAC-60 to</p>

**consultation of the Annex XV report,** focusing on the following items:

- Regarding the scope and derogations, the effects of a potential change of limits of the restriction from a lead concentration of 1% to 3% were discussed. Potential derogations for specific bullets in hunting (full metal jacket, other non-expanding bullets, etc) are being assessed by the rapporteurs and will be discussed with the next version of the opinion.
- Regarding the risk assessment for birds, the Working Group supported the rapporteurs' proposal to focus on the number of species at risk (92) rather than bird mortality, including sub-lethal effects and welfare issues. The rapporteurs pointed out that 54 out of the 92 sensitive species are red-listed (some threatened) and that also effects in individual birds may affect populations (risk for extinction).
- Regarding the risks to soil and groundwater, the Working Group concluded that the groundwater risks depend on soil characteristics and that soil and surface water contamination is likely but effects are localized. The rapporteurs have refined the assessment and these conclusions will be included in the opinion.
- Regarding the human health hazards, public comments have been taken into account in the RAC opinion. The Working Group supported the use of the EFSA BMDLs recognizing that there are uncertainties in the dose responses of lead especially at low exposure levels and that it can be considered as conservative.
- Regarding the risks from game meat consumption, the Working Group continued to support the use of the EFSA data as the most appropriate available, recognizing their high variability and potential over-/underestimation of exposure. The DS's change from the use of the 95<sup>th</sup> percentile to the median

report back (fishing sector related opinion).

**RAC members** to provide the remaining written comments on the fourth draft opinion via the ongoing SCIRCABC Newsgroup by 15 February 2022.

**Rapporteurs** to take the discussions (and outcome of the third party consultation) into account for the next version of the opinion by April 2022 prior to the May RAC Working Group on restrictions. The RAC opinion deadline has been extended until June 2022 due to the broad scope and complexity of the Dossier Submitter's proposal and a high volume of third party consultation comments received.

**Secretariat** to table this item for discussion at RAC61 WG in May and for adoption at RAC-61, in June 2022.

values for the daily intake of game meat (based on the comments received) results in slightly lower exposure and risk estimates. However, the difference is very small and does not change the overall conclusions.

- Regarding the risks from shooting, no major changes in the opinion were proposed by the rapporteurs. RAC has already concluded that health risks are likely to be generally low for adults in outdoor shooting. The Working Group highlighted that RAC's main concerns are related to potential neurodevelopmental risks to fertile age/pregnant females at low exposure levels.
- Regarding the risks from home-casting, the Working Group agreed that the information received does not trigger further changes to the opinion.
- Regarding the risks of alternatives, no further changes in the opinion were envisaged by the Working Group based on the information submitted in the consultation.
- Regarding the RMMs at shooting ranges, the assessment of the rapporteurs is still ongoing. The changes regarding the bullets will be included in the next version of the opinion, once the comments of the consultation and the updated proposal from the DS have been assessed.

**No further discussion recommended at RAC-60:**

The Working Group discussed and agreed on the following items, recommending that they did not need further discussion at RAC-60:

**For fishing tackle**

**Regarding that the restriction is the most appropriate EU wide measure**

The Working Group supported a ban on the placing on the market and use of lead fishing sinkers and lures without an upper limit, as this option reduces the risk both to birds (sinkers) and humans (home-casting). Also, it is practical and enforceable since it also concerns placing on the market.

Limited evidence is provided to show a risk from (fly)fishing wire containing lead. However, as risk cannot be excluded depending on how the wire is being used, the Working Group supported the ban of fishing wires as well. ECHA is requested to improve the definition of fishing wires to ensure a better understanding of the type of articles included.

#### **Regarding risk characterisation**

The Working Group agreed that:

- for swans and loons there is ample evidence for a very likely exposure and severe effects, resulting in a very **high** risk.
- A similar exposure of other (22) sensitive bird species is likely, but the evidence is limited and therefore it is concluded that there is a **moderate** risk for the other species.
- There may be accidental ingestion of sinkers among fishermen, but it is difficult to conclude on a risk level for humans exposed to lead fishing tackle.
- There is no data available from Europe on exposure to lead during home-casting, but considering the conditions at home-casting, a **moderate risk** is assumed for adult fishermen based on it being very likely with exposure resulting in mild effects, and likely with exposure resulting in medium severe effects.

#### **Regarding scope and derogations**

The Working Group agreed on a concentration limit of 1% in lead for sinkers, lures and wires, including information at the point of sale.

The Working Group did not support a derogation for plugs and from fishing wires from the conditions of the restriction as proposed by the rapporteurs, due to the lack of evidence that these articles do not present a risk to the environment.

Furthermore, the Working Group did not support a derogation for lead split shots as requested in the consultation of the Annex XV report. Lead split shots ( $\leq 0.06$  gram) may be easily lost at the shore or in the water and are highly bioavailable and easily eaten by many bird species.

#### **Regarding alternatives**

The Working Group concluded that alternatives exist, and that the suitability is clear for some of them but that further use of alternative materials is needed to fully explore their usefulness in practice (e.g., for different types of weights and lures).

#### **Regarding practicality and enforceability**

The Working Group agreed that a ban on the placing on the market of fishing sinkers, lures, and fishing wire is practical and enforceable. However, the Working Group concluded that, although in principle enforcement of the restriction as proposed is possible, present enforcement structures in the MS are not well suited for this task (i.e., enforcing use by individuals).

Monitorability seems to be difficult, particularly related to home-casting since lead for home-casting is available from a variety of secondary sources, largely beyond the control of enforcement.

#### **Further work required**

The Working Group recommended that the rapporteurs continue their work concerning the assessment of the comments from the third



<p>party consultation and present the final version of the opinion at RAC-61 REST WG in May.</p>	
<p>Regarding the presentation on the third party comments received, the invited expert from AEWA Technical Committee as well as expert accompanying the EEB regular stakeholder observer, and the EAA and ISSF/FITASC occasional stakeholder observers commented on the scope and derogations (e.g. limit value, exposure and release) and on hazards and risks.</p> <p>The regular stakeholder observers (EUROMETAUX) commented on the concentration limits and the expert accompanying EEB regular stakeholder observer on bird exposure and risk to children and pregnant females in home-casting. The invited expert (UNEP/AEWA) commented on risks to birds. The occasional stakeholder observer (EAA) commented on limit values. The expert accompanying the regular ClientEarth stakeholder observer commented on the risk levels for soils.</p>	

## 5. AOB: REST horizontal issues

The participants were provided with a Capacity building session on risk assessment for restriction (HH and ENV). The aim of the series of sessions is to learn lessons from previous cases, ensure coherence and consistency of evaluation and increase efficiency of RAC's work. The sessions planned at the RAC REST WG in 2022 are twofold, on non-threshold hazard paradigms for the environment; on hazard assessment for human health and on exposure assessment. It was also suggested to organise a joint session with SEAC on common issues (e.g. derogations).

Furthermore, the Secretariat gave a short presentation on the proposed changes in the opinion development for restrictions. The participants were invited to provide further feedback on how to optimise the new ways of working on the restriction process via a questionnaire to be sent out by the Secretariat in due course. Once the optimal way of working is found, the aim is to update the RAC and SEAC working procedure for opinion development in restrictions accordingly.

## 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 4<sup>th</sup> Meeting, requesting the Secretariat to make any necessary editorial changes.

## **LIST OF ANNEXES**

- Annex I**      **Final Agenda of the of the 4th 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**

RAC WG/A/REST4/2022rev1  
FINAL

**Agenda**

**Meeting of the Committee for Risk Assessment Restrictions  
Working Group (RAC REST WG) reporting to RAC-60**

**9-10 February 2022**

**Virtual meeting**

**9 February starts at 10.00  
10 February ends at 16.40**

***Times are Helsinki times***

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***RAC WG/A/REST4/2022  
For adoption***

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

**Item 4 – Restriction proposals**

6. 2,4-dinitrotoluene (not for discussion at this meeting)
7. PAHs in clay targets for shooting – first draft opinion
8. Dechlorane Plus - third draft opinion
9. Lead in outdoors shooting and fishing – fourth draft opinion

***For discussion***

**Item 5 – AOB**

1. Capacity building on risk assessment for restriction (HH and ENV)
2. REST horizontal issues

***For discussion***

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

***For discussion and adoption***

## ANNEX II

### List of participants

<b>RAC Members</b>	
<b>Surname</b>	<b>Name</b>
Bjørge	Christine
De la Flor Tejero	Ignacio
Doak	Malcolm
Facchin	Manuel
Geoffroy	Laure
Hakkert	Betty
Husa	Stine
Lund	Bert-Ove
Menard Srpčič	Anja
Moeller	Ruth
Mohamed	Ifthekhar Ali
Moldov	Raili
Neumann	Michael
Paris	Pietro
Printemps	Nathalie
Santonen	Tiina
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Tobiassen	Lea Stine
Viegas	Susana

<b>RAC Members' advisers</b>		
<b>Surname</b>	<b>Name</b>	<b>Nominated by</b>
Marinkovic	Marino	Gerlienke Schuur
Russo	Maria Teresa	Gabriele Aquilina
Seba	Julie	Wendy Rodriguez
Stalter	Daniel	Agnes Schulte

<b>Invited experts</b>		
<b>Surname</b>	<b>Surname</b>	<b>Substance</b>
Cromie	Ruth	Lead in outdoors shooting and fishing
Dereliev	Sergey	Lead in outdoors shooting and fishing

<b>SEAC Rapporteurs</b>		
<b>Surname</b>	<b>Name</b>	<b>Substance</b>
Alexandre	João	Dechlorane Plus
Bücker	Michael	PAHs in clay targets
Hard	Sebastiana	PAHs in clay targets
Rouw	Aarnout	Lead in outdoors shooting and fishing
Thiele	Karen	Lead in outdoors shooting and fishing
Urban	Klaus	PAHs in clay targets

<b>Dossier Submitters</b>			
<b>Surname</b>	<b>Name</b>	<b>Authority</b>	<b>Substance</b>
Correll Myhre	Ingunn	Norwegian Environment Agency	Dechlorane Plus
Fotland	Tor Oystein	Norwegian Environment Agency	Dechlorane Plus
Langtvet	Espen	Norwegian Environment Agency	Dechlorane Plus
Lefevre	Sandrine	ECHA	Lead in outdoor shooting and fishing
Logtmeijer	Christiaan	ECHA	Lead in outdoor shooting and fishing
Olsen	Christel	Norwegian Environment Agency	Dechlorane Plus
Persson Dahlberg	Marie Johanne	Norwegian Environment Agency	Dechlorane Plus
Reuter	Ulrike	ECHA	Lead in outdoor shooting and fishing
Tolfen	Christina Charlotte	Norwegian Environment Agency	Dechlorane Plus

<b>Regular Stakeholder Observers</b>		
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>
Barry	Frank	ETUC
Cassart	Michel	PlasticsEurope
Duguy	Hélène	ClientEarth
Jànosi	Amaya	Cefic
Romano	Dolores	EEB
Robinson	Jan	A.I.S.E.
Ruelens	Paul	CropLife Europe
Verougstraete	Violaine	Eurometaux
Waeterschoot	Hugo	Eurometaux

<b>Occasional Stakeholder Observers</b>			
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>	<b>Substance</b>
Barbu	Luminita	EDANA	Dechlorane Plus and AOB
Kappel	Jan	EAA	Lead in outdoor shooting and fishing
Niemelä	Helena	Concawe	All agenda points
Palinkas	Jean-François	FITASC	Lead in outdoors shooting and fishing
Puustinen	Seppo	FACE	Lead in outdoor shooting and fishing

<b>Stakeholder Experts</b>			
<b>Surname</b>	<b>Name</b>	<b>Nominated by</b>	<b>Substance</b>
Green	Rhys	EEB	Lead in outdoors shooting and fishing
Höke	Hartmut	Cefic	PAHs in clay targets
Pain	Debbie	EEB	Lead in outdoors shooting and fishing
Seveque	Jean-Louise	FITASC	Lead in outdoor shooting and fishing
Verdonck	Frederik	Eurometaux	Lead in outdoor shooting and fishing

Williams	Cris	Cefic	Lead in outdoor shooting and fishing
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<b>European Commission</b>	
<b>Surname</b>	<b>Name</b>
Bertato	Valentina
Pirselova	Katarina
Tosetti	Patrizia

<b>ECHA Staff</b>	
<b>Surname</b>	<b>Name</b>
Bowmer	Tim, Chairman
Di Bastiano	Augusto
Doyle	Simone
Gmeinder	Michael
Klausbruckner	Carmen
Lazic	Nina
Loukou	Christina
Marquez-Camacho	Mercedes
Nurmi	Väinö
Orispää	Katja
Peltola-Thies	Johanna, co-Chair
Rheinberger	Christoph
Simpson	Peter, Co-chair
Skowron	Michal
Sokolova	Maia
Smilovici	Simona
Thierry-Mieg	Morgane
Tissier	Chrystelee
van Haelst	Anniek
Wilk	Matteusz
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
<b>ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)</b>		
<b>Restrictions</b>		
<b>Dechlorane Plus™</b> (NO)	Stine HUSA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Christine BJØRGE	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.