

**Report
of the Meeting of the Committee for Risk Assessment
Restrictions Working Group (RAC REST WG)
reporting to RAC-59**

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

**Wednesday 3 November 2021 at 10.00
to
Thursday 4 November at 17.30**

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Tim Bowmer, welcomed the participants of the 3rd 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 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.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/REST/3/2021), 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. Three 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 three Chairs, all declared that they are no potential interests related to any of the agenda points for the meeting.

4. Restriction proposals

1. PAHs in clay targets for shooting – introductory presentation by DS	
The Chair welcomed and thanked the DS representative from ECHA to give an introductory presentation to the RAC WG on restrictions.	
The working group took note of the introductory presentation by the Dossier Submitter.	SECR to launch the 30-day conformity check procedure on this dossier on 4 November and table it for agreement at RAC-59.
2. 2,4-dinitrotoluene – first draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA. The Chair also welcomed the regular stakeholder observers and the occasional stakeholder observer (EDANA). The Chair informed the participants that the restriction dossier had been submitted in July 2021 and concerns the placing on the market or use of 2,4 dinitrotoluene in articles for supply to the general public or to professional workers in concentrations greater than 0.1 % weight by weight. In accordance with Article 69(2) of REACH, ECHA considers that there are uses of the substance which may lead to a non-adequately controlled risk from 2,4-DNT presence in articles.	
<p>The working group discussed and recommended that the following could be agreed without further discussion at RAC-59:</p> <ul style="list-style-type: none"> - Regarding scope, The group agreed that there is evidence of use in the EU (e.g. seat belt pretensioners). - Hazard and risk evaluation; The group noted that 2,4 DNT is a non threshold carcinogen and a substance of very high concern. The evidence from the short latency period seen in the rat study tends to increase this concern. The working group agreed on the hazard assessment. - Exposure assessment The working group concluded that there is potential for exposure from professional and consumer articles but the extent of the possible exposure is very uncertain and would depend on the type of article and the concentration of DNT used. One potential exposure is 	<p>Rapporteur to prepare a short presentation to RAC-59 to report back. The February RAC WG and plenary meeting of RAC-60 would be skipped to wait for the end of third party consultation.</p> <p>RAC members to provide the remaining written comments on the 1st draft opinion via the ongoing SCIRCABC Newsgroup by 10 December 2021.</p> <p>Rapporteur to take the discussions (as well as written comments) into account for the next version of the opinion.</p> <p>Secretariat to table the item for RAC REST WG agenda (4-5 May 2022) and for the RAC-61 agenda for discussion and adoption.</p> <p>Dossier Submitter to provide further clarifications for the definition of industrial/professional uses and explosives in the draft Background Document. The appropriateness and effectiveness of the RMMs to control professional exposure via explosive articles to be further explored.</p>

from residual 2,4 DNT in polyurethane (used as an intermediate in the process). Any information submitted in the general consultation will be assessed to strengthen the assessment.

- Risk characterisation (preliminary assessment)

- The working group noted that as the substance is a non-threshold carcinogen it is not possible or feasible to perform a quantitative risk assessment. The working group noted the opinion should be focused on minimisation of risk by preventing releases (and thereby exposure).
- The extent of the current use of imported articles present on the EU market, or in the future is uncertain but may lead to risk.
- Risks of exposure to other articles on the EU market or from potential future import cannot be excluded.

The working group recommended that rapporteur continue her work on these elements in the next version of the opinion:

- Scope: There is a need to better define explosives and clarify RMM to prevent exposure after combustion. Furthermore, it was suggested that the Dossier Submitter would better define industrial settings.

- Risk characterisation:
- Effectiveness,
 - Alternatives;
 - Practicability and Monitorability.

3. Dechlorane Plus - second draft opinion

The Chair Johanna Peltola Thies welcomed the Dossier Submitter's representatives from Norway. The Chair also welcomed the regular stakeholders, the occasional

<p>stakeholder observers from EDANA as well as the invited experts from Derac. 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>The rapporteurs informed the group on the Forum advice and also on recent developments regarding the Annex XV report consultation.</p> <p>The group discussed and recommended that the following could be agreed without further discussion at RAC-59:</p> <ul style="list-style-type: none"> - the DS's approach regarding the estimation of emissions and exposure, noting that this largely relies on emission factors developed by OECD and ECHA. - The group agreed with the DS that by far the highest share of emissions is attributable to the waste stage. - Regarding monitoring, the group agreed with the DS that there is a large set of measured data for various environmental compartments on Dechlorane Plus that provides a consistent picture of ongoing exposure of the environment and humans in line with the emission estimates. - The group agreed that, in line with REACH Annex I, based on the vPvB properties of the substance a quantitative risk characterisation is not appropriate and the emission estimates should be used as a proxy for risk. The group found no uncertainties that would have a major impact on the overall conclusions of the risk characterisation. - It was noted that alternatives appear to be available, but that many of them may pose hazards similar to Dechlorane Plus. RAC's analysis is limited to the alternatives explored by the DS but further alternatives may exist. - The WG agreed that the current operational conditions and risk management measures are not effective to control the risks from Dechlorane Plus in particular because most releases appear to stem from the waste stage. 	<p>SECR to table the 2nd draft opinion for agreement on the basis of the WG recommendation at RAC-59 (no further discussion recommended).</p> <p>Rapporteurs to prepare a short presentation to RAC-59.</p> <p>Rapporteurs to take the discussions into account for the next version of the opinion.</p>

<ul style="list-style-type: none"> - The WG agreed that a restriction is the most appropriate EU-wide measure to reduce the identified risks of Dechlorane Plus. <p>The WG recommended that the rapporteurs continue their work on the following elements and present the next version of the opinion at the RAC-60 REST WG in February 2022:</p> <ul style="list-style-type: none"> - Regarding monitoring, the WG suggested that the rapporteurs explore whether monitoring data could support the assumption that landfills are also large-scale sources of emissions. - With respect to the restriction options, the opinion should elaborate on the effectiveness of the various restriction options and how robust the assumptions underlying each one are. Clarification on the potentially small difference between the effectiveness of RO1 and RO2 (which includes proposed derogations) is needed. For instance, it should be clarified whether the difference of 3% is significant or negligible compared to the uncertainties in the emission estimates. In addition, the WG suggested that the opinion should qualitatively explore the potential challenges to implement on-site risk management measures in the waste lifecycle stage. 	
<p>The DS commented on the monitoring data as well as risk management measures in the waste lifecycle stage.</p>	
<p>4. Lead in outdoors shooting and fishing – third draft opinion</p>	
<p>The Chair Tim Bowmer welcomed the Dossier Submitter's representatives from ECHA, invited experts from UNEP/AEWA, as well as the regular and occasional stakeholder observers from CEFIC, EUROMETAUX, EAA, EEB, FACE, FITASC, and their accompanying experts from ARCHE Consulting, ILA, and University of Cambridge. 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 and agreed on the following items, recommending that they did not need further discussion at RAC.</p>	<p>RAC members to provide the written comments on the third draft opinion by 15 November.</p>

Regarding the qualitative risk assessment

The group provisionally agreed on the qualitative risk assessment (QRA) proposed by the rapporteurs for hunting, sports shooting and fishing.

The group proposed to:

- add surface water as a receptor in the QRA for sports shooting/hunting;
- review the proposed risk level for the soil receptor in the sports shooting and hunting scenario,
- the groundwater scenario for hunting and
- to review the appropriateness of the use of the marine PNEC for the groundwater scenarios.

The working group also recommended to discuss pregnant females as a receptor in the game meat consumption and home-casting scenarios in the opinion and/or QRA tables.

Finally, the working group proposed to review the risk levels proposed for birds to ensure they are balanced, taking into account the risk levels for other receptors.

Regarding alternatives:

Overall, the group provisionally agreed with the Dossier Submitter that for the main alternatives to lead for gunshot, bullets and fishing tackle the risks for human health and the environment are lower than for lead. However, the working group recognised that there are uncertainties regarding the risks (e.g. aquatic risks from zinc), resulting from the use of alternatives in certain activities.

On the specific issue regarding the potential of steel shot to mobilise lead from soil in areas where lead shot has previously been deposited by the liberation of iron from the steel shot, the group provisionally concluded that there is currently little evidence to support the claim that steel shot would promote the mobility of lead, or increase the acidity in soils.

Rapporteurs to prepare a short presentation to RAC-59 to report back.

Rapporteurs to take the discussions (and outcome of the third party consultation) into account for the next version of the opinion by January 2022 prior to the February RAC Working Group on restrictions. The RAC opinion deadline has been extended until March 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 and adoption at RAC-60, in March 2022.

Regarding the RMMs at shooting ranges:

The working group agreed that implementation of appropriate operational conditions (OCs) and environmental RMMs reduces the risks from lead ammunition used at shooting ranges.

The group also agreed with the Dossier Submitter that a recovery rate of > 90% must be achieved. This level of environmental protection is most probably only achievable with a combination of OCs and RMMs implemented depending on the type of shooting range and shooting discipline. The group acknowledged that whilst a lead recovery rate expressed as a percentage presents significant challenges for enforcement it may be the most appropriate means of achieving risk reduction. However, which OCs and RMMs are needed at a specific site and during a specific discipline to reach > 90% recovery rate of lead does not need to be defined in the restriction.

It is expected that the analysis of the comments received in the consultation will provide further insight into the effectiveness of different RMMs at shooting ranges.

Regarding the analysis of the risk management options:

For hunting and sport shooting, the group agreed that the ban on the placing on the market and use of lead shots and the ban on the use of lead bullets (both large and small calibre centrefire and rimfire) are the only risk management options capable to effectively eliminate the risks for the environment and human health related to the use of lead ammunition.

The group supported the derogations proposed for lead ammunition in sport shooting (both for gunshot and bullets), since the use will only be allowed at designated shooting ranges with adequate and effective risk management measures and potential agricultural uses within shooting ranges are banned.

However, the group also noted that the enforceability of the ban on lead shot would be greatly improved if the optional derogation

related to the placing on the market and use of gunshot for sport shooting is not implemented. The working group proposed to encourage discussions with Olympic/ISSF on their requirement for the use of lead gunshot in competitions.

For fishing, the working group supported the ban on the placing on the market and use of lead in fishing sinkers and lures.

Finally, the working group supported the requirement to provide compulsory information regarding lead to shooters and fishers at the point of sale. Additionally, the working group supported the labelling requirements for lead-containing ammunition presented in the restriction proposal.

Regarding practicality and enforcement:

The working group provisionally concluded that although enforcement of the restriction is possible, present enforcement structures are not well suited for this task. New cooperating structures might need to be developed adding complexity and costs. Furthermore, some definitions used in the restriction proposal need a better description in order to allow efficient enforcement.

The conclusions from the working group will potentially be revised once the Forum advice is available.

The working group recommended that the rapporteurs continue their work on these elements and present the next version of the opinion at February REST WG and RAC-60:

- the qualitative risk assessment;
- RMMs at shooting ranges;
- Practicality and enforceability.

The experts accompanying the EEB regular stakeholder observer and the FITASC occasional stakeholder asked clarifying questions related to qualitative risk assessment. The regular stakeholder observers (EUROMETAUX) commented on the uncertainties and (EEB) on risk minimisation to children. The invited expert (UNEP/AEWA) commented on probability. The occasional stakeholder observer (EAA) commented on alternatives for home casting and asked clarifying questions on sinkers (weight of lures ingested by birds) and (FACE) commented on the waste management. The expert accompanying the EUROMETAUX regular stakeholder observer asked clarifying questions on ground water issue for hunting and on fully jacketed lead bullets. Furthermore, the representatives or their accompanying experts of EUROMETAUX, EAA, EBB, FACE, FITASC commented on the risks of alternatives to lead bullets. The expert accompanying the regular EEB stakeholder observer commented on the risk levels allocated in the QRA for birds, soils, surface waters and offered to provide information on the fragmentation of encased bullets.

The regular and occasional stakeholder observers and their accompanying experts (EBB, EUROMETAUX, FACE, FITASC) commented on the RMMs at shooting ranges.

The expert accompanying the occasional stakeholder observer (FITASC) commented on dust formation at clay target sports shooting ranges; dermal exposure; lead recovery with backstop berms and bullet traps; calculating the recovery of lead at shooting ranges; and the mobility of lead on shooting ranges where alternatives are used.

5. AOB: REST horizontal issues

The Secretariat gave a short presentation on the current ways of working in the RAC Restriction Working Group. A general plan for opinion-making in RAC was presented including a description of the quarterly working group and plenary cycle. The timing of deliverables and meetings within each cycle was also included in the presentation as well as a description of the newly adapted template for conclusions and action points. The group then discussed the approach including elements such as the importance of member's attendance, members' workload, the timing of the WG vis-à-vis the RAC consultation as well as related procedural issues. The Secretariat will draft a document summarising the approach based on the discussion and share this document in Q1 2022 with RAC. Further discussions on the approach are expected in the coming meetings.

Furthermore, the Commission representative presented the role of the opinion for the decision-making phase in restrictions.

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 3rd Meeting, requesting the Secretariat to make any necessary editorial changes.

LIST OF ANNEXES

- Annex I** **Final Agenda of the of the 3rd 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/REST3/2021rev1
FINAL

Agenda

**Meeting of the Committee for Risk Assessment Restrictions
Working Group (RAC REST WG) reporting to RAC-59**

3 - 4 November 2021

Virtual meeting

**3 November starts at 10.00
4 November ends at 17.30**

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

***RAC WG/A/REST3/2021
For adoption***

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Restriction proposals

10. PAHs in clay targets for shooting

For information

11. 2,4-dinitrotoluene

12. Dechlorane Plus™

13. Lead in outdoors shooting and fishing

For discussion

Item 5 – AOB

1. REST horizontal issues: The role of the opinion for the decision-making phase

2. RAC working group on restrictions: ways of working

For discussion

Item 6 – Adoption of the Report from the WG

For discussion and adoption

Annex II

List of participants

RAC Members	
Surname	Name
Bjørge	Christine
De la Flor Tejero	Ignacio
Doak	Malcolm
Facchin	Manuel
Hakkert	Betty
Husa	Stine
Mohamed	Ifthekhar Ali
Leinonen	Riitta
Lund	Bert-Ove
Moeller	Ruth
Moldov	Raili
Paris	Pietro
Pribu	Mihaela
Printemps	Nathalie
Rodriguez	Wendy
Santonen	Tiina
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Tsitsimpikou	Christina
Viegas	Susana

RAC Members' advisers		
Surname	Name	Nominated by
Hoffmann	Frauke	Agnes Schulte
Marinkovic	Marino	Gerlienke Schuur
Stalter	Daniel	Agnes Schulte
Tarvainen	Emma	Riitta Leinonen

Invited experts		
Surname	Surname	Substance
Dereliev	Dereliev	Lead in outdoors shooting and fishing
Deviller	Genevieve	All items

SEAC Rapporteurs		
Surname	Name	Substance
Alexandre	João	Dechlorane Plus
Bücker	Michael	PAHs in clay targets for shooting
Svostrup Petersen	Ida	Dechlorane Plus
Thiele	Karen	Lead in outdoors shooting and fishing
Urban	Klaus	PAHs in clay targets for shooting

Dossier Submitters			
Surname	Name	Authority	Substance
Correll Myhre	Ingunn	Norwegian Environment Agency	Dechlorane Plus
Dahlberg Persson	Marie	Norwegian Environment Agency	Dechlorane Plus
Fotland	Tor Oystein	Norwegian Environment Agency	Dechlorane Plus
Kopangen	Marit	Norwegian Environment Agency	Dechlorane Plus
Langtvet	Espen	Norwegian Environment Agency	Dechlorane Plus
Lefevre	Sandrine	ECHA	Lead in outdoors shooting and fishing
Logtmeijer	Christiaan	ECHA	Lead in outdoors shooting and fishing
Mazzolini	Anna	ECHA	Lead in outdoors shooting and fishing
Olsen	Christel	Norwegian Environment Agency	Dechlorane Plus
Rheinberger	Christoph	ECHA	Lead in outdoors shooting and fishing

Reuter	Ulrike	ECHA	Lead in outdoor shooting and fishing
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Regular Stakeholder Observers		
Surname	Name	Organisation
Duguy	Hélène	ClientEarth
Jànosi	Amaya	Cefic
Romano	Dolores	EEB
Waeterschoot	Hugo	Eurometaux

Occasional Stakeholder Observers			
Surname	Name	Organisation	Substance
Barbu	Luminita	EDANA	2,4-DNT; Dechlorane Plus; Item 5 - REST horizontal issues
Kappel	Jan	EAA	Lead in outdoors shooting and fishing
Palinkas	Jean-François	FITASC	Lead in outdoors shooting and fishing
Puustinen	Seppo	FACE	Lead in outdoors shooting and fishing

Stakeholder Experts			
Surname	Name	Nominated by	Substance
Green	Rhys	EEB	Lead in outdoors shooting and fishing
Seveque	Jean-Louise	FITASC	Lead in outdoors shooting and fishing
Verdonck	Frederik	Eurometaux	Lead in outdoors shooting and fishing
Williams	Cris	Cefic	Lead in outdoors shooting and fishing

European Commission	
Surname	Name
Krassnig	Christian
Tosetti	Patrizia

ECHA Staff	
Surname	Name
Blainey	Mark
Bowmer	Tim, Chair
Gmeinder	Michael
Marquez-Camacho	Mercedes
Nurmi	Väinö
Nyman	Anna-Maija
Orispää	Katja
Peltola-Thies	Johanna, Chair
Reuter	Ulrike
Simpson	Peter, Chair
Smilovici	Simona
Sosnowski	Piotr
Thierry-Mieg	Morgane
van Haelst	Anniek
Väänänen	Virpi
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
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Restrictions		
Dechlorane Plus™ (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.