

RAC WG/REST/R/5/2022

16 May 2022

RAC/61/2022/05

**Report
of the Meeting of the Committee for Risk Assessment
Restrictions Working Group (RAC REST WG)
reporting to RAC-61**

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

**Thursday 5 May 2022 at 10.00
to
Friday 6 May 2022 at 16.30**

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Tim Bowmer, welcomed the participants of the 5th 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 and Peter Simpson would chair sections of the meeting 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/5/2022), 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. No 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 Chairs, all declared that they are no potential interests related to any of the agenda points for the meeting.

4. Restriction proposals

1. Per- and polyfluoroalkyl substances (PFASs) in firefighting foams – first draft opinion	
<p>The WG Chair Mercedes MARQUEZ-CAMACHO introduced herself and welcomed the Dossier Submitter's representatives from ECHA. The Chair also welcomed the regular stakeholders from Plastics Europe, Cefic and EEB including their accompanying experts as well as the occasional stakeholder observers Eurofeu and their accompanying expert. They informed the participants that the restriction dossier had been submitted in January 2022 and concerns PFASs in firefighting foams.</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-61:</i></p> <p>Scope:</p> <ul style="list-style-type: none"> - The scope of the restriction proposal - Grouping of PFASs The RAC WG supported the approach to grouping based on structural similarity (in accordance with the OECD definition of PFASs) and rationale that they have a common concern (hazard property of persistence in combination with other supporting concerns, including effects on human health). The WG noted that the proposed grouping addresses the uncertainties in current and future compositions of firefighting foams (specifically the potential for regrettable substitution) and the inefficiency of regulating PFASs individually. - Targeting of firefighting foam The RAC WG supported the targeting of the proposed restriction on firefighting foams due to the significant potential (and evidence) for environmental contamination from the use. The WG noted that clarifications to the text of the proposed restriction are needed to 	<p>SECR to table the opinion for reporting back at RAC-61.</p> <p>Rapporteurs to prepare a presentation to RAC-61 to briefly report back to plenary.</p> <p>Rapporteurs to take the discussions into account for the next version of the opinion.</p> <p>Dossier Submitter is requested to clarify the wording of the proposed restriction.</p>

ensure that (i) manufacture of PFASs, rather than the formulation or placing on the market of firefighting foams, is not inadvertently restricted (ii), the intention of the proposal regarding export of firefighting foams and (iii) that portable fire extinguishers are included in the scope. The WG also supported the clarification that extinguishers referred to in paragraph 3(d) of the restriction proposal are those in accordance with norm EN3-7 and that they are intended to be included in the labelling requirements in paragraphs 6 and 7.

- **Hazard assessment** The RAC WG supported the rapporteurs in their assessment that persistence combined with a variety of supporting hazards (and in particular mobility) are the main hazard concerns to be addressed by the proposed restriction.

- **Risk assessment** The RAC WG supported the proposed 'case-by-case' risk assessment approach according to REACH Annex 1 (section 0.10). The WG further supported that PFASs be considered **non-threshold substances** and to be assessed in a similar way to PBT/vPvB substances and that environmental releases are used as a proxy for risk.

Further work required

The WG recommended that rapporteurs continue their work on these elements and present the next version of the opinion at RAC-62 REST WG:

- **Common hazard of persistence in PFASs in combination with supporting hazards.** Rapporteurs were asked to further assess the underlying studies and rationale used by the Dossier Submitter to justify the presence of these hazards.

<p>- Exposure assessment Rapporteurs were asked to further assess assumptions underlying the emission modelling of the Dossier Submitter to evaluate whether emission estimates provided by them are justified.</p>	
<p>The occasional stakeholder observer from Eurofeu and the regular stakeholder observer from Plastics Europe and EEB commented on scope of the proposed restriction as well as the hazard assessment. Eurofeu and EEB also commented on the exposure assessment. EEB further commented on the risk assessment. The Commission commented on the scope of the proposed restriction.</p>	
<p>2. 2,4-dinitrotoluene – third draft opinion</p>	
<p>The WG Chair Peter Simpson welcomed the Dossier Submitter's representatives from ECHA and the regular stakeholder observers. He 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 in articles for which the risks are not adequately controlled.</p>	
<p><u>No further discussion recommended</u> <i>The WG discussed and recommended that the following could be agreed without further discussion at RAC-61:</i></p> <ul style="list-style-type: none"> - Justification for action on an EU-wide basis - Justification that the suggested restriction is the most appropriate EU wide measure - The proposed restriction is an effective measure (see also further below) for addressing the identified risks assessed by the DS. - The proposed restriction is practical, enforceable and monitorable. - The proposed derogations. <p><u>Additional discussion recommended</u> <i>The WG discussed and recommended that RAC-61 further discuss the following:</i></p> <ul style="list-style-type: none"> - Uncertainties regarding the effectiveness of the restriction in relation to professional use of explosives and industrial uses (noting the potential applicability for a binding OEL). For 	<p>RAC members to provide remaining written comments on the third draft opinion by 6 May.</p> <p>Rapporteur to prepare the revised 3rd draft opinion for adoption at RAC-61 with the following editorial changes:</p> <ul style="list-style-type: none"> - Uncertainties regarding the effectiveness of the restriction in relation to professional use of explosives and industrial uses (noting applicability of OEL). <p>Rapporteur to prepare a short presentation to RAC-61 to report back.</p> <p>SECR to table the revised 3rd draft opinion for adoption at RAC-61.</p>

<p>example: risks from 2,4-DNT as a constituent in other substances, industrial vs professional car repair, general uncertainties of the Art. 69(2) approach.</p> <p><u>Recommendation to adopt</u> The WG recommended that RAC-61 could adopt the opinion, with the changes agreed at the RAC-61 WG.</p>	
<p>No interventions from stakeholders were made.</p>	
<p>3. Substances containing polycyclic aromatic hydrocarbons (PAHs) in clay targets for shooting – second draft opinion</p>	
<p>The WG Chair Christiaan Logtmeijer welcomed the Dossier Submitter's representatives from ECHA, the regular stakeholders, as well as the expert accompanying CEFIC (from Coal Chemicals Europe). 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><u>No further discussion recommended</u></p> <p><i>The WG discussed and recommended that the following could be agreed without further discussion at RAC-61:</i></p> <p><i>Evaluation on the exposure and emissions</i></p> <ul style="list-style-type: none"> - Evaluation on the estimation of releases - Qualitative approach to address human exposure <p><i>Characterisation of risk</i></p> <ul style="list-style-type: none"> - Many PAHs contained in clay targets are PBT/vPvB and genotoxic carcinogens, emissions are a suitable proxy of risks, consistent with previous similar restrictions. <p><u>Evidence whether the RMMs and OCs are not sufficient to control the risk</u></p> <p>That existing OCs and RMMs are not sufficient:</p>	<p>RAC members to provide the remaining written comments on the second draft opinion by 6 May 2022.</p> <p>Rapporteurs to prepare a short presentation to RAC-61 to report back (including to present the advantages and disadvantages of the modified list of 18 indicators as well as the original list of indicators proposed by DS).</p> <p>SECR to clarify on any preference between the two proposed indicator lists by the Forum.</p> <p>Rapporteurs to take the WG discussions (and outcome of the third-party consultation) into account for the next version of the opinion by August 2022</p>

<ul style="list-style-type: none"> - Conclusions from Authorisation decisions for use of CTPHT in clay targets apply to this restriction. - The aim is minimisation of releases to the environment. <p><u>Evidence if the existing regulatory risk management instruments are not sufficient to control the risk</u></p> <p>That existing regulatory risk management instruments are insufficient to control the identified risk.</p> <p><u>Justification that action is required on an EU wide basis</u></p> <p>That action is required on an EU wide basis.</p> <ul style="list-style-type: none"> - A union-wide action to address the risks associated with manufactured or imported clay targets with substances containing PAHs is needed to ensure a harmonised high level of protection of environment across the EU. - Due to the PBT and vPvB properties of PAHs containing binder materials, and due to the widespread use and exposure, considering also the carcinogenicity of PAHs, there a reason to act on a Union-wide basis. <p><u>Justification that the suggested restriction is the most appropriate EU wide measure</u></p> <p>That the proposed restriction is the most appropriate EU wide measure.</p> <p><u>Effectiveness in reducing the identified risks</u></p> <ul style="list-style-type: none"> - That the effectiveness of the list of indicators proposed by the Dossier Submitter and the 'modified list of indicators' proposed by RAC is the same for binders containing high concentrations of PAHs . - That the impact of the list of indicators on the effectiveness of the restriction for 	<p>prior to the August RAC-62 Working Group on restrictions.</p> <p>Secretariat to table this item for discussion at RAC62 WG in August and for adoption at RAC-62, in September 2022.</p> <p>Dossier Submitter is requested to contact ISSF regarding analytical methods for enforcement.</p>
---	--

eco resin binders and binders of unknown composition need further scrutiny.

Practicality and monitorability

That the restriction is generally practical, enforceable and monitorable. But some issues still need to be clarified on monitorability.

That the analytical feasibility of whichever list is ultimately favoured (Dossier Submitters or RAC's) is critical to establish with advice from the Forum. Likewise, the Dossier Submitter was requested to revert to the ISSF for information on the analytical method they have implemented for clay target shooting.

Further work required

The Working Group recommended that the rapporteurs continue their work concerning

- Advantages and disadvantages of different lists of indicators, including dynamic link to CLP Regulation, REACH candidate list and POP Regulation with regard to their effectiveness at RAC-61 plenary meeting.
- Regarding the introduction of a dynamic link to CLH etc, the probability of further individual CMR/PBT/vPvB components being proposed for classification is seen as low and the link itself complex to manage, so it needs to be considered whether it is worth the added complication.

and present the next version of the opinion at RAC-62 REST WG in August:

- Practicability and monitorability of the proposed and modified lists of indicators, including dynamic link to the CLP Regulation, REACH candidate list and the POP Regulation.
- Forum's view on analytical feasibility.
-

<p>- The assessment of the remaining comments from the third-party consultation.</p>	
<p>The expert accompanying Cefic regular stakeholder observer commented on risk characterisation, on effectiveness (modified list of indicators) and on existing regulatory risk management instruments (e.g. POP Regulation.)</p>	
<p>4. Lead in outdoor shooting and fishing – fifth draft opinion</p>	
<p>The Chair of RAC, Tim Bowmer welcomed the Dossier Submitter's representatives from ECHA, invited experts from UNEP/AEWA and University of Cambridge, as well as the regular and occasional stakeholder observers from CEFIC, EUROMETAUX, EAA, EEB, 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><u>No further discussion recommended</u></p> <p><i>The WG discussed and recommended that the following could be agreed without further discussion at RAC-61 (hunting and sports shooting):</i></p> <p><u>Evidence whether the RMMs and OCs are not sufficient to control the risk</u></p> <p>That there is evidence that the OCs and RMMs are not sufficient to control the risks both in hunting and sports shooting, including at least mortality of birds, levels of lead in game meat, and poisoning of livestock.</p> <p><u>Evidence if the existing regulatory risk management instruments are not sufficient to control the risk</u></p> <p>That the many adverse effects caused by lead in wild birds clearly show that existing risk management instruments are not sufficient.</p> <p>That existing regulatory risk management instruments to limit game meat lead levels are not sufficient: there is for example no maximum residue</p>	<p>RAC members to provide remaining written comments on the fifth draft opinion by 6 May.</p> <p>Rapporteurs to prepare the revised 5th draft opinion for adoption at RAC-61 with the recommended editorial changes.</p> <p>Rapporteurs to prepare a short presentation to RAC-61 to report back.</p> <p>SECR to table the revised 5th draft opinion for adoption at RAC-61. 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.</p>

level for lead in game meat in Europe and no regulatory monitoring required. In addition, there are no labelling requirements to warn of the hazards of lead ammunition for the environment and human health.

That contamination of topsoil and surface waters at the local scale, as well as exposure of livestock grazing on shooting ranges or fed with silage produced at shooting ranges reinforces the concern.

Justification if action is required on a Union-wide basis

That the use of lead in hunting and sports shooting is widespread and presents a risk to the environment and to human health that is not adequately controlled.

That the risks posed by lead are observed Union-wide and therefore that Union-wide regulatory measures are justified.

Justification whether the suggested restriction is the most appropriate EU-wide measure

That the suggested restriction is the most appropriate EU-wide measure.

Targeting of the risks

That the restriction is targeted at the identified risks. Additionally, the RAC WG agrees that non-civilian uses by police, military and border control when they are "on duty" should be out of scope. Finally, the RAC WG agrees that voluntary military training taking place in civilian shooting ranges should be in the scope of the restriction.

That risks to shooters caused by lead-containing primers should also be considered. The RAC WG also notes that indoor shooting may result in high exposure to shooters and that risk management measures are also needed to tackle the risks to shooters in indoor shooting ranges.

Effectiveness in risk reduction

That the proposed restriction **would** be effective and result in a significant reduction of lead emissions and that there are alternative materials generally available for lead shot and bullets in hunting and in sports shooting which reduce the human health and environmental risks.

That there is no evidence to support the claim that steel-induced acidity in soils would promote the mobility of lead and therefore increase lead-caused risks to the environment.

That the liming of shooting terrain soils is not an adequate RMM.

That the proposed derogation for the use of lead gunshot in sports shooting by licenced individuals would significantly complicate enforcement and reduce effectiveness. However, if the decision-maker would decide that such a derogation is still needed, the derogation should be limited to the shot sizes used in sports shooting.

That trap chambers and/or 'best practice' sand traps will enable recovery of lead, while noting that there is still some uncertainty as to the effectiveness of 'best practice' sand traps.

That the remediation of all shooting ranges at the end of their service life is recommended.

Practicality, including enforceability

That although in principle enforcement of the restriction as proposed is possible, present enforcement structures as they exist in the various Member States are not well suited for this task. Additionally, if implementation of the proposed restriction would necessitate enforcement to inspect private persons or shooting ranges, this will present problems for inspectors. The hierarchical organisation of National Sports shooting Federations was noted by the WG in this regard.

To apply a concentration limit of $\geq 1\%$ w/w for the information and labelling requirements instead of $\geq 0.3\%$ w/w as proposed by the DS (apart from for copper and copper alloy projectiles, where the concentration limit should be $\geq 3\%$ w/w) to facilitate implementation and enforcement of the restriction.

Monitoring

That the proposed restriction is monitorable.

That monitoring lead concentrations in game meat is suitable to monitor the effectiveness of the proposed restriction. In addition, another method of monitoring compliance is to explore the prevalence of ingested or embedded shot in birds.

That effective monitoring of the proposed derogation for gunshot will depend on "book-keeping of lead use" at permitted shooting ranges.

The RAC REST WG recommended

-
- That the transition period of 5 years for gunshot use in hunting could be shorter.
-
- That risk management measures to limit exposure to lead from primers also need to be considered.
- That risk management measures are also needed to tackle the risks to consumers practicing shooting in indoor shooting ranges.
- That information on lead hazards and alternatives should be displayed at shooting ranges.
- That colour coding could be used as an alternative to the text proposed for the labelling of individual gunshot cartridges.
- That a lead limit for game meat similar to lead limits already defined for other types of meat should be established

Recommendation to adopt

The WG recommended that RAC-61 could adopt the opinion, with the changes agreed at the RAC-61 WG, regarding:

- Qualitative assessment of risks to birds: clarify reasons for risk ranking of birds.
- Clarify the potential difference of exposure of shooters from

<p>shooting with shotguns vs bullets.</p> <ul style="list-style-type: none"> • Review disciplines to be included in the licencing system for athletes. 	
<p>The ISSF/FITASC occasional stakeholder observers commented widely on the recovery rate of lead, risk management measures for lead at sports shooting ranges, derogations, practicality, and uncertainties.</p> <p>The regular stakeholder observer (EUROMETAUX) and their expert commented on the concentration limits, sport shooting, derogations, monitoring for hunting and on effectiveness. The expert accompanying EEB regular stakeholder observer commented on lead concentrations in game meat, derogations, alternatives and on monitoring measures on hunting. The invited expert (University of Cambridge) commented on risks to birds and on uncertainties in the evaluation.</p>	

5. AOB: REST horizontal issues

The participants were informed that a Capacity building session on risk assessment for restriction (HH and ENV) was postponed to RAC-61 plenary meeting.

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 5th Meeting, requesting the Secretariat to make any necessary editorial changes.

LIST OF ANNEXES

- Annex I** **Final Agenda of the of the 5th 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 May 2022
RAC WG/A/REST5/2022
Final

Agenda

Meeting of the Committee for Risk Assessment Restrictions Working Group (RAC REST WG) reporting to RAC-61

5-6 May 2022

Virtual meeting

5 May starts at 10.00
6 May ends at 16.20

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/REST5/2022

For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Restriction proposals

5. PFASs in firefighting foams – first draft opinion
6. 2,4-dinitrotoluene – third draft opinion
7. PAHs in clay targets for shooting – second draft opinion
8. Lead in outdoor shooting and fishing – fifth draft opinion

For discussion

Item 5 – AOB

1. Capacity building on risk assessment for restriction –
The item has been postponed until RAC-61 plenary

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
Deviller	Genevieve
Doak	Malcolm
Facchin	Manuel
Geoffroy	Laure
Ginnity	Bridget
Hakkert	Betty
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Menard Srpčič	Anja
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Neumann	Michael
Paris	Pietro
Printemps	Nathalie
Rodriguez	Wendy
Santonen Tiina	Santonen Tiina
Schlüter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Spetseris	Nikolaos
Strumylaite	Loreta
Varnai	Veda Marija
Viegas	Susana

RAC Members' advisers		
Surname	Name	Nominated by
Bauer	Kevin	Michael Neumann
Catone	Tiziana	Gabriele Aquilina
De Groot	Stan	Betty Hakkert
Hoffmann	Frauke	Agnes Schulte
Marinkovic	Marino	Gerlienke Schuur
Nielsen	Peter Juhl	Lea Stine Tobiassen
Rehrl	Anna-Lena	Manuel Facchin
Russo	Maria Teresa	Gabriele Aquilina
Smith	Jenny	Malcom Doak
Stalter	Daniel	Agnes Schulte

Invited experts		
Surname	Name	Substance
August	Christina	PFAS in firefighting foams
Dannenberg	Carl	PFAS in firefighting foams
Dereliev	Sergey	Lead in outdoors shooting and fishing
Ivarsson	Jenny	PFAS in firefighting foams
Peltzer	Eike	PFAS in firefighting foams
Wiebke	Drost	PFAS in firefighting foams
Winther	Toke	PFAS in firefighting foams
Beekman	Martijn	PFAS in firefighting foams

SEAC Rapporteurs		
Surname	Name	Substance
Rouw	Aarnout	Lead in outdoors shooting and fishing
Thiele	Karen	Lead in outdoors shooting and fishing
Urban	Klaus	PAHs in clay targets

Dossier Submitters			
Surname	Name	Authority	Substance
Blainey	Mark	ECHA	2,4 DNT - third draft opinion
Lefevre	Sandrine	ECHA	Lead in outdoor shooting and fishing
Logtmeijer	Christiaan	ECHA	Lead in outdoor shooting and fishing
Mazzolini	Anna	ECHA	Lead in outdoor shooting and fishing
Rheinberger	Christoph	ECHA	2,4 DNT - third draft opinion
Reuter	Ulrike	ECHA	Lead in outdoors shooting and fishing

Regular Stakeholder Observers		
Surname	Name	Organisation
Duguay	Hélène	ClientEarth
Fernandez	Ana	EEB
Auda		
Jànosi	Amaya	Cefic
Robin	Nicolas	PlasticsEurope
Romano	Dolores	EEB
Ruelens	Paul	CropLife Europe
Waeterschoot	Hugo	Eurometaux

Occasional Stakeholder Observers			
Surname	Name	Organisation	Substance
Ballach	Jochen	CIRFS	AOB
Kappel	Jan	EAA	Lead in outdoor shooting and fishing
Leonhardt	Thomas	Eurofeu	PFAs in firefighting foams
Palinkas	Jean-François	FITASC	Lead in outdoors shooting and fishing
Rizzo	Federica	EPEE	PFAs in firefighting foams

Stakeholder Experts			
Surname	Name	Nominated by	Substance
DeWitt	Jamie	EEB	PFAs in firefighting foams
Green	Rhys	ClientEarth	Lead in outdoor shooting and fishing
Hannebaum	Peter	Eurofeu	PFAs in firefighting foams
Höke	Hartmut	Cefic	PAHs in clay targets
Möller	Guido	Cefic	PFAs in firefighting foams
Pain	Debbie	EEB	Lead in outdoors shooting and fishing
Seveque	Jean-Louise	FITASC	Lead in outdoor shooting and fishing
Sebastiani	Giuliana	Eurometaux	Lead in outdoor shooting and fishing
Williams	Cris	Cefic	Lead in outdoor shooting and fishing

European Commission	
Surname	Name
Bertato	Valentina
Lekatos	Stylios
Tosetti	Patrizia

ECHA Staff	
Surname	Name
Bin	Essi
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
Sosnowski	Piotr
Smilovici	Simona
Thierry-Mieg	Morgane
Tissier	ChrysteLe
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
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Restrictions		
n/a		