RAC WG/REST/R/1/2021
Final
12 May 2021
RAC/57/2021/03

Report
of the 1st Meeting of the Committee for Risk Assessment Working Group on Restrictions (RAC-REST WG-1)

ECHA Conference Centre
(Telakkakatu 6, Helsinki)
via Webex

Tuesday 11 May 2021 at 10.00
to
Wednesday 12 May at 16.00

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Tim Bowmer, welcomed the participants of the 1st meeting of the RAC Working Group on restrictions and reminded that the Committee had agreed on its establishment at RAC-56 in March 2021. Three RAC-57 cases (dechlorane Plus™, lead in outdoor shooting and fishing, substances in single-use baby diapers) were chosen for this WG and the RAC consultations had been organised on the two ongoing dossiers prior to the WG meeting.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/REST/1/2021), 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. Four 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 Chair declared that no potential interests related to any of the agenda points for the meeting.

4. Restriction proposals

1. Dechlorane Plus™ - introductory presentation	
The Chair welcomed and thanked the DS representatives from Norway to give an introductory presentation to the RAC WG on restrictions.	
The WG took note of the introductory presentation by the Dossier Submitter.	**Rapporteurs** to prepare the draft conformity check outcome and draft recommendations to the Dossier Submitter and to provide it to SECR. **SECR** to table the outcome of the conformity check for agreement at RAC-57.
2. Lead in outdoors shooting and fishing – first draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA, invited experts from UNEP/AEWA and WWT, as well as the regular and occasional stakeholder observers from CEFIC, EURAMETAUX, EEB, FACE and their accompanying experts from ARCHE Consulting, ILA and Independent Environmental Consultant. He informed the participants that the restriction dossier had been submitted in January 2021 and concerns lead in outdoor shooting and fishing.	
The working group discussed the following: **Regarding the scope:** The group provisionally agreed with the scope as proposed by the Dossier Submitter. The group suggested that 'carrying' might need to be considered by the DS. The group agreed that targeting of the restriction to the use of lead in projectiles and fishing tackle in outdoor uses is appropriate to address the risks to the environment. However, the group noted that human health risks are only partly addressed by the proposal. Although the group acknowledged that it is not able to extend the scope of the proposal, the group noted the following: Exposure and risks to shooters caused by lead in ammunition is not caused only by bullets but also lead containing primers, which typically contain lead styphnate. The group suggested that risk	**SECR** to table the opinion for discussion at RAC-57. **Rapporteurs** to prepare a presentation to RAC-57. **Rapporteurs** to take the discussions into account for the next version of the opinion. **RAC** to review the data submitted on new publications related to the benchmark dose modelling of lead hazards. **DS** to further develop the analysis of risks to groundwater, specifically considering permeation of groundwater bodies.

management measures to limit exposure from primers will be also considered. (This is further discussed in WG3 report). The group also noted that indoor shooting may result in high exposure of shooters. Although professionals working or practising in these indoor shooting ranges are covered by EU OSH legislation (Chemical Agents Directive), this does not cover risks to non-professionals. Therefore, the group also noted that additional measures to tackle the risks to consumers at indoor shooting ranges might be considered. The group agreed that non-civilian uses by police, military and border control when they are "on duty" should be out of scope. However, the group noted that training using lead ammunition by these groups at shooting ranges could pose risks and might usefully be subject to the same conditions of use (i.e. mandatory RMMs) as those proposed for civilian shooting ranges. This would also apply to voluntary military training. Further information on the likelihood of this scenario could become available via the consultation. The group considered that the limit of ≥0.3% w/w of lead for the information-provision elements of the restriction may cause confusion since otherwise the concentration limit of 1% w/w is applied. **Regarding hazard:** The working group agreed with the hazard assessment as proposed by the Dossier Submitter. The agreed with the Dossier Submitter that neurodevelopmental effects are the most critical toxic endpoint of lead. Young children and pregnant females are the sensitive groups for these effects and both groups should be covered in the risk assessment. Overall, the group supported the DS approach to use EFSA $BMDL_{01}$ and the 'old' value of 12 µg/L, noting that some further discussion on this might be needed. The group supported the use of kidney effects and cardiovascular effects in the risk characterisation in adults.	**SECR** and **DS** to investigate and clarify the numbers on the bird-life and wildlife mammals at risk.

Regarding risk, the RAC working group discussed: **Regarding environmental risk from shooting ranges:** RAC WG noted that the risks to environmental compartments and indirectly to humans via the environment are sufficient to justify a restriction. Overall the group concluded that lead contamination of shooting ranges at 200 – 300 g of lead/m^2 can be found, constituting a risk to on and off-site terrestrial receptors. The group considered the risks from the use of lead ammunition via a source, pathway receptor model implemented in a conceptual site model. The group considered that surface water migrating from shooting ranges without RMMs, may constitute a risk of contaminating receiving surface waters, and their off-site animal/bird/fish/drinking water receptors. the group noted that the Dossier Submitter's analysis of the risks posed by lead ammunition was currently insufficient to demonstrate that its use at shooting ranges would result in an EU-wide risk to groundwater and groundwater derived drinking water via infiltration (with the possible exception of groundwater upwelling areas). The group suggested several potential improvements for the Dossier Submitter to consider. The group recognises that for the use of lead in ammunition at shooting ranges. There appears to be limited general risk to groundwater in aquifers with overlying depths of soil, as migration of lead in soil can be very limited; but there are cases, such as at a shooting range lying close to a discharge zone (shallow water table and groundwater mixing with surface runoff), or on acidic thin layers of soil above the aquifer, or through preferential flow paths bypassing the soil matrix, where contamination may occur. Although such water may not be used generally as drinking water, the situation may vary depending on the EU countries.	

Regarding environmental risks to birds and mammals: supported the Dossier Submitter's estimate of 1% of the bird population affected by primary poisoning, while noting the limited data and that higher values seem to come from 'shooting estates'. The working group supported the Dossier Submitter's evaluation that many species of birds are at risk, but cannot currently evaluate the total number of birds at risk as the underlying calculations are not available. The DS agreed to provide the calculations. Overall, the group noted that both primary and secondary poisonings of birds from lead are well documented. There is robust evidence that the use of lead ammunition and fishing tackle remains widespread in Europe and the exposure of different bird species can induce adverse effects as well as mortality; potentially affecting the survival of endangered species. The group suggested that toxic effects can be expected in livestock if fed lead-contaminated grass or silage, while the field evidence for poisoning of wildlife mammalian species, whilst feasible, is currently limited. Hunting dogs and poultry could be additional receptors at risk. **Regarding exposure:** **Human health risks from shooting** The group supported the Dossier Submitter's qualitative assessment of human health exposure but noted some substantial uncertainties (i.e. contribution to exposure from lead primers). The group agreed that a qualitative assessment is the most appropriate way forward and would not need to be further discussed (subject to further information submitted in the consultation). **Exposure from home-casting** The group provisionally agreed that exposure from home-casting is plausible, but the quantitative contribution is probably highly case-specific and no quantitative assessment is currently possible in relation to overall exposure	

to lead. The group recommended that this would not need to be further discussed (subject to further information submitted in the consultation). The available data on exposure is limited, but based on the studies available, the group concluded that exposure to lead from direct contact with lead fishing sinkers is possible, but quantification of exposure and risk is not possible. The group concluded that direct oral exposure to lead from fishing sinkers is possible and likely occurs, but quantification of exposure and risk is not possible. **Human health risk from eating game or dairy products/cattle meat** The group concluded that exposure to lead via environment is an important concern in particular for uses 1 and 2b for meat consumption and 3b, 3c and 4C for food. More detailed assessment on consumption of game meat to be done by the rapporteurs. For the dairy products and cattle meat, the group recommended that this would not need to be further discussed (subject to further information submitted in the consultation). **The group recommended that:** RAC-57 further discuss the following: - Number of birds at risk - DS quantitative risk assessments - Ground water issues - Game consumption and lead exposure - Size of fishing tackle in relation to conditions of the restriction.	
The occasional stakeholder observer from FACE commented on the scope and on the risk estimates. The expert (ILA) accompanying the regular CEFIC stakeholder observer, commented on the hazard assessment. The expert accompanying the regular Eurometaux stakeholder observer, commented on the risks to groundwater and the risks. The invited experts from UNEP/AEWA and WWT commented on the risk estimates to birds and mammals referring to the additional studies available.	

3. Substances in single-use baby diapers – second draft opinion	
The Chair welcomed the Dossier Submitter's representatives from France, the occasional stakeholder observers from EDANA and their accompanying expert from Procter&Gamble, CIRFS and their accompanying expert from Lenzing as well as CONCAWE. He informed the participants that the restriction dossier had been submitted in October 2020 and concerns substances in single-use baby diapers.	
The WG discussed the following: **Regarding the scope:** The working group considers that the Dossier Submitter has not sufficiently justified the exclusion of fragrances from the scope of the proposal and that there is insufficient information to evaluate their risk further. **Regarding the hazard:** The group agreed that for formaldehyde, the local effect (i.e. skin sensitisation) is more relevant than systemic effects. The group further agreed with the DS's approach for setting DMELs for PAHs based on dermal studies (BAuA and Knafla studies). The group agreed with the DS's approach in that the DMEL for PAH mixtures is appropriate for risk assessment and noted that the DS's use of a 10^{-6} risk level for DMEL derivation is in line with typical practice and ECHA guidance. The group discussed the provisional agreement from RAC-56 to separate DL and Non-DL PCBs, noting that despite not being measured during the underlying analytical study, Non-DL PCBs are likely to make up the largest share of PCBs overall. RAC WG recommended that, contrary to the provisional agreement and in line with the DS's proposal, DL PCBs and PCDD/Fs should be considered together (for the estimation of TEQ). **Regarding exposure:** The working group noted that the exposure assessment is well explained but considers that the approach leads to a significant overestimation, particularly of the 'rewet' factor, and hence exposure. The group also noted that there are significant uncertainties regarding the analytical methods.	**SECR** to table the opinion for discussion at RAC-57. **Rapporteurs** to prepare a presentation to RAC-57. **Rapporteurs** to take the discussions into account for the next version of the opinion. **Dossier Submitter** to provide additional information regarding the diaper samples tested, including blank samples and their variation and include this into the background document. **Dossier Submitter** also to provide reference data for substances detected in feminine hygiene products.

Pending the arrival of additional data requested and agreed by the DS, the rapporteurs will further elaborate on the exposure assumptions in the next version of the opinion; in particular on: the 600 ml of urine simulant used, on the impact of the number of changes of diaper, on the timing of the release of the substances from the diapers as well as the use of the LOD as the measured value even when the substance was not detected. The group suggested to include a sensitivity analysis into the next version of the opinion in order to determine the impact of the different factors on exposure. The group noted that PAHs were only ever detected by the laboratory but not quantified. Available exposure data is thus expressed in terms of LOD/LOQ and the group noted that this needed further consideration as to its appropriateness. **Regarding risk:** The working group noted that an allocation factor to the RCR is usually only applied in risk management not in the characterisation of the risk. An allocation factor could potentially be justified for substances where the DNEL is based on oral exposure and a proportion of the total exposure could be expected from other sources i.e. diet. However, the precise value of the allocation factor (i.e. 10% and what this was based on) has not been justified by the DS. It should also be noted, that in other similar risk assessments the correction is made in the risk characterisation, not to the DNEL. For formaldehyde and PAHs, the group concluded that an allocation factor to the RCR is not justified in any case since local effects (i.e. dermal) are the most relevant ones for these substances. For formaldehyde, the group agreed that the skin sensitising effects (dermal route) are of most relevance compared to systemic and irritative effects, and that the elicitation threshold is the most relevant for the risk characterisation. Also,	

the RAC rapporteurs' calculations should be checked. The group pointed out that there are many remaining uncertainties but that preliminary analysis with more realistic exposure assumptions related to the rewet factor and RCR allocation shows that RCR values < 1 were calculated for formaldehyde, PCDD/Fs, and PCBs. The group asked the rapporteurs to further develop the analysis considering industry's stated rewet factor, the number of changes of nappies, considering the change in the risk approach for PCDD/Fs and PCBs. The group agreed that, based on the DS's approach, a RCR >1 can be demonstrated for PAHs. However, it was also noted that regarding PAHs, there are significant uncertainties in the analytical determination in diapers. For example, the latest round of results on 32 diapers (2019 testing) show no detectable level of PAHs except in 4 samples where only 1 PAH, (benzo(a)anthracene), was detected. **The working group discussed and recommended that**: RAC-57 further discuss the following: the risk characterisation for all substances in the scope of the restriction. the exposure assessment and its underlying assumptions. The reliability and representativeness of the available analytical data for PAHs; specifically considering use of non-quantified (detected) data for exposure estimation; including any additional information provided by the DS or from the consultation.	
The occasional stakeholder observers from CIRFS and EDANA and their expert from Procter&Gamble commented on the analytical method used by the dossier submitter. EDANA also commented on associated industry initiatives over the past years.	

5. AOB: REST horizontal issues

The Secretariat presented and the participants discussed the updated RAC and SEAC Framework paper on in checking conformity and developing opinions on restriction proposals. The Secretariat will make the necessary amendments based on feedback received (where relevant) and to table the revised version for RAC-57 for information. The members confirmed the need for the training course which can be organised in June 2021. Some members suggested that it might be useful to include restriction experts from the member states in the training on how RAC evaluates restrictions – the Secretariat to look into this and to inform the Restriction Task Force.

6. Adoption of the report from the RAC CLH working group

Before the Chair thanked the participants and closed the meeting, the WG adopted its report of the 1st Meeting, requesting the Secretariat to make any necessary editorial changes.

LIST OF ANNEXES

Annex I	**Final Agenda of the of the 1st 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

20 April 2021
RAC WG/A/REST1/2021rev1
Final

Agenda

1st Meeting of the Committee for Risk Assessment Working Group on Restrictions (RAC-REST WG-1)

11-12 May 2021

WebEx meeting

11 May starts at 10.00
12 May ends at 17.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC WG/A/REST1/2021
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Restriction proposals

1. Dechlorane Plus™

For information

2. Lead in outdoors shooting and fishing
3. Substances in single-use baby diapers

For discussion

Item 5 – AOB

1. REST horizontal issues

For discussion

Item 6 – Adoption of the Report from the WG

For discussion and agreement

Annex II

List of participants

RAC Members	
Surname	**Name**
Barański	Bogusław
Bjørge	Christine
De la Flor Tejero	Ignacio
Doak	Malcolm
Facchin	Manuel
Geoffroy	Laure
Hammer Sørensen	Peter
Husa	Stine
Mohamed	Ifthekhar Ali
Kapelari	Sonja
Leinonen	Riitta
Lund	Bert-Ove
Martinek	Michal
Moeller	Ruth
Neumann	Michael
Peczkowska	Beata
Printemps	Nathalie
Santonen	Tiina
Schlueter	Urs
Schulte	Agnes
Schuur	Gerlienke
Uzomeckas	Zilvinas
Varnai	Veda

RAC Members' advisers		
Surname	**Name**	**Nominated by**
Buckley	Kevin	Malcom Doak
Losert	Annemarie	Manuel Facchin
Stalter	Daniel	Agnes Schulte
Tarvainen	Emma	Riita Leinonen

Invited experts		
Surname	**Name**	**Substance**
Cromie	Ruth	Lead in outdoor shooting and fishing
Dereliev	Sergey	Lead in outdoor shooting and fishing
Viegas	Susana	All agenda points

Dossier Submitters			
Surname	**Name**	**Authority**	**Substance**
Correll Myhre	Ingunn	Norwegian Environment Agency	Dechlorane Plus
Dahlberg Persson	Marie	Norwegian Environment Agency	Dechlorane Plus
DUBOIS	Céline	ANSES	Substances in single-use diapers
Kopangen	Marit	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
MATHIEU	Aurelie	ANSES	Substances in single-use diapers
Mazzolini	Anna	ECHA	Lead in outdoor shooting and fishing
Øystein Fotland	Tor	Norwegian Environment Agency	Dechlorane Plus
Reuter	Ulrike	ECHA	Lead in outdoor shooting and fishing

Regular Stakeholder Observers		
Surname	**Name**	**Organisation**
De Backer	Liisi	Cefic
Duguy	Hélène	ClientEarth
Robinson	Jan	A.I.S.E
Romano	Dolores	EEB
Van de Broeck	Steven	Cefic
Verougstraete	Violaine	Eurometaux
Waeterschoot	Hugo	Eurometaux

Occasional Stakeholder Observers			
Surname	**Name**	**Organisation**	**Substance**
Ballach	Jochen	CIRFS	Substances in single-use diapers
Di Pietra	Marco	EURATEX	Substances in single-use diapers
Lagemaat	Marines	EDANA	Substances in single-use diapers
Niemela	Helena	CONCAWE	Items 1,2,3,5, Substances in single-use diapers
Puustinen	Seppo	FACE	Lead in outdoor shooting and fishing

Stakeholder Experts			
Surname	**Name**	**Nominated by**	**Substance**
Pain	Debbie	EEB	Lead in outdoor shooting and fishing
Rahbaran	Shayda	CIRFS	Substances in single-use diapers
Taryn	Kirsch	EDANA	Item 5, Substances in single-use diapers
Verdonck	Frederik	Eurometaux	Lead in outdoor shooting and fishing
Williams	Cris	CEFIC	Lead in outdoor shooting and fishing

European Commission	
Surname	**Name**
Blass	Ana
PIRSELOVA	Katarina
Tosetti	Patrizia

ECHA Staff	
Surname	**Name**
Blainey	Mark
Bowmer	Tim
Gmeinder	Michael
Henrichson	Sanna
Marquez-Camacho	Mercedes
Orispää	Katja
Ottati	Maria
O'Rourke	Regina
Regil	Pablo
Sihvonen	Kirsi
Simpson	Peter
Smilovici	Simona
Sosnowski	Piotr
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		
Diapers (FR)	Nathalie PRINTEMPS	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
	Laure GEOFFROY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
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.