

RAC WG/REST/R/2/2021
20 August 2021

Report
of the Meeting of the Committee for Risk Assessment
Restrictions Working Group (RAC REST WG)
reporting to RAC-58

ECHA Conference Centre
(Telakkakatu 6, Helsinki)
via Webex

Thursday 19 August 2021 at 10.00
to
Friday 20 August at 16.20

Summary Record of the Proceedings

1. Welcome and apologies

The Chair, Tim Bowmer, welcomed the participants of the 2nd 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 Mark Blainey 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/2/2021), 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 co-Chairs, all declared that they are no potential interests related to any of the agenda points for the meeting.

4. Restriction proposals

1. Dechlorane Plus - first draft opinion	
<p>The Chair Johanna Peltola Thies welcomed the Dossier Submitter's representatives from Norway. 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 WG discussed the following:</p> <p>Regarding scope:</p> <p>The working group agreed that the substance scope and the overall scope of the restriction are clear and well defined. The group further noted that there is a link between the proposed restriction and the ongoing process of identifying Dechlorane Plus as a persistent organic pollutant under the Stockholm Convention. The group noted that derogations were not evaluated as part of the scope discussion and will be assessed later in the opinion development. The Rapporteurs will modify the RAC conclusions accordingly.</p> <p>Regarding hazard:</p> <p>The working group supported the Rapporteurs findings that a hazard has already been established by the MSC and no further justification is needed to proceed with the evaluation of the proposed restriction by RAC. The group considered it unlikely that any relevant new data would be submitted in the consultation which would bring the vPvB properties into question.</p> <p>Regarding exposure and releases:</p> <p>The group had an initial discussion on exposure and releases and noted that the assessment provided by the DS is plausible. It clearly demonstrates that current uses result in emissions and that there is an ongoing exposure of the environment and humans. Release pathways and long-range transport were pointed out as issues to be addressed by the Rapporteurs in future versions of the opinion. Updates to the</p>	<p>SECR to table the opinion for discussion at RAC-58.</p> <p>SECR to reach out to stakeholders regarding manufacture and import of Dechlorane Plus.</p> <p>SECR to consider the timing of the next steps in the opinion development process.</p> <p>Rapporteurs to take the discussions into account for the next version of the opinion.</p>

dossier on the ceasing of import to the EU by the single REACH registrant of Dechlorane Plus were discussed and this will be addressed in the next version of the opinion. This is not likely to have a significant impact on the emissions, as most of them arise from the waste stage.

Regarding risk characterisation:

The group had an initial discussion on risk characterisation and noted that a quantitative risk assessment was not appropriate given that Dechlorane Plus is a vPvB. Release and exposure data provided by the DS was found to be conclusive in that it provides evidence of ongoing exposure and thus the presence of a risk that should be controlled. The working group noted that emission estimates can be used as a proxy for risk. The group discussed that available monitoring data could be used to further elaborate on exposure and risk.

The working group discussed and recommended that:

- RAC agree on the scope of the restriction
- RAC agree on the hazard assessment as proposed in the restriction proposal
- RAC agree at a general level that there is a risk to address based on the type of uses and on the measured data on ongoing exposures in the environment and humans

NOTE by the secretariat: the emissions would still need to be considered in detail.

The DS commented on the derogations discussed in the restriction proposal and on releases to air and long-range transport vis-a-vis the substance characteristics. It was noted that no representative of the manufacturer of the substance was present at the working group meeting

2. Lead in outdoors shooting and fishing – second draft opinion

The Chair Tim Bowmer welcomed the Dossier Submitter's representatives from ECHA and their experts (Triskelion and WCA), invited experts from UNEP/AEWA, as well as the regular and occasional stakeholder observers from CEFIC, EUROMETAUX, EEB, FACE, EAA 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 human health risk from home-casting:

The working group agreed that exposure from home-casting is plausible, but the quantitative contribution is probably highly case-specific and no quantitative assessment is currently possible. According to the report by Triskelion, neither monitoring data nor modelling are truly adequate or representative of the exposure resulting from home-casting.

The working group provisionally concluded that the human health risk from home-casting is moderate, as worst-case conditions may occasionally occur.

Regarding environmental risk from shooting ranges to ground water:

The working group welcomed the WCA analysis of the risks posed by lead ammunition to an EU-wide groundwater receptor. According to WCA's findings, hydrogeological conditions typically control the potential for transport of lead through the vadose zone and into groundwaters. The working group noted that detailed GIS analysis would be required to estimate the number and location of the high risk areas characterised by the report, noting that this would be a complex task.

The working group agreed that the risk of ground water contamination may vary from very low to high depending on the specific characteristics of the site. The combination of acidic soils, coarse soils, preferential flow pathways or macropores and shallow depths to groundwater (<3m) lead to high vulnerability to lead contamination. It is difficult to estimate the prevalence and extent of groundwater vulnerability to lead contamination at shooting ranges at European, national or even regional scale. Local factors will always influence potential risks more than generic considerations,

SECR to table the opinion for discussion at RAC-58.

Rapporteurs to prepare a presentation to RAC-58.

Rapporteurs to take the discussions into account for the next version of the opinion.

RAC members to comment on the second draft opinion by 24 August 2021, especially with regard to the qualitative risk assessment.

but some areas with high intrinsic vulnerability are likely to occur in all EU Member States, although to differing extents.

Regarding environmental risks to birds

The working group confirmed its support for the Dossier Submitter's evaluation of the number of species and number of birds at risk.

For terrestrial birds, the working group agreed that in the order of 1 million birds may die annually after ingestion of lead gun shot. The working group noted however that the data does not allow mortality of birds resulting from secondary ingestion to be calculated.

Overall, the group concluded that the use of lead ammunition and fishing tackle remains widespread in Europe and the exposure of different bird species can induce sublethal effects as well as mortality and potentially affect the survival of endangered species. New data submitted in the consultation on the Annex XV Dossier will be considered by the Dossier Submitter for the update of the Background Document and will be assessed for the next version of the draft opinion.

The definition of lures needs to be further assessed.

Regarding Human health risk from eating game or dairy products/cattle meat

The working group considered different scenarios of game meat consumption and estimated that, similar total intakes of lead to that calculated by the Dossier Submitter may follow even after a few meals/year of highly contaminated meat.

The working group agreed with the Dossier Submitter that there is a high risk for neurodevelopmental effects in children resulting from game meat consumption.

For adults, the working group concluded that low risk is expected. However, the group highlighted

the risks of game meat consumption for females at fertile age, and especially pregnant females.

The working group agreed with the approach chosen by the Dossier Submitter for the estimation of the human health impacts based on the whole distribution of game meat lead levels and considered that it provides a more realistic overview than focusing on a single point estimate. The working group concluded that the Dossier Submitter's evaluation is sufficient for health impact assessment, as long as related uncertainties are recognised.

Regarding the qualitative risk assessment

The working group agreed to use the approach proposed by the rapporteurs for the evaluation of the qualitative risk assessment based on a conceptual model considering potential source of exposure, receptor, pathway as well as the probability and severity of effects.

The working group did not go through the individual conclusions on the risk levels for each of the activities (see below).

The group recommended that:

RAC-58 further discuss the following:

- Qualitative risk assessment (individual conclusions on the risk levels)
- Uncertainties.

The occasional stakeholder observer from EAA commented on the lead exposure estimates from home-casting (no data available). The regular Eurometaux stakeholder observer, and its accompanying expert, as well as the regular EEB stakeholder, commented on the risks to groundwater.

The expert accompanying the regular EEB stakeholder informed about the new research on lead exposure in bird population. The invited experts from UNEP/AEWA commented that the risk estimates to birds were underestimated and highlighted the impacts on mammals. The regular Eurometaux stakeholder observer commented on the risks to birds and on robustness of estimates for terrestrial birds, and the occasional stakeholder observer FACE commented on mortality rates of birds.

The expert (ILA) accompanying the regular Cefic stakeholder commented on the alternative risk assessment scenarios, regarding peak exposure. The regular Eurometaux stakeholder observer commented on exposure levels. The occasional stakeholder observer FACE, and the expert accompanying the regular EEB stakeholder commented on lead concentration in game meat (EFSA study).

3. Substances in single-use baby diapers – third draft opinion

The Chair, Mark Bainey welcomed the Dossier Submitter's representatives from France, the occasional stakeholder observers from EDANA and their accompanying expert from Procter&Gamble and CIRFS. He informed the participants that the restriction dossier had been submitted in October 2020 and concerns substances in single-use baby diapers.

The rapporteurs summarised the state of play underlining the overall conclusion that the DS has not conclusively demonstrated a risk that needs to be addressed by an EU wide restriction. Namely, due to the high level of uncertainties related to the exposure assessment and risk characterisation of the substances in the scope of this restriction proposal, the risk for babies has not been sufficiently demonstrated for formaldehyde, PCDDs/Fs/DL-PCBs and NDL-PCBs and cannot be characterised for PAHs. The working group highlighted that this finding does not mean that there is no risk from carcinogenic PAHs and substances with endocrine disrupting properties, i.e. PCDDs/Fs/DL-PCBs as impurities/contaminants in single use diapers, but that the Dossier Submitter has not reliably demonstrated that there is an EU-wide risk that needs to be addressed.

The WG discussed the following:

Regarding the appropriateness of industry's existing and recommended RMMs and OCs to control the risk:

The working group noted that none of the substances in the scope are added intentionally and that concentrations should be kept as low as possible/feasible.

The working group recommended that fragrances are not added intentionally in line with the Consumer Products Regulation and Toy Safety Directive.

SECR to table the opinion for adoption at RAC-58.

Rapporteurs to prepare a presentation to RAC-58.

Rapporteurs to take the discussions into account for the final version of the opinion.

The working group also highlighted the link to the restriction proposal for skin sensitising substances regarding fragrances with harmonised classification as skin sensitisers.

Regarding sufficiency of existing RRM instruments:

The working group noted that RAC cannot currently rule out possible health risks associated with the substances in the scope for babies and children under the age of three.

There is no binding EU wide regulation specific to baby diapers.

The working group noted that the risk of allergic effects from formaldehyde exposure in babies would very likely be addressed by the restriction proposal on skin sensitising substances.

Regarding a justification of action required on Union wide basis:

The group noted that RAC would propose action on a Union wide basis if a risk from exposure would have been demonstrated. However, the working group reiterated that an EU-wide risk has not been demonstrated by the DS.

Regarding a justification of a restriction being the most appropriate EU wide measure:

The working group agreed that a restriction would be the most appropriate RMO for substances which pose a risk for babies and children under the age of three.

Uncertainties and shortcomings noted by RAC may be addressed by the DS in the future, for example by providing more realistic exposure assumptions in the exposure scenario as well as suitably low and consistent limits of detection and quantification for the analysis of the substances of concern.

The group noted that the scope of the restriction proposal regarding the articles covered was clear

and that RAC considers concentration limits in the proposal to be migration limits.

The group recommended to encourage existing voluntary programs such as the one led by EDANA to establish voluntary industry standards dealing with impurities/contaminants.

The group pointed out a possible conflict of the proposed restriction with the POPs Regulation.

Regarding effectiveness in reducing risk and practicability:

The working group pointed out that the effectiveness of the proposed restriction to reduce the risk cannot be assessed, due to the uncertainties in the risk characterisation.

The group also noted that there is currently no standardised analytical method, which will have an effect on monitorability and enforceability.

Regarding uncertainties:

The group reiterated the uncertainties encountered during the assessment of the proposal, including the extraction and analytical methods, the exposure assessment and risk characterisation.

The DS and the stakeholder observer EEB commented on the risk characterisation and compared RAC's current approach to that taken by RAC regarding previous restriction proposals.

The accompanying expert from Procter&Gamble invited by the occasional stakeholder observer EDANA commented on the extraction method.

The Commission commented on the difference between demonstrating a risk and the absence of a risk and on the difference between concentration and migration limits.

The stakeholder observer EEB also commented on the precautionary principle and how it relates to RAC's assessment as well as recommendations for improving the current restriction proposal.

The DS commented on the voluntary programs highlighted by the rapporteurs.

The DS and the occasional stakeholder observer EDANA commented on the extraction method used in EDANA's voluntary program.

The occasional stakeholder observer CIRFS commented on the importance of blanks in the analytical method.

5. AOB: REST horizontal issues

The Secretariat presented the update on the upcoming restriction dossiers.

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 2nd Meeting, requesting the Secretariat to make any necessary editorial changes.

LIST OF ANNEXES

Annex I **Final Agenda of the of the 2nd 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

24 August 2021
RAC WG/A/REST2/2021
FINAL

Agenda

**Meeting of the Committee for Risk Assessment Restrictions
Working Group (RAC REST WG) reporting to RAC-58**

19-20 August 2021

WebEx meeting

**19 August starts at 10.00
20 August ends at 16.00**

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

***RAC WG/A/REST2/2021
For adoption***

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Restriction proposals

1. Dechlorane Plus™
2. Lead in outdoors shooting and fishing
3. Substances in single-use baby diapers

For discussion

Item 5 – AOB

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
Husa	Stine
Mohamed	Ifthekhar Ali
Leinonen	Riitta
Lund	Bert-Ove
Moeller	Ruth
Moldov	Raili
Neumann	Michael
Pribu	Mihaela
Rodriguez	Wendy
Santonen	Tiina
Schlueter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Tobiassen	Lea Stine
Varnai	Veda

Invited experts		
Surname	Name	Substance
Cromie	Ruth	Lead in outdoor shooting and fishing
Dereliev	Sergey	Lead in outdoor shooting and fishing
Kapelari	Sonja	Substances in single-use diapers

RAC Members' advisers		
Surname	Name	Nominated by
Abeysinghe	Amanda	Karen Thiele
Losert	Annemarie	Manuel Facchin
Lotus Lottrup	Grete	Lea Stine Tobiassen
Marinkovic	Marino	Betty Hakkert
Tarvainen	Emma	Riita Leinonen

SEAC Rapporteurs		
Surname	Name	Substance
Alexandre	João	Dechlorane Plus
Cogen	Simon	Substances in single-use diapers
Måge	Marit	Substances in single-use diapers
Thiele	Karen	Lead in outdoor shooting and fishing

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
Filtvedt	Anne Line	Norwegian Environment Agency	Dechlorane Plus
Kopangen	Marit	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

Olsen	Christel	Norwegian Environment Agency	Dechlorane Plus
Øystein Fotland	Tor	Norwegian Environment Agency	Dechlorane Plus
Pasquier	Elodie	ANSES	Substances in single-use diapers
Tolfsen	Christina	Norwegian Environment Agency	Dechlorane Plus
Reuter	Ulrike	ECHA	Lead in outdoor shooting and fishing
Marquart	Hans	Triskelion (ECHA Expert)	Lead in outdoor shooting and fishing
Merrington	Graham	WCA (ECHA Expert)	Lead in outdoor shooting and fishing
Whelan	Mick	Leicester University (ECHA Expert)	Lead in outdoor shooting and fishing

Regular Stakeholder Observers		
Surname	Name	Organisation
Jànosi	Amaya	Cefic
Romano	Dolores	EEB
Waeterschoot	Hugo	Eurometaux

Occasional Stakeholder Observers			
Surname	Name	Organisation	Substance
Ballach	Jochen	CIRFS	Substances in single-use diapers
Kappel	Jan	EAA	Lead in outdoor shooting and fishing
Lagemaat	Marines	EDANA	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
Taryn	Kirsch	EDANA	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
Tosetti	Patrizia

ECHA Staff	
Surname	Name
Blainey	Mark
Bowmer	Tim
Gmeinder	Michael
Henrichson	Sanna
Marquez-Camacho	Mercedes
Orispää	Katja
Peltola-Thies	Johanna
Regil	Pablo
Roberts	Julian
Rheinberger	Christoph
Smilovici	Simona
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)	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.