

**Report
of the third Meeting of the Committee for Risk Assessment
Drinking Water Working Group (RAC DWD WG)
reporting to RAC-68**

**Thursday 14 March 2024 at 14:30 EET to
Friday 15 March 2024 at 17:15 EET**

Summary Record of the Proceedings, and Conclusions and action points

1. Welcome and apologies

The RAC Chair, Roberto Scazzola, made an introduction to express how pleased he is to see RAC and the RAC DWD Working Group have come together and his hopes for productive collaboration. The Working Group brings in important new expertise which the RAC needs. This is the first joint meeting of RAC with its DWD Working Group and it is hoped to foster a closer relationship and cohesion among all members.

The Deputy Chair of RAC, Piotr Sosnowski, acting as the chair in the afternoon of 14 March, also welcomed the participants of the 3rd meeting of the RAC Working Group on Drinking Water Directive. He noted that Panos Zarogiannis would chair the morning part of the meeting on Friday.

The Chair thanked all experts at RAC and the DWD Working Group for their valuable contributions on the documents that were disseminated by the RAC Secretariat following the October meeting.

The Chair explained that this meeting has a very strong focus on the presentation of two case studies. These are based on real applications previously submitted to a German National Authority and will be used to familiarise the Committee members to future applications and also train participants on important new concepts.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/A/3/2024), which was adopted without amendments and is attached to this Report as Annex I.

3. Declarations of conflicts of interests to the Agenda

No conflict of interest was declared either by the Chair Piotr Sosnowski, co-Chair of the Working Group meeting Panos Zarogiannis or any of the participants.

4. Action points from the last meeting

The Chair presented main action points from the last meeting. All action points from the last meeting are listed below:

Action point 1: SECR to consider further streamlining and shortening the guidance, avoiding repetitions and ensure consistency with other guidance (e.g. REACH, CLP). Where possible reference to be provided to other guidance instead of repeating text (e.g. use of QSARs, read-across, weight of evidence (WoE)).	In progress
Action point 2: SECR to reflect in the Guidance clear criteria where migration modelling can be used instead of physical testing.	In progress
Action point 3: SECR to develop criteria on how the accordance check will address gaps and shortcomings in the data provided by the applicants and when the application should be rejected.	In progress
Action point 4: SECR to further clarify in the guidance the relation between determination of TOC and analytical methods.	In progress
Action point 5: SECR to make available to RAC and DWD WG members the versions of the two Guidance documents that will be shared with the DWD Guidance user group for a second round of commenting (13 October to 12 November).	Done
Action point 6: SECR to open a consultation on the document identifying 'simple' and 'complex' DWD cases, which was previously prepared by ECHA, and invite written comments after the meeting.	Done: consultation "Approach to distinguishing 'simple' from 'complex' applications With Attachments" launched on 23 January via the Interact portal, comments received by 16 February and a summary has been disseminated
Action point 7: SECR to take the input provided during the meeting and further written comments into account in the further development of the	Planned for a future meeting

scenarios and criteria, which will be presented in one of the next meetings of the WG.	
Action point 8: Participants to take note of the possibility to comment on the legal acts during the "Have Your Say" consultation.	Done
Other action taken: SECR circulated an EU Survey on the availability of standards to RAC and RAC DWD WG members was launched.	Around 20% response rate and so far only few respondents have full access. RAC/DWD WG members to respond if not already done so.

5. DWD

5.1 Update on the adoption of the DWD implementing legislation	
The Secretariat orally presented the progress made since October 2023. The implementing acts were voted favourably by the DWD Committee on 15 December 2023 and the Commission adopted all six implementing and delegated acts on 23 January 2024. The Commission shall publish all 6 acts at the same time. Publication in the EU Official Journal is expected by the end of March 2024.	
The link to the legal acts is: https://environment.ec.europa.eu/publications/delegated-acts-drinking-water-directive_en	RAC members and DWD WG members to familiarise themselves with the legal acts.
5.2. Case study 1: Starting substance	
On Day 1, two members of the RAC DWD WG presented an introduction to the first case study, the application submitted to the German National Authority for the starting substance AATMP. On Day 2, the Secretariat presented in more detail the different parts of the application made for AATMP to the German National Authority and made a comparison of what was submitted to what the information requirements under the DWD legislation are.	
Introduction - Day 1 Helping applicants: It was questioned how much ECHA can help applicants to prepare dossiers in addition to issuing guidance. SECR explained that there will be additional collective activities to support the applicants, but	SECR to consider and propose a consistent way of using information not included in a DWD application.

<p>due to the workload it will not be possible to support them individually.</p> <p>Drinking water and food contact materials: Legislation for the two is different, but where possible alignment and harmonisation should be considered. ECHA and EFSA collaborate in the preparation of DWD guidance.</p> <p>How RAC could use additional information: It was clarified that RAC may use any information, even if not in the application, that is available for drafting its opinion. However, further information cannot be used for filling in information gaps in the application submitted by the applicant.</p> <p><u>Detailed discussion - Day 2</u></p> <p>Substance identity</p> <p>There is good alignment between what was required and submitted under the German national system and requirements under DWD, while more detailed information on composition may be required under DWD.</p> <p>It was clarified that the substance identity information will be checked during the accordance check and only if/when identity will be clear, the case will progress to RAC.</p> <p>Use description and identification of relevant chemical species.</p> <p>Description of the analytical methods used for analysis of non-intentionally added species (NIAS) such as oligomers is crucial. Under DWD the description of these methods may need to be more detailed.</p> <p>There were questions raised on the information that would need to be provided in addition to the information of monomer, e.g. information on curing agent. It was clarified that under DWD a separate application would need to be provided for the curing agent. In general, the formulation in the manufacturing process should be fully provided.</p> <p>It was clarified that it is in the interest of the applicant to identify all the non-intentionally added species (NIASs) related to the substance, because these may then appear when the product is evaluated for certification and if not</p>	<p>SECR to further develop the working relationship between the WG and RAC to manage the considerable workload.</p> <p>SECR to continue the close cooperation with EFSA.</p> <p>SECR to clarify exceptions from the scope of Art 11 in collaboration with COM.</p> <p>SECR to explore how any new information on a NIAS that RAC has assessed could or should impact the maximum tolerable concentration at the tap (MTC_{tap}) values of other entries in the EUPL.</p>
--	---

mentioned on the positive list, the product will not be certified.

Possibilities of grouping applications will be pursued and joint RAC opinions are allowed by the legal framework.

Migration

A question was raised on whether we could accept a substance on positive list tested under conditions that do not reflect worst foreseeable ones. This would need to be considered by the WG in the future.

Uses outside the scope of Art. 11, e.g. membranes were raised. Definition of what exactly is outside of the scope may need to be provided.

Toxicological assessment

Several parts of the toxicological information in the case study would not meet the information requirements under DWD.

For non-intentionally added species, the studies are expected to be carried out on those chemical species. However, if these cannot be tested, read-across and QSARs can be used.

A chronic study is required only at the high migration tier, 90-day (not 28-day) at the mid migration. Additional assessment factor will be used to account for life-time exposure when maximum tolerable concentration at the tap (MTC_{tap}) is based on the 90-day repeated dose toxicity study.

In generating an MTC_{tap} value, an allocation factor (ALF) must be used to account for other sources of exposure.

Risk acceptance

Several questions were raised and clarifications were provided in relation to the limited acceptance methodology. It was clarified that under DWD, a maximum tolerable concentration at the tap (MTC_{tap}) value that is lower than 0,1 µg/l may be obtained from a sufficiently low parametric value in Annex I of DWD.

It was also clarified that a classification of the substance means either the harmonised classification or the "self-classification" indicated by the applicant.

5.3. Case study 2: Metallic composition

On Day 1, a member of the RAC DWD WG presented an introduction to the second case study, the application submitted to a national authority for the metallic composition (alloy) CW727R.

On Day 2, the Secretariat presented in more detail the different parts of the application made for CW727R to the German National Authority and made a comparison of what was submitted to what the information requirements under the DWD legislation are.

Introduction - Day 1

Some differences in approaches in assessment between metallic compositions and organic materials were highlighted during discussion.

There is a good alignment in relation to the required migration data needed for national application and EU application, but stricter maximum tolerable concentration at the tap (MTC_{tap}) values would apply under the EU legislation.

For many metallic compositions, no toxicological information will be required, but in some special cases (e.g., bismuth), toxicological information will be needed for the creation of a maximum tolerable concentration at the tap (MTC_{tap}) value.

For assessing metallic compositions, specific expertise in corrosion may be needed for the assessment of the worst case test piece. Important for a worst-case testing is the length of migration testing, the choice of test water(s) and the test piece composition.

Detailed discussion – Day 2

Identity of composition: A full report of composition analysis would be preferred by the WG. An accreditation of the laboratory may not be necessary (and not required in Annex I of 1.IA (Implementing Act)).

Migration of relevant chemical species: Micrographs of the tested samples may be useful to clarify any surface effects which may affect long-term migration, however this is not required by the migration EN standard.

SECR to investigate whether information on the surface of tested samples would be useful for RAC's opinion drafting.

<p>The scope of the accreditation of the laboratory that is testing migration must cover the relevant migration standard. If not, full validation reports and calibration information would be required. The one known laboratory undertaking migration testing for metallic compositions is known to be suitably accredited.</p>	
<p>5.4. Update on development of DWD Guidance</p>	
<p>The Secretariat presented an overview of the key comments received from RAC and RAC DWD WG members on the draft DWD Guidance documents which were shared with the Committee in October 2023. Responses to those comments by ECHA were also disseminated before the meeting. Next steps for the conclusion of the guidance documents, also taking into account inputs from stakeholders (members of the DWD Guidance user group), were discussed.</p>	
<p>The aim is to publish the English versions of Volume I and II of the guidance by the end of the year.</p> <p>ECHA is also drafting:</p> <ul style="list-style-type: none"> - Volume III of the guidance which will clarify the scope of DWD applications. - Volume IV which aims to explain the contents of the Notification of intention under DWD. <p>JRC is drafting guidance (Volume V) on calibrants.</p> <p>The guidance documents (Volume I and II) will be translated in 23 EU languages.</p>	<p>SECR to share in May 2024 new versions of Volume I and II of the guidance, as well as all the comments received. The drafts of Volume III and IV will also be shared when available.</p> <p>SECR to share Volume V when available.</p>
<p>5.5. Update on development scenarios for simple vs complex applications</p>	
<p>The Secretariat thanked members for inputs made. Responses to certain questions addressed to ECHA were given and it was explained that the useful inputs made will be used to develop Part II of this document where scenarios will be set out for each individual material type. These scenarios will support the planning and process development that ECHA is performing internally for the set-up of the accordance check and the Committee's planning for processing applications. Part II will be shared with the Committee.</p>	
<p>SECR provided clarifications and answers to the main comments received on the document.</p>	<p>SECR to share a table with the ECHA responses to comments.</p>
<p>5.6. Proposal for a support group on toxicokinetics for DWD guidance</p>	
<p>The Secretariat announced the setting up of a small informal group that will work in the period April-September 2024 towards supporting ECHA experts with the drafting of the toxicokinetics parts of Volumes I and II of the DWD Guidance. Three</p>	

members have already been invited and the invitation to participate is extended to all Committee and Working Group members.	
The Secretariat presented the scope and timelines for the support group on toxicokinetics for DWD Guidance and invited the participants to express interest to participate in this work by 25 March.	<p>RAC members and DWD WG members to express their interest in joining the group by 25 March 2024.</p> <p>SECR to provide written description of the task to those with an interest.</p>
6. AOB	
There was no other item discussed.	

7. Adoption of the RAC-68 DWD WG report

The report was presented to participants. The WG adopted the RAC-68 DWD WG report by consensus at the WG meeting.

The Chair thanked the participants for the fruitful and informative discussions and closed the meeting.

The exact date and duration of the next meeting, planned for the end of September will be communicated to members soon after this meeting.

LIST OF ANNEXES

- Annex I** **Final Agenda of the of the 3rd Meeting of the Committee for Risk Assessment Working Group on Drinking Water**
- Annex II** **List of participants**

Annex I

Final Agenda

**3rd Meeting of the Committee for Risk Assessment
DWD Working Group
reporting to RAC-68**

14 March 2024 at 14.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Action points from the last meeting

Item 5 - DWD

- 5.1 Update on the adoption of the DWD implementing legislation
- 5.2 Case Study 1: Starting substance
 - 5.2.1 Introduction
 - 5.2.2 Detailed presentation and discussion
- 5.3 Case Study 2: Metallic composition
 - 5.3.1 Introduction
 - 5.3.2 Detailed presentation and discussion
- 5.4 Update on development of DWD Guidance
- 5.5 Update on development of scenarios for simple vs complex applications
- 5.6 Proposal for a support group on toxicokinetics for DWD guidance

For information/discussion

Item 6 – AOB

Item 7 – Adoption of the RAC-68 DWD WG report

For adoption

Annex II

List of participants Day 1

DWD WG Members	
Surname	Name
Almeida	Cristina
Antoniou	Maria
Baron	Jean
Berger	Sabrina
Bergkvist	Charlotte
Georgieva	Tzveta
Junek	Ralf
Kontou	Stella
Lampi	Evgenia
Liadakis	Georgios
Mendaš Starčević (RAC Member)	Gordana
Neumann (RAC Member)	Michael
Novelli	Anne
Pavlova	Vera
Rapp	Thomas
Sanchis Sandoval	Josep Angel
Spiteri	David
van de Ven	Bianca
Vogel	Lisa
Uurasjärvi	Emilia

RAC members	
Surname	Name
Angeli	Karine
Aquilina	Gabriele
Baranski	Boguslaw
Brovkina	Julija
Chiurtu	Elena-Ruxandra
Christodoulou	Sotirios
Deviller	Genevieve
Docea	Anca Oana
Esposito	Dania
Facchin	Manuel
Geoffroy	Laure

Hoffmann	Frauke
Kadikis	Normunds
Karadjova	Irina
Kloslova	Zuzana
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Manusadzianas	Levonas
Martinek	Michal
Menard Srpič	Anja
Mohammed	Ifthekhar Ali
Murray	Brendan
Piña	Benjamin
Pribu	Mihaela
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Santonen	Tiina
Schuur	Gerlienke
Sørensen	Peter Hammer
Tekpli	Nina
Tobiassen	Lea Stine
Užomeckas	Žilvinas
van der Haar	Rudolf
Varnai	Veda Marija
Wildemann	Tanja

RAC Advisers

Surname	Name	Nominated by
Beestra	Renske	Hakkert Betty and Schuur Gerlienke
Jankowska	Agnieszka	Baranski Boguslaw
Kristensen	Mette Albæk	Lea Stine Tobiassen
Moilanen	Marianne	Leinonen Riitta
Möller	Ruth	Hoffmann Frauke
Russo	Maria Teresa	Aquilina Gabriele
Suutari	Tiina	Leinonen Riitta

Stakeholder Regular Industry Observers

Surname	Name	Organisation
Barry	Frank	ETUC
Ruelens	Paul	CropLife Europe
Van de Merckt	Lara	Eurometaux

European Commission Observers	
Surname	Name
Roebben	Gert

EU Agencies Observers		
Surname	Name	Organisation
Barthélémy	Eric	EFSA

Stakeholder Regular NGO Observers		
Surname	Name	Organisation
Hermann	Christine	EEB

Stakeholder Occasional Industry Observers		
Surname	Name	Organisation
Loebel	Oliver	EurEau

Stakeholder Occasional Industry Observer Experts		
Surname	Name	Nominated by
Nödler	Karsten	Loebel Oliver

ECHA Staff	
Surname	Name
Atanasova	Marina
Basmatzi	Theodora
Bercaru	Ofelia
Blainey	Mark
Fabjan	Evelin
Frattini	Stefano
Galetsa Feindt	Athina E.
Hellsten	Niko
Herbatschek	Nicolas
Lehto Hürlimann	Mikko
Martinelli	Erikka
Nicot	Thierry
Niemela	Helena
O'Rourke	Regina

ECHA Staff	
Surname	Name
Portugal	Laura
Rueda	Clara
Ruoss	Jurgen
Sadam	Diana
Scazzola	Roberto (Chair)
Sokolova	Maia
Sosnowski	Piotr (co-Chair)
Stoyanova	Evgenia
Tai	Kaihsu
Vitcheva	Vessela
Xydaki	Elena
Zarogiannis	Panos (co-Chair)

List of participants Day 2

DWD WG Members	
Surname	Name
Almeida	Cristina
Antoniou	Maria
Baron	Jean
Berger	Sabrina
Bergkvist	Charlotte
Georgieva	Tzveta
Junek	Ralf
Kontou	Stella
Lampi	Evgenia
Liadakis	Georgios
Mendaš Starčević	Gordana
Neumann	Michael
Novelli	Anne
Pavlova	Vera
Rapp	Thomas
Sanchís	Josep
Spiteri	David
van de Ven	Bianca
Vogel	Lisa
Uurasjärvi	Emilia

RAC Members	
Surname	Name
Geoffroy	Laure
Hakkert	Betty
Karadjova	Irina
Piña	Benjamin
Rodriguez	Wendy
Schuur	Gerlienke
Tobiassen	Lea Stine

RAC Advisers		
Surname	Name	Nominated by
Kristensen	Mette Albæk	Lea Stine Tobiassen

Stakeholder Regular NGO Observers		
Surname	Name	Organisation
Hermann	Christine	EEB

Stakeholder Regular Industry Observers		
Surname	Name	Organisation
Van de Merckt	Lara	Eurometaux

EU Agencies Observers		
Surname	Name	Organisation
Barthélémy	Eric	EFSA

ECHA Staff	
Surname	Name
Basmatzi	Theodora
Bercaru	Ofelia
Blainey	Mark
Fabjan	Evelin
Frattini	Stefano
Hellsten	Niko

ECHA Staff	
Surname	Name
Herbatschek	Nicolas
Martinelli	Erikka
O'Rourke	Regina
Rueda	Clara
Ruoss	Jurgen
Scazzola	Roberto (Chair)
Sokolova	Maia
Sosnowski	Piotr (co-Chair)
Tai	Kaihsu
Vitcheva	Vessela
Xydaki	Elena
Zarogiannis	Panos (co-Chair)