

**Report  
of the second Meeting of the Committee for Risk Assessment  
Drinking Water Working Group (RAC DWD WG)  
reporting to RAC-67**

**WebEx Conference**

**Wednesday 4 October 2023 at 10:00 EET**

**Summary Record of the Proceedings, and Conclusions and action points**

**1. Welcome and apologies**

The Chair of RAC, Roberto Scazzola, welcomed the participants of the 2<sup>nd</sup> meeting of the RAC Working Group on Drinking Water. He noted that Panos Zarogiannis would chair the afternoon part of the meeting.

The Chair briefly presented himself as the new Chair of ECHA and thanked all experts at RAC and the DWD Working Group for their valuable contributions in July-September on the topics and documents that were disseminated by the RAC Secretariat following the June meeting.

The Chair explained that this meeting has a very strong focus on the draft DWD Guidance documents which were reviewed by RAC and the RAC DWD WG between August and September: the discussion would cover the most critical comments and would address how Stakeholder Organisations will be able to make their input into these drafts.

The Chair commended the high interest in this WG by RAC members. It was announced that the plan is to have a joint face to face meeting in March 2024 during the week of the RAC plenary (11-15 March). This is intended to bring WG members and RAC members into the same room and build cohesion.

The Chair further explained that a second important topic in the agenda was the start of ECHA's analysis of what constitutes a simple or a complex application case. ECHA's first step in that direction is to see under what circumstances certain parts of a DWD application may be more or less complex. The relevant agenda point required participants to have familiarised themselves with a document disseminated by the RAC Secretariat before the meeting.

The Chair announced that the meeting will also cover the preliminary results of an external study on the intentions of stakeholders as regards the number of potential DWD applications to be submitted to ECHA from 2026 onwards.

## 2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/A/2/2023), 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, co-Chair or any of the participants.

## 4. Action points from the last meeting

A series of slides were presented by Panos Zarogiannis to review the activities undertaken under the 9 action points set out in the minutes of the previous meeting.

<b>Action point 1: SECR</b> to invite EFSA representatives to future meetings of the RAC drinking water working group	Done – EFSA accepted the invite and will act as observer to the WG.
<b>Action point 2: SECR</b> to plan the meetings for 2024 and inform the working group	Done – first meeting for 2024 is planned in 11-15 March during the RAC plenary. Further meetings to be decided upon and announced before end of 2023. RAC members requested that early announcement would be useful.
<b>Action point 3: SECR</b> to launch consultations to collect initial ideas of the working group on <ul style="list-style-type: none"> <li>• criteria to classify applications as “simple cases”</li> <li>• RAC opinion template</li> <li>• application evaluation procedures and horizontal issues</li> <li>• IT requirements</li> <li>• training needs</li> </ul>	Done.
<b>Action point 4: Members of the Working Group</b> to provide comments on consultation topics by 15 August 2023	Done – ECHA presented in brief the progress made in relation to the consultation topics since the last meeting.
<b>Action point 5: SECR</b> to organise in June 2023 an initial IUCLID training for the working group	Done – Meeting of the IT tools user Group was held on

members and then launch consultations with the working group on the IUCLID format	13 June – a slot for IUCLID Q&A has been included in today's agenda
<b>Action point 6: Members of the Working Group</b> to provide comments on the first version of the IUCLID format by the end of August 2023	No comment was received so far. If anyone wishes to make comments, there is still time until end of October.
<b>Action point 7: SECR and industry associations</b> to consider the planning relevant training for future applicants on preparation and submission of applications	No action taken yet. When the legal acts will be adopted and guidance is available, ECHA will work very closely with stakeholders.
<b>Action point 8: SECR</b> to disseminate draft guidance documents to RAC and the Working Group members by mid-August for comments	Done – Draft documents were shared with WG members on 15 August with a commenting deadline of 15 September.
<b>Action point 9: Members of the Working Group</b> to provide comments on the draft documents that the secretariat will disseminate to the working group in August	Done – Several commented files submitted by the Working Group and RAC members. Multiple comments were received.

ECHA presented the progress in developing the draft RAC opinion template. Templates from other processes will be considered and account will be taken of the information requirements; the level of detail in the opinion will need to be balanced. This will be further discussed in upcoming meetings. One size will probably not fit all – ECHA suggested that there is a need to consider the needs of different types of materials, differences between negative/positive opinions, etc.

In relation to the review of past cases, relevant input has been received from UBA and RIVM. ECHA's proposal is to make a start with a few cases among those shared by UBA. ECHA will collaborate with UBA to select more than one case studies, share documents with RAC and WG members in advance of the next meeting and present and review those at the next meeting in March 2024.

Action point: **SECR** to finalise arrangements for the RAC DWD WG meetings in 2024 and to advise RAC and WG members as soon as possible.

## 5. DWD

### 5.1. Review of the draft guidance documents

The Secretariat presented the most critical comments made by RAC and Working group members on the two draft DWD Guidance documents and a discussion followed among participants on the comments and the next steps in developing and

adopting the Guidance documents. The Chair clarified that Stakeholders will be invited to comment on the revised draft Guidance through the DWD Guidance user group.

Several RAC members commented that the guidance is too long, contains repetitions and concerns were raised that there may be inconsistencies with other guidance or references to outdated guidance. Some suggestions were provided on how to streamline. STO commented that the length as such is not an issue, but the guidance should be clear.

Concerns were raised that despite different checks by ECHA applications with data gaps and shortcomings could still reach RAC. ECHA clarified that due to the large number of applications and tight timelines it will not be possible to discuss with every applicant on how to improve the application or to generate new data during the process. Guidance will be given in advance, but we cannot exclude that there will be substances with data gaps. In such cases the applications may get a very low  $MTC_{tap}$  or applications may fail the accordance check.

Some participants commented that we cannot expect any materials where the migration would be  $>250 \mu\text{g/L}$  and the information requirements for the medium migration tier appear to be too low. It was clarified that there are some cases with such high migration, e.g. metallic materials (cu and galvanised steel pipes) and some substances originating from the plastic FCM list.

Some suggestions were provided on which information could be used to prove that the substance does not bioaccumulate and on the use of toxicokinetic studies in the hazard assessment.

There is some unclarity in the guidance related to the determination of the TOC.

**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, WoE).

**SECR** to reflect in the Guidance clear criteria where migration modelling can be used instead of physical testing.

**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.

**SECR** to further clarify in the guidance the relation between determination of TOC and analytical methods.

**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).

<p>It was clarified that parametric values take into account sources outside the drinking water while the allocation factor expresses how much of exposure from drinking water is allowed to come from the contact material.</p> <p>The Secretariat provided an update on further development and commenting of the guidance. Concerns were raised that a different approach is taken in case of DWD compared to other legislations.</p> <p>Two additional guidance documents are under development, Guidance on notifications of intention and Guidance on the scope of the applications.</p>	
<p><b>5.2. Feedback on scenarios for simple vs. complex applications</b></p>	
<p>The Secretariat presented the initial analysis undertaken on the identification of elements of DWD applications of low or high complexity, as a first step in identifying 'simple' and complex' DWD applications. The aim is to develop scenarios to facilitate, early in the process, identification of applications suitable for the 'ECHA track' (simple) and 'RAC track' (complex).</p>	
<p>The Secretariat clarified that the aim is to develop a simple methodology and criteria to differentiate between the applications based on complexity.</p> <p>There was discussion on some scenarios presented and participants provided views and proposals on which scenarios or combinations would be more or less complex, in particular in relation to substance-material combination, intended use, identity and composition of the applied for entry, identity of relevant substances and migration estimation. Some scenarios were considered not very relevant (e.g., phys-chem properties).</p>	<p><b>SECR</b> to open a consultation and invite written comments after the meeting.</p> <p><b>SECR</b> to take the input provided during the meeting and further written comments into account in the further development of the scenarios and criteria, which will be presented in one of the next meetings of the WG.</p>
<p><b>5.3. Activities on IUCLID familiarisation and training</b></p>	
<p>The Secretariat presented an overview of the ongoing work on the development of the DWD IUCLID templates and explained the next steps in the next few months. Participants were invited to address any IUCLID/IT questions to the Secretariat.</p>	
<p><b>5.4. Update on the progress of the adoption of the DWD implementing legislation</b></p>	

<p>The European Commission gave a brief oral update on the progress made since June towards the completion of the drafts of the implementing legislation and explained the next steps towards the adoption of those acts.</p>	
<p>The COM informed that the DWD legal acts have been published on 27 September for WTO consultation which will run until 26 November.</p> <p>Have Your Say consultation will be launched in the course of the week starting 9 October (with a one month commenting period). Everyone can comment on each individual act.</p> <p>The DWD Committee vote on the legal acts is planned for the beginning of December. The Commission is still on schedule to adopt all six legal acts by January or latest by mid-March 2024.</p>	<p><b>Participants</b> to take note of the possibility to comment on the legal acts during the "Have Your Say" consultation.</p>
<p><b>5.5. Findings of external study on stakeholders' intentions on future DWD applications</b></p>	
<p>The Secretariat presented the preliminary findings of an external study commissioned by ECHA on the investigation of the intentions of industry stakeholders as regards the number of future DWD applications to be submitted to the Agency.</p>	
<p>The preliminary results of the study show that 50 – 60 % of the draft 1<sup>st</sup> EUPL has received some interest for application. The preliminary numbers also show that there could be a substantial number of applications for substances not yet on the EUPL, in particular for starting substances and cementitious constituents.</p> <p>A variety of actors in the supply chain expressed interest in the substances on the EUPL – not necessarily manufacturers who may hold important data and absence of legally mandated data sharing was raised as an issue in the study.</p> <p>IND asked if there will be any future attempt to repeat/update this study. Currently there are no plans to repeat the study, but if anybody wishes to still provide input, they can do it through their representatives or directly to ECHA.</p>	

<b>6. AOB</b>
No other agenda points were discussed.

**7. Adoption of the report from the RAC DWD working group**

The report was presented to participants and its adoption as requested by the Chair. The report was adopted without modification. The Chair thanked the participants for the fruitful and informative discussions and closed the meeting.

**LIST OF ANNEXES**

- Annex I**      **Final Agenda of the of the 2nd Meeting of the Committee for Risk Assessment Working Group on Drinking Water**
- Annex II**     **List of participants**

**Annex I**

**Final Agenda**

**2<sup>nd</sup> Meeting of the Committee for Risk Assessment  
DWD Working Group  
reporting to RAC-65**

**4 October 2023 at 10.00**

**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 Review of the draft guidance documents
- 5.2 Feedback on scenarios for simple vs. complex applications
- 5.3 Activities on IUCLID familiarisation and training
- 5.4 Update on the progress of the adoption of the DWD implementing legislation
- 5.5 Findings of external study on stakeholders' intentions on future DWD applications

*For information/discussion*

**Item 6 – AOB**

**Item 7 – Summary of meeting conclusions and planning for next meeting**

*For discussion and agreement*



**Annex II**
**List of participants**

<b>DWD WG Members</b>	
<b>Name</b>	<b>Surname</b>
Almeida	Cristina
Baron	Jean
Junek	Ralf
Konevski	Karolina
Kontou	Stella
Liadakis	Georgios
Mendaš Starčević	Gordana
Nepper-Rasmussen	Nadine Heidi
Neumann	Michael
Novelli	Anne
Rapp	Thomas
Sanchís	Josep
Spiteri	David
van de Ven	Bianca

<b>RAC Members</b>	
<b>Surname</b>	<b>Name</b>
Angeli	Karine
Karadjova	Irina
Losert	Annemarie
Lund	Bert-Ove
Menard Srpčič	Anja
Piña	Benjamin
Rodriguez	Wendy
Schuur	Gerlienke
Spetseris	Nikolaos
Tekpli	Nina
Tobiassen	Lea Stine

Tsitsimpikou	Christina
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<b>DWD Advisers</b>		
<b>Surname</b>	<b>Name</b>	<b>Nominated by</b>
Uurasjärvi	Emilia	Leinonen Riitta

<b>Stakeholder Regular Industry Observers</b>		
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>
Mueller	Patrik	PlasticsEurope
Prieto Arranz	Miguel Angel	Cefic
Van de Merckt	Lara	Eurometaux

<b>Stakeholder Regular NGO Observers</b>		
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>
Hermann	Christine	EEB

<b>European Commission Observers</b>	
<b>Surname</b>	<b>Name</b>
Leemans	Bert

<b>EU Agencies Observers</b>		
<b>Surname</b>	<b>Name</b>	<b>Organisation</b>
Barthélémy	Eric	EFSA

<b>ECHA Staff</b>	
<b>Surname</b>	<b>Name</b>
Scazzola	Roberto (Chair)
Zarogiannis	Panos (co-Chair)
Blainey	Mark
Burchard-Sosnowska	Dorota
Fabjan	Evelin
Frattini	Stefano
Haag	Tommy
Hellsten	Niko

<b>ECHA Staff</b>	
<b>Surname</b>	<b>Name</b>
O'Rourke	Regina
Sokolova	Maia
Sosnowski	Piotr
Tai	Kaihsu
Vitcheva	Vessela