

**Report
of the first Meeting of the Committee for Risk Assessment
Drinking Water Working Group (RAC DWD WG)
reporting to RAC-65**

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

**Thursday 1 June 2023 at 10:00
to
Friday 2 June 2023 at 13:30**

Summary Record of the Proceedings, and Conclusions and action points

1. Welcome and apologies

The Chair of RAC, Tim Bowmer, welcomed the participants of the 1st meeting of the RAC Working Group on Drinking Water. He noted that Piotr Sosnowski would chair sections of the meeting.

He congratulated the 16 experts who were nominated to the group and some also appointed as advisers to RAC members, noting that this commitment is really appreciated by the Agency.

He emphasized that together we are starting to prepare a new and challenging process in RAC and ECHA and that the Agency is really counting on the expertise of the participants of this working group.

The Chair then handed over to Mark Blainey (Head of Unit Prioritisation) who welcomed the participants on behalf of Ofelia Bercaru, Director of Prioritisation and Integration. He noted that the Directorate B is the 'home' of drinking water directive implementation but many other colleagues outside Dir B have been essential in getting to where we are today. The DWD implementation started in 2020 and ECHA and MSs reached several important milestones, such as submitting to the Commission several pieces of implementing legislation, including a draft European Positive List. Today is also another milestone in that the members of the working group, RAC and ECHA start the preparations leading up to the future assessment of EU Positive List applications in RAC with the start of this RAC working group.

The scope of working group's work (until 2025) is to help prepare the tools necessary to RAC for assessing incoming applications starting from 2026. Mark Blainey ensured the working group that they can rely on the support of ECHA staff in these preparations and for the applications. He noted that just over 2000 entries are at present first positive lists, but it's probable that not all entries in the 1st EU Positive Lists will be applied for. However, the working group and ECHA need to find ways of

streamlining the work

of ECHA and RAC ('keep it simple') and ensuring that we smooth workload peaks out. The working group's preparations until 2025 will be important in this 'keep it simple' context. There are clear links to the Food Contact Materials work that EFSA is responsible for. He informed the working group that we have had EFSA's support in developing the DWD information requirements and ECHA will strive to maintain a very close collaboration with EFSA in the spirit of One Substance-One Assessment. In the discussion it was raised that it is important EFSA are invited to the meeting. In concluding, he wished the participants a fruitful meeting.

2. Adoption of the Agenda

The Chair reviewed the agenda for the meeting (RAC WG/A/DWD 65/2023), which was adopted without amendments and is attached to this Report as Annex I.

3. Declarations of conflicts of interests to the Agenda

At this first meeting, the Secretariat explained ECHA's transparency approach and policy for avoidance of conflicts of interest in detail.

4. RAC

4.1. RAC and its role in ECHA	
The Secretariat presented an overview of RAC its role, tasks, the duties of its members and then gave an overview of the current four processes where RAC provides opinions.	
It was noted that for the evaluation of drinking water applications, new expertise is required that is not currently present in RAC. Therefore, the involvement of RAC members who have come forward and who are connected to advisors/experts in the drinking water working group will be critical going forward.	
4.2. Mandate and practicalities of the RAC DWD WG	
The Secretariat introduced the mandate for the RAC drinking water working group its organisation and the scope of the working group.	
The mandate agreed for the working group by RAC was presented briefly. The working group asked for information on how it will be planned in the future. The secretariat replied that for 2024 an agenda for the whole year will be provided as part of the	SECR to invite EFSA representatives to future meetings of the RAC drinking water working group.

<p>RAC workplan, as required by the Rules of Procedure.</p> <p>The working group noted that only RAC members can be appointed as rapporteurs. The Chair explained that advisors to members can provide complete opinions and present them following approval in the name of a Committee member as a rapporteur. When rapporteurs are needed (from 2026) the situation may have evolved.</p>	<p>SECR to plan the meetings for 2024 and inform the working group.</p>
<p>4.3. RAC IT tools</p>	
<p>The Secretariat presented IT tools used by RAC to share meeting documents and to organise consultations and collaboration between meetings.</p>	
<p>The immediate availability of ECHA's communication platform 'Interact' was explained to the members.</p>	
<p>4.4. Discussion on stakeholders' engagement</p>	
<p>The Secretariat presented ECHA policy concerning the role and participation of stakeholders in ECHA processes.</p>	
<p>As with all ECHA bodies and working groups, the Agency's policy is to allow accredited stakeholders to attend all open sessions as observers and to contribute in well-defined ways. This also applies to the RAC drinking water working group. The stakeholders code of conduct and confidentiality obligations of stakeholders were briefly outlined.</p>	
<p>4.5. DWD work plan and expected workload</p>	
<p>The Secretariat presented the proposal for a Work Plan for the drinking water working group for the period 2023-2024. The proposal includes involvement of the working group IT development.</p>	
<p>The workplan for the working group covers the remainder of 2023 and 2024 in outline and includes several key topics, e.g. to develop Committee procedures and to scrutinise new guidance documents (in prep.). Members responded positively to the plans and provided some additional suggestions. The intention to use IUCLID as the main data repository was outlined by the Secretariat.</p>	<p>SECR to launch consultations to collect initial ideas of the working group on</p> <ul style="list-style-type: none"> - criteria to classify applications as "simple cases" - RAC opinion template - application evaluation procedures and horizontal issues - IT requirements - training needs.

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	<p>Members of the working group to provide comments by 15 August 2023.</p> <p>SECR to organise in June 2023 an initial IUCLID training for the working group members and then launch consultations with the working group on the IUCLID format.</p> <p>Members of the working group to provide comments by the end of August 2023.</p>
5. DWD	
5.1 DWD and implementing acts	
<p>The Secretariat presented Directive (EU) 2020/2184 on the quality of water intended for human consumption with special focus on content of Article 11 of the Directive and role of RAC and ECHA.</p>	
<p>The working group discussed the provisions of the parts of the directive that are relevant to the work of RAC and the working group (Article 11, Annexes I and V). The group asked for further consideration of the relationship between applications for food contact materials and applications for entries on the EU Positive List plus any efficiencies that can be gained by coordination with EFSA. The secretariat agreed to explore this with EFSA regarding collaboration but noted that a common application for both processes was not envisaged and it is outside the remit of the working group.</p>	
5.2. Information requirements for DWD applications submitted	
<p>The Secretariat presented Information requirements for DWD applications set in the draft 1st Implementing Act (1.IA).</p>	
<p>The working group discussed concerns that most of the specific migration limits values under the food contact material legislation may be older than 15 years and questioned their suitability noting that their review might impact the workload of applicants and the Committee. The group discussed the requirement to provide information on impurities and the</p>	

<p>manufacturing process of a substance and raised the issue of the validity of migration mathematical models that applicants may use.</p> <p>In further discussion it was clarified that migration tests should represent the worst case conditions of use and the different contact areas in different materials.</p> <p>The Secretariat explained that it will be up to industry to ensure that applications for substances will be submitted according to the expiry dates on the EU Positive List. The agency will continue to consolidate the current estimates for the EU Positive List by reaching out to industry but has no plans to encourage or coordinate applications beyond what is required in the legislation.</p>	
<p>5.3. Steps to the DWD application process</p>	
<p>The Secretariat presented the step-by-step description of the application process as described in 3.DA.</p>	
<p>The working group discussed the role of only representatives in the DWD process and expressed concerns when using data provided for assessment processes of other EU bodies. The working group asked how information on expiry dates and new applications will be communicated to the industry. That will be very important for certifiers of materials/products foreseen for contact with drinking water. The secretariat explained that the ECHA website will act as the key source of information on the latest approval status of a substance on the EU Positive List.</p> <p>The working group expressed concerns on expected quality of applications and discussed how submission of bad quality applications can be avoided.</p> <p>The working group asked why there is no plan to involve RAC/the working group in the accordance check. The secretariat informed that this approach was recommended based on previous experience in RAC and the expected heavy workload.</p> <p>One stakeholder requested transparent criteria on how applications will be prioritised. They recommended to ECHA to consider</p>	<p>SECR and industry associations to consider the planning relevant training for future applicants on preparation and submission of applications.</p>

<p>dialogue meetings (applicants, RAC rapporteurs, ECHA) for large joint applications. At the same time, they pointed to potential difficulties in identifying substances and preparation of joint applications.</p>	
<p>5.4. The 1st European positive lists</p>	
<p>The Secretariat presented the first European Positive Lists - The draft 2nd Implementing Act (2.IA)</p>	
<p>The group discussed how detailed the requirements will be to define the identity of approved contact materials for each substance on the organic materials EU Positive List. The secretariat replied that the applicant will provide details in their application, but the EU Positive List will only list the high-level approved material categories (e.g., plastics, rubber, silicones, etc.).</p> <p>The group also discussed the exclusion from the organic materials positive list of a small number of substances originating from the plastic Food Contact Material list of Regulation (ECU) No 10/2011, on the basis of their irrelevance to the manufacture of drinking water contact materials.</p>	
<p>5.5. Guidance development (plans, procedures)</p>	
<p>The Secretariat presented the role of the working group in the development of guidance documents for DWD applications.</p>	
<p>There was discussion on how to handle commenting by the working group on the large volume of guidance, as well as when the guidance would be first needed. Some members recommended not to rush to meet unrealistic early deadlines (the end of 2023) given the importance of guidance to a new process. ECHA replied that due to financial reasons the guidance documents have to be sent for translation by the end of 2023 although the work on the documents will continue and some changes will be possible in 2024 and during later updates.</p>	<p>Members of the working group to provide comments on the draft documents that the secretariat will disseminate to the working group in August. The commenting period is envisaged to be mid-August to mid-September 2023.</p>
<p>6. AOB</p>	

6.1 Reflections on the discussions of the last two days

The secretariat requested feedback from the members of the group on this first meeting and on the introductory information presented, expressing the wish for members to engage fully with the work going forward. Members showed their appreciation of the extensive material presented by ECHA and the thorough preparations, including information on the role of the Committee and its Rules of procedure governing the working group, the work plan and the detailed descriptions of the components of the DWD application evaluation process.

One member suggested that informal calls could help to progress work items between meetings in the future. The secretariat responded that it was common practise to hold dialogues with the members between meetings and this would be arranged as needed.

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

The Chair thanked the participants and closed the meeting, noting that as the report did not contain any agreements on work items on this occasion it could be adopted by written procedure on this occasion rather than in the meeting.

LIST OF ANNEXES

- Annex I Final Agenda of the of the 1st Meeting of the Committee for Risk Assessment Working Group on Drinking Water**
- Annex II List of participants**
- Annex III Declarations of potential conflicts of interest**

Annex I

Final Agenda

**1st Meeting of the Committee for Risk Assessment
DWD Working Group
reporting to RAC-65**

1 - 2 June 2023

Thursday 1 June starts at 10.00

Friday 2 June ends at 13.30

Times are Helsinki times

Item 1 – Welcome and Apologies

- 1.1. Welcome
- 1.2. Presentation of RAC WG membership

Item 2 – Adoption of the Agenda

For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

- 3.1. Conflict of Interest management at ECHA and RAC

Item 4 – RAC

- 4.1 RAC and its role in ECHA
 - independent body, transparency role of Stakeholders Observers, rapporteurs, remuneration, other RAC processes, RAC Rules of Procedures, future of Scientific Committees (ECHA Basic Regulation)
- 4.2. Mandate and practicalities of the RAC DWD WG
 - Role of WG; links to plenary and RAC members; meeting frequency, travel arrangements; support (secretariat, ECHA staff); role of COM and stakeholders; advisors vs WG members; workload expectations
- 4.3. RAC IT tools
- 4.4. Discussion on stakeholders' engagement and their contribution to the work of RAC and its working group on the Drinking Water Directive
- 4.5. DWD work plan and expected workload (Development of working procedures, standards, templates, no of cases after 2025, IT tools and infrastructure planned for DWD applications)

Presentation of a proposal for a Work Plan for the period 06/2023 to 12/2024

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WG Task 1: Work on criteria and procedures for evaluating applications for EUPL inclusions and removals.

WG Task 2: Support the development of 2-track process ('ECHA track' vs. 'RAC track'; development of criteria and interaction between Accordance Check and work of RAC DWD WG

WG Task 3: Review of DWD guidance (overview of 2 Guidance volumes, status and timeline for further development; WG work required)

WG Task 4: Capacity building (pilot cases/review of past relevant work; involvement in trialling relevant parts of IT solution; other internal training)

Item 5 - DWD

- 5.1. Introduction to DWD Article 11 and the preparatory work for its implementation
 - History of Art. 11; structure of Art. 11; links between substances and materials; work of the two Sub-groups; role of Expert group and DWD Committee
- 5.2. Information requirements for DWD applications submitted
 - Contents and scope of 1.IA; key concepts; status, timeline and date of application
- 5.3. Steps to the DWD application process
 - Contents and scope of 3.DA; from notification to COM decision; actors, roles and responsibilities; process timelines; timeline and date of application
- 5.4. The 1st European positive lists
 - Contents and scope of 2.IA; nature of entries per material type; number of entries; expiry dates and how they have been assigned; transitional provisions; workload per expiry date
- 5.5. Guidance development (plans, procedures)

Item 6 – AOB

- 6.1 Reflections on the discussions of the last two days; suggestions for priorities or additions in Work Plan; Q&A

Item 7 – Adoption of the RAC DWD WG Report

For discussion and agreement

Annex II
List of participants
Annex II
List of participants

DWD Members		
Surname	Name	
Georgieva	Tsveta	
Pavlova	Vera	
Antoniou	Maria	
Baron	Jean	
Lampi	Evgenia	
Liadakis	Georgios	
Kontou	Stella	
Spiteri	David	
Bergkvist	Charlotte	
RAC Members		
Surname	Name	
Mendaš Starčević	Gordana	
Neumann	Michael	
Piña	Benjamin	
Rodriguez	Wendy	
Schlüter	Urs	
Tobiassen	Lea Stine	
Tsitsimpikou	Christina	
DWD Advisers		
Surname	Name	Nominated by
Nepper-Rasmussen	Nadine Heidi	Lea Stine Tobiassen
Novelli	Anne	Karine Angeli
Junek	Ralf	Michael Neumann
Rapp	Thomas	Urs Schlüter
van de Ven	Bianca	Gerlienke Schuur
Almeida	Cristina	Susana Viegas
Sanchís	Josep	Benjamin Pina

Annex II
List of participants

Invited experts	
Surname	Name
Wendelboe	Kim

Stakeholder Regular Industry Observers		
Surname	Name	Organisation
Waeterschoot	Hugo	EUROMETAUX

Stakeholder Occasional Industry Observers		
Surname	Name	Organisation
Mc Carthy	Adam	ETRMA

Stakeholder Experts		
Surname	Name	Nominated by
Finazzi	Emanuele	ETRMA
Prieto Arranz	Miguel Angel	Cefic

European Commission	
Surname	Name
Leemans	Bert

Annex II
List of participants

ECHA Staff	
Surname	Name
Bowmer	Tim (Chair)
Sosnowski	Piotr (co-Chair)
Alami-Eerikiharju	Wafa
Anagnostakis	Konstantinos
Blainey	Mark
Burchard-Sosnowska	Dorota
Doyle	Simone
Fabjan	Evelin
Hellsten	Niko
Nygård	Daniel
Njoroge	Wanjiru
O'Rourke	Regina
Pillet	Monique
Sokolova	Maia
Vesentini	Damiano
Vitcheva	Vessela
Zaerogiannis	Panos

ANNEX III

Declarations of potential conflicts of interest

Not applicable at the first meeting of the working group.

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	Member	Reason for potential CoI / Working for