

**Minutes of the 85th Meeting
of the Member State Committee
(MSC-85)**

Tuesday 13 February 2024

Summary Record of the Proceedings and Conclusions and action points

Chair's opening address

The Chair, Katinka van der Jagt, welcomed all participants to the 85th MSC meeting with remote participation. The Chair mentioned a few highlights of the meeting, including one testing proposal evaluation (under Dossier evaluation), the MSC opinion on the update of the CoRAP and a status update on the draft for the 12th Annex XIV recommendation.

Agenda point	
Conclusions / agreements / adoptions	Action requested after the meeting (by whom/by when)
Item 2 – Adoption of the Agenda	
The Agenda (MSC/A/85/2024) was adopted as modified at the meeting.	SECR to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-85 minutes.
Item 3 – Declaration of specific interests to items on the Agenda	
No potential conflicts of interests were declared by the MSC Chair, any members, experts or advisers with any item on the agenda of MSC-85.	
Item 4 – Administrative issues	
<ul style="list-style-type: none"> Outlook for MSC-86 The Chair presented an outlook on the potential length of the MSC-86 (June 2024) meeting.	
Item 5 – Minutes of the MSC-84	
SECR informed the Committee that the minutes of MSC-84, adopted by MSC at that meeting, are published on Interact and on ECHA's website.	
Item 6 - Substance evaluation	
No items.	
Item 7 - Dossier evaluation - Discussion and seeking agreement on draft decisions (DDs) on compliance checks and testing proposals when amendments were proposed by MS-CA's	
Testing proposal	
TPE-096/2023 4,4'-methylenedi-2,6-xyleneol (EC No. 226-378-9)	
Session 1 & 2 (open & closed)	
A representative of the Registrant joined the meeting to follow the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held followed by discussion and voting in closed session.	
ECHA Secretariat (SECR) introduced the proposals for amendment (PfAs) that required discussion in the meeting. The PfAs suggested to include Cohort 3 (developmental	

immunotoxicity, DIT) in the extended one-generation reproductive toxicity study. The proposals were justified by available data on the Substance:

- 1) specific mechanism/mode of action with an association to DIT, namely estrogenic/androgenic/steroidogenic (EAS) mode of action or sex steroid-related potential, observed *in vitro* and *in vivo* in fish and rats;
- 2) immunotoxicity, namely thymus epithelial cell proliferation;
- 3) arguments 1 and 2 combined.

SECR had not modified the draft decision before the meeting, awaiting discussion in the meeting. The Registrant had not submitted written comments on the PfAs.

MSC discussed the relevance of the available data.

MSC acknowledged that the evidence raised in the PfAs is sufficient to indicate that the Substance may have EAS activity in rats *in vivo*.

MSC also acknowledged that the evidence raised in the PfAs shows histopathological effects in thymus.

MSC held that both arguments, independently, satisfy the column 2 conditions (Annex X, section 8.7.3.) for triggering the DIT cohort.

Discussion outcome:

MSC concluded that the evidence presented in this case justifies inclusion of the DIT cohort in EOGRTS. MSC agreed to modify the draft decision in line with the arguments presented in the PfAs. Finnish member abstained from voting.

<p>The MSC reached unanimous agreement on the following ECHA draft decision as modified at the meeting:</p> <ul style="list-style-type: none"> • TPE-096/2023 4,4'-methylenedi-2,6-xyleneol (EC No. 226-378-9) 	<p>SECR to upload on Interact the agreed decision in the respective case agenda point.</p>
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Item 8 - SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC

Not applicable for this meeting

Item 9 – ECHA’s recommendations of priority substances to be included in Annex XIV and opinion of MSC

Short status update on the 12th draft recommendation

SECR gave a short status update regarding the draft 12th recommendation for inclusion of substances into Annex XIV. In its presentation SECR summarised the comments received from MSC and responded to the written comments received since the previous meeting. Following the feedback and further considerations Bis(2-ethylhexyl) tetrabromophthalate was included by SECR as the fifth substance to the draft recommendation. SECR informed MSC that the consultation of interested parties was launched on 7 February and will run until 7 May 2024. In its June meeting MSC may expect to hear some highlights of the comments received and will also need to appoint a Rapporteur to draft its opinion.

<p>MSC took note of the progress and next steps.</p>	<p>SECR to provide some highlights from the comments received at MSC-86. MSC members and alternates to consider volunteering as a Rapporteur, Co-Rapporteur or possible membership to a working group to support the Rapporteur by end of May.</p>
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Item 10 – ECHA’s draft update of the Community Rolling Action Plan and opinion of MSC

<p>The MSC Rapporteur presented the draft opinion of MSC on ECHA's draft update of the Community Rolling Action Plan for (CoRAP 2024-2026)</p> <p>The update included 11 new substances for evaluation. One substance was withdrawn from the CoRAP. In the discussion an observer raised that having the majority of new substances allocated for evaluation already for 2024 will not allow industry to update their registrations. SECR took note and will consider how to accommodate this in future updates. MSC supported the addition of these 11 new substances to the CoRAP update and the one withdrawal.</p>	
<p>MSC adopted by consensus the opinion and its Annex on the draft CoRAP update 2024-2026 as prepared by the Rapporteurs.</p>	<p>MSC-S to upload the MSC CoRAP opinion including its annex on MSC Interact by 19 February 2024.</p> <p>SECR to publish the opinion on the ECHA website together with the annual CoRAP update on 19 March 2024.</p>
<p>Item 11 – Any other business</p>	
<p>1. Presentation on the Commission NAM workshop of December 2023 and the ongoing work of Commission on the non-animal testing roadmap</p>	
<p>Under this agenda item the MSC was introduced to the Commission's Roadmap towards phasing out animal testing for chemical safety assessment. The roadmap is expected to address all relevant pieces of chemicals legislation (e.g. REACH, Biocidal Product Regulation, Plant Protection Products Regulation and human and veterinary medicines). It is to be considered as a policy document and will include the interim steps and actions that would be needed. It was explained that the workshop that was held in December 2023 [recordings and presentations available on COM website] contributes to developing the roadmap, and a second one is already planned for the second half of 2024. Communication, outreach and involvement of stakeholders were mentioned as key elements of the roadmap, together with an action plan and acceleration of validation and regulatory acceptance of non-animal testing. The roadmap is expected to be finalized by the beginning of 2026. Some comments and clarifying questions were raised in the discussion.</p>	
<p>2. Updates on appeals and court cases of relevance to MSC</p>	
<p>SECR gave an overview of pending appeal and court cases and recent judgements on Evaluation and SVHC identification in open session. Also an overview of litigation in 2023 was provided, together with some highlights from the past year.</p>	
<p>3. Update on PARC</p> <p>SECR provided a short update on the project Partnership for the Assessment of Risks from Chemicals (PARC), highlighting the relevance of several of its projects to MSC. SECR also invited input from MSC as regards research areas that should be further developed or where regulatory challenges might be an issue.</p>	
<p>MSC took note of the presentation.</p>	<p>MSC to provide input on the topics by end of February 2024.</p>
<p>Item 12 – Adoption of summary record of the proceedings and conclusions and action points</p>	
<p>Table with summary record and conclusions and action points from MSC-85</p>	
<p>MSC adopted the Summary Record of the Proceedings and Conclusions and Action points at the plenary meeting.</p>	<p>SECR to upload the Summary Record of the Proceedings and Conclusions and Action points from MSC-85 on Interact by 15 February 2024 as well as ECHA website without undue delay.</p>

Experts and advisers to MSC members

MUEHLEGGER, Simone (AT) – (Expert to STOCKER, Eva)
FILIPOVA, Hristina (BG) – (Expert to YORDANOV Yordan)
KOZMIKOVA, Jana (CZ) – (Expert to KULHANKOVA, Pavlina)
ROSENTHAL, Esther (DE) – (Expert to FINDENEKG, Helene)
TRUBIROHA, Achim (DE) – (Expert to FINDENEKG, Helene)
UNKELBACH, Christian (DE) – (Expert to FINDENEKG, Helene)
MARTIN, Nellie Anne (DK) – (Expert to BOLWIG, Asger)
EINOLA, Juha (FI) – (Expert to RISSANEN, Eeva)
LAAKKONEN, Anita (FI) – (Expert to RISSANEN, Eeva)
ZELJEZIC, Davor (HR) – (Expert to GRIZELJ, Romana)
ALIVERNINI, Silvia (IT) – (Expert to ATTIAS, Leonello)
CATONE, Tiziana (IT) – (Expert to ATTIAS, Leonello)
BALCIUNIENE, Jurgita (LT) – (Expert to ŠPURIENĖ, Otilija)
BIL, Wieneke (NL) – (Expert to DE KNECHT Joop)
PROQUIN, Héloïse (NL) – (Expert to DE KNECHT Joop)
VERMEENT, Bob (NL) – (Expert to DE KNECHT Joop)
CIESLA, Jacek (PL) – (Expert to DUDRA, Agnieszka)
COPOIU, Oana (RO) – (Expert to MIHALCEA UDREA, Mariana)
ARABI, Azadeh (SE) – (Expert to MALKIEWICZ, Katarzyna)

Occasional Stakeholder Experts

N/A

Experts to regular observers

N/A

Case owners

The case owner representative was attending under the Agenda Item 7.1 for TPE-096/2023 4,4'-methylenedi-2,6-xylenol (EC No. 226-378-9)

Final Agenda

85th meeting of the Member State Committee

13 February 2024

13 February 2024: starts at 10:00 am and ends at 5.30 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/085/2024
For adoption

Item 3 – Declaration of specific interests to items on the Agenda

Item 4 – Administrative issues

- Outlook for MSC-86

For information

Item 5 – Minutes of the MSC-84

- [Adopted minutes of MSC-84](#)

For information

Item 6 – Substance evaluation

Closed session for 6.2

1. Introduction to and preliminary discussion on draft decisions on substance evaluation when amendments were proposed by MS-CA's/ECHA (*Session 1, open session*):

For discussion followed by agreement seeking under 6.2:

No cases¹

[For discussion]

2. Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA (*Session 2, closed*)

No cases

[For agreement]

3. General topics

[For information]

Item 7 – Dossier evaluation

Closed session for 7.2

¹ List of cases agreed in MSC Written Procedure is available in the Appendix of this draft agenda.

1. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals when amendments were proposed by MS-CA's (Session 1, open session)

For discussion followed by agreement seeking under 7.2:

ECHA/MSC-85/2024/004
For information

Compliance checks

No cases¹

Testing proposal examinations

MSC code	Substance name	EC No./ Documents
TPE-096/2023	4,4'-methylenedi-2,6-xylenol	226-378-9/ ECHA/MSC-85/2024/001-002

For information and discussion

2. Seeking agreement on draft decisions on compliance checks and testing proposal examinations when amendments were proposed by MS-CA's (Session 2, closed)

Case as listed under 7.1

For agreement

3. General topics

[For information]

Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC

Not applicable for this meeting

[For information]

Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC

Short status update on the 12th draft recommendation

For information

Item 10 – ECHA's draft update of the Community Rolling Action Plan and opinion of MSC

Draft opinion of MSC on ECHA's draft update of the Community Rolling Action Plan for (CoRAP 2024-2026)

ECHA/MSC-85/2024/003

For discussion and adoption

Item 11 – Any other business

1. Presentation on the Commission NAM workshop of December 2023 and the ongoing work of Commission on the non-animal testing roadmap

For information

2. Updates on appeals and court cases of relevance to MSC

4. Update on PARC

For information

For information

Item 12 – Adoption of summary record of the proceedings and conclusions and action points

- Table with summary record and conclusions and action points from MSC-85

For adoption

INFORMATION DOCUMENTS

Information documents are not allocated a specific agenda time but the documents are available on Interact MSC Meetings module before the meeting. Based on the listed documents and the meeting agenda, if any MSC member considers that information documents may merit a discussion under any agenda point, they should inform MSC Secretariat.

- Written procedure report on seeking agreement on draft decisions on substance evaluation (For members only)
- Written procedure report on seeking agreement on draft decisions on dossier evaluation (For members only)
- Report of MSC work in 2023 (presentation slides)

APPENDIX to the MSC-85 agenda:

List of cases agreed by MSC in written procedure in advance of the MSC-85 meeting:

Substance evaluation

MSC code	Substance name	EC/List No.
SEV-FR-002/2022	1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylindeno[5,6-c]pyran	214-946-9

Dossier evaluation

Compliance checks (CCH)

MSC code	Substance name	EC/List No.
CCH-218/2023	Guanidinium nitrate	208-060-1
CCH-222/2023	1,3-diphenyl-2-thiourea	203-004-2