

**Minutes of the 81<sup>st</sup> Meeting**  
**of the Member State Committee**  
**(MSC-81)**

**Tuesday 7 February**  
**to Wednesday 8 February 2023**

# 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 81<sup>st</sup> MSC meeting (online). While looking forward to a lively meeting she mentioned a few of the highlights of the meeting, including interesting substances such as nanoforms as Compliance checks under Annex VI (under Dossier evaluation) and two opinions that are for adoption at this meeting.

<b>Agenda point</b>	
<b>Conclusions / agreements / adoptions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<b>Item 2 – Adoption of the Agenda</b>	
The Agenda (MSC/A/81/2023) was adopted	<b>SECR</b> to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-81 minutes.
<b>Item 3 – Declaration of specific interests to items on the Agenda</b>	
No potential conflicts of interests were declared by the MSC Chair, any members, experts or advisers with any item on the agenda of MSC-81.	
<b>Item 4 – Administrative issues</b>	
<ul style="list-style-type: none"> <li>Outlook for MSC-82</li> </ul>	
The Chair presented an outlook on the potential length of the MSC-82 (May-June 2023) meeting. Among other administrative matters MSC was also reminded of the timelines of the upcoming SVHC round.	
<b>Item 5 – Minutes of the MSC-80</b>	
SECR informed the committee that the minutes of MSC-80, adopted by MSC at that meeting, are published on Interact and on ECHA's website.	
<b>Item 7. Dossier evaluation - Discussion and seeking agreement on draft decisions (DDs) on compliance checks when amendments were proposed by MS-CA's, and testing proposal examinations</b>	
<b>CCH-208/2022 3,5-dimethyl-1,2-dioxolane-3,5-diol (EC. 237-438-9)</b>	
<b>Session 1 &amp; 2 (open &amp; closed)</b>	
A representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.	
ECHA Secretariat (SECR) introduced the proposal for amendment (PfA) that required discussion in the meeting. The PfA proposed to place on hold the request for long-term toxicity to fish until the information from studies requested in the present decision is provided (e.g. Extended one-generation reproductive toxicity study (EOGRTS)). This would allow a more robust decision on the type of Long-term toxicity testing on fish (OECD 210 or OECD 234) to be requested for the Substance.	

<p>The Registrant had submitted written comments on the PfA and MSC duly considered them in its discussion.</p> <p>SECR had modified the decision before the meeting as proposed by the PfA.</p> <p>In the meeting, the representative of the Registrant addressed the EOGRTS request with the investigation for learning and memory. SECR clarified that, as mentioned under agenda point 7.3, decisions with such requests are on hold until further notice.</p> <p>MSC took note of the statement from the Registrant’s representative.</p> <p>MSC members agreed with the PfA and concurred that it follows the approach for requesting OECD 234 under CCH agreed at MSC-76.</p> <p>MSC members agreed to modify the draft decision as proposed in the PfA.</p>	
<p>The MSC reached unanimous agreement on the following ECHA draft decision without further amendment at the meeting:</p> <p>CCH-208/2022 3,5-dimethyl-1,2-dioxolane-3,5-diol (EC. 237-438-9)</p>	<p>MSC to consider the DD as uploaded for the meeting as the agreed version.</p>
<p><b>CCH-244/2022 Titanium dioxide (EC. 236-675-5)</b>  <b>CCH-245/2022 Titanium dioxide (EC. 236-675-5)</b>  <b>CCH-246/2022 Titanium dioxide (EC. 236-675-5)</b>  <b>CCH-247/2022 Titanium dioxide (EC. 236-675-5)</b>  <b>CCH-248/2022 Titanium dioxide (EC. 236-675-5)</b>  <b>CCH-249/2022 Titanium dioxide (EC. 236-675-5)</b>  <b>CCH-250/2022 Titanium dioxide (EC. 236-675-5)</b>  <b>CCH-251/2022 Titanium dioxide (EC. 236-675-5)</b>  <b>CCH-252/2022 Titanium dioxide (EC. 236-675-5)</b></p>	
<p><b>Session 1 &amp; 2 (open &amp; closed)</b></p> <p>In absence of specific confidentiality concerns in the DDs, an open session was held.</p> <p>ECHA Secretariat (SECR) explained the background for these cases. SECR provided a short introduction to REACH requirements for Nanoforms and explained that for these CCHs, only Annex VI requirements for sets of similar nanoforms were addressed.</p> <p>SECR introduced the proposal for amendment (PfA), which was identical for all the cases, that required discussion in the meeting. The PfA proposes to clarify the text on (a) information reporting requirements for sets of the nanoforms, and (b) exposure considerations relevant to a set of nanoforms.</p> <p>SECR had modified the decisions before the meeting as proposed in the PfA.</p> <p>MSC took note of the current strategy for addressing nanoforms under the CCH process. SECR reminded that, in principle, the lead registrant (LR) submits jointly information on nanoforms and sets of nanoforms, also for the sets/nanoforms that the LR does not report in his legal entity dossier. The LR will only be an addressee of the decisions regarding the sets/nanoforms he manufactures or imports. Moreover, SECR clarified that the next regulatory actions for these sets of titanium dioxide nanoforms will be decided after receiving the information requested in the current decisions.</p> <p>MSC members agreed to modify the draft decisions as proposed in the PfA.</p>	
<p>MSC reached unanimous agreement on the following ECHA draft decisions without further amendment at the meeting:</p> <p>CCH-244/2022 Titanium dioxide (EC. 236-675-5)  CCH-245/2022 Titanium dioxide (EC. 236-675-5)  CCH-246/2022 Titanium dioxide (EC. 236-675-5)  CCH-247/2022 Titanium dioxide (EC. 236-675-5)  CCH-248/2022 Titanium dioxide (EC. 236-675-5)</p>	<p>MSC to consider the DDs as uploaded to Interact for the meeting as the agreed versions.</p>

<p>CCH-249/2022 Titanium dioxide (EC. 236-675-5)  CCH-250/2022 Titanium dioxide (EC. 236-675-5)  CCH-251/2022 Titanium dioxide (EC. 236-675-5)  CCH-252/2022 Titanium dioxide (EC. 236-675-5)</p>	
<p><b>7.3. General topics</b>  Reporting back on learnings from DEv written procedure</p>	
<p>SECR briefly presented topics addressed in PfAs to the DEv draft decisions on which MSC had reached agreement in written procedure (WP). The presentation focussed on additional investigations on learning and memory within extended one-generation reproductive toxicity studies, with learnings from the present cases as well as future considerations. Decisions with such requests are on hold until further notice.</p>	
<p><b>Item 9 – ECHA’s recommendations of priority substances to be included in Annex XIV and opinion of MSC</b></p>	
<p>Draft opinion of MSC on ECHA’s draft 11<sup>th</sup> recommendation of priority substances to be included in Annex XIV</p>	
<p>The Rapporteur presented the MSC draft opinion on ECHA’s 11<sup>th</sup> draft recommendation for inclusion of priority substances in Annex XIV and the support document of the opinion highlighting the main changes since the previous draft, taking into account the feedback received from MSC. MSC considered the support document of its opinion in detail and supported recommending all eight substances that were subject of the consultation for inclusion in Annex XIV. The transitional arrangements for lead including the long Latest Application Date (LAD) of at least 36 months and a sunset date of 18 months after the LAD, were also supported by MSC in its opinion. As regards the Sunset Dates an IND observer stressed that the MSC opinion does not properly take into account the fact that if lead is included in the Annex XIV it would not be feasible for the RAC and SEAC to deal with the very high number of expected applications for authorisation and related opinions within the 18 months.</p> <p>In relation to Article 58(2) exemptions, MSC discussed the precise wordings to use in its opinion and suggested that COM should examine the possibility for exemptions for uses of lead that are exempted or authorised and subject to regular review under the Restriction of Hazardous Substances (RoHS), End of Life Vehicles (ELV) and Drinking Water Directive (DWD) legislation as the conditions for an exemption of some uses may be met. MSC provided further text suggestions which were taken onboard by the Rapporteur.</p> <p>MSC’s German member provided a statement to be included in the minutes as, while acknowledging that ECHA has correctly applied the agreed prioritisation approach, they are not in favour of including lead to the Annex XIV considering that authorisation is not the most appropriate regulatory tool (see Appendix xx). MSC Austrian member expressed support to those concerns.</p> <p>MSC’s Slovakian and Czech member abstained from the voting as they do not consider inclusion of lead into Annex XIV either proportionate nor efficient. MSC Bulgarian member expressed support to those concerns but did not abstain from voting.</p>	
<p>MSC adopted by consensus the opinion as amended at the meeting and the MSC Chair closed the item by thanking the Rapporteur and the Working Group for their work.</p>	<p><b>MSC-S</b> to submit the opinion to ECHA’s prioritisation unit and publish the final MSC opinion on MSC Interact by 15 February and on ECHA website without undue delay.</p> <p><b>SECR</b> to take into account the MSC opinion when finalising ECHA’s 11<sup>th</sup> recommendation for inclusion of substances in Annex XIV and to submit it to the Commission.</p>

<b>Item 10 – Opinion of MSC on ECHA’s draft update of the Community Rolling Action Plan</b>	
1. Update of the draft Community Rolling Action Plan (CoRAP 2023-2025)	
MSC was informed that one more substance had been proposed to be included to the draft CoRAP update for assessment since the introduction of the update in December. The Rapporteur’s evaluation includes the opinion on this late addition (see under item 10.2). SECR also informed MSC that one substance planned for evaluation in 2025 is removed from the CoRAP update since there are currently no registrations for it.	
2. Draft opinion of MSC on ECHA’s draft update of the Community Rolling Action Plan (CoRAP 2023-2025)	
The Rapporteur presented the MSC draft opinion on the draft CoRAP update for 2023-2025, which included six new substances for evaluation. In the discussion a member pointed out that for one of the new substances besides the initial concerns listed in the justification document, there may be further exposure-based concerns including exposure of environment and consumers based on the information available from the Nordic SPIN database. MSC supported addition of these six new substances to the CoRAP update.	
MSC adopted by consensus the opinion and its Annex on the draft CoRAP update 2023-2025 as prepared by the Rapporteur.	<p><b>MSC-S</b> to upload the MSC CoRAP opinion including its annex on MSC Interact by 15 February 2023.</p> <p><b>SECR</b> to publish the opinion on the ECHA website together with the annual CoRAP update on 21 March 2023.</p>
<b>Item 11 – Any other business</b>	
1. Update on appeals and court cases of relevance to MSC	
A short update was provided on behalf of BoA on two recent decisions.	
SECR gave an overview of litigation in 2022 and pending appeal and court cases on Evaluation and SVHC identification in both open and closed sessions.	
2. Suggestions from members:	
a. Discussion and sharing of experiences with OECD TG 234	
<p>One MSC member provided a presentation on experiences with assessing OECD TG 234 (FSDT) studies requested under Substance Evaluation to clarify concerns for endocrine disruption, highlighting issues identified regarding the quality and performance of the test. In detail, the main issues identified were no sexual maturity of fish in controls, high variability in measured concentrations, and microbial growth up observed in test vessels.</p> <p>One MSC member also presented their experiences, noting similar issues regarding increasing bacterial growth, variability between replicates, interpretation of vitellogenin, and sex ratio in control.</p> <p>One MSC member noted that the issues highlighted were not encountered in their own assessment of 2 FSDT studies although issues with ensuring sufficient exposure were experienced.</p> <p>MSC members provided further clarifications regarding the re-distribution of fish, and proportion of undifferentiated fish.</p> <p>MSC members considered how to further share and discuss the issues experienced, to ensure an aligned approach to assessments, where possible.</p>	
MSC took note of the issues identified and the clarifications provided.	<b>MSC members</b> to discuss their experiences during the upcoming FSDT training workshop provided by ECHA

	and to decide whether further discussion during a future MSC meeting would be warranted.
<b>Item 12 – Adoption of summary record of the proceedings and conclusions and action points</b>	
Table with summary record and conclusions and action points from MSC-81	
MSC adopted the Summary Record of the Proceedings and Conclusions and Action points at the plenary meeting.	<b>SECR</b> to upload the Summary Record of the Proceedings and Conclusions and Action points from MSC-81 on Interact by 10 February 2023 as well as ECHA website without undue delay.



## **Experts and advisers to MSC members**

ALIVERNINI, Silvia (IT) (Expert to ATTIAS, Leonello)  
ALJARILLA, Ana (ES) (Expert to FERNANDEZ SANCHEZ, Raquel)  
ARABI, Azadeh (SE) (Expert to MALKIEWICZ, Katarzyna)  
ARNING, Jürgen (DE) (Expert to FINDENEGG, Helene)  
BALCIUNIENE, Jurgita (LT) (Expert to ŠPURIENĖ, Otilija)  
BEAUSOLEIL, Claire (FR) (Expert to BARTHELEMY-BERNERON, Johanna)  
BOEL, Els (BE) (Expert to VANDERSTEEN, Kelly)  
BOLWIG, Asger (DK) (Expert to HJORTH, Rune)  
BRODERICK, Mike (IE) (Expert to COSGRAVE Majella)  
BURGA, Karen (FR) (Expert to BARTHELEMY-BERNERON, Johanna)  
CIESLA, Jacek (PL) (Expert to DUDRA, Agnieszka)  
COPOIU, Oana (RO) (Expert to MIHALCEA UDREA, Mariana)  
DE KNECHT, Joop (NL) (Expert to VAN BERLO, Damien)  
DOBRAK – VAN BERLO, Agnieszka (BE) (Expert to VANDERSTEEN, Kelly)  
EINOLA, Juha (FI) (Expert to RISSANEN, Eeva)  
GUDBRANDSEN, Marius (NO) (Expert to BAUMBUSCH, Angelika)  
GÜNDEL, Ulrike (DE) (Expert to FINDENEGG, Helene)  
HERARD, Fanny (FR) (Expert to BARTHELEMY-BERNERON, Johanna)  
HOLBECH, Henrik (DK) (Expert to HJORTH, Rune)  
HOULIHAN, Margarete (IE) (Expert to COSGRAVE Majella)  
JOMINI, Stéphane (FR) (Expert to BARTHELEMY-BERNERON, Johanna)  
KAARTINEN, Tomi (FI) (Expert to RISSANEN, Eeva)  
KINZL, Maximilian (AT) (Expert to STOCKER, Eva)  
KOZMÍKOVÁ, Jana (CZ) (Expert to KULHANKOVA, Pavlina)  
KUCHERYAVENKO, Olena (DE) (Expert to FINDENEGG, Helene)  
LADEGAARD PEDERSEN, Knud (DK) (Expert to HJORTH, Rune)  
MENDONCA, Elsa (PT) (Expert to ALMEIDA, Ines)  
MICHEL, Cecile (FR) (Expert to BARTHELEMY-BERNERON, Johanna)  
VEGA, Milagros (ES) (Expert to FERNANDEZ SANCHEZ, Raquel)  
MÜHLEGGGER, Simone (AT) (Expert to STOCKER, Eva)  
REIERSON, Linda (NO) (Expert to BAUMBUSCH, Angelika)  
UNKELBACH, Christian (DE) (Expert to FINDENEGG, Helene)

## **Occasional Stakeholder Experts**

BARBEAU Sophie (Europacable) for AP 9

## **Experts to regular observers**

ALLEN, Lisa (ILA) (Expert to Eurometaux observer) for AP 9  
BURZLAFF, Arne (expert to Eurometaux observer) for AP 7.1 CCH-244/2022-CCH-252/2022  
KNIGHT, Derek (expert to Cefic observer) for AP 7.1 CCH-244/2022-CCH-252/2022

## **Case owners**

The case owner representative was attending under the Agenda Item 7.1 for CCH-208/2022 3,5-dimethyl-1,2-di oxolane-3,5-diol (EC No. 237-438-9).



## Final Agenda

### 81<sup>st</sup> meeting of the Member State Committee

**7 – 8 February 2023**  
(ECHA Conference Centre)  
Web conference

**7 February 2023: starts at 1:00 pm**  
**8 February 2023: ends at 4:30 pm**

#### Item 1 – Welcome and Apologies

#### Item 2 – Adoption of the Agenda

MSC/A/081/2023  
**For adoption**

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

#### Item 4 – Administrative issues

- Outlook for MSC-82

**For information**

#### Item 5 – Minutes of the MSC-80

- [Adopted minutes of MSC-80](#)

**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 cases<sup>1</sup>

**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]**

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<sup>1</sup> List of cases agreed in MSC written procedure are available as an Appendix to this document.

**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)**ECHA/MSC-81/2023/024  
**For information****For discussion followed by agreement seeking under 7.2:****Compliance checks<sup>1</sup>**

<b>MSC code</b>	<b>Substance name</b>	<b>EC/List No.</b>	<b>Documents</b>
CCH-208/2022	3,5-dimethyl-1,2-dioxolane-3,5-diol	237-438-9	ECHA/MSC-81/ 2023/001-2
CCH-244/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/003-4
CCH-245/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/005-6
CCH-246/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/007-8
CCH-247/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/09-10
CCH-248/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/11-12
CCH-249/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/13-14
CCH-250/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/15-16
CCH-251/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/17-18
CCH-252/2022	Titanium dioxide	236-675-5	ECHA/MSC-81/2023/19-20

**Testing proposal examinations<sup>1</sup>**

No cases

**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)**

Cases as listed under 7.1

**For agreement****3. General topics**

Learnings from MSC written procedure

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

Not applicable to this meeting

**Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC**Draft opinion of MSC on ECHA's draft 11<sup>th</sup> recommendation of priority substances to be included in Annex XIV

ECHA/MSC-81/2023/021-022

**Item 10 – Opinion of MSC on ECHA’s draft update of the Community Rolling Action Plan**

3. Update of the draft Community Rolling Action Plan (CoRAP 2023-2025)

ECHA/MSC/D/2023/013

*For information*

4. Draft opinion of MSC on ECHA’s draft update of the Community Rolling Action Plan (CoRAP 2023-2025)

ECHA/MSC-81/2023/023

*For discussion and adoption*

**Item 11 – Any other business**

*Partly closed session for 11.1  
Closed session for 11.2*

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

*For information*

2. Suggestions from members:

- a. Discussion and sharing of experiences with OECD TG 234

*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-81

*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 from 2022 (presentation slides)

**APPENDIX to the MSC-81 agenda:**

**List of evaluation cases agreed by MSC in written procedure in advance of the MSC-81 meeting:**

**Substance evaluation**

<b>MSC code</b>	<b>Substance name</b>	<b>EC/List No.</b>
SEV-DE-005/2021	4,4'-isopropylidenedi-o-cresol	201-240-0

**Dossier evaluation**

**Compliance checks**

<b>MSC code</b>	<b>Substance name</b>	<b>EC/List No.</b>
CCH-215/20221	Dimethyl itaconate	210-519-6
CCH-220/20221	Lanthanum oxide	215-200-5

**Testing proposal examinations**

<b>MSC code</b>	<b>Substance name</b>	<b>EC/List No.</b>
TPE-141/20221	m-xylene	203-576-3
TPE-142/20221	p-xylene	203-396-5
TPE-143/20221	o-xylene	202-422-2

**MSC 81**

**DE statement on the inclusion of lead in Annex XIV**

In its opinions on ECHA's draft recommendations for priority substances to be included in Annex XIV, MSC considers whether the substances proposed for prioritisation meet the criteria of Article 58(3) of REACH. In doing so, MSC uses the agreed approach on prioritisation of substances of very high concern for inclusion in the Annex XIV and the general approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV .

We therefore agree with the MSC opinion on ECHA's draft 11th recommendation, although we do not support the inclusion of lead in Annex XIV.

In general, the German CA supports the idea of regulating lead and lead compounds in order to eliminate sources of exposure to humans and the environment.

However, as already mentioned in the context of the identification of lead metal as an SVHC, we are not of the opinion that authorisation is an appropriate risk management measure for lead and we do not support the inclusion of lead in Annex XIV for the following reasons:

1. Overlaps and/or contradictions between the authorisation requirement or a restriction under REACH and regulations such as the new Batteries Regulation and RoHS, in particular with regard to recycling matters.
2. The implications of the complexity of the value chain of uses outside battery production. Although small in percentage, these are still high tonnages and potentially many companies with wide dispersive uses (e.g. in the case of the use of lead as an alloy additive in steel, aluminum or copper). This may lead to a very high number of applications for authorisation.
3. The availability of feasible alternatives and whether they will lead to a faster phase-out of lead via authorisation under REACH than foreseen in existing regulations or potential sectoral restrictions. In addition, sectoral restrictions will not longer be possible once lead is included in Annex XIV.
4. The question if REACH authorisation, covering all uses, will lead to a lower residual exposure of workers and the environmental to lead compared to specific measures already in place or that may be envisaged under targeted restrictions.