

Minutes of the 83rd Meeting
of the Member State Committee
(MSC-83)

Tuesday 10 October
to Wednesday 11 October 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 83rd MSC meeting held remotely online. She mentioned few highlights of the meeting, including several generic topics related to the Dossier evaluation process, among others the topic of Learning and memory investigations as a continuation from MSC-82. One Compliance check case that had been stopped from written procedure is also for agreement at this meeting. New entries to update to the MSC Manual of decisions (MoD) are also again on the meeting agenda as well as other interesting items.

Agenda point	
Conclusions / agreements / adoptions	Action requested after the meeting (by whom/by when)
Item 2 – Adoption of the Agenda	
The Agenda (MSC/A/83/2023) was adopted with addition of one AOB at the start of the meeting.	SECR to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-83 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-83.	
Item 4 – Administrative issues	
<ul style="list-style-type: none"> • Outlook for MSC-84 The Chair presented an outlook on the potential length of the MSC-84 (December 2023) meeting.	
Item 5 – Minutes of the MSC-82	
SECR informed the committee that the minutes of MSC-82, adopted by MSC at that meeting, are published on Interact and on ECHA's website.	
Item 6 - Substance evaluation	
3. General topics	
Discussion on the way forward with a substance under Substance evaluation: poorly soluble substance in a hydrolysis study – case specific discussion of tris (4-nonylphenyl, branched) phosphite (TNPP) EC No. 701-028-2 (<i>Closed session</i>)	
An invited expert from a Member State gave a presentation on an ongoing substance evaluation case related to the evaluation of a hydrolysis study to clarify degradation to 4-nonylphenol, branched (4-bNP). The case has not been referred to MSC but the MSC members were invited to express their views on the potential next steps of the follow-up evaluation.	
A technical expert representing the Consortium participated in part of discussion regarding the available hydrolysis study and provided further clarifications to questions raised by the MSC Members.	

<p>MSC considered that there may be sufficient information available to clarify degradation of the Substance to 4-nonylphenol, branched (4-bNP). Consequently, requesting further information related to this matter may not be necessary.</p> <p>MSC considered that there is not a fixed threshold value regarding the formation of the (4-nonylphenol, branched (4-bNP)) transformation product to identify the parent substance as an SVHC based on its environmental ED properties.</p>	<p>Evaluating Member State to consider the feedback received in deciding on how to proceed with this substance evaluation.</p>
<p>Item 7 - Dossier evaluation - Discussion and seeking agreement on draft decisions (DDs) on compliance checks when amendments were proposed by MS-CA's</p>	
<p>2. Seeking agreement on draft decisions on compliance checks and testing proposal examinations when amendments were proposed by MS-CA's (Session 2, closed)</p>	
<p>Case stopped in MSC written procedure:</p>	
<p>CCH-130/2023 Valeraldehyde (EC No. 203-784-4)</p>	
<p>A member of the MSC had requested stopping the written procedure. The MSC member considered that the response to the registrant's comments on the PfA as regards the rationale for doing the germ cell investigation in a comet assay should be further clarified.</p> <p>In its comments on the PfA the registrant had agreed with the recommendation to collect germ cells insofar as it concerns the TGR assay but disagreed insofar as it concerns the comet assay. These comments of the registrant were initially addressed by the SECR in the draft decision.</p> <p>Following the stop vote, the SECR took the comments from the MSC member into account and redrafted the decision by adding further explanation on the rationale of collecting germ cells in the comet assay.</p> <p>MSC agreed to modify the draft decision as proposed in the PfA, with the further clarification explained above.</p>	
<p>The MSC reached unanimous agreement on the following ECHA draft decision: CCH-130/2023 Valeraldehyde (EC No. 203-784-4)</p>	<p>MSC to consider the DD as uploaded for the meeting as the agreed version.</p>
<p>7.3. General topics</p>	
<p>1. Learning and memory (L&M) investigations – follow up discussion after MSC-82 on the way forward with the pending EOGRTS decisions and future insights</p>	
<p>Closed session</p>	
<p>This is a follow-up to the agenda point from MSC-81 ('Learnings from DEV written procedure') where SECR informed MSC of technical difficulties related to the L&M investigations, and to the agenda point from MSC-82 ('Update on some unresolved issues with learning and memory investigations') where SECR informed MSC of some unresolved issues and challenges related to the additional investigations on L&M requested within extended one-generation reproductive toxicity studies.</p> <p>For MSC-83 meeting, SECR had prepared a background document which provides options on the way forward with the pending EOGRTS decisions as well as some future insights. At the MSC meeting, SECR presented these considerations as slides, followed by presentations on relevant classification aspects as well as legal considerations.</p> <p>MSC considered two papers which were previously used in a decision, namely, van Wijk et al. (2008) and Amano et al. (2018). MSC confirmed the following conclusion: these papers have treated the pup as the statistical unit of variation, and this approach underestimates the variation in the population. Statistical inference based on an erroneous estimate of variation in these papers is unreliable. Since the main conclusions of these two papers are based upon these statistical inferences, ECHA considers that despite the biological plausibility of the link between</p>	

hypothyroidism and the observed effects, these papers cannot be fully relied upon to justify the triggering of L&M investigations.

MSC discussed other aspects presented, including the OECD TG 426 study design specifications, if that is requested in the future. Further follow up will be considered in due time. In addition, MSC members were invited to propose further discussion points e.g. on the triggering criteria for requesting OECD TG 426.

MSC also discussed the pending decisions from MSC-81, which have been adopted but not yet notified to registrants. MSC gave ECHA-S the mandate to edit CCH-205/2022 and CCH-208/2022 by removing the L&M request (but not the EOGRTS request). Furthermore, MSC gave ECHA-S the mandate to edit CCH-220/2022 by removing the EOGRTS request in its entirety, agreeing that the EOGRTS requirement will be addressed later in the context of the category approach.

Open session

The Chair summarized the content and outcome of the closed session discussion before giving the floor to StOs. CEFIC presented slides with their considerations on L&M.

For the pending cases from MSC-81:

- MSC gives ECHA-SECR the mandate to edit the already-adopted decisions of CCH-205/2022 and CCH-208/2022 from MSC-81 by removing the L&M request (but not the EOGRTS request), and then notify the decisions to registrants.
- MSC gives ECHA-SECR the mandate to edit the already-adopted decision of CCH-220/2022 from MSC-81 to remove the EOGRTS request in its entirety, and then to notify the decision to registrants. The EOGRTS requirement will be addressed later, in the context of the category approach.

For test specifications, MSC agrees that

- the choice of L&M test should be based on existing information indicating that the required test is likely to address the identified concern;
- for OECD TG 426, there could be a possibility to limit the options of tests.

SECR to edit the already-adopted decisions (from MSC-81) which are not yet notified to registrants.

2. Quantification of non-extractable residues (NERs) in OECD TG 309: follow-up to the Board of Appeal decision on appeal A-001-2022

SECR introduced the modification applying to surface water simulation requests, according to OECD TG 309, in consequence of the BoA decision in case A-001-2022. Modifications were applied to the procedural section, by removing the requirement to quantify the non-extractable residues (NERs), and to the study design section of the requests, by introducing explanation regarding the relevance of NERs to the test. Furthermore, SECR asked MSC mandate to apply such modifications to the relevant decisions previously agreed on MSC-82 and MSC-82bis referrals and which were not yet notified to the registrants.

MSC agreed with the implemented modifications and mandated SECR to modify the relevant decisions previously agreed. The MSC agreed that the quantification of NERs will not be explicitly required in the operative part of the decision for OECD TG 309 study requests

SECR to amend the relevant decisions previously agreed at MSC-82 and MSC-82bis and notify them to the registrants.

<p>in dossier evaluation whilst the relevance of quantification of NERs is clarified in the respective study design section of the decisions.</p>	
<p>3. Category approach: overview of Cobalts testing proposals</p>	
<p>SECR presented the category approach for testing proposals on Cobalts substances.</p> <p>Following the presentation, MSC members and stakeholders had the opportunity to ask clarifying questions. A stakeholder noted that in addition to the testing strategy presented, there is one testing proposal for a pre-natal developmental toxicity study outstanding for the 'poorly soluble organic ligands' group. Further work on the inhalation read-across approach is also ongoing.</p>	
<p>4. Mutagenicity testing requests and germ cells: proposed alignment under dossier evaluation</p>	
<p>SECR introduced a proposal to align the germ cell related recommendations and requests in the mutagenicity tests in the dossier evaluation decisions. The proposed policy alignment was triggered by the 2022 amendments in the REACH testing annexes.</p> <p>SECR proposed, regarding germ cell collection:</p> <ul style="list-style-type: none"> - The germ cell collection will remain as a recommendation for both comet assay and TGR in the decisions with addressees only at Annex VII and VIII level. - The germ collection is no longer recommended for comet assay in decisions in which at least one registrant is at Annex IX or X level. - The germ cell collection in TGR will remain as a requirement in decisions in which at least one registrant is at Annex IX or X level. <p>The two-decision approach in the Annex IX and X requests as agreed in MSC-65 will remain unchanged.</p> <ul style="list-style-type: none"> - In the first decision, if an <i>in vitro</i> study indicates a concern, the registrants are requested to conduct an <i>in vivo</i> genotoxicity test on somatic cells. <p>If the result in the somatic cell study is positive, and the registrants did not follow it up accordingly, ECHA will request further investigation on the germ cells in a second decision under the specific provisions of Annex IX and X.</p>	
<p>Several MSC members disagreed with the SECR's proposal to remove the recommendation of germ cell collection for comet assay at Annex IX and X. A proposal was made also to stop the two-decision approach for TGR requests.</p>	<p>SECR took note of the MSC members' opinion and awaits discussions at future MSC meetings.</p> <p>SECR to place the two-decision approach for discussion at the MSC-84 (partly for closed session).</p>
<p>Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC</p>	
<p>Prioritisation results in preparation for ECHA's 12th draft recommendation for inclusion of substances in Annex XIV and update on recommendation planning</p>	
<p>MSC took note of the prioritisation results and had few questions of clarification. Related to the topic one stakeholder observer raised a question about the status of the substances that were included in ECHA's previous recommendations for Annex XIV, notably ECHA's 10th recommendation. In a response from a COM representative it was noted that currently there is no confirmed planning for the implementation of the 10th recommendation,</p>	<p>MSC to provide any comments on the application of the prioritization approach and the results presented by 27 October 2023.</p> <p>SECR to consider the comments from MSC and to provide a draft recommendation for discussion at MSC-84 by 30 November 2023.</p>

also due to ongoing discussions on reform of authorisation/restriction.	
Item 10 – ECHA’s draft update of the Community Rolling Action Plan and opinion of MSC	
<p>Invitation for volunteers and appointment of Rapporteur for drafting of the MSC opinion on draft annual CoRAP update</p> <ul style="list-style-type: none"> • Draft Terms of Reference and appointment of the Rapporteur and Co-Rapporteur 	
<p>MSC adopted the mandate and the tasks of the rapporteur and appointed one alternate member as the Rapporteur for drafting the opinion of the MSC on the draft CoRAP 2024-2026 update. Another member was appointed as a Co-Rapporteur. The absence of any specific interests will be confirmed in writing once the substances on the draft CoRAP update for 2024-2026 are available.</p>	<p>SECR to send the appointment letter to the Rapporteurs after the meeting.</p> <p>SECR to provide MSC with the draft CoRAP update by 30 November 2023.</p>
Item 11 – MSC Manual of decisions (MoD)	
<p>SECR introduced a number of new entry suggestions to MSC’s MoD based on suggestions from members and SECR. MSC was invited to review if those additions would be feasible additions to the current MSC MoD.</p>	
<p>MSC welcomed the update of its MoD as it helps tracking the development in the decision-making.</p> <p>MSC took note of the suggested new entries and proposed some further considerations and modifications to be included.</p>	<p>Members to provide comments on the suggested entries by 27 October 2023.</p> <p>SECR to share the comments received with MSC and to prepare the next version for possible adoption at MSC-84 by 30 November</p>
Item 12 – Review of stakeholder organisations’ participation in the work of MSC	
<ul style="list-style-type: none"> • Discussion and update of the MSC decision about the invited organisations (closed session) 	
<p>SECR presented the outcome of the MSC accredited stakeholder organisations (ASO) participation review and proposed a way forward, as outlined in the respective meeting document. MSC considered the ASO participation in the past year in line with the <i>Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees</i>¹ and commitments made by MSC regular observers.</p>	
<p>MSC took note of the update of the ASO observers’ participation in the MSC work and decided the following:</p> <p>With regard to the admission of ASOs as MSC regular stakeholder observers (StOs) in different quotas, MSC decided to:</p> <p>Reconfirm the MSC regular StO status of:</p> <ul style="list-style-type: none"> • five Environmental and Health Care NGOs (ChemSec, Client Earth, EEB, Greenpeace and HEAL) within their rotation group to share four seats when participating in MSC plenary meetings; • five Animal Welfare NGOs (ECEAE, Eurogroup for Animals, HSI, PSCI and CFE within their rotation group to share 	<p>MSC to review ASO participation in its work in one year’s time.</p> <p>SECR to share the document for this item with the MSC regular StOs via Interact portal.</p> <p>SECR to publish the list on ECHA’s webpage.</p>

¹https://echa.europa.eu/documents/10162/17091/admission_of_stakeholder_organisations_as_observers_en.pdf/51298e6b-1dda-4e23-88c3-7b96a6fc3e73?t=1622536575278

<p>two seats when participating in MSC plenary meetings;</p> <ul style="list-style-type: none"> • ETUC, Cefic, CONCAWE, Eurometaux and ORO • CEPE and FECC within a rotation group to share one seat when participating in MSC plenary meetings • SMEUnited who is to be represented on a regular basis by the MSC observer from Cefic and will participate in the MSC meetings on occasional basis. <p>MSC noted that any ECHA accredited stakeholder organisations can indicate their interest in taking part in a specific meeting of ECHA 's committees as an occasional observer. Participation in MSC plenary meetings would be on an occasional basis, in accordance with the <i>Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees</i> and at the discretion of the MSC Chair's decision.</p>	
<p>Item 13 – Any other business</p>	
<p>1. Updates on appeals and court cases of relevance to MSC</p>	
<p>A short update was provided on behalf of BoA on recent decisions.</p> <p>SECR gave an overview of pending appeal and court cases and recent judgements on Evaluation and SVHC identification in open session.</p>	
<p>2. Brief update from survey on FSOT among MSs</p>	
<p>Following discussion at MSC-82 (item 12.5.c), one MSC member presented an update on a survey performed to gather feedback on the OECD TG 234 studies received, and the effectiveness of OECD TG 234 studies to identify substances as endocrine disruptors.</p> <p>The survey was addressed to Member States and covers substances assessed under REACH and Biocides regulations.</p>	
<p>MSC took note of the update and some Members expressed support for a discussion group on possible follow-up actions of the survey.</p>	<p>FR to provide a further update at MSC-84 following more in-depth analysis of the survey results.</p>
<p>3. Suggestions from members (closed session)</p>	
<p>Sterile controls under substance evaluation (SEv) and dossier evaluation (DEv)</p> <p>One MSC member raised for discussion the question concerning sterile controls in biodegradation simulation test requests under SEv and DEv. The Members were invited to consider if further discussion at a future MSC meeting was needed to clarify changes to how the requirement for sterile controls should be included in SEv and DEv decisions. The topic was discussed. One Member noted that repetition of guidance text should be avoided wherever possible. Moreover, the limitation of DEv process with regards to standard information requirements were reminded.</p> <p>Since advice on sterile controls had been suggested to be included for the MoD, the Members were reminded that the MoD entries must represent the state of play, based on concrete decisions of MSC hence, regardless of the ongoing revision of R.7b and R.11 guidance, extrapolation from SEv cases to DEv in the MoD was considered premature.</p>	

Item 14 – Adoption of summary record of the proceedings and conclusions and action points

Table with summary record and conclusions and action points from MSC-83

MSC adopted the Summary Record of the Proceedings and Conclusions and Action points at the plenary meeting.	SECR to upload the Summary Record of the Proceedings and Conclusions and Action points from MSC-83 on Interact by 12 October 2023 as well as ECHA website without undue delay.
---	---

Experts and advisers to MSC members

Romana HORNEK (AT) (Expert to STOCKER, Eva)
Christine HÖLZL (AT) (Expert to STOCKER, Eva)
Annemarie LOSERT (AT) (Expert to STOCKER, Eva)
Simone MUEHLEGGGER (AT) (Expert to STOCKER, Eva)
Anna-Lena REHRL (AT) (Expert to STOCKER, Eva)
Ulrike GÜNDEL (DE) (Expert to FINDENEGG, Helene)
Ulrich JOEHNCKE (DE) (Expert to FINDENEGG, Helene)
Esther ROSENTHAL (DE) (Expert to FINDENEGG, Helene)
Pía BASAURE GARCÍA (ES) (Expert to FERNÁNDEZ SÁNCHEZ, Raquel)
Patricia GARCÍA HERNANDEZ (ES) (Expert to FERNÁNDEZ SÁNCHEZ, Raquel)
Isabelle BILLAULT (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
Karen BURGA (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
Anne STRACZEK (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
Davor ZELJEZIC (HR) (Expert to GRIZELJ, Romana)
Margarete HOULIHAN (IE) (Expert to COSGRAVE Majella)
Jurgita BALCIUNIENE (LT) (Expert to ŠPŪRIENĖ, Otilija)
Jacek CIESLA (PL) (Expert to DUDRA, Agnieszka)
Oana COPOIU (RO) (Expert to MIHALCEA UDREA, Mariana)
Lars ANDERSSON (Expert to MALKIEWICZ, Katarzyna)
Azadeh ARABI (SE) (Expert to MALKIEWICZ, Katarzyna)
Liselotte SÄLL (SE) (Expert to MALKIEWICZ, Katarzyna)
ÅKERBLOM Nina (SE) (Expert to MALKIEWICZ, Katarzyna)

Occasional Stakeholder Experts

N/A

Experts to regular observers

ARTS, Josje (Expert to Cefic observer) for AP 7.3.1 Learning and memory investigations
FAULHAMMER, Frank (expert to Eurometaux observer) for AP 7.3.1 Learning and memory investigations
VIEGAS, Vanessa (expert to Eurometaux observer) for AP 7.3.4 Category approach: overview of Cobalts

Other experts

The technical expert representative from the Consortium was attending during part of the Agenda Item 6.3 Poorly soluble substance in a hydrolysis study – case specific discussion of tris (4-nonylphenyl, branched) phosphite (TNPP) EC No. 701-028-2.

III Final Agenda

Final Agenda 83rd meeting of the Member State Committee

10 - 11 October 2023
(ECHA Conference Centre)
Web conference

10 October 2023: starts at 11:00 am
11 October 2023: ends at 5:00 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/083/2023
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-84

For information

Item 5 – Minutes of the MSC-82

[Adopted minutes of MSC-82](#)

For information

Item 6 – Substance evaluation

Closed session for 6.3

4. 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:

MSC code	Substance name	EC/List No.
----------	----------------	-------------

No cases

[For discussion]

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

No cases

[For agreement]

6. General topics

Discussion on the way forward with a substance under Substance evaluation: poorly soluble substance in a hydrolysis study – case specific discussion (*Closed session*)

For discussion

Item 7 – Dossier evaluation

Closed session for 7.2 and partly closed for 7.3.1

3. 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:

Compliance checks

No cases²

Testing proposal examinations

No cases¹

[For information and discussion]

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

Cases stopped in MSC written procedure:

CCH-130/2023 Valeraldehyde (EC No. 203-784-4)

ECHA/MSC-83/2023/007-8,
ECHA/MSC/D/2023/58

For agreement

3. General topics

1. Learning and memory investigations – follow up discussion after MSC-82 on the way forward with the pending EOGRTS decisions and future insights (*Partly closed session*)

ECHA/MSC-83/2023/005
For discussion

2. Quantification of non-extractable residues (NERs) in OECD TG 309: follow-up to the Board of Appeal decision on appeal A-001-2022

For information and discussion

3. Category approach: overview of Cobalts testing proposals (summary from MSC written procedure)

For information

4. Mutagenicity testing requests and germ cells: proposed alignment under dossier evaluation

For information and discussion

² List of cases agreed in MSC written procedure is available as an Appendix to this document.

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

Not relevant for this meeting

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

Prioritisation results in preparation for ECHA’s 12th draft recommendation for inclusion of substances in Annex XIV and update on recommendation planning

ECHA/MSC-83/2023/006

For information

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

Invitation for volunteers and appointment of Rapporteur for drafting of the MSC opinion on draft annual CoRAP update

- Draft Terms of Reference and appointment of the Rapporteur and Co-Rapporteur

ECHA/MSC-83/2023/002

For decision

Item 11 – MSC Manual of decisions (MoD)

Update of MSC MoD

ECHA/MSC-83/2023/003-4

For discussion

Item 12 – Review of stakeholder organisations’ participation in the work of MSC

- Discussion and update of the MSC decision about the invited organisations

ECHA/MSC-83/2023/001

For discussion and decision

Item 13 – Any other business

Partly closed session

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

(Partly closed session)

For information

2. Brief update from survey on FSDT among MSs

For information

3. Suggestions from members

- a. Approach on sterile controls in degradation simulation test requests under substance and dossier evaluation.

For information/discussion

Item 14 – Adoption of summary record of the proceedings and conclusions and action points

- Table with summary record and conclusions and action points from MSC-83

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 dossier evaluation
(For members only)

APPENDIX to the MSC-83 agenda:

List of cases agreed by MSC in written procedure in advance of the MSC-82 meeting:

Substance evaluation

No cases

Dossier evaluation

Compliance check

MSC code	Substance name	EC/List No.
Compliance check		
CCH-137/2023	1,2-Benzenedicarboxylic acid, di-C16-18-alkyl esters	290-580-3
CCH-145/2023	1,3-Isobenzofurandione, hexahydro-, reaction products with epichlorohydrin	696-026-0

Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-063/2023	Tricobalt tetraoxide	215-157-2
TPE-064/2023	Cobalt hydroxide oxide	234-614-7
TPE-065/2023	Cobalt sulphide	215-273-3
TPE-066/2023	Cobalt lithium dioxide	235-362-0