

**Minutes of the 82nd Meeting
of the Member State Committee
(MSC-82)**

**Wednesday 31 May
to Friday 2 June 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 82nd MSC meeting in Helsinki. While looking forward to a lively in-person meeting she mentioned a few of the highlights of the meeting, including two Compliance checks (under Dossier evaluation), update to the MSC Manual of decisions (MoD) and several interesting AOBs at this meeting. She also thanked members for actively bringing topics to the agenda. She noted the importance of the joint efforts in maintaining the good spirit and cohesion of this decision-making Committee also via face to face interactions. The June and December meetings of MSC are opportune for that.

Agenda point	
Conclusions / agreements / adoptions	Action requested after the meeting (by whom/by when)
Item 2 – Adoption of the Agenda	
The Agenda (MSC/A/82/2023) was adopted.	SECR to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-82 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-82.	
Item 4 – Administrative issues	
<ul style="list-style-type: none"> Outlook for MSC-83 The Chair presented an outlook on the potential length of the MSC-83 (October 2023) meeting. <ul style="list-style-type: none"> Upcoming guidance consultations MSC was informed of the upcoming guidance consultations, with the consultation on information requirements and chemical safety report related to PBT assessment starting in early June and the consultation for the new hazard classes in CLP in September.	
Item 5 – Minutes of the MSC-81	
SECR informed the committee that the minutes of MSC-81, adopted by MSC at that meeting, are published on Interact and on ECHA's website.	
Item 6.3. Substance evaluation – General topics	
Templates for draft decisions and conclusion documents	
ECHA Secretariat (SECR) presented a summary of the recently revised templates for draft decisions and conclusion documents for substance evaluation, highlighting the key changes and expected improvements the revisions will provide. The revised templates were made available to evaluating MSCAs for the drafting of all new outcome documents.	
Item 7. Dossier evaluation - Discussion and seeking agreement on draft decisions (DDs) on compliance checks when amendments were proposed by MS-CA's	
CCH-017/2023	Diallyl phthalate (EC No. 205-016-3)

Session 1 & 2 (open & closed)

In absence of specific confidentiality concerns in the draft decision (DD), an open session was held followed by discussion and voting in closed session.

ECHA Secretariat (SECR) introduced a proposal for amendment (PfA) for the case, which proposed to remove the request for Mammalian spermatogonial chromosomal aberration test since the conditions for further investigation of germ cell genotoxicity according to Annex IX, Section 8.4, column 2 of REACH are not fulfilled.

SECR modified the decision on what concerns the PfA on Mammalian spermatogonial chromosomal aberration test before the meeting.

The Registrant had not submitted written comments on the PfA.

MSC members agreed to modify the draft decision as proposed in the PfA stated above without further discussion.

SECR introduced a second PfA that required discussion in the meeting. The PfA proposed to add a request for Fish Sexual Development Test according to OECD TG 234, based on Annex IX, Section 9.1, column 2. The currently available information demonstrates that the substance has potential endocrine disrupting properties in fish, which justifies requesting an OECD TG 234. There is no need to wait for the outcome of the other studies requested in the decision (e.g. EOGRTS) to decide on the most appropriate test to meet the information requirement, as initially proposed in the draft decision

The Registrant had not submitted written comments on the second PfA, on Fish Sexual Development Test.

SECR had not modified the decision on what concerns the second PfA before the meeting.

MSC members acknowledged that the information raised in the second PfA indicated that there is *in vitro* evidence showing that the Substance has the potential to disrupt sex hormone balance which, in combination with *in vivo* data for the structurally similar substance dibutyl phthalate (DBP) with mammals and fish, already justifies further investigations on the endocrine disrupting properties of the Substance in fish.

After a short discussion on the use of *in vitro* data and data on the analogue substance to support the concern on endocrine disrupting properties of the substance, the MSC members agreed to modify the draft decision as proposed in the PfA.

The MSC reached unanimous agreement on the following ECHA draft decision CCH-017/2023 Diallyl phthalate (EC. 205-016-3)	SECR to upload on Interact the agreed decision in the respective case agenda point.
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CCH-064/2023 Paraffin waxes and Hydrocarbon waxes, chloro (EC No. 264-150-0)

Session 1 & 2 (open & closed)

A representative of the Registrant participated in 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 proposal for amendments (PfAs):

- 1) Proposal to:
 - a. remove simulation requests from the decision (due to availability of data to conclude that the Substance is P/vP, based on read-across data), and reduce deadline to 36 months; or
 - b. keep the simulation requests only at Annex IX (referring to test material specification introduced under bioaccumulation request), indicating that parallel testing is to be carried out for PBT assessment, and reduce the deadline to 36 months.

- 2) Proposal to further clarify, under bioaccumulation in aquatic species request, the choice of test material(s) and analytical monitoring.

SECR modified the decision, in line with PfA 1.b and 2 above, before the meeting.

The Registrant had submitted written comments on the PfA and MSC duly considered them in its discussion. In particular, in the comments to the PfAs, the registrants agreed with the conclusion that the Substance is P/vP but did not agree with the reduction of the deadline.

In the meeting, the representative of the Registrant presented further their reasoning regarding:

- a. the use of OECD TG 317 (bioaccumulation in soil organisms), or OECD TG 315 (bioaccumulation in sediment organisms), to assess bioaccumulation in aquatic species;
- b. the parallel SEv assessment ongoing by UK;
- c. analytical monitoring possibilities.

SECR clarified that either OECD TG 315 or 317, performed in sediment and soil species respectively, are not adequate tests, in isolation, to cover the information requirement for bioaccumulation in aquatic species. MSC members supported this view and agreed that this should be reflected in the decision in the reply to the Registrant comments on the PfAs. One member took the floor to emphasize the need for coordination with UK and asked if such collaboration is taking place. SECR clarified that as the UK is no longer part of the EU any interaction takes place on that basis.

MSC members agreed to modify the draft decision as proposed in the PfAs, agreeing with option 1 b above to keep the request at Annex IX for the simulation requests as currently there is no information in the dossier to cover this standard information requirement.

MSC reached unanimous agreement on the following ECHA draft decision:

CCH-064/2023 Paraffin waxes and Hydrocarbon waxes, chloro (EC No. 264-150-0)

SECR to upload on Interact the agreed decision in the respective case agenda point.

7.3. General topics

- a) Reporting back on learnings from DEv written procedure

SECR briefly presented topics addressed in PfAs to the DEv draft decisions on which MSC had reached agreement in written procedure (WP).

7.3. General Topics

- b) Nano compliance challenges - Example case of MWCNT (Closed session)

Due to confidentiality issues of the information to be discussed, related to boundaries of the sets, the presentation was held in closed session.

SECR presented an illustration of Annex VI compliance check challenges. The example case of multi-walled carbon nano tubes (MWCNT) was used to demonstrate the case-by-case applicability of analytical methods to measure size parameter such as tube length. The example case gave an opportunity to the MSC members to be aware of potential adaptations of Annex VI/2.4 requirements on the use of 'Set of similar nanoforms' derogation.

7.3. General Topics

- c) Update on some unresolved issues with learning and memory investigations (Closed session)

SECR informed the MSC of some unresolved issues and challenges related to the additional investigations on learning and memory (L&M) requested within extended one-generation reproductive toxicity studies. 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. MSC was now informed on other developments, such as the recent Board of Appeal decisions on the first L&M related appeals.

<p>It was agreed to discuss the way forward with the pending decisions at the MSC-83 meeting.</p>	<p>SECR to provide background documents well in advance of the regular MSC-83 document deadline to allow for sufficient discussion at MSC-83.</p> <p>For adopted and notified decisions requesting learning and memory investigations within EOGRT study, the MSC members to provide their considerations on the consequences by 17 July 2023.</p>
<p>Item 11 – MSC Manual of decisions (MoD)</p>	
<p>SECR introduced a number of new entry suggestions to MSC’s MoD, proposing MSC to review if those additions would be feasible additions to the current MSC MoD. SECR also highlighted the need to further review several of the existing entries since some of the policies around those entries are no longer applicable and therefore the text in the current MoD may rather be misleading.</p>	
<p>MSC took note of the suggested new entries and proposed some further edits to be included. As a conclusion SECR noted that the MSC MoD in long term should become a reference source for generic approaches and could serve also broader audience with the intention to make this available via the MSC web pages.</p>	<p>MSC to provide comments on the suggested entries or to propose new topics by 22 June 2023.</p> <p>SECR to review the current MoD entries regarding their validity and to propose how to deal with those in one of the upcoming MSC meetings.</p>
<p>Item 12 – Any other business</p>	
<p>1. Update on PARC project</p>	
<p>SECR gave an update on the PARC project status and on the relevance of ECHA’s role in the project of ensuring implementation and adoption addressing current regulatory challenges. Moreover, the latest Key Areas of Research (KARC) were presented. Some questions were raised in the presentation for MSC to consider.</p>	
<p>2. Update 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 both open and closed sessions.</p>	
<p>3. Update on CSS from COM as regards CLH and SVHCs</p>	
<p>A representative from the Commission updated MSC on the next steps as regards the new hazard classes and SVHC identification process that the Delegated Act on CLP is bringing. The presentation also included an outline for the anticipated switching from REACH identification of substances to CLP identification.</p>	
<p>Responding to a question COM explained that certain transition period will be needed for substances that are under an ongoing process or added to the Candidate List after the 20 April 2023, before REACH revision is in place. COM clarified that in their view in the future potential SVHC dossiers for substances that have been classified under the new hazard classes are foreseen to be similar to those of CMR substances at the moment, i.e. relatively condensed and referring to the CLH dossier of the same substance, noting that until the REACH legal text has been changed ELoC still needs to be considered.</p>	
<p>MSC raised concerns about the workload and expertise unbalance in future between the Committees (RAC and MSC) and the process for substances identified in future as Cat. 2 EDs, where the direct equivalence between SVHC identification and CLP hazard classes was not</p>	

foreseen by COM. As for expertise COM reflected that Expert Groups (EGs) would continue to be involved. MSC noted that the timelines for classification are remarkably longer than those for SVHC identification, potentially slowing down regulatory risk management measures, and that MSC has expertise in hazard assessment which RAC may need to build up to manage the new tasks. The direct impact of SVHC identification, reducing marketed volumes of SVHCs considerably in a short time frame, was also raised by one MSC Stakeholder observer.

Further clarification was requested also on why the transfer to CLP of substances identified as PMTs or vPvMs under SVHC was not considered straight forward as the current CLP criteria seem quite clear, and the conclusion was that this might still need further discussion and reflection.

4. Learnings from the EOGRTS review project (final report)

SECR gave a presentation on the learnings of the Extended one-generation reproductive toxicity study (EOGRTS) review project which aimed at analysing the performance of the EOGRTS in relation to the design, conduct and toxicological findings of the study. MSC members expressed their appreciation on the conduct of the project, with the expectation that the learnings of the project and recommendations published will be useful for future studies.

Following the presentation, MSC members and stakeholders had the opportunity to ask clarifying questions. The topics of the discussion included e.g. the availability of materials presented in the ECHA/CRO workshop held in May 2023 as well as the regulatory follow-up actions of the evaluated studies as well as the satellite projects and possible involvement of Industry. It was then further clarified that due to the confidential nature of the data used for the satellite projects, direct involvement of industry would not be possible.

5. Suggestions from members:

- a. Topic from Sweden: Information on a recent article on "Economic interests cloud hazard reductions in the European regulation of substances of very high concern"

An invited expert from a member state gave a presentation regarding a recent publication in Nature "Economic interests cloud hazard reductions in the European regulation of substances of very high concern" (Coria *et al.*, 2022). The authors claim that substances of secondary importance have been included in the Candidate List, and that regulators are less likely to place a substance on the list if it is currently being produced or imported in the EEA. According to the member state expert the publication has a number of shortcomings with regard to methodology and assumptions as well as several misunderstandings on the regulatory process. A post-publication commentary is being prepared by the member state authority with support by ECHA SECR.

Two MSC members expressed their support to the action taken by the MS authority and ECHA. An observer said that including non-registered substances on the Candidate List to prevent regrettable substitution may have been falsely interpreted as listing of substances of secondary importance. The speaker added that some of the comparisons made between different lists (e.g. SIN List vs. Candidate List) in the publication are not valid as such as the lists have different purposes.

5. Suggestions from members:

- c. Proposal from France for a survey on FSDT among MSs

Following the discussions at MSC-81 (item 11.2.a) and a workshop organized by ECHA, one MSC member presented a proposal for a survey to gather feedback on the OECD TG 234 studies received, and the effectiveness of OECD TG 234 studies to identify substances as endocrine disruptors.

The survey will be addressed to Member States and covers substances assessed under REACH and Biocides regulations. The survey results will be used to decide on any follow-up actions including communication with the OECD as appropriate.

<p>MSC took note of the planned survey. Several participants supported the initiative, indicating the importance of this test guideline but also the need to reflect further how best to consider this in the CCH context.</p>	<p>MSC members to fill out the short survey or to inform their MSCA counterparts of the survey, for completion by the deadline, including those responsible for biocidal products and plant protection products.</p> <p>FR to collate the results and present them at a future MSC meeting.</p>
<p>Item 13 – 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-82</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-82 on Interact by 5 June 2023 as well as ECHA website without undue delay.</p>

Experts and advisers to MSC members

Romana HORNEK (AT) – remotely (Expert to STOCKER, Eva)
Christine HÖLZL (AT) – remotely (Expert to STOCKER, Eva)
Simone MUEHLEGGGER (AT) – remotely (Expert to STOCKER, Eva)
Anna-Lena REHRL (AT) – remotely (Expert to STOCKER, Eva)
Agnieszka DOBRAK – VAN BERLO (BE) – remotely (Expert to VANDERSTEEN, Kelly)
Jana KOZMIKOVA (CZ) (Expert to KULHANKOVA, Pavlina)
Ulrich JOEHNCKE (DE) – remotely (Expert to FINDENEKG, Helene)
Esther ROSENTHAL (DE) – remotely (Expert to FINDENEKG, Helene)
UNKELBACH, Christian (DE) - remotely (Expert to FINDENEKG, Helene)
BOLWIG, Asger (DK) – expert to Rune HJORTH
Juha EINOLA (FI) (Expert to RISSANEN, Eeva)
Tomi KAARTINEN (FI) – remotely (Expert to RISSANEN, Eeva)
Karen BURGA (FR) – remotely (Expert to BARTHELEMY-BERNERON, Johanna)
Davor ZELJEZIC (HR) (Expert to GRIZELJ, Romana)
Margarete HOULIHAN (IE) – remotely (Expert to COSGRAVE Majella)
Tiziana CATONE (IT) (Expert to ATTIAS, Leonello)
Silvia ALIVERNINI (IT) – remotely (Expert to ATTIAS, Leonello)
Jurgita BALCIUNIENE (LT) (Expert to SPŪRIENĖ, Otilija)
Elīna LAZDEKALNE (LV) – remotely (Expert to MATĪSA, Sandra)
ZhiChao DANG (NL) – remotely (Expert to VAN BERLO, Damien)
Eric VERBRUGGEN (NL) – remotely (Expert to VAN BERLO, Damien)
Bob VERMEENT (NL) (Expert to VAN BERLO, Damien)
Linda REIERSON (NO) – remotely (Expert to BAUMBUSCH, Angelika)
Jacek CIESLA (PL) (Expert to DUDRA, Agnieszka)
Oana COPOIU (RO) (Expert to MIHALCEA UDREA, Mariana)
Ilona SILINS (SE) – remotely (Expert to MALKIEWICZ, Katarzyna)

Occasional Stakeholder Experts

N/A

Experts to regular observers

N/A

Case owners

The case owner representative was attending (remotely) under the Agenda Item 7.1 for CCH-064/2023 - Paraffin waxes and Hydrocarbon waxes, chloro (EC No. 264-150-0).

III Final Agenda

Final Agenda

82nd meeting of the Member State Committee

31 May 2023 - 2 June 2023
ECHA Conference Centre
Telakkakatu 6, in Helsinki, Finland

31 May 2023: starts at 11:00 am
2 June 2023: ends at 12:00 am

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/082/2023
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-83

For information

Item 5 – Minutes of the MSC-81

- [Adopted minutes of MSC-81](#)

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:

MSC code	Substance name	EC/List No.
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No cases

[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

- Information about updated templates for the draft decisions and conclusion documents

Item 7 – Dossier evaluation

Closed session for 7.2 and 7.3b&c

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-82/2023/029

For information

For discussion followed by agreement seeking under 7.2:

Compliance checks¹

MSC code	Substance name	EC/List No.	Documents
CCH-017/2023	Diallyl phthalate	205-016-3	ECHA/MSC-82/2023/025-26
CCH-064/2023	Paraffin waxes and Hydrocarbon waxes, chloro	264-150-0	ECHA/MSC-82/2023/027-28

Testing proposal examinations

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

- a) Learnings from MSC written procedure cases
- b) Nano compliance challenges - Example case of MWCNT (*Closed session*)
- c) Update on some unresolved issues with learning and memory investigations
(*Closed session*)

For information

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

1. Seeking agreement on Annex XV proposals for identification of SVHC

Substance name¹

EC/List No.

No cases

[For discussion]

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

Not relevant for this meeting

[For discussion]

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

Not relevant for this meeting

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

Item 11 – MSC Manual of decisions (MoD)

Update of MSC MoD

ECHA/MSC-82/2023/030

For discussion and possible adoption

Item 12 – Any other business

Partly closed session

1. Update on PARC project
For information
2. Updates on appeals and court cases of relevance to MSC
(Partly closed session)
For information
3. Update on CSS from COM as regards CLH and SVHCs
For information
4. Learnings from the EOGRTS review project (final report)
For information
5. Suggestions from members:
 - a. Topic from Sweden: Information on a recent article on “Economic interests cloud hazard reductions in the European regulation of substances of very high concern”
 - b. Proposal from France for a survey on FSDT among MSs
For information

Item 13 – Adoption of summary record of the proceedings and conclusions and action points

- Table with summary record and conclusions and action points from MSC-82
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)
- Written procedure report on seeking agreement on identification of SVHCs

APPENDIX to the MSC-82 agenda:

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

Substance evaluation

No cases

Dossier evaluation

MSC code	Substance name	EC/List No.
CCH-004/2023	Multi-Walled Carbon Nanotubes (MWCNT), synthetic graphite in tubular shape	936-414-1
CCH-005/2023	Silicon dioxide	231-545-4
CCH-006/2023	Silicon dioxide	231-545-4
CCH-016/2023	4,4'-Isopropylidenedicyclohexanol, oligomeric reaction products with 1-chloro-2,3-epoxypropane	500-070-7
CCH-035/2023	γ -butyrolactone	202-509-5
CCH-050/2023	m-phenylenebis(methylamine)	216-032-5
CCH-057/2023	Tetrabromophthalic anhydride	211-185-4
CCH-072/2023	Cyclohex-1,2-ylenediamine	211-776-7

SVHC identification²

Substance name	EC No.
Bis(4-chlorophenyl) sulphone	201-247-9

² SVHC proposal for Diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide (EC No. 278-355-8) will be placed on the Candidate List without MSC involvement.