MSC/M/79/2022
11 October 2022

Minutes of the 79th Meeting

of the Member State Committee

(MSC-79)

Monday 10 October
to Tuesday 11 October 2022

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 79th MSC meeting. While looking forward to a lively meeting she mentioned a few of the highlights of the meeting, noting the discussion on the dossier evaluation cases that are to be agreed at this meeting as regards the EOGRTS designs and the first discussion on the draft opinion of MSC on endocrine-disrupting properties of some bisphenols. She also noted the information on the Annex VI CCH decisions on substances containing nanoforms, the annual stakeholders review and the election of the CoRAP rapporteur.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
Item 2 – Adoption of the Agenda	
The Agenda (MSC/A/79/2022) was adopted with the addition of a sub-item on administrative matters regarding the satisfaction survey among MSC regular observers.	**SECR** to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-79 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-79.	
Item 4 – Administrative issues	
• Outlook for MSC-80	
The Chair presented an outlook on the potential length of the MSC-80 (December 2022) meeting.	
• Feedback from MSC regular observers	
The Chair drew attention to the survey results that were collected from the MSC Stakeholder observers in September. The need to increase transparency of MSC work was reflected in many of the responses even if the general satisfaction to the participation possibilities was considered good. The Chair explained that we continue developing the proceedings to a more transparent direction, for example by trying to bring forward any learnings from the MSC written procedures also in open session, at the meeting.	
MSC took note of the survey results from MSC ASOs.	MSC to submit any further suggestions on how to improve observers' involvement to MSC work by 31 October 2022.
Under other administrative matters the Chair informed MSC about the availability of the process timelines (SEv and DEv) for next year which are available under MSC-00.	
Item 5 – Minutes of the MSC-78	

SECR informed the committee that the minutes of MSC-78, adopted by MSC at that meeting, are published on Interact and on ECHA's website.

Item 7 – Dossier evaluation - Discussion and seeking agreement on draft decisions on compliance checks and testing proposal examinations when amendments were proposed by MS-CA's

CCH-098/2022 Octabenzone (EC No. 217-421-2)

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.

ECHA Secretariat (SECR) introduced the proposal for amendment (PfA) that required discussion in the meeting. The PfA on an extended one-generation reproductive toxicity study (EOGRTS) suggested including the developmental neurotoxicity (DNT) cohorts 2A and 2B, justified by a) adverse effects (foot splay) and b) a mechanism with an association to neurotoxicity (thyroid toxicity) by the Substance.

The Registrant had submitted written comments on the PfA and MSC duly considered them in its discussion.

SECR had not modified the decision before the meeting, as they did not consider that the reasons explained in the PfA justified the inclusion of the DNT cohorts.

In the meeting, the representative of the Registrant presented an overview of the available information, concluding that the Substance does not show endocrine-disrupting properties or adverse effects related to fertility, development or neurotoxicity.

Therefore, they did not consider it justified to include the DNT cohorts.

MSC took note of the findings from the Registrant's representative.

In a closed session, the MSC further discussed foot splay as a neurotoxic effect, effects on thyroid weight, the use of historical and concurrent control data as well as the toxicological relevance of changes in thyroid hormone levels.

During the discussion, some MSC members expressed support to the PfA and considered that the reasons put forward in the PfA show a sufficient level of concern and therefore justify the inclusion of the DNT cohorts.

Other MSC members considered that the overall evidence does not justify inclusion of the DNT cohorts.

After considering all arguments, the MSC concluded not to modify the draft decision based on the PfA.

The MSC reached unanimous agreement on the following ECHA draft decision without further amendment at the meeting: CCH-098/2022: Octabenzone (EC No. 217-421-2) Six members abstained from voting, including the MSC member from Austria, Denmark, France, Netherlands, Norway and Sweden. Five MSC members provided a written justification for their abstention (see section IV).	**SECR** to upload on Interact the agreed decision in the respective case agenda point.

TPE-115/2022 Polysulfides, di-tert-dodecyl (EC No. 270-335-7)

Session 1 & 2 (open & closed)

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 on extended one-generation reproductive toxicity study (EOGRTS) suggested including the developmental neurotoxicity (DNT) cohorts 2A and 2B, as well as the developmental immunotoxicity (DIT) cohort 3.

In the PfA, the DNT cohorts are justified by a) adverse effects (higher mean numbers of horizontal and/or rearing movements; changes in landing foot splay) and b) a mechanism with an association to neurotoxicity (thyroid toxicity) by the Substance. The DIT cohort is justified by adverse effects (changes in white blood cell, lymphocyte and neutrophil counts; Albumin/Globulin ratio; spleen, thymus and mesenteric lymph node weights; cellularity of mesenteric lymph nodes).

The Registrant had submitted written generic comments on the PfA. As the comments were not substance-specific, the MSC did not further consider them.

For DNT, SECR had not modified the decision before the meeting, as they did not consider that the reasons explained in the PfA justified the inclusion of the DNT cohorts.

For DIT, SECR agreed that the available data shows evidence of immunomodulation. In advance of the meeting, SECR had modified the draft decision to include the DIT cohort 3.

In the meeting, the PfA submitter clarified that after re-assessment of all available information, they agree with the SECR for not including the DNT cohorts. No further discussion took place.

Considering the available data and PfA reasoning, the MSC members agreed with the inclusion of the DIT cohort.

MSC reached unanimous agreement on the following ECHA draft decision without further amendment at the meeting: TPE-115/2022: Polysulfides, di-tert-dodecyl (EC No. 270-335-7) The member from Denmark abstained from voting.	**SECR** to upload on Interact the agreed decision in the respective case agenda point.

7.3. General topics

Reporting back on any learnings from WP

SECR briefly presented mutagenicity-related issues addressed in PfAs to the draft decisions on which MSC had reached agreement in written procedure (WP).

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

1. Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update
   - Draft Terms of Reference and appointment of the Rapporteur and Co-Rapporteur

MSC adopted the mandate and the tasks of the rapporteur and appointed one member as the Rapporteur for drafting the opinion of the MSC on the draft CoRAP 2023-2025 update. The absence of any specific interests will be confirmed in writing once the substances on the draft CoRAP update for 2023-2025 are available.	**SECR** to send the appointment letter to the Rapporteur after the meeting. **SECR** to provide MSC with the draft CoRAP update by 30 November 2022.

Item 11 – Request to MSC for an opinion in accordance with Article 77(3) c of REACH Regulation

1. Presentation of the updated Hazard assessment reports of bisphenol F (BPF) and bisphenol AF (BPAF) and its salts and the respective RCOMs by the dossier submitter

The dossier submitter presented the comments received in the public consultation on their reports on evaluation of endocrine disrupting properties of BPF and BPAF and eight BPAF salts. The dossier submitter introduced the revisions made in the BPF report to address the comments, while explaining that the comments on BPAF and its salts had not required changes in the report.	
2. Presentation of the 1st draft MSC opinion on the endocrine disrupting (ED) properties of BPF and BPAF and its salts by the Rapporteurs	
The Rapporteur and the Co-Rapporteur presented the first draft of the MSC opinion on ED properties for environment of BPF and BPAF and eight BPAF salts. The MSC opinion supports the conclusion by the dossier submitter i.e. that the substances are EDs to environment. The Rapporteurs introduced the differences in the draft opinion compared to the reports by the dossier submitter, namely including additional supporting studies and changing Klimisch scores of two studies, and stated that the differences do not change the overall conclusion.	**SECR** will launch a consultation via Interact Collaboration on 17 October on the draft MSC opinion. **MSC** to submit comments on the draft opinion by 31 October. **The Rapporteurs** to submit revised version of the opinion by 29 November, which will be presented at MSC-80.
Item 12 – Annual review of stakeholder observers' participation at MSC	
• Discussion and update of the MSC decision about the invited organisations	
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 *Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees*[1] and commitments made by MSC regular observers.	
MSC took note of the update of the ASO observers' participation in the MSC work and decided the following: With regard to the admission of ASOs as MSC regular stakeholder observers (StOs) in different quotas, MSC decided to: Reconfirm the MSC regular StO status of: • 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 two seats when participating in MSC plenary meetings; • 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	**MSC** to review ASO participation in its work in one year's time. **SECR** to share the AP12 document with the MSC regular StOs via Interact portal. **SECR** to publish the list on ECHA's webpage.

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

Cefic and will participate in the MSC meetings on occasional basis. 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 *Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees* and at the discretion of the MSC Chair's decision.	

Item 13 – Any other business

1. Information related to ongoing Annex VI CCH decisions on substances containing nanoforms

SECR updated MSC with ongoing work related to Annex VI compliance check draft decisions on substances containing nanoforms. Besides the legal requirements appropriate terminology and way of reporting of nanoforms were briefly explained. ECHA is following a two-tiered approach in the compliance checks. It was explained that the first tier (Annex VI CCH) is ongoing for three substances. The update covered also the role of nanomaterial expert group (NMEG) and how the collaboration with MSC is foreseen.

2. Update on the EOGRT review project

SECR gave an update of the Extended one-generation reproductive toxicity study (EOGRTS) review project which aims at analysing the performance of the EOGRTS in relation to the design, conduct and toxicological findings of the study.

Following the presentation, MSC members and stakeholders had the opportunity to ask clarifying questions. The topics of the discussion included e.g. work in satellite projects, future workshop, and the possibility to take learnings from the project into account in the ECHA decisions.

3. Update on appeals and court cases of relevance to MSC

A short update was provided on behalf of BoA on two cases on which the BoA had reached its decision in August and September 2022.

SECR gave an overview on new and pending appeal and court cases on SVHC identification and Evaluation in both open and closed sessions.

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-79

MSC adopted the Summary Record of the Proceedings and Conclusions and Action points by consensus at the plenary meeting.	SECR to upload the Summary Record of the Proceedings and Conclusions and Action points from MSC-79 on Interact by 13 October 2022 as well as ECHA website without undue delay.

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ATTIAS, Leonello (IT)
BARTHELEMY-BERNERON, Johanna (FR)
BAUMBUSCH, Angelika (NO)
BOLWIG, Asger (DK)
CONWAY, Louise (IE)
DUDRA, Agnieszka (PL)
ELLUL, Nathanael (MT)
FERNANDEZ SANCHEZ, Raquel (ES)
FILIPOVA, Hristina (BG)
FINDENEGG, Helene (DE)
GIMNAOU, Panagiotis (CY)
GRIZELJ, Romana (HR)
HUMAR JURIC, Tatjana (SI)
JANTONE, Anta (LV)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina (CZ)
KUROVA, Martina (SK)
MALKIEWICZ, Katarzyna (SE)
MENARD SPRČIČ, Anja (SI)
MIHALCEA UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY)
RISSANEN, Eeva (FI)
SAKSA, Jana (EE)
SPURIENE, Otilija (LT)
STOCKER, Eva (AT)
TÁRNOCZAI, Timea (HU)
TREZZI, Jean (LU)
VAN BERLO, Damien (NL)
VANDERSTEEN, Kelly (BE)
Representatives of the Commission:
KOBE, Andrej (DG ENV)
CERIDONO, Mara (DG ENV)
Observers
ARROYO, Jesus (Cefic)
CINGOTTI, Natacha (HEAL)
DROHMANN, Dieter (ORO)
ENGELBRECHT, Vera (PSCI)
LOONEN, Helene (EEB)
NIEMELÄ, Helena (Concawe)
PROCHAZKA, Erik (CFE)
WAETERSCHOOT, Hugo (Eurometaux)
ECHA staff
AJAO, Charmaine
ANAGNOSTAKIS, Konstantinos
BELL, David
BROERE, William
DE COEN, Wim
ELO, Pertti
JUTILA, Arimatti
KENINGSWALD, Hugues
KIMERSTORFER, Karin
LE CURIEUX, Frank
LEPPARANTA, Outi
LUOMA, Leena
PELLIZZATO, Francesca
RASENBERG, Mike
RONTY, Kaisu
ROSSI, Laura
SIHVOLA, Virve
TRNKA, Jan Peter
VAHTERISTO, Liisa
VAN DER JAGT, Katinka
Board of Appeal
SCHURMANS, Marijke

Apologies

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Proxies

Panagiotis GYMNAOU (CY) to Aglaia KOUTSODIMOU (GR) (10/10/2022 starting from 14.20)

Experts and advisers to MSC members

ALIVERNINI, Silvia (IT) (Expert to ATTIAS, Leonello)
ARABI, Azadeh (SE) (Expert to MALKIEWICZ, Katarzyna)
ARNING, Jurgen (DE) (Expert to FINDENEGG, Helene)
BALCIUNIENE, Jurgita (LT) (Expert to SPURIENE, Otilija)

BIL, Wieneke (NL) (Expert to VAN BERLO, Damien)
CATONE, Tiziana (IT) (Expert to ATTIAS, Leonello)
CHARRON, Isabelle (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
CIESLA, Jacek (PL) (Expert to DUDRA, Agnieszka)
COPOIU, Oana (RO) (Expert to MIHALCEA UDREA, Mariana)
EINOLA, Juha (FI) (Expert to RISSANEN, Eeva)
ELIESEN, Gaby (NL) (Expert to VAN BERLO, Damien)
HORSKA, Alexandra (SK) (Expert to KUROVA, Martina)
KOVACEVIC, Tajana (HR) (Expert to GRIZELJ, Romana)
MÜHLEGGER, Simone (AT) (Expert to STOCKER, Eva)
REIERSON, Linda (NO) (Expert to BAUMBUSCH, Angelika)
ROSENTHAL, Esther (DE) (Expert to FINDENEGG, Helene)
UNKELBACH, Christian (Expert to FINDENEGG, Helene)
ZELJEZIC, Davor (HR) (Expert to GRIZELJ, Romana)

Case owners

Representative of the Registrant was attending under the Agenda Item 7.1 for CCH-098/2022

MSC/A/079/2022 Final agenda
10 October 2022

Final Agenda
79th meeting of the Member State Committee

10-11 October 2022

(ECHA Conference Centre)

Web conference

10 October 2022: starts at 11:00 am
11 October 2022: ends at 4:00 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/079/2022
For adoption

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

Item 4 – Administrative matters

- Outlook for MSC-80
- Feedback from MSC regular observers

For information

Item 5 – Minutes of the MSC-78

- Adopted minutes of MSC-78

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

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. 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-79/2022/007
For information

For discussion followed by agreement seeking under 7.2:

Compliance checks[2]

MSC code	Substance name	EC No. / Documents
CCH-098/2022	Octabenzone	217-421-2 ECHA/MSC-79/2022/003-4

Testing proposal examinations[1]

MSC code	Substance name	EC No. / Documents
TPE-115/2022	Polysulfides, di-tert-dodecyl	270-335-7 ECHA/MSC-79/2022/005-6

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

Reporting back on any learnings from WP

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

No cases

For information

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

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

Not applicable for this meeting

[For discussion]

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

1. Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update
   - Draft Terms of Reference and appointment of the Rapporteur and Co-Rapporteur

ECHA/MSC-79/2022/001

For decision

Item 11 – Request to MSC for an opinion in accordance with Article 77(3) c of REACH Regulation

1. Presentation of the updated Hazard assessment reports of bisphenol F and bisphenol AF and its salts and the respective RCOMs by the dossier submitter
2. Presentation of the 1st draft MSC opinion on the endocrine disrupting properties of BPF and BPAF and its salts by the Rapporteurs

ECHA/MSC-79/2022/008

For discussion

Item 12 – Annual review of stakeholder observers' participation at MSC

Closed session

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

ECHA/MSC-79/2022/002

For discussion and decision

Item 13 – Any other business

Partly closed session

1. Information related to ongoing Annex VI CCH decisions on substances containing nanoforms

For information

2. Update on the EOGRT review project

For information

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

(Partly closed session)

For information

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-79

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)
- Summary of the feedback from the satisfaction survey with regular MSC stakeholder observers (MSC ASO’s)

APPENDIX to the MSC-79 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-79 meeting:

Dossier evaluation

Compliance checks

MSC code	Substance name	EC/List No.
CCH-097/2022	Antimony	231-146-5
CCH-110/2022	Dimethyl azelate	217-060-0
CCH-111/2022	Dimethyl heptanedioate	217-057-4
CCH-155/2022	2,3-dichlorobuta-1,3-diene	216-721-0

Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-090/2022	1,8-naphthylenediamine	207-529-8

IV. Statement from AT, FR, NL, NO, and SE members related to agenda item 7.1 with regard to CCH-098/2022 on *Octabenzone* (EC No. 217-421-2).

In our opinion, there is sufficient experimental evidence to warrant inclusion of the Developmental Neurotoxicity cohorts within the EOGRT study requested by ECHA in their Draft Decision. We consider the following findings from a TG 422 study as relevant triggers:

1) A statistically significant decrease in T4 in F1 males (low and high dose) supported by non-statistically significant decreases in T4 levels in F1 females and parental F0 males of the high dose group;
2) A statistically significant decrease in foot splay in high dose females; we consider it as adverse. We note that either increases or decreases in foot splay have been observed after exposure to neurotoxicants. We consider that comparison to concurrent controls is an appropriate approach and the historical controls should be used to ensure study quality.

Therefore, we abstained from voting.