

Minutes
of the 69th Meeting of the Member State Committee (MSC-69)
22-23 April 2020
Web conference

Adopted on 10 June 2020

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chairman of the Committee, Mr Watze de Wolf, opened the meeting and welcomed the participants to the 69th meeting of the Member State Committee (MSC) which was held as a web conference meeting (for the full list of attendees and further details see Part II of the minutes). The Chairman referred to the web conference instructions which the participants had received prior to the plenary meeting. The Chairman also informed MSC that all ECHA Committee plenaries and expert groups in May and June are to be held remotely, thus including MSC-70.

Item 2 - Adoption of the Agenda

The Chairman suggested including an any other business-item about dossier evaluation selection criteria for the cases included in the MSC-70bis notification to Member State Competent Authorities (MSCAs), based on a request from a member. The agenda was adopted with this modification (final Agenda is attached to these minutes as Section III).

Item 3 - Declarations of conflicts of interest to the items on the Agenda

No potential conflicts of interests were declared by the Chairman, any members, experts or advisers with any item on the agenda of MSC-69.

Item 4 - Administrative issues

- *Alternative options to the identification of rapporteurs and update to the MSC Rules of procedures*

As a follow-up action from the previous MSC discussions on the alternative options to the identification and appointment of rapporteurs the Chairman presented a suggestion on how extending the rapporteurship after expiry of the membership could be dealt with by MSC, and under which conditions. MSC reached a general agreement on the approach, in which both the individual's but also their respective MS's views are catered for, after which MSC would decide on the continuation of the rapporteurship.

SECR had also prepared a proposal on how the text of the MSC Rules of procedure could be amended, in line with MSC's wish to extend the responsibility of the alternate member to include the possibility of acting as a rapporteur or co-rapporteur. MSC supported the proposal as a way to broaden the potential to identify rapporteurs in the future. The Chairman concluded the topic by saying that after adoption of this change by the Management Board, possibly in their June meeting, this change could be applied already in the next round of rapporteur calls for the opinions on the Annex XIV recommendation process and CoRAP update.

- *Outlook for MSC-70, MSC-70bis and MSC-71*

The Chairman presented an outlook on the potential length of the next meeting which is expected to require up to 2,5 plenary days. The Chairman informed MSC that due to the extension of ongoing Member State Competent Authority (MSCA) consultations the MSC-70 evaluation deadlines are no longer fitting to the scheduled June plenary. Substance and dossier evaluation cases referred to MSC will therefore not be for formal agreement seeking during MSC-70, but will be presented to MSC for discussion and exchange of views, followed by agreement seeking in written procedure after the plenary.

The Chairman also presented a timeline for dossier evaluation (DEv) draft decisions in MSC-70bis interim round, which will have no associated plenary meeting. This additional MSCA consultation will be necessary due to the increased output of DEv draft decisions and to accelerate decision making for DEv decisions.

For MSC-71, the Chairman refrained from providing an outlook due to the uncertainties around the development of the Corona virus pandemic.

Item 5 – Minutes of the MSC-68 meeting

SECR informed the committee that the minutes of MSC-68 were adopted on 6 April 2020 by MSC in written procedure and published in MSC S-CIRCABC and on ECHA's website.

Item 6 – Substance evaluation

1. Written procedure report on seeking agreement on a draft decision on substance evaluation

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on 1 substance evaluation (SEv) case (see Appendix to the final agenda in Section III for more detailed identification of the case). WP was launched on 26 March 2020. By the closing date 6 April 2020, MSC reached unanimous agreement on this one SEv case.

2. Introduction to and preliminary discussion on a draft decision on substance evaluation after MS-CA's/ECHA reactions (*Session 1, open session*):

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

SEV-DE- 001/2018 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione (MMBI) (EC No. 258-904-8)

SEV-DE- 002/2018 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt (ZnMMBI) (EC No. 262-872-0)

Session 1 (open) and Session 2 (closed)

No representatives of the Registrants participated in the initial discussion. In the absence of specific confidentiality concerns an open session was held.

The expert from the evaluating Member State Competent Authority (eMSCA) from Germany (DE-CA) presented the current status of the two SEv cases (SEV-DE-001/2018 and SEV-DE-002/2018) in one presentation, as both draft decisions (DDs) were requesting for the same test on the same substance. The expert guided the MSC through the unresolved proposals for amendment (PfAs) received from Member State Competent Authorities (MSCAs) and ECHA, the Registrants' comments on those PfAs and the eMSCA's response to them. MSC confirmed that the remaining PfAs and Registrants' comments had been duly considered by the eMSCA, and, where appropriate, introduced as amendments to the DD in advance of the meeting. MSC considered these PfAs as resolved requiring no further discussion at the meeting.

MSC discussed the unresolved PfAs, all related to the appropriate test to request in order to address the endocrine disruption concern on vertebrate wildlife species, for MMBI and its Zn salt - ZnMMBI. Both SEv DDs request for an amphibian metamorphosis assay (AMA) according to OECD TG 231 with MMBI. PfAs were received to request for a larval amphibian growth and development assay (LAGDA; OECD TG 241) instead, arguing that it: 1) is a more comprehensive *in vivo* test listed at a level 4 according to the OECD Conceptual Framework for testing and assessment of endocrine disruptors; 2) allows closer investigation of thyroid effects of a substance; 3) has a longer exposure time than AMA. Furthermore, apical endpoints in AMA may be insufficient to indicate population relevance.

The eMSCA expert, in addressing the PfAs and similar concerns expressed by a stakeholder observer at the meeting, explained that due to its physico-chemical properties (e.g. high water solubility) they do not expect slow uptake kinetics for MMBI. Furthermore, the essential life-stages for thyroid sensitivity are covered in both AMA and LAGDA. Hence the shorter test duration should not impact on the test results. The Registrants, in their written comments, also argued this and they expressed agreement with the request for AMA. The already available data for these cases, points to an anti-thyroidal mode of action via TPO inhibition. This can alter metamorphosis which the eMSCA considers as being population relevant. Due to these reasons, the need to follow up the AMA with a LAGDA becomes less likely for these cases, hence the risk of using extra animals is low. MSC supported this reasoning and thereby the request for the AMA study in these cases.

Regarding the number of test concentrations to be used in the AMA, MSC supported the PfAs received proposing the use of five test concentrations with the highest concentration to be chosen to give a clear systemic (i.e. non endocrine-specific) toxicity. The Registrants' comments on the PfAs did not give arguments against the use of five test concentrations in the AMA.

The Registrants' comments on the PfAs referred to a recently completed extended one generation reproductive toxicity study (EOGRTS; OECD TG 443) on ZnMMBI, and its impact on the possible next steps following a positive or a negative result in the AMA study. MSC recognised that this EOGRTS study, together with the results of the AMA and other available data, may inform on the need for further testing, specifically in case of a negative or inconclusive AMA. In such cases, tests can be requested on a level 4 or 5 study as described in OECD Guidance No. 150 (OECD, 2018). In case of positive results in the AMA, MSC considered it likely that a conclusion whether MMBI and ZnMMBI meet the WHO definition for endocrine disruptors in the environment can be reached.

The MSC unanimously agreed on the decisions for MMBI and ZnMMBI as amended during the meeting, requesting for an AMA according to OECD TG 231 with five test concentrations using MMBI as test material, with the information to be generated and provided within 15 months.

On a general level, MSC recognised that comparison of the sensitivity of the AMA and LAGDA tests, for instance by the ECHA ED Expert Group, may inform whether AMA testing in its own right could be sufficient to conclude a substance as meeting the WHO definition for endocrine disruptors.

Item 7 – Dossier evaluation

1. Written procedure report on seeking agreement on draft decisions on dossier evaluation

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on three dossier evaluation cases (see Section III Final agenda "Appendix to the MSC-69 agenda" for more detailed identification of the cases). WP was launched on 26 March 2020. By the closing date 6 April 2020, MSC reached unanimous agreement on three DDs.

Item 8 – SVHC identification

Not relevant for this meeting

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

Not relevant for this meeting

Item 10 – Opinion of MSC on ECHA’s draft update of the Community Rolling Action Plan (CoRAP 2021-2023)

SECR presented to MSC a proposal regarding the timeline for the next CoRAP update which included a suggestion to shorten the overall MSC opinion forming process by one month. MSC opinion on the next CoRAP update would then be expected in February 2021, thus enabling ECHA to update the CoRAP update for years 2021 to 2023 in March. Based on that plan MSC should identify and appoint the next MSC rapporteur and possible co-rapporteur for its opinion-drafting in the October plenary (MSC-71).

Responding to a question SECR explained that in case the number of substances for inclusion on the draft CoRAP and respective justification documents would be higher than last year, MSC could appoint a Working Group to share the workload and the opinion drafting would not become overly heavy despite the shorter time available for it. MSC agreed the new timings of the Rapporteur appointment and to discuss, with the aim to adopt, the draft opinion in one meeting only.

Item 11 – Any other business

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

SECR gave an overview of a new decision of the Board of Appeal (BoA) of ECHA in Case A-006-2018 dismissing an appeal against an ECHA dossier evaluation decision. MSC took note of the information received and in particular the BoA’s considerations which refuted an alleged conflict of opinion with EFSA. SECR further gave an overview on a new appeal case submitted to the European Court of Justice concerning the identification of a substance of very high concern as an endocrine disrupter. SECR also gave a short overview on litigation cases in 2019 and a brief update on pending and new appeal and court cases.

2. Suggestions from members: Selection of dossier evaluation cases to the MSC-70bis round

An MSC member queried whether there had been any specific criteria to select cases for the interim MSC-70bis round for dossier evaluation only. SECR informed that the batch for the round was compiled as per the normal procedure. The dossier evaluation teams preparing the cases were informed beforehand on the nature of this round, which would have only the written procedure for agreement-seeking in case of proposals for amendment (PfA). This may have resulted in postponing selected cases that may have resulted in in-depth interaction with the MSC. SECR noted that it was difficult to predict which cases could trigger PfAs or a plenary meeting discussion and thus no strict screening criteria were in place. The MSC took note of the clarification.

Item 12– Adoption of conclusions and action points

The conclusions and action points of the meeting were adopted at the meeting (see Section IV).

II. List of attendees

<u>Members/Alternate members</u>	<u>ECHA staff</u>
ALMEIDA, Inês (PT)	AJAO, Charmaine
ATTIAS, Leonello (IT)	BERCARU, Ofelia
BARTHELEMY-BERNERON, Johanna (FR)	BROERE, William
CONWAY, Louise (IE)	CONSOLI, Elisa
DE KNECHT, Joop (NL)	DE COEN, Wim
DIMITROVA, Rada (BG)	DE WOLF, Watze
DUDRA, Agnieszka (PL)	DELOFF-BIALEK, Anna
ELLUL, Nathanael (MT)	HALLING, Katrin
FERNÁNDEZ SÁNCHEZ, Raquel (ES)	JOHANSSON, Matti
FINDENEGG, Helene (DE)	JUTILA, Arimatti
HERMES, Joe (LU)	KARKOLA, Sampo
HJORTH, Rune (DK)	KORJUS, Pia
HORSKÁ, Alexandra (SK)	LUOMA, Leena
HUMAR-JURIČ, Tatjana (SI)	NAUR, Liina
JANTONE, Anta (LV)	MUSSET, Christel
KOUTSODIMOU, Aglaia (EL)	PELLIZZATO, Francesca
KREKOVIC, Dubravka (HR)	RÖNTY, Kaisu
KULHÁNKOVÁ, Pavlína (CZ)	SIMON, Rupert
MALKIEWICZ, Katarzyna (SE)	VAHTERISTO, Liisa
MIHALCEA UDREA, Mariana (RO)	WOLLENBERGER, Leah
NUGIN, Merike (EE)	
PALEOMILITOU, Maria (CY)	
REIERSON, Linda (NO)	
RISSANEN, Eeva (FI)	
ŠPŪRIENĖ, Otilija (LT)	
STOCKER, Eva (AT)	
VANDERSTEEN, Kelly (BE)	
<u>Representatives of the Commission:</u>	
KOBE, Andrej (DG ENV)	
<u>Observers</u>	
DREVE, Simina (FECC)	
DROHMANN, Dieter (ORO)	
FERNANDES DE BARROS, Mariana (Cefic)	
LOONEN, Helene (EEB)	
PEREIRA, Marina (HSI)	
SUSNIK, Marko (UEAPME)	
TAYLOR, Katy (CFE)	
VEROUGSTRAETE, Violaine (Eurometaux)	

Experts and advisers to MSC members

ALIVERNINI, Silvia (IT) (Advisor to ATTIAS, Leonello)
 BALČIŪNIENĖ, Jurgita (LT) (Expert to ŠPŪRIENĖ, Otilija)
 BOEL, Els (BE) (Advisor to VANDERSTEEN, Kelly)
 BOLWIG, Asger (DK) (Expert to HJORTH, Rune)
 CATONE, Tiziana (IT) (Expert to ATTIAS, Leonello)
 CIESLA, Jacek (PL) (Expert to DUDRA, Agnieszka)
 COPOIU, Oana (RO) (Expert to MIHALCEA UDREA, Mariana)
 DOBRAK-VAN BERLO, Agnieszka (BE) (Expert to VANDERSTEEN, Kelly)
 EINOLA, Juha (FI) (Advisor to RISSANEN, Eeva)
 FILIPOVA, Hristina (BG) (Expert to DIMITROVA, Rada)
 JÖHNCKE, Ulrich (DE) (Advisor to FINDENEGG, Helene)
 JOMINI, Stephane (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
 KAARTINEN, Tomi (FI) (Advisor to RISSANEN, Eeva)
 KINZL, Maximilian (AT) (Expert to STOCKER, Eva)

KOKAVCOVA, Martina (SK) (Advisor to HORSKÁ, Alexandra)
KOZMÍKOVÁ, Jana (CZ) (Expert to KULHÁNKOVÁ, Pavlína)
KUROVA, Martina (SK) (Expert to HORSKÁ, Alexandra)
LANDVIK, Nina (NO) (Expert to REIERSON, Linda)
LUNDBERGH, Ivar (SE) (Expert to MALKIEWICZ, Katarzyna)
MENDONÇA, Elsa (PT) (Expert to ALMEIDA, Inês)
MÜHLEGGGER, Simone (AT) (Expert to STOCKER, Eva)
REDMOND, Aisling (IE) (Expert to CONWAY, Louise)
ROSENTHAL, Esther (DE) (Advisor to FINDENEKG, Helene)
UNKELBACH, Christian (DE) (Expert to FINDENEKG, Helene)

MSCA experts for SEv cases

ARNING, Jürgen (DE)
KABNER, Franziska (DE)

Apologies:

STESSEL, Helmut (AT)
TARNOCZAI, Tímea (HU)
WAGENER, Alex (LU)

Draft Agenda
69th meeting of the Member State Committee
(Web conference)

22-23 April 2020
ECHA Conference Centre

22 April: starts at 10:30 am (Helsinki time, CET+1)
23 April: ends at 16:00 (Helsinki time, CET+1)

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/069/2020
For adoption

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

Item 4 – Administrative issues

- Alternative options to the identification of rapporteurs and update to the MSC Rules of procedures

ECHA/MSC-69/2020/005
For discussion and decision

- Outlook for MSC-70, MSC-70bis and MSC-71

For information

Item 5 – Minutes of the MSC-68

- Final minutes of MSC-68

MSC/M/68/2020
For information

Item 6 – Substance evaluation

Closed session for 6.3

1. Written procedure report on seeking agreement on draft decisions on substance evaluation¹

ECHA/MSC-69/2020/006

¹ List of agreed cases is available in an Appendix at the end of this document.

For information

2. 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 6.3:

Case	Substance	EC N:o/Doc. N:o
SEV-DE-001/2018	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione	258-904-8 / ECHA/MSC-69/2020/001-2
SEV-DE-002/2018	1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt	262-872-0 / ECHA/MSC-69/2020/003-4

For discussion

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

Cases as listed above under 6.2

For agreement

4. General topics

None

[For information]

Item 7 – Dossier evaluation

Closed session for 7.3

1. Written procedure report on seeking agreement on draft decisions on dossier evaluation¹

ECHA/MSC-69/2020/007
For information

2. 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 7.3:

Compliance checks

MSC code	Substance name	EC/List No.
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No cases

Testing proposal examinations

MSC code	Substance name	EC/List No.
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No cases

[For discussion]

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

[For agreement]

4. General topics

None

[For information]

Item 8 – SVHC identification

Not relevant for this meeting

[For information]

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

Not relevant for this meeting

[For information]

Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)

- Timeline for the next CoRAP update and rapporteur appointment

For information and discussion

Item 11 – Any other business

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

(Partly closed session)

For information

2. Suggestion from a member: Selection of dossier evaluation cases to the MSC-70bis round

For information

Item 12 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-69

For adoption

INFORMATION DOCUMENTS

Information documents are not allocated a specific agenda time but the documents are available on MSC CIRCABC 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.

- Status report on on-going substance evaluation work (presentation slides)
- Status report on on-going dossier evaluation work (presentation slides)
- Identification of SVHCs under Article 57(f) – ELoC overview (ECHA/MS/1/2020/008)

APPENDIX to the MSC-69 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-69 meeting:

Substance evaluation

MSC code	Substance name	EC No.
SEV-SE-011/2018	Butanone	201-159-0

Dossier evaluation

Compliance checks

MSC code	Substance name	EC No.
CCH-004/2020	3a,4,7,7a-tetrahydro-4,7-methanoindene	201-052-9
CCH-031/2020	Barium dodecairon nonadecaoxide	234-974-5

Testing proposal examinations

MSC code	Substance name	EC No.
TPE-001/2020	3a,4,7,7a-tetrahydro-4,7-methanoindene	201-052-9

IV. Main Conclusions and Action Points



Main conclusions and action points
MSC-69 22-23 April 2020
(adopted at MSC-69)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
<ul style="list-style-type: none"> Alternative options to the identification of rapporteurs and update to the MSC Rules of procedures 	
<p>MSC decided that an appointed rapporteur should have a possibility to deliver the draft opinion to MSC even after expiry of the individual's MSC membership. MSC should decide on such possible continuation upon a request of that individual and his/her Member State.</p> <p>MSC supported the proposal for amendment of the MSC RoPs to extend the role of the alternate member to be able to become rapporteur, provided ECHA MB could approve such a change.</p>	<p>MSC-S to submit the proposal to ECHA MB for amending MSC RoPs to allow alternate members to become rapporteurs.</p>
<ul style="list-style-type: none"> Web conference feedback 	<p>MSC members and stakeholder observers to provide written feedback to the MSC FMB on any learnings from the web conference by 6th May 2020.</p>
Item 6.1 – Substance evaluation	
Written procedure report on seeking agreement on draft decisions on substance evaluation	
<p>MSC took note of the report.</p>	<p>MSC to consider the decision uploaded on MSC S-CIRCABC for the written procedure as agreed one.</p>
Item 6.3 – Substance evaluation	
Seeking agreement on draft decisions when amendments were proposed by MSCA's/ECHA (<i>Session 2, closed</i>)	
<p>MSC reached unanimous agreement on the following ECHA draft decisions:</p> <ul style="list-style-type: none"> SEV-DE-001/2018, 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione (EC No. 258-904-8) SEV-DE-002/2018, 1,3-dihydro-4(or 5)-methyl-2H-benzimidazole-2-thione, zinc salt (EC No. 262-872-0) 	<p>MSC-S to upload on MSC S-CIRCABC the agreed decisions in the respective case folder.</p>
Item 7.1– Dossier evaluation	
Written procedure report on seeking agreement on draft decisions on dossier evaluation	
<p>MSC took note of the report.</p>	<p>MSC to consider the decisions uploaded on MSC S-CIRCABC for the written procedure as agreed ones.</p>
Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)	
<ul style="list-style-type: none"> Timeline for the next CoRAP update and rapporteur appointment 	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC took note of the timeline for the next CoRAP update and the expected timings for rapporteur appointment and opinion drafting.	MSC-S to launch a call for volunteers for rapporteurships in June.
Item 12 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-69 at the meeting.	MSC-S to upload the main conclusions and action points on MSC S-CIRCABC by 24 April 2020.