

#### MSC/M/68/2020 Adopted by written procedure on 6 April 2020

Minutes of the 68th Meeting of the Member State Committee (MSC-68)

6 February 2020

Web conference

#### 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 68<sup>th</sup> 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 also referred to the web conference instructions which the participants had received prior to the plenary meeting.

#### Item 2 - Adoption of the Agenda

The Agenda was adopted as provided for the meeting by the MSC Secretariat without further changes (final Agenda is attached to these minutes as Section III).

#### Item 3 - Declaration of specific interests to 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-68.

#### Item 4 - Administrative issues

• Alternative options to the identification and appointment of rapporteurs

Based on the meeting document and a brief refresher from the Chairman on the topic, MSC continued the general discussion on alternative options to the identification and appointment of rapporteurs. Several members expressed support for the approach, whereas SECR emphasised that volunteering would still remain as the main way for identification of potential rapporteurs. In the discussion it was clarified that corapporteurships are considered in a similar manner as rapporteurships. If any member would need to waive his or her turn, this would have to happen early on so as to maintain the predictability the list otherwise provides. Further discussion will take place at MSC-69 on the suggestion that a rapporteurship continuous in case MSC membership expires during the rapporteurship. For all other aspects, MSC supported the proposals in the meeting document, and final agreement could take place in the next meeting. As a next step, SECR offered to prepare a text revision of the MSC Rules of Procedure for MSC-69 to allow alternate members also to take on a rapporteurship, which could then be proposed for adoption by the ECHA Management Board later in the year.

#### Outlook for MSC-69

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 also presented an early stage estimation for the length of the MSC-70 meeting in June 2020. The Chairman informed members of the planned MSC-70bis dossier evaluation round, which will have no associated plenary meeting, but which retains the possibility to provide proposals for amendments on draft decisions and agreement seeking in written procedure.

#### Status update for case CCH-099/2019

The Chairman informed MSC on the status of a compliance check case CCH-099/2019, which had been agreed on at MSC-67. The Registrant of the registered substance Polyhaloalkene (EC No. 468-710-7) had opted-out for some endpoints from a joint submission and was required to obtain the *in vivo* mutagenicity study at Annex IX level which existed in the lead registrant's dossier. As agreed at MSC-67, ECHA Secretariat (SECR) contacted the Registrant and received confirmation that the Registrant has a letter of access to the *in vivo* mutagenicity study in the lead registrant's dossier. Following its inclusion in the registration dossier, SECR will remove the mutagenicity request before issuing the decision to the Registrant.

#### Item 5 – Minutes of the MSC-67 meeting

The minutes of MSC-68 were adopted as modified for the meeting.

#### Item 6 - Substance evaluation

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

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on a draft decision on one substance evaluation (SEv) case (see Appendix to the final agenda in Section III for more detailed identification of the case). WP was launched on 13 January 2020. By the closing date 23 January 2020, MSC reached unanimous agreement on this one SEv case.

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

No cases

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

No cases

#### 4. General topics

1) Fundamentals in Substance Evaluation (Closed session)

SECR introduced to MSC a draft document on fundamentals in Substance Evaluation (SEv) to guide eMSCA experts when preparing SEv decisions. A discussion with MSCAs on the document was foreseen in the RIME+ meeting the week after MSC-68. MSC took note of the document.

2) Cut-off date for dossier updates during Substance Evaluation (Closed session)

SECR introduced to MSC a draft document for cut-off dates for dossier updates during SEv to guide eMSCA experts when preparing SEv decisions. A discussion with MSCAs on the document was foreseen in the RIME+ meeting the week after MSC-68. MSC took note of the document.

#### 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 draft decisions (DD) for three dossier evaluation cases (see Appendix to the final agenda in Section III for more detailed identification of the case). WP was launched on 13 January 2020. By the closing date 23 January 2020, MSC reached unanimous agreement on all DDs. One member abstained from voting on two cases.

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)

Not applicable to this meeting round.

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

Not applicable to this meeting round.

#### 4. General topics

1) Request of comet assay under CCH for chemicals showing both chromosomal aberrations and gene mutation concerns? (Partly closed session)

SECR gave a presentation on a possible generic approach for chemicals showing concerns for both gene mutation (GM) and chromosomal aberration (CA), in particular when both concerns are unequivocally identified. The MSC took note of the presentation, which used the case-specific agreement of MSC-67 as starting point (see item 7.3 in MSC/M/67/2019). The MSC took note of a member's suggestion that comet assay is considered to be more sensitive than the micronucleus test or the chromosomal aberration test. It deliberated on situations, where different concerns had been identified and where various options and combinations of studies could be envisaged.

An important situation for more detailed consideration at the next meeting is where one concern (due to mechanism of action GM or CA) is considered to be stronger than the other. In such cases, a potential testing strategy could include first an in vivo somatic test which focuses on the stronger concern/mechanism of action. In the situation, where the outcome of such a test gives a negative result, it would be possible to request a second somatic test to clarify the remaining concern/mechanism of action in a follow up decision. The MSC also tentatively explored further situations, including ones where giving several study options would be the preferred approach over a single study request.

The MSC took note that the comet assay alone cannot detect aneugenicity; however, if combined with a micronucleus (MN) test this mechanism of action could be detected. It also noted that such a combined study could be requested as one setup. In summary, the MSC expressed its general support for the presented scientific assessment. Also, it was supportive of the tentative proposal that ECHA may request comet assay only, if both GM and CA concerns were identified. The MSC agreed to discuss the REACH regulatory implications at the next MSC meeting; to this end it asked SECR to prepare a discussion document in collaboration with experts who are to be volunteered by MSC members and regular stakeholder observers.

## 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

Updated prioritisation results and substances for the 10<sup>th</sup> recommendation:

- Discussion on the substances suggested for inclusion in the draft recommendation and the respective draft Annex XIV entries
- Invitation for volunteers for the rapporteurship and possible working group membership and decision on timing of rapporteur appointment

SECR thanked the MSC for the useful feedback on the prioritisation results in preparation for the 10th draft recommendation, and responded to the written comments made. While introducing the draft 10th recommendation of priority substances to be included in Annex XIV, SECR reiterated some general considerations which are applied while aiming for a proportionate Annex XIV recommendation. The draft presented included seven substances (D4; D5; D6; Terphenyl, hydrogenated; Dicyclohexyl phthalate (DCHP); Disodium

octaborate and Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride, TMA)), five of which were with the highest total scores. Two substances are prioritised based on grouping considerations. SECR suggested to use the standard approach for setting the latest application dates (use of 18, 21 or 24 months) without a precise assignment to a specific slot in advance of the three months consultation.

A member stated that when the German Competent Authority (DE-CA) proposed D4 and D5 for identification as SVHCs, this was to formally recognize the PBT/vPvB properties of the cyclosiloxanes, without aiming for authorisation. Instead, the main aim was to require the registrants to acknowledge the PBT/vPvB properties of D4 and D5 and to minimize their emissions to the environment. The member assumed that only a very low tonnage would remain in the scope of authorisation with the currently ongoing restriction in place. The member added that DE-CA is considering to make a further restriction proposal to cover all remaining uses and hence, suggested not to include D4, D5 and D6 to the 10th draft recommendation. Another member suggested addition of three more substances (ethylenediamine, lead, and HFPO-DA) to the draft given their relatively high priority score also as compared to the previous recommendation round, and noted that MSC members have a limited insight into the anticipated workload, and hence it is difficult to evaluate the appropriateness of the number of substances on the list.

In response, SECR explained that the cut-off value to include substances is a relative one which is applicable to one draft recommendation only, and that comparison of cut-off values between different recommendation rounds is inappropriate. As regards the three cyclosiloxanes, SECR repeated the information from the priority assessment that the scores for these substances would remain high even if the uses covered by the anticipated restriction are not considered for the priority. SECR further noted that any planned restriction should be included in the Registry of Intentions (including the anticipated scope) to be able to take it into account and to aid the overall planning. SECR recognised that the workload estimates can at this stage of the process be made only on a rough basis. An observer flagged there should be priority for an action on HFPO-DA and was also calling for reassessment of its score in the prioritisation round, given that the Candidate List entry actually covers many substances (salts and halides). The observer invited ECHA to reconsider the number of substances to be included in the draft recommendation, and called for quick action on substances of very high concern, such as PFAS and other similar substances, either via restrictions or inclusion in Annex XIV. Another observer echoed the concerns raised about inclusion of D4, D5 and D6 in the draft recommendation due to the other ongoing risk management process, i.e. restriction of uses, which was considered by the German competent authority in their SVHC proposal on D4/D5 the more appropriate regulatory risk management measure.

SECR thanked MSC for the feedback and indicated it will consider this when finalising the draft recommendation for consultation of all interested parties, which is to be launched on ECHA's website in early March.

Furthermore, MSC was made aware of some editorial updates that are to be included in an update of the prioritisation approach document on ECHA's website. One member proposed to further refine the approach that is currently used for the prioritisation of substances to Annex XIV to score substances identified as SVHC based on impurities in a more proportionate manner. As this proposal goes beyond an editorial update of the approach, it was proposed to reflect at a later stage if indeed a more extensive update would be useful.

Finally, MSC discussed the invitation for volunteers for the rapporteurship on MSC's opinion on ECHA's draft 10th recommendation of priority substances to be included in Annex XIV. MSC agreed the timings of the Rapporteur appointment, taking into account the time plan for drafting of the MSC opinion and the suggestions of the Rapporteur of MSC's opinion on the draft 9th recommendation.

Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2020-2022)

Not relevant for this meeting

#### Item 11 - Any other business

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

SECR gave an overview of the status of recent appeals on dossier and substance evaluation submitted to the Board of Appeal of ECHA (BoA). MSC took note of the information received, and in particular on the BoA's considerations on the level of concern and the link between the substance and the concern, which ECHA needs to demonstrate in the context of its substance evaluation decisions. A brief update on new appeals was provided in a closed session to the members only.

2. Suggestions from members

No suggestions were received by members under this agenda item.

#### Item 12 - Adoption of main conclusions and action points

MSC adopted the main conclusions and action points after the MSC-68 meeting in a written procedure (see Section IV).

#### II. List of attendees<sup>1</sup>

Members/Alternate members	ECHA staff
<del></del>	
AAVIK, Jaanika (EE)	AHRENS, Birgit AJAO, Charmaine
ALMEIDA, Inês (PT)	· · · · · · · · · · · · · · · · · · ·
ATTIAS, Leonello (IT)	ANASTASI, Audrey Anne
CIESLA, Jacek (PL)	BELL, David
CONWAY, Louise (IE)	BROERE, William
DE KNECHT, Joop (NL)	CONSOLI, Elisa
DUNAUSKIENE, Lina (LT)*	DE COEN, Wim
FINDENEGG, Helene (DE)	DE WOLF, Watze
FRANZ, Michel (FR)	HALLING, Katrin
HJORTH, Rune (DK)	JOHANSSON, Matti
HORSKA, Alexandra (SK)	KARHU, Elina
HUMAR-JURIC, Tatjana (SI)	KORJUS, Pia
KOZMIKOVA, Jana (CZ)	LE CURIEUX, Frank
KOUTSODIMOU, Aglaia (EL)	MUSSET, Christel
MALKIEWICZ, Katarzyna (SE)	NAUR, Liina
MARTIN, Esther (ES)	RÖNTY, Kaisu
MIHALCEA UDREA, Mariana (RO)	VAHTERISTO, Liisa
PALEOMILITOU, Maria (CY)	VIEIRA LISBOA, Duarte
REIERSON, Linda (NO)	
RISSANEN, Eeva (FI)	
STESSEL, Helmut (AT)	
VANDERSTEEN, Kelly (BE)	
WAGENER, Alex (LU)	
Representatives of the Commission:	
KOBE, Andrej (DG ENV)	
LINTU, Ioana (DG ENV)	
SCHUTTE, Katrin (DG ENV)	
<u>Observers</u>	
DROHMANN, Dieter (ORO)*	
FERNANDES DE BARROS, Mariana (Cefic)*	
GRANGE, Emma (Cruelty Free Europe)	
LOONEN, Helene (EEB)	
WAGNER, Kristina (ECEAE)	
WAETERSCHOOT, Hugo (Eurometaux)*	

#### **Proxies**

HUMAR-JURIC, Tatjana (SI) also acting as proxy of JANTONE, Anta (LV) PALEOMILITOU, Maria (CY) also acting as proxy of DIMITROVA, Rada (BG) STESSEL, Helmut (AT) also acting as proxy of KREKOVIC, Dubravka (HR)

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

BARTHELEMY BERNERON, Johanna (FR) (expert to FRANZ, Michel)

BOLWIG, Asger (DK) (expert to HJORTH, Rune)

CATONE, Tiziana (IT) (expert to ATTIAS, Leonello)

COPOIU, Oana (RO) (expert to MIHALCEA UDREA, Mariana)

DOBRAK-VAN BERLO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)

EINOLA, Juha (FI) (advisor to RISSANEN, Eeva)

FERNANDEZ-SANCHEZ, Raquel (ES) (expert to MARTIN, Esther)

GYMNAOU, Panagiotis (CY) (expert to PALEOMILITOU, Maria)

GÜNDEL, Ulrike (DE) (advisor to FINDENEGG, Helene)

HERMES, Joe (LU) (expert to WAGENER, Alex)

HOELZL, Christine (AT) (expert to STESSEL, Helmut)

<sup>1</sup> The MSC-68 meeting was held as a web conference. The participants that joined the meeting physically in the ECHA premises (other than the ECHA staff) are indicated by an asterisk.

KOKAVCOVA, Martina (SK) (advisor to HORSKA, Alexandra) KUROVA, Martina (SK) (expert to HORSKA, Alexandra) LANDVIK, Nina (NO) (expert to REIERSON, Linda) LUNDBERGH, Ivar (SE) (expert to MALKIEWICZ, Katarzyna) MARTIN, Nellie Anne (DK) (advisor to HJORTH, Rune) MENDONÇA, Elsa (PT) (expert to ALMEIDA; Ines) ROSENTHAL, Esther (DE) (expert to FINDENEGG; Helene) SPURIENE, Otilija (LT) (expert to DUNAUSKIENE, Lina) TARNOCZAI, Timea (HU) (expert to DEIM, Szilvia) TARVAINEN, Emma (FI) (advisor to RISSANEN, Eeva) WIJMENGA, Jan (NL) (expert to DE KNECHT, Johan)

#### **Apologies**

ANDRIJEWSKI, Michal (PL) DIMITROVA, Rada (BG) JANTONE, Anta (LV) KREKOVIC, Dubravka (HR) KULHANKOVA, Pavlina (CZ) DEIM, Szilvia (HU)



# Agenda 68<sup>th</sup> meeting of the Member State Committee

#### 6 February 2020

ECHA Conference Centre Telakkakatu 6, Helsinki, Finland (web conference)

February: starts at 10:30 am February: ends at 4:00 pm

#### Item 1 - Welcome and Apologies

#### Item 2 - Adoption of the Agenda

MSC/A/068/2020

For adoption

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

#### Item 4 – Administrative issues

• Alternative options to the identification and appointment of rapporteurs

ECHA/MSC-68/2020/003

For discussion and decision

• Outlook for MSC-69

For information

#### Item 5 - Minutes of the MSC-67

Draft minutes of MSC-67

MSC/M/67/2019

For adoption

#### Item 6 - Substance evaluation

Closed session for 6.4

1. Written procedure report on seeking agreement on draft decisions on substance evaluation<sup>2</sup>

 $<sup>^{2}</sup>$  List of agreed cases is available in an Appendix at the end of this document.

2. Introduction to and preliminary discussion on draft decisions on substance evaluation when amendments were proposed by MS-CA's/ECHA (Session 1, open):

No cases

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

No cases

[For agreement]

- 4. General topics
  - 1) Fundamentals in Substance Evaluation (Closed session)

ECHA/MSC-68/2020/004

2) Cut-off date for dossier updates during Substance Evaluation (Closed session)

ECHA/MSC-68/2020/008

For information

#### Item 7 - Dossier evaluation

#### Partly closed session for 7.4.1

1. Written procedure report on seeking agreement on draft decisions on dossier evaluation<sup>1</sup>

ECHA/MSC-68/2020/001

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** 

No cases

#### **Testing proposal examinations**

No cases

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

No cases

[For agreement]

#### 4. General topics

1) Request of comet assay under CCH for chemicals showing both chromosomal aberrations and gene mutation concerns? (Partly closed session)

For information and discussion

#### 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

Updated prioritisation results and substances for the 10<sup>th</sup> recommendation:

• Discussion on the substances suggested for inclusion in the draft recommendation and the respective draft Annex XIV entries

ECHA/MSC-68/2020/005-007

Room document ECHA/MSC-68/2020/009

For discussion

 Invitation for volunteers for the rapporteurship and possible working group membership and decision on timing of rapporteur appointment

For discussion/decision

Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2020-2022)

Not relevant for this meeting

#### Item 11 - Any other business

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

(Partly closed session)

For information

2. Suggestions from members

For information

#### Item 12 - Adoption of main conclusions and action points

• Table with conclusions and action points from MSC-68

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)
- Report of MSC work in 2019 (presentation slides)

#### APPENDIX to the MSC-68 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-68 meeting:

#### **Substance evaluation**

MSC code	Substance name	EC/List No.
SEV-DE-006/2018	Diantimony trioxide	EC No. 215-175-0

#### **Dossier evaluation**

MSC code	Substance name	EC/List No.
CCH-152/2019	N-methylaniline	EC No. 202-870-9
CCH-172/2019	Dioctadecyl disulphide	EC No. 219-702-5
TPE-106/2019	Biphenyl-4,4'-diol	EC No. 202-200-5

#### IV. Main Conclusions and Action Points



## Main conclusions and action points MSC-68 (6 February 2020)

(adopted in written procedure after the meeting on 12 February 2020)

CONCLUSIONS / DECISIONS / MINORITY	ACTIONS REQUESTED			
OPINIONS				
Item 4 – Administrative issues				
Alternative options to the identification and appoint	Alternative options to the identification and appointment of rapporteurs			
MSC supported back-up approach for identification of its rapporteurs and the two lists in Appendix of document ECHA/MSC-68/2020/003. One outstanding issue on the impact of MSC membership expiration is to be resolved,	MSC members to continue volunteering for rapporteurships.  MSC-S to prepare a proposal for amendment to			
with final agreement on the approach planned for MSC-69.	the MSC Rules of Procedure.			
MSC supported extension of the role of the alternate member to allow him/her to take on a rapporteurship provided ECHA MB could approve such a change in the MSC Rules of Procedure (RoPs).				
Web conference feedback	MSC members and stakeholder observers to provide written feedback to the MSC FMB on any learnings from taking part in a plenary web conference by 12 February 2020.			
Item 5 – Minutes of the MSC-67				
MSC adopted the draft minutes as submitted to the meeting.	MSC-S to upload final version of the minutes on MSC S-CIRCABC by 12 February 2020 and on ECHA website without undue delay.			
Item 6.1 – Substance evaluation Written procedure report on seeking agreement on	draft decisions on substance evaluation			
MSC took note of the report.	MSC to consider the decision uploaded on MSC S-CIRCABC for the written procedure as agreed one.			
Item 6.4 – Substance evaluation				
General topics				
1) Fundamentals in Substance Evaluation				
MSC took note of the report	MSC to provide feedback to their MSCA representative before the RIME+ meeting.			
2) Cut-off date for dossier updates during Substance	Evaluation			
MSC took note of the report	MSC to provide feedback to their MSCA representative before the RIME+ meeting.			
Item 7.1- Dossier evaluation				
Written procedure report on seeking agreement on	draft decisions on dossier evaluation			
MSC took note of the report.	<b>MSC</b> to consider the decisions uploaded on MSC S-CIRCABC for the written procedure as agreed ones.			
Item 7.4 – Dossier evaluation	•			

CONCLUSIONS / DECISIONS / MINORITY	ACTIONS REQUESTED			
OPINIONS				
General topics				
1. Request of comet assay under CCH for chemicals showing both chromosomal aberrations (CA) and gene mutation (GM) concerns?				
MSC took note of the presentation on when to request the comet assay, in particular when both concerns were unequivocally identified (CA and GM).	MSC and StOs to submit written comments to the MSC FMB, and MSC to indicate contributing experts by 20 February 2020.			
	<b>SECR</b> to prepare a further discussion at MSC-69, partly with contributing experts.			
Item 9 – ECHA's recommendations of priority substate opinion of MSC	nces to be included in Annex XIV and			
Discussion on the substances suggested for inclusion in the draft recommendation and the respective draft Annex XIV entries				
MSC took note of the substances and respective Annex entries to be included in the draft recommendation.	MSC to submit any further feedback on the draft recommendation using MSC FMB by 12 Feb 2020.			
	<b>SECR</b> to publish the 10 <sup>th</sup> draft recommendation on the website early March 2020.			
<ul> <li>Invitation for volunteers for the rapporteurship and decision on timing of rapporteur appointment</li> </ul>	possible working group membership and			
MSC agreed to postpone invitation of volunteers for the rapporteurship to June, with an appointment latest at the	<b>MSC Chairman</b> to invite for volunteers for the rapporteurship in June 2020.			
MSC-71 meeting.	<b>MSC-S</b> to upload the MSC meeting work plan for 2020 in Circabc applying the agreed plan for rapporteur appointment.			
Item 12 – Adoption of main conclusions and action p	oints			
MSC to adopt the main conclusions and action points of MSC-68 after the meeting via a tacit agreement.	MSC-S to upload the main conclusions and action points on MSC S-CIRCABC by 7 February 2020 for a tacit agreement (remarks to be sent to MSC FMB by 12 February 2020).			