MSC/M/67/2019

Minutes of the 67th Meeting of the Member State Committee (MSC-67)

9-11 December 2019

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 67th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Section II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as modified at the meeting based on the draft agenda as provided for the meeting by the MSC Secretariat (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-67.

Item 4 - Administrative issues

- Alternative options to the identification and appointment of rapporteurs

This item was postponed to the next meeting.

- MSC mandates for evaluation decisions – general considerations

ECHA Secretariat (SECR) introduced a suggestion to MSC on how it could facilitate its decision making at the meetings. SECR suggested MSC to agree on the exact information requests and after discussion and agreement on all the arguments for the requests, and give a mandate for developing the text of the appendices after the meeting. In case of dossier evaluation MSC could mandate ECHA Secretariat, and in case of substance evaluation MSC could mandate the evaluating MSCA and ECHA Secretariat, to finalise the decision after the MSC meeting. A proposal for an approach and necessary timeframe and expected resource implications for such mandates was outlined. Several MSC members fully supported the proposal with the expectation that the current approach, which is to agree on text for the appendices during the meeting, would be kept for all complicated cases. SECR also emphasised that a mandate to finalise (parts of the) appendices text is not to be construed as delaying the agreement. It was also reminded that it remains meaningful to keep as an element of a PfA a suggestion with a clear text proposal for the arguments to be included in the appendices.

Few members had clarifying questions on how the actors for the post-meeting finalisation should be nominated. SECR explained that this depends on the case and for SEV e.g. the eMSCA co-ordinator could be the one bringing in any necessary experts in collaboration with an ECHA representative. Where warranted, this might be further described by MSC when the mandate is specified and agreed upon. The Chairman also explained that his role after the meeting would always be to verify that the mandate, once implemented, was followed and in line with the MSC discussion.

The Chairman concluded that MSC supported by consensus the general rationale and principles on how MSC could mandate ECHA Secretariat (and eMSCA) to finalise the text of a draft decision. He also noted that additional details on how to implement these mandates would need further planning and likely become apparent during the next meetings.

- Outlook for MSC-68

The Chairman presented an outlook on the potential length of the next meeting which is expected to require 1,5 plenary days. The Chairman also presented an early stage estimation for the length of the MSC-69 meeting in April 2020.

Item 5 – Minutes of the MSC-66 meeting

The minutes of MSC-66 were adopted as provided 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 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 14 November 2019. By the closing date 25 November 2019, 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)

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

SEV-NL-017/2017 Sepisol Fast Blue 85219 (EC No. 700-579-6)

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from the Netherlands (NL-CA) presented the current status of this SEv case (SEV-NL-017/2017). The initial grounds of concern when placed on the Community Rolling Action Plan (CoRAP) were relating to suspected PBT/vPvB and wide dispersive use.

MSC was guided by the expert from NL-CA through the information on the substance and through the proposals for amendment (PfAs) received from Member State Competent Authorities (MSCAs), ECHA, the Registrants' comments on the PfAs and the eMSCA's response to them.

All of the PfAs submitted were accepted by the eMSCA and led to an amendment of the DD in advance of the meeting. These were not discussed at the meeting. The expert from NL-CA explained that in the comments to the PfAs the Registrant requested insight into the SMILES code used to derive the Log Kow values (reported in table 1 of Appendix 4 of the decision) of one of the dissociation products of the substance. The eMSCA updated Appendix 4 with this information. The Registrant had raised this point also in their comments on the first SEv DD, but this comment had not been sufficiently addressed. Therefore, the Registrant was heard on this updated part of the draft decision in advance of the meeting.

In the discussion, MSC members expressed support to the approach in the DD, to request first for the water solubility test method, OECD 105 column elution method, with the substance, with analytical determination of the Substance and the dissociation products.

Session 2 (closed)

The MSC unanimously agreed on the decision as amended before the meeting.

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 seven dossier evaluation cases (see Section III Final agenda "Appendix to the MSC-67 agenda" for more detailed identification of the cases). WP was launched on 14 November 2019. By the closing date 25 November 2019, MSC reached unanimous agreement on six DDs. One member abstained from voting on six cases. The MSC Chairman terminated the WP for one DD, based on a request from an MSC member.

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)*

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

MSC noted that it would combine the discussion and agreement seeking on the following four category cases, which were linked to each other through a read across, with the aim to perform the studies with the substance DTPMP, 5-7 Na-salt (CCH-106/2019).

CCH-105/2019 [[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis (methylene)]] tetrakisphosphonic acid (EC No. 239-931-4)

CCH-106/2019 Sodium salts of [[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]]tetrakisphosphonic acid (5-7 Na:1) (List No. 701-216-4)

CCH-107/2019 Sodium salts of [[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]]tetrakisphosphonic acid (1-3 Na:1) (List No. 701-215-9)

CCH-108/2019 Pentasodium pentahydrogen [[(phosphonatomethyl)-imino]bis[ethane-2,1-diylnitrilobis(methylene)]]-tetrakisphosphonate (EC No. 263-212-4)

Session 1 (open)

ECHA Secretariat (SECR) first noted that the substances of the four cases were registered as part of a category with four members. The proposed read across for the category comprised the registered substance of CCH-105/2019 as a source substance (at Annex X tonnage level), and the three others as target substances (at Annex X level, except for CCH-108/2019 at Annex IX level). The endpoint-specific PfAs discussed below were similar and submitted for all four cases, except those on the extended one-generation reproductive toxicity study (EOGRTS) that were submitted for cases other than CCH-108/2019.

Two representatives of the Registrants of the four cases participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.

SECR introduced the proposals for amendment (PfA) that, in their view, required discussion in the meeting. MSC agreed that the other PfAs did not require further consideration at the meeting. The first PfA on EOGRTS suggested requesting both the cohorts 2A and 2B (developmental neurotoxicity, DNT) and the cohort 3 (developmental immunotoxicity, DIT). The DNT request was based on evidence from available repeated dose toxicity studies showing iron-deficiency, which causes anaemia and various neurodevelopmental risks, for example, lower brain weight. The DIT request was based on available studies which show iron deficiency causes altered immune responses.

The second PfA on mutagenicity suggested requesting, for the *in vivo* follow up, solely the *in vivo* comet assay and not giving a choice between three assays (the comet assay (OECD TG 489), the micronucleus test (OECD TG 474) and the chromosomal aberration test

(OECD TG 475)). The available *in vitro* studies had indicated concerns on both chromosomal aberrations and gene mutation. Only the *in vivo* comet assay covers both modes of action.

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

The representatives of the Registrants first reconfirmed that they deemed the read across for the category valid and that ECHA has considered the grouping approach acceptable. They reaffirmed their comments disagreeing with the PfAs on EOGRTS, considering that the referred studies did not allow to conclude on specific concerns for triggering additional cohorts. Additionally, they expressed a concern on the administration route in the studies that may have resulted in chelation of iron in food by the substance and subsequently to iron deficiency due to reduced iron absorption, being probably the main reason for the recorded effects, none of which resulting in an adverse effects being either reversible or recorded at the end of the study with no consequences through the duration of the experiments on the animals. The representatives of the Registrants also considered that, even though gavage could minimise such effects of reduced iron intake, administration with the diet is preferable, as causing less stress to animals. Regarding the mutagenicity request, the representatives of the Registrants informed that, since their comments on the initial draft decision (DD) they had changed their view and wished to review the original reports and toxicokinetic data, and consequently that they would now prefer to leave the choice of the most proper *in vivo* study open. As a general remark, they informed that the substances are marketed in maximum 50% concentrations in water, although also available as powder.

The MSC first discussed the PfA on EOGRTS, in particular on the reliability of the referenced studies, the dose levels where effects from iron deficiency were detected, the range of parameters evaluated, and the detected links between iron deficiency and adverse effects. MSC discussed the relevance and scientific basis of the registrant's hypothesis of reduced dietary absorption subsequent to chelation, and noted that a scientific hypothesis of reduced dietary absorption subsequent to chelation was considered in RAC's opinion on DTPA-Na5 (EC 205-391-3) (proposing a Repro 1B classification). The MSC concluded that, based on studies available, there was an unequivocal connection between iron deficiency and developmental neurotoxicity and immunotoxicity, that available data showed a concern for iron deficiency for the registered substances and thus that there are triggers for the additional DNT and DIT cohorts.

The MSC then discussed the mutagenicity test(s) request. The substance seemed not to reach the bone marrow, which is a contraindication to performing an *in vivo* micronucleus test (OECD TG 474) or chromosomal aberration test (OECD TG 475). The MSC emphasized that there were concerns on both chromosomal aberration and gene mutation on these substances. SECR maintained that the comet assay was suitable to address both concerns to which the representatives of the Registrant and MSC could agree. SECR highlighted, as agreed in the previous MSC meeting, if the outcome of the *in vivo* somatic cell study is positive and no clear conclusion about germ cell mutagenicity can be made, a subsequent germ cell testing may still be required under REACH Annex IX.

Session 2 (closed)

The MSC agreed based on the PfA on EOGRTS to include the DNT and DIT cohorts.

Then, continuing with the PfA on mutagenicity, the MSC concluded that the comet assay would be the most appropriate study to request in these specific cases and remove the options for other *in vivo* mutagenicity tests. In addition, the MSC invited SECR to present, in its next meeting, further considerations on the *in vivo* genotoxicity test(s) to be requested under compliance check or testing proposal examination for chemicals showing concerns for both chromosomal aberrations and gene mutation.

The MSC summarized its overall agreement based on the PfAs, as specified in the amended DDs, to request, (a) the *in vivo* mammalian alkaline comet assay for all cases,

(b) the DNT and DIT cohorts for the EOGRTS and confirmed administration via the oral route for cases CCH-105/2019, CCH-106/2019 and CCH-107/2019.

CCH-099/2019 Polyhaloalkene (EC No. 468-710-7)

Session 2 (closed)

SECR explained that agreement was initially sought in written procedure. An MSC member requested stopping the written procedure to allow a discussion on two specific proposals for amendment (PfA). The first PfA on *in vitro* gene mutation study in mammalian cells suggested removing the request. The second PfA on pre-natal developmental toxicity study (PNDT) suggested additionally requesting the study on a second species. Subsequently, the Chairman terminated the written procedure for the case.

The Registrant had not provided any comments on the PfAs.

The MSC first took note of the setting of this case, notably that the Registrant had opted-out from a joint submission (see considerations on such situations under the presentation in section 7.4 below) and only had acquired selected studies from the lead dossier.

The MSC member who requested discussion reiterated the considerations of the PfAs, first focussing on the mutagenicity aspects. The member noted that the requirement at Annex IX level, at which this Registrant is, was to perform an *in vivo* mutagenicity study in due to the positive *in vitro* study in the lead registrant's dossier; therefore, a new *in vitro* study would not be necessary. The draft decision (DD) requested an *in vitro* mutagenicity study, based on REACH Annex VIII, because this information requirement was not fulfilled in the Registrant's dossier.

SECR informed that the Registrant had not acquired the *in vitro* study but referred to it in its chemical safety assessment (CSA). SECR agreed that the *in vitro* study in the lead dossier was positive, thus it would already trigger an *in vivo* study for this Registrant. However, SECR clarified that for *in vitro* studies the legal basis only allows to recommend the member to acquire an available *in vitro* study from the lead dossier. Although, in case of vertebrate studies there is a clear legal basis for the requirement to acquire an available study.

The MSC recognised that the registered substance and the endpoint on mutagenicity were also covered in a substance evaluation (SEv) decision, implemented in 2015 by the Commission after agreement by the REACH Committee, whereas this Registrant failed to update his registration dossier accordingly.

The MSC concluded that the *in vitro* test would not contribute any additional relevant information beyond what the *in vivo* test would provide. The MSC agreed to remove the request for an *in vitro* test.

The MSC member who requested discussion then further elaborated on the second PfA to request a PNDT study in a second species. The member noted that this opt-out Registrant had not considered the results of a study available in the lead dossier. These results are also publicly available from a review by the German MAK Commission for Occupational Safety, who used them for the occupational exposure level (OEL) recommendation in Germany. These results are thereby also important for establishing derived no-effect levels (DNEL) as part of the CSA.

SECR considered that, for legal reasons, it was not possible to request the PNDT test in a second species from this Registrant. According to Annex IX, section 8.7.2. column 2 the study in the second species is triggered either by results from the first study, not applicable here, or by "all other relevant available data". The second species PNDT study available in the Annex X joint submission registration dossier, cannot be used to trigger the same study, hence it cannot be considered as "other available data". Therefore, SECR concluded that there was no legal requirement for a second species PNDT.

The MSC took note that there were no PfAs on establishing DNELs, but that the Registrant could be reminded to take into account national assessments. SECR agreed that they could include this aspect in the decision notification letter, which would point out the obligation to consider all available relevant information when setting a DNEL for human health,

including those "from assessments carried out under other international and national programmes".

The MSC summarised its conclusions on this case, firstly concluding to drop the mutagenicity *in vitro* request but keeping the request for the *in vivo* mutagenicity study, additionally aligning the DD text on triggering germ cell testing, as agreed in MSC-65. Secondly the MSC agreed not to request a PNDT on a second species.

Finally, the MSC made a remark that in future the DDs could be more direct in explaining to opt-out Registrants that they must request the data on vertebrate studies on the registered substance from the other registrants, if studies covering the information requirement are already available in another dossier for the same substance. Furthermore, the deadline given to the Registrants to provide the requested data should be limited, considering that they are not expected to perform new studies.

MSC agreed unanimously to the DD as amended in the meeting. Two MSC members abstained from voting, including members from Belgium and Ireland.

4. General topics

Registrants submitting information separately as per Article 11(3) of REACH – impact on compliance checks *(closed session)*

SECR gave a presentation on how ECHA deals with registrants who opt-out, partly or in full, from a joint submission of information requirements. The REACH Article 11(3) allows registrants to submit information separately under certain conditions (opt-out members). The discussion focused on particular situations where ECHA finds that the opt-out registrant is incompliant, while the lead dossier was compliant.

In case of vertebrate studies, available studies have to be used and data sharing becomes obligatory, whereas in case of non-vertebrate studies the opt-out registrant has the option to perform a test himself. REACH provides for a mechanism to resolve data sharing disputes, where ECHA may facilitate as a last resort by assessing the efforts made by the negotiating parties to reach an agreement and may grant the data claimant permission to refer to the study in question.

MSC took note of the generic presentation and its links to the discussion on CCH-099/2019 (see section 7.3 above).

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

1. Written procedure report on seeking agreement on identification of SVHC

Not relevant for this meeting

2. Seeking agreement on Annex XV proposals for identification of SVHC Substance

Perfluorobutane sulfonic acid (PFBS) and its salts

The dossier submitter representatives (DS) from the Norwegian CA presented to MSC the Annex XV proposal for identification of *Perfluorobutane sulfonic acid and its salts*, referred further as PFBS, as SVHCs under Article 57 (f) of REACH due to a combination of concerns caused by the properties of PFBS for which there is scientific evidence of probable serious effects to human health (HH) and the environment giving rise to equivalent level of concern (ELoC) to CMR and PBT/vPvB substances under Article 57 (a)-(e) of the REACH Regulation. The DS explained the rationale for preparing the dossier and underlined that the proposal is based on different elements, none of which may be of ELoC in isolation, but in combination, they demonstrate that there is scientific evidence of probable serious

effects of these substances to human health and the environment, jointly constituting ELoC to those CMR and PBT/vPvB substances which are identified as SVHC on the basis of points (a) to (e) in Article 57.

The DS presented as well a brief overview of the comments received in the consultation of the interested parties on this Annex XV proposal and of their responses provided in the Response-to-comments document (RCOM) and the modifications made in this regard in the draft MSC Support document (SD).

MSC thoroughly considered the comments received in the consultation, the way the new data had been addressed in the SD and/or responded in the RCOM by DS. The main discussion points for MSC during its meeting were the following concern elements in the SD – 1. Very high persistence, 2. hormonal disturbance leading to potential developmental and reprotoxic effects in humans and environment, 3. Co-exposure, and how to further clarify and strengthen the argumentation provided in the ELoC assessment and in the overall conclusions

Regarding very high persistence, MSC decided to include more detail in the SD on the available biodegradation screening studies showing that PFBS is not primary biodegradable and not readily biodegradable. Based on these studies as well as other available data, degradation of PFBS at relevant environmental conditions is expected to be very slow or negligible.

Regarding thyroid hormonal disturbance leading to potential developmental effects for human health, MSC further clarified the reasoning in the SD for the conclusion, based on the study from Feng et al., (2017) , that there is an indication that prenatal PFBS exposure causes permanent hypothyroxinemia accompanied by deficits in perinatal growth, pubertal onset, and reproductive organ development in female mice taking into account that the serum thyroid hormone levels were reduced also in dams in the absence of marked general toxicity. MSC concluded that these developmental deficiencies are of serious adverse health effects.

Additionally, the reported reproductive effects seen also in other studies included disturbed estrus cyclicity in rodents and were concluded by MSC as serious adverse effects. Furthermore, MSC was of the view that the effects seen in rodents provide also evidence for adverse effects for the environment.

Regarding effects in environmental organisms, MSC discussed the data generated by Chen et al. (2018, 2019) on marine Medaka. The DS raised some limitations about the study, however, MSC was of the view that the limitations raised do not impact the reliability of the study specifically considering that the concentration of DMSO used was very low (<0.001% v/v), water concentrations were monitored regularly, nominal and measured concentrations did not vary much, and data not fully reported in one paper can be derived from data in another paper on the same study. MSC viewed the reprotoxic effects shown in the study as reliable and that they fulfill the T criteria for ecotoxicity, even though this is not a prerequisite for ELoC, hence that they constitute a serious adverse effect. In addition, the observed thyroid hormone disturbances are considered as reliable. Following the discussion the DS agreed with this view and the SD was updated accordingly.

Regarding co-exposure, MSC supported the view of the DS that often more than one per- and polyfluoralkylsubstances (PFASs) can be identified in environmental or human biomonitoring studies. Furthermore, it may be expected that perfluoroalkyl acids (PFAAs) cause similar effects, and hence that their individual contributions add up to the total effect. Co-exposure may lead to additive effects and may last for a very long time, because natural degradation processes for these substances are slow or negligible. MSC considered this as a supportive concern.

MSC concluded on the elements of concern arising from the properties of PFBS based on the application of a Weight of Evidence (WoE) approach by taking into account all available relevant information and the MSC conclusions made in the context of previously identified SVHCs under Article 57 (f).

Consequently, MSC unanimously agreed the SD and agreement document, as modified at the meeting, and thereby identified PFBS and its salts as SVHCs in accordance with Article 57(f) of the REACH Regulation.

The MSC Chairman thanked the DS and the Committee for the constructive discussions and unanimous outcome on this SVHC proposal.

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 2020-2022)

- First MSC draft opinion on the draft annual CoRAP update

The MSC Rapporteur presented the draft MSC opinion prepared by the Co-Rapporteur and herself on the draft annual update of the Community Action Plan (CoRAP) for years 2020 to 2022. She reminded MSC that there were seven new entries that were included on the draft CoRAP and had now been assessed using the respective (updated) justification documents (JDs), as well as 10 updated JDs for substances previously included to the CoRAP.

The Rapporteur explained that the draft opinion followed a somewhat streamlined structure, and made a suggestion for a reduction of some details also from the opinion Annex. Based on their review the suggestion from the (Co)-Rapporteurs was that MSC support the draft CoRAP annual update for the years 2020-2022 as there are grounds for considering that these substances may constitute a potential risk to human health and/or the environment. MSC members neither requested further clarifications, nor did they comment on the draft opinion. MSC adopted by consensus the opinion and its Annex after few editorial changes at the meeting.

It was concluded that the next steps will follow the original time plans so that the annual update of the CoRAP will be adopted by ECHA in March 2020 when also the MSC opinion will be made publicly available.

Item 11 – Any other business

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

   Not relevant for this meeting.

2. Suggestions from members and other meeting participants

The Chairman announced that in February ChemSec will be presenting their updated SIN-List to the ECHA staff, inviting MSC to join the presentation.

Item 12 - Adoption of main conclusions and action points

Table with conclusions and action points from MSC-67 was adopted at the meeting.

II. List of attendees

Members/Alternate members
AAVIK, Jaanika (EE)
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
ATTIAS, Leonello (IT)
CONWAY, Louise (IE)
DE KNECHT, Joop (NL)
DIMITROVA, Rada (BG)
DUNAUSKIENE, Lina (LT)
ELLUL, Nathanael (MT)
FERNANDEZ SANCHEZ, Raquel (ES)
FINDENEGG, Helene (DE)
FRANZ, Michel (FR)
HERMES, Joe (LU)
HJORTH, Rune (DK)
HORSKA, Alexandra (SK)
HUMAR-JURIC, Tatjana (SI)
JANTONE, Anta (LV)
KREKOVIĆ, Dubravka (HR)
KULHANKOVA, Pavlína (CZ)
LUNDBERGH, Ivar (SE)
MIHALCEA UDREA, Mariana (RO)
REIERSON, Linda (NO)
RISSANEN, Eeva (FI)
STESSEL, Helmut (AT)
VANDERSTEEN, Kelly (BE)
Representatives of the Commission:
BARICIC, Peter (DG GROW)
SCHUTTE, Katrin (DG ENV)
Observers
BERNARD, Alice (ClientEarth)
CINGOTTI, Natacha (HEAL)
DREVE, Simina (FECC)
DROHMANN, Dieter (ORO)
FERNANDES DE BARROS, Mariana (Cefic)
GRANGE, Emma (Cruelty Free Europe)
KERÄNEN, Hannu (CONCAWE)
LENNQUIST, Anna (ChemSec)
LOONEN, Helene (EEB)
SAUNDERS, Samantha (PETA)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BELL, David
BECKER, Falk
BROERE, William
CALEY, Jane
CONSOLI, Elisa
DE WOLF, Watze
HALLING, Katrin
HAUTAMÄKI, Anne
JACQUET, Cyril
JOHANSSON, Matti
KARKOLA, Sampo
KLOSLOVA, Zuzana
LE CURIEUX, Frank
NAUR, Liina
O'FARRELL, Norah
PELLIZZATO, Francesca
RIBEIRO, Lucie
RÖNTY, Kaisu
VAHTERISTO, Liisa
VIEIRA LISBOA, Duarte
WALKER, Lee
SIMON, Rupert
MUSSET, Christel

Proxies

ATTIAS, Leonello (IT) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
DIMITROVA; Rada (BG) also acting as proxy of PALEOMILITOU, Maria (CY)
HJORTH, Rune (DK) also acting as proxy of DUNAUSKIENE, Lina (LT) during short periods

Experts and advisers to MSC members

ALIVERNINI, Silvia (IT) (adviser to ATTIAS, Leonello)
BARTHELEMY BERNERON, Johanna (FR) (expert to FRANZ, Michel)
BIL, Wieneke (NL) (expert to DE KNECHT, Johan)
BOLWIG, Asger (DK) (expert to HJORTH, Rune)
CATONE, Tiziana (IT) (expert to ATTIAS, Leonello)
CIESLA, Jacek (PL) (expert to ANDRIJEWSKI, Michal)
COPOIU, Oana (RO) (expert to MIHALCEA UDREA, Mariana)

DOBRAK-VAN BERLO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
EINOLA, Juha (FI) (adviser to RISSANEN, Eeva)
FILIPOVA, Hristina (BG) (expert to DIMITROVA, Rada)
JÖHNCKE, Ulrich (DE) (advisor to FINDENEGG, Helene)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
KUROVA, Martina (SK) (expert to HORSKA, Alexandra)
LANDVIK, Nina (NO) (expert to REIERSON, Linda)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
PASQUIER, Elodie (FR) (adviser to FRANZ, Michel)
ROSENTHAL, Esther (DE) (expert to FINDENEGG; Helene)
SPURIENE, Otilija (LT) (expert to DUNAUSKIENE, Lina)
TARNOCZAI, Timea (HU) (expert to DEIM, Szilvia)

MSCA experts and advisers for SVHC cases:
GUTZKOW, Kristine Bjerve (NO)
HEGGELUND, Audun (NO)
PERSSON DAHLBERG, Marie Johanne (NO)

Registered to the Secure WEBEX-phone connection:
BAUMBUSCH, Angelica (NO)
BOISEN, Anne (DK)
BURGA, Karen (FR)
CORRELL MYHRE, Ingunn (NO)
FABRE, Julien (FR)
HERZLER, Matthias (DE)
KOBE, Andrej (DG ENV)
KOPANGEN, Marit (NO)
LINDEMAN, Birgitte (NO)
MENDONÇA, Elsa (PT)
MÜHLEGGER, Simone (AT)
RORIJE, Emiel (NL) (eMSCA expert)
STOCKER, Eva (AT)
STRECK, Georg (DG GROW)
UNKELBACH, Christian (DE)

Case owners:
Representatives of the Registrants were attending under the Agenda Item 7.2 for CCH-105/2019, CCH-106/2019, CCH-107/2019 and CCH-108/2019.

Apologies:
PALEOMILITOU, Maria (CY)
KOUTSODIMOU, Aglaia (EL)
MARTIN, Esther (ES)
DEIM, Szilvia (HU)
WAGENER, Alex (LU)
COCKSHOTT, Amanda (UK)

III. Final Agenda

MSC/A/067/2019

Agenda

67th meeting of the Member State Committee

9-11 December 2019
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

9 December: starts at 9 am
11 December: ends at 1 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/067/2019
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-67/2019/001
For discussion and decision

- MSC mandates for evaluation decisions – general considerations

ECHA/MSC-67/2019/002
For discussion and possible decision

- Outlook for MSC-68

For information

Item 5 – Minutes of the MSC-66

- Draft minutes of MSC-66

MSC/M/66/2019
For adoption

Item 6 – Substance evaluation

Closed session for 6.3

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

ECHA/MSC-67/2019/003
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)*:**

Substance **Documents**

SEV-NL-017/2017 Sepisol Fast Blue 85219 (EC No. 700-579-6)

ECHA/MSC-67/2019/017-18
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 and 7.4

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

ECHA/MSC-67/2019/004
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)***

ECHA/MSC-67/2019/005
For information

For discussion followed by agreement seeking under 7.3:

<u>Compliance checks</u>

MSC code	Substance name	EC/List No./ Documents
CCH-105/2019	[[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]]tetrakisphosphonic acid	239-931-4 ECHA/MSC-67/2019/006-7
CCH-106/2019	Sodium salts of [[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]]tetrakisphosphonic acid (5-7 Na:1)	701-216-4 ECHA/MSC-67/2019/008-9
CCH-107/2019	Sodium salts of [[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]]tetrakisphosphonic acid	

[1] List of cases agreed in written procedure is available in the Appendix of the draft agenda

(1-3 Na:1) 701-215-9
ECHA/MSC-67/2019/010-11

CCH-108/2019 pentasodium pentahydrogen [[(phosphonatomethyl)-imino]bis[ethane-2,1-diylnitrilobis(methylene)]]-tetrakisphosphonate 263-212-4
ECHA/MSC-67/2019/012-13

Testing proposal examinations

MSC code	Substance name	EC/List No.
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)*

Cases as listed above under 7.2 and a case stopped in written procedure:

CCH-099/2019[2] Polyhaloalkene (EC No. 468-710-7)

For agreement

4. General topics *(Closed session)*

Registrants submitting information separately as per Article 11(3) of REACH – impact on compliance checks

For discussion

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

Start time: Day 1 morning

1. Written procedure report on seeking agreement on identification of SVHC

Not relevant for this meeting

For information

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

Substance name[3]	EC No.	CAS No.
Perfluorobutane sulfonic acid (PFBS) and its salts	-	-

Documents
ECHA/MSC-67/2019/014-15

For discussion and agreement

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 2020-2022)

[2] Documents are available in the substance specific folder in MSC S-CIRCABC
[3] RCOM is available in MSC S-CIRCABC, 03 SVHC folder, in corresponding Substance-specific folder

- First MSC draft opinion on the draft annual CoRAP update

ECHA/MSC-67/2019/016

For discussion and possible adoption

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 and other meeting participants

For information

Item 12 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-67

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

- MSC Meetings plan for 2021
- Status report on on-going substance evaluation work (presentation slides)
- Status report on on-going dossier evaluation work (presentation slides)
- Action Point from MSC-66: Item 8 – SVHC identification *(For members only)*

APPENDIX *to the MSC-67 agenda:*

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-67 meeting:

Substance evaluation

SEV-DE-010/2016	1,3-dioxolane	(EC No. 211-463-5)

Dossier evaluation

Compliance checks		**EC/List No.**
CCH-100/2019	Octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine	220-260-0
CCH-101/2019	Perhydro-1,3,5-trinitro-1,3,5-triazine	204-500-1
CCH-117/2019	p-cumenesulphonic acid	240-210-1
CCH-128/2019	Reaction mass of [[(2-hydroxyethyl)imino]bis-(methylene)]bisphosphonic acid and Phosphonic acid, P-[(tetrahydro-2-hydroxy-2-oxido-4H-1,4,2-oxazaphosphorin-4-yl)methyl]-	911-811-2
CCH-133/2019	Benzyl benzoate	204-402-9
CCH-147/2019	(Z)-9-Octadecen-1-ol ethoxylated	500-016-2

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-67 (9-11 December 2019)
(adopted at the meeting on 11 December 2019)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
• MSC mandates for evaluation decisions – general considerations	
MSC supported the general approach for mandating the finalisation of justification for a request in evaluation draft decisions to ECHA SECR and to eMSCA and ECHA SECR in dossier and substance evaluation, respectively.	**MSC-S** to indicate in the meeting action points the cases with a mandate (2020 onwards). **MSC-S** to develop instructions for ECHA SECR and eMSCA on how to implement mandates for a SEv-case. **MSC members** to inform their respective eMSCA experts of a possibility in future to finalise decision text after the meeting (case by case decisions for such a mandate at the MSC meeting) and the respective timeframes for its implementation.
Item 5 – Minutes of the MSC-66	
MSC adopted the draft minutes as submitted to the meeting.	**MSC-S** to upload final version of the minutes on MSC S-CIRCABC by 16 December 2019 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 6.3 – Substance evaluation **Seeking agreement on draft decisions when amendments were proposed by MSCA's/ECHA *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decision: SEV-NL-017/2017, Sepisol Fast Blue 85219 (EC No. 700-579-6)	**MSC-S** to upload on MSC S-CIRCABC the agreed decision in the respective case folder.
Item 7.1– Dossier evaluation **Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	**MSC** to consider the decisions uploaded on MSC S-CIRCABC for the written procedure as agreed ones.
Item 7.3 – Dossier evaluation **Seeking agreement on draft decisions on compliance checks and testing proposal examinations when amendments were proposed by MS-CA's *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions (as modified in the meeting):	**MSC-S** to upload on MSC S-CIRCABC the agreed decisions in the respective case folders.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Compliance checks • CCH-099/2019, Polyhaloalkene (EC No. 468-710-7) • CCH-105/2019, [[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]]tetrakisphosphonic acid (EC No. 239-931-4) • CCH-106/2019, Sodium salts of [[(phosphonomEthyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]] tetrakisphosphonic acid (5-7 Na:1) (EC No. 701-216-4) • CCH-107/2019, Sodium salts of [[(phosphonomethyl)imino]bis[ethane-2,1-diylnitrilobis(methylene)]] tetrakisphosphonic acid (1-3 Na:1) (EC No. 701-215-9) • CCH-108/2019, pentasodium pentahydrogen [[(phosphonatomethyl)-imino]bis[ethane-2,1-diylnitrilobis(methylene)]]-tetrakisphosphonate (EC No. 263-212-4)	
Item 8.2 – SVHC identification **Seeking agreement on Annex XV proposals for identification of SVHC**	
MSC unanimously agreed to identify the following substances as SVHCs (and unanimously agreed on the respective agreement and support document): • Perfluorobutane sulfonic acid (PFBS) and its salts	**MSC-S** to upload the MSC agreement, as well as the support document and RCOM, on MSC S-CIRCABC and to publish them on the ECHA website. **SECR** to add the newly identified SVHCs to the Candidate List (update foreseen in January 2020).
Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2020-2022) • First MSC draft opinion on the draft annual CoRAP update	
MSC adopted by consensus the draft opinion and its Annex on the draft CoRAP update 2020-2022 as prepared by the Rapporteur and Co-Rapporteur.	**MSC-S** to upload the MSC CoRAP opinion including its annex on MSC S-CIRCABC by 20 December 2019. **MSC Chairman** to share the MSC CoRAP opinion with the ECHA's process owner once finalised. **SECR** to publish the opinion on the ECHA website together with the annual CoRAP update in March 2020.
Item 12 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-67 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 12 December 2019.