MSC/M/72/2020

Minutes
of the 72nd Meeting of the Member State Committee (MSC-72)
8-10 December 2020
web conference

Adopted on 10 February 2021

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 72nd meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes). Parts of the meeting were announced to be chaired by the Deputy Chair, Ms Charmaine Ajao.

Item 2 - Adoption of the Agenda

The Agenda was adopted as modified by the MSC Secretariat (MSC-S) with addition of the topic of "Improvement proposal for Declarations of Interests handling" under Administrative matters (final Agenda is attached to these minutes as Section III).

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

No potential specific interests were declared by any members, experts or advisers with any item on the agenda of MSC-72.

Item 4 - Administrative issues

- Interact Portal: Update and a demo on the collaboration tool

SECR gave an update on the status of Interact and explained what is planned as regards the use of the Collaboration tool. SECR demonstrated the use of the tool and invited MSC members' and experts' feedback based on the first pilots planned over the Christmas break.

- Outlook for MSC-73

The Chairman presented an outlook on the potential length of MSC-73 (February 2021) and MSC-74 (June 2021) meetings.

- MSC meetings in 2021 and 2022

SECR provided MSC with the tentative dates for the MSC meetings in 2021 and 2022. Starting 2021, the number of meetings will be reduced from five to four meetings per year.

- MSC workplan for 2021

SECR informed MSC about ECHA's decision to hold all Committee meetings virtually until the end of June 2021. Therefore, MSC-73 and MSC-74 are planned to be virtual meetings. SECR also provided MSC with the overall workplan for 2021 regarding the five MSC processes.

- Improvement proposal for handling of annual Declarations of Interest (DoI)

SECR gave a presentation about the administrative improvement proposals proposed to be implemented for the upcoming annual review of ECHA declarations of interest for members as well as the simplification of the stakeholder involvement in the ECHA Committees.

- Annex XV SVHC report template

SECR informed MSC that the Annex XV SVHC report template is currently undergoing revision. The MSC members had been asked to submit comments on the proposed revisions, and SECR thanked those who had submitted comments. The revised template is foreseen to be available in early 2021, and in use by the second SVHC round of 2021.

Item 5 – Minutes of the MSC-71 meeting

The minutes of MSC-71 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 three substance evaluation (SEv) cases (see Appendix to the final agenda in Section III for more detailed identification of the cases). WP was launched on 12 November 2020. By the closing date 23 November 2020, MSC reached unanimous agreement on the three SEv cases.

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)*:

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

Cases as listed under 6.2

SEV-IT-015/2019 2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl) 3oxobutyramide (PY 65) (EC No. 229-419-9)

Open session and closed session:

A representative 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 Italy (IT-CA) presented the current status of the SEv case (SEV-IT-015/2019).

The initial grounds of concern when placed on the Community Rolling Action Plan (CoRAP) were relating to persistence, bioaccumulation and toxicity (PBT), exposure of environment, high (aggregated) tonnage, and wide dispersive use.

MSC was guided by the experts from IT-CA through the information on the substance and through the proposals for amendment (PfAs) to the DD received from Member State Competent Authorities (MSCAs), the Registrants' comments on the PfAs and the eMSCA's response to them. Some of the PfAs submitted were accepted by the eMSCA and led to an amendment in the DD in advance of the meeting. The MSC agreed with these amendments and discussion focused on the unresolved PfA.

MSC discussed the unresolved PfA, related to the test requested to address the bioaccumulation concern in terrestrial organisms. The substance evaluation (SEv) DD requested a bioaccumulation in terrestrial Oligochaetes test according to OECD TG 317 with the registered substance, using the species *Eisenia fetida* or *Eisenia andrei* (*Lumbricidae*). A PfA was received to withdraw the request for a bioaccumulation in terrestrial Oligochaetes test (OECD 317), on the basis that the test was not suitable to address the concern for air-breathing organisms and that earthworms are not the best test model for such organisms Furthermore, the assessment of the bioaccumulation potential could be improved by an accurate determination of the physico-chemical properties.

The Registrants submitted written comments on the PfAs, the main points of which they reiterated at the meeting. The Registrant supported the PfA to withdraw the request for a bioaccumulation in terrestrial Oligochaetes test (OECD 317) and agreed that an accurate determination of the physico-chemical properties would be useful for assessment of the bioaccumulation potential.

During the discussion the eMSCA expert explained that bioaccumulation in air breathing organisms is not the only concern. Since the substance will preferentially partition into the soil/sediment compartment, as also expected from the high Koc of the substance, they considered that testing of bioaccumulation potential in soil or sediment could provide the necessary information for concluding on the bioaccumulative potential. Furthermore, the octanol solubility of the substance is well above the critical body burden and substances with a similar log Koa to the one derived for the substance were shown to biomagnify. Based on this weight of evidence they requested in the DD a less expensive study than what could be requested to investigate bioaccumulation in air breathing organisms.

The PfA submitter however was of the view that a high Koc is not used as a trigger for bioaccumulation in the guidance and noted that itis usually used as a bioavailability indicator. Secondly, the derived log Kow of the substance is far below 4.5, the screening criterion for bioaccumulation, even though, the exact value is debatable. They also referred to QSAR predictions for earthworms that predicted very low BCF values for porewater. Thirdly, the octanol solubility for PBT substances is expected to be much higher than what it is for this substance.

The MSC supported the proposal of the PfA submitter to wait for the results from the experimental determination of the physico-chemical properties requested in an ongoing compliance check (CCh).

A stakeholder observer requested clarification on the advice of the PBT-EG on the B assessment of this substance. She also expressed doubts on the QSARS referred to by the PfA submitter and asked if the substance was within the applicability domain of the models, e.g. for water solubility. She also expressed the view that ingestion could be a more important factor for bioaccumulation in earthworms than uptake via pore water.

The eMSCA agreed that the bioaccumulation test in terrestrial organisms with oligochaetes may not be suitable to address the concern for air-breathing organisms and that assessment of the bioaccumulation potential could be improved by an accurate determination of the physico-chemical properties of the Substance.

The eMSCA proposed to withdraw the SEv DD requesting a bioaccumulation test in terrestrial organisms with oligochaetes (OECD TG 317) from agreement seeking at MSC-72. Consequently, the current substance evaluation would be suspended, pending the submission and acceptance of further information on physico-chemical properties to be requested under an ongoing compliance check on the substance. Subsequently the eMSCA will assess whether the concern has been clarified and/or whether further information is necessary. The eMSCA also noted that currently the PBT concern remains unclarified.

The MSC unanimously agreed on this approach.

4. General topics

None

Item 7 – Dossier evaluation

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

For the list of cases agreed in MSC written procedure, please see the Appendix of the draft agenda.

ECHA Secretariat (SECR) introduced the report on the outcome of the written procedure (WP) for agreement seeking on draft decisions (DD) for five dossier evaluation cases (see Section III Final agenda “Appendix to the MSC-72 agenda” for more detailed identification of the cases). WP was launched on 12 November 2019. By the closing date 23 November

2020, MSC reached unanimous agreement on four DDs. 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)*

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)*

A case stopped in written procedure:

CCH-172/2020 Potassium benzoate (EC No. 209-481-3)

Session 2 (closed)

ECHA Secretariat (SECR) explained that agreement was initially sought in written procedure. An MSC member requested stopping the written procedure to allow a discussion on the PfA on reproductive and/or developmental toxicity. Subsequently, the Chairman terminated the written procedure for the case.

The PfA suggested combining the 28-day short-term repeated dose toxicity study with the screening study for reproductive/developmental toxicity (OECD Testing Guideline (TG) 422).

The Registrant had provided written comments disagreeing with the PfA and MSC duly considered them in its discussion.

The MSC took note that for this compliance check case, there was a need to further review the text of the draft decision in order to ensure it aligned with the approach for mutagenicity testing as agreed in its earlier meeting. In its MSC-71 meeting the MSC had acknowledged a technical issue for the collection of spermatogonia, which requires prior administration of a metaphase arresting agent that may impact the comet assay in a combined study with the micronucleus (MN) test. In that MSC-71 draft decision (DD), which requested a combination of a comet assay (OECD Testing Guideline (TG) 489) and an *in vivo* mammalian erythrocyte MN test (OECD TG 474), the recommendation for the collection of spermatogonia was removed.

The MSC now concluded that mutagenicity requests in CCH-172/2020 and similar decisions would not include such a recommendation for the collection of spermatogonia in the MN test, whether stand-alone or combined with the comet assay.

The analysis on collected spermatogonia would have been performed in agreement with the mammalian spermatogonial chromosome aberration test (OECD TG 483). SECR informed that, to its knowledge, there were currently no contract research organisations (CRO) that have validated the test and could perform it. The MSC suggested SECR to reflect how best to inform CROs on a need, based on REACH regulation, to develop capacity for testing with OECD TG 483.

MSC agreed unanimously to the DD as circulated for the written procedure.

4. General topics

No items

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

SECR gave a brief report on the written procedure for SVHC agreement seeking on the identification of substances dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety (EC/List No. **-**) (hereafter, the Substance), proposed to be identified as SVHC based on Article 57 of Regulation (EC) 1907/2006. The substances were proposed as SVHC due to toxicity for reproduction. The MSC written procedure was triggered by the comments concerning the substance identity that were submitted in consultation of the interested parties. The written procedure was launched on 16 November 2020. On 26 November 2020, the MSC Chairman terminated the written procedure for agreement seeking following a request of an MSC member, and the case was brought for further discussion and agreement seeking in the MSC-72 meeting.

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

As the written procedure was terminated (see section on written procedure report), the Substance was addressed in plenary. In the meeting, the member who had requested to stop the written procedure expressed that the proposed SVHC identification is based on a harmonised classification as toxic for reproduction cat 1B, and thus did not disagree there are sufficient grounds for identification of the Substance, but doubted if the timing was appropriate due to other ongoing processes. The member explained that during the consultation of interested parties on the SVHC proposal the registrants had informed about a new study and submitted a short summary, which raised doubts as to whether the classification of the substance can remain valid. The member further explained that the registrant had submitted a testing proposal well before the SVHC process had started, and the proposal is yet to be processed. The member added that it may not be possible to remove the substance from the candidate list even if the basis for the SVHC identification has been annulled.

The Dossier Submitter (DS) expert considered that the data included in the summary of the new study is insufficient to conclude, and there is no information on when the full study would become available. She added that the RAC opinion on the harmonised classification was based on a weight of evidence approach, and the new data would have to be analysed by RAC together with the other available evidence. The DS expert emphasised the importance of maintaining the integrity of the regulatory processes.

SECR explained that the testing proposal process has been delayed due to a possible misunderstanding by the registrant related to the substance identity requests. An ECHA legal advisor clarified that REACH does not prevent the removal of substances from the candidate list if new information shows that they no longer meet the criteria of Article 57 as a result of new information. This is supported by the fact that Article 58(8) of REACH allows the European Commission to remove substances from Annex XIV of REACH which as a result of new information no longer meet the criteria of Article 57 of REACH. In addition, the European Court of Justice has confirmed that as a general rule, all decisions can be reviewed subsequently in the light of new available information, even if there is not any provision expressly provided for in that legislation requiring such review[1] Thus, if as a result of new information the harmonised classification of the substance is changed, the existing candidate list entry of the substance can be reviewed.

[1] See the judgments of the Court in Cases T-636/17 (paragraph 165) and more recently Case T-207/18 (paragraph 54).

Several MSC members and observers expressed support for the DS expert's views.

MSC unanimously agreed to the identification of dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety as SVHC under Article 57 (c) of the REACH Regulation due to its toxic for reproduction properties. One member abstained from the vote.

The Chairman thanked the dossier submitter for this SVHC proposal and MSC for its deliberations on it and the unanimous agreement reached.

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

1. Impact of comments and registration updates: Introduction to the responses and foreseen updates to ECHA's (draft) 10th recommendation

MSC had received by end of October a number of documents (response documents, updated prioritisation table, draft Annex XIV entries including the foreseen Latest Application Dates (LADs) and information on how the LADs had been derived), and in addition, for the meeting the "Comments and reference to comments" documents (ComRefs) per substance. SECR's presentation focussed on specific issues raised in the consultation of interested parties related to priority, LADs and exemption requests per substance or group of substances and how SECR had considered and responded to those. SECR concluded that the seven substances[2] would remain on its updated draft recommendation for Annex XIV inclusion, and also presented the foreseen draft Annex entries.

In the discussion a comment was made that for disodium octaborate there could be a recommendation to align the LAD with the previously prioritised borates. SECR clarified that LADs are suggested per round of recommendation by ECHA but recognised that the European Commission (COM) could be assumed to consider this. A member asked for clarification about the main arguments of ECHA in relation to the exemption request for the use of terphenyl hydrogenated for heat transfer fluids. SECR referred to the responses in the 'ECHA's general responses on issues commonly raised…'[3] available on ECHA website which describe the elements that need to be fulfilled for ECHA to make an Art. 58(2) exemption recommendation. After a few other clarifying questions and respective responses, the Chairman thanked for the presentation of the status of the draft recommendation work by ECHA SECR, and MSC for the discussion.

2. Discussion on the first draft MSC opinion on ECHA's draft 10th recommendation

The MSC rapporteur introduced the draft opinion and its support document that had been prepared by the Rapporteurs, supported by the MSC Working Group (WG). Based on the review of ECHA's draft recommendation, the comments from the consultation of interested parties, and the documents from SECR assessing the impact of the comments and registration updates, and the outcome from LAD derivation, the Rapporteur outlined the views of the WG for MSC's consideration. Those views, which were much aligned with SECR's assessment, were captured to the draft opinion text and were presented as proposals to MSC for its commenting and final views.

Before the discussion the Chairman reminded MSC that the Co-Rapporteur had declared a specific interest for the terphenyl, hydrogenated when accepting the task, and hence she

[2] Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5); Dodecamethylcyclohexasiloxane (D6); Terphenyl, hydrogenated; Dicyclohexyl phthalate (DCHP); Disodium octaborate; Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride; TMA).

[3] https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c

has not contributed to that part of the opinion. Division of the work in the WG was also presented by the Rapporteur.

In addition to expressing support to the current draft, few suggestions were brought up to further improve the opinion text. As another reaction, a member informed MSC about ongoing preparation of a restriction proposal for terphenyl hydrogenated. He elaborated further the reasons for moving forward at this stage and the plan to discuss the possibility with COM to postpone the inclusion of that substance into Annex XIV for now, in view of the planned restriction proposal.

The draft opinion as presented supported ECHA's draft 10th recommendation. In addition, the WG made a proposal to MSC for a specific recommendation to be included in its opinion. It is for COM to decide on the upcoming restriction of D4, D5 and D6 and on Annex XIV inclusion, and it can review also whether conditions for an exemption under Article 58(2) of REACH could be met. While MSC considers that the restriction cannot be taken into account at this stage, the draft opinion supports an invitation to COM to review the possibility for an exemption under Article 58(2) at the stage of drafting of, and discussions amongst REACH Committee experts on, the Annex XIV entry for the siloxane substances D4, D5 and D6, as the final scope of an ongoing restriction process will be known at that stage. The Rapporteur invited comments on the whole opinion from MSC in writing by 8 January 2021 in order to revise it in time for adoption at the next MSC meeting in February. The Chairman closed the item thanking the rapporteur and WG for the work until now.

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

1. Introduction of the annual draft CoRAP update (CoRAP 2021-2023) by ECHA

SECR presented the draft Community Rolling Action Plan (CoRAP) update for 2021-2023 which had been referred to MSC on 4 November 2020. The draft CoRAP update for years 2021-2023 has a total of 58 substances, three new CoRAP candidates and 55 substances that were already included in the CoRAP. Five substances have been withdrawn from the previous list, and justification for their withdrawal was also made available to MSC. It was explained that each substance has an accompanying justification document. The year of evaluation had been postponed for 28 entries on the list, mainly due to ongoing dossier evaluation. The draft CoRAP including the initial grounds for concern and contact details of the evaluating Member State Competent Authorities (eMSCA) were published on 8 December 2020, and MSC has been invited to provide its opinion on it by February 2021. Following that the annual update of the CoRAP is planned to be adopted by ECHA in March 2021.

2. First reflections from the MSC Rapporteur and invitation for input

The MSC Rapporteur presented the draft MSC opinion prepared by the Co-Rapporteur and herself on the draft annual update of the CoRAP for years 2021 to 2023. The new entries that were included on the draft CoRAP had been assessed using the respective justification documents (JDs). Based on their review, the (Co)-Rapporteurs suggested that MSC could support the draft CoRAP annual update for the years 2021-2023 as there are grounds for considering that these substances may constitute a potential risk to human health and/or the environment.

During the discussion the reason for withdrawing some substances from the CoRAP was clarified. An observer asked why few substances have been added to the draft update compared to the many substances that have been identified in the integrated regulatory strategy as requiring further work, and requested what impact that might have. SECR explained that the numbers reflect the changes done in the process. Now all substance concerns, related to standard information requirements are tackled first through compliance check. This approach could result in a faster conclusion. It was reminded that ECHA is still focussing on high tonnage substances, most of which have already been

assessed. In future the start of the evaluation of low tonnage substances could bring an increase in the number of CoRAP additions. In this regard, the representative from COM reminded on the benefit to utilise all the tools that REACH offers. The Deputy Chair thanked the (Co-)Rapporteurs for the first draft and work carried out until now. To conclude, MSC members were invited to provide feedback on the draft opinion to the (Co-) Rapporteurs by 13 January.

Item 11 – Any other business

1. Update on appeals and court cases of relevance to MSC (*Partly closed session*)

SECR gave a recap on Board of Appeal and European Court of Justice processes. SECR gave an overview of a new decision of the Board of Appeal (BoA) of ECHA in Case A-001-2019 dismissing an appeal against an ECHA follow-up dossier evaluation decision adopted under Article 42(1). MSC took note of the information received. SECR also gave a brief update on a new appeal cases A-008-2020 and A-009-2020 on Evaluation. SECR further gave an update of pending court cases on Authorisation and Evaluation and pending appeals on Evaluation. A brief update on new court cases was provided in a closed session to the members only.

2. Impact study on the advice of PBT EG

ECHA Secretariat (SECR) presented the outcome of the study on the impact of the scientific advice given by the PBT Expert Group. The study demonstrates that the advice has been useful support to the eMSCAs in carrying out their assessments as well as to the MSC in its decision making in the SEv and SVHC regulatory processes. SECR recommended the MSC members to encourage their MSCA colleagues to 1) follow the informal advice of the PBT EG, especially in cases where the PBT EG minutes indicate consensus, and 2) to consider the relevance of a PfA so as to avoid repetition of discussions held in the PBT EG at the MSC. If the MSCA's opinion deviates from the PBT EG advice, SECR encouraged to capture the arguments raised in the PBT EG and the elements leading to different conclusion.

Several MSC members expressed their appreciation for the Expert Group work. ECHA informed that in addition to the substance cases, several approach development topics such as growth correction in bioaccumulation test with fish, toxicokinetics in mammals and non-extractable residues (NER) are under discussion in the PBT EG. ECHA added that also an impact study had been carried out in the context of the ED Expert Group, and the results had been similar to this study. The MSC wished to keep receiving the links to the summary reports of the Expert Group meetings. The Deputy Chair encouraged the MSC members to contact either their EG member or the EG Secretariat, if they wish to receive full minutes of the EG.

3. EOGRTS review project

ECHA Secretariat (SECR) presented the review project on extended one-generation reproductive toxicity studies (EOGRTS) based on the results of EOGRT studies provided under REACH. The project is commanded by the European Commission and managed by SECR.

The project aims to analyse, among others, aspects relating to study conduct including methodologies and compliance, confirmation of triggers in the decisions and/or proposals for amendment, as well as regulatory relevance. SECR requested the MSC members to convey an invitation to their MSCAs to nominate experts in reproductive toxicity to participate in the project. In addition, SECR invited the MSC regular Stakeholder observers to nominate one expert to provide consolidated inputs on selected aspects of the project.

The MSC welcomed the project as an important activity for the coming years. It took note of the tentative support expressed by MSC members, on behalf of their experts, to participate in the study reviews.

4. Suggestion from members: A proposal of the evidence required to include the cohorts into the design of the EOGRTS for substances with SSH-related activity (*Closed session*)

The MSC member from the Netherlands presented a position paper on the evidence needed to trigger the DNT and DIT cohorts of the EOGRTS, prepared by the MSC members from the Netherlands, Sweden, and Denmark.

The paper is largely based on the scientific conclusions from the Dutch workshop on extended one-generation reproductive toxicity studies (EOGRTS), held in ECHA in 2019. The workshop had explored the state of scientific knowledge on the association between sex steroid hormones (SSH) and developmental neurotoxicity (DNT) and immunotoxicity (DIT) in the context of REACH Regulation.

The paper proposes three scenarios, with different levels of evidence, which could be considered sufficient to trigger the DNT and DIT cohorts into the design of the EOGRTS. (A) The available *in vivo* data provide clear evidence of SSH-related activity; for example, changes of SSH levels, or a positive finding in an *in vivo* targeted investigation of hormonal mechanisms or modes of action such as specific SSH markers, or endpoints pointing towards endocrine activity. (B) *In vivo* effects are indicative - but not conclusive - of SSH-related activity, supported by additional mechanistic data; for example, isolated *in vivo* findings in conjunction with mechanistic/*in vitro*/*in silico* data linking them to SSH-related activity. (C) *In vitro* evidence showing SSH-related activity, supported by toxicokinetic information; for example, in case toxicokinetic information would be available, evidence of SSH-related activity observed *in vitro* could be expected to occur *in vivo*.

Initial discussion on the position paper took place. Some MSC members reconfirmed their support to the workshop conclusions. Also, some argued that, in general, evidence from different sources could together provide a sufficient basis for triggering. The MSC noted the various views on the topic, with some MSC members wishing to accept the three proposed scenarios for triggering of the DNT and DIT cohorts, while some others expressed only support to scenario A, possibly scenario B, but not scenario C.

SECR and few members considered that the forthcoming results of the EOGRTS review project could be beneficial. Hence, these suggested to await its outcome, whereas several other Members argued against that suggestion. Furthermore, SECR and a member shared initial reflections on their reading of the legal text.

The MSC invited its members to submit their written comments on the presented report and its three scenarios. Those comments would engage further discussion planned for the next MSC meeting.

Item 12 - Adoption of main conclusions and action points

MSC adopted the main conclusions and action points at the MSC-72 meeting (see Section IV).

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ATTIAS, Leonello (IT)
BARTHELEMY-BERNERON, Johanna (FR)
CONWAY, Louise (IE)
de KNECHT, Joop (NL)
DIMITROVA, Rada (BG)
DUDRA, Agnieszka (PL)
FERNÁNDEZ SÁNCHEZ, Raquel (ES)
FINDENEGG, Helene (DE)
GYMNAOU, Panayiotis (CY)
GRIZELJ, Romana (HR)
HERMES, Joe (LU)
HJORTH, Rune (DK)
HORSKÁ, Alexandra (SK)
JANTONE, Anta (LV)
KOUTSODIMOU, Aglaia (EL)
KULHÁNKOVÁ, Pavlína (CZ)
LANDVIK, Nina (NO)
MALKIEWICZ, Katarzyna (SE)
MENARD SPRČIČ, Anja (SI)
MIHALCEA UDREA, Mariana (RO)
RISSANEN, Eeva (FI)
SAKSA, Jana (EE)
ŠPŪRIENĖ, Otilija (LT)
STOCKER, Eva (AT)
TÁRNOCZAI, Tímea (HU)
VANDERSTEEN, Kelly (BE)
Representatives of the Commission:
KOBE, Andrej (DG ENV)
SCHUTTE, Katrin (DG ENV)
Observers
CINGOTTI, Natacha (HEAL)
BERNARD, Alice (ClientEarth)
DE MATOS, Oliver (ECETOC – AP 11.3)
DRMAC, Dunja (Cefic)
DROHMANN, Dieter (ORO)
LEINALA, Eeva (OECD)
LENNQUIST, Anna (ChemSec)
LOONEN, Helene (EEB)
MERSMANN, Oliver (Cefic) expert during AP 9
NIEMELÄ, Helena (Concawe)
PEREIRA, Marina (HIS)
PROCHAZKA, Erik (PISC)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
ANASTASI, Audrey Anne
AHRENS, Birgit
BELL, David
BERCARU, Ofelia
BICHLMAIER, Ingo
BRENZEL, Steffen
BROERE, William
CARTON DE TOURNAI, Laure-Anne
CATHERINE, Arnaud
CESNAITIS, Romanas
CONSOLI, Elisa
de WOLF, Watze
HALLING, Katrin
HAUTAMÄKI, Anne
HOFFSTADT, Laurence
HUUSKONEN, Hannele
JOHANSSON, Matti
JUTILA, Arimatti
KAPANEN, Anu
KARHU, Elina
KARJALAINEN, Anne-Mari
KARKOLA, Sampo
LE CURIEUX, Frank
LEPPÄRANTA, Outi
LISBOA VIEIRA, Duarte
LUOMA, Leena
MUSSET, Christel
NAUR, Liina
O'FARREL, Norah
PELLIZZATO, Francesca
RUOSS, Jurgen
RÖNTY, Kaisu
SERRA, Helene
SIHVOLA, Virve
SIMANAINEN, Ulla
SIMON, Rupert
SOBANSKA, Marta
VAHTERISTO, Liisa
WALKER, Lee
WOLLENBERGER, Leah

Apologies:
ELLUL, Nathanael (MT)
HUMAR-JURIČ, Tatjana (SI)
PALEOMILITOU, Maria (CY)
TREZZI, Jean (LU)

Experts and advisers to MSC members

ALIVERNINI, Silvia (IT) (Expert to ATTIAS, Leonello)
ANDERSEN, Sjur (NO) (Expert to LANDVIK, Nina)
BALČIŪNIENĖ, Jurgita (LT) (Expert to ŠPŪRIENĖ, Otilija)
BIL, Wieneke (NL) (Expert to de KNECHT, Joop)
BOLWIG, Asger (DK) (Expert to HJORTH, Rune)
CATONE, Tiziana (IT) (Expert to ATTIAS, Leonello)
CIEŚLA, 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) (Expert to RISSANEN, Eeva)
FABRE, Julien (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
GARCÍA HERNANDEZ, Patricia (ES) (Expert to FERNÁNDEZ SÁNCHEZ, Raquel)
GUDBRANDSEN, Marius (NO) (Expert to LANDVIK, Nina)
HASSLOD, Enken, (DE) (Expert to FINDENEGG, Helene)
HORNEK-GAUSTERER, Romana (AT) (Expert to STOCKER, Eva)
JÖHNCKE, Ulrich (DE) (Expert to FINDENEGG, Helene)
KOZMÍKOVÁ, Jana (CZ) (Expert to KULHÁNKOVÁ, Pavlína)
KUROVA, Martina (SK) (Expert to HORSKÁ, Alexandra)
LUNDBERGH, Ivar (SE) (Expert to MALKIEWICZ, Katarzyna)
MENDONÇA, Elsa (PT) (Expert to ALMEIDA, Inês)
MÜHLEGGER, Simone (AT) (Expert to STOCKER, Eva)
NUGIN, Merike (EE) (Expert to SAKSA, Jana)
PASQUIER, Elodie (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
REDMOND, Aisling (IE) (Expert to CONWAY, Louise)
REIERSON, Linda (NO) (Expert to LANDVIK, Nina)
ROSENTHAL, Esther (DE) (Expert to FINDENEGG, Helene)
VERBRUGGEN, Eric (NL) (Expert to de KNECHT, Joop)

MSCA experts for SEv cases:

ESPOSINO, Dania (IT) (Expert to ATTIAS, Leonello)
ORRÚ, Maria Antonietta (IT) (Expert to ATTIAS, Leonello)
PANIERI, Emiliano (IT) (Expert to ATTIAS, Leonello)

MSCA experts for SVHC cases:

LARSSON, Kristin (SE) (Expert to MALKIEWICZ, Katarzyna)
SILINS, Ilona (SE) (Expert to MALKIEWICZ, Katarzyna)

Case owners by WEBEX-phone connection:

Representative of the Registrant was attending under the Agenda Item 6.2 for SEV-IT-015/2019

III. Final Agenda

MSC/A/072/2020 Draft agenda
26 November 2020

Draft Agenda
72nd meeting of the Member State Committee

8-10 December 2020

(ECHA Conference Centre)

Web conference

8 December: starts at 2:00 pm
10 December: ends at 2:00 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/072/2020
For adoption

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

Item 4 – Administrative issues

- Interact Portal: Update and a demo on the collaboration tool
- Outlook for MSC-73
- MSC meetings in 2021 and 2022
- Improvement proposal for handling of annual DoI
- MSC workplan for 2021

For information

Item 5 – Minutes of the MSC-71

- Draft minutes of MSC-71

MSC/M/71/2020
For adoption

Item 6 – Substance evaluation
Start on Day 1, Closed session for 6.3

5. Written procedure report on seeking agreement on draft decisions on substance evaluation[4]

ECHA/MSC-72/2020/002
For information

[4] For the list of cases agreed in MSC written procedure, please see the Appendix of the draft agenda

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

MSC code	Substance name	EC/List number / Documents
SEV-IT-015/2019	2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3oxobutyramide (PY 65)	229-419-9 / ECHA/MSC-72/2020/003-004

For discussion

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

Cases as listed under 6.2

For agreement

8. **General topics**

No items

[For information]

Item 7 – Dossier evaluation

Closed session for 7.3

1. **Written procedure report on seeking agreement on draft decisions on dossier evaluation[5]**

ECHA/MSC-72/2020/005

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.
No cases		

Testing proposal examinations

MSC code	Substance name	EC/List No.
No cases		

[For information and 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)***

A case stopped in MSC written procedure[6]:

CCH-172/2020 Potassium benzoate EC No. 209-481-3

[5] For the list of cases agreed in MSC written procedure, please see the Appendix of the draft agenda
[6] Documents are available in MSC S-Circabc under the substance specific folder in 05. Dossier evaluation

For agreement

4. General topics

No items

[For information]

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

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

ECHA/MSC-72/2020/006

For information

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

A case stopped in MSC written procedure:

Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety (EC/List No. **-**)

Documents
ECHA/MSC/D/2020/080-082[7]

For discussion and agreement

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

Start on Day 2 am

3. Impact of comments and registration updates: Introduction to the responses and foreseen updates to ECHA's (draft) 10th recommendation

ECHA/MSC-72/2020/011-17

For information

4. Discussion on the first draft MSC opinion on ECHA's draft 10th recommendation

ECHA/MSC-72/2020/007

For discussion

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

Start on Day 2 am

3. Introduction of the annual draft CoRAP update (CoRAP 2021-2023) by ECHA

ECHA/MSC-72/2020/001

For information

4. First reflections from the MSC Rapporteur and invitation for input

Room document: ECHA/MSC-72/2020/018

For discussion

Item 11 – Any other business

Partly closed session

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

(Partly closed session)

[7] Available in MSC S-Circabc under the substance specific folder in 03. SVHC identification

For information

6. Impact study on the advice of PBT EG

ECHA/MSC-72/2020/009
For information

7. EOGRTS review project

For information

8. Suggestion from members: A proposal of the evidence required to include the cohorts into the design of the EOGRTS for substances with SSH-related activity

ECHA/MSC-72/2020/010
(Closed session)
For discussion

9. Suggestions from members

For information

Item 12 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-72

For adoption

INFORMATION DOCUMENTS

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

- Status report on on-going substance evaluation work (presentation slides)
- Status report on on-going dossier evaluation work (presentation slides)
- Follow-up from MSC-71: BoA decisions on long-term aquatic toxicity testing (For members only)

APPENDIX to the MSC-72 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-72 meeting:

Substance evaluation

MSC code	Substance name	EC/List No.
SEV-2-DK-011/2012	Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol	700-960-7
SEV-FR-007/2019	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	201-618-5
SEV-IT-012/2019	1-phenylethanol	202-707-1

Dossier evaluation

Compliance checks

MSC code	Substance name	EC/List No.
CCH-173/2020	Phenethyl benzoate	202-336-5
CCH-178/2020	Methyl benzoate	202-259-7
CCH-181/2020	Ethyl benzoate	202-284-3

Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-053/2020	Asphalt, oxidized	265-196-4

IV. Main conclusions and action points

Main conclusions and action points
MSC-72, 8-10 December 2020
(adopted at MSC-72)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
• Interact portal: Update and a demo on the collaboration tool	
MSC took note of the presentation.	**MSC members, experts and advisors** with no access to collaboration tool to submit a remedy request via Contact Form (https://comments.echa.europa.eu/comments_cms/ContactFormAuthorities.aspx) **MSC-S** to launch a test collaboration by 17 December 2020. **MSC members** to test the informal collaboration by 8 January 2021. **MSC** to provide feedback to MSC-S via MSC Functional Mailbox (msc@echa.europa.eu) on the collaboration tool based on the first pilots by 8 January 2021.
Item 5 – Minutes of the MSC-71	
MSC adopted the draft minutes as submitted to the meeting.	**MSC-S** to upload the final version of the minutes on MSC S-CIRCABC and Interact by 11 December 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 decisions uploaded on MSC S-CIRCABC and Interact for the written procedure as agreed ones.
Item 6.3 – Substance evaluation **Seeking agreement on draft decisions when amendments were proposed by MSCA's/ECHA *(Session 2, closed)***	
SEV-IT-015/2019 2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide (PY 65) (EC No. 229-419-9) MSC unanimously agreed to withdraw the substance evaluation draft decision from agreement seeking at MSC-72 and no substance evaluation decision would need to be adopted by ECHA meaning that no decision will be sent to the Registrant(s) at this time (as reflected in an agreement document).	**MSC-S** to upload on MSC S-CIRCABC and Interact the agreement document 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 and Interact for the written procedure as agreed ones.
Item 7.3 – Dossier evaluation **Seeking agreement on draft decisions when amendments were proposed by MSCA's/ECHA**	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
(Session 2, closed)	
MSC reached unanimous agreement on the following ECHA draft decisions: - CCH-172/2020 Potassium benzoate EC No. 209-481-3	**MSC-S** to upload on MSC S-CIRCABC and Interact the agreed decision in the respective case folder.
Item 8. – SVHC identification **2. 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): Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety (EC/List No. -; CAS No. -)	**MSC-S** to to upload the MSC agreement, the support document and RCOMs, on MSC S-CIRCABC and Interact and to publish them on the ECHA website. **SECR** to add the newly identified SVHC to the Candidate List (update foreseen in mid January 2021).
Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC	
MSC discussed its first draft opinion prepared by the Rapporteur jointly with the Co-rapporteur and the MSC Working Group.	**MSC** to submit further input to the Rapporteurs and WG using MSC FMB by 8 January 2021.
Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)	
MSC discussed the first reflections from the Rapporteurs on the annual draft CoRAP update as presented in the draft opinion and the comments received will be captured in the final draft opinion.	**MSC** to submit further input to the Rapporteurs using MSC FMB by 13 January 2021.
Item 11 – Any other business	
• Impact study on the advice of PBT Expert Group	
MSC took note of the report	
• EOGRTS review project	
MSC took note of the report.	**MSC members** to convey the invitation to their **MSCAs** to nominate experts on reproductive toxicity to participate in the EOGRTS review project. Nominations are welcomed via email to **extended-one@echa.europa.eu** with cc: to **msc@echa.europa.eu** by **15 January 2021**. **MSC regular Stakeholder observers** may nominate one expert, who provides consolidated inputs, to the two functional mailboxes within the given deadline

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
• A proposal of the evidence required to include the cohorts into the design of the EOGRTS for substances with SSH-related activity	
MSC took note of the report.	**MSC members** to submit their comments on the presented report and its three scenarios via email to msc@echa.europa.eu by **15 January 2021**.
Item 13 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-72 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC and Interact by 11 December 2020.