MSC/M/73/2021
Adopted by written procedure
on 15 April 2021

Minutes of the 73rd Meeting of the Member State Committee (MSC-73)

9-11 February 2021

Web conference

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Deputy Chair of the Committee, Ms Charmaine Ajao, opened the meeting and welcomed the participants to the 73rd meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

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 specific interests were declared by any members, experts or advisers with any item on the agenda of MSC-73.

Item 4 - Administrative issues

- Interact Portal: Update

SECR informed MSC of the status of the onboarding of the observers and the third pilot of the meetings module. MSC Interact users were asked to look into Interact meetings tool, flag any questions and share their experiences with MSC-S and report any technical issues via Contact Form. SECR also informed MSC that an assessment will be made after MSC-73 to decide on the next steps on the use of Interact.

- Outlook for MSC-74

The Deputy Chair presented an outlook on the potential length of the MSC-74 (June 2021) meeting.

Item 5 – Minutes of the MSC-72 meeting

The minutes of MSC-72 were adopted as provided for the meeting.

Item 6 – Substance evaluation

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

ECHA Secretariat (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 15 January 2021. By the closing date 25 January 2021, MSC reached unanimous agreement on the SEv case.

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)* and

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

SEV-FR-008/2019 Resorcinol (EC No. 203-585-2)

Session 1 (open)

One representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the draft decision (DD), an open session was held.

The expert from the evaluating Member State Competent Authority (eMSCA) from France (FR CA) presented the status of the SEv case (SEV-FR-008/2019).

The initial grounds of concern when placed on the Community Rolling Action Plan (CoRAP) were relating to endocrine disruption.

MSC was guided by the experts from FR CA through the information on the substance and through the proposals for amendment (PfAs) to the DD received from Member State Competent Authorities (MSCAs), Registrants' comments on the PfAs and 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 eMSCA accepted the PfAs proposing to recommend instead of requesting measurement of vitellogenin (VTG) and removing the request to double the size of the control group. MSC agreed with these amendments and the discussion focused on the unresolved PfAs related to the need to add as mandatory extra parameters to the Larval Amphibian Growth and Development Assay (LAGDA) (OECD TG 241) test design, and their timing.

The Registrants had submitted written comments on the PfAs which the representative of the Registrants summarised in the meeting. MSC duly considered them in its discussion.
The representative of the Registrants clarified that their concern on the LAGDA validation was linked to the inter-variability between laboratories. Increasing the size of the control group in the LAGDA as suggested by the eMSCA would not tackle this concern from the Registrants. The representative of the Registrants also questioned the need for the extra parameters.
One PfA submitter was of the view that histopathology of the thyroid gland was sufficient and that the arguments for including the extra parameters were still not well substantiated in the decision. For them the cross-species interlinkage was not needed. Another PfA submitter requested further clarification on the need of measuring the additional parameters at the end of exposure.
On one hand, a representative of stakeholders' organisations stated that there is no longer a need to generate more data to regulate the substance. On the other hand, another representative supported the LAGDA request with the additional parameters for vitellogenin and thyroid hormones as it would strengthen the evidence for the next regulatory step, possibly the proposal as a substance of very high concern (SVHC).

The eMSCA requested that the additional thyroid hormone parameters and the measurements of such parameters at the end of exposure are discussed in the closed session due to the regulatory consequences on the whole strategy of such a discussion on the next possible regulatory measure – an SVHC Annex XV proposal. The MSC Deputy Chair clarified that scientific arguments are to be made in the open session. The representative of the Registrants expressed their disappointment in the reduced opportunity for discussion in the open session.
The MSC Deputy Chair informed that the representative of the registrants will receive the outcome of the discussions by email.

Session 2 (closed)

The MSC further discussed the need to add the thyroid hormones as extra mandatory parameters for this specific case, and the stage(s) of development of the larval amphibian growth at which they should be measured. In this specific case, these additional measurements were requested to confirm that the adverse effects occurring on development and time to metamorphosis potentially observed in the LAGDA result from an impact of the substance on thyroid gland function and not through general systemic toxicity.
MSC agreed unanimously to request the standard LAGDA test on the Substance, with additional measurements of TSH, free T3, Total T3, free T4, Total T4 in the plasma at NF

stage 62[1]. Additionally, MSC agreed unanimously (i) to remove the request for TSHβ gene expression, MIT and DIT at any stage, and TSH, free T3, Total T3, free T4, Total T4 at the end of exposure; and (ii) to recommend, instead of request, for the measurement of VTG, as the available data primarily raise a concern for thyroid disruption.
MSC confirmed the deadline of 15 months to perform the request. The draft decision was amended accordingly.
Subsequently MSC agreed unanimously to the draft decision as amended during the meeting.

4. General topics

None

Item 7 – Dossier evaluation

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

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-73 agenda" for more detailed identification of the cases). WP was launched on 15 January 2021. By the closing date 25 January 2021, MSC reached unanimous agreement on all DDs.

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)*

CCH-206/2020 1,1'-(1,1,2,2-tetramethylethylene)-dibenzene (EC No. 217-568-2)

Session 1 (open)

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

ECHA Secretariat (SECR) introduced the proposals for amendment (PfA) that required discussion in the meeting. The first PfA on extended one-generation reproductive toxicity study (EOGRTS) suggested including cohorts 2A and 2B (developmental neurotoxicity, DNT) and cohort 3 (developmental immunotoxicity, DIT) in the study design. The second PfA on EOGRTS suggested a range-finding study for the selection of appropriate dose levels. The third PfA suggested adding a request for pre-natal developmental toxicity (PNDT) study in a second species (rabbit).

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

The representatives of the Registrants reconfirmed their disagreement on the first and third PfA. They agreed with the second PfA with an additional pre-test to ensure adequate dose setting.

SECR informed that after the PfAs and the Registrant's comments on them it had included in the DD the DNT cohort in the EOGRTS design based on malformations in the brain observed in the available PNDT study in rats and the PNDT study in a second species, as well as modified the timeline to reflect the addition of the PNDT study.

[1] Nieuwkoop and Faber stage 62, corresponding to a tadpole of age about 49 days at 22-24 Celsius and having specific external morphological criteria.

At this stage the MSC considered the second and third PfAs resolved without further discussion.

First, the MSC discussed including DNT and DIT cohorts in EOGRTS based on the first PfA. The MSC considered that the basis for triggering the DNT due to malformations in the brain was agreeable, and took note of the *in vivo* and *in silico* arguments of the PfA which would trigger the DNT and DIT cohorts on the basis of sex steroid hormone related activities (SSH-related activities).

Regarding the *in vivo* arguments presented in the PfA, it was discussed whether the effects observed on seminal vesicles and on corpora lutea, together with other effects on reproductive function, were considered indicative of sex steroid hormone related activities (SSH-related activities). SECR maintained that the effects observed *in vivo* were not diagnostic of a specific mechanism of action and other hormonal effects expected from an anti-androgen had not been seen; this information did not demonstrate SSH-related hormonal activities.

On the two *in silico* models referred to in the PfA, the MSC noted that they operated on different approaches and training sets with different sensitivities. The model with higher sensitivity is a consensus model yielding a positive anti-androgenic result for the substance compared to the negative result by the other model. MSC noted that the PfA however, did not provide details that the Substance falls within the applicability domain of the model. SECR acknowledged QSAR data as very useful mechanistic data, that can be used to support the effects seen *in vivo*. However, in their view, the *in silico* data does not match the *in vivo* evidence for this case.

The representatives of the Registrants supported the view of the SECR.

The *in vivo* and *in silico* arguments were considered by some MSC members to comprise sufficient evidence for triggering DNT and DIT based on SSH-related activities.

Session 2 (closed)

The MSC considered the weight of evidence in justifying the triggering of DNT and DIT based on SSH-related activities in this case. The MSC concluded not to include the SSH-related activities as an additional justification to request the DNT cohort nor as a basis for triggering the DIT cohort. Consequently, the DIT cohort was not included in the EOGRTS design.

MSC agreed unanimously to the DD as provided for the meeting.

Seven members abstained from voting, including the MSC member from Austria, Bulgaria, Denmark, France, the Netherlands, Norway, and Sweden. Six MSC members provided a written justification for their abstention (see Section IV).

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

No items

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

1. Update by SECR

Secretariat presented a brief update explaining the slightly revised responses to the comments received during the consultation on the draft recommendation, for D4, D5 and D6 and terphenyl, hydrogenated. Besides these clarifications SECR indicated that for now no further changes were foreseen since the previous discussion.

2. Draft opinion of MSC on ECHA's draft 10th recommendation of priority substances to be included in Annex XIV

MSC Rapporteur presented the draft opinion and its support document as complemented since the first discussion in December and the feedback received. MSC went through the edits and discussed some text options on how to best reflect the view of MSC in relation to the intentional/unintentional presence of unreacted monomers of D4, D5 and D6 in polymers, and related authorisation obligations. Given the ongoing processes for restricting certain uses of some of the siloxanes, MSC confirmed that they would like ECHA to invite the European Commission to review the possibility for an exemption under Article 58 (2) at the inclusion of Annex XIV stage. MSC adopted its opinion supporting ECHA's draft recommendation of the seven substances that were subject of the consultation for inclusion in Annex XIV, as drafted by (Co-)Rapporteur and the working group.

To conclude, the Deputy Chair thanked the Rapporteur, Co-Rapporteur and MSC Working Group for its efforts in bringing the opinion process to the end.

3. Update by the European Commission about substances previously recommended for inclusion to Annex XIV

A representative of the Commission gave an update to MSC regarding the progress made and status of substances previously recommended for inclusion to Annex XIV, followed by few clarifying questions from some MSC stakeholder observers.

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

1. Draft opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)

MSC Rapporteur presented the draft opinion. In absence of further questions MSC adopted the opinion by consensus as prepared by the Rapporteur and Co-Rapporteur.

The Deputy Chair closed the item by thanking the rapporteurs also on behalf of MSC. She also informed MSC that the actual update of the CoRAP is expected on 17 March.

Item 11 – Updates to the approach for admission of ASO Observers and MSC Rules of Procedure

1. Update to the approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees

SECR presented an update to the procedure for admission of observers from stakeholder organisations to the work of MSC. It was explained that the aim was to harmonise this procedure between all ECHA Committees and to modify the concept of an occasional stakeholder observer so that occasional participation to a Committee meeting would be possible to any organisation that is listed as ECHA's accredited stakeholder organisation. Such attendance would be decided by the Chair of the Committee. In practise each Committee would then need to review annually only the list of its regular stakeholder observers.

Given the limited scope of the update MSC decided to apply it without further discussion.

2. Update to the MSC Rules of procedure

SECR made a proposal for a small revision of MSC's Rules of Procedure. MSC supported the update in which an edit to the procedure for admission of stakeholder observers was made and a clarification is included in relation to the renewal of the mandate of co-opted members. ECHA's Management Board will receive the proposal for its approval later this year.

Item 12 – Any other business

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

SECR gave a short overview of litigation cases in 2020. SECR gave an overview of the judgements of the European Court of Justice in cases C-471/18 P and T-176/19 on Evaluation and in case T-207/18 on Authorisation. SECR gave an update of the new decisions of Board of Appeal (BoA) of ECHA in cases A-010-2019 and A-007-2019 dismissing appeals against ECHA dossier evaluation decisions. MSC took note of the information received. SECR further gave a short summary on pending court cases on Authorisation and pending appeals and court cases on Evaluation. A brief update on new appeal cases was provided in a closed session to the members only.

2. Suggestion from members: Continuation of the MSC-72 discussion - A proposal of the evidence required to include the cohorts into the design of the EOGRTS for substances with SSH-related activity

At MSC-72, an initial discussion took place on a position paper, prepared by three MSC members, regarding the evidence needed to trigger the DNT and DIT cohorts of the EOGRTS. For MSC-73, other MSC members' and SECR's written comments, submitted following MSC-72, were responded to and the position paper was amended accordingly. The position paper proposed two different levels of evidence, which could be considered sufficient to trigger the DNT and DIT cohorts, namely Scenario A) The available *in vivo* data provide direct evidence of SSH-related activity**,** and Scenario B) *In vivo* effects indicative for sex steroid hormone – related activity (SSH-related activity) that is confirmed by additional mechanistic data. Before MSC started discussing, SECR shared its legal view that both scenarios can be supported in general, however, such support depends on the strength of case-specific scientific evidence.

MSC carefully reviewed the comments and the amended position paper, and with the further discussion, this opened-up and created insights on what to make use of in future case-specific decisions.

To explore the MSC support concerning which SSH-related activities can be used as a trigger for DNT and DIT, a list of statements was presented to MSC. Two initial statements targeted only a single type of activity and effect(s) (i.e. statement 1 on estrogenicity and DNT/DIT and statement 2 on anti-androgenicity and DIT). The third statement was broader and covered all SSH-related activities (i.e. estrogenicity, anti-estrogenicity, androgenicity, anti-androgenicity, steroidogenesis) without the need of necessarily being able to distinguish them.

MSC, unanimously supported the three statements above. Hence MSC unanimously supported the approach that all SSH-related activities are considered a specific mechanism/mode of action with an association to DNT or DIT that could, in line with the REACH legal text, be used as a trigger to justify the inclusion of the DNT and DIT cohorts in the design of the EOGRTS.

MSC concluded that no further discussion on application of the outcome of the Dutch EOGRTS Workshop, held in 2019, in the REACH regulatory context would be needed.

MSC will continue to consider the inclusion of the DNT and DIT cohort for substances with SSH-related activity case-by-case, based on the two levels of evidence proposed using case-specific scientific arguments.

Finally, MSC considered the science in this area is likely to progress in the coming years and welcomed to get more information from the EOGRTS project.

Item 13 – Address by ECHA's Director of Hazard Assessment

ECHA's Director of Hazard Assessment, Ms Christel Schilliger-Musset, addressed the MSC congratulating it for the good work and achievements in 2020. She also outlined the prospects and main activities for MSC and ECHA in 2021.

Item 14 - Adoption of main conclusions and action points

MSC adopted the main conclusions and action points as presented at the meeting (see Section V).

II. List of attendees

Members/Alternate members
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)
GRIZELJ, Romana (HR)
HJORTH, Rune (DK)
HORSKÁ, Alexandra (SK)
JANTONE, Anta (LV)
KOUTSODIMOU, Aglaia (EL)
KULHÁNKOVÁ, Pavlína (CZ)
LANDVIK, Nina (NO)
MALKIEWICZ, Katarzyna (SE)
MENDONÇA, Elsa (PT)
MENARD SPRČIČ, Anja (SI)
MIHALCEA UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY)
RISSANEN, Eeva (FI)
SAKSA, Jana (EE)
ŠPŪRIENĖ, Otilija (LT)
STOCKER, Eva (AT)
TÁRNOCZAI, Tímea (HU)
TREZZI, Jean (LU)
VANDERSTEEN, Kelly (BE)
Representatives of the Commission:
KOBE, Andrej (DG ENV)
CERIDONO, Mara (DG ENV)
DE BUSTOS, Aurora (DG GROW)
Observers
ASHFORD, Paul (Cefic) expert during AP 6
BROWN, Patience (OECD)
DRMAC, Dunja (Cefic)
DROHMANN, Dieter (ORO)
DREVE, Simina-Virginia (FECC)
GRANGE, Emma (CFE)
LENNQUIST, Anna (ChemSec)
LOONEN, Helene (EEB)
MERSMANN, Oliver (Cefic) expert during AP 9
MUSU, Tony (ETUC)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
AHRENS, Birgit
BELL, David
BERCARU, Ofelia
BICHLMAIER, Ingo
BRENZEL, Steffen
BROERE, William
CONSOLI, Elisa
de WOLF, Watze
DELOFF-BIALEK, Anna
ERIKSEN, Hilde Renate
GONZÁLEZ, Artunev
HALLING, Katrin
HOFFSTADT, Laurence
HUUSKONEN, Hannele
JOHANSSON, Matti
JUTILA, Arimatti
KARHU, Elina
KARI, Johanna
KARJALAINEN, Anne-Mari
LEPPÄRANTA, Outi
LISBOA VIEIRA, Duarte
LUOMA, Leena
MUSSET, Christel
NAUR, Liina
PELLIZZATO, Francesca
RICHARZ, Andrea
RUOSS, Jurgen
RÖNTY, Kaisu
SCHULTZ, Bernadette
SERRA, Helene
SIMANAINEN, Ulla
SIMON, Rupert
TRNKA, Jan-Peter
VAHTERISTO, Liisa

Apologies
ALMEIDA, Inês (PT)

Proxies
KOUTSODIMOU, Aglaia (EL) to PALEOMILITOU, Maria (CY) for parts of the meeting

Experts and advisers to MSC members

ALIVERNINI, Silvia (IT) (Expert to ATTIAS, Leonello)
APERGI, Elli Maria (EL) (Expert to KOUTSODIMOU, Aglaia)
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)
DANG, Zhichao (NL) (Expert to de KNECHT, Joop)
DOBRAK-VAN BERLO, Agnieszka (BE) (Expert to VANDERSTEEN, Kelly)
EINOLA, Juha (FI) (Expert to RISSANEN, Eeva)
FILIPOVA, Hristina (BG) (Expert to DIMITROVA, Rada)
GARCÍA HERNANDEZ, Patricia (ES) (Expert to FERNÁNDEZ SÁNCHEZ, Raquel)
GYMNAOU, Panagiotis (CY) (Expert to PALEOMILITOU, Maria)
GÜNDEL, Ulrike (DE) (Expert to FINDENEGG, Helene)
JÖHNCKE, Ulrich (DE) (Expert to FINDENEGG, Helene)
KAARTINEN, Tomi (FI) (Expert to RISSANEN, Eeva)
KNOFLACH, Georg (AT) (Expert to STOCKER, Eva)
KOZMÍKOVÁ, Jana (CZ) (Expert to KULHÁNKOVÁ, Pavlína)
KUROVA, Martina (SK) (Expert to HORSKÁ, Alexandra)
LOSERT, Annemarie (AT) (Expert to STOCKER, Eva)
LUNDBERGH, Ivar (SE) (Expert to MALKIEWICZ, Katarzyna)
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)
TEINE, Adina (SE) (Expert to MALKIEWICZ, Katarzyna)
UNKELBACH, Christian (Expert to FINDENEGG, Helene)

MSCA experts for SEv cases:

JOMINI, Stéphane (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
FINI, Jean-Baptiste (FR) (Expert to BARTHELEMY-BERNERON, Johanna)

Case owners by WEBEX-phone connection:

Representatives of the Registrants attended under the Agenda Item 6.2 for SEV-FR-008/2019, and under the Agenda Item 7.2 for CCH-206/2020.

III. Final Agenda

MSC/A/073/2021 Draft agenda
28 January 2021

Draft Agenda
73rd meeting of the Member State Committee

9-11 February 2021[2]

(ECHA Conference Centre)

Web conference

9 February: starts at 10:00 am
11 February: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/073/2021
For adoption

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

Item 4 – Administrative issues

- Interact Portal: Update
- Outlook for MSC-74

For information

Item 5 – Minutes of the MSC-72

- Draft minutes of MSC-72

MSC/M/72/2020
For adoption

Item 6 – Substance evaluation

Closed session for 6.3

5. Written procedure report on seeking agreement on draft decisions on substance evaluation[3]

[2] Day 2 morning is dedicated for redrafting work by eMSCA, ECHA, PfA submitters and other interested MSC members and the afternoon is planned for the plenary.

ECHA/MSC-73/2021/005
For information

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-FR-008/2019	Resorcinol	203-585-2

ECHA/MSC-73/2021/006-7
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

Item 7 – Dossier evaluation

Closed session for 7.3

1. Written procedure report on seeking agreement on draft decisions on dossier evaluation[2]

ECHA/MSC-73/2021/003

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-73/2021/004

For information

For discussion followed by agreement seeking under 7.3:

Compliance checks

MSC code	Substance name	EC/List No. / Documents
CCH-206/2020	1,1'-(1,1,2,2-tetramethylethylene)-dibenzene	217-568-2 / ECHA/MSC-73/2021/001-2

Testing proposal examinations

MSC code	Substance name	EC/List No.
No cases		

For discussion

[3] List of cases agreed in MSC Written Procedure is available in the Appendix of this document.

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 under 7.2

For agreement

4. **General topics**

None

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

No cases

[For information]

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

1. Update by SECR

ECHA/MSC-73/2021/008-9

For information

2. Draft opinion of MSC on ECHA's draft 10th recommendation of priority substances to be included in Annex XIV

ECHA/MSC-73/2021/010

For discussion and adoption

3. Update by the European Commission about substances previously recommended for inclusion to Annex XIV

For information

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

1. Draft opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)

ECHA/MSC-73/2021/015
For discussion and adoption

Item 11 – Updates to the approach for admission of ASO Observers and MSC Rules of Procedure

Partly closed session

1. Update to the approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees

ECHA/MSC-73/2021/011

Closed session

For decision

2. Update to the MSC Rules of procedure

For endorsement / adoption

Item 12 – Any other business

Partly closed

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

(Partly closed session)
For information

2. Suggestion from members: Continuation of the MSC-72 discussion - A proposal of the evidence required to include the cohorts into the design of the EOGRTS for substances with SSH-related activity

ECHA/MSC-73/2021/013-14
(Closed session)
For discussion and agreement

Item 13 – Address by ECHA's Director of Hazard Assessment

For information

Item 14 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-73

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)
- EOGRTS review project: Update on nominations to the EOGRTS review project
- Report of MSC work from 2020 (presentation slides)

APPENDIX to the MSC-73 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-73 meeting:

Substance evaluation

MSC code	Substance name	EC/List No.
SEV-BE-002/2019	N-[4-[(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthryl)amino]phenyl]acetamide	267-636-0

Dossier evaluation

Compliance checks

MSC code	Substance name	EC/List No.
CCH-202/2020	1,3-diethyl-2-thiourea	203-308-5
CCH-205/2020	Methacrylic acid	201-204-4
CCH-209/2020	2-[(4-methoxy-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	229-419-9
CCH-214/2020	Reaction products of hexane-1,6-diol with 2-(chloromethyl)oxirane (1:2)	618-939-5
CCH-215/2020	1,4-bis(2,3-epoxypropoxy)butane	219-371-7

IV. Statement from AT, DK, FR, NL, NO and SE members related to agenda item 7.3 with regard to CCH-206/2020 on *1,1'-(1,1,2,2-tetramethylethylene)-dibenzene* (EC No. 217-568-2).

We remain of the position that, for case CCH-206/2020, there are endocrine activity related *in vivo* findings indicative of sex-steroid hormone related activity. Furthermore, there is *in silico* mechanistic evidence available, pointing towards anti-androgenic activity. In our opinion, this information warrants inclusion of both the DNT and DIT cohorts in the EOGRTS design. Although the Registered Substance was within the applicability domain of the US-EPA CoMPARA model used for the *in silico* prediction, it is recognized that more detailed information on the prediction would have been needed to allow the registrant and MSC to judge on the usability of the prediction. We therefore abstained from voting.

V. Main conclusions and action points

Main conclusions and action points
MSC-73, 9-11 February 2021
(adopted at MSC-73)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
• Interact portal: Update	
MSC took note of the report.	**MSC observers** with no access to Interact to submit a remedy request via Contact Form (https://comments.echa.europa.eu/comments_cms/ContactFormAuthorities.aspx) **MSC** to provide feedback to MSC-S via MSC Functional Mailbox (msc@echa.europa.eu) on the use of Interact based on the pilots by 18 February 2021.
Item 5 – Minutes of the MSC-72	
MSC adopted the MSC-72 draft minutes as submitted to the meeting.	**MSC-S** to upload the final version of the minutes on MSC S-CIRCABC and Interact by 12 February 2021 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 and Interact 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 case: SEV-FR-008/2019 Resorcinol (EC No. 203-585-2)	**MSC-S** to upload on MSC S-CIRCABC and Interact 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 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 *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decision: CCH-206/2020 1,1'-(1,1,2,2-tetramethylethylene)-dibenzene (EC No. 217-568-2)	**MSC-S** to upload on MSC S-CIRCABC and Interact the agreed decision in the respective case folder.
Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC	
4. Draft opinion of MSC on ECHA's draft 10th recommendation of priority substances to be included in Annex XIV	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC in its opinion supported recommending the seven substances that were subject of the consultation for inclusion in Annex XIV. MSC adopted by consensus the opinion and its Annex on ECHA's draft 10th recommendation as prepared by the Rapporteur and Co-Rapporteur supported by a Working Group (as amended at the meeting).	**MSC Chair** to share the MSC opinion with the ECHA's process owner once finalised. **MSC-S** to publish the final MSC opinion on Interact and MSC S-CIRCABC and on ECHA website without undue delay. **SECR** to take into account the MSC opinion when finalising ECHA's 10th recommendation for inclusion of substances in Annex XIV and to submit it to the Commission by early April 2021.
Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)	
2. Draft opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)	
MSC adopted by consensus the opinion and its Annex on the draft CoRAP update 2021-2023 as prepared by the Rapporteur and Co-Rapporteur.	**MSC-S** to upload the MSC CoRAP opinion including its annex on Interact and MSC S-CIRCABC by 16 February 2021. **MSC Chair** to share the MSC CoRAP opinion with ECHA's process owner once finalised. **SECR** to publish the opinion on the ECHA website together with the annual CoRAP update in March 2021.
Item 11 – Updates to the approach for admission of ASO Observers and MSC Rules of Procedure	
3. Update to the approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees	
MSC decided to update its general approach on the admission of observers from accredited stakeholder organisations to its work.	After respective decision on the update by RAC and SEAC, **MSC-S** to: - publish the updated approach on the ECHA website - update the list of MSC StOs from the website to include only the regular StOs
4. Update to the MSC Rules of procedure	
MSC supported the suggested amendments to its Rules of Procedure.	**MSC-S** to submit the updated Rules of Procedure for approval by ECHA's Management Board.
Item 12 – Any other business	
• Suggestion from members: Continuation of the MSC-72 discussion - A proposal of the evidence required to include the cohorts into the design of the EOGRTS for substances with SSH-related activity	
MSC considers estrogenic activity as a specific mechanism/mode of action with an association to development neurotoxicity (DNT) and immunotoxicity (DIT) that could, in line with the REACH legal text, be used as a trigger to justify the inclusion of the DNT and DIT cohorts in the design of the EOGRTS. MSC considers anti-androgenic activity, on a case-by-case basis, with more supporting evidence on such as association to DNT, as a specific mechanism/mode of	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
action with an association to DNT that could, in line with the REACH legal text, be used as a trigger to justify the inclusion of the DNT cohorts in the design of the EOGRTS. MSC considers SSH-related activity as a specific mechanism/mode of action with an association to DNT or DIT that could, in line with the REACH legal text, be used as a trigger to justify the inclusion of the DNT and DIT cohorts in the design of the EOGRTS. MSC agreed to conclude their discussions on application of the outcome of the Dutch EOGRTS Workshop, held in 2019, in the REACH regulatory context. In practice, MSC will continue to treat substances case-by-case, based on the case-specific scientific arguments.	
Item 14 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-73 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC and Interact by 12 February 2021.