

**Minutes of the 75th Meeting
of the Member State Committee
(MSC-75)**

**Tuesday 12 October
to Wednesday 13 October 2021**

Summary Record of the Proceedings and Conclusions and action points

Chair's opening address

The Deputy Chair, Charmaine Ajao, informed the Committee that all issues raised in the evaluation cases through proposals for amendment (PfAs) have been solved before the plenary through discussions between the PfA submitters, leading to a relatively short meeting. MSC is benefiting from the hard work of past general discussions on simulation testing parameters, mutagenicity, EOGRTS pre-tests. PfAs during this round aimed to align the Dev decision with recent MSC agreements or to ensure consistency with previous cases.

Apart from the two agenda items related to the formal established regulatory processes or procedures, the rest of the items on the agenda were a result of re-assessment, re-evaluation of past discussions or policies either by the Secretariat or the Members. The Deputy Chair acknowledged the importance of topics suggested by members as seen in agenda item 12.3.

Agenda point	
Conclusions / agreements / adoptions	Action requested after the meeting (by whom/by when)
Item 2 – Adoption of the Agenda	
The Agenda (MSC/A/75/2021) was adopted.	SECR to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-75 minutes.
Item 3 – Declaration of specific interests to items on the Agenda	
No potential conflicts of interests were declared by the Deputy Chair, any members, experts or advisers with any item on the agenda of MSC-75.	
Item 4 – Administrative issues	
<ul style="list-style-type: none"> • Outlook for MSC-76 • Bis rounds in 2022 • Presentation of pilot for adoption of minutes at the meeting 	
<p>The Deputy Chair presented an outlook on the potential length of the MSC-76 (December 2021) meeting.</p> <p>SECR presented the plan for MSC-77bis and MSC-78bis rounds in 2022.</p> <p>SECR introduced the pilot project for adopting the meeting minutes at the end of the meeting, removing the need to prepare minutes of the meeting afterwards. SECR explained that this pilot project was being launched with the support of the MSC members that have proposed items for the MSC-75 agenda. Practically, the main conclusion and action points of the MSC meeting are restructured by adding an introductory text to the agenda item and possibly any discussion points that would not be reflected in the conclusion and action points.</p>	
MSC accepted to proceed with the pilot project.	MSC to share lessons learnt and proposals for future meetings with case discussions in the survey launched at the end of the

	meeting. Feedback to be provided by 18 October.
Item 5 – Minutes of the MSC-74	
SECR informed the committee that the minutes of MSC-74 were adopted by MSC in written procedure and published on Interact and on ECHA's website.	
Item 6 – Substance evaluation¹	
6.3. General topics	
Feedback from written procedure	
SECR presented questions raised during the MSC-75 WP bilateral discussions concerning the extent of information to be included within a PfA, and proposals for parameters that deviate from what is specified within (e.g.) published guidelines. SECR also provided some recommendations for the structure/content of PfAs.	
MSC took note of the presentation and recommendations for the structure/content of PfAs.	MSC members to encourage their colleagues involved in PfA submission to review the recommendations when considering the need of a PfA.
Item 7 – Dossier evaluation¹	
No items.	
Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan	
<ol style="list-style-type: none"> 1. Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update <ul style="list-style-type: none"> • Draft Terms of Reference and appointment of the Rapporteur and Co-Rapporteur 	
MSC adopted the mandate and the tasks of the rapporteur and appointed one member as the Rapporteur and another member as the Co-Rapporteur for drafting the opinion of the MSC on the draft CoRAP 2022-2024 update. The absence of any specific interests will be confirmed in writing once the substances on the draft CoRAP update for 2022-2024 are available.	<p>SECR to send the appointment letters to the Rapporteur and the Co-Rapporteur after the meeting.</p> <p>SECR to provide MSC with the draft CoRAP update by 29 November 2021.</p>
Item 11 – Annual review of stakeholder observers' participation at MSC (closed session)	
<ul style="list-style-type: none"> • Discussion and update of the MSC decision about the invited organisations 	
SECR presented the outcome of the MSC accredited stakeholder organisations (ASO) participation review and proposed a way forward, as outlined in the respective meeting document. MSC considered the ASO participation in the past year in line with the <i>Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees²</i> and commitments made by MSC regular observers in different quotas.	

¹ No cases were for discussion at the meeting. The list of cases agreed in MSC Written Procedure is available in the Appendix at the end of the Agenda

²https://echa.europa.eu/documents/10162/17091/admission_of_stakeholder_organisations_as_observers_en.pdf/51298e6b-1dda-4e23-88c3-7b96a6fc3e73?t=1622536575278

<p>MSC took note of the update of the ASO observers' participation in the MSC work and took the following decisions:</p> <p>With regard to the admission of ASOs as MSC regular stakeholder observers (StOs) in different quotas, MSC decided to:</p> <p>Reconfirm the MSC regular StO status of:</p> <ul style="list-style-type: none"> • five Environmental and Health Care NGOs (ChemSec, Client Earth, EEB, Greenpeace and HEAL) within their rotation group to share four seats when participating in MSC plenary meetings; • five Animal Welfare NGOs (ECEAE, Eurogroup for Animals, HSI, PISC and CFE within their rotation group to share two seats when participating in MSC plenary meetings; • ETUC, Cefic, CONCAWE, Eurometaux and ORO • CEPE and FECC within a rotation group to share one seat when participating in MSC plenary meetings • SMEUnited who is to be represented on a regular basis by the MSC observer from Cefic and will participate in the MSC meetings on occasional basis. <p>MSC noted that according to the new ECHA stakeholder procedure (May 2021) any ECHA accredited stakeholder organisations can indicate their interest in taking part in a specific meeting of ECHA's committees as an occasional observer. These are invited to participate in MSC plenary meetings on an occasional basis, in accordance with the <i>Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees</i> and at the discretion of the MSC Chair's decision.</p>	<p>MSC to review ASO participation in its work in one year's time.</p> <p>SECR to share the AP11 document with the MSC regular StOs via Interact portal.</p> <p>SECR to publish the list on ECHA's webpage.</p>
<p>Item 12 – Any other business</p>	
<p>1. Update on appeals and court cases of relevance to MSC (<i>partly closed session</i>)</p>	
<p>SECR gave an overview of the judgments of the General Court on the D4, D5 and D6 SVHC cases. (cases T-226/18 and T-519/18) and the aluminium substance evaluation case (case T-127/20). SECR also gave an update of the new decision of Board of Appeal (BoA) of ECHA in case A-001-2020 concerning a compliance check of a monomer registration. SECR further provided a brief update on the status of the on-going cases including a new substance evaluation appeal (case A-009-2021). A brief update on new appeal and court cases was provided in a closed session to the members only.</p>	
<p>2. Use of the Fish Sexual Development Test (OECD 234) under compliance check (CCH) (<i>closed session</i>)</p>	
<p>SECR gave a presentation on the scientific discussion paper put forward for consultation with MSCAs and MSC, describing SECR's proposal of the scenarios in which the Fish Sexual Development Test (FSDT) study could be requested under compliance check (CCH). In the presentation, SECR explained the previous discussions that took place on this topic, briefly</p>	

<p>highlighted the proposal explained in the discussion paper and provided responses to the comments by MSCAs and MSC members. SECR also indicated how the proposal would be amended and explained that deviations from the default scenario (<i>i.e.</i> the need of <i>in vivo</i> information to trigger such test under CCH) may be considered based on case-specific considerations.</p> <p>MSC generally supported the aims of the proposed strategy. Several MSC members were of the view that OECD 234 can be requested based on structural similarity, <i>in silico</i>, and/or <i>in vitro</i> indicating ED concerns from two independent lines of evidence.</p>	
<p>MSC took note of the presentation and clarifications of the proposed strategy.</p> <p>MSC agreed that on a case-by-case basis deviations from the default scenario should be considered and FSDT triggered in the absence of <i>in vivo</i> information using case-specific scientific arguments.</p>	<p>SECR to revise the scientific discussion paper and share it for information with MSC in December.</p>
<p>3. Suggestions from members:</p> <p>a. Discussion paper: Proposal on the use of the Chromosome Aberration (CA) test under REACH both in <i>in vitro</i> and <i>in vivo</i> (<i>Partly closed session</i>)</p>	
<p>At MSC-74 (June 2021), the DK MSC member gave a presentation regarding a proposal to remove the option to perform the chromosomal aberration (CA) test in ECHA decisions. The MSC was supportive of the tentative proposal. The DK MSC member agreed to prepare a discussion paper in collaboration with experts volunteered by MSC members and regular stakeholder observers. DK MSC member presented the main points from the discussion paper, prepared with the assistance of the <i>ad hoc</i> working group formed after MSC-74. The paper proposed to remove the option to request for CA test <i>in vitro</i> and to reconsider the use of CA test <i>in vivo</i> in ECHA decisions under REACH.</p>	
<p>MSC took note of the presentation and clarifications for the proposed strategy for the assessment of CA concern.</p> <p>MSC supported the proposal to:</p> <ul style="list-style-type: none"> - request the assessment of the aneugenic potential of the tested substance by using a centromere staining in case of the <i>in vitro</i> MN test is positive. - request two positive controls using known clastogenic and aneugenic substances. <p>MSC in principal supported the proposal to:</p> <ul style="list-style-type: none"> - remove the choice between the <i>in vitro</i> CA test and the <i>in vitro</i> micronucleus (MN) test from ECHA decisions, and request solely the <i>in vitro</i> MN test. MSC agreed that an analysis to the test results for substances in ECHA database for which reliable data for both <i>in vitro</i> MN test and <i>in vitro</i> CA test are available should be performed to substantiate further the decision to remove the choice for <i>in vitro</i> CA test from ECHA decisions. <p>MSC noted the proposals for <i>in vivo</i> testing strategy to follow-up the different scenarios with CA concern.</p>	<p>SECR to analyse the results for substances in ECHA database for which reliable data for both <i>in vitro</i> MN test and <i>in vitro</i> CA test are available and report back in the MSC-76 meeting.</p> <p>MSC members to provide written comments on the proposal to remove the option to request for CA test <i>in vitro</i> and on the <i>in vivo</i> testing scenarios to DK MSC member by 5 November 2021, with a copy to MSC functional mailbox.</p>

<p>MSC members were invited to provide written comments on the proposal to remove the option to request for CA test <i>in vitro</i> and on the scenarios presented for <i>in vivo</i> testing to DK MSC member before the next plenary, MSC-76.</p>	
<p>b. Substance Evaluation process and ECHA Expert Group consultation – How to increase the visibility of Expert Group work</p>	
<p>FR MSC member presented the main points from the discussion paper, put forward for consultation with MSC. In detail, the need to consider how to increase visibility of the ECHA expert group (EG) advice so that it may be considered during the later stages of the decision-making process, namely during PfA consultation and agreement-seeking at MSC.</p>	
<p>MSC took note of the:</p> <ul style="list-style-type: none"> - presentation and proposals by FR for increasing the visibility of the ECHA expert group advice. - actions already in place by SECR to communicate the EG advice at PfA submission and decision-making stage <p>MSC agreed on the importance of PfA submitters to review the EG minutes when considering the scientific merits and/or relevance of a PfA.</p> <p>Due to the informal nature of the ECHA EGs and its general outcomes, MSC agreed that direct reference to the EG discussions in PfAs and DDs is not necessary as the justifications provided need to be self-standing.</p> <p>MSC supported the use of other informal approaches to further increase the visibility of EG discussions, such as:</p> <ul style="list-style-type: none"> - Informal discussions between MSCA and eMSCA when considering PfAs. - use of the PfA responses by eMSCA within the RCOM document to highlight EG discussions in more detail. - Direct accessibility of EG minutes and presentations by MSC members. 	<p>MSC members to encourage their colleagues involved in PfA submission to review the EG minutes when considering the scientific merits and/or relevance of a PfA.</p> <p>SECR to consider/implement ways to make EG minutes and presentations more easily available to MSC members.</p>
<p>Item 13 Summary Record of the Proceedings and Conclusions and action points</p>	
<p>MSC adopted the Summary Record of the Proceedings and Conclusions and Action points by consensus at the plenary meeting.</p>	<p>SECR to upload the Summary Record of the Proceedings and Conclusions and Action points from MSC-75 on Interact by 15 October 2021 as well as ECHA website without undue delay.</p>

II. List of attendees

Members/Alternate members	ECHA staff
ALMEIDA, Inês (PT)	AJAO, Charmaine
ATTIAS, Leonello (IT)	ANASTASI, Audrey Anne
BARTHELEMY-BERNERON, Johanna (FR)	BROERE, William
CONWAY, Louise (IE)	CATHERINE, Arnaud
DE KNECHT, Joop (NL)	CESNAITIS, Romanas
DUDRA, Agnieszka (PL)	CLENAGHAN, Conor
FERNANDEZ SANCHEZ, Raquel (ES)	DE WOLF, Watze
FINDENEGG, Helene (DE)	KIMERSTORFER, Karin
FILIPOVA, Hristina (BG)	HAUTAMÄKI, Anne
GRIZELJ, Romana (HR)	HERBATSCHEK, Nicolas
GYMNAOU, Panagiotis (CY)	HÄMÄLÄINEN, Eva
HJORTH, Rune (DK)	JUTILA, Arimatti
HORSKA, Alexandra (SK)	KAPANEN, Anu
JANTONE, Anta (LV)	LE CURIEUX, Frank
KOZMIKOVA, Jana (CZ)	LUOMA, Leena
MALKIEWICZ, Katarzyna (SE)	NAUR, Liina
MENARD SPRČIČ, Anja (SI)	PELLIZZATO, Francesca
MIHALCEA UDREA, Mariana (RO)	RASENBERG, Mark
RISSANEN, Eeva (FI)	RÖNTY, Kaisu
SAKSA, Jana (EE)	VAHTERISTO, Liisa
SPURIENE, Otilija (LT)	WALKER, Lee
STOCKER, Eva (AT)	VIEIRA LISBOA, Duarte
TÁRNO CZAI, Timea (HU)	
TEKPLI, Nina Landvik (NO)	
TREZZI, Jean (LU)	
VANDERSTEEN, Kelly (BE)	
Representatives of the Commission:	
KOBE, Andrej (DG ENV)	
CERIDONO, Mara (DG ENV)	
Observers	
BROWNE, Patience (OECD)	
DRMAC, Dunja (Cefic)	
DROHMANN, Dieter (ORO)	
DREVE, Simina-Virginia (FECC)	
LENNQUIST, Anna (ChemSec)	
LOONEN, Helene (EEB)	
NIEMELÄ, Helena (Concawe)	
SAUNDERS, Samantha (CFE)	
SUSNIK, Marko (SMEunited)	
WAETERSCHOOT, Hugo (Eurometaux)	

Apologies

ELLUL, Nathanael (MT)
 KOUTSODIMOU, Aglaia (EL)
 KULHANKOVA, Pavlina (CZ)
 PALEOMILITOU, Maria (CY)

Proxies

KOUTSODIMOU, Aglaia (EL) to GYMNAOU, Panagiotis (CY)

Experts and advisers to MSC members

ALIVERNINI, Silvia (IT) (Expert to ATTIAS, Leonello)
 ARABI, Azadeh (SE) (Expert to MALKIEWICZ, Katarzyna)
 ATTOFF, Kristina (SE) (Expert to MALKIEWICZ, Katarzyna)
 BALCIUNIENE, Jurgita (LT) (Expert to SPURIENE, Otilija)

BOLWIG, Asger (DK) (Expert to HJORTH, Rune)
CATONE, Tiziana (IT) (Expert to ATTIAS, Leonello)
CIESLA, Jacek (PL) (Expert to DUDRA, Agnieszka)
COPOIU, Oana (RO) (Expert to MIHALCEA UDREA, Mariana)
DOBRAK-VAN BERLO, Agnieszka (BE) (Expert to VANDERSTEEN, Kelly)
EINOLA, Juha (FI) (Expert to RISSANEN, Eeva)
GÜNDEL, Ulrike (DE) (Expert to FINDENEGG, Helene)
HÖLZL, Christine (AT) (Expert to STOCKER, Eva)
JOMINI, Stephane (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
JÖHNCKE, Ulrich (DE) (Expert to FINDENEGG, Helene)
KNOFLACH, Georg (AT) (Expert to STOCKER, Eva)
KUROVA, Martina (SK) (Expert to HORSKA, Alexandra)
LUNDBERGH, Ivar (SE) (Expert to MALKIEWICZ, Katarzyna)
MARTIN, Nellie (DK) (Expert to HJORTH, Rune)
MÜHLEGGGER, Simone (AT) (Expert to STOCKER, Eva)
NUGIN, Merike (EE) (Expert to SAKSA, Jana)
PASQUIER, Elodie (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
REIERSON, Linda (NO) (Expert to LANDVIK, Nina)
ROSENTHAL, Esther (DE) (Expert to FINDENEGG, Helene)
SCHMEISSER, Sebastian (DE) (Expert to FINDENEGG, Helene)
SILINS, Ilona (SE) (Expert to MALKIEWICZ, Katarzyna)
SVENDSEN, Camilla (NO) (Expert to LANDVIK, Nina)
ZELJEZIC, Davor (HR) (Expert to GRIZELJ, Romana)
UNKELBACH, Christian (Expert to FINDENEGG, Helene)

Expert appointed by EFSA

CREBELLI, Riccardo for AP 12.3a

Final Agenda

75th meeting of the Member State Committee

12-13 October 2021
(ECHA Conference Centre)
Web conference

12 October: starts at 10 am
13 October: ends at 1 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/075/2021
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-76
- Bis rounds in 2022
- Presentation of pilot for adoption of minutes at the meeting

For information

Item 5 – Minutes of the MSC-74

- [Adopted minutes of MSC-74](#)

MSC/M/74/2021
For information

Item 6 – Substance evaluation

Closed session for 6.2

1. 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

No cases³

[For discussion]

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

No cases

For agreement

3. General topics

Feedback from written procedure

For information

Item 7 – Dossier evaluation

Closed session for 7.2

1. 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)

No cases¹

[For information and discussion]

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

No cases

[For agreement]

3. General topics

Not applicable for this meeting

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

Not applicable for this meeting

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

Not applicable for this meeting⁴

Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan

1. Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update

- Draft Terms of Reference and appointment of the Rapporteur and Co-Rapporteur

ECHA/MSC-75/2021/003

For decision

Item 11 – Annual review of stakeholder observers' participation at MSC

Closed session

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

⁴ Written consultation of MSC on the prioritisation results is foreseen in October 2021

- Discussion and update of the MSC decision about the invited organisations

ECHA/MSC-75/2021/001

For discussion and decision

Item 12 – Any other business

Partly closed session

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

(Partly closed session)

For information

2. Use of the Fish Sexual Development Test (OECD 234) under compliance check (CCH)

(Closed session)

ECHA/MSC-75/2021/002, 006,

ECHA/MSC-75/2021/007 (room document)

For information and discussion

3. Suggestions from members:

- a. Discussion paper: Proposal on the use of the Chromosome Aberration (CA) test under REACH both in *in vitro* and *in vivo*

ECHA/MSC-75/2021/004

Partly closed session

For discussion and possible agreement

- b. Substance Evaluation process and ECHA Expert Group consultation – How to increase the visibility of Expert Group work

ECHA/MSC-75/2021/005

For information and discussion

Item 13 – Adoption of the summary record of the proceedings and main conclusions and action points

- Summary Record of the Proceedings and Main Conclusions and Action Points from MSC-75

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.

- Written procedure report on seeking agreement on draft decisions on substance evaluation
- Written procedure report on seeking agreement on draft decisions on dossier evaluation
- MSC workplan for 2022

APPENDIX to the MSC-75 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-75 meeting:

Substance evaluation

MSC code	Substance name	EC/List No.
SEV-2-NO-033/2014	Alkanes, C16–(branched), C20-(branched) and C24-(branched)	700-992-1
SEV-PT-017/2019	Bis(2-ethylhexyl)amine	203-372-4

Dossier evaluation

Compliance checks

MSC code	Substance name	EC/List No.
CCH-112/2021	Vinyl neodecanoate	256-905-8
CCH-118/2021	Benzenesulfonic acid, C10-13-alkyl derivs., sodium salts	270-115-0
CCH-121/2021	Piperazine	203-808-3
CCH-130/2021	Potassium isopentyl dithiocarbonate	213-180-2
CCH-149/2021	2,6-xylenol	209-400-1

Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-069/2021	N,N'-diphenyl-p-phenylenediamine	200-806-4
TPE-071/2021	Disodium 5-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]azo]-4-hydroxy-6-(methylamino)naphthalene-2-sulphonate	274-436-7
TPE-074/2021	Reaction mass of Disodium dihydroxy[3-(hydroxy-kO)-4-{ [5-(hydroxy-kO)-3-methyl-1-phenyl-1Hpyrazol-4-yl] diazenyl-kN1}naphthalene-1-sulfonato(3-)]chromate(2-) and sodium [4-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-3-hydroxynaphthalene-1-sulphonato(3-)]hydroxychromate(1-)	944-272-7
TPE-077/2021	Dimethyl 2,2'-azobis(2-methylpropionate)	219-976-6