

Minutes of the 76th Meeting
of the Member State Committee
(MSC-76)

Tuesday 14 December
to Wednesday 15 December 2021

Summary Record of the Proceedings and Conclusions and action points

Chair's opening address

The Deputy Chair, Charmaine Ajao, reflected on the past year and peeked into the future work for MSC.

As follow-up actions from MSC-75, she thanked MSC for the feedback provided via the survey after the previous meeting. Those results were shared with MSC and assist Secretariat in the planning of next meetings. The responses encouraged Secretariat to continue piloting the adoption of summary record of the meeting during this meeting as well. She also directed MSC where to find the follow-up items from the mutagenicity discussion of MSC-75 for future discussion in a later meeting.

With regards to the present meeting round, the Deputy Chair thanked the Committee for the three written procedures (all together 11 cases) that were successfully completed ahead of the plenary.

In preparation for 2022, the Deputy Chair informed MSC of the plan to hold the June and December meetings as physical meetings.

Agenda point	
Conclusions / agreements / adoptions	Action requested after the meeting (by whom/by when)
Item 2 – Adoption of the Agenda	
The Agenda (MSC/A/76/2021) was adopted.	SECR to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-76 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-76.	
Item 4 – Administrative issues	
<ul style="list-style-type: none"> Outlook for MSC-77 	
The Deputy Chair presented an outlook on the potential length of the MSC-77 (February 2022) meeting.	
Need for a MSC-77 plenary meeting to be assessed exceptionally only in mid-January 2022.	MSC to propose topics for MSC-77 plenary by 12 January 2022 if any.
Item 6 – Substance evaluation¹	
No items.	
Item 7 – Dossier evaluation¹	
CCH-179/2021: O,O,O-triphenyl phosphorothioate (EC No. 209-909-9) Session 1 & 2 (open & closed)	

¹ The list of cases agreed in MSC Written Procedure is available in the Appendix at the end of the Agenda

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 proposal for amendment (PfA) that required discussion in the meeting. The PfA on extended one-generation reproductive toxicity study (EOGRTS) suggested (a) including additional investigations for spatial learning and memory in the developmental neurotoxicity (DNT) cohorts 2A and 2B; and (b) additionally requesting the developmental immunotoxicity (DIT) cohort 3. The parts (a) and (b) of the PfA were justified by the anti-androgenic effects by the Substance, and part (a) additionally by the thyroid effects by the Substance. The Registrant had submitted written comments on the PfA and MSC duly considered them in its discussion.

The representatives of the Registrant reconfirmed their unaltered position on that there was no evidence of anti-androgenic activity based on available *in vitro* and *in vivo* data. Therefore, they did not consider justified to include additional investigations on spatial learning and memory in the DNT cohorts, or the inclusion of the DIT cohort.

The MSC acknowledged that there was evidence of anti-androgenicity *in vitro* and *in vivo* and that there were signs of thyroid function perturbation.

Inclusion of additional investigations for spatial learning and memory in the developmental neurotoxicity (DNT) cohorts 2A and 2B:

SECR supported the PfA to include additional investigations for spatial learning and memory in F1 animals. The MSC acknowledged that changes in testosterone levels could affect spatial cognitive abilities, and this particular concern requires examination of spatial learning and memory function in F1 animals. The MSC supported the PfA that the changes in thyroid hormone levels can be considered to have occurred at perinatal phase, leading to further justification for requesting the investigations on learning and memory function.

Developmental immunotoxicity (DIT) cohort 3:

The representatives of the Registrants reflected on the trigger of DNT and DIT cohorts based on sex steroid hormones (SSH) and specifically anti-androgens. In their view there is not anti-androgenic activity and there are not justifications to include the DIT cohort in the EOGRT study.

The MSC shared the reasoning of the PfA that the information available indicates anti-androgenic activity both *in vitro* and *in vivo*, and that there is specific evidence on anti-androgens to show that this is a specific mechanism/mode of action with an association to developmental immunotoxicity.

Regarding the DIT, the MSC concluded, after considering the information available and in line with the approach supported in MSC-73, that the case-specific data established anti-androgenic effects of the Substance, and that anti-androgenicity can be considered a particular concern for DIT and hence triggering the DIT cohort.

The MSC agreed, firstly, to include additional investigations for spatial learning and memory in F1 animals, and secondly, to include a request of the DIT cohort in the EOGRT study. MSC agreed unanimously to the DD as amended at the meeting.

MSC reached unanimous agreement on the following ECHA draft decision:

CCH-179/2021: O,O,O-triphenyl phosphorothioate (EC No. 209-909-9)

SECR to upload on Interact the agreed decisions in the respective case agenda points.

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

The Deputy Chair reported that MSC had agreed via a written procedure to unanimously identify (\pm)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one covering any of the individual isomers and/or combinations thereof (4-MBC) as SVHC due to their endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern.

On 26 November 2021, the Deputy Chair had terminated the written procedure for agreement seeking on the SVHC proposal for S-(tricyclo(5.2.1.0^{2,6})deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate (EC 401-850-9) following receipt of comments from a MSC member. The substance is proposed as SVHC because it meets the criteria of Article 57 (d) of Regulation (EC) 1907/2006 (REACH) due to its persistent, bioaccumulative and toxic (PBT) properties in accordance with the criteria set out in Annex XIII of REACH.

The member who had requested to stop the written procedure explained that this had been due to a proposal to change the reliability score of one of the ready biodegradability tests (OECD TG 301C, M.S.I. Report N° 6B061G) from “unreliable” to “reliable with restrictions”. The Dossier Submitter presented the changes that had been made in the RCOM and Support Document after the termination of the written procedure.

MSC agreed with the changes proposed and unanimously agreed to the identification of EC 401-850-9 as SVHC under Article 57 (d) of the REACH Regulation due to its PBT properties.

SECR to upload the MSC agreement, the support document and RCOMs, on MSC 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 2022).

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

Presentation and discussion of 11th draft recommendation

SECR presented ECHA’s response to comments received from MSC on the 11th prioritisation assessment, as well as the draft 11th recommendation. The recommendation had been prepared on the basis of the updated prioritisation results. All the substances included on the Candidate List by July 2021 which have not yet been recommended for inclusion to Annex XIV have been considered for the prioritisation exercise.

The eight substances included to the draft 11th recommendation [Ethylenediamine; 2-(4-tert-butylbenzyl) propionaldehyde; Lead; Glutaral; 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one; 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone; Diisohexyl phthalate and Orthoboric acid, sodium salt] are substances having high priority based on their intrinsic properties, volume and uses or substances included based on grouping considerations with other substances already recommended or proposed to be recommended.

SECR explained that other ongoing risk management activities (restrictions, upcoming POPs identification) were the main reasons for not including few of the high priority substances to the current draft recommendation. MSC was invited to provide feedback on the draft recommendation and on the draft entries for the eight substances. A three months consultation on ECHA’s website is planned to be launched early February 2022.

MSC took note of the draft recommendation which included eight substances and MSC requested for some further clarification as well as provided some further feedback.

MSC to provide any further feedback on the draft recommendation by 7 January 2022 using MSC FMB.

SECR to finalise ECHA’s draft 11th recommendation for publishing it for three-month consultation.

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

1. Introduction of the draft CoRAP update by SECR

SECR presented the draft Community Rolling Action Plan (CoRAP) update for 2022-2024 which had been referred to MSC on 1 December 2021. The draft CoRAP update for years 2022-2024

<p>has a total of 27 substances for evaluation, two new CoRAP candidates and 25 substances that were already included in the CoRAP. 25 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 20 entries on the list, mainly due to ongoing dossier evaluation.</p>	
<p>MSC took note of the draft CoRAP update for 2022-2024. MSC rapporteur introduced the initial plans for the opinion drafting and invited MSC to provide any reactions or feedback on the draft CoRAP update.</p>	<p>MSC to submit any input to the Rapporteurs using MSC FMB by 15 January 2022. Rapporteur (supported by the Co-Rapporteur) to prepare MSC's draft opinion on the draft CoRAP update for adoption in February 2022.</p>
<p>Item 11 – Any other business</p>	
<p>1. Update on appeals and court cases of relevance to MSC SECR gave an overview of the judgment of the General Court in Case T-661/19. SECR further provided a brief update on the status of the pending SVHC Court cases and pending evaluation appeals and Court cases. The Chair of Board of Appeal (BoA) of ECHA gave an update of the new decision of the BoA annulling the decision of the Agency in joined cases A-006-2020 and A-007-2020. He further gave a recap on the decision of the BoA rejecting the appeal in case A-009-2020.</p>	
<p>Item 12 – Adoption of summary record of the proceedings and conclusions and action points</p>	
<p>Table with summary record and conclusions and action points from MSC-76</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-76 on Interact by 17 December 2021 as well as ECHA website without undue delay.</p>

II. List of attendees

Members/Alternate members	
ALMEIDA, Inês (PT)	LENNQUIST, Anna (ChemSec)
ATTIAS, Leonello (IT)	LOONEN, Helene (EEB)
BARTHELEMY-BERNERON, Johanna (FR)	PEREIRA, Marina (HIS)
BOLWIG, Asger (DK)	SUSNIK, Marko (SMEunited)
CONWAY, Louise (IE)	VAN DER JAGT, Katinka
DUDRA, Agnieszka (PL)	WAETERSCHOOT, Hugo (Eurometaux)
FERNANDEZ SANCHEZ, Raquel (ES)	ECHA staff
FILIPOVA, Hristina (BG)	AJAO, Charmaine
FINDENEKG, Helene (DE)	BECKER, Falk
GRIZELJ, Romana (HR)	BELL, David
GYMNAOU, Panagiotis (CY)	BICHLMEIER, Ingo
HORSKA, Alexandra (SK)	BROERE, William
JANTONE, Anta (LV)	BUCHET Antoine
KOUTSODIMOU, Aglaia (EL)	CALEY, Jane
KULHANKOVA, Pavlina (CZ)	CARTON DE TOURNAI Laure-Anne
MALKIEWICZ, Katarzyna (SE)	DE COEN, Wim
MENARD SPRČIČ, Anja (SI)	FABJAN, Evelin
MIHALCEA UDREA, Mariana (RO)	HALLING, Katrin
RISSANEN, Eeva (FI)	HÄMÄLÄINEN, Eva
SAKSA, Jana (EE)	HAUTAMÄKI, Anne
SPURIENE, Otilija (LT)	JARNSTROM, Helena
STOCKER, Eva (AT)	JOHANSSON, Matti
TÁRNO CZAI, Timea (HU)	JUTILA, Arimatti
TEKPLI, Nina Landvik (NO)	KARHU, Elina
TREZZI, Jean (LU)	KARKOLA, Sampo
VANDERSTEEN, Kelly (BE)	LEPPÄRANTA, Outi
VAN BERLO, Damiën (NL)	LUOMA, Leena
Representatives of the Commission:	POLCI, Letizia
KOBE, Andrej (DG ENV)	RASENBERG, Mike
CERIDONO, Mara (DG ENV)	RÖNTY, Kaisu
Observers	RUOSS, Juergen
BERNARD, Alice (ClientEarth)	SERRA, Helene
CINGOTTI, Natacha (HEAL)	SIMANAINEN, Ulla
DROHMANN, Dieter (ORO)	VAHTERISTO, Liisa
DREVE, Simina-Virginia (FECC)	VIEIRA LISBOA, Duarte

Apologies

ELLUL, Nathanael (MT)
HJORTH, Rune (DK)
PALEOMILITOU, Maria (CY)

Proxies

BARTHELEMY-BERNERON, Johanna (FR) to MENARD SRPCIC, Anja (SI) for 15/12

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)
BIL, Wieneke (NL) (Expert to VAN BERLO, Damiën)
BURGA, Karen (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
CATONE, Tiziana (IT) (Expert to ATTIAS, Leonello)
CIESLA, Jacek (PL) (Expert to DUDRA, Agnieszka)
COPOIU, Oana (RO) (Expert to MIHALCEA UDREA, Mariana)
DE KNECHT, Joop (NL) (Expert to VAN BERLO, Damiën)

DOBRAK-VAN BERLO, Agnieszka (BE) (Expert to VANDERSTEEN, Kelly)
EINOLA, Juha (FI) (Expert to RISSANEN, Eeva)
FILTVEDT, Anne Line (NO) (Expert to LANDVIK TEPLI, Nina)
HOULIHAN, Margarete (IE) (Expert to CONWAY, Louise)
JÖHNCKE, Ulrich (DE) (Expert to FINDENEGG, Helene)
KOZMIKOVA, Jana (CZ) (Expert to KULHANKOVA, Pavlina)
KUROVA, Martina (SK) (Expert to HORSKA, Alexandra)
MENDONCA, Elsa (PT) (Expert to ALMEIDA, Ines)
MÜHLEGGGER, Simone (AT) (Expert to STOCKER, Eva)
NUGIN, Merike (EE) (Expert to SAKSA, Jana)
REHRL, Anna-Lena (AT) (Expert to STOCKER, Eva)
REIERSON, Linda (NO) (Expert to LANDVIK, Nina)
ROSENTHAL, Esther (DE) (Expert to FINDENEGG, Helene)
TRUBIROHA, Achim (DE) (Expert to FINDENEGG, Helene)
UNKELBACH, Christian (Expert to FINDENEGG, Helene)
VAN ELSAKER, Paul (BE) (Expert to VANDERSTEEN, Kelly)
ZELJEZIC, Davor (HR) (Expert to GRIZELJ, Romana)

Case owners:

Representatives of the Registrants were attending under the Agenda Item 7.2 for CCH-179/2021

Final Agenda

76th meeting of the Member State Committee

14-15 December 2021
(ECHA Conference Centre)
Web conference

14 December: starts at 10:00 am
15 December: ends at 1:00 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/076/2021
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-77

For information

Item 5 – Minutes of the MSC-75

- Adopted minutes of MSC-75

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*):

No cases²

For discussion

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

² List of cases agreed in MSC Written Procedure is available in the Appendix of this document.

No cases

For agreement

3. General topics

[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)

For discussion followed by agreement seeking under 7.2:

ECHA/MSC-76/2021/010

For information

Compliance checks

MSC code¹	Substance name	EC/List No./ Documents
CCH-179/2021	O,O,O-triphenyl phosphorothioate	209-909-9 ECHA/MSC-76/2021/002-3

For 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)

As listed under 7.1

For agreement

3. General topics

[For information]

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

Seeking agreement on Annex XV proposals for identification of SVHC

A case stopped from MSC written procedure

Substance name¹	EC/List No.	CAS No.	Documents
S-(tricyclo(5.2.1.0 ^{2,6})deca-3-en-8(or 9)-yl O-(isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl) phosphorodithioate	401-850-9	255881-94-8	ECHA/MSC-76/2021/006-9

For agreement

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

Presentation and discussion of 11th draft recommendation

ECHA/MSC-76/2021/004-5³

For discussion

³ Comments received from MSC during 30 September - 1 November are available in Interact MSC-75 under RECOM Pre-meeting folder.

Item 10 – ECHA’s draft update of the Community Rolling Action Plan and opinion of MSC

Introduction of the draft CoRAP update by SECR

ECHA/MSC-76/2021/001

For information

Item 11 – Any other business

Partly closed session

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

(Partly closed session)

For information

2. Suggestions from members

For information

Item 12 – Adoption of summary record of the proceedings and conclusions and action points

- Table with summary record and conclusions and action points from MSC-76

For adoption

INFORMATION DOCUMENTS

Information documents are not allocated a specific agenda time but the documents are available on 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 (For members only)
- Written procedure report on seeking agreement on draft decisions on dossier evaluation (For members only)
- Written procedure report on seeking agreement on Annex XV proposals for identification of SVHC
- Approach paper on requesting the Fish sexual development test (OECD TG 234) under Compliance Check (For members only)
- Comments received on mutagenicity discussion paper: Proposal on the use of the Chromosome Aberration (CA) test under REACH both in *in vitro* and *in vivo* (Follow up to MSC-75 Item 12.3a)

APPENDIX to the MSC-76 agenda:

List of cases agreed by MSC in written procedure in advance of the MSC-76 meeting:

Substance evaluation

MSC code	Substance name	EC/List No.	
SEV-BE-025/2020	Perfluamine	206-420-2	
SEV-NL-021/2020	Phenol, isopropylated, phosphate (3:1)	273-066-3	
SEV-DE-022/2020	1-(5,6,7,8-tetrahydro-3,5,5,6,8,8-hexamethyl-2-naphthyl)ethan-1-one	216-133-4	and
SEV-DE-023/2020	(3E)-1,7,7-trimethyl-3-(4-methylbenzylidene)bicyclo[2.2.1]heptan-2-one	244-240-6 701-394-3	

Dossier evaluation

Compliance checks

MSC code	Substance name	EC/List No.
CCH-178/2021	N,N-diethylhydroxylamine	223-055-4

Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-095/2021	1,1,1,2,2,4,5,5,5-nonafluoro-4-(trifluoromethyl)-3-pentanone	436-710-6
TPE-096/2021	1,1,1,2,2,4,5,5,5-nonafluoro-4-(trifluoromethyl)-3-pentanone	436-710-6
TPE-099/2021	N-[2-[(2-cyano-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]acetamide	246-058-2
TPE-109/2021	3-(benzothiazol-2-yl)-7-(diethylamino)-2-oxo-2H-1-benzopyran-4-carbonitrile	274-668-9

SVHC identification⁴

Substance name	EC/List No.	CAS No.
(±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one covering any of the individual isomers and/or combinations thereof (4-MBC)	-	-

⁴ SVHC proposals for 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol (DBMC) (EC No. 204-327-1, Cas 119-47-1) and tris(2-methoxyethoxy)vinylsilane (EC No. 213-934-0, Cas 1067-53-4) were not referred to MSC but will be added to the Candidate List without MSC involvement.