MSC/M/74/2021
Adopted by written procedure
on 6 September 2021

Minutes of the 74th Meeting of the Member State Committee (MSC-74)
14-17 June 2021
web conference

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 74th 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). Agenda point 4 (Outlook for MSC-75), and Agenda Points 7 and 11.2 were announced to be chaired by the MSC Deputy Chair, Ms Charmaine Ajao.

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

No potential conflicts of interests were declared by the Chairman, Deputy Chair, any members, experts or advisers with any item on the agenda of MSC-74.

Item 4 - Administrative issues

- Updates to MSC Working procedures

In advance of the meeting SECR had shared updates to five MSC Working procedures (Processing substance evaluation draft decisions, Processing dossier evaluation draft decisions, Identification of SVHCs, Providing opinions on draft CoRAP updates and Providing opinions on ECHA's draft recommendations of priority substances to be included in Annex XIV) for commenting. These updates covered mainly procedural updates to reflect the current working practises and tools, including some process efficiencies and streamlining. SECR presented the feedback received and the revised versions were adopted by MSC as provided for the meeting.

- Outlook for MSC-75

The Deputy Chair presented an outlook on the potential length of the MSC-75 (October 2021) meeting.

Item 5 – Minutes of the MSC-73 meeting

SECR informed the committee that the minutes of MSC-73 were adopted by MSC in written procedure and published on Interact and on ECHA's website.

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 four substance evaluation (SEv) cases (see Appendix to the final agenda in Section III for more detailed identification of the cases). WP was launched on 21 May 2021. By the closing date 31 May 2021, MSC reached unanimous agreement on these four SEv cases.

Item 7 – Dossier evaluation

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

SECR introduced the report on the outcome of the written procedure (WP) of the MSC-73bis round for agreement seeking on 2 dossier evaluation cases (see Section III Final agenda "Appendix to the MSC-74 agenda" for more detailed identification of the cases). WP was launched on 31 March 2021. By the closing date 14 April 2021, MSC reached unanimous agreement on all 2 DDs.

SECR introduced the report on the outcome of the written procedure (WP) of the MSC-74 round for agreement seeking on 7 dossier evaluation cases (see Section III Final agenda "Appendix to the MSC-74 agenda" for more detailed identification of the cases). WP was launched on 21 May 2021. By the closing date 31 May 2021, MSC reached unanimous agreement on all 7 DDs.

2. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions *(Session 1, tentatively open session)*

3. Seeking agreement on draft decisions on testing proposals when amendments were proposed by MS's *(Session 2, closed)*

CCH-019/2021	1-[(2,4-dinitrophenyl)azo]-2-naphthol	(EC No. 222-429-4)
CCH-020/2021	1-(4-methyl-2-nitrophenylazo)-2-naphthol	(EC No. 219-372-2)
CCH-030/2021	1,3,2-dioxathiane 2,2-dioxide	(EC No. 214-022-5)
TPE-031/2021	Lithium tetrafluoroborate, anhydrous	(EC No. 238-178-9)

Session 1 (open)

ECHA Secretariat (SECR) clarified that the cases would be presented and discussed together as the proposals for amendments (PfA) that required discussion were similar.

No representative of the Registrants participated in the initial discussion.

SECR introduced the PfAs that required discussion in the meeting. The draft decisions (DDs) had Annex VII and Annex VIII addressees. The PfAs on *in vivo* mammalian alkaline comet assay suggested to request also to Registrants at Annex VII level the combination of the *in vivo* comet assay with micronucleus test in case the *in vitro* chromosomal aberration study

results are positive. This was the approach agreed at MSC-70 for Annex VIII and IX Registrants. At this stage the combined study was recommended and not requested at Annex VII.

The Registrants had not submitted written comments on the PfAs.

SECR supported the PfAs. The MSC took note that the PfAs extend to Annex VII Registrants the approach agreed at MSC-70 for Annex VIII and IX Registrants for the same advantages discussed at MSC-70 – 1) it can be viewed as one *in vivo* study and 2) uses less animals to address two concerns – gene mutation and chromosomal aberrations.

Session 2 (closed)

MSC supported the PfAs received for the four DDs. MSC unanimously agreed on the four DEv DDs, as provided for the meeting.

MSC supported the general approach that an *in vivo* comet assay combined with micronucleus study should be requested at Annex VII for TPE and CCH decisions. The following three conditions should be met for the combination study to be requested:

a) an *in vitro* gene mutation study in bacteria is positive,
b) there is an indication of chromosomal aberration concern,
c) and no other adequate and appropriate *in vivo* genotoxicity data is available in the dossier.

SECR will implement the approach in future decisions and disseminate the approach via the ECHA's website.

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

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

SECR gave a brief report on the outcome of the written procedure (WP) for SVHC agreement seeking on the identification of the three following substances, proposed to be identified as SVHC based on Article 57 of Regulation (EC) 1907/2006.

4,4'-(1-methylpropylidene)bisphenol (EC No. 201-025-1), proposed as SVHC under Article 57(f) due to its endocrine disrupting properties for environment and human health.

Glutaral (EC No. 203-856-5), proposed as SVHC under Article 57(f) due to its respiratory sensitising properties.

2,2-bis(bromomethyl)propane1,3-diol (BMP), 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA), 2,3-dibromo-1-propanol (2,3-DBPA) (EC No. 221-967-7, 253-057-0, 202-480-9), proposed as SVHC under Article 57(a) due to their carcinogenic properties.

It was explained that MSC agreed unanimously on the identification of these three substances as SVHC in the WP launched on 24 May 2021 and closed on 3 June 2021. One member abstained from voting on Glutaral and another member provided a note to the vote concerning 4,4'-(1-methylpropylidene)bisphenol, which has been included in the WP report. SECR explained that the final documents have been published in Interact and will be published on the ECHA website, and that these substances will be included in the Candidate List of SVHCs in its next update in July 2021.

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

Medium-chain chlorinated paraffins (MCCP)[1] (EC No. -)

The dossier submitter (DS) expert from ECHA presented to MSC the draft Support Document (SD) based on Annex XV proposal for MCCP and the comments of the consultation of interested parties. The substances were proposed for SVHC identification due to their PBT and/or vPvB properties under Art 57(d) and (e) of the REACH Regulation.

The justification for identification was based on weight-of-evidence of the data available on the persistence, bioaccumulation, toxicity of MCCP, and its potential for long-range environmental transport.

The DS expert outlined the main comments received in the consultation of the interested parties on the Annex XV report and the DS's responses to them. The consultation had yielded both supporting and diverging views.

MSC agreed to the DS's considerations on which issues raised in the consultation were resolved, and which MSC should further reflect upon. The adviser to Cefic's regular observer representative revisited some of the industry comments submitted in the consultation. These included the use of the 0.1% (w/w) substance concentration trigger for identification supposedly misapplied to congener groups of MCCP, a claim that MCCP products below a certain chlorination level (e.g. < 50 % Cl wt.) do not fulfill the P/vP criteria, a claim that lower tier studies were disregarded in favor of a higher tier study, a claim on the need to collect more information on MCCP such as an OECD TG 314B study, a comment challenging the reliability of the fish OECD TG 305 dietary study, outcome of the BAT tool commissioned by the Industry which considers only two representative structures for their bioaccumulation properties and a claim that all risks are already managed for MCCP. Regarding both the issues for potential further reflection and those brought up by the Cefic adviser, MSC considered them being sufficiently addressed in the SD and/or the RCOM, and MSC endorsed the SD as submitted for the meeting.

MSC unanimously agreed to the identification of MCCP as SVHC under Articles 57 (d) and (e) of REACH Regulation due to their PBT and/or vPvB properties.

The Chairman thanked the DS for providing the proposal on MCCP to the SVHC identification process and MSC for the unanimous agreement.

1,4-dioxane (*EC No. 204-661-8*)

The dossier submitter (DS) expert from the German CA presented to MSC the draft Support Document (SD) based on the Annex XV proposal for 1,4-dioxane and on the comments of the consultation of the interested parties. The proposal was based on Article 57 (f) of the REACH Regulation due to scientific evidence of probable serious effects to the environment and human health (man via the environment).

The justification for identification was based on very high persistency, high mobility in water, potential for being transported in the water phase over long distances, difficulty of remediation and water purification, carcinogenicity of 1,4-dioxane and yet unknown environmental effects.

[1] Medium-chain chlorinated paraffins [UVCB substances consisting of more than or equal to 80% linear chloroalkanes with carbon chain lengths within the range from C_{14} to C_{17}].

The DS expert outlined the main comments received in the consultation on the Annex XV report and DS's responses to them. The consultation had yielded both supporting and diverging views. Several comments proposed adding SVHC identification based on Article 57(a) owing to the classification of 1,4-dioxane as Carc 1B.

ECHA informed MSC of a previous case for which the Court accepted that additional grounds for identification can be included in response to comments. MSC agreed to broaden the scope of the SVHC proposal and add SVHC identification due to the carcinogenic properties based on Article 57(a) owing to the classification of 1,4-dioxane as Carc 1B to strengthen the legal grounds of the SVHC identification and to facilitate communication on the concern expressed for man exposed via the environment.

An alternate member proposed changes in the SD regarding biodegradation, and these were accepted by MSC. MSC mandated the alternate member and the DS expert to finalise the wording of specific paragraphs on biodegradation in the SD outside the MSC meeting. MSC considered other issues raised in the consultation as resolved. The Cefic observer revisited some of the industry comments submitted in the consultation regarding scientific evidence of 1,4-dioxane having probable serious effects to the environment, but MSC considered them being sufficiently addressed in the SD and RCOM.

MSC unanimously agreed to the identification of 1,4-dioxane as SVHC under Article 57(a) of the REACH Regulation owing to its classification in the hazard class carcinogenicity category 1B, and under Article 57(f) of REACH Regulation because it is a substance for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of the REACH Regulation.

The Chairman thanked the DS for providing the proposal on 1,4-dioxane to the SVHC identification process and MSC for the unanimous agreement.

Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP) (*EC No.* -)

The dossier submitter (DS) expert from the German CA presented to MSC the draft Support Document (SD) based on Annex XV proposal for PDDP and the comments of the consultation of the interested parties. The proposal was based on Articles 57(c) and 57(f) of the REACH Regulation due to the toxic to reproduction properties and the endocrine disrupting (ED) properties for which there is scientific evidence of probable serious adverse effects to human health and the environment.

The justification of the proposal was based on the harmonised classification of PDDP in the hazard class reproductive toxicity category 1B, and the adverse effects on fertility and sexual function, particularly in females, that are plausibly linked to the oestrogenic activity of PDDP and in the environment have relevance on a population level.

The DS expert outlined the main comments received in the consultation on the Annex XV report and DS's responses to them. The consultation had yielded both supporting and diverging views.

Regarding the scope of the proposal, in response to a comment received in consultation to exclude linear alkyl chains, the substance identity was changed to *Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP).* The exclusion of linear alkyl chain substances was due to their lack of harmonised classification as reproductive toxicant. MSC agreed to the change of the scope of the SVHC proposal.

An alternate member proposed changes in the SD regarding degradation of PDDP, and these were accepted by MSC. MSC considered other issues raised in the consultation as solved.

The Occasional Stakeholder representative from ATC revisited some of the industry comments submitted in the consultation claiming that the available data was insufficient for identification as ED, but MSC considered the comments being sufficiently addressed in the SD and RCOM. She expressed her view that the timing was unfortunate, and the ED identification should be postponed until the ED criteria under CLP are available.

MSC unanimously agreed to the identification of PDDP as SVHC under Article 57(c) of the REACH Regulation owing to its classification in the hazard class toxic to reproduction category 1B, and under Article 57(f) of REACH Regulation because it is a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of the REACH Regulation.

The Chairman thanked the DS for providing the proposal on PDDP to the SVHC identification process and MSC for the unanimous agreement.

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

No items.

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

No items.

Item 11 – Any other business

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

SECR gave an overview of judgment of the Court in case T-177/19 and new appeal case C-119/21 challenging General Court judgment in case T-207/18 relating to the Authorisation process. SECR gave an update of the new decisions of the Board of Appeal (BoA) of ECHA in cases A-014-2019, A-015-2019 and A-016 to A-029-2019, and introduced new appeals A-004-2021 and A-005-2021 on Evaluation in open session. 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 and court cases was provided in a closed session to the members only.

2. Suggestions from members

- Clarification of the REACH requirement for *in vivo* genotoxicity testing if *in vitro* genotoxicity tests are not applicable/appropriate *(Closed session)*

An MSC member gave a presentation on REACH requirements for *in vivo* genotoxicity testing if *in vitro* genotoxicity tests are not applicable. The MSC discussed on the possibility to request *in vivo* genotoxicity testing when *in vitro* testing is not applicable and/or technically not possible under compliance check (CCH) and testing proposal examination (TPE) processes, and whether this would depend on the Annex level or other factors. MSC acknowledged that where *in vitro* mutagenicity studies are not technically feasible, this could lead to a data gap in the registration dossier. With regards to TPEs, MSC agreed with the approach used by SECR to request for *in vivo* genotoxicity testing upon justification by the Registrant that testing *in vitro* is not technically possible and proposing in vivo testing. With regards to CCH, MSC took note of the SECR view that the current legal text appears sufficiently clear on these aspects and that the current REACH text does not allow ECHA to request an *in vivo* test under CCH in case *in vitro* tests are not technically possible. Based on

the objectives of REACH to ensure the safe use of the substance, some MSC members considered that the legal text of REACH Annexes could be modified to clarify the requirement for *in vivo* genotoxicity testing in case the *in vitro* genotoxicity tests are not applicable/appropriate. The MSC agreed that members can submit written comments to the concerned MSC member for further consideration in other discussion fora.

- Use of the Chromosome Aberration (CA) test under REACH both in *in vitro* and *in vivo (Open session)*

An MSC member gave a presentation on the use of the *in vitro* and *in vivo* chromosomal aberration (CA) tests under REACH. The tests investigate different chromosomal aberration effects. Regarding the options for *in vitro* testing (i.e. Annex VIII data requirement 8.4.2), the CA test (OECD 473, *in vitro* mammalian chromosomal aberration test) covers only clastogenic effects (structural chromosomal aberrations) and it is not optimised to investigate aneugenic effects (numerical chromosomal aberrations). The other *in vitro* option, the MN test (OECD 487, *in vitro* mammalian cell micronucleus test) covers both clastogens and aneugens.

Regarding *in vivo* follow-up tests, SECR currently gives three options to follow-up a CA concern *in vivo*: the micronucleus test (MN/OECD TG 474) that covers both aneugens and clastogens, the bone marrow chromosomal aberration test (CA/OECD TG 475) that covers clastogens and the comet assay (OECD TG 489) that detects primary DNA damages that may become chromosomal aberrations or gene mutations.

Overall, both for *in vitro* and *in vivo*, the MN test seems to be a better option as it covers both types of chromosomal aberrations. This is also in line with the EFSA scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment.

The MSC took note that all the tests have their limitations and there are substance specific aspects that could influence the choice of test method.

The MSC took note of the information and concluded to establish an ad hoc working group to assist the MSC member in preparing a background document addressing a possible new testing strategy for the assessment of the CA concern, and to share it before the next MSC meeting (MSC-75).

Item 12 - Adoption of main conclusions and action points

Table with conclusions and action points from MSC-74

MSC adopted the main conclusions and action points as presented at the meeting.

II. List of attendees

Members/Alternate members	**ECHA staff**
ALMEIDA, Inês (PT)	AJAO, Charmaine
ATTIAS, Leonello (IT)	ANASTASI, Audrey Anne
BALCIUNIENE, Jurgita (LT)	BRENZEL, Steffen
BARTHELEMY-BERNERON, Johanna (FR)	BROERE, William
CONWAY, Louise (IE)	CALEY, Jane
DE KNECHT, Joop (NL)	CLENAGHAN, Conor
DUDRA, Agnieszka (PL)	DA SILVA, Emilie
ELLUL, Nathanael (MT)	DE COEN, Wim
FERNANDEZ SANCHEZ, Raquel (ES)	DE WOLF, Watze
FINDENEGG, Helene (DE)	DEMATTIO, Silvia
FILIPOVA, Hristina (BG)	ERIKSEN, Hilde Renate
GRIZELJ, Romana (HR)	GONZALEZ, Arutnev
GYMNAOU, Panagiotis (CY)	HANSEN, Bjorn
HJORTH, Rune (DK)	HAUTAMÄKI, Anne
HORSKA, Alexandra (SK)	JOHANSSON, Matti
JANTONE, Anta (LV)	JUTILA, Arimatti
KOUTSODIMOU, Aglaia (EL)	LE CURIEUX, Frank
KULHANKOVA, Pavlina (CZ)	LEFEVRE, Sandrine
LANDVIK, Nina (NO)	LEPPER, Peter
MALKIEWICZ, Katarzyna (SE)	LUOMA, Leena
MENARD SPRČIČ, Anja (SI)	NAUR, Liina
MIHALCEA UDREA, Mariana (RO)	NICOLAS, Ronan
RISSANEN, Eeva (FI)	RÖNTY, Kaisu
SAKSA, Jana (EE)	TRNKA, Jan-Peter
STOCKER, Eva (AT)	VAHTERISTO, Liisa
TÁRNOCZAI, Timea (HU)	WALKER, Lee
TREZZI, Jean (LU)	VIEIRA LISBOA, Duarte
VANDERSTEEN, Kelly (BE)	
Representatives of the Commission:	
BERTATO, Valentina (DG ENV)	
KOBE, Andrej (DG ENV)	
CERIDONO, Mara (DG ENV)	
STRECK, Georg (DG GROW)	
Observers	
BAINES, Julia (PETA)	
BERNARD, Alice (ClientEarth)	
BROWN, Patience (OECD)	
CINGOTTI, Natacha (HEAL)	
DRMAC, Dunja (Cefic)	
DROHMANN, Dieter (ORO)	
DREVE, Simina-Virginia (FECC)	
HOWICK, Chris (Cefic) expert during AP 8	
KEAN, Helen (ATC) during AP 8	
LENNQUIST, Anna (ChemSec)	
LOONEN, Helene (EEB)	
NIEMELÄ, Helena (Concawe)	
PEREIRA, Marina (HSI)	
SWEET, Len (ATC) during AP 8	
WAETERSCHOOT, Hugo (Eurometaux)	

Apologies

PALEOMILITOU, Maria (CY)
SPURIENE, Otilija (LT)

Proxies
MALKIEWICZ, Katarzyna (SE) to HJORTH, Rune (DK) for 16 June between 10:00-14:15

Experts and advisers to MSC members
ALIVERNINI, Silvia (IT) (Expert to ATTIAS, Leonello)
ANDERSSON, Lars (SE) (Expert to MALKIEWICZ, Katarzyna)
BOLWIG, Asger (DK) (Expert to HJORTH, Rune)
BURGA, Karen (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
CATONE, Tiziana (IT) (Expert to ATTIAS, Leonello)
CHARRON, Isabelle (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
CIEŚLA, Jacek (PL) (Expert to DUDRA, Agnieszka)
CLAßEN, Daniela (DE) (Expert to FINDENEGG, Helene)
COPOIU, Oana (RO) (Expert to MIHALCEA UDREA, Mariana)
DOBRAK-VAN BERLO, Agnieszka (BE) (Expert to VANDERSTEEN, Kelly)
EINOLA, Juha (FI) (Expert to RISSANEN, Eeva)
GERMER, Sabine (DE) (Expert to FINDENEGG, Helene)
GÜNDEL, Ulrike (DE) (Expert to FINDENEGG, Helene)
HALIN LEJONKLOU, Margareta (SE) (Expert to MALKIEWICZ, Katarzyna)
HORNEK-GAUSTERER, Romana (AT) (Expert to STOCKER, Eva)
HÖLZL, Christine (AT) (Expert to STOCKER, Eva)
JOHANSSON, Olof (SE) (Expert to MALKIEWICZ, Katarzyna)
JÖHNCKE, Ulrich (DE) (Expert to FINDENEGG, Helene)
KAARTINEN, Tomi (FI) (Expert to RISSANEN, Eeva)
KNOFLACH, Georg (AT) (Expert to STOCKER, Eva)
KOZMIKOVA, Jana (CZ) (Expert to KULHANKOVA, Pavlina)
KUROVA, Martina (SK) (Expert to HORSKA, Alexandra)
LUNDBERGH, Ivar (SE) (Expert to MALKIEWICZ, Katarzyna)
MENDONÇA, Elsa (PT) (Expert to ALMEIDA Inês)
MARTIN, Nellie (DK) (Expert to HJORTH, Rune)
MÜHLEGGER, Simone (AT) (Expert to STOCKER, Eva)
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)
SANTOS, Luis (PT) (Expert to ALMEIDA Inês)
STRACZEK, Anne (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
SÄTTLER, Daniel (DE) (Expert to FINDENEGG, Helene)
ZELJEZIC, Davor (HR) (Expert to GRIZELJ, Romana)
UNKELBACH, Christian (Expert to FINDENEGG, Helene)

Dossier submitter experts for SVHC cases:
ARNING, Jürgen (DE)
DANNENBERG, Carl (DE)
RIBEIRO, Lucie (ECHA)
SCHLIEBNER, Ivo (DE)
TRUBIROHA, Achim (DE)

III. Final Agenda

MSC/A/074/2021 Final agenda
14 June 2021

Final Agenda

74th meeting of the Member State Committee

14-17 June 2021

(ECHA Conference Centre)

Web conference

14 June: starts at 10:00 am
17 June: ends at 3:15 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/074/2021
For adoption

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

Item 4 – Administrative issues

- Updates to MSC Working procedures:
  - For processing dossier evaluation draft decisions
  - For processing substance evaluation draft decisions
  - For SVHC identification
  - For providing opinions on CoRAP updates
  - For providing opinions on ECHA's draft recommendations

ECHA/MSC-74/2021/001-005
For adoption

- Outlook for MSC-75

For information

Item 5 – Minutes of the MSC-73

- Adopted minutes of MSC-73

MSC/M/73/2021
For information

Item 6 – Substance evaluation

Closed session for 6.3

6.1 Written procedure report on seeking agreement on draft decisions on substance evaluation[2]

ECHA/MSC-74/2021/006

For information

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

No cases

[For discussion]

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

No cases

[For agreement]

Item 7 – Dossier evaluation

Closed session for 7.3

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

Written procedure reports for MSC-73bis and MSC-74 rounds

ECHA/MSC-74/2021/007-8

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:

ECHA/MSC-74/2021/029

For information

Compliance checks

MSC code	Substance name	EC/List No./ Document
CCH-019/2021	1-[(2,4-dinitrophenyl)azo]-2-naphthol	222-429-4 / ECHA/MSC-74/2021/009-10
CCH-020/2021	1-(4-methyl-2-nitrophenylazo)-2-naphthol	219-372-2 ECHA/MSC-74/2021/011-12
CCH-030/2021	1,3,2-dioxathiane 2,2-dioxide	214-022-5 ECHA/MSC-74/2021/013-14

Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-031/2021	Lithium tetrafluoroborate, anhydrous	238-178-9 ECHA/MSC-74/2021/015-16

For information and discussion

[2] 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

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

Start on Day 1 am

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

ECHA/MSC-74/2021/017
(Room document)
For information

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

Substance name	**EC/List No.**	**CAS No./ Documents**
Medium chain-chlorinated paraffins (MCCP)	-	- ECHA/MSC-74/2021/020 and 024-25, 28
Phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)	-	- ECHA/MSC-74/2021/018 and 022-023, 27
1,4-dioxane	204-661-8	123-91-1 ECHA/MSC-74/2021/019 and 021, 026

For discussion and agreement

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

Not applicable for this meeting

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

Not applicable for this meeting

Item 11 – Any other business

Partly closed session

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

(Partly closed session)
For information

4. Suggestions from members:

- Clarification of the REACH requirement for *in vivo* genotoxicity testing if *in vitro* genotoxicity tests are not applicable/appropriate *(Closed session)*

ECHA/MSC-74/2021/030

For information and discussion

- Use of the Chromosome Aberration (CA) test under REACH both in *in vitro* and *in vivo (Open session)*

For information and discussion

Item 12 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-74

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)
- Presentation to Expert Groups about MSC

APPENDIX to the MSC-74 agenda:
List of evaluation and SVHC cases agreed by MSC in written procedure in advance of the MSC-74 meeting:

Substance evaluation

MSC code	Substance name	EC/List No.
SEV-NL-016/2019	Methylethylketone peroxide trimer (Trigonox 301)	429-320-2
SEV-ES-004/2019	A mixture of: propan-2-one-O,O'(methoxy-vinylsilandiyl)dioxime; propan-2-one-O-(dimethoxyvinylsilyl)oxime; propan-2-one-O,O',O''-(vinylsilantriyl)trioxime	458-680-3
SEV-2-DE-011/2014	Di-tert-butyl 3,3,5-trimethylcyclo-hexylidene diperoxide	229-782-3
SEV-FR-009/2018	Titanium dioxide	236-675-5

Dossier evaluation

Compliance checks

MSC code	Substance name	EC/List No.
CCH-011/2021[3]	Strontium fluoride	232-000-3
CCH-016/2021[6]	Bis(2,4-dichlorobenzoyl) peroxide	205-094-9
CCH-029/2021	N'-(1,3-dimethylbutylidene)-3-hydroxy-2-naphthohydrazide	435-860-1
CCH-070/2021	Ferrate(4-), hexakis(cyano-C)-, Et 2-[6-(ethylamino)-3-(ethylimino)-2,7-dimethyl-3H-xanthen-9-yl]benzoate copper(2+) salts	235-469-2

Testing proposals

MSC code	Substance name	EC/List No.
TPE-021/2021	Distillates (petroleum), hydrodesulfurized middle	265-183-3
TPE-022/2021	Distillates (petroleum), hydrotreated middle	265-148-2
TPE-023/2021	Gas oils (petroleum), hydrodesulfurized	265-182-8
TPE-024/2021	Bis(2-(2-butoxyethoxy)ethoxy)methane	205-598-9
TPE-026/2021	Barium sulfate	231-784-4

SVHC identification[4]

Substance name	EC/List No.	CAS No.
4,4'-(1-methylpropylidene)bisphenol	201-025-1	77-40-7
2,2-bis(bromomethyl)propane1,3-diol (BMP), 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA), 2,3-dibromo-1-propanol (2,3-DBPA)	221-967-7, 253-057-0, 202-480-9	3296-90-0, 36483-57-5, 1522-92-5, 96-13-9
Glutaral	203-856-5	111-30-8

[3] Agreed in the MSC-73bis round

[4] SVHC proposals for Orthoboric acid, sodium salt (EC No. 237-560-2, Cas 13840-56-7) and 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers (EC No. 201-289-8, Cas 80-54-6) were not referred to MSC but will be added to the Candidate List without MSC involvement.

IV. Main conclusions and action points

Main conclusions and action points
MSC-74, 14-17 June 2021
(adopted at MSC-74)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
• Update for MSC working procedures	
MSC adopted the working procedures for: • Processing dossier evaluation draft decisions • Processing substance evaluation draft decisions • SVHC identification • Providing opinions on CoRAP updates • Providing opinions on ECHA's draft recommendations	**SECR** to upload the adopted documents on Interact MSC-00 and the ECHA website after editorial check.
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 Interact for the written procedure as agreed ones.
Item 7.1– Dossier evaluation **Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the reports.	**MSC** to consider the decisions uploaded on Interact for the written procedure as agreed ones.
Item 7.2 – 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 decisions: • CCH-019/2021: 1-[(2,4-dinitrophenyl)azo]-2-naphthol (EC No. 222-429-4) • CCH-020/2021: 1-(4-methyl-2-nitrophenylazo)-2-naphthol (EC No. 219-372-2) • CCH-030/2021: 1,3,2-dioxathiane 2,2-dioxide (EC No. 214-022-5) • TPE-031/2021: Lithium tetrafluoroborate, anhydrous (EC No. 238-178-9)	**SECR** to upload on Interact the agreed decisions in the respective case agenda points.
Item 8.1– SVHC Identification **Written procedure report on seeking agreement on draft decisions on SVHC Identification**	
MSC took note of the report.	**SECR** to publish the final MSC agreements, the support documents and RCOMs on the ECHA website. **SECR** to add the newly identified SVHC to the Candidate List (update foreseen in July

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	2021).
Item 8.2 – SVHC Identification **Seeking agreement on draft agreementss when amendments were proposed by MSCA's/ECHA *(Session 2, closed)***	
MSC unanimously agreed to identify the following substances as SVHCs (and unanimously agreed on the respective agreements and support documents): • Medium chain-chlorinated paraffins (MCCP) • Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP) • 1,4-dioxane (EC No. 204-661-8; 123-91-1)	**SECR** to publish on Interact the agreed documents in the respective case agenda points and to publish them on the ECHA website. **SECR** to add the newly identified SVHC to the Candidate List (update foreseen in July 2021).
Item 11 – Any other business	
• Suggestion from members: Clarification of the existing REACH requirement for *in vivo* genotoxicity testing if *in vitro* genotoxicity tests are not applicable/appropriate *(closed session)*	
MSC took note of the information presented.	**MSC members** to send written comments on the topic to MSC member from SE in Katarzyna.Malkiewicz@kemi.se by 30 June 2021, with a copy to MSC functional mailbox in msc@echa.europa.eu.
• Suggestion from members: Use of the Chromosome Aberration (CA) test under REACH both in *in vitro* and *in vivo*	
MSC took note of the topic related to Chromosome Aberration (CA) test under REACH both in in vitro and in vivo	**MSC member from DK** to organise an informal expert group. **MSC** to nominate mutagenicity experts to the expert group by 30 June 2021 to DK member with MSC functional mailbox in copy **Expert group** to submit a meeting document for MSC-75 by 24 September 2021.
Item 12 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-74 at the meeting.	**SECR** to upload the main conclusions and action points on Interact by 18 June 2021.