

**Minutes of the 86<sup>th</sup> Meeting**  
**of the Member State Committee**  
**(MSC-86)**

**Tuesday 11 June to Thursday 13 June 2024**

# Summary Record of the Proceedings and Conclusions and action points

## Chair's opening address

The Chair, Katinka van der Jagt, welcomed all participants to the 86<sup>th</sup> MSC meeting.

<b>Agenda point</b>	
<b>Conclusions / agreements / adoptions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<b>Item 2 – Adoption of the Agenda</b>	
The Agenda (MSC/A/86/2024) was adopted as modified at the meeting.	<b>SECR</b> to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-86 minutes.
<b>Item 3 – Declaration of specific interests to items on the Agenda</b>	
No potential conflicts of interests were declared by the MSC Chair, any members, experts or advisers with any item on the agenda of MSC-86.	
<b>Item 4 – Administrative issues</b>	
<ul style="list-style-type: none"> <li>Outlook for MSC-87</li> </ul> <p>The Chair presented an outlook on the potential length of the MSC-87 (October 2024) meeting.</p> <ul style="list-style-type: none"> <li>Update on Interact functionalities</li> </ul> <p>SECR updated MSC on new functionalities of the Interact platform.</p> <ul style="list-style-type: none"> <li>Committee procedures: Interaction with stakeholders during ongoing MSC procedures</li> </ul> <p>MSC was reminded that in line with the 'General principles and guidance for Committee members of ECHA' the MSC members are expected to refrain from communicating with stakeholders on dossiers that are currently ongoing with the Committee. It is of importance that those wishing to communicate with MSC members are made aware of these principles and also that these are respected by all parties.</p>	
<b>Item 5 – Minutes of the MSC-85</b>	
SECR informed the Committee that the minutes of MSC-85, adopted by MSC at that meeting, are published on Interact and on ECHA's website.	
<b>Item 6 - Substance evaluation</b>	
<b>1. Introduction to and preliminary discussion on draft decisions on substance evaluation when amendments were proposed by MS-CA's/ECHA</b>	
<p><b>SEV-2-PT-017/2019 bis(2-ethylhexyl)amine EC No. 203-372-4</b></p> <p><b>Session 1 &amp; 2 (open &amp; closed)</b></p> <p>No representatives of the Registrant participated in the discussion. In the absence of specific confidentiality concerns in the DD, an open session was held to introduce the case, followed by discussion and agreement-seeking in closed session.</p> <p>The evaluating MSCA presented the case to the MSC, summarising the proposals for amendment (PfAs) received from an MSCA.</p> <p>MSC discussed the requests in the DD and the PfAs. Considering the revisions required, and to provide the Registrant(s) an opportunity to comment on the revised draft decision and more detailed justification for each request, the evaluating MSCA proposed to:</p> <ul style="list-style-type: none"> <li>withdraw the existing SEv draft decision from agreement-seeking at MSC-86 and no</li> </ul>	

<p>substance evaluation decision would be adopted by ECHA meaning that no decision will be sent to the Registrant(s) at this time; and</p> <ul style="list-style-type: none"> <li>restart the decision-making process with a revised SEv draft decision.</li> </ul> <p>The MSC unanimously agreed on this approach in closed session.</p>	
<p>The MSC reached unanimous agreement on the proposal to withdraw the existing draft decision for SEV-2-PT-017/2019 (bis(2-ethylhexyl)amine, EC No. 203-372-4) and restart the decision-making process with a revised draft decision requesting the information as considered by MSC.</p>	<p><b>SECR</b> to upload on Interact the withdrawal agreement in the respective case agenda point.</p>
<p><b>Item 7 - Dossier evaluation - Discussion and seeking agreement on draft decisions (DDs) on compliance checks when amendments were proposed by MS-CA's</b></p>	
<p>Compliance check</p> <p><b>CCH-026/2024</b> <b>2,4,6-tribromophenol (EC No. 204-278-6)</b></p>	
<p><b>Session 1 &amp; 2 (open &amp; closed)</b></p> <p>A representative of the Registrant joined the meeting to follow the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held followed by discussion and voting in closed session.</p> <p>ECHA Secretariat (SECR) introduced the proposals for amendment (PfAs) that required discussion in the meeting.</p> <p>The PfA suggested to include a request to perform a fish sexual development test (OECD TG 234), triggered at Annex VIII based on the identified endocrine disruption (ED) potential and to extend the deadline to provide the data accordingly.</p> <p>The PfA was justified by publicly available data on the Substance, assessed based on the OECD Conceptual Framework (OECD CF, i.e. OECD 150):</p> <ul style="list-style-type: none"> <li>OECD CF Level 2 (in vitro data): increase of aromatase activity in the human adrenocortical cell line; inhibition of estradiol sulfotransferase activity and reduction of estrogen sulfation in recombinant yeast assays; weak estrogenic activity in vitro in the human breast cancer cell line; reduction of transcriptional activity of both estrogen and androgen receptors in recombinant yeast assays;</li> <li>OECD CF Level 3 (in vivo data): zebrafish adults showing higher plasma vitellogenin (VTG); effects on gonadal morphology (e.g. increased number of atretic follicles and decreased number of spermatid cysts); reduced fertilisation;</li> <li>OECD CF Level 4 (in vivo data): zebrafish embryos showing increase of plasma testosterone and estradiol levels in males and decrease in females; increase of expression of steroidogenic genes in the brain and testes of males and decrease in the brain and ovary of females; decrease of the expression of the gene encoding vitellogenin in females and increased in males; sex ratio alteration resulting in higher number of males.</li> </ul> <p>SECR had modified the draft decision, in line with the PfA, awaiting discussion in the meeting.</p> <p>The Registrant had submitted written comments, however, they were considered out of scope of the PfA as they reiterated comments provided to the initial draft decision, on requests other than the fish sexual development test (OECD TG 234).</p> <p>MSC discussed the relevance of the available data. MSC acknowledged that the evidence raised in the PfAs is sufficient to indicate that the Substance may have Estrogen/Androgen/Steroidogenesis (EAS) activity in fish based on e.g. information on vitellogenin concentration, gonadal effects and sex ratio variations observed in zebrafish.</p>	

MSC considered that the ED hazard potential satisfy the column 2 condition (Annex VIII, section 9.1) for triggering additional long-term aquatic toxicity testing, i.e. a fish sexual development test (OECD TG 234).

Discussion outcome:

MSC concluded that the evidence presented in this case justifies inclusion of the fish sexual development test (OECD TG 234) request and agreed to modify the draft decision in line with the arguments presented in the PfA.

The MSC reached unanimous agreement on the following ECHA draft decision:

- CCH-026/2024  
2,4,6-tribromophenol (EC No. 204-278-6)

**MSC** to consider the draft decision uploaded in Interact in the respective case agenda point as the agreed decision.

### **7.3. General topics**

#### **1. Discussion on requests related to aneugenicity assessment in the *in vivo* MN test**

SECR presented a proposal for clarification of the text included in the decisions for aneugenicity potential assessment when an *in vivo* Micronucleus test is requested.

MSC agreed to:

- Keep the conditional request for aneugenicity potential assessment as agreed in MSC-78.
- Keep a general reference to paragraph 42 of OECD TG 474 (which indicates several methods for differentiation between clastogens and aneugens: e.g. FISH, CREST, other methods if scientifically justified).
- Explain why information on aneugenicity is important.

#### **2. Update on tonnage band downgrades and cessations of manufacture/import**

SECR presented an update on tonnage band downgrades and cessations of manufacture or import, and the consequences of combination of both of them for the dossier evaluation decision-making.

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

#### **Triphenyl phosphate**

The dossier submitter from the French CA had requested by email on 10 June 2024 that ECHA suspend the MSC agreement seeking process for the SVHC identification of triphenyl phosphate (TPhP) originally foreseen to take place at MSC-86. This is because the lead registrant of TPhP had provided on 6 June 2024 (seven weeks after the expiry of the deadline for commenting on the Annex XV dossier) substantial new information on the substance that should be considered before continuation of the agreement seeking process. The information appears to relate to an OECD Conceptual Framework level 5 study (Medaka Extended One Generation Reproduction Test) commissioned by the Japanese Ministry of Environment. The original study documentation is in Japanese. The potential existence of the study was referred to in a comment submitted by the UK Environment Agency during the consultation of interested parties (comment #5839).

MSC discussed the procedural and legal aspects of the case in closed session. Under these circumstances, MSC considered it appropriate for ECHA to exceptionally suspend the process for the MSC to reach unanimous agreement on the SVHC identification of TPhP. This suspension of the procedure ensures that the newly provided data will be properly evaluated and considered in the SVHC identification process. Agreement seeking on the SVHC identification of TPhP was taken off the agenda of MSC-86.

In the open session, an expert to Cefic said that they expect to receive an official translation of the new study in the beginning of July 2024 and that they have requested also for the raw data of the study. To address the questions from ClientEarth and ChemSec, the MSC Chair said that the documents related to the new study will be made available to the stakeholders after their ownership and confidentiality have been clarified.

This suspension means that the MSC will not be able to reach agreement within the procedural time-line of 30 days from the date of referral, but instead the agreement will be sought in a future MSC meeting. This arrangement is to be considered exceptional and applies only in the conditions specific to this case.

MSC supported ECHA to suspend the agreement seeking process for the SVHC identification of triphenyl phosphate TPhP under these exceptional conditions.

**The dossier submitter** to evaluate and consider the relevance of the new study on TPhP in their SVHC proposal.

One SVHC case had been agreed by MSC in written procedure (see Appendix of the Final Agenda below).

**SECR** to add the SVHC identified in written procedure to the Candidate List (update foreseen by 3 July 2024).

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

**A. Draft 12<sup>th</sup> recommendation for priority substances to be included in Annex XIV**

SECR presented some highlights from the comments received during the consultation of interested parties (7 February - 7 May 2024) on ECHA’s draft 12th recommendation, that included the following 5 substances/group of substances:

- Melamine
- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
- Barium diboron tetraoxide
- bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof
- 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

Vast majority of the comments received are on melamine. The main issues raised in the comments were presented in a brief summary format grouped to priority and general issues, comments on dates and comments related to exemptions. The summary aimed to give a preliminary idea on questions to be assessed during the next steps of the process.

As regards the next steps, SECR informed that it will provide its draft responses to comments received, updated prioritisation table and Latest Application Date (LAD) proposed assignments to MSC by end of October, enabling MSC opinion-development with the target of having the first discussion on the draft opinion at MSC-88.

Volunteers for the opinion drafting had been invited in advance of the meeting, and in the discussion MSC saw a need to appoint rapporteur and co-rapporteur for the tasks and to set up a working group to support them.

MSC took note of the highlights presented and the planned next steps.

**SECR** to send the appointment letters to the Rapporteur and the Co-Rapporteur after the meeting.

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. The absence of any specific interests will be confirmed in writing as part of the appointment process.

**SECR** to share the outcome of its assessments of the comments, updated prioritisation table and proposed LAD assignment with MSC by end of October 2024.

MSC established a working group with a defined mandate to support the rapporteurs and appointed four members to it, in addition to the rapporteur and co-rapporteur.

**B. Draft recommendation to amend Annex XIV entry of dibutyl phthalate (EC No. 201-557-4)**

SECR informed about the outcome of the consultation of interested parties (7 February – 7 May 2024) on the amendment recommendation of the substance dibutyl phthalate. No comments were received. SECR introduced the expected MSC task and possible options for the timeline of the MSC opinion development and adoption.

The MSC expressed a preference for an early adoption of the opinion (i.e., discussion and adoption in MSC-87 in October). Volunteers for the opinion drafting had been invited in advance of the meeting, and in the discussion MSC saw a need to appoint rapporteur for this task.

MSC adopted the mandate and the tasks of the rapporteur and appointed one member as the Rapporteur for drafting the opinion of the MSC. The absence of any specific interests will be confirmed in writing as part of the appointment process.

**SECR** to send the appointment letter to the Rapporteur after the meeting.  
**Rapporteur** to prepare draft opinion for discussion and possible adoption in the MSC-87 meeting in October.

**Item 11 – Any other business**

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

A short update was provided on behalf of BoA on recent decisions. The update triggered several comments and questions which the BoA representative addressed in his responses.

SECR gave an overview of pending appeal and court cases and recent judgements on Evaluation and SVHC identification in open session.

2. Updated Guidance on IR&CSA Chapter R.11 and specific sections of Chapters R.7b and R.7c

SECR gave an overview of the changes introduced in R.7b, R.7c and R.11 updates (Dec. 2023). The new updates were related to the assessment of Persistence, Bioaccumulation and (eco)Toxicity. The need for further revision of the Guidelines was acknowledged.

3. Access to documents requests at ECHA

SECR gave presentation on the ATD (access to documents) rules, ECHA policy and procedure, and on the recent ATD request concerning the closed session documents of MSC-83.

The MSC members and stakeholders made clarifying questions and observations on the presentation.

4. Update on developments regarding new approach methods (NAMs)

SECR gave an update on the developments regarding NAMs.

Following the presentation, MSC members and stakeholders had several detailed questions and observations which reflected the importance of the subject also within this forum.

**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-86

MSC adopted the Summary Record of the Proceedings and Conclusions and Action points at the plenary meeting.

**SECR** to upload the Summary Record of the Proceedings and Conclusions and Action points from MSC-86 on Interact by 18 June 2024 as well as ECHA website without undue delay.



## **Proxies**

n/a

## **Experts and advisers to MSC members**

MÜHLEGGER Simone (AT) – Expert to STOCKER, Eva (remote attendance)  
REHRL Anna-Lena (AT) – Expert to STOCKER, Eva (remote attendance)  
DOBRAK-VAN BERLO Agnieszka (BE) - Expert to VANDERSTEEN, Kelly  
FILIPOVA Hristina (BG) - Expert to HOROZOVA, Petya  
KOZMÍKOVÁ Jana (CZ) -Expert to KULHANKOVA, Pavlina  
GÜNDEL Ulrike(DE) – Expert to FINDENEKG, Helene (remote attendance)  
JÖHNCKE Ulrich (DE) – Expert to FINDENEKG, Helene (remote attendance)  
KAßNER Franziska (DE) – Expert to FINDENEKG, Helene (remote attendance)  
ROSENTHAL Esther (DE) – Expert to FINDENEKG, Helene (remote attendance)  
UNKELBACH Christian (DE) – Expert to FINDENEKG, Helene (remote attendance)  
MARTIN Nellie Anne (DK) - Expert to BOLWIG, Asger  
RATUŠNAJA Sofia (EE) – Expert to SAKSA, Jana (remote attendance)  
KAARTINEN Tomi (FI) - Expert to RISSANEN, EEVA  
LAAKKONEN Anita (FI) - Expert to RISSANEN, EEVA (remote attendance)  
BEAUSOLEIL Claire (FR) -Expert to BARTHELEMY BERNERON, Johanna (remote attendance)  
BURGA Karen (FR) - Expert to BARTHELEMY BERNERON, Johanna (remote attendance)  
LOZACH Jérôme (FR) - Expert to BARTHELEMY BERNERON, Johanna (remote attendance)  
PASQUIER Elodie (FR) - Expert to BARTHELEMY BERNERON, Johanna (remote attendance)  
ŽELJEŽIĆ Davor (HR) - Expert to GRIZELJ, Romana  
ALIVERNINI Silvia (IT) - Expert to ATTIAS, Leonello (remote attendance)  
CATONE Tiziana (IT) - Expert to ATTIAS, Leonello  
VOLUJEVIĆ Beata (LT) - Expert to BALCIUNIENE, Jurgita  
VERBRUGGEN Eric (NL) - Expert to DE KNECHT Joop (remote attendance)  
REIERSON Linda Marie (NO) - Expert to BAUMBUSCH, Angelika  
CIEŚLA Jacek (PL) - Expert to DUDRA, Agnieszka  
MENDONÇA Elsa (PT) - Expert to ALMEIDA, Ines  
SANTOS Sónia (PT) - Expert to ALMEIDA, Ines  
COPOIU Oana (RO) - Expert to MIHALCEA UDREA, Mariana  
ANDERSSON Yvonne (SE) - Expert to MALKIEWICZ, Katarzyna (remote attendance)  
KARLSSON Maja (SE) - Expert to MALKIEWICZ, Katarzyna

## **Occasional Stakeholder Experts**

N/A

## **Experts to regular observers**

GIANMOENA, Kathrin (Expert for Cefic Observer) for AP 8.1. SVHC identification for Triphenyl phosphate  
AGYEMAN-BUDU Esther (Expert for Cefic Observer) for AP 9. ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC

## **Case owners**

The case owner representative was attending under the Agenda Item 7.1 for CCH-026/2024 - 2,4,6-tribromophenol (EC No. 204-278-6)



### III Final Agenda

# Final Draft Agenda

## 86<sup>th</sup> meeting of the Member State Committee

11 - 13 June 2024  
ECHA Conference Centre

11 June 2024: starts at 11:00 am  
13 June 2024: ends at 3:00 pm

#### Item 1 – Welcome and Apologies

#### Item 2 – Adoption of the Agenda

MSC/A/086/2024  
**For adoption**

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

#### Item 4 – Administrative issues

- Outlook for MSC-87
  - Update on Interact functionalities
- For information**
- Committee procedures: Interaction with stakeholders during ongoing MSC procedures (*Open and closed session*)
- For information and discussion**

#### Item 5 – Minutes of the MSC-85

- [Adopted minutes of MSC-85](#)
- 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*):

**For discussion followed by agreement seeking under 6.2:**

MSC code	Substance name	EC/List No./ Documents
SEV-2-PT-017/2019	bis(2-ethylhexyl)amine	203-372-4 / ECHA/MS-86/2024/ 012-013

**For discussion**

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

As listed under 6.1

**For agreement**

### 3. General topics

[For information]

#### Item 7 – Dossier evaluation

*Closed session for 7.2, 7.3.1 and 7.3.3*

#### 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)

ECHA/MSC-86/2024/005  
(members only)  
**For information**

*For discussion followed by agreement seeking under 7.2:*

##### Compliance checks

MSC code	Substance name	EC No. / Documents
CCH-026/2024	2,4,6-tribromophenol	204-278-6 / ECHA/MSC-86/2024/ 006-7

##### Testing proposal examinations

None

**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)

As listed under 7.1

**For agreement**

### 3. General topics

- 1) Discussion on requests related to aneugenicity assessment in the *in vivo* MN test (Closed session)

**For discussion**

- 2) Update on tonnage band downgrades and cessations of manufacture/import

**For information**

- 3) Follow-up on germ cells at Annex IX & X: requests for TGR assay and recommendations for comet assay (Closed session)

ECHA/MSC-86/2024/011  
**For information**

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

- Discussion on late submission of data and legal procedures (Closed session)

**For information and discussion**

- Seeking agreement on Annex XV proposals for identification of SVHC

<b>Substance name</b>	<b>EC No.</b>	<b>Documents</b>
Triphenyl phosphate	204-112-2	ECHA/MSC-86/2024/008-10

**[For discussion and agreement]**

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

**A. Draft 12<sup>th</sup> recommendation for priority substances to be included in Annex XIV**

- 1) Highlights of comments received

**For information**

- 2) Appointment of Rapporteur(s) and possible Working Group

ECHA/MSC-86/2024/001-2

**For decision**

**B. Draft recommendation to amend Annex XIV entry of dibutyl phthalate (EC No. 201-557-4)**

- 1) Introduction and discussion of the MSC task and timeline

ECHA/MSC-86/2024/003-4

**For discussion**

- 2) Appointment of Rapporteur(s)

**For decision**

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

Not applicable to this meeting

**[For information]**

**Item 11 – Any other business**

**Partly closed session for 11.1**

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

*(Partly closed session)*

**For information**

2. Introduction to the updated ECHA Guidance on IR&CSA, Chapter R.11: PBT-assessment and Chapters R.7b/c: End point specific guidance

**For information**

3. Access to documents requests at ECHA

**For information**

4. Update on developments regarding NAMs

**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-86

**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 dossier evaluation (For members only)
- Written procedure report on seeking agreement on identification of SVHCs
- Compilation of comments from MSC to the MSC-84 topic 'Effects meeting the classification criteria in testing proposals'

## APPENDIX to the MSC-86 agenda:

### List of cases agreed by MSC in written procedure in advance of the MSC-86 meeting:

#### *Dossier evaluation*

##### **Compliance checks**

<b>MSC code</b>	<b>Substance name</b>	<b>EC/List No.</b>
CCH-013/2024	tert-pentyl 2-ethylperoxyhexanoate	211-687-3
CCH-029/2024	Monalazone disodium	262-810-2
CCH-047/2024	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	202-112-7
CCH-051/2024	2,4-dioxo-1,3-diazetidone-1,3-bis(methyl-m-phenylene) diisocyanate	247-953-0
CCH-056/2024	Reaction products of tetrakis(hydroxymethyl)phosphonium chloride, urea and tetradecan-1-amine	436-230-7

##### **Testing proposal examinations**

<b>MSC code</b>	<b>Substance name</b>	<b>EC/List No.</b>
TPE-016/2024	Cyclohex-1,2-ylenediamine	211-776-7

#### *Identification of SVHCs*

<b>Substance</b>	<b>EC No.</b>
Bis( $\alpha,\alpha$ -dimethylbenzyl) peroxide	201-279-3