

**Minutes of the 80<sup>th</sup> Meeting  
of the Member State Committee  
(MSC-80)**

**Tuesday 13 December  
to Thursday 15 December 2022**

# 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 80<sup>th</sup> MSC meeting. While looking forward to a lively meeting she mentioned a few of the highlights of the meeting, including interesting substances such as melamine (under SVHC item) and lead (under Annex XIV recommendations). For decision making she mentioned the Substance evaluation draft decision for which MSC is expected to have a thorough discussion before it can conclude. Furthermore, she noted the adoption of the MSC opinion on some phenols, namely BPF and BPAF and its salts, which is also planned for this meeting. She also noted the launch of the CoRAP update process and Annex XIV recommendations where ECHA is presenting to MSC the impact of comments and registration updates.

<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/80/2022) was adopted with the addition of a sub-item of ECHA's Executive Director's address to MSC.	<b>SECR</b> to upload the adopted Agenda to Interact and the ECHA website as part of the MSC-80 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-80.	
<b>Item 4 – Administrative issues</b>	
Outlook for MSC-81	
The Chair presented an outlook on the potential length of the MSC-81 (February 2023) meeting.	
The Chair thanked the MSC Deputy Chair Charmaine Ajao for her contribution in the MSC Secretariat at the event of change of her role in ECHA.	
ECHA's Executive Director in her address to MSC highlighted the importance of MSC's work and its contributions for continuation of processes within ECHA, the decision-making and in implementing REACH. She congratulated MSC for its 80 <sup>th</sup> meeting and expected that the good collaboration will be essential also in future.	
<b>Item 5 – Minutes of the MSC-79</b>	
SECR informed the committee that the minutes of MSC-79, adopted by MSC at that meeting, are published on Interact and on ECHA's website.	
<b>Item 6 – Substance evaluation - Introduction to and preliminary discussion on draft decisions on substance evaluation when amendments were proposed by MS-CA's/ECHA (session 1) &amp; agreement seeking on draft decisions (session 2):</b>	
<b>SEV-FR-001/2021</b>	<b>Reaction products of diphenylamine with nonene, branched (EC No. 701-385-4)</b>

### **Session 1 & 2 (open & closed)**

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

The evaluating MSCA presented the case to the MSC, summarising the proposals for amendment (PfAs) received from an MSCA and ECHA.

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

The representatives of the Registrants summarised their comments on the PfA. In particular, they restated their position that the existing OECD TG 211 study with the substance delivered inconclusive data to determine T for environment. Furthermore, they supported the PfA to clarify T for environment on the constituent MNDPA via a Daphnia magna reproduction test (OECD TG 211). They reiterated their view that the OECD TG 211 study should be performed using passive dosing to avoid physical effects due to emulsion.

The MSC agreed that the available information raised a concern as to whether the constituent MNDPA may be PBT/vPvB in the environment, and that further information was needed to clarify this concern. Furthermore, the MSC agreed that an OECD TG 211 study was the most appropriate and least onerous approach to provide information to further clarify the concern.

MSC agreed unanimously to the DD with further amendment at the meeting.

The MSC reached unanimous agreement on the following ECHA draft decision with further amendment at the meeting:

SEV-FR-001/2021 Reaction products of diphenylamine with nonene, branched (EC No. 701-385-4)

One MSC member abstained from voting.

**SECR** to upload on Interact the agreed Decision document in the respective case agenda point.

### **6.3. General topics**

Reporting back on any learnings from WP

SECR presented learnings from the Substance Evaluation (SEv) written procedure and meeting cases, specifically:

- Highlighting the request for a combined Fish short term reproduction assay (OECD TG 229) and Fish Sexual Development Test (OECD TG 234), which was not previously requested in SEv draft decisions referred to MSC.

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

#### **8.1 Melamine (EC No. 203-615-4)**

The dossier submitter (DS) expert from the German CA presented to MSC the draft Support Document (SD) based on the Annex XV proposal for melamine 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) 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 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 from the environment and water purification, urinary tract toxicity, carcinogenic effects and reproductive toxicity of melamine and effects on fish and aquatic invertebrates and reproductive toxicity in rats and other mammals.

The DS expert outlined the main comments received in the consultation on the Annex XV report, DS's responses to them and how they have been reflected in the SD. The consultation had yielded both supporting and diverging views. An observer made reference to 'new data'

introduced in the revised SD regarding probable serious effects on the environment. It was explained that the new data (extended one-generation reproductive toxicity study conducted in rats as relevant for mammals in the environment, study on birds) were added as part of the response to comments received.

An alternate member and a member proposed changes in the SD regarding mobility of melamine and data on melamine in indoor dust. These were accepted by MSC. MSC further discussed the issues of removal of melamine from aqueous media and of deriving a safe concentration of melamine. MSC considered other issues raised in the consultation as resolved without further discussion. In addition, an observer and two experts to observers revisited some of the industry comments submitted in the consultation regarding increasing and irreversible concentration of melamine in the environment and yet unknown effects of melamine, but MSC considered them being sufficiently addressed in the SD and RCOM. EEB also on behalf of some other NGO observers supported the identification of melamine as SVHC and reminded that exposure, risks and socio-economic considerations are not part of SVHC identification.

MSC agreed with the changes proposed in the Support Document and unanimously agreed that Melamine is a substance under Article 57 (f) of Regulation (EC) 1907/2006 (REACH), 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 REACH Regulation.

Four MSC members abstained from voting:  
AT, CZ, DK, HU.

One MSC member provided a written justification for their abstention (see section IV).

**SECR** to upload the MSC agreement, the support document and RCOMs, on Interact and to publish them on the ECHA website.

**SECR** to add the newly identified SVHC to the Candidate List (update foreseen on 17 January 2023).

## 8.2. General topics

Reporting back on any learnings from WP

SECR reported that MSC had agreed via a written procedure to unanimously identify six substances as SVHC as described in the Written Procedure report. Regarding learnings from WP SECR emphasised the importance of trying to resolve any potential scientific issues in the Expert Group discussion to avoid them coming up again in the SVHC consultation. SECR also recommended the MSC members to try to be very clear in their wordings when they are submitting proposals for editorial comments in the WP.

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

#### 1. Impact of comments and registration updates: Introduction to the responses and foreseen updates to ECHA’s (draft) 11<sup>th</sup> recommendation

Secretariat presented the outcome of its assessment on the impact of the comments and registration updates on ECHA’s draft 11th recommendation of priority substances for inclusion in Annex XIV. It was explained that for three substances (2-(4-tert-butylbenzyl) propionaldehyde, ethylenediamine, glutaral) the scores for volume and/or wide-dispersiveness of use were revised. However, these changes did not impact the overall priority, but the substances remained to be recommended for inclusion in Annex XIV.

SECR described the feedback received regarding the latest application dates (LADs) and that it had applied the agreed approach for transparent assessment and setting of the LADs. For lead, ECHA concluded that a LAD of at least 36 months would be justified. Furthermore, considering the Agency’s capacity to handle applications, Commission might contemplate the possibility to define additional longer LADs for certain uses.

Specific exemption requests had been received for three of the substances (ethylenediamine, glutaral and lead) and these were addressed separately in the presentation as well as in the draft response documents prepared by ECHA. The Agency did not propose exemptions for any of the substances, however if the Commission would consider exemptions possible for lead, ECHA sees stronger cases for uses exempted/authorised and subject to regular review under RoHS, ELV and DWD.

The updated prioritisation table, LAD assignments and draft responses as provided to MSC provided further details of the modifications and reasons for them.

In the following discussion related to lead, further clarification was requested by industry observers on the relevance of the scoring where effects of existing and new risk management measures are not known. Another concern raised by industry observers was on the workability due to the expected high number of authorisation applications for uses of lead, as well as the expected long delays in processing those through the Committees. While importance of exemptions based on existing legislation was highlighted it was also questioned if there are any emissions from uses in the scope of authorisation that would not be covered by current risk management measures.

**2. Feedback from the MSC Rapporteur and discussion of the draft opinion on ECHA's draft 11<sup>th</sup> recommendation**

MSC took note of the first draft support document of the opinion prepared by the MSC Rapporteurs and the Working Group. In the discussion no objections to the draft opinion were raised while further comments were provided concerning exemption possibilities for lead.

**MSC** to provide feedback and input to the Rapporteur by 16 January 2023.  
**Rapporteur** to prepare the draft opinion and support document for adoption at the February plenary by 25 January.

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

Introduction of the draft CoRAP update for 2023-2025 by SECR

MSC took note of the draft CoRAP update for 2023-2025 and the changes and new substances that were added to it.

**MSC** to provide any feedback to the Rapporteur for the opinion drafting by 13 January 2023.  
**Rapporteur** to provide the draft opinion of MSC on the draft CoRAP update by 25 January 2023 for adoption in MSC-81.

**Item 11 – Request to MSC for an opinion in accordance with Article 77(3) c of REACH Regulation**

Presentation of the second draft MSC opinion on the endocrine disrupting properties of BPF and BPAF and its salts by the Rapporteurs

The Rapporteur presented the second draft of the MSC opinion on ED properties for environment of BPF and BPAF and eight BPAF salts. The Rapporteurs introduced the comments received in the MSC commenting round and how they had been addressed in the RCOM, and the respective revisions made in the draft MSC opinion. The MSC agreed to the revisions and adopted the revised opinion by consensus. The MSC agreed that BPF and BPAF and its salts are endocrine disruptors to the environment.

**SECR** to submit a cleaned version of the opinion to the Rapporteurs, and the **Rapporteurs** to review it by 19 December.  
**MSC Chair** to submit the MSC opinion to the Chair of ECHA's Risk Assessment Committee.

	SECR to upload the MSC opinion in Interact and to publish it on ECHA's website without undue delay.
<b>Item 12 – Any other business</b>	
1. Update on appeals and court cases of relevance to MSC	
<p><b>Session (open &amp; closed)</b></p> <p>A short update was provided on behalf of BoA on one case on which the BoA had reached its decision in October 2022.</p> <p>SECR gave an overview on new and pending appeal and court cases on SVHC identification and Evaluation in both open and closed sessions.</p>	
2. Introduction of EEB report Need for Speed	
<p>A presentation regarding the Need for Speed report was given by the EEB in an open session. This report analyses the time needed to conclude different REACH and CLP procedures (CLH, SVHC identification, AfAs, etc) and suggest changes that could speed up the process.</p> <p>The MSC and COM commented that although some of the timelines could be reconsidered, the general push for achieving results was appreciated.</p>	
<b>Item 13 – Adoption of summary record of the proceedings and conclusions and action points</b>	
Table with summary record and conclusions and action points from MSC-80	
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-80 on Interact by 16 December 2022 as well as ECHA website without undue delay.



CIESLA, Jacek (PL) (Expert to DUDRA, Agnieszka)  
COPOIU, Oana (RO) (Expert to MIHALCEA UDREA, Mariana)  
EINOLA, Juha (FI) (Expert to RISSANEN, Eeva)  
HORSKA, Alexandra (SK) (Expert to KUROVA, Martina)  
REIERSON, Linda (NO) (Expert to BAUMBUSCH, Angelika)  
UNKELBACH, Christian (DE) (Expert to FINDENEGG, Helene)  
ZELJEZIC, Davor (HR) (Expert to GRIZELJ, Romana)  
JOHANSSON, Tommy (SE) (Expert to MALKIEWICZ, Katarzyna)  
DE KNECHT, Joop (NL) (Expert to VAN BERLO, Damien)  
BRODERICK, Mike (IE) (Expert to CONWAY, Louise)  
HOULIHAN, Margarete (IE) (Expert to CONWAY, Louise)  
ANGELI, Karine (FR) (Expert to BARTHELEMY-BERNERON, Johanna)  
PASQUIER, Elodie (FR) (Expert to BARTHELEMY-BERNERON, Johanna)  
KAARTINEN, Tomi (FI) (Expert to RISSANEN, Eeva)  
KUITTINEN, Marko (FI) (Expert to RISSANEN, Eeva)  
NIEMINEN, Antti (FI) (Expert to RISSANEN, Eeva)  
BURGA, Karen (FR) (Expert to BARTHELEMY-BERNERON, Johanna)  
WAECHTER, Tobias (DE) (Expert to FINDENEGG, Helene)  
BOLWIG, Asger (DK) (Expert to HJORTH, Rune)  
UOTILA, Elina (ES) (Expert to FERNANDEZ SANCHEZ, Raquel)  
VEGA, Milagros (ES) (Expert to FERNANDEZ SANCHEZ, Raquel)  
REHRL, Anna-Lena (AT) (Expert to STOCKER, Eva)  
MÜHLEGGGER, Simone (AT) (Expert to STOCKER, Eva)  
DOBRAK – VAN BERLO, Agnieszka (BE) (Expert to VANDERSTEEN, Kelly)  
GYMNAOU, Panayiotis (CY) (Expert to PALEOMILITOU, Maria)  
KOZMIKOVA, Jana (CZ) (Expert to KULHANKOVA, Pavlina)  
JOEHNCKE, Ulrich (DE) (Expert to FINDENEGG, Helene)  
KUCHERYAVENKO, Olena (DE) (Expert to FINDENEGG, Helene)  
SCHMEISSER, Sebastian (DE) (Expert to FINDENEGG, Helene)

#### **SEV expert**

CHARRON, Isabelle (FR)

#### **SVHC expert**

SCHLIEBNER, Ivo (DE)

#### **Occasional Stakeholder Experts**

TILLIEUX, Geoffroy (EUPC) for AP 8 and AP11

DE KORT, Patrick (Europur), expert to TILLIEUX, Geoffroy

BARBEAU Sophie (Europacable) for AP 9

#### **Experts to regular observers**

ALLEN, Lisa (ILA) (Expert to Eurometaux observer) for AP 9

HYNES, Jarlath (EMPA) (Expert to Cefic observer) for AP 8

#### **Case owners**

Representatives of the Registrant was attending under the Agenda Item 6.1 for SEV-FR-001/2021 - Reaction products of diphenylamine with nonene, branched (EC/List No. 701-385-4):



## Final Agenda

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

13-15 December 2022

ECHA Conference Centre

13/12/2022: starts at 11:00 am

15/12/2022: ends at 3:00 pm

#### Item 1 – Welcome and Apologies

#### Item 2 – Adoption of the Agenda

MSC/A/080/2022  
*For adoption*

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

#### Item 4 – Administrative issues

- Outlook for MSC-81
- ECHA's Executive Director's address to MSC

*For information*

#### Item 5 – Minutes of the MSC-79

- [Adopted minutes of MSC-79](#)

*For information*

#### Item 6 – Substance evaluation

*Start on Day 1, 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-FR-001/2021	Reaction products of diphenylamine	701-385-4

*For discussion*

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

Case as listed above

*For agreement*

**3. General topics**

Learnings from written procedure

*For information*

**Item 7 – Dossier evaluation**

**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:*

**Compliance checks and**

**Testing proposal examinations**

No cases

*[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)**

No cases

*[For agreement]*

**3. General topics**

*[For information]*

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

*Start on Day 1*

**1. Seeking agreement on Annex XV proposals for identification of SVHCs**

<b>Substance name</b>	<b>EC/List No.</b>	<b>Documents</b>
Melamine	203-615-4	ECHA/MSC-80/2022/002-5

*For discussion and agreement*

**2. General topics**

Learnings from written procedure

*For information*

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

3. Impact of comments and registration updates: Introduction to the responses and foreseen updates to ECHA's (draft) 11<sup>th</sup> recommendation<sup>1</sup>

***For information and discussion***

4. Feedback from the MSC Rapporteur and discussion of the draft opinion on ECHA's draft 11<sup>th</sup> recommendation

ECHA/MSC-80/2022/008

***For discussion***

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

Introduction of the draft CoRAP update for 2023-2025 by SECR

ECHA/MSC-80/2022/001

***For information***

#### **Item 11 – Request to MSC for an opinion in accordance with Article 77(3) c of REACH Regulation**

Presentation of the second draft MSC opinion on the endocrine disrupting properties of BPF and BPAF and its salts by the Rapporteurs

ECHA/MSC-80/2022/009-010

***For discussion and adoption***

#### **Item 12 – Any other business**

***Partly closed session***

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

*(Partly closed session)*

***For information***

2. Introduction of EEB report Need for Speed

***For information***

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

- Table with summary record and conclusions and action points from MSC-80

***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 Annex XV proposals for identification of SVHC

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<sup>1</sup> Documents, as shared on 31 October 2022, are available in the MSC-80 folder under 'RECOM pre-meeting' item

## APPENDIX to the MSC-80 agenda:

### List of evaluation cases agreed by MSC in written procedure in advance of the MSC-80 meeting:

#### Substance evaluation

MSC code	Substance name	EC number
SEV-2-DE-025/2016	Isopentyl p-methoxycinnamate	275-702-5
SEV-2-ES-019/20161	Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene	271-867-2

#### Dossier evaluation

No cases

#### SVHC identification<sup>2</sup>

Substance name	EC/List No.
Perfluoroheptanoic acid and its salts (PFHpA)	-
1,1'-[ethane-1,2-diylbisoxo]bis[2,4,6-tribromobenzene] (BTBPE)	253-692-3
Isobutyl 4-hydroxybenzoate (isobutylparaben)	224-208-8
Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof	-
Reaction mass of 2,2,3,3,5,5,6,6-octafluoro- 4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4- (heptafluoropropyl)morpholine (FC-770)	473-390-7
4,4'-sulphonyldiphenol (bisphenol S)	201-250-5

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<sup>2</sup> SVHC proposals for Barium diboron tetraoxide (EC No. 237-222-4) and 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (EC No. 201-236-9) were not referred to MSC but will be added to the Candidate List without MSC involvement.

**IV. Statement from AT member related to agenda item 8.1 with regard to abstaining from voting on SVHC identification of melamine.**

It is currently not clear, which, if any, risk management measure will follow the SVHC identification of melamine. Therefore - notwithstanding the question as to whether melamine fulfils the criteria under art. 57 (f) REACH – Austria is of the opinion that melamine is not adequate for an eventual inclusion in Annex XIV in the sense of art. 59 (1) REACH. Thus, Austria abstains from voting.