Draft Agenda

65th meeting of the Member State Committee

24-27 June 2019
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

24 June: starts at 9 am
27 June: ends at 1 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda
MSC/A/065/2019
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-66
For information

Item 5 – Minutes of the MSC-64
MSC/M/64/2019
For adoption

Item 6 – Substance evaluation
Closed session for 6.3

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

ECHA/MSC-65/2019/007
For information

2. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA’s/ECHA reactions (Session 1, open):

No cases

1 List of agreed cases can be found as an appendix at the end of this draft agenda.
3. **Seeking agreement on draft decisions when amendments were proposed by MS-CA’s/ECHA (Session 2, closed)**

A case stopped in written procedure:

SEV-BE-001/2017\(^2\) 2,4-di-tert-butylphenol  
EC No. 202-532-0

**For agreement**

4. **General topics**

No topics

**[For information]**

**Item 7 – Dossier evaluation**

*Closed session for 7.3 and partly for 7.4*

1. **Written procedure report on seeking agreement on draft decisions on dossier evaluation**\(^1\)  
ECHA/MSC-65/2019/002

**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)**  
ECHA/MSC-65/2019/003

**For discussion followed by agreement seeking under 7.3:**

### Compliance checks

<table>
<thead>
<tr>
<th>MSC code</th>
<th>Substance name</th>
<th>EC No./ Doc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCH-015/2019</td>
<td>Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. residues</td>
<td>272-712-1</td>
</tr>
</tbody>
</table>
|                |                                                                                 | ECHA/MSC-65/2019/004-5

**For discussion**

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

Case as listed above under 7.2  
**For agreement**

4. **General topics**

1) Request of *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers - Implementation proposal (Closed session)  
ECHA/MSC-65/2019/006

**For discussion and agreement**

2) Feedback from ED EG on issues raised by MSC in relation to the use of OECD TG 234 in Dossier Evaluation  
**For information**

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

*Timing: Start Day 1 morning*

1. **Written procedure report on seeking agreement on identification of SVHC**\(^1\)

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\(^2\) Documents are available in the substance specific folder in MSC Circabc under 06. Substance evaluation
2. **Seeking agreement on Annex XV proposals for identification of SVHC**

**Substance**
2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)

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

1. **9th Draft recommendation for inclusion of substances into Annex XIV**
   - Update from SECR
   - **For information and discussion**
     - MSC opinion on ECHA’s Draft 9th recommendation for inclusion of priority substances to be included in Annex XIV
       - Discussion on the draft MSC opinion
       - Adoption of MSC opinion

2. **Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV**
   - Update from SECR
   - **For information and discussion**
     - MSC opinion on ECHA’s Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV
       - Discussion on the draft MSC opinion
       - Adoption of MSC opinion

Item 10 – Opinion of MSC on ECHA’s draft update of the Community Rolling Action Plan (CoRAP 2020-2022)

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update
   - Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur

Item 11 – Any other business
   - **Partly closed session**

1. Update on appeals and court cases of relevance to MSC (Partly closed session)
2. ECHA’s approach to grouping of substances
3. MSC and the development of OECD test guidelines

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3 RCOM is available in MSC S-CIRCABC, 03 SVHC folder, in corresponding Substance-specific folder
4. Use and exposure information in regulatory risk management (Closed session)
ECHA/MSC-65/2019/013

5. Suggestions from members

**Item 12 – Adoption of main conclusions and action points**

- Table with conclusions and action points from MSC-65

**Information documents**

Information documents are not allocated a specific agenda time but the documents are available on MSC CIRCABC 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)
- Option to address non-extractable residues in regulatory persistence assessment (ECHA/MSC-65/2019/014)
APPENDIX to the MSC-65 agenda:

List of evaluation and SVHC cases agreed by MSC in written procedure in advance of the MSC-65 meeting:

### Substance evaluation

<table>
<thead>
<tr>
<th>MSC code</th>
<th>Substance name</th>
<th>EC No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEV-2-SE-032/2013</td>
<td>Bis(isopropyl)naphthalene</td>
<td>254-052-6</td>
</tr>
<tr>
<td>SEV-IT-015/2017</td>
<td>Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides</td>
<td>264-120-7</td>
</tr>
</tbody>
</table>

### Dossier evaluation

**Compliance checks**

<table>
<thead>
<tr>
<th>MSC code</th>
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</tr>
</thead>
<tbody>
<tr>
<td>CCH-017/2019</td>
<td>2-hydroxyethyl acrylate</td>
<td>212-454-9</td>
</tr>
<tr>
<td>CCH-020/2019</td>
<td>Violet sodium polysulfide aluminosilicate with a SOD-type framework structure</td>
<td>701-186-2</td>
</tr>
<tr>
<td>CCH-021/2019</td>
<td>N,N',N'',N''''-tetrakis(4,6-bis(butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)-amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine</td>
<td>401-990-0</td>
</tr>
<tr>
<td>CCH-022/2019</td>
<td>N,N',N'',N''''-tetrakis(4,6-bis(butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine</td>
<td>401-990-0</td>
</tr>
<tr>
<td>CCH-023/2019</td>
<td>Cyclohexylidenebistert-butylperoxide</td>
<td>221-111-2</td>
</tr>
<tr>
<td>CCH-033/2019</td>
<td>Cetrimonium chloride</td>
<td>203-928-6</td>
</tr>
<tr>
<td>CCH-037/2019</td>
<td>Bis(2-(2-butoxyethoxy)ethyl) adipate</td>
<td>205-465-5</td>
</tr>
</tbody>
</table>

### Testing proposal examinations

<table>
<thead>
<tr>
<th>MSC code</th>
<th>Substance name</th>
<th>EC/List No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPE-049/2019</td>
<td>Terpineol</td>
<td>701-188-3</td>
</tr>
<tr>
<td>TPE-050/2019</td>
<td>Silver</td>
<td>231-131-3</td>
</tr>
<tr>
<td>TPE-053/2019</td>
<td>Aluminium oxide</td>
<td>215-691-6</td>
</tr>
<tr>
<td>TPE-054/2019</td>
<td>2-(2-thienyl)ethyl toluene-p-sulphonate</td>
<td>254-911-5</td>
</tr>
<tr>
<td>TPE-055/2019</td>
<td>Fatty acids, C16-18 and C18-unsatd., branched and linear, butyl esters</td>
<td>441-620-5</td>
</tr>
</tbody>
</table>

### Substances of Very High Concern (SVHC)

Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)