

## OVERVIEW OF REQUIRED EVIDENCE AND CONSIDERATIONS FOR PRIORITISING

Evidence to be provided		Considerations for priority setting
Substance family		
Substance		
CAS number		
1. Evidence of exposure	<ul style="list-style-type: none"> <li>• Yes/No – give evidence</li> </ul>	<ol style="list-style-type: none"> <li>1. Quality and quantity of human exposure evidence (provider, consistency, use)</li> <li>2. Geographical extent of human exposure (hotspots, regional, EU wide...)</li> <li>3. Population groups exposed (workers, consumers, children (+))</li> <li>4. Source (e.g. diet, workplace) and route of exposure (oral, dermal, inhalation...)</li> <li>5. Emerging substance, mainly environmental monitoring data available</li> </ol>
2. Evidence of potential health impact	<ul style="list-style-type: none"> <li>• Yes/No – indicate which impact and evidence</li> </ul>	<ol style="list-style-type: none"> <li>1. Established hazard(s), incl. PBT characteristics, and link to human health effects including severity of effect and irreversibility</li> <li>2. Evidence involving human data</li> <li>3. Data from animal/in vitro models considered relevant for human health (if available)</li> <li>4. Population groups concerned by the health impact (children (+))</li> <li>5. Emerging substance: uncertainties in hazard data, reason to apply precautionary principle</li> </ol>
3. Evidence of public concern	<ul style="list-style-type: none"> <li>• Yes/No – list evidence</li> </ul>	<ol style="list-style-type: none"> <li>1. Public demand for action and its credibility</li> </ol>
4. Rationale for action/inaction (regulatory aspects)	<ul style="list-style-type: none"> <li>• Yes/No – please indicate relevant legislation, existing opinions, open questions, policy needs and ability to act</li> </ul>	<ol style="list-style-type: none"> <li>1. Regulatory status of substance: banned or restricted substances are of lower priority unless there is risk of exposure or other special reason for monitoring</li> <li>2. Requirement for public health action</li> <li>3. Supporting information for the development/update of legislation</li> <li>4. Monitoring of effectiveness of regulatory measures to reduce exposure</li> </ol>
5. Rational for action/inaction (technical aspects)	<ul style="list-style-type: none"> <li>• Yes/No – list evidence</li> </ul>	<ol style="list-style-type: none"> <li>1. Technical feasibility and available methods for biomonitoring the substance</li> <li>2. Availability and quality of required background knowledge</li> <li>3. Information on risk assessment capacity</li> <li>4. Realistic time frame to allow to respond to policy need</li> </ol>
6. Action expected from EJP	<ul style="list-style-type: none"> <li>• Describe what the EHBMI EJP should be doing and how the expected results will support policy making</li> </ul>	<ol style="list-style-type: none"> <li>1. Concreteness of action required</li> <li>2. Going beyond the state-of-art (incl. avoiding duplication of efforts)</li> <li>3. Use of HBM data &amp; methods is justified</li> <li>4. Cost/benefit ratio estimate</li> </ol>

**TEMPLATE**

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