CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding DEHP in air, water, and other media are summarized in Table 7-1. This table is not an exhaustive list, and current regulations should be verified by the appropriate regulatory agency.

ATSDR develops MRLs, which are substance-specific guidelines intended to serve as screening levels by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites. See Section 1.3 and Appendix A for detailed information on the MRLs for DEHP.

<table>
<thead>
<tr>
<th>Agency</th>
<th>Description</th>
<th>Information</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Air</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EPA</td>
<td>RfC</td>
<td>Not evaluated</td>
<td>IRIS 1988</td>
</tr>
<tr>
<td>WHO</td>
<td>Air quality guidelines</td>
<td>Not listed</td>
<td>WHO 2010</td>
</tr>
<tr>
<td><strong>Water &amp; Food</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EPA</td>
<td>Drinking water standards and health advisories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DWEL</td>
<td>0.7 mg/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10⁻⁴ cancer risk</td>
<td>0.3 mg/L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>National primary drinking water regulations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum contaminant level</td>
<td>0.006 mg/L</td>
<td></td>
<td>EPA 2009c</td>
</tr>
<tr>
<td>Public health goal</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RfD</td>
<td>2×10⁻² mg/kg/day</td>
<td></td>
<td>IRIS 1988</td>
</tr>
<tr>
<td>WHO</td>
<td>Drinking water quality guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guideline value</td>
<td>0.008 mg/L (8 μg/L)</td>
<td></td>
<td>WHO 2017</td>
</tr>
<tr>
<td>Tolerable daily intake</td>
<td>25 μg/kg body weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDA</td>
<td>Substances added to food&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Not listed</td>
<td>FDA 2020</td>
</tr>
<tr>
<td>Indirect additives used in food contact substances&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Allowed for some uses</td>
<td></td>
<td>FDA 2019a</td>
</tr>
<tr>
<td>Allowable level in bottled water</td>
<td>0.006 mg/L</td>
<td></td>
<td>FDA 2019b</td>
</tr>
<tr>
<td>Tolerable intake value (oral)</td>
<td>0.04 mg/kg/day</td>
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<td>FDA 2001</td>
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<tr>
<td><strong>Cancer</strong></td>
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</tr>
<tr>
<td>HHS</td>
<td>Carcinogenicity classification</td>
<td>Reasonably anticipated to be a human carcinogen</td>
<td>NTP 2016</td>
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<tr>
<td>EPA</td>
<td>Carcinogenicity classification</td>
<td>Group B2&lt;sup&gt;c&lt;/sup&gt;</td>
<td>IRIS 1988</td>
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<tr>
<td>IARC</td>
<td>Carcinogenicity classification</td>
<td>Group 2B&lt;sup&gt;d&lt;/sup&gt;</td>
<td>IARC 2013</td>
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### Table 7-1. Regulations and Guidelines Applicable to DEHP

<table>
<thead>
<tr>
<th>Agency</th>
<th>Description</th>
<th>Information</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Occupational</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>OSHA</td>
<td>PEL (8-hour TWA) for general industry, shipyards, and construction</td>
<td>5 mg/m³</td>
<td>OSHA 2019a, 2019b, 2019c</td>
</tr>
<tr>
<td>NIOSH</td>
<td>REL (up to 10-hour TWA)</td>
<td>5 mg/m³</td>
<td>NIOSH 2019</td>
</tr>
<tr>
<td></td>
<td>STEL</td>
<td>10 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Emergency Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPA</td>
</tr>
<tr>
<td>DOE</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

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*a* The Substances Added to Food inventory replaces EAFUS and contains the following types of ingredients: food and color additives listed in FDA regulations, flavoring substances evaluated by FEMA or JECFA, GRAS substances listed in FDA regulations, substances approved for specific uses in food prior to September 6, 1958, substances that are listed in FDA regulations as prohibited in food, delisted color additives, and some substances "no longer FEMA GRAS."

*b* The Indirect Additives Used in Food Contact Substances list is a compilation of substances found in 21 CFR parts 175–178.

*c* Group B2: probable human carcinogen.

*d* Group 2B: possibly carcinogenic to humans.

*e* Potential occupational carcinogen.

*f* Definitions of PAC terminology are available from DOE (2018b).

AEGL = acute exposure guideline levels; CFR = Code of Federal Regulations; DEHP = di(2-ethylhexyl)phthalate; DOE = Department of Energy; DWEL = drinking water equivalent level; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; FEMA = Flavor and Extract Manufacturers Association of the United States; GRAS = generally recognized as safe; HHS = Department of Health and Human Services; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; JECFA = Joint FAO/WHO Expert Committee on Food Additives; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = Protective Action Criteria; PEL = permissible exposure limit; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure limit; TWA = time-weighted average; WHO = World Health Organization