§ 439.17  Pretreatment standards for new sources (PSNS).

Except as provided in 40 CFR 403.7, any new source subject to this subpart must achieve the same standards as specified in §439.16.

(a) Sources that discharge to a POTW with nitrification capability (defined at §439.2(i)) are not required to achieve the pretreatment standard for ammonia (as N).

(b) The pretreatment standards for cyanide are as follows:

<table>
<thead>
<tr>
<th>Regulated parameter</th>
<th>Maximum daily discharge</th>
<th>Maximum monthly discharge must not exceed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyanide (T)</td>
<td>33.5 mg/L (ppm)</td>
<td>9.4 mg/L (ppm)</td>
</tr>
</tbody>
</table>

1 mg/L (ppm)  
2 Not applicable to sources that discharge to a POTW with nitrification capability.

(c) When monitoring for cyanide at the end-of-pipe is impractical because of dilution by other process wastewaters, compliance with the cyanide standards in §439.17(b) must be demonstrated at in-plant monitoring points pursuant to 40 CFR 403.6(e)(2) and (4). Under the same provisions, the permitting authority may impose monitoring requirements on internal wastestreams for any other parameter(s) regulated by this section.

(d) Compliance with the standards in paragraph (b) or (c) of this section may be achieved by certifying to the permit issuing authority that a facility’s manufacturing processes neither use nor generate cyanide.


Subpart B—Extraction Products

§ 439.20  Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by extraction.

[63 FR 50430, Sept. 21, 1998]

§ 439.21  Special definitions.

For the purpose of this subpart:

(a) Extraction means process operations that derive pharmaceutically active ingredients from natural sources such as plant roots and leaves, animal glands, and parasitic fungi by chemical and physical extraction.

(b) Product means any substance manufactured by an extraction process, including blood fractions, vaccines, serums, animal bile derivatives, endocrine products and medicinal products such as alkaloids that are isolated from botanical drugs and herbs.

[68 FR 12272, Mar. 13, 2003]

§ 439.22  Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BPT:

(a) The limitation for BOD₅ is the same as specified in §439.12(a). No facility shall be required to attain a monthly average limitation for BOD₅ that is less than the equivalent of 45 mg/L.

(1) The long-term average daily BOD₅ load of the raw process wastewater (i.e., the base number to which the percent reduction is applied) is defined as the average daily BOD₅ load during any calendar month, over 12 consecutive months within the most recent 36 months, and must include one or more
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periods during which production was at a maximum.

(2) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily BOD \(_5\) load in the influent to the wastewater treatment system must exclude any portion of the load associated with separable mycelia and solvents, except for residual amounts of mycelia and solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent BOD \(_5\) loading.

(3) The practices of recovery, and/or separate disposal or reuse include: physical separation and removal of separable mycelia; recovery of solvents from wastestreams; incineration of concentrated solvent wastestreams (including tar still bottoms); and broth concentration for disposal other than to the treatment system. This part does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for BOD \(_5\) may be achieved by any of several, or a combination, of these practices.

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) Except for the provisions in paragraph (d) of this section, the limitations for COD are as follows:

<table>
<thead>
<tr>
<th>Regulated parameter</th>
<th>Maximum daily (^1)</th>
<th>Maximum monthly average (^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COD</td>
<td>228</td>
<td>86</td>
</tr>
</tbody>
</table>

\(^1\) mg/L (ppm)

(d) If the maximum monthly average COD concentration in paragraph (c) of this section is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then a monthly average limitation for COD corresponding to the lower concentration value must be applied.


§ 439.23 Effluent limitations attainable by the application of the best conventional pollutant control technology (BCT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BCT. Limitations for BOD \(_5\), TSS and pH are the same as the corresponding limitations in § 439.22.

[63 FR 50430, Sept. 21, 1998]

§ 439.24 Effluent limitations attainable by the application of best available technology economically achievable (BAT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT. Limitations for COD are the same as the corresponding limitations in § 439.22(c) and (d).

[63 FR 50431, Sept. 21, 1998]


(a) Any new source subject to this subpart must achieve the following standards:

<table>
<thead>
<tr>
<th>Regulated parameter</th>
<th>Maximum daily (^1)</th>
<th>Maximum monthly average (^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOD (_5)</td>
<td>35</td>
<td>18</td>
</tr>
<tr>
<td>TSS</td>
<td>58</td>
<td>31</td>
</tr>
<tr>
<td>COD</td>
<td>228</td>
<td>86</td>
</tr>
</tbody>
</table>

\(^1\) mg/L (ppm)

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified in 40 CFR 122.29(d)(1), after which the source must achieve the