

authorized for any categorical pollutant (1) for which EPA have established a numerical pollutant limit in Part 503; or (2) which EPA has determined will not threaten human health and the environment when used or disposed of in sewage sludge. The pollutants described in paragraphs (1)–(3) above include all those pollutants that EPA either specifically regulated in Part 503 or evaluated for regulation and determined would not adversely affect sludge use and disposal.

Consequently, in the case of a pollutant for which EPA did not perform a risk assessment in developing the Phase One sewage sludge regulations, removal credit for pollutants will only be available when the Agency determines either a safe level for the pollutant in sewage sludge or that regulation of the pollutant is unnecessary to protect public health and the environment from the reasonably anticipated adverse effects of such a pollutant.³ Therefore, any person seeking to add additional categorical pollutants to the list for which removal credits are now available would need to submit information to the Agency to support such a determination. The basis for such a determination may include information showing the absence of risks for the pollutant (generally established through an environmental pathway risk assessment such as EPA used for Phase One) or data establishing the pollutant's presence in sewage sludge at low levels relative to risk levels or both. Parties, however, may submit whatever information they conclude is sufficient to establish either the absence of any potential for harm from the presence of the pollutant in sewage sludge or data demonstrating a "safe" level for the pollutant in sludge. Following submission of such a demonstration, EPA will review the data and determine whether or not it should propose to amend the list of pollutants for which removal credits would be available.

EPA has already begun the process of evaluating a number of pollutants for adverse potential to human health and the environment when present in sewage sludge. In May, 1993, pursuant to the terms of the consent decree in the *Gearhart* case, the Agency notified the United States District Court for the

District of Oregon that, based on the information then available at that time, it intended to propose 31 pollutants for regulation in the Round Two sewage sludge regulations. These are acetic acid (2,4-dichlorophenoxy), aluminum, antimony, asbestos, barium, beryllium, boron, butanone (2-), carbon disulfide, cresol (p-), cyanides (soluble salts and complexes), dioxins/dibenzofurans (all monochloro to octochloro congeners), endsulfan-II, fluoride, manganese, methylene chloride, nitrate, nitrite, pentachloronitrobenzene, phenol, phthalate (bis-2-ethylhexyl), polychlorinated biphenyls (co-planar), propanone (2-), silver, thallium, tin, titanium, toluene, trichlorophenoxyacetic acid (2, 4,5-), trichlorophenoxypropionic acid ([2-(2,4,5-)], and vanadium.

The Round Two regulations are not scheduled for proposal until December, 1999 and promulgation in December 2001. However, given the necessary factual showing, as detailed above, EPA could conclude before the contemplated proposal and promulgation dates that regulation of some of these pollutants is not necessary. In those circumstances, EPA could propose that removal credits should be authorized for such pollutants before promulgation of the Round Two sewage sludge regulations. However, given the Agency's commitment to promulgation of effluent limitations and guidelines under court-supervised deadlines, it may not be possible to complete review of removal credit authorization requests by the time EPA must promulgate these guidelines and standards.

4. Relationship of Effluent Limitations to NPDES Permits and Monitoring Requirements

Effluent limitations act as a primary mechanism to control the discharges of pollutants to waters of the United States. These limitations are applied to individual facilities through NPDES permits issued by the EPA or authorized States under section 402 of the Clean Water Act.

The Agency has developed the limitations and standards for this proposed rule to cover the discharge of pollutants for this industrial category. In specific cases, the NPDES permitting authority may elect to establish technology-based permit limits for pollutants not covered by this proposed regulation, on a case-by-case basis using best professional judgment. See section 402(a)(1)(B) of the Clean Water Act; 40 CFR 125.3. In addition, if State water quality standards or other provisions of State or Federal law require limits on pollutants not covered by this regulation

(or require more stringent limits on covered pollutants), the permitting authority must apply those limitations. See, e.g., section 301(b)(1)(C) of the Clean Water Act.

For determination of effluent limits where there are multiple products or multiple categories and subcategories, the effluent guidelines would be applied using a flow-weighted combination of the appropriate guideline for each category or subcategory. Where a facility has added a new production facility in conjunction with an existing production facility, the effluent guidelines would also be applied by using a flow-weighted combination of the NSPS limit for the new line and the BAT and BCT standards to the existing lines to derive the limitations. However, as stated above, if State water quality standards or other provisions of State or Federal law require limits on pollutants not covered by this regulation (or require more stringent limits on covered pollutants), the permitting authority must apply those limitations regardless of the limitation derived using the production-weighted combinations.

The Agency does not consider certain wastewaters or materials to be process wastewaters; therefore, these proposed effluent limitations guidelines and standards would not apply to the discharge of such wastewaters. Such materials include, for example, any active anti-microbial materials, wastewater from imperfect fermentation batches, or process area spills. Any pharmaceutical manufacturing facility wishing NPDES authorization to discharge any materials and/or non-process wastestream(s) must specifically disclose this in its permit application. If the permitting authority wishes to authorize this discharge, the permit must specifically authorize the discharge of the specified materials and/or non-process wastestream(s). The effluent limitations in the permit must also reflect a separate analysis, done by the permitting authority on a best professional judgment basis, of the levels of pollutants in such materials and/or non-process wastestream(s) that are commensurate with the application of BPT, BCT, BAT, and PSES. Caution should be exercised in permitting such discharges. Treatment systems may not be designed to accommodate these types of materials and their discharge could adversely affect the treatment systems and receiving waters.

Working in conjunction with the effluent limitations are the monitoring conditions set out in an NPDES permit. An integral part of the monitoring conditions are the monitoring points. The point at which a sample is collected

³In the Round One sewage sludge regulation, EPA concluded, on the basis of risk assessments, that certain pollutants (see Appendix G to Part 403) did not pose an unreasonable risk to human health and the environment and did not require the establishment of sewage sludge pollutant limits. As discussed above, so long as the concentration of these pollutant in sewage sludge are lower than a prescribed level, removal credits are authorized for such pollutants.