

2. Describe any assumptions that you used.

3. Provide any technical information and/or data you used that support your views.

4. If you estimate a potential burden or costs, explain how you arrived at your estimate.

5. Provide specific examples to illustrate your concerns.

6. Offer alternatives.

7. Make sure to submit your comments by the comment period deadline identified.

8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Abbreviations and Acronyms Used

AMSA—Association of Metropolitan Sewerage Agencies
 BDMS—Biosolids Data Management System
 CAFO—Concentrated Animal Feeding Operations
 CDC—Centers for Disease Control and Prevention
 CFR—Code of Federal Regulations
 CWA—Clean Water Act
 EC—European Community
 EMS—Environmental Management System
 EPA—U.S. Environmental Protection Agency
 EQ—Exceptional Quality
 EU—European Union
 FTIR—Fourier Transform Infrared
 GC/MS—Gas Chromatography/Mass Spectrometry
 IAC—EPA Intra-Agency Committee for Biosolids
 ICMA—International City/County Management Association
 IRIS—Integrated Risk Information System
 ISG—Information Sharing Group
 LGEAN—Local Government Environmental Assistance Network
 NBP—National Biosolids Partnership
 NEBRA—New England Biosolids and Residuals Association
 NPDES—National Pollutant Discharge Elimination System
 NODA—Notice of Data Availability
 NRC—National Research Council
 NSSS—National Sewage Sludge Survey
 ORD—Office of Research and Development
 OW—Office of Water
 PA—State of Pennsylvania
 PCBs—Polychlorinated biphenyls
 PCDDs/Fs—Polychlorinated dibenzo-p-dioxins/dibenzofurans
 PCS—Permit Compliance System
 PEC—EPA's Pathogen Equivalency Committee

POTW—Publicly Owned Treatment Works
 PFRP—Processes to Further Reduce Pathogens
 PSRP—Processes to Significantly Reduce Pathogens
 QA/QC—Quality Assurance/Quality Control
 QMRA—Quantitative Microbial Risk Assessment
 RME—Reasonable Maximum Exposure
 SSI—Sewage Sludge Incinerator
 UA—University of Arizona, Water Quality Center
 UCAL—University of California
 UPA—University of Pennsylvania
 USDA—United States Department of Agriculture
 WEF—Water Environment Federation
 WERF—Water Environmental Research Foundation

Table of Contents

- I. What is the Legal Background of the Standards for the Use or Disposal of Sewage Sludge?
- II. What Requirements are Included in the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503)?
- III. What is the Purpose of Today's Notice?
- IV. What was EPA's Charge to the National Research Council?
- V. What Were the National Research Council's Major Findings and Recommendations Concerning Land Application of Biosolids?
- VI. What Process did EPA Use to Address the NRC recommendations?
- VII. EPA's Strategy for Responding to the NRC Recommendations
- VIII. EPA Responses to the NRC Recommendations by Category
- IX. How did EPA Conduct the Review of Part 503 Regulations under the CWA Section 405(d)(2)(C)?
- X. What are the Primary Issues for Public Comment?
- XI. References

I. What Is the Legal Background of the Standards for the Use or Disposal of Sewage Sludge?

EPA promulgated Standards for the Use or Disposal of Sewage Sludge (40 CFR part 503) under section 405(d) and (e) of the Clean Water Act (CWA), 33 U.S.C. section 1345(d), (e), as amended by the Water Quality Act of 1987. In these amendments to section 405 of the CWA, Congress, for the first time, set forth a comprehensive program for reducing the potential environmental risks and maximizing the beneficial use of sewage sludge. As amended, section 405(d) of the CWA requires EPA to establish numerical limits and management practices that protect public health and the environment from the reasonably anticipated adverse effects of toxic pollutants in sewage sludge. Section 405(e) prohibits any

person from disposing of sewage sludge from publicly owned treatment works (POTW) or other treatment works treating domestic sewage for any use except in compliance with regulations promulgated under section 405.

Section 405(d) calls for two rounds of sewage sludge regulations and sets deadlines for promulgation. In the first round, EPA was to establish numerical limits and management practices for those toxic pollutants which, based on "available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations that may adversely affect public health or the environment." CWA section 405(d)(2)(A). The second round is to address toxic pollutants not regulated in the first round "which may adversely affect public health or the environment." CWA section 405(d)(2)(B).

EPA did not meet the timetable in section 405(d) for promulgating the first round of regulations, and a citizen's suit was filed to require EPA to fulfill this mandate, (*Gearhart v. Reilly*, Civ. No. 89-6266-HO (D. Ore.)). A consent decree was entered by the court in this case, establishing schedules for both rounds of sewage sludge rules. EPA promulgated the first rule in 1993, 40 CFR part 503. 58 FR 9248 (Feb. 19, 1993) ("Round One"). For the second round ("Round Two"), EPA identified 31 pollutants and pollutant categories not regulated in Round One that EPA was considering for regulation. In November 1995, EPA narrowed the original list of 31 pollutants to two pollutant groups for the second round rulemaking: polychlorinated dibenzo-p-dioxins/dibenzofurans (PCDDs/Fs) and dioxin-like coplanar polychlorinated biphenyls (PCBs) (USEPA, 1996). The consent decree required the Administrator to sign a notice for publication proposing Round Two regulations no later than December 15, 1999, and to sign a notice taking final action on the proposal no later than December 15, 2001. (*Gearhart v. Whitman*, Civ. No. 89-6266-HO (D. Ore.)).

On December 15, 1999, the Administrator signed a proposal to establish numerical limits for dioxins, dibenzofurans, and co-planar PCBs ("dioxins") in sewage sludge that is applied to the land and proposed not to regulate dioxins in sewage sludge that is disposed of in a surface disposal unit or fired in a sewage sludge incinerator. 64 FR 72045 (December 23, 1999). On December 21, 2001, the Administrator gave final notice of EPA's determination