ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 257, 403 and 503

[FRL-4203-3]

Standards for the Use or Disposal of Sewage Sludge

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Under authority of Sections 405(d) and (e) of the Clean Water Act (CWA), as amended (33 U.S.C.A. 1251, *et seq.*), the Environmental Protection Agency (EPA) is promulgating regulations to protect public health and the environment from any reasonably anticipated adverse effects of certain pollutants that may be present in sewage sludge. The regulations establish requirements for the final use and disposal of sewage sludge in three circumstances. First, the regulations establish requirements for sewage sludge when the sludge is applied to the land for a beneficial purpose (including sewage sludge or sewage sludge products that are sold or given away for use in home gardens). Second, the regulations establish standards for sludge when the sludge is disposed on land by placing it on surface disposal sites (including sewage sludge-only landfills). Third, the regulations establish requirements for sewage sludge when incinerated. The standards for each end use and disposal practice consist of general requirements, numerical limits on the pollutant concentrations in sewage sludge, management practices and, in some cases, operational requirements. The final rule also includes monitoring, recordkeeping and reporting requirements.

Standards apply to publicly and privately owned treatment works that generate or treat domestic sewage sludge, as well as to any person who uses or disposes of sewage sludge from such treatment works. The rule requires compliance with these standards as expeditiously as possible but no later than 12 months from the date the rule is published, or within 24 months of publication if construction of new pollution control facilities is required to comply with the regulations. The final rule also includes conforming amendments to 40 CFR parts 257 and 403.

DATES: The effective date is March 22, 1993. Additional comments and data will be accepted until May 20, 1993.

The incorporation by reference of certain publications listed in this regulation is approved by the Director of the Federal Register as of May 20, 1993.

ADDRESSES: This Notice is requesting comments and data the Agency will consider for Round Two part 503 rulemaking. Send written comments and data described in this Notice to Round Two Part 503 Sewage Sludge Use and Disposal Rule; Comment Clerk; Water Docket MC-4101; Environmental Protection Agency; 401 M Street, SW; Washington, DC 20460. Respondents are also requested to submit an original and 3 copies of their written information. Respondents who want receipt of their information acknowledged should include a self-addressed, stamped envelope. All submissions must be postmarked or delivered by hand, no facsimiles (faxes) will be accepted.

A copy of the comments and supporting documents cited in the reference section of this Notice are available for review at EPA's Water Docket; 401 M Street, SW.; Washington, DC 20460. The Docket is located in room L-102. For access to Docket materials, call (202) 260-3027 between 9 a.m. and 3:30 p.m. for an appointment. The EPA public information regulation (40 CFR part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Further information on the part 503 rule may be obtained by writing or calling Dr. Alan Rubin, U.S. Environmental Protection Agency, Office of Water, Sludge Risk Assessment Branch (WH-586), 401 M Street, SW., Washington, DC 20460, (202) 260-1306. Information on the availability of single copies of the final rule, technical support documents, and copies of the data, analyses and models discussed in today's final rule is provided in part XIV of **SUPPLEMENTARY INFORMATION.**

SUPPLEMENTARY INFORMATION: The preamble to this Notice is organized as follows:

Overview

With the publication of today's rule, EPA has now met its longstanding obligation to promulgate regulations to establish standards for the use and disposal of sewage sludge. EPA's undertaking required an unprecedented effort to assess the potential for pollutants in sewage sludge to affect public health and the environment through a number of different routes of exposure. As a result, EPA's effort, an enormously complex one, has required it to address issues that affect many of the Agency's other major regulatory responsibilities. For example, evaluation of the risks posed by pollutants that may be present in sludge applied to land required the Agency to consider human exposure through inhalation, direct ingestion of soil fertilized with sewage sludge and through consumption of crops grown on this soil, among others. EPA also assessed the potential risk to human health through contamination of drinking water sources or surface water when sludge is disposed of on the land. EPA also evaluated the potential effects directly on crops, on cattle, on surface water aquatic species and wildlife. EPA also evaluated the effect of emissions from sewage sludge incinerators on human health. Thus, development of the sewage sludge regulation had obvious implications for Agency activities under the Clean Air Act, the Resource Conservation and Recovery Act, the Toxic Substances Control Act, the Comprehensive Environmental Response, Compensation and Liability Act and the Safe Drinking Water Act.

Development of this rule presented the Agency with a number of specific challenges in addition to those associated with coordinating these standards with other Agency programs. Not the least of these was assessing the potential for adverse effects on public health and the environment from pollutants in sludge. This is particularly difficult with respect to non-human health effects, given the limited

information available to the Agency in this area. This evaluation was further complicated by the fact that the methods for evaluating non-human health effects are less well-developed than those the Agency has traditionally relied on for evaluating human health effects.

Nevertheless, EPA is confident that the regulations it is promulgating today adequately protect public health and the environment from all reasonably anticipated adverse effects, as required by section 405(d), for several reasons. First, EPA has evaluated its regulations for aggregate national health impact. As explained in more detail below, even given very conservative assumptions that probably overstate exposure, there are virtually no effects when sludge is disposed of on the land or used as a soil conditioner or fertilizer in compliance with these rules. Further, even when sludge is incinerated and the population potentially exposed to the incinerator emissions is greater, the effects are small.

Second, use and disposal of sewage sludge is not new in this country. In the process of developing these regulations, EPA reviewed the available scientific and technical literature for information on sewage sludge. That search did not turn up any evidence that the use of sewage sludge is causing any significant or widespread adverse effects. While anecdotal, this evidence tends to confirm what EPA's risk assessment review showed more scientifically.

Finally, the Agency's sewage sludge assessment effort is not over. This is the first stage of EPA's sewage sludge regulatory program—"Round One." The statute under which these regulations are issued requires the Agency to develop regulations in two steps and to revise these regulations periodically if additional information suggests the need for regulation of other pollutants. The Agency has committed to identifying in May, 1993, the additional pollutants it will consider for regulation in "Round Two" and announcing its schedule for completion of the second stage effort. The Agency is comfortable that the regulations promulgated here are adequately protective because most of the effects that these regulations are designed to prevent are largely chronic, not acute ones. Even in the unlikely event that new information dictates reconsideration of some of the determinations on which EPA has based its health conclusions for this rule, there would be no adverse short-term human health consequences since standards to protect against chronic effects are well below acute effects levels. Moreover, the Agency is committed to an effort that investigates many of the assumptions it used in determining what levels of pollutants in sewage sludge were consistent with broad protection of public health and the environment as discussed below. Based on the results of this study or any new information showing an increased potential for adverse effects on public health, the Agency is prepared to move aggressively to address any problems with sewage sludge use should the evidence warrant.

Clean Water Act

Congress adopted the Clean Water Act (CWA) to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." Section 101(a), 33 U.S.C. 1251(a). To achieve this goal, the CWA prohibits the discharge of pollutants into navigable waters except in compliance with the statute. The CWA directs EPA to promulgate regulations establishing limits on the types and amounts of pollutants discharged from various industrial, commercial, and public sources of wastewater.

Congress recognized that regulating only those sources discharging effluent directly into the nation's waters alone would not sufficiently achieve the CWA's goals. Consequently, the CWA requires EPA to promulgate nationally applicable pretreatment standards which restrict pollutant discharges for those who discharge wastewater indirectly through sewers flowing to publicly owned treatment works (POTWs). Section 307 (b) and (c), 33 U.S.C. 1317 (b) & (c). Generally, these national pretreatment standards are designed to ensure that wastewaters from direct and indirect industrial dischargers are subject to similar levels of treatment. In addition, POTWs are required to implement local treatment limits applicable to their industrial indirect dischargers to satisfy any local requirements. 40 CFR 403.5.

Direct dischargers must comply with effluent limitations in National Pollutant Discharge Elimination System ("NPDES") permits; indirect dischargers must comply with pretreatment standards. These limitations and standards are established by regulation for categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology. In addition, pretreatment standards must be established for those pollutants which are not susceptible to treatment by POTWs or which would interfere with POTW operations. CWA Sections 301(b), 304(b), 306, 307 (b)–(d), 33 U.S.C. 1311(b), 1314(b), 1316, and 1317 (b)–(d).

POTWs receive wastewater from industrial facilities, domestic wastes from private residences, and run-off from various sources that must be treated prior to discharge. Treatment results in an effluent that may be discharged and a residual material, sewage sludge. The sewage sludge, usually more than 90 percent water, also contains solids and dissolved substances. The chemical composition and biological constituents of the sludge depend upon the composition of the wastewater entering the treatment facilities and the subsequent treatment processes. Typically these constituents may include volatile organics, organic solids, nutrients, disease-causing pathogenic organisms (e.g., bacteria, viruses, and others), heavy metals and inorganic ions, and toxic organic chemicals from industrial wastes, household chemicals, and pesticides.

Implementation of the CWA has resulted in greater levels of treatment of and pollutant removal from wastewater before discharge to surface waters, and the generation of large quantities of residual sewage sludge as a by-product of this treatment. Proper management of ever-growing amounts of sewage sludge is becoming increasingly important as efforts to remove pollutants from wastewater have become more effective. In the United States, the quantity of municipal sewage sludge has almost doubled since the enactment of the Clean Water Act in 1972. Municipalities currently generate over 5.3 million dry metric tons of wastewater sludge per year, or approximately 47 pounds per person per year (dry weight basis).

A POTW has a number of options to dispose of sewage sludge, including applying it to land, incineration, disposing of it in a landfill, or selling it to the public for use as a fertilizer or soil nutrient. However, the composition of the sludge can limit these choices.

One important avenue for sewage sludge disposal is through beneficial use and recycling projects. Sewage sludge is a valuable resource. The nutrients and other properties commonly found in sludge make it useful as a fertilizer and a soil conditioner. Sludge has been used for its beneficial qualities on agricultural lands, in forests, for landscaping projects, and to reclaim strip-mined land.

At the same time, in some situations, disposal of sewage sludge may present an environmental concern because of contamination by harmful pollutants. Greater focus on surface water toxics control, as well as Resource Conservation and Recovery Act (RCRA) provisions such as the ban on land disposal of certain hazardous wastes

(section 3004(d)) and the exclusion of discharges into municipal sewers from RCRA requirements (section 1004(27)), may result in increased volumes of toxic and hazardous pollutants that reach POTWs and consequently may adversely affect sludge quality when these pollutants are removed from the wastewater.

Proper disposal of sewage sludge is important because contaminated or improperly handled sludge can result in pollutants in the sludge re-entering the environment, and possibly contaminating a number of different media through a variety of exposure routes. Further, improper sludge management could lead to environmental degradation of land and air. Failure to dispose of sludge properly or contaminated sludge could also have adverse effects on surface and ground water and wetlands, as well as human health. For example, sewage sludge disposed on land where there is minimal depth to ground water is of concern because contaminants in the sludge may leach out and reach an existing or potential potable water source. Concern for air quality necessitates proper controls over sludge incineration. The interrelationship among these media requires a tightly coordinated, comprehensive approach to encourage the beneficial use of sludge and to avoid creating environmental loopholes, thereby helping to assure that solving problems in one media will not create problems for another.

Section 405 of the Clean Water Act

The CWA, as enacted in 1972, addressed sewage sludge use and disposal in only one limited circumstance: when the use or disposal posed a threat to navigable waters. Thus, section 405(a) of the Act prohibited the disposal of sludge if it would result in any pollutant from the sludge entering navigable waters unless in accordance with a permit issued by EPA. In 1977, Congress amended section 405 to add a new section 405(d) which required EPA to develop regulations containing guidelines for the use and disposal of sewage sludge. These guidelines must: (1) Identify uses, for sludge including disposal; (2) specify factors to be taken into account in determining the methods and practices applicable to each of these identified uses; and (3) identify concentrations of pollutants that would interfere with each use.

In 1987, Congress amended section 405 and for the first time set forth a comprehensive program for reducing the potential environmental risks and maximizing the beneficial use of sludge. Amended section 405(d) established a timetable for the development of the sewage sludge use and disposal guidelines. H. Rep. No. 1004, 99th Cong. 2d. Sess., 158 (1986). The basis of the program Congress mandated to protect public health and the environment is the development of technical requirements or standards for sewage sludge use and disposal and the implementation of these standards, in part, through a permit program.

Under section 405(d), EPA must first identify, based on available information, toxic pollutants which may be present in sewage sludge in concentrations which may affect public health and the environment. Next, for each identified use or disposal method, EPA must promulgate regulations that specify acceptable management practices and numerical limitations for sludge that contains these pollutants. These regulations must be "adequate to protect human health and the environment from any reasonably anticipated adverse effect of each pollutant." Section 405(d)(2)(D). The statute requires EPA to promulgate sewage sludge regulations in two stages and periodically to review these regulations for the purpose of identifying additional toxic pollutants for regulation.

After the technical standards have been promulgated, section 405 directs that any permit under section 402 of the CWA (NPDES permits) issued to a POTW or any other treatment works treating domestic sewage must include conditions to implement the technical standards unless these conditions are included in a permit issued under: Subtitle C of the Resource Conservation and Recovery Act; Part C of the Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act or the Clean Air Act; or under State permit programs approved by EPA, where EPA determines that such programs assure compliance with any applicable requirements of section 405. 33 U.S.C. 1345(f)(1). Section 405 also provides that EPA may issue permits that implement the sludge requirements to treatment works that are not subject to NPDES permitting or to any of the other enumerated programs or approved State programs. 33 U.S.C. 1345(f)(2). These permits are referred to in this preamble as "sludge-only" permits.

Congress provided little guidance for the Agency in carrying out its broad mandate to protect public health and the environment. For example, Congress did not speak directly or provide the Agency guidance about how to interpret certain key phrases in the statute. Consequently, the Agency in determining appropriate sludge standards has faced a number of difficult policy issues. The Agency has addressed the following issues in determining what standards adequately protected public health and the environment from pollutants in sewage sludge when used or disposed.

Regulatory Issues

In determining what standards adequately protected public health and the environment from pollutants in sewage sludge when used or disposed of, the Agency needed to address a myriad of issues including the following:

Scope of the Regulation. Different types of sewage sludge are generated and there are different ways of using or disposing of it. Given the different types of sludge that are generated, which types should the Agency regulate? Of the methods used by communities to dispose of their sewage sludge, which types of methods should the Agency regulate?

Pollutant Coverage. On what basis should the Agency select the pollutants (metals, pesticides, organic contaminants, pathogenic organisms) which are regulated in today's rule?

Pathways of Exposure. What media (air, water, soil) transport the pollutants in sewage sludge into and through the environment?

Target Organisms. What individuals or groups of individuals, plants, or animals are most likely to be affected by the pollutants in sewage sludge?

Models. How will the Agency simulate the movement of the pollutants in sewage sludge into and through the various environmental media to the target organisms?

Type of Risks. What are the potential human health and environmental risks posed by the use or disposal of sewage sludge (e.g., breathing air around a sewage sludge incinerator, drinking water from a well near a monofill, eating food grown on soil to which sludge has been applied, plants growing on sludge-enriched soil, etc.) that the Agency should examine?

Effect Levels. At what concentrations does a pollutant adversely affect human health and the environment? Pollutants from sewage sludge potentially may move through the environment to reach a plant, animal, or human. Plant, animal and human systems may "respond" to the presence of the pollutant. That is, biological systems within the plant, animal or human, may exhibit variations from normal conditions. At what point does this variation constitute an adverse effect? Must the standards protect against all adverse effects or only significant adverse effects? What

are the effects the standards should be designed to prevent (e.g., increased risk of developing cancer or hypertension, phytotoxicity, animal toxicity)?

Acceptable Level of Risk. The statute requires that the sludge regulations "adequately protect human health and the environment from reasonably anticipated adverse effects." What level of risk adequately protects human health and the environment? By requiring "adequate protection" of public health and the environment did Congress intend to leave to EPA's discretion the determination of what adverse effects public health and environmental protection required? Is a consideration of whether the effects are widespread, particularly with respect to non-public health effects, part of the determination of what constitutes adequate protection?

Background Pollutant Levels. What are the sources of pollutant exposure other than sludge (e.g., lead from gasoline or from water supply pipes, etc.)?

Uncertainties. How should the Agency measure and account for the unavoidable uncertainties in its analyses (e.g., use conservative assumptions, add a margin of safety)?

Types of Effects to be Evaluated. Should the Agency evaluate the human health and environmental effects on the most exposed target organisms (individual, plant, or animal) or should the Agency also examine the incidence of adverse effects on the total population associated with sewage sludge use or disposal?

Pollutant Limits. Should a single pollutant limit be established for all use or disposal practices or should a separate pollutant limit be established for each use or disposal method?

Form of the Pollutant Limits. How should the pollutant limits be expressed (e.g., a limitation on pollutant concentrations in sewage sludge, a limitation on pollutant loading rates to land, a limitation on pollutant emission rates, etc.)?

Regulatory Responsibility. Who should be responsible for meeting the requirements in the rule (end user, treatment work)?

Impacts. Who is affected by the rule? What are the benefits and costs of the rule?

Since 1984, the Agency has been conducting an extensive information-gathering and analytical program to support the development of today's regulation. Subsequent to the 1987 amendments to the CWA, the Agency redoubled its efforts. This preamble, the technical support documents, and related analyses of the regulation's impact are the product of that effort and explain the basis for the determinations the Agency has made in establishing these standards.

Fundamental Regulatory Principles

The fundamental assumptions underlying today's final rule are discussed below:

Control Sewage Sludge Quality

Section 405(d) of the CWA directs the Agency to control the quality of sewage sludge by establishing limits for pollutants in sludge applicable to methods of use or disposal. Preventing the contamination of sewage sludge before it is used or disposed of is more equitable than requiring others to contain the contaminated sewage sludge or to deal with the consequences. When it is not feasible for the Agency to set pollutant limits, section 405(d)(3) authorizes EPA to establish a design or equipment standard, management practice, or operational standard or combination of these in lieu of numerical limitations. This is the approach EPA took in the criteria promulgated for municipal solid waste landfills (MSWLFs). There, EPA adopted a containment approach rather than numerical limitations for solid waste, including sewage sludge disposed of in MSWLFs, in part because of the infeasibility of developing and enforcing numerical limitations for mixtures of sewage sludge and other solid waste materials disposed of in MSWLFs (56 FR 50978, October 9, 1991).

By setting limits on sewage sludge quality, this regulation creates incentives for treatment works to generate less contaminated sewage sludge. Treatment works with sewage sludge that does not meet the sludge quality conditions under the standards for a use and disposal practice must clean up the influent (e.g., strengthen the pretreatment programs), improve the treatment of sewage sludge (e.g., reduce the densities of pathogenic organisms), or select another use or disposal method.

Emphasize Waste Reduction and the Beneficial Reuse of Sewage Sludge

Achieving desired national levels of environmental quality depends on the reduction and elimination of the substantial volumes of waste and wastewater generated at home and at work. Without a significant reduction in these volumes (e.g., by home composting food scraps rather than putting them down a garbage disposal), and a corresponding reduction in the residual from wastewater treatment (sewage sludge is also often referred to as "biosolids") that must then be either used or disposed of, attaining these goals is severely hampered.

EPA's policy (i.e., the 1984 Beneficial Reuse Policy and the 1991 Interagency Policy on Beneficial Use of Sewage Sludge) of strongly supporting the beneficial reuse of sewage sludge is closely linked to its objective of reducing the volume of waste generated. The term biosolids has been used to distinguish sewage sludge that has been treated and can be beneficially recycled. Improving the productivity of our land using the soil conditioning properties and nutrient content of sewage sludge has human health and environmental advantages beyond those that are directly associated with applying sewage sludge to the land. Secondary or related benefits of reusing sewage sludge result from a reduction in the adverse human health effects of incineration, a decreased dependence on chemical fertilizers, a reduction in the emissions associated with incineration that may contribute to the "greenhouse effect" and a reduction in fuel or energy costs associated with incineration. In finalizing the rule, the Agency carefully considered, and placed heavy emphasis on, those approaches that supported its policy of beneficial reuse.

Preserve a Local Community's Choice of a Disposal Practice

Although the Agency prefers local communities to use their sewage sludge for its beneficial properties rather than simply disposing of it, EPA's responsibility is to set standards for each practice that are adequate to protect public health and the environment. While the choice of a use or disposal practice is reserved to local communities by section 405(e) of the CWA, protection of public health and the environment, where risks are significant, dictate stringent pollutant limits. One result is that in certain cases communities may be unlikely to meet the limits the Agency has promulgated.

Base the Rule on Minimizing Risks to Individuals and to the Population as a Whole

In developing today's rule, the Agency evaluated the effect of a pollutant on a highly exposed individual, plant, or animal (HEI) and on populations at higher risk. It also examined regulatory options that would have resulted in a rule based on aggregate incidence analyses only (the effect on the whole population), on the most exposed individual, plant, or animal (MEI) analyses only, and a rule

based on a combination of aggregate and MEI analyses. Today's final rule uses an HEI analysis supported by an aggregate risk assessment on higher risk populations or special subpopulations (e.g., children) to ensure protection of public health and the environment.

Promulgate Reasonable Standards

Section 405(d)(2)(D) of the CWA requires the Agency to establish standards adequate to protect public health and the environment from any reasonably anticipated adverse effects of each pollutant found in sewage sludge. In establishing standards, the Agency examined the effect of long-term pollutant exposure and circumstances that could: (1) Increase the toxicity and potency of a pollutant in the environment, (2) speed the movement of a pollutant into and through the environment, and (3) intensify the adverse effect that the pollutant may have on human health or the environment.

This approach is used throughout the rule but it does not protect against every conceivable combination of adverse conditions. In taking such an approach, the Agency recognizes that some risks may not have been fully evaluated and that some risks may remain after regulation. For example, the Agency used the average background value of metals in agricultural soils for applying sewage sludge to agricultural lands and assumed that users of sewage sludge products, such as compost, would follow simple label instructions. EPA expects that few, if any, individuals will receive higher doses of a pollutant than the doses used to establish the standards. Therefore, the Agency has determined that today's rule meets the statutory directive that the standards protect against reasonably anticipated adverse effects of the pollutants. EPA concluded that adequate protection of public health and the environment did not require the adoption of standards designed to protect human health or the environment under exposure conditions that are unlikely and where effects were not significant or widespread.

Promulgate an Implementable Rule

The final rule balances the flexibility associated with site-specific analyses against the simplicity of national numerical limits and self-implementing regulations. A rule that allows exceptions for every conceivable contingency would prove difficult to understand. Moreover, implementation of such a rule would require an unwarranted commitment of the Agency's limited resources without any offsetting increased benefits to public health or the environment. Therefore, the limited exceptions to national pollutant limits are restricted to circumstances in which site-specific conditions may make a significant difference in the pollutant limits without any compromise to public health and environmental protection.

In those cases where site-specific conditions are appropriate, persons disposing of sewage sludge may use EPA approved models and recalculate numerical pollutant limits for sewage sludge disposed of at their site. The modeling analysis, supporting information and recalculated numerical limits are to be submitted to the permitting authority for approval, and if approved, become the numerical limits for sludge quality disposed of at the site.

Section 405(e) of the CWA requires any person that uses or disposes of sewage sludge generated by a treatment works to comply with part 503 standards. Realistically, the Agency cannot issue permits to every user of sewage sludge. Therefore, primary responsibility, and liability, is placed on treatment works for ensuring that sewage sludge is disposed in accordance with the rule's requirements. The final part 503 rule is designed to be self-implementing, and therefore, clearly spells out how the requirements apply to persons using or disposing of sewage sludge. When sewage sludge or sewage sludge products are sold or given away to the general public, sewage sludge must generally meet higher standards of quality. However, the national limits were not designed to protect the public against every conceivable misuse of the product that is distributed and marketed. Rather, the rule assumes that simple instructions on proper use will be followed.

Coordinate With Other Programs

The use and disposal of sewage sludge affects air, soil, and water. In preparing the final rule, the Agency carefully examined the requirements of other media programs and media-specific statutes. Where possible for consistency, the Agency used the tools and standards developed under these other programs. For example, the air models used in developing the limits for incinerating sewage sludge are similar to the models used under EPA's air program. The pollutant limit for incinerating sewage sludge containing lead is designed to be consistent with the National Ambient Air Quality Standard (NAAQS) for lead. This principle is followed throughout the rule. As another example, when the pollutant limits are designed to protect ground water, the Agency used the drinking water standards (maximum contaminant levels—MCLs), where available. Further, when protecting surface water, the Agency used the Water Quality Criteria developed for individual pollutants. In some cases, Agency regulatory standards are undergoing revision. If a new standard is promulgated, the numerical pollutant limit for a use or disposal practice will be revised in later rulemakings.

Expand the Standards Later

The scope of the part 503 standards is necessarily constrained by the adequacy of information on sewage sludge pollutants and means of use or disposal. However, rather than wait for more complete information in order to promulgate all-inclusive regulations, the Agency is promulgating standards for those pollutants and use or disposal practices for which sufficient information exists. The Agency may expand and refine these standards in future rulemakings. Section 405 specifically contemplates that the Agency will issue these standards in stages and revise them periodically.

To remedy information gaps, the Agency conducted the National Sewage Sludge Survey (NSSS) which gathered, among other things, additional information on the pollutants in sewage sludge, how sludge is used and disposed, and information on POTW management of sludge. See, 55 FR 47210 (November 9, 1990). Furthermore, in cooperation with other Agency offices and outside expert reviewers, EPA has gathered data on the movement of certain pollutants into and through the environment (e.g., cadmium), refined and expanded its modeling capability for specific pollutants or disposal practices (e.g., surface disposal sites), supplemented its information on other disposal practices (e.g., sewage sludge incinerators), and further examined the characteristics of domestic septage. Sewage sludge pollutants and methods of use or disposal not covered by today's final rule are candidates for coverage under subsequent phases of the part 503 rulemaking process as adequate data are developed.

In addition, EPA had experts from both inside and outside the Agency review the scientific and technical bases of the rule. This review included the EPA Science Advisory Board, the Cooperative State Research Service, the Regional Research Technical Committee (sometimes called the W–170 committee), representatives of academia, and other scientific/technical bodies with experience in the areas covered by the rule. With the additional

data and the scientific and technical review, the Agency was able to expand and refine the standards for today's final rule.

The preamble summarizes the major scientific peer review and public comments and provides the Agency's response and actions taken in developing today's final part 503 rule. A complete description of all the public comments is provided in Reference No. 109. Information on this and other documents used in developing the final part 503 regulation may be found in Part XIV—Availability of Technical Information on the Final Rule.

Coverage of Today's Rule and the Round Two Rule

Today's rule establishes standards for those pollutants and sludge use or disposal methods for which the Agency had sufficient information to establish protective numerical limits, management practices, and other requirements. The Agency recognizes that today's rule may not regulate all pollutants in sewage sludge that may be present in concentrations that may adversely affect public health and the environment.

Section 405(d) of the CWA specifically contemplates a phased approach to establishing numerical limits for sewage sludge pollutants. Moreover, section 405(d)(2)(D) of the CWA provides that "(f)rom time to time, but not less often than every 2 years, the Administrator shall review the regulation * * * for the purpose of identifying additional toxic pollutants and promulgating regulations for such pollutants * * *." EPA will be using data from the NSSS to identify additional pollutants in sewage sludge that may interfere with the safe use or disposal of the sludge for a second round of rulemaking (Round Two).

For the NSSS, EPA analyzed sewage sludge samples for 419 toxic pollutants. Many of these pollutants were undetected in the samples, infrequently detected or present at levels below detection limits. Consequently, the first step in the process of identifying what additional pollutants EPA may regulate in Round Two is to determine what pollutants are present in sludge in a sufficient number of samples or at concentrations that warrant further examination for national regulation. EPA statisticians have now reviewed the analytical data and completed their initial screening assessment for each pollutant by frequency and level of occurrence.

The next step with respect to Round Two will be review of the scientific literature for toxicity, fate, effect and transport information on the pollutants identified by the initial statistical screening. EPA will use data from the scientific literature on the adverse human health and environmental effects of these pollutants to calculate pollutant concentrations in sludge that would be associated with the identified adverse effects. Through a comparison of the calculated sludge levels associated with adverse effects with the NSSS screening data on actual level and frequency of occurrence, EPA can make a preliminary determination of the pollutants that it should propose for regulation.

If, based on the results of the exposure assessment models, the pollutant presents an unreasonable human health or environmental risk, the Agency would propose numerical limits or other standards (if numerical limits are infeasible or unenforceable) for the pollutant appropriate to a particular method of use or disposal.

Summary of the Final Rule

Today's rule establishes standards for the final use or disposal of sewage sludge when the sewage sludge is applied to agricultural and non-agricultural land (including sewage sludge and sewage sludge products sold or given away—described in the proposed rule as distributed and marketed sludge), placed in or on surface disposal sites, or incinerated. The rule does not apply to the processing of sewage sludge before its ultimate use or disposal. In addition, EPA, in this rule, is not specifying process operating methods or requirements for sludge entering or leaving a particular treatment process.

EPA has not established standards in this rule for sewage sludge that is disposed with municipal solid waste in MSWLFs or that is used as a cover material at MSWLF sites. Under the joint authority of sections 4004 and 4010 of RCRA and section 405(d) of the CWA, the Agency has adopted requirements for MSWLFs that apply to sewage sludge that is placed in these landfills. The disposal of sewage sludge in MSWLFs is regulated under 40 CFR part 258 (see, 56 FR 50978, October 9, 1991). The Agency adopted this approach for reasons explained in more detail below. Treatment works using a MSWLF to dispose of their sewage sludge must ensure that their sewage is non-hazardous and passes the Paint Filter Liquid Test. If these requirements are met, treatment works will be in compliance with section 405(e) of the CWA.

The standards also do not apply to sewage sludge that is co-incinerated with large amounts of solid waste (see, 56 FR 5507, February 11, 1991). However, the standards established in the rule do apply to sewage sludge that is incinerated in a sewage sludge incinerator with incidental amounts of solid waste used as an auxiliary fuel (i.e., 30 percent or less solid waste by weight).

The rule applies to sewage sludge that is generated or treated by publicly owned and privately owned treatment works treating domestic sewage and municipal wastewater. The rule does not apply to domestic sewage that is treated along with industrial wastewater by privately owned industrial facilities. The Agency has the authority under section 405(d) of the CWA to regulate industrial sludges with a domestic sewage component, and it plans to consider regulating these sludges in future part 503 rulemakings. However, until the Agency develops part 503 regulations to cover industrial sludges produced by privately owned facilities from the treatment of industrial wastewater with a domestic sewage component, those sludges (as well as non-hazardous industrial sludges without a domestic sewage component) will be regulated under 40 CFR part 257.

The regulations promulgated here today do not establish disposal standards for sewage sludge that is determined to be hazardous under procedures in appendix II of 40 CFR part 261. Hazardous sewage sludge must be disposed of in compliance with the hazardous waste regulations in 40 CFR parts 261–268. Compliance with these requirements will constitute compliance for purposes of section 405. Also, sewage sludge found to contain 50 ppm or more of PCBs is excluded from this rule. Sewage sludge with 50 ppm or more of PCBs must be disposed of according to the requirements established in 40 CFR part 761. Similarly, while EPA has not established standards the disposal of PCB-contaminated sludge, a disposer complying with 40 CFR part 761 would not violate section 405.

Finally, no standards are established for the ocean disposal of sewage sludge regulated by the Marine Protection, Research, and Sanctuaries Act (MPRSA). The Ocean Dumping Ban Act of 1988, Public Law 100–688, amended MPRSA to prohibit any person from dumping sewage sludge into ocean waters after December 31, 1991. In addition, Congress limited ocean dumping during the interim period o those who were authorized as of September 1, 1988, to dump either under an MPRSA permit or a court order. Further, Congress prohibited

dumping after August 15, 1989, unless an MPRSA permit had been obtained by that time. All remaining communities that dumped their sewage sludge in the ocean ceased dumping at the end of June, 1992.

The rule includes specific numerical limits (or equations for calculating these limits) for 10 pollutants when sewage sludge is used or disposed by one or more methods. Not every pollutant is regulated under each practice. EPA developed these numerical limits by using exposure assessment models designed to protect individuals, plants, animals or other organisms potentially at greater risk from pollutants in sewage sludge. In the case of sewage sludge that is incinerated, in addition to numerical limits, the Agency is also establishing an operational standard for total hydrocarbons rather than for individual organic pollutants.

The numerical limits derived from the exposure assessment models are designed to protect public health or the environment from reasonably anticipated adverse effects. These models incorporated well-established measures of human health or environmental protectiveness as their design end-point. Thus, EPA based its environmental assessment on human health or environmental criteria already published or promulgated by the Agency, on human health criteria developed by the Agency, or on plant and animal toxicity values published in the scientific literature. Thus, for example, when sewage sludge is incinerated, the numerical limit for lead is based on the NAAQS for lead. When the objective is to protect sources of drinking water, pollutant limits were developed which would ensure that drinking water MCLs established under the Safe Drinking Water Act are not violated. When the objective is to protect surface water, Water Quality Criteria issued under section 304 of the Clean Water Act are used. In its exposure assessment, if the Agency had not published or promulgated criteria for specific pollutants, EPA evaluated non-cancer human health risks from pollutant exposure using reference doses. EPA evaluated cancer risk using cancer potency factors—so-called Q_1* or Q* values—listed in the Agency's computerized Integrated Risk Information System (IRIS). In all cases, EPA used cancer potency values corresponding to an incremental carcinogenic risk level of 1×10^{-4} to evaluate the risk from pollutants found in sewage sludge. (The exposure level of a pollutant associated with a 1×10^{-4} cancer risk implies that one additional cancer case will occur in a population of 10,000 exposed at that level for 70 years.) For purposes of establishing the numerical limits for incinerators promulgated today, EPA did, however, evaluate exposure at different incremental cancer risk levels (i.e., 1×10^{-4} through 1×10^{-6}). In the case of human health, the final limits for pollutants in sewage sludge ensure that the use and disposal of sludge does not result in ambient concentrations of the regulated pollutants that exceed an incremental carcinogenic risk level of 1×10^{-4}.

For sewage sludge disposed of in or on surface disposal sites (including sludge-only landfills, often referred to as "monofills") or incinerated, treatment works may submit modeling and data analyses (for certain physical parameters related to the site) used to recalculate site-specific numerical limits. The permitting authority will review and approve the treatment works' site-specific modeling and data analyses used to recalculate numerical limits using EPA-approved exposure assessment methods. Since these recalculated numerical limits are based on EPA-approved models and the same human health and environmental criteria as the national numerical limits, the recalculated limits will also adequately protect human health and the environment from reasonably anticipated adverse effects of pollutants found in sewage sludge.

EPA has also acted today to amend 40 CFR part 403 to authorize treatment works to authorize removal credits for certain pollutants. The amendment lists those pollutants for which removal credits may be authorized. In addition to the pollutants for which specific numerical limits are established, removal credits may be available for pollutants that EPA evaluated for regulation and for which EPA decided not to establish numerical limits.

In the case of sewage sludge applied to the land or disposed of in or on surface disposal sites, the final rule establishes requirements for pathogenic organisms or pathogenic indicator organisms such as fecal coliform. The rule also includes requirements for destroying or reducing those characteristics of sewage sludge that attract birds, insects, rats and other animals (so-called "vectors"). "Vector" exposure to the pathogenic organisms in sludge can cause transfer of pathogens (and consequently spread disease) from these disease vectors to humans. The final rule consequently requires measures for reducing the attraction of vectors to sewage sludge. These measures could include destruction of the odor causing properties of sludge that lure insects and animals.

Supplementing the numerical pollutant limits are management practices and general requirements to protect human health and to prevent gross abuse of the environment. In the case of small quantity sludge that is sold or given away in a bag or other container, the rule requires the treatment works (or other person, if different from the treatment works) to label the product. The label is to provide instructions on properly using the product.

The rule also includes monitoring, recordkeeping, and reporting requirements. The frequency with which sewage sludge is to be monitored depends on the quantity of sludge used or disposed by a treatment works. The pollutants for which treatment works must monitor their sewage sludge similarly depend on the use or disposal method selected. The recordkeeping and reporting requirements are also specific to a particular method of use or disposal.

The final rule is expected to cover nearly 35,000 entities. These entities include: primary treatment POTWs, secondary and advanced treatment POTWs, privately owned treatment works, Federally owned treatment works, and domestic septage haulers.

Based on the NSSS, this rule is expected to affect approximately 6,300 of the 12,750 secondary, advanced, and primary POTWs that use one or more of the disposal practices included in the rule. These 6,300 facilities generate or treat approximately 60 percent of the sewage sludge produced in the United States. Of the remaining POTWs, an estimated 2,700 dispose of their sewage sludge (34 percent of the total sewage sludge generated) in MSWLFs that are to be regulated under 40 CFR part 258 (56 FR 50978, October 9, 1991). The remaining 3,750 POTWs use other disposal practices not covered in either this regulation or the MSWLF rule. In some cases, compliance with the requirements for those other practices constitutes compliance with 405(d) of the CWA.

The aggregate risk assessment estimates that current use and disposal practices contribute from less than one up to five cancer cases annually, with a lifetime cancer risk to a highly exposed individual ranging from 6×10^{-4} for land application and surface disposal of sludge and from 6×10^{-4} to 7×10^{-3} for incineration. The other health effects associated with sewage sludge use and disposal are primarily related to lead exposure and result in approximately 2,000 individuals who exceed a

threshold blood lead level associated with adverse health effects and 700 instances of hypertension in adult males or diminished learning capacity in children. The Agency estimates that the rule reduces cancer cases by 0.09–0.7, exceedences of lead adverse health threshold by 600–2,000 and instances of lead cases by 90–600.

For the purpose of the regulatory impact analysis, the Agency estimated that approximately 130 of the 6,300 affected POTWs may have sewage sludge which does not meet the numerical limits. This estimate does not take into consideration the possibility that some POTWs may come into compliance by using site-specific data to calculate new numerical limits and by imposing more stringent pretreatment requirements on their industrial dischargers. The Agency estimates annual compliance costs of $45.9 million or an increase of less than $1 annually for each household served by the affected POTWs. The total annual incremental compliance costs include costs for sludge monitoring, management practices, and in some cases, incremental costs of changing a practice for POTWs that fail to meet the numerical pollutant limits for a practice.

The technical support documents, aggregate human health risk analyses, the regulatory impact analyses, and the preamble discuss the factors that EPA considered, the data and comments it evaluated, and the determinations that it made in developing the final rule. The preamble summarizes this information in 15 parts.

Part I briefly describes the generation, volume, and constituents of sewage sludge and the factors that communities must consider in using or disposing of the sewage sludge that results from the treatment of domestic sewage and municipal wastewater. Part I also identifies the ways in which communities commoniy use or dispose of their sewage sludge, the benefits of reusing sewage sludge, and the risks associated with its disposal.

Part II lists existing Federal and State requirements for the use and disposal of sewage sludge including the relationship of the existing requirements to today's rule.

In part III, the preamble begins to describe how the Agency developed the final rule. Initially, the Agency selected pollutants most likely to interfere with the safe use or disposal of sewage sludge and then refined the list of pollutants based on the availability of information on the toxic effects of the pollutants. In refining the initial list of pollutants, the Agency simulated the movement of pollutants into and through the environment with a series of exposure assessment models to determine the concentrations of pollutants reaching an individual, plant, or animal.

In part IV, the preamble briefly describes the February 6, 1989 proposed rule.

In part V, the preamble discusses the Agency's effort to develop current data on sewage sludge quality and an accurate characterization of current methods of sludge use and disposal employed by treatment works. This part describes EPA activity following the proposal including efforts to obtain additional information on sewage sludge incinerators and domestic septage. This part also describes the November 9, 1990 Notice of Availability of Information and Data, and Anticipated Impacts on Proposed Regulations.

Parts VI and VII discuss the alternative regulatory approaches and public comments the Agency considered in developing the risk assessment methodology for the final rule. Included in the discussion are the factors on which the Agency based its risk management decisions and its selection of a risk assessment methodology that would adequately protect public health and the environment.

Part VIII discusses the proposed exposure assessment methodology and public comments the Agency considered in developing the exposure assessment methodology for the final rule. This part also describes the (1) critical exposure assessment models, pathways, parameters and assumptions; (2) other risk management issues evaluated by the Agency; and (3) the human health and environmental criteria used to establish numerical limitations for each sewage sludge use and disposal practice.

Part IX describes the criteria the Agency used to select pollutants for regulation in the final part 503 rule.

Prior to selecting its approach for establishing standards for a particular use or disposal practice, the Agency examined the aggregate human health effects on highly exposed individuals and the nation from the use and disposal of sewage sludge. The methods used to conduct these analyses and the results are described in part X.

Part XI describes, in separate subparts, the requirements that apply to the use and disposal of sewage sludge. In addition, part XI describes the requirements for septage use and disposal, the pathogen and vector attraction requirements; and the monitoring, record-keeping and reporting requirements.

Part XII briefly discusses the implementation of the final rule through Federal and State permit programs and the self-implementing nature of the regulations. Under a separate rulemaking, the Agency promulgated State program management requirements and changes in the National Pollutant Discharge Elimination System permitting requirements (54 FR 18716, May 2, 1989).

The benefits, costs, and regulatory impact of the rule are described in part XIII. This part also discusses the data limitations and assumptions, and determinations that the Agency made in fulfilling its responsibilities under Executive Order 12291.

Part XIV provides information on where interested persons may obtain copies of today's rule, the technical support documents, the aggregate risk assessment, and the regulatory impact analysis. Included in this part is the list of references cited throughout the preamble.

Part XV describes the changes in 40 CFR parts 257 and 403. These changes are limited to revisions to part 403 and to removing from coverage in part 257 sewage sludge use and disposal methods which will be subject to the new standards the Agency is establishing in 40 CFR part 503. Finally, part XV lists the subjects in 40 CFR parts 257, 403 and 503.

Part I: Generation, Use, and Disposal of Sewage Sludge

Generation of Sewage Sludge

The CWA requires municipalities to clean their wastewater prior to discharging it. Wastewater treatment generates sludge which in turn must either be disposed of or used. Sludge management begins with sludge generation and continues through sludge processing and ultimate disposal.

Domestic wastewater contains material flushed into household drains through toilets, sinks, and tubs. Components of domestic sewage include soaps, shampoos, human excrement and tissue, food stuffs, detergents, pesticides, household hazardous waste, and oil and grease. Typically a family of four discharges 300 to 400 gallons of wastewater per day.

Domestic wastewater is treated (or partially treated) at its source in septic tanks, cesspools, portable toilets, or in publicly or privately owned wastewater treatment works. These treatment works may treat domestic wastewater alone or a combination of domestic wastewater and industrial wastewater.

Municipal wastewater treatment works may use one or more levels of treatment (i.e., primary, secondary, or tertiary) to clean this wastewater. Each level of treatment provides both greater wastewater cleanup and greater amounts of sewage sludge.

Primary treatment processes remove the solids that settle out of the wastewater by gravity. This generates 2,500 to 3,500 liters of sludge per million liters of wastewater treated. Primary sludge contains 3 to 7 percent solids, 60 to 80 percent of which is organic matter. The water content of primary sludge can easily be reduced by thickening or by removing water.

Secondary treatment produces a sludge generated by biological treatment processes. Biological treatment processes (e.g., activated sludge systems, trickling filters, and other attached growth systems) utilize microbes to break down and convert the organic substances in the wastewater to microbial residue. These processes remove up to 90 percent of the organic matter in the wastewater and produce a sludge that typically contains from 0.5 to 2 percent solids. These solids are generally more difficult to de-water than primary sludges. The organic content of the solids ranges from 50 to 60 percent. Secondary treatment processes increase the volume of sludge generated over primary treatment by 15,000 to 20,000 liters of sludge per million liters of wastewater treated.

Advanced wastewater treatment processes, such as chemical precipitation and filtration, produce an advanced or tertiary sludge. Chemical precipitation uses chemicals to remove organics and nutrients and to separate the solids from the wastewater. Characteristics of these sludges vary, depending upon the type of advanced treatment process used and the type of wastewater entering the treatment process. Since these sludges typically contain considerable amounts of added chemicals, the solids content will vary from 0.2 to 1.5 percent, while the organic content of the solids will be in the 35 to 50 percent range. Tertiary treatment increases the volume of sludge generated over secondary treatment by another 10,000 liters of sludge per million liters of wastewater treated.

Unprocessed sewage sludge contains from 93 to 99.5 percent water, as well as the solids and dissolved substances that were present in the wastewater or that were added or cultured by the wastewater treatment process. While virtually all sewage sludge contains nutrients (e.g., nitrogen, phosphorus) and significant numbers of pathogens (e.g., bacteria, viruses, protozoa, and eggs of parasitic worms), some sludges also contain more than trace amounts of organic chemicals (e.g., chloroform) and inorganic chemicals (e.g., iron). These pollutants come from domestic wastewater, from the discharge of industrial wastewater to municipal sewers, and from the runoff from parking lots and lawns and fields where fertilizers and pesticides were incorrectly applied.

Sludge Processing

Prior to reusing or disposing of sewage sludge, treatment works generally thicken, stabilize, and de-water the sewage sludge. Sludge thickening is the removal of water from sludge to achieve a volume reduction. The reduction in sludge volume decreases the capital and operating costs of subsequent sludge processing and disposal operations. For example, lowering the volume of sewage sludge reduces transportation costs. EPA estimates that the cost of transporting sewage sludge with a 22 percent solids content over a 20-mile trip is about one-half the cost of transporting sewage sludge with a 6 percent solids content over the same distance.

Treatment works frequently digest or compost their sewage sludge to reduce the level of pathogens and odors. The degree to which a sludge is processed is very important when applying sewage sludge to land, when distributing and marketing it, and when placing sewage sludge in monofills or on surface disposal sites in order to eliminate the spread of pathogenic diseases.

Amount of Sewage Sludge Generated

Approximately 12,750 POTWs generate 5.4 million dry metric tons of sludge annually (see Table I–1), or 47 pounds of sewage sludge (dry weight basis) for every individual in the United States (based on Questionnaire Survey and other sources).

Unless the volume of sludge is reduced, the nation cannot achieve its environmental quality objectives. Treatment alone is not the answer. Communities should consider the following additional measures to reduce the quantity of sludge generated by wastewater treatment: implement waste separation and water conservation programs, encourage the recycling of garbage in compost piles, separate household hazardous waste prior to collection and handling, and separate storm water from wastewater sewer systems. These measures have proved successful in reducing the volume of wastewater generated and in improving the quality of the sewage sludge that is ultimately used or disposed.

Use and Disposal Methods

Sewage sludge is commonly used or disposed of in a number of ways. These include the following: Application of sludge to agricultural and non-agricultural lands; sale or give-away of sludge for use in home gardens (often referred to as distribution and marketing of sludge); disposal of sludge in municipal landfills, sludge-only landfills (known as monofills), and surface disposal sites; and incineration of sludge.

Table I–1 shows the amount of sludge that is generated based on the size of a facility and on the amount of sewage sludge that is disposed of by a use or disposal practice. Table I–2 shows the number of facilities using a particular method of use or disposal.

TABLE I–1.—ESTIMATED MASS OF SEWAGE SLUDGE DISPOSED ANNUALLY BY PRIMARY, SECONDARY, OR ADVANCED TREATMENT POTWS BY SIZE OF POTW AND USE/DISPOSAL PRACTICE

[Thousands of dry metric tons]

Use or disposal practice	Reported flow rate (MGD)				Total (percent of total)
	>100	>10 to 100	>1 to 10	≤1	
Incineration	382.9	346.5	124.8	10.5	864.7 (16.1)
Land application:					
Agricultural	203.0	400.8	423.9	143.2	1,170.9 (21.9)
Compost	22.4	65.3	31.7	30.8	150.2 (2.8)

TABLE I–1.—ESTIMATED MASS OF SEWAGE SLUDGE DISPOSED ANNUALLY BY PRIMARY, SECONDARY, OR ADVANCED TREATMENT POTWS BY SIZE OF POTW AND USE/DISPOSAL PRACTICE—Continued

[Thousands of dry metric tons]

Use or disposal practice	Reported flow rate (MGD)				Total (percent of total)
	>100	>10 to 100	>1 to 10	≤1	
Forests	4.5	24.5	1.0	1.3	32.3 (0.6)
Public contact	62.1	60.5	40.3	6.3	166.1 (3.1)
Reclamation	52.6	9.8	2.4	1.0	65.8 (1.2)
Sale	30.6	27.8	11.9	0.8	71.1 (1.3)
Undefined	12.7	76.4	27.2	13.0	129.3 (2.4)
Co-disposal: Landfill	518.6	674.0	495.6	110.4	1,818.7 (34.0)
Surface disposal:					
Dedicated site	34.2	124.9	83.2	36.5	258.8 (4.8)
Monofill	13.8	79.8	41.6	22.2	157.4 (2.9)
Other	31.5	60.0	17.4	28.5	137.5 (2.6)
Unknown:					
Ocean*	166.1	157.9	8.0	3.4	335.5 (6.3)
Other	0	0	0	0	0
Transfer	N/A	N/A	N/A	N/A	N/A
Total	1,532.0	2,128.3	1,284.1	407.7	5,357.2
(Percent of total)	(28.6)	(39.7)	(24.1)	(7.6)	(100.0)

Note: * This survey was conducted before the Ocean Dumping Ban Act of 1988, generally prohibited the dumping of sewage sludge into the ocean after December 31, 1991. Ocean dumping of sewage sludge ended in June, 1992. Numbers may not add up to 100 percent because of rounding.
Source: Prepared by ERG for EPA—1988 National Sewage Sludge Survey and 1988 Needs Survey.

TABLE I–2.—NUMBER OF PRIMARY, SECONDARY, AND ADVANCED TREATMENT POTWS AND THE QUANTITY OF SEWAGE SLUDGE DISPOSED ANNUALLY BY USE OR DISPOSAL PRACTICE

[Thousands of dry metric tons]

Use/disposal practice	POTWs using a use/disposal practice		Quantity of sewage sludge disposed	
	Number	Percent of POTWs	Quantity (1,000 dmt)	Percent of sludge
Incineration	381	2.8	864.7	16.1
Land application	4,657	34.6	1,785.3	33.3
Co-disposal: Landfill	2,991	22.2	1,818.7	33.9
Surface disposal	1,351	10.0	553.7	10.3
Unknown:				
Ocean disposal*	133	1.0	335.5	6.3
Other	3,920	29.1	0	0.0
Transfer	25	0.2	N/A	N/A
All POTWs	13,458	100.0	5,357.2	100.0

Note: The total number of POTWs does not equal the number in the text because some of the POTWs utilize more than one use or disposal practice and are counted twice in this table.
* The National Sewage Sludge Survey was conducted before the Ocean Dumping Ban Act of 1988, generally prohibited the dumping of sewage sludge into the ocean after December 31, 1991. Ocean dumping of sewage sludge ended in June, 1992. Numbers may not add up to 100 percent because of rounding.
Source: Prepared by ERG for EPA—1988 National Sewage Sludge Survey (Questionnaire Survey) and 1988 Needs Survey, and ERG estimates.

Benefits of Reusing Sewage Sludge

The organic and nutrient content of sewage sludge (biosolids) makes it a valuable resource to use both in improving marginal lands and as a supplement to fertilizers and soil conditioners. A study of sewage sludge and effluent use on selected agricultural crops in one area of Oregon found that the return per acre of sludge application ranged from a loss of $6 to an increase of $15 per acre. This was compared to traditional fertilizer sources and depended on crop rotation, previous soil management practices, soil type, and level of sludge application. The farmer gained net savings in the cost of fertilizers, taking into account the fact that the sludge was available at no cost (Reference No. 10).

The beneficial uses of sludge are not limited to the production of agricultural commodities. Sewage sludge is used in silviculture to increase forest productivity and to re-vegetate and stabilize harvested forest land and forest land devastated by fires, landslides, or other natural disasters. The application of sewage sludge to forest land shortens wood production cycles by accelerating tree growth, especially on marginally productive soils. Studies at the University of Washington on the use of sludge as a fertilizer in silviculture show height increases of up to 1,190 percent and diameter increases of up to 1,250 percent compared to controls in certain tree species. University of Washington research has also shown

that trees grow twice as fast on sludge-amended soil. This means that a tree which would typically be cut after 60 years could be cut after only 30 years to supply lumber for a variety of purposes.

Sludge is productively used to stabilize and re-vegetate areas destroyed by mining, dredging, and construction activities. Air-dried sludge that looks like compost is frequently used to fertilize highway median strips, cloverleaf exchanges, and for covering expired landfills. Historically, land reclamation has been very successful and comparable in cost to other commercial methods. In a strip-mined area in Fulton County, IL, reclamation using municipal sewage sludge cost $3,660 an acre, as compared with a range of $3,395 to $6,290 an acre using commercial methods (Reference No. 49). Pennsylvania has used the sludge Philadelphia generates to reclaim more than 3,000 acres of devastated lands. Sludge, in combination with fly ash, is currently used in the re-vegetation of soils that have become highly contaminated from the operation of a zinc smelter in Palmerton, PA, over the past 90 years.

EPA analyses show that current beneficial use practices (i.e., land application, and sale and give-away) pose less carcinogenic risk than disposal practices. On a per ton basis, carcinogenic risks from reusing sewage sludge range from 8×10^{-8} to 4×10^{-7}, while those from incinerating and disposing of sewage sludge in monofills range from 2×10^{-7} to 5×10^{-6}.

Studies using Philadelphia sludge have shown that the microbial communities in reclaimed mined soils revert to those of normal soils within 2 to 3 years. Conventional reclamation could take as long as 10 to 15 years, or even longer (Reference No. 49).

Forest soils have been found to be well suited to sludge application because they have high rates of infiltration (which reduce run-off and ponding), large amounts of organic material (which immobilize metals from the sludge), and perennial root systems (which allow year-round application in mild climates). Although forest soils are frequently quite acidic, research at the University of Washington has found no problems with metal leaching following sludge application (Reference No. 14). In addition, studies of animals living on sludge-treated sites have found that the animals are healthier than those on control sites because of the increased production of vegetative matter.

The sale of sewage sludge products can be used to defray the costs of de-watering and composting the sewage sludge, but no similar mechanism exists to defray the costs of de-watering sewage sludge placed in landfills or incinerated. Further, the labor, capital, and operating and maintenance costs of incinerating sewage sludge are substantially higher.

The Municipality of Metropolitan Seattle (METRO), which treats wastewater in the Seattle-King County region, began using sludge to improve soil in several Seattle area parks, restore land disturbed during strip mining, restore a gravel pit used for Interstate 90 construction, and enhance grass growth at the King County International Airport at Boeing Field. In October 1983, the METRO Council adopted a sludge management plan that outlined a goal to use at least eight alternative sludge recycling or disposal methods through the year 2000. METRO reports that its plants produced 65,000 tons of sludge in 1985 and more than 91,000 tons in 1987. Sludge production is expected to increase dramatically in the next decade after METRO's Puget Sound plants are upgraded from primary to secondary treatment. METRO says that by creating a demand for sludge and developing a variety of recycling options, it reduced program expenses from $227 per ton of sludge solids in 1983 to $148 in 1987.

The benefits of using sewage sludge to improve land productivity are substantial. However, if sewage sludge containing high levels of pathogenic organisms (e.g., viruses, bacteria) or high concentrations of pollutants is improperly handled, the sludge could contaminate the soil, water, crops, livestock, fish, and shellfish. The major human health, environmental, and aesthetic factors of concern in the land application of sewage sludge are related to pathogens, metals and persistent organic chemicals content, and odors. The standards promulgated today would prevent the contamination of soil and crops by pathogens, as well as the contamination of food and animal feed crops when sewage sludge is applied to lands used in the production of agricultural crops or to lands that may be converted to residential use.

While the use of sewage sludge for beneficial purposes is primarily related to farm and home garden use, use of sewage sludge to aid in the growth of a final vegetative cap for municipal solid waste landfills is also considered a beneficial use of sewage sludge and should be encouraged. By taking advantage of the nutrient content and soil amendment characteristics of sewage sludge, a vegetative cover or cap can be quickly grown to facilitate the municipal solid waste closure plan.

In spite of the benefits of reusing sludge, only one-third of the sewage sludge generated in the United States is effectively reused by applying it to the land, or sold or given away for use in home gardens (see Table I–2). In comparison, Japan uses 42 percent of its sewage sludge for coastal reclamation and home garden or farming uses. The United Kingdom applies 51 percent of its sewage sludge to the land (Reference No. 4).

While section 405(e) of the CWA reserves the choice of use and disposal practices to local communities, EPA's preference is for local communities to reuse this resource in beneficial ways. On June 12, 1984, the EPA published its policy on the management of sewage sludge stating that the Agency will actively promote those municipal sludge management practices that provide for the beneficial use of sludge while maintaining or improving environmental quality and protecting public health (see 49 FR 24358).

When the quality of the sewage sludge appears to be a limiting factor for an otherwise desirable use, POTWs can establish discharge limits for non-domestic users discharging wastewater to the POTW. Controlling the quality of non-domestic wastewater discharged into municipal sewers is an important element in managing the quality of sewage sludge.

All dischargers of non-domestic wastewaters are required to meet all applicable National Pretreatment Standards. These may include general and specific prohibited discharge standards, categorical pretreatment standards, and local limits.

In addition, POTWs designed to accommodate design flows of more than 5 million gallons per day and smaller POTWs with significant industrial discharges are required to establish local pretreatment programs. Currently 2,015 of the nation's POTWs operated by 1,528 authorities have local pretreatment programs. The local program must include adequate legal authorities, industrial user permitting, compliance monitoring, enforcement, and public participation. These 1,528 approved programs are estimated to receive 80 percent of the national wastewater flow discharged to POTWs.

In addition to wastewater reduction and the separation of contaminated waste from uncontaminated wastes, pretreatment of non-domestic wastewater is another key step in managing the quality of sewage sludge. If pretreatment does not reduce the pollutant levels sufficiently, communities may have to dispose rather than use their sludge and, depending on the disposal method, add pollution

controls and thereby increase the cost of sludge disposal.

Use of Sewage Sludge

Land Application to Agricultural Lands

Some 66 percent of the sludge applied to land (approximately 1.2 million dry metric tons) is used to improve the condition and nutrient content of soil for agricultural crops, including row and feed crops and pastures. The method of applying sludge to agricultural land depends on the physical characteristics of the sludge and soil and on the crops grown. Liquid sludge may be applied with tractors, tank wagons, irrigation systems, or special application vehicles. Liquid sludge may also be injected under the surface layer of the soil. Dewatered sludge, on the other hand, is typically applied to cropland by equipment similar to that used for applying limestone, animal manures, or commercial chemical fertilizers. Generally, the dewatered sludge is applied to the land surface and then incorporated by plowing or disking. When applied to pasture land, sludge is usually not incorporated into the soil.

Land Application to Non-Agricultural Lands

Ten or more States have undertaken sludge application to forest land, at least on an experimental field-scale level. The most extensive experience with this practice is in the Pacific Northwest. Sludge is most often sprayed from mobile equipment into established forest stands as a partially dewatered, but still liquid, material. Other types of non-agricultural land application include sewage sludge applied to public contact sites (e.g., parks, cemeteries, golf courses) and reclamation sites.

When sewage sludge is used to stabilize and re-vegetate land at reclamation sites, typically large amounts of sludge (up to 112 metric tons per hectare or more) are applied on a one-time basis. This large amount is necessary to ensure that sufficient organic matter and nutrients are introduced into the soil to support vegetation until a self-sustaining ecosystem is established.

Land Application—Sale or Give-Away of Sewage Sludge

Approximately 12 percent of the sewage sludge generated is sold or given away for use on home gardens. As a method of managing sewage sludge, this is a highly beneficial practice and one the Agency encourages.

Usually, sewage sludge that is sold or given away is composted, or heat dried and formed into pellets. In composting sewage sludge, the sludge is dewatered; mixed with a bulking agent, such as wood chips, bark, rice hulls, straw, or previously composted sludge; and allowed to decompose aerobically for a period of time. In this form, the sewage sludge is dry, practically odorless, and easier to distribute. It is also easier for the user to handle. Sewage sludge that is distributed and marketed is used as a substitute for topsoil and peat on lawns, golf courses, parks, and in ornamental and vegetable gardens. Yield improvements have been valued at $35 to $50 per dry ton over other potting media.

Risks of Disposal Methods

Communities should consider alternatives other than burying or burning their sludge. These are wasteful practices that pose risks and incur costs. Some methods of sewage sludge disposal, such as incineration and uncovered landfills, may contribute to global warming (i.e., the "greenhouse effect") by releasing carbon dioxide and methane.

Sewage sludge with high concentrations of certain organic and metal pollutants may pose human health problems when disposed of in sludge-only landfills (often referred to as monofills) or simply left on the land surface, if the pollutants leach from the sludge into the ground water. Therefore, the pollutant concentration may need to be limited or other measures such as impermeable liners must be taken to ensure that ground water is not contaminated.

For the incineration of sewage sludge, municipalities must take sufficient measures to control the emissions from sewage sludge incinerators. Otherwise, particulates, heavy metals, toxic organic compounds, and hydrocarbons will add to a community's air pollution problems.

Ocean dumping of sludge, which Congress banned after 1991, may result in the destruction of biota that influence the balance between oxygen and carbon dioxide. In ocean disposal, certain pollutants often associated with municipal sludge, including mercury, cadmium, and polychlorinated biphenyls, can bioaccumulate. High levels of these pollutants can interfere with the reproductive systems of certain marine organisms, may produce toxic effects in aquatic life, or may present public health problems if individuals eat contaminated fish and shellfish.

Disposal Methods

Surface Disposal

Sewage sludge surface disposal—a term used to describe what are essentially piles of sludge left on the land surface and includes land application to dedicated non-agricultural land and disposal in sludge-only landfills—is a common means of sludge disposal. The majority of surface disposal sites are smaller than 1 acre and receive less than 50 gallons per day of waste.

Generally, surface disposal sites do not have a vegetative or soil cover. Depending on the State in which they are located, surface disposal sites may be regulated in a manner similar to monofills or landfills. In other cases, surface disposal sites are areas of land where sewage sludge has been placed for many years with little or no consideration given to its ultimate disposal.

Disposal on Dedicated Sites

Contained in the surface disposal subpart of today's final rule is the provision for applying sewage sludge at greater than agronomic rates to grow food, feed and fiber crops. These crops may be grown and animals grazed if the owner/operator demonstrates to the permitting authority, that through management practices, public health and the environment are protected from reasonably anticipated adverse effects of pollutants in sludge.

Municipal sewage sludge is often applied at greater than agronomic rates at sites specifically set aside for municipal sludge management. Such application rates are needed to reclaim and restore marginal and disturbed soils, such as strip mines, to full agricultural productivity. Sludge contains organic matter typically in the range of 30 to 50 percent. Barren and strip-mine soils contain organic matter levels of less than one-half percent which is considerably less than the three to five percent needed for full agricultural productivity. In addition, such sites may likely be barren, very erodible and acidic, and a threat to ground and surface waters. Sludge applications greater than agronomic rates and even cumulative rate limits can overcome the barren, erosion and acid problems. Moreover, these applications can restore the organic matter levels to that needed to produce such commercial agricultural crops such as corn which would have been impossible to produce otherwise.

Sites which use sludge application at greater than agronomic rates are generally owned, operated, and

controlled by, or are controlled under long-term leases to, the municipal sludge operator. Generally, public access to these sites is strictly controlled. Sites may range in size from ten acres to greater than 10,000 acres. Sludges applied to such dedicated beneficial use sites apply nitrogen, phosphorus, and other macro- and micro-nutrients to crops and as was already stated may also be used to condition soils at sites containing disturbed lands. For example, the Metropolitan Water Reclamation District of Greater Chicago has been operating a 15,600 acre site for 20 years in Fulton County, Illinois. Sewage sludge is applied to condition and fertilize strip-mine spoils to produce crops, such as corn, which are sold as animal feed or for alternative fuel production, and is also used to reclaim acid coal refuse piles with vegetative cover.

In contrast to their large, rural, Fulton County site, the Metropolitan Water Reclamation District of Greater Chicago also operates a site in the Village of Hanover Park, one of Chicago's residential suburbs. The site lies on the property of the District's Hanover Park Water Reclamation Plant and the entire annual sludge production is utilized to fertilize row crops and nursery stock. This 120 acre farm, complete with a tile drainage system for recirculation of field percolate, has been successfully operated for 13 years and has harmoniously coexisted with its "across the fence" neighbors, a grade school and a community of single family homes.

However, the primary objective of this practice is to employ the land as a treatment system by using soil to bind metals and by using soil microorganisms, sunlight, and oxidation to destroy the organic matter and pathogens in the sludge. These sites are generally owned by, or are under long-term leases to, a treatment work. Frequently, the dedicated land disposal site has a non-food chain vegetative cover crop (e.g., sod, pulpwood) to reduce the potential for runoff or leaching of the pollutants to surface or ground water. In some cases, as discussed above, an attempt is made to use the nutrient and soil conditioning properties of the sewage sludge to grow crops for methanol production or for other purpose.

Landfilling

Landfilling is a sludge disposal method in which sludge is deposited in a dedicated area, alone or with solid waste, and buried beneath a soil cover. Landfilling is another disposal method that does not attempt to recover the nutrient content of the sludge for beneficial uses. However, the decomposition of organic matter in sewage sludge that is landfilled produces methane gas. The methane gas can be recovered and yields an energy value more than half as great as that of natural gas.

Thirty-three percent of the sewage sludge disposed of by 22 percent of the POTWs is landfilled with municipal solid waste. In co-disposal, the absorption characteristics of the solid waste and soil conditioning characteristics of the sludge complement each other. The solid waste absorbs excess moisture from sludge and reduces leachate migration. Sewage sludge usually makes up 5 percent or less of the material in a solid waste landfill.

Slightly less than 3 percent of the sewage sludge generated is disposed of in monofills (landfills only accepting sewage sludge). EPA has identified approximately 320 POTWs that dispose of their sewage sludge in monofills. Most monofills consist of a series of trenches, dug into the ground, into which dewatered sludge is deposited and then covered with soil. Other monofill designs, in which the sludge is deposited on the ground surface (area fill mounds, area fill layers, and diked containment), do exist but are not commonly used.

Incineration

Incineration is a method of disposal that destroys the organic pollutants and reduces the volume of sewage sludge. Incineration takes place in a closed device using a controlled flame. EPA estimates that approximately 0.9 million dry metric tons of sewage sludge are incinerated each year, accounting for more than 16 percent of the sewage sludge disposed of by POTWs.

If the sewage sludge contains 20 percent solids, incinerators reduce the volume of sewage sludge by about 90 percent, on a wet weight basis. While this reduces the amount of material that must be landfilled, owners or operators must control the concentration of the pollutants in the incinerator emissions to prevent exacerbation of a community's air pollution control problems. They must also allocate sufficient funds to pay for the labor, capital, operating, and maintenance costs of sewage sludge incinerators.

Approximately 110 (52 percent) of the sewage sludge incinerators operated by secondary and advanced treatment works in the United States were built prior to 1973, when the New Source Performance Standards for Sewage Sludge Incinerators were published (40 CFR part 60, subpart O). Multiple hearth incinerators are the most commonly used sewage sludge incinerators with 156 multiple hearth incinerators (74 percent firing sewage sludge). Other types include 49 fluidized bed incinerators (23 percent of the total), 3 flash drying incinerators, and 2 electric furnaces. A description of these incinerators is included in the Technical Support Document for Incineration (Reference No. 100).

The total estimated volume of sewage sludge fired in incinerators operated by POTWs in 1988 was approximately 860,000 dry metric tons. Not represented in this estimate are incinerators which fire sewage sludge with solid waste in municipal waste combustors. The Agency estimates that seven facilities practice co-incineration of sewage sludge with municipal solid waste.

Part II: Federal and State Requirements

The use or disposal of sewage sludge is currently subject to some Federal regulation. Existing Federal regulations are authorized under several statutes and have been developed independently along media-specific concerns. State regulations generally are keyed to Federal regulatory requirements, primarily those in 40 CFR part 257, covering the land application and landfilling of sewage sludge, and those in 40 CFR part 60, subpart O, covering sewage sludge incinerators.

This part starts with a discussion of the requirements of the CWA, followed by a description and summary of other Federal and State regulatory requirements and how they relate to today's rule.

Clean Water Act Statutory Requirements

Sewage sludge has been an important concern of the Agency since 1972, when EPA, through the Federal Water Pollution Control Act construction grants program, began assisting in the financing of wastewater treatment facilities. The Clean Water Act of 1977 amended section 405, mandating that EPA develop guidelines for the use and disposal of sewage sludge. As previously explained, under section 405(d), EPA was required to issue regulations that:

(1) Identify uses for sewage sludge, including disposal;

(2) Specify factors to be taken into account in determining the measures and practices applicable to each such use or disposal (including publication of information on costs); and

(3) Identify concentrations of pollutants which interfere with each such use or disposal.

Responding to this mandate, in 1979, EPA adopted criteria that provided guidelines for sewage sludge use and disposal when sewage sludge was applied to land or disposed of in landfills. These criteria were included in regulations co-promulgated under Subtitle D of RCRA and section 405(d) of the CWA and are found in 40 CFR part 257. These regulations contain a number of specific requirements for the management of sewage sludge. To protect the ground water, the regulations prohibit any use or disposal of sewage sludge that causes the concentration of 10 heavy metals and 6 organic chemicals in an underground drinking water source to exceed maximum contaminant levels (MCLs) specified in the criteria. The criteria also included management standards applicable to sewage sludge use or disposal methods to protect surface waters, flood plains, and endangered species. The criteria contain limitations on the concentration of two pollutants (cadmium and PCBs) in sewage sludge when the sewage sludge is applied to the surface of land used for the production of animal feed or food-chain crops. In addition, the requirements in part 257 restrict sewage sludge use and disposal except in compliance with certain measures to control pathogens and disease-carrying rodents, insects, and birds. The regulation provided for different levels of pathogen reduction, depending on whether crops for direct human consumption were grown or animals for human consumption were allowed to graze on the sewage sludge-amended soil. The processes for reducing the levels of pathogens include aerobic and anaerobic digestion, composting, lime stabilization, and heat treatment and drying.

As part of its sludge regulatory program, EPA has prepared a number of documents which provide guidance and direction to local POTWs on the proper management and handling of sewage sludge. EPA has actively encouraged and assisted in the development and implementation of various practices and processes leading to the beneficial use of sewage sludge. In addition to supporting long-term research and demonstration projects, the Agency has also assisted in the development of detailed design guidance for various beneficial methods of disposal and such technologies as digestion, composting, and lime stabilization. The Agency has also supported development of improved de-watering systems, pyrolysis, and other technologies to improve energy recovery from thermal conversion systems, methane recovery from anaerobic digestion systems, and the recovery of various potentially marketable by-products from sewage sludge.

To aid in developing the comprehensive sewage sludge regulations promised in the preamble to the 40 CFR part 257 rule (44 FR 53439, September 13, 1979), EPA created an Intra-Agency Sludge Task Force in 1982. The task force was assigned the following tasks: (1) Conduct a multimedia examination of sewage sludge management, focusing on sewage sludge generated by POTWs; and (2) develop a cohesive Agency policy on sewage sludge management, designed to guide the Agency in implementing sewage sludge regulatory and management programs. Numerous Agency offices and *ad hoc* groups had wrestled with sewage sludge management, but none of these groups had been able to decide how to equitably regulate nationally a complex and variable waste in an environmentally protective and cost-effective manner. Sewage sludge use or disposal involved a myriad of site-specific circumstances, could result in multimedia effects, and depended on proper planning and decision-making at the local level. The Agency lacked experience in developing performance standards for solid waste that would attenuate multimedia environmental effects. Furthermore, at that time, Congress had not provided a compliance mechanism for the regulations.

The task force, which included representatives from all parts of the Agency, recommended that the Agency develop an integrated, comprehensive regulatory structure for sewage sludge use or disposal using the combined authorities of section 405 of the CWA and other laws. This structure would also incorporate existing regulations and, where appropriate, new regulations to complete regulatory coverage where important gaps remained.

While the Agency was working on a regulatory approach consistent with the recommendations of the Task Force, the Natural Resources Defense Council sued the Agency over EPA's pretreatment regulation (40 CFR part 403). In that suit, the U.S. Court of Appeals for the Third Circuit ruled that the pretreatment regulation was invalid in four respects. [*Natural Resources Defense Council* v. *EPA*, 790 F.2d 289 (3rd Cir. 1986)]. Most relevant here is the court's fourth holding:

> We hold that, despite EPA's contention that sludge regulations are in place, EPA's device of incorporating other regulations does not meet the statute's command for a comprehensive framework to regulate the disposal and utilization of sludge and that EPA cannot, in the absence of section 405(d) regulations authorize the issuance of removal credits under section 307(b)(1).

Throughout its lengthy consideration of the amendments to the CWA, some members of Congress expressed concern that, without sewage sludge regulations, industry would continue to discharge toxic pollutants into wastewater for POTWs to treat, making it more difficult for a city to find sewage sludge management alternatives. They believed sludge criteria would stimulate effective pretreatment programs and would encourage recycling and reuse of toxic pollutants by industry. In the Water Quality Act of 1987 (Pub. L. 100–4, February 4, 1987), Congress reaffirmed its directive that EPA develop comprehensive sewage sludge regulations and set forth a schedule for the Agency to do so. The Water Quality Act amended section 405(d) to include requirements that:

> (1) By November 30, 1986, EPA propose regulations establishing numerical limits and acceptable management practices for toxic pollutants that EPA identified as present in sewage sludge in concentrations which, on the basis of information available on their toxicity, persistence, concentration, mobility, or potential for exposure, may adversely affect public health or the environment;
>
> (2) By August 31, 1987, EPA promulgate regulations specifying acceptable management practices and establishing numerical limits for these pollutants that "shall be adequate to protect public health and the environment from any reasonable anticipated adverse effects of each pollutant";
>
> (3) By July 31, 1987, EPA identify and propose regulations for those toxic pollutants not identified in the regulations promulgated August 31, 1987, and promulgate regulations for those toxic pollutants by June 15, 1988; and
>
> (4) From time to time, but no less often than every two years, EPA review the regulations for the purpose of identifying additional toxic pollutants and promulgating regulations.

The amendments specify that compliance with the regulations' requirements must occur not later than 1 year after publication of the regulations, unless the regulations require the construction of new pollution control facilities. In this latter case, compliance must occur no later than 2 years from the date of publication of the regulations.

Section 405(d)(5) also provides that nothing in the section is intended to waive more stringent requirements in the CWA or in any other law. This means that States and local communities remain free to impose more stringent requirements than those

included in today's rule. In addition, as described later in the preamble, where EPA has established requirements applicable to sewage sludge under other statutes, compliance with regulations established under those statutes also constitutes compliance with part 503.

Section 405(e) was further amended to read as follows:

> The determination of the manner of disposal for use of sludge is a local determination, except that it shall be unlawful for any person to dispose of sludge from a publicly owned treatment works or any other treatment works treating domestic sewage for any use for which regulations have been established pursuant to subsection (d) of this section, except in accordance with such regulations.

The implications of this section are discussed later in the preamble.

CERCLA Liability

Questions have been raised about conditions under which sewage sludge disposed at a Superfund site might give rise to liability under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA).

Section 107 of CERCLA generally imposes liability for cleanup costs on, among others, persons who own or operate facilities at which hazardous substances are disposed. Section 107 liability extends to the costs of cleanup necessitated by a release or threat of release of a hazardous substance. However, section 101(22) defines "release" to exclude the "normal application of fertilizer."

If the placement of sludge on land were considered to be "the normal application of fertilizer," that placement could not give rise to liability under CERCLA. Today's rule, as previously noted, establishes standards for sewage sludge when applied to the land for a beneficial purpose (i.e., as a fertilizer substitute or soil conditioner). Sludge placed on the land for such beneficial purpose and applied in compliance with the requirements for land application of sewage sludge provided in §§ 503.13(b) (2) and (4), § 503.14 and § 503.15 (where applicable) of the final rule today, and in accordance with accepted agricultural practices using appropriate application rates, which constitutes the normal application of fertilizer, does not constitute a "release."

Under CERCLA, protection from liability is also provided when there is a release of a CERCLA hazardous substance and the release occurs pursuant to Federal authorization. Thus under CERCLA, in defined circumstances, the application of sewage sludge to land in compliance with a permit required by section 405 of the Clean Water Act is a Federally permitted release as defined in CERCLA. Recovery for response costs or damages under section 107 of CERCLA is not authorized for Federally permitted releases. The Act defines Federally permitted releases as, among others, discharges in compliance with an NPDES permit under section 402 of the Clean Water Act. (See, *Idaho v. Hanna Mining Co.* 699 F. Supp. 827 (D. Idaho 1987) (State cannot recover under CERCLA for damages resulting from releases authorized by NPDES permit) *aff'd*, 882 F.2d 392 (9th Cir. 1989)). Consequently, releases of hazardous substances from the land application of sewage sludge authorized under and in compliance with an NPDES permit would constitute a Federally permitted release.

Other Federal Requirements

Traditionally, the Agency has used the standards, definitions, and approaches developed under other Federal public health and environmental programs in responding to the broad mandate of section 405(d) when they are consistent with the goals and objectives of the CWA. The use of other Federal standards is desirable in order to minimize duplicative, overlapping, and conflicting policies and programs. Further, as discussed above, section 405(d)(5) provides that nothing in section 405(d) is intended to waive more stringent requirements established under other statutes. Therefore, as previously indicated, in developing today's rule EPA based pollutant limits on human health or environmental criteria established under other statutory authorities.

Under section 304(a) of the CWA, the Agency publishes Water Quality Criteria. For the purposes of part 503, these criteria are used in determining whether a pollutant limit for a particular use or disposal practice would not exceed a freshwater quality criterion, should the pollutant reach the surface water. When the concern is to protect the drinking water supplies, the basis of the pollutant limits is the MCLs promulgated under authority of the Safe Drinking Water Act.

The NAAQS for lead, promulgated under authority of section 109 of the Clean Air Act, was used in developing the pollutant limit for lead when sewage sludge is incinerated. The National Emission Standards for Hazardous Air Pollutants (NESHAPs) for beryllium and mercury, used in the part 503 proposal to develop the numerical pollutant limits for these pollutants when sewage sludge is incinerated, have been omitted from the final part 503 regulations because these pollutants are already regulated under the authority of section 112 of the Clean Air Act and found at 40 CFR part 61. Other applicable regulatory requirements for the incineration of sewage sludge include the New Source Performance Standards for Sewage Sludge Incinerators promulgated under section 111 of the Clean Air Act and found at 40 CFR part 60, subpart O. Owners or operators of sewage sludge incinerators also must ensure that their operations, including the location of new incinerators, conform to state implementation plans approved under the regulations authorized by section 110 of the Clean Air Act and are found at 40 CFR parts 50–51.

State Requirements

The information on existing State requirements summarized below was gathered as part of EPA's effort in developing guidance for writing sewage sludge interim permits prior to promulgation of the part 503 standards. Under section 510 of the CWA, States, political subdivisions of States and interstate agencies retain the authority to adopt or enforce more stringent standards than those provided in today's part 503 regulations.

At present, 42 States have regulations or guidelines covering the land application of sewage sludge which set either a maximum allowable concentration or maximum pollutant loading rate for at least one pollutant. Paralleling the requirements in 40 CFR part 257, 41 States have set restrictions on the growing of crops on soil to which sludge has been applied (e.g., human food chain crops cannot be grown on sludge-amended soil until 18 months after the application of the sewage sludge). In addition, 41 States have established management practices for the land application of sewage sludge.

The give-away or sale of composted sludge is regulated under State land application requirements. Eleven States have set numerical limits on the concentration of pollutants in sewage sludge that is distributed and marketed and 22 States have established management practices regulating this use.

Many States enforce landfilling restrictions for nonhazardous sludge that follow the requirements in 40 CFR part 257. While States have not set maximum pollutant concentrations for sewage sludge that is landfilled, 31 States do have some site restrictions or other management practices governing landfills.

Many States regulate the emissions of sewage sludge incinerators. State implementation plans under the Clean Air Act limit emissions of various pollutants subject to NAAQS or NESHAPs. Twenty States have established opacity limits as well as emission limits for beryllium, mercury, particulates, sulfur dioxide, and carbon monoxide. No State has established a limitation on lead emissions from sewage sludge incinerators. Twenty-nine States have regulations or guidelines governing operation of incinerators, including disposal of ash.

In one State, the development and enforcement of controls on all methods of sewage sludge use and disposal are delegated entirely to local agencies, as is the issuance of permits. In other States, local as well as State controls are imposed on the use and disposal of sewage sludge.

Part III: Selection of Pollutants Considered for Regulation

This part describes how the Agency selected the initial list of pollutants for which numerical limits are promulgated in today's rule and data bases used to collect information about the pollutants. Additional information may be found in "The Record of Proceedings on the OWRS Municipal Sewage Sludge Committees" and "Summary of the Environmental Profiles" (Reference Nos. 62 and 67).

Initial List of Pollutants

In the spring of 1984, EPA enlisted the assistance of Federal, State academic, and private sector experts to determine which pollutants likely to be found in sewage sludge should be examined closely as possible candidates for numerical limits. These experts screened a list of approximately 200 pollutants in sewage sludge that, if disposed of improperly, could cause adverse human health or environmental effects. The experts were requested to revise the list, adding or deleting pollutants. The test for inclusion or exclusion was the potential risk to human health and the environment when sewage sludge containing a particular pollutant was applied to the land, placed in a landfill, or incinerated. The Agency also requested that the experts identify the most likely route which a pollutant could travel to reach target organisms, whether human, plant, or wild or domestic animals. The experts attending the meetings recommended that the Agency gather additional environmental information on approximately 50 pollutants. These pollutants are listed in Table III–1.

TABLE III–1.—POLLUTANTS SELECTED FOR ENVIRONMENTAL PROFILES/HAZARDS INDICES

Pollutants	Land application	Landfill	Incineration
Aldrin/Dieldrin	X		X
Arsenic	X	X	X
Benzene		X	X
Benzidine			
Benzo(a)anthracene	X		X
Benzo(a)pyrene	X	X	X
Beryllium			X
Bis(2-ethylhexyl) phthalate	X	X	X
Cadmium	X	X	X
Carbon tetrachloride			X
Chlordane	X	X	X
Chlorinated dibenzodioxins			X
Chlorinated dibenzofurans			X
Chloroform			X
Chromium	X	X	X
Cobalt	X	X	
Copper	X	X	X
Cyanide	X	X	
DDT/DDD/DDE	X	X	X
3,3'-Dichlorobenzidine			
2,4-Dichlorophenoxy-acetic acid		X	X
Dimethylnitrosamine	X		
Fluoride	X		
Heptachlor	X		X
Hexachlorobenzene	X		
Hexachlorobutadiene	X		
Iron	X		
Lead	X	X	X
Lindane	X	X	X
Malathion		X	X
Mercury	X	X	X
Methylene bis(2-chloroaniline)	X		
Methylene chloride	X	X	X
Methylethyl ketone		X	
Molybdenum	X	X	
Nickel	X	X	X
PCBs	X	X	X
Pentachlorophenol	X		X
Phenanthrene		X	X
Phenol			X
Selenium	X		
Tetrachloroethylene			X
Toxaphene	X	X	X
Trichloroethylene	X		X
Trichlorophenol			X
Tricresyl phosphate	X		
Vinyl chloride			X
Zinc	X	X	X

Environmental Profiles

During 1984 and 1985, the Agency collected data and information from published scientific reports on the toxicity, persistence, means of transport, and environmental fate of these 50 pollutants. EPA also developed preliminary information on their relative frequency of concentration in sewage sludge by analyzing the sewage sludge of 43 to 45 POTWs (depending on the pollutant) in 40 cities ("Fate of Priority Pollutants in Publicly Owned Treatment Works"—the "40 City Study"—Reference No. 60). The sewage sludge data from the "40 City Study" consist of concentrations of 40 pollutants (12 metals, 6 base neutral organic compounds, 6 volatile organic compounds, 9 pesticides, and 7 PCBs) in sewage sludge analyzed from the target POTWs.

Using this preliminary information on the relative frequency and concentration of pollutants in sewage sludge, their toxicity and persistence, the pathways by which the pollutants travel through the environment to a receptor organism (plant, animal, or human), the mechanisms that transport or bind the pollutants in the pathway, and the effects of the pollutants on the target organism, EPA made an assessment of the likelihood that each pollutant would adversely affect human health or the environment. For this analysis, EPA relied on simple screening models and calculations to predict the concentration of a pollutant that would occur in surface or ground water, soil, air, or food. EPA then compared the predicted concentration with an Agency human health criterion, such as a drinking water standard promulgated under the Safe Drinking Water Act, to determine whether the pollutant could be expected to have an adverse effect on human health. For purposes of this initial screening, EPA assumed conditions that would maximize the pollutant exposure of an individual, animal, or a plant, as well as the worst possible pollutant-related effects.

Based on the factors previously listed (concentration, toxicity, persistence, and others), EPA scored each pollutant and ranked them for more rigorous analysis. EPA excluded two categories of pollutants for further evaluation. First, EPA excluded pollutants which, when compared to a simple index, presented no risk to human health or the environment at the highest concentration that the Agency found in the "40 City Study" or in other available data bases. Second, EPA deferred consideration of pollutants for which EPA lacked human health criteria or sufficient data.

Information on each pollutant, the simple screening models and calculations used to describe the pollutant's path through the environment, and the indices used to evaluate the pollutant are compiled in an environmental profile for each pollutant. The summary of the environmental profiles is listed as Reference No. 64 in part XIV of the preamble.

Table III–2 shows the pollutants EPA did not analyze further because the pollutant did not exceed an EPA human health or environmental criterion at the highest concentrations shown in the "40 City Study." The pollutants listed in Table III–2 are also included in the list of pollutants for which eligible POTWs, complying with the requirements in part 503, may under 40 CFR part 403, apply for authorization to grant removal credits to their industrial dischargers (see Part XV—Description of the Amendments to 40 CFR Parts 257 and 403).

Table III–3 shows the pollutants for which a lack of data at the time of developing these regulations precluded the Agency from promulgating numerical limits at this time.[1] Included on the list in Table III–3 is dioxin. When EPA initiated these pollutant assessments in 1984, the Agency did not include dioxin as a pollutant evaluated for this rule. At that time, EPA lacked the data required to assess numerical limitations for dioxin in sewage sludge. In addition, adequate data were not available on the levels of dioxin or its pervasiveness in sewage sludge.

TABLE III–2.—POLLUTANTS EVALUATED AND FOUND NOT TO INTERFERE WITH SEWAGE SLUDGE USE OR DISPOSAL

Pollutants	Use/disposal practice (concentration)
Chlordane	Monofill over Class II, III ground water (12 mg/kg).
Chromium	Monofill over Class II, III ground water (1,499.7 mg/kg).
Copper	Incineration (1,427 mg/kg).
Cyanide*	Land Application, Distribution and Marketing, Monofill (2,686.6 mg/kg).
Dimethyl nitrosamine*	Distribution and Marketing (2.55 mg/kg).
2,4–Dichlorophenoxy-acetic acid	Monofill (7.16 mg/kg).
Fluoride*	Land Application, Distribution and Marketing (738.7 mg/kg).
Heptachlor	Incineration (0.09 mg/kg).
Iron*	Land Application, Distribution and Marketing (8,700 mg/kg).
Malathion	Monofill (0.63 mg/kg).
Molybdenum	Monofill (40 mg/kg).
Nickel	Monofill over Class II, III ground water (662.7 mg/kg).
Pentachlorophenol	Land Application, Distribution and Marketing (30.43 mg/kg).
Phenol	Monofill (82.06 mg/kg).
Selenium	Monofill, Incineration (4.85 mg/kg).
Tetrachloroethylene*	Distribution and Marketing (13.07 mg/kg).
Zinc	Monofill, Incineration (4,580 mg/kg)

*Exposure assessment models were used in determining that these pollutants, at the concentrations shown, do not interfere with the use or disposal of sewage sludge.

[1] Some of the organic pollutants for which development of regulatory limits were deferred are, in fact, regulated in this rule. As explained, incinerator organic pollutant emissions are limited by an operational standard for total hydrocarbons. Thus, because the emissions of total hydrocarbons are regulated, emissions of the following Table III–3 pollutants are, in actuality, regulated in the final rule: benzo(a)anthracene, phenanthrene and vinyl chloride.

TABLE III–3.— POLLUTANTS DEFERRED BECAUSE OF INSUFFICIENT DATA

Pollutants	Use/Disposal Practice
Benzo(a) anthracene	Land Application, Distribution and Marketing, Incineration.
Bis(2-ethylhexyl) phthalate.	Distribution and Marketing.
Chlorinated dibenzo-dioxins.	Land Application, Distribution and Marketing, Monofills.
Chlorinated dibenzo-furans.	Land Application, Distribution and Marketing, Monofills.
Cobalt	Land Application, Distribution and Marketing, Monofills.
Methylene bis (2-chloroaniline).	Land Application, Distribution and Marketing.
Methylene chloride	Land Application, Distribution and Marketing, Monofills.
Methylethyl ketone	Monofills.
Pentachlorophenol	Land Application, Distribution and Marketing.
Phenanthrene	Monofills, Incineration.
Tricresyl phosphate	Land Application, Distribution and Marketing.
Vinyl chloride	Incineration.

The Agency did not analyze sewage sludge for dioxins as part of the "40 City Study" because, at the time the samples were collected (1979–1980), methodologies did not exist for analyzing trace quantities (parts per trillion) of dioxins in sewage sludge. Since better analytical methods now exist, the Agency has collected sewage sludge samples for dioxins analyses as part of the National Sewage Sludge Survey (NSSS) (see discussion below).

EPA will use the NSSS data and the results of recent scientific studies to complete its analysis of dioxins in sewage sludge—a likely candidate for regulation in the second round of sewage sludge regulation. In the interim, as explained later in the preamble, the Agency is limiting the emission of dioxins from sewage sludge incinerators by establishing operating standards for total hydrocarbons.

Part IV: February 6, 1989 Proposed Rule

This part describes the sewage sludge use and disposal standards EPA proposed in February, 1989. In that notice, EPA proposed to include septage from septic tanks in the definition of sewage sludge and thus within the scope of the proposed requirements. A more detailed explanation of the proposed rule is found at 54 *FR* 5746, 5791–5855 (February 6, 1989).

The proposed standards included numerical pollutant limits, management practices, and other requirements that defined a level of control which owners or operators of treatment works and users or disposers of sewage sludge must attain over the use or disposal of sewage sludge in order to protect human health and the environment. EPA proposed pollutant limits, management practices, and other requirements that were specific to the method of use or disposal employed by treatment works use.

EPA proposed requirements that owners or operators of treatment works and users or disposers of sewage sludge would have to meet whenever they ultimately used or disposed of the sludge. The use or disposal methods included in the proposal were: (1) application to agricultural or non-agricultural land, (2) distribution and marketing (now referred to as sale or give-away of sewage sludge), (3) disposal in monofills, (4) disposal on surface disposal sites, and (5) incineration. EPA did not propose separate standards for septage from septic tanks. Rather, septage, when used or disposed of by any method regulated under the proposal (e.g., applied to land, placed in a monofill or surface disposal site) would have to meet the applicable requirements in the same manner as those for sewage sludge.

Land Application

EPA proposed standards for the spreading of liquid, de-watered, dried, or composted sewage sludge on or just below the surface of agricultural and non-agricultural land. Sewage sludge applied to agricultural land was subject to different numerical pollutant limits from those limits proposed for sludge applied to non-agricultural lands.

EPA based the numerical limits for sewage sludge when applied to agricultural land on a modelled assessment of potential risk to public health and the environment through 14 pathways of exposure. The numerical limits for sewage sludge when applied to agricultural land were expressed in terms of a limitation on the cumulative loading of 10 metals and an annual pollutant loading of 12 organic pollutants. The cumulative loading rate for each of the metals represented the limit on how much of a given metal in sludge could be added to the soil. The additional "load" of the metal could be applied all at once or over a period of years from repeated applications of sludge. No further application of sludge containing the metal would be allowed, however, once the cumulative loading is reached. In addition, the proposed rule also limited, on an annual basis, the quantity of 12 organic pollutants that could be applied to land. In order to ensure that the cumulative loading level and annual pollutant rates would not be exceeded, the proposal required owners and operators of treatment works to keep records on the amount of organic and inorganic pollutants applied to each land application site. In addition, before sewage sludge could be applied to the land by any one other than the treatment works, under the proposal the treatment works would have to enter into an agreement with the distributor or applier of the sludge to provide that they must comply with the standards.

In the case of non-agricultural land, EPA developed pollutant ceilings for the concentration in sewage sludge of these 22 organic and inorganic pollutants. The standards were premised on the assumption that pollutants in sludge applied to non-agricultural land would not reach individuals through the food chain. The ceiling concentrations were based on 98th-percentile values for pollutant concentrations in municipal sewage sludge based on data from a 1981–82 study.

Distribution and Marketing

Different requirements were proposed for sewage sludge which is distributed and marketed—what is now denominated sludge that is sold or given away—for use as a fertilizer and soil conditioner for potting medium, lawns, ornamental plants and gardens. In the case of distributed and marketed sludge, the Agency proposed to limit the quantity of sludge (or a product derived from the sludge) of a given concentration that could be applied to land in one year. When a treatment works was not the distributor of the sludge or sludge product, the proposal required an agreement between the distributor and treatment works to ensure compliance with the requirements.

An important difference between the proposed land application requirements and the proposed distribution and marketing requirements was in the numerical limits for some of the organic pollutants and some metals. In the exposure assessment pathway scenarios for both, it was assumed that the sewage sludge is used in the production of crops intended for human consumption. The numerical limits for the application of sewage sludge to agricultural land were based on crops intended for direct human consumption or fed to animals intended for direct human consumption, whichever was the more stringent loading rate. For the organic pollutants, which tend to bioaccumulate through the food chain, the limiting numerical limit was based on crops fed to animals intended for human consumption. However, the distribution and marketing scenario was designed to protect a fruit and vegetable home garden, not a garden in which feed is raised for animals intended for human consumption. Therefore, the numerical limits for organic pollutants in

distribution and marketing tended to be higher than those for agricultural land application.

Another major difference in the proposed requirements between the land application standards and the distribution and marketing standards was that for the land application requirements to apply, as noted, there had to be an agreement between the treatment works and the distributor or applier of the sewage sludge to abide by the requirements, such as the access and use restrictions. In the absence of an agreement, the proposal required the treatment works to comply with the requirements for the distribution and marketing standards.

Monofills

EPA also proposed requirements that would apply to landfills receiving only sewage sludge (monofills) and any person disposing of sewage sludge in a monofill. EPA developed numerical limits on the concentration of 16 pollutants in sludge that could not be exceeded if the sludge was disposed of in a monofill. These limits, derived from a modelled exposure pathway analysis, would vary depending the type of ground water under the unit. Moreover, the proposal provided for the determination of site-specific limits for monofills in defined circumstances.

Surface Disposal

In addition to the disposal of sewage sludge in sludge-only landfills, EPA also developed standards for another widely practiced means of sludge land disposal. EPA called this disposal method "surface disposal"—typically piles of sludge placed on the land—and defined them as areas of land where sludge is placed for a year or longer. Because EPA concluded that surface disposal sites are generally small and in rural areas, these sites did not expose individuals to significant concentrations of pollutants. EPA proposed pollutant concentration limits for sludge placed on a surface disposal site based on the 98th-percentile values derived from the data on sewage sludge quality. The effect of using 98th-percentile data was to cap pollutant concentrations at the level of quality represented by the data base. EPA concluded that this would protect public health and the environment because analysis of aggregate effects of sewage sludge use and disposal showed a low incidence of adverse health effects associated with this method of disposal. Because surface disposal and monofills shared a number of common characteristics, where the most stringent numeric monofill limits exceeded the 98th-percentile concentration, these were substituted for the 98th-percentile concentrations.

In addition, because of the similarity of surface disposal to non-agricultural land application of sludge and to monofills, EPA committed to revisiting for the final rule the issue of whether distinguishing these different use and disposal methods was appropriate. Furthermore, EPA committed to develop exposure assessment models to evaluate potential risk to health and the environment from surface disposal units for the final rule.

Pathogen and Vector Attraction Reduction Requirements

As noted, sewage sludge typically includes contaminants like bacteria, viruses, protozoa and helminth ova. These organisms can cause diseases, usually enteric diseases through direct human contact with the organism or through the ingestion of an infected animal. These contaminants may be spread by birds, rats and other animals exposed to them. The proposal included requirements for control of the pathogens in sludge as well as measures for reducing the contact of the disease "vectors" with the sludge pathogens. The proposal included pathogen reduction and vector attraction reduction requirements for sewage sludge that is applied to agricultural and non-agricultural land, distributed and marketed or disposed of on a monofill or surface disposal site.

In the proposal, treatment works could use any one of three levels of pathogen reduction when sewage sludge is applied to either agricultural or non-agricultural land as long as the treatment works or applier complied with the applicable restrictions on public access to the land and on growing crops or raising animals on the sludge-amended soil. In addition, two sets of numerical limits were included in this part. The applicability of these limits depended on whether the sewage sludge is used in the production of crops intended, directly or indirectly, for human consumption or for animals raised for human consumption.

One key difference between the proposed requirements of subpart B (land application) and subpart C (distribution and marketing) was the level of pathogen reduction in sludge required for a treatment works. Under the proposal, treatment works that distribute and market their sewage sludge to the general public had to process their sludge to attain the highest level of pathogen reduction provided. In contrast, the land application subpart of the proposal allowed a treatment works the option of selecting alternative pathogen reduction standards as long as the landowner imposed public access and animal grazing controls and restricted the growing and harvesting of crops in accordance with the standards of the class of pathogen reduction selected.

In developing the requirements for the land application of sewage sludge, the Agency assumed that, except for the applier, there would be little public contact with the sewage sludge itself or with the land receiving the sewage sludge. EPA also assumed that public access restrictions could be imposed on either agricultural or non-agricultural land for a period of time. The underlying premise in developing sewage sludge distribution and marketing requirements was that the sludge would be used in a home garden where there would be immediate and continuous human contact with the sewage sludge or with the land receiving it. Under such circumstances, the Agency could not restrict access.

Incineration

EPA proposed the following requirements for sewage sludge that is incinerated in an incinerator firing only sewage sludge. First, the proposed rule required a sludge incinerator to comply with the National Emission Standards for Hazardous Air Pollutants for mercury and beryllium. Second, in the case of lead, arsenic, cadmium, chromium and nickel, the proposal established a limit on the sludge concentration of these metals that could be incinerated. That concentration would vary depending principally on two factors: The control efficiency of the incinerator, and the dispersion factor (i.e., the relationship between ground level concentrations and pollutant emissions). These limits were designed to ensure that ground level concentrations (called the "risk-specific concentration") for a given pollutant did not exceed a value associated with protection of human heath at a cancer risk level of 10^{-5}. In the case of lead, the standard was designed to ensure that the National Ambient Air Quality Standard for lead was not violated. For purposes of this calculation, sewage sludge incinerators were assigned 25 percent of the air-shed loading for lead.

Third, the February 6, 1989 notice proposed a limit for maximum allowable total hydrocarbon concentration in sewage sludge. Again, this limitation, like the metal limits would vary with dispersion factors and control efficiency. Similarly, it was designed to ensure that ground level concentrations of total hydrocarbon emissions from the incinerator stack

would not exceed a level associated with a cancer risk of 10^{-5}. In order to determine the risk-specific concentration for total hydrocarbons, EPA made a number of assumptions about which organic pollutants comprised the total hydrocarbon mixture and at what levels these organics were present.

Monitoring, Recordkeeping and Reporting

The proposal required owners and operators of treatment works to sample and analyze their sludge and keep certain records. The pollutants for which monitoring was required depended on the method of sludge use or disposal employed. The frequency of monitoring would vary with the design capacity of the treatment works. In addition, treatment works were to monitor the sewage sludge for compliance with the pathogen reduction requirements when the sludge was used or disposed of other than by incineration. Further, the proposal required owners or operators of sewage sludge incinerators to monitor continuously for incinerator stack hydrocarbon concentrations, sludge feed rate, combustion temperature, and oxygen content of the exit gas.

As noted, the proposal required an agreement between the treatment works and the distributor or land applier. The information needed for the proposed reporting requirements would be contained in these agreements. EPA proposed that treatment works applying sewage sludge to agricultural lands keep the records for the life of the treatment works to ensure that the cumulative pollutant loading rate is not exceeded for a particular parcel of land receiving sewage sludge.

The monitoring, recordkeeping, and reporting requirements proposed for non-agricultural lands were similar to those required for agricultural lands. One difference was that treatment works did not have to keep track of annual and cumulative pollutant loading rates. Therefore, retention was only required for 5 years.

The proposal required retention of the analytical data on sewage sludge concentrations and pathogen reduction for 10 years for monofills and for five years for surface disposal sites. Incinerator records under the proposal were required to be kept for 5 years.

Part V: November 9, 1990 Notice of Availability of Information and Data, and Anticipated Impacts on Proposed Rule

Subsequent to publication of the proposed part 503 regulation in the **Federal Register**, three data gathering efforts were undertaken to gather information for the final part 503 regulation. They include the National Sewage Sludge Survey, a sewage sludge incinerator study, and a domestic septage sample collection and analytical study. This part of today's preamble describes those efforts briefly.

Background

Public Comment and Scientific Peer Review

In the preamble to the part 503 proposal, the Agency solicited public comment on a wide range of issues including the fundamental principles of the rule, the carcinogenic risk levels used, other human health and environmental criteria that could be used in establishing the numerical limits, changes that may occur because of other Agency actions (e.g., changes in MCLs and air standards for lead), the models, the MEI and aggregate risk analyses, the anticipated benefits and costs of the rule, and data deficiencies. In addition, EPA committed to seek and support scientific peer review of the technical bases of the rulemaking package during the public comment period on the proposed rule (54 FR 5747):

> EPA will have experts from both inside and outside the Agency review the scientific and technical bases of the proposal. This review may include the Agency's Science Advisory Board, the Cooperative State Research Service, Regional Research Technical Committee (sometimes called the W–170 Committee), representatives of academia, and/or other scientific/technical bodies with expertise in the areas covered by this proposed rule. With the additional data and the scientific and technical review of the proposal, the Agency should be able to expand and refine the standards.

The Agency worked with two peer review groups during the public comment period to review in detail the scientific and technical bases of the proposed rule. These two peer review groups were as follows:

1. Land Practices Peer Review Committee—The land application, distribution and marketing, monofill and surface disposal provisions of the proposal were reviewed in depth by a specially convened group of sewage sludge experts. This group included many nationally known experts on sludge use and disposal including several members of the U.S. Department of Agricultural W–170 Committee and represented a broad diversity of views. A representative of the Natural Resources Defense Council served on this committee. The final report was officially submitted to EPA on July 24, 1989 (Reference No. 58). Members of the committee and their organizations volunteered their time for this effort. Contributions to travel expenses for committee members were provided by several outside organizations (Association of metropolitan Sewerage Agencies, Water Environment Federation).

2. EPA Science Advisory Board (SAB)—The SAB reviewed the technical bases of the sludge incineration regulations. In the past, various SAB committees have reviewed the technical bases of similar EPA incineration regulations, most notably municipal solid waste combustion and hazardous waste incineration. The final report was submitted on August 7, 1989 (Reference No. 97). A representative of the Natural Resource Defense Council served on this committee.

In addition to the two peer review reports, EPA received in excess of 5,500 pages of comments from 656 commenters during the 183-day public comment period on the proposed rule. The type and number of commenters are broken down as follows:

Municipalities	278
Industry	51
States	36
Septage haulers	36
Septage association	3
Consultants	34
Associations	29
Federal agencies	17
Individuals	16
Academic	12
Public interest	9
Congressional	72
Public hearing	63
Total:	656

The public and scientific peer review groups provided a comprehensive range of opinions, comments, and recommendations. Many of the comments were critical of the Agency's risk assessment methodology (stating it was overconservative for some use and disposal practices, and under conservative for others); the risk levels used by the Agency (questioning which risk levels are most appropriate, 10^{-4}/10^{-5} versus 10^{-6}); the selection of data and parameters used in the exposure assessment analyses (providing additional/better data and parameters); and the impacts the proposed rule would have on beneficial reuse of sewage sludge.

On November 9, 1990, EPA provided public notice of the availability of the National Sewage Sludge Survey data. That notice described some of the results of the survey. In addition, the notice contained information and data from the Sewage Sludge Incinerator Study and the Domestic Septage Study, and described the changes the Agency

was considering making to the proposed part 503 regulation as a result of these studies. Further, the notice requested comments on a number of changes to the use and disposal standards that were being considered for the part 503 proposal in light of the comments submitted earlier, peer review of the Agency's effort and new information developed since the February 8, 1989 proposal. (55 FR 47210–47823).

The 60-day public comment period for the notice closed on January 8, 1991. During that time, the Agency received more than 1,000 pages of comments from 153 commenters. Many of the comments made by the commenters supported the changes identified in the notice as revisions that the Agency was considering for the final part 503 rule.

Need for Information on Current Sewage Sludge Quality and Use and Disposal Practices

The "40 City Study" Data Base

As required by section 405(d), EPA relied on available information in developing proposed 40 CFR part 503. The primary source of information on the occurrence and concentration of pollutants in sewage sludge was determined from analyzing data on 40 pollutants from POTWs in 40 cities ("40 City Study"—Reference No. 60).

As discussed earlier, at the time of proposal the Agency relied on the "40 City Study" data as the primary source of information on the pollutant concentrations in municipal sewage sludge. The "40 City Study" provided the most comprehensive and best documented nationwide data base on the concentrations of pollutants in sewage sludge. Consequently, EPA concluded these data were an appropriate basis for developing the proposal. However, EPA recognized several deficiencies in using the "40 City Study" data. Key among them was the fact that data on final processed sewage sludge was generally not available from the "40 City Study." Further, the procedure used to select POTWs in the "40 City Study" did not follow the statistical methods required to support unbiased national estimates of pollutant concentrations in POTW sewage sludge.

The study was designed not to measure pollutant concentrations in the sewage sludge leaving a POTW, but to determine what happened to section 307(a)(1) priority toxic pollutants in POTWs employing secondary or advanced treatment. The study approach required that some sewage sludge samples be taken at points within the POTW prior to final sewage sludge processing in order to account for organic pollutants that may be transformed into more elementary compounds or gases before final sewage sludge processing, as in anaerobic digestion. However, the study did include information that enabled the Agency to estimate the dry weight concentrations of pollutants in POTW sewage sludge.

Another deficiency of the data from the "40 City Study" is that they are not current. Sewage sludge quality had changed since 1978, because of the initiation of many pretreatment programs, development of new industrial facilities discharging wastewater to the POTW, and changes in wastewater treatment processes. Therefore, pollutant concentrations from the "40 City Study" did not reflect the current quality of sewage sludge. Moreover, analytical method advancements since the "40 City Study" allow for more accurate analyses of pollutants in the presence of suspended solids.

Although other sources of data on sewage sludge quality existed, these also suffered from deficiencies rendering them unsuitable for regulatory purposes. Some data were drawn from too narrow a geographic area or were drawn from POTWs of a particular size. Frequently, these data were not collected systematically and different sampling and analytical protocols were used in the same survey. In addition, many of these other data were collected prior to the "40 City Study" data.

While EPA believed that the "40 City Study" data were the appropriate data to use in developing the proposed part 503 regulations, EPA concluded the data needed to be replaced, or at a minimum, be supplemented to support the final regulations. Therefore, EPA undertook the NSSS to obtain a current and reliable data base for developing the final part 503 rule. This data base, as previously explained, will also be used in developing a list of pollutants from which the Agency will select additional pollutants for further analyses and potential regulation under section 405(d) of the CWA.

The NSSS data collection effort began in August 1988 and was completed in September 1989. EPA collected sewage sludge samples at 180 POTWs and analyzed them for more than 400 pollutants. In addition, through the use of detailed questionnaires, the survey collected information on sewage sludge use and disposal practices from 475 public treatment facilities with at least secondary treatment of wastewater. The results of the NSSS have provided EPA current data and information essential to establishing numerical pollutant limits in the final part 503 rule that will encourage the beneficial reuse of sewage sludge and provide a greater degree of public health and environmental protection than the February 6, 1989, proposal.

The National Sewage Sludge Survey

The NSSS, a massive undertaking, was conducted to obtain credible analytical data in order to characterize the quality of final process sewage sludge (55 FR 47210, November 9, 1990). These data were used to develop national estimates for the probability distribution of pollutant concentrations in sewage sludge. The estimates of pollutant distribution were used in developing the regulatory impact analysis for the final part 503 rule. EPA augmented sewage sludge quality data with information concerning sewage sludge generation and treatment processes, current and alternative sewage sludge use and disposal practices, and treatment and disposal cost data. These data, from a national sampling of POTWs employing secondary or advanced treatment of wastewater, were necessary for a number of essential analyses required for promulgating the final part 503 regulations including the aggregate risk analysis (ARA) and the regulatory impact analysis (RIA) which project the benefits and expected effects associated with the final part 503 rule. The ARA and the RIA are discussed later in part XIII.

In establishing numerical limits, pollutant concentration data from the NSSS were required to estimate the level of risk posed by current sewage sludge quality and current use or disposal practices. EPA also used the data from the survey to test the reasonableness of its analyses and regulatory approach. Some areas of earlier concern included the accuracy of anticipated risks and analyzed characteristics of increased incidence of chemically induced disease in proximity to particular use or disposal practices. The survey information assisted the Agency in further evaluating its regulatory approach and in capping those pollutants at the 99th-percentile pollutant concentration where the Agency believes the strictly risk-based numerical limitations do not provide an adequate margin of safety to protect public health and the environment.

The results of the survey were also used to assess the potential shifts among the various use or disposal practices as a result of the final regulations. The effect of the rule is an important

element in determining how rapidly to implement the regulations. For instance, if there is likely to be only a slight impact from a particular numerical limitation, immediate implementation of the regulations may be appropriate. If, on the other hand, wide shifts in current methods of use or disposal are anticipated from the numerical limits, the POTWs may need assistance in developing more stringent pretreatment limits for their industrial dischargers or in the adoption of alternative use or disposal practices.

In addition, EPA will study the analytical results of the NSSS to identify a preliminary list of pollutants for second round rulemaking. Potential candidate pollutants are those that have elevated concentrations in sewage sludge. A final decision to regulate pollutants in the second round will significantly depend on the availability of sufficient information on a pollutant's toxicity and environmental fate, effect, and transport properties. As explained earlier, the process EPA will follow to identify these pollutants will be similar to the process used in developing the pollutants controlled in this rulemaking.

Description of the National Sewage Sludge Survey

The NSSS was a data collection effort relying on analytical sampling and an informational questionnaire to obtain data on sewage sludge quality and management. The NSSS was designed to collect information and data necessary to produce national estimates of: (1) Concentrations of toxic pollutants in municipal sewage sludge, (2) sewage sludge generation and treatment processes, (3) sewage sludge use and disposal practices and alternative use and disposal practices, and (4) sewage sludge treatment and disposal costs.

Participants in the NSSS were selected from 11,407 POTWs in the United States, Puerto Rico, and the District of Columbia, identified in the EPA 1986 Needs Survey as having at least secondary wastewater treatment. Secondary treatment was defined as a primary clarification process followed by biological treatment and secondary clarification. In identifying POTWs for the NSSS, EPA excluded POTWs with "Present Effluent Characteristics" codes of "No Discharge," "Raw Discharge," and "Advanced Primary" from the 1986 Needs Survey.

As noted above, the NSSS effort consisted of a questionnaire and analytical survey. The sample of POTWs for each component was selected from the 11,407 secondary treatment POTWs identified by the Agency. The POTWs included in the two samples were selected according to stratified probability design. The two POTW samples are related in that all POTWs in the analytical survey were selected from among those POTWs that were already selected to receive the questionnaire.

The questionnaire survey was designed to allow survey results to be analyzed separately by flow rate group and by sewage sludge use and disposal practice. The secondary treatment POTWs identified by the Agency were divided into 24 mutually exclusive groups. Membership in these groups is based on four categories of wastewater flow rate and six primary use and disposal practices. The flow rates and use and disposal categories are as follows:

1. POTW average daily flow rate categories:
   a. Flow less than or equal to one million gallons per day (MGD).
   b. Flow more than one MGD but less than or equal to 10 MGD.
   c. Flow more than 10 MGD but less than or equal to 100 MGD.
   d. Flow greater than 100 MGD.
2. POTW sewage sludge use and disposal practice groups:
   a. Land application.
   b. Distribution and marketing.
   c. Incineration.
   d. Monofill (sewage sludge only landfill).
   e. Ocean disposal.
   f. Co-disposal landfill and other.

A 50-page questionnaire was mailed to every POTW selected for the NSSS. A total of 479 POTWs were selected to receive the questionnaire. General information gathered by the questionnaire concerned service area, POTW operating information, general sewage sludge use and disposal practices, pretreatment activities, wastewater and sewage sludge testing frequencies, and POTW financial information. POTWs also supplied use and disposal practice specific information and indicated which practice(s) would be likely alternatives to current use and disposal practices.

POTWs in the analytical survey were restricted to the contiguous States and the District of Columbia. The POTWs in the analytical survey were drawn from those included in the questionnaire survey. A total of 208 POTWs from the four flow rate categories were selected for sampling and analysis. EPA contract personnel collected sewage sludge samples just prior to disposal from each POTW according to sampling and preservation protocols.

Samples were analyzed for a total of 412 analytes. These analytes included every organic, pesticide, dibenzofuran, dioxin and PCB for which EPA has gas chromatography and mass spectrometry (GC/MS) standards. The remaining pollutants are inorganics. The pollutants were also selected in consideration of: (1) The CWA section 307(a) priority pollutants, (2) toxic compounds highlighted in the Domestic Sewage Study, and (3) Resource Conservation and Recovery Act (RCRA, Pub. L. 94–580) appendix VIII pollutants.

Sewage sludge sampling, preservation, and analytical protocols were specifically developed for this survey. Analytical methods 1624 and 1625 were adapted from methods to deal specifically with the sludge matrix for volatile and semivolatile organics, respectively, and utilize gel permeation chromatography sample clean-up followed by isotope dilution gas chromatography-mass spectrometry analyte identification and quantification. Pesticides and PCBs, and dibenzofurans and dioxins were analyzed using analytical methods 1618 and 1613, respectively. Metals and other inorganics and classicals were analyzed by standard EPA methods. The analytical methods were either developed, chosen, or adapted specifically for the sludge matrix to give the most reliable, accurate, and precise measurements of the 412 analytes undertaken in any previous analytical survey.

All raw analytical results were subjected to a two-step quality assurance/quality control (QA/QC) procedure. In the first step, each result and analytical procedure was checked against analytical method specifications. If this step was satisfied, then the result was evaluated for potential outlier characteristics by checking on laboratory identification number validity as well as sample origin. If the sample raw data passed both of these checks, it was certified and reported to EPA. Information on the availability of the NSSS data base and analytical protocols is provided in Part XIV—Availability of Technical Information on the Final Rule.

Sewage Sludge Incinerator Field Studies

In 1987, the Agency initiated a series of field studies on sewage sludge incinerators to support the part 503 rulemaking effort. The purposes of the on-site tests were to obtain: (1) Information about the percentage of hexavalent chromium in the total chromium in the exit gas from a sewage sludge incinerator, (2) information on the percentage of nickel subsulfide in the total nickel in the exit gas from a sewage sludge incinerator, (3) total

hydrocarbon (THC) emissions data for the sewage sludge incinerators, and (4) information about organic compounds in the exit gas from a sewage sludge incinerator.

As part of the studies, information was collected at 10 sewage sludge incinerators. Eight of the incinerators were multiple hearth incinerators and one was a fluidized bed incinerator. The incinerators had various combinations of air pollution control devices including wet scrubbers and wet electrostatic precipitators.

For the final rule, risk-specific concentrations are used to develop allowable pollutant concentrations for metals in sewage sludge. The risk-specific concentration for chromium depends on the percentage of hexavalent chromium in the total chromium in the exit gas. Based on tests at several sewage sludge incinerators, the Agency determined that the conversion to hexavalent chromium varies with the type of sewage sludge incinerator and air pollution controls. From the results, EPA derived different risk-specific concentration values (shown in Table 2 of section 503.43 of today's final part 503 regulation) based on four combinations of sewage sludge incinerators and air pollution control technologies.

The results of the nickel speciation tests revealed that nickel subsulfide is not emitted from sewage sludge incinerators above the level of detection for the analytical methods used in the tests. In order to be protective, EPA decided to base the standard risk-specific concentration for nickel on the higher of two detection limit values for nickel subsulfide. The risk-specific concentration for nickel in Table 1 of section 503.43 of today's final part 503 regulation is based on there being 10 percent nickel subsulfide in total nickel emitted from a sewage sludge incinerator.

Data from the studies on the total hydrocarbon concentration in the exit gas from sewage sludge incinerators were used, along with the aggregate risk analysis, as the basis for the THC operational standard in today's final part 503 regulation. This standard is technology-based in that it is based on performance data from sewage sludge incinerators. The THC operational standard is partly based on THC emissions measured using a heated sampling line and corrected to seven percent oxygen and zero percent moisture.

Information on total organic pollutants and THC in the exit gas from the sewage sludge incinerator was the basis for THC being used as a surrogate for measuring organic compounds in the exit gas. These tests showed that there is a significant correlation between THC and organic compounds, which is important because sampling and analysis techniques are not available to identify or quantify all potential organic compounds emitted from sewage sludge incinerators, nor are toxicity data available for all compounds. In addition, THC is easier and less expensive to monitor than are total organics, and THC can be measured on a continuous basis, which enhances operating and management practices.

Further, information on the organic pollutants in the exit gas from the sewage sludge incinerator was used to judge whether the technology-based THC limit protects public health and the environment from the reasonably anticipated adverse effects of organic pollutants in sewage sludge. Knowing which organic pollutants are in the exit gas (or potentially in the exit gas) allowed the Agency to develop an ambient risk-specific concentration for the organic compounds. This value was then used to estimate the risk level for the technology-based THC limits, which is an exit gas concentration.

The sewage sludge incinerator tests were also used to demonstrate that (1) wet electrostatic precipitators were effective at controlling metals emissions, (2) improved incinerator operating procedures and afterburners were effective at controlling THC emissions, and (3) THC analyzers were reliable instruments for measuring THC in the exit gas. More details on the sewage sludge incinerator field studies may be found in the Technical Support Document for Incineration. Information on the availability of single copies of this and other technical support documents is provided in part XIV.

Domestic Septage Study

In 1991, EPA initiated a sampling and analysis study for domestic septage. The purpose of this study was to characterize domestic septage. It was conducted because data on organic pollutants in domestic septage were not available.

As part of the study, nine samples of domestic septage were collected and analyzed for over 400 pollutants. These samples were collected and preserved in accordance with approved protocols.

Analytical results from this study were used for two purposes. First, the total Kjeldahl nitrogen and ammonia concentrations in the domestic septage were used to calculate the factor in the annual application rate equation for domestic septage in the final part 503 regulation. Second, the data were used in the justification of the domestic septage annual application rate.

More details on the domestic septage study and how it was used in developing the final regulation may be found in the Technical Support Document for Land Application. Information on the availability of single copies of this and other technical support documents is provided in Part XIV—Availability of Technical Information on the Final Rule.

Part VI: Risk Assessment Methodology

The purpose of risk assessment for EPA is to identify the potential for adverse effects associated with a pollutant in order to determine what, if any, measures are needed to protect public health and the environment. EPA, in developing these use and disposal standards, evaluated the potential risk to public health or the environment from individual pollutants present in sewage sludge. In performing this assessment, EPA relied on its traditional risk assessment processes and tools.

The methods for performing a risk assessment used by EPA were originally outlined by the National Academy of Sciences (NAS, 1983—Risk Assessment and Management: Framework for Decision Making. Washington, DC) and published in the **Federal Register**. EPA followed the following guidelines in its work in developing these regulations: U.S. EPA, 1986a—Guidelines for Carcinogen Assessment; Guidelines for Estimating Exposure; Guidelines for Mutagenicity Risk Assessment; Guidelines for Health Assessment of Suspect Developmental Toxicants; and Guidelines for Health Risk Assessment of Chemical Mixtures. FR Vol. 51, No. 185.

EPA's methodology for risk assessment may be broken down into four stages: hazard identification, dose-response evaluation, exposure evaluation, and characterization of risks. These are explained below.

Hazard Identification

The first element in this process is hazard identification—a determination of the nature of the effects that may be experienced by an exposed human or ecosystem from an identified pollutant. Hazard identification is used to determine whether the pollutant poses a hazard and whether sufficient information exists to perform a quantitative risk assessment. Hazard identification consists of gathering and evaluating all relevant data that help determine whether a pollutant poses a specific hazard, then qualitatively evaluating those data on the basis of the

type of health effect produced, the conditions of exposure, and the metabolic processes that govern pollutant behavior within the body or organism. It may also involve characterization of the behavior of a pollutant in the environment (or within an organism) as well as interactions the pollutant may undergo within the environment or within an organism. Thus, hazard identification helps to determine whether it is appropriate scientifically to infer that effects observed under one set of conditions (e.g., in experimental animals) are likely to occur in other settings (e.g., in human beings), and whether data are adequate to support a quantitative risk assessment.

The first step in hazard identification is to gather information on the toxic properties of pollutants through animal studies and controlled epidemiological investigations of exposed human populations.

The use of animal toxicity studies is based on the longstanding assumption that effects in human beings can be inferred from effects in animals. Three categories of animal bioassay are: Acute exposure tests, subchronic tests, and chronic tests. The usual starting point for such investigations is the study of acute toxicity in experimental animals. Acute exposure tests expose animals to high doses for short periods of time, usually 24 hours or less. The most common measure of acute toxicity is the median lethal dose (LD_{50}), defined as the dose level that is lethal to 50 percent of the test animals. This dose is usually experimentally determined by administering the test compound orally or intraperitoneally to mice or rats. Less commonly, tests can also be conducted by administering the pollutant by inhalation, dermal exposure or intravenously. LD_{50} is also used for aquatic toxicity tests and refers to the concentration of the test substance in the water that results in 50 percent mortality in the test species. Substances exhibiting a low LD_{50} (e.g., for sodium cyanide, 6.4 mg/kg) are more acutely toxic than those with higher values (e.g., for sodium chloride, 3,000 mg/kg) (NIOSH, 1979—Registry of Toxics Effects of Chemical Substances).

Subchronic tests for pollutants involve repeated exposures of test animals for 5 to 90 days, depending on the animal, by exposure routes corresponding to human exposures. The tests are used to determine the No Observed Adverse Effect Level (NOAEL), the Lowest Observed Adverse Effect Level (LOAEL), and the Maximum Tolerated Dose (MTD). The MTD is the largest dose a test animal can receive for most of its lifetime without demonstrating adverse effects other than cancer. In studies of chronic effects of pollutants, test animals receive daily doses of the test agent for approximately 2 to 3 years. The doses are lower than those used in acute and subchronic studies and the number of animals is larger because these tests are trying to detect effects that will be observed in only a small percentage of animals.

The second method of evaluating health effects uses epidemiology—the study of patterns of disease in human populations and the factors that influence these patterns. In general, scientists view well-conducted epidemiological studies as the most valuable information from which to draw inferences about human health risks. Unlike the other approaches used to evaluate health effects, epidemiological methods evaluate the direct effects of hazardous substances on human beings. These studies also help identify human health hazards without requiring prior knowledge of what causes disease, and they complement the information gained from animal studies.

Epidemiological studies compare the health status of a group of persons who have been exposed to a suspected causal agent with that of a comparable nonexposed group. Most epidemiological studies are either case-control studies or cohort studies. In case-control studies, a group of individuals with a specific disease is identified (cases) and compared with individuals not having the disease (controls) in an attempt to find past commonalities in exposures. Cohort studies start with a group of people (a cohort) considered free of the specific disease. The health status of the cohort known to have a common exposure is examined over time to determine whether any specific condition or cause of death occurs more frequently than might be expected from other causes.

Epidemiological studies are well suited to situations in which exposure to the risk agent is relatively high; the adverse health effects are unusual (e.g., rare forms of cancer); the symptoms of exposure are known; the exposed population is clearly defined; the link between the causal risk agent and adverse effects in the affected population is direct and clear; the risk agent is present in the bodies of the affected population; and high levels of the risk agent are present in the environment.

The next step in hazard identification is to combine the pertinent data to ascertain the degree of hazard associated with each pollutant. In general, EPA uses different approaches for qualitatively assessing the risk or hazard associated with carcinogenic versus noncarcinogenic effects. For noncarcinogenic health effects (e.g., mutagenic effects, systemic toxicity), the Agency's hazard identification/weight-of-evidence determination has not been formalized and is based on qualitative assessment.

EPA's guidelines for carcinogenic risk assessment (U.S. EPA, 1986a) group all human and animal data reviewed into the following categories based on degree of evidence of carcinogenicity:

- Sufficient evidence.
- Limited evidence (e.g., in animals, an increased incidence of benign tumors only).
- Inadequate evidence.
- No data available.
- No evidence of carcinogenicity.

Human and animal evidence of carcinogenicity in these categories is combined into the following weight-of-evidence classification scheme:

- Group A—Human carcinogen
- Group B—Probable human carcinogen
  B1—Higher degree of evidence
  B2—Lower degree of evidence
- Group C—Possible human carcinogen
- Group D—Not classifiable as to human carcinogenicity
- Group E—Evidence of noncarcinogenicity

Group B, probable human carcinogen, is usually divided into two subgroups: B1—pollutants for which some limited evidence of carcinogenicity from epidemiology studies exists, and B2—pollutants for which sufficient evidence exists from animal studies but inadequate evidence exists from epidemiology studies. EPA treats pollutants classified in categories A and B as suitable for quantitative risk assessment. Pollutants classified as Category C receive varying treatment with respect to dose-response assessment (see discussion below), and they are determined on a case-by-case basis. Pollutants in Groups D and E do not have sufficient evidence to support a quantitative dose-response assessment.

The following factors are evaluated by judging the relevance of the data for a particular pollutant:

- Quality of data.
- Resolving power of the studies (significance of the studies as a function of the number of animals or subjects).
- Relevance of route and timing of exposure.
- Appropriateness of dose selection.
- Replication of effects.
- Number of species examined.

• Availability of human epidemiologic study data.

Although the information gathered during the course of identifying each pollutant hazard is not used to estimate risk quantitatively, hazard identification enables researchers to characterize the body of scientific data in such a way that two questions can be answered: (1) Is a pollutant a hazard? and (2) Is a quantitative assessment appropriate? The following two sections discuss how such quantitative assessments are conducted.

Dose-Response Evaluation

Estimating or evaluating the dose-response relationships—what "dose" of a chemical produces a given "response"—for the pollutant under review is the second step in the risk assessment methodology. Evaluating dose-response data involves quantitatively characterizing the connection between exposure to a pollutant (measured in terms of quantity and duration) and the extent of toxic injury or disease. Most dose-response relationships are estimated based on animal studies, because even good epidemiological studies rarely have reliable information on exposure. Therefore, this discussion focuses primarily on dose-response evaluations based on animal data.

Two general approaches to dose-response evaluation are used, depending on whether the health effects are based on threshold or nonthreshold characteristics of the pollutant. In this context, "threshold" refer to exposure levels below which no adverse health effects are assumed to occur. For effects that involve altering genetic material (including carcinogenicity and mutagenicity), the Agency's position is that effects may take place at very low doses; therefore, they are modeled with no thresholds. For most other biological effects, it is usually, but not always, assumed that threshold levels exist.

For nonthreshold effects, the key assumption is that the dose-response curve for such pollutant exhibiting these effects in the human population achieves zero risk only at zero dose. A mathematical model is used to extrapolate response data from doses in the observed (experimental) range to response estimates in the low-dose ranges. Scientists have developed several mathematical models to estimate low-dose risks from high-dose experimental risks. Each model is based on general theories of carcinogenesis rather than on data for specific pollutants. The choice of extrapolation model can have a significant impact on the dose-response estimate. For this reason, the Agency's cancer assessment guidelines recommend the use of the multistage model, which yields estimates of risk that are conservative, representing a plausible upper limit of risk. With this approach, the estimate of risk is not likely to be lower than the true risk (U.S. EPA, 1986a).

The potency value, referred to by the Carcinogenic Assessment Group as Q_1^* (also referred to as Q^*), is the quantitative expression derived from the linearized multistage model that gives a plausible upper-bound estimate to the slope of the dose-response curve in the low-dose range. The Q_1^* is expressed in terms of risk-per-dose and has units of $(mg/kg/day)^{-1}$. These values should be used only in dose ranges for which the statistical dose-response extrapolation is appropriate. EPA's Q_1^* values can be found in the Integrated Risk Information System (IRIS), accessible through the National Library of Medicine. IRIS is EPA's computerized data base on health effects for carcinogenic and non-carcinogenic pollutants and contains the Agency's Q_1^* and RfD values for these pollutants.

Systemic toxicants or other compounds exhibiting noncarcinogenic and nonmutagenic health effects are assumed to exhibit threshold effects. Dose-response evaluations for substances exhibiting threshold responses involve calculating what is known as the Reference Dose (oral exposure) or Reference Concentration (inhalation exposure), abbreviated to RfD and RfC, respectively. RfDs and RfCs are estimates of a daily exposure to the human population that is likely to be without appreciable risk of deleterious effects during a lifetime. The RfDs and RfCs developed by EPA can be found in IRIS.

No Observed Effect Level (NOEL), No Observed Adverse Effect Level (NOAEL), Lowest Observed Effect Level (LOEL), or Lowest Observed Adverse Effect Level (LOAEL) can be used to calculate RfDs and RfCs values. Each value is stated in mg/kg/day, and all the values are derived from laboratory animal and human epidemiology data. Uncertainty factors are applied to RfD and RfC values depending on the level of confidence the Agency has in the data used to derive them. The magnitude of uncertainty factors varies according to the nature and quality of the data from which the NOAEL or LOAEL is derived. The uncertainty factors range from 10 to 10,000. They are used to extrapolate from acute to chronic effects, to account for differences in species sensitivity or variation in sensitivity in human populations and, when appropriate, to extrapolate from a LOAEL to a NOAEL. Ideally, route-specific (e.g., exposure through dermal contact, inhalation, etc.) RfDs and RfCs should be developed. If information is available for only one route of exposure, this information is used to extrapolate to other routes. Once an RfD or RfC is derived, the next step in the risk assessment is to estimate actual human (or animal) exposure.

Exposure Evaluation

The first step in exposure evaluation is to estimate environmental concentrations of pollutants. The Agency relies on two methods to determine pollutant concentration:

(1) Directly monitoring levels of pollutants, and

(2) Using mathematical models to predict pollutant concentrations.

Once environmental pollutant concentrations are determined, the Agency must then determine the severity of the exposure. In this step, the Agency evaluates data on the nature and size of the population exposed to a pollutant, the route of exposure (i.e., oral, inhalation, dermal), the extent of exposure (concentration times time), and the circumstances of exposure.

Monitoring

Monitoring involves collecting and analyzing environmental samples. These data provide the most accurate information about pollutant concentrations. The two kinds of exposure monitoring are personal monitoring and ambient (or site and location) monitoring.

Most exposure assessments are complicated in that people move from place to place and are therefore exposed to different pollutants throughout the day. Some exposure assessments attempt to compensate for this variability by personal monitoring. Personal monitoring uses one or more techniques to measure the actual concentrations of hazardous substances to which individuals are exposed. One technique is sampling air and water. The amount of time spent in various microenvironments (i.e., home, car, or office), may be combined with data on environmental concentrations of risk agents in those microenvironments to estimate exposure.

Personal monitoring may also include the sampling of human body fluids (e.g., blood, urine, or semen). This type of monitoring is often referred to as biological monitoring or biomonitoring. Biological markers (also called biomarkers) can be classified as markers of exposure, of effect, and of susceptibility. Biological markers of exposure measure exposure either to the exogenous material, its metabolite(s), or

to the interaction of the xenobiotic agent with the target cell within an organism. An example of a biomarker of exposure is lead concentration in blood. In contrast, biologic markers of effect measure some biochemical, physiologic, or other alteration within the organism that points to impaired health. (Sometimes the term biomonitoring is also used to refer to the regular sampling of animals, plants, or microorganisms in an ecosystem to determine the presence and accumulation of pollutants, as well as their effects on ecosystem components.)

Ambient monitoring (or site/or location monitoring) involves collecting samples from the air, water, soil, or sediments at fixed locations, then analyzing the samples to determine environmental concentrations of hazardous substances at the locations. Exposures can be further evaluated by modeling the fate and transport of the pollutants.

Modeling

Measurements are a direct and preferred source of information for exposure analysis. However, such measurements are expensive and are often limited geographically. The best use of such data is to calibrate mathematical models that simulate the movement of pollutants into and through the environment with mathematical equations or algorithms that can be more widely applied. Estimating concentrations using mathematical models must account not only for physical and chemical properties related to fate and transport, but must also document mathematical properties (e.g., analytical integration vs. statistical approach), spatial properties (e.g., one, two, or three dimensions), and time properties (steady-state vs. nonsteady-state).

Hundreds of models for fate, transport, and dispersion from the source are available for all media. Models can be divided into five general types by media: atmospheric models, surface-water models, ground water and unsaturated-zone models, multimedia models, and food-chain models. These five types of models are primarily applicable to pollutants or to radioactive materials associated with dusts and other particles.

Selecting a model for a given situation depends on the following criteria: Capability of the model to account for important transport, transformation, and transfer mechanisms; fit of the model to site-specific and substance-specific parameters; data requirements of the model, compared to availability and reliability of off-site information; and the form and content of the model output that allow it to address important questions regarding human exposures.

To the extent possible, selection of the appropriate fate and transport model should follow guidelines specified for particular media where available; for example, the Guidelines on Air Quality Models (U.S. EPA, 1986b—Guidelines on Air Quality Models (Revised), EPA/OAQPS–450/2–78–027R.).

Population Analysis

Population analysis involves describing the size and characteristics (e.g., age/sex distribution), location (e.g., workplace), and habits (e.g., food consumption) of potentially exposed human and nonhuman populations. Census and other survey data often are useful in identifying and describing populations exposed to a pollutant.

Integrated exposure analysis involves calculating exposure levels, along with describing the exposed populations. An integrated exposure analysis quantifies the contact of an exposed population to each pollutant under investigation via all routes of exposure and all pathways from the sources to the exposed individuals. Finally, uncertainty should be described and quantified to the extent possible.

Risk Characterization

It is EPA policy to describe statements about risks in major regulatory and policy documents to convey the extent of the Agency's confidence in those risk estimates. Risk assessment information must be clearly presented, separate from any risk management considerations. EPA seeks to present information on the range of exposures and risks and to identify all major uncertainties and address their influence on the assessment.

One way to identify uncertainties in risks is to evaluate how exposure assessments were conducted. For example, in human health risk assessment for this rule, the technical support documents define several exposure pathways for the three sludge management practices. EPA used point estimates for each exposure pathway and did not consider variability of the parameters describing exposure among individuals.

EPA's confidence in the risk assessment is necessarily limited by the data available to the EPA and by the lack of accepted risk assessment methodologies in certain areas. Overall, it is difficult to judge whether the point estimates in the human health risk assessment and assumptions made in the ecological effects assessment are likely to underestimate or overestimate actual risks. Some aspects of the risk analysis may contain conservative or protective assumptions, while other factors may bias results in the opposite direction. In addition, some assumptions are based on longstanding Agency policy and reflect risk management choices. Again, some of these assumptions are conservative while others are less conservative.

The sections that follow examine the uncertainties in several important aspects of the risk assessment: human health, human exposure pathway, plant toxicity and uptake, effects on wildlife, and ground water impacts.

Human Health Assessment

In accordance with standard Agency practice, human-health dose-response assessments are based on reference doses (RfDs) for non-carcinogens and cancer potency factors (Q_1^*) for carcinogens. Both of these measures are generally considered conservative, that is, they predict a greater impact on human health than is likely to actually occur. The reference dose is defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime". It is calculated by taking the most sensitive adverse effect found in toxicological testing and applying a series of uncertainty factors, so that higher exposures may also not present any appreciable risk. It is assumed, for example, that humans may be an order of magnitude more sensitive than the animals tested, but in fact humans may also be less sensitive. It is also assumed, except as noted, in the risk assessments relied on for these regulations that exposures may last an entire lifetime, whereas they may in fact be much shorter.

Similarly, calculated cancer risks are described in the Agency's risk assessment guidelines as "plausible upper bounds" to the actual risk. Conservative assumptions are used in the calculations, such as use of the most sensitive animal data in bioassays, linear extrapolation to low doses, species-to-species conversion based on surface area, and use of an upper confidence limit for the dose-response slope. Thus, it is unlikely that the cancer risk would be greater than is calculated, but it could be orders of magnitude less or even zero.

Human Exposure Assessment

There are uncertainties concerning the long-term behavior of metals in sludge. The sludge experts that EPA

relied on conclude, based on field studies, that iron oxides and manganese oxides found in sludge as a result of wastewater treatment and metal oxides naturally found in soils may form complexes with the metals and significantly reduce their bioavailability. Documentation to support these conclusions is limited. At a minimum, when the organic component of the sludge breaks down, it is possible that average concentrations of pollutants may increase or they may become more bioavailable.

The risk assessment for the soil ingestion pathway assumes the child ingests 0.2 grams of undiluted sludge every day for a five-year period, and has a "typical" background intake of the contaminants. The Agency has determined that this assumption is conservative and will protect children who inadvertently ingest sewage sludge.

The exposure assessment for many pathways assumes that the sludge will be fully incorporated into the top six inches of soil, although there is no labeling requirement to provide these instructions on sludge products.

Home Garden Scenario

The Agency characterized the data and assumptions used for exposure analysis in the human food chain pathway; specifically the calculations for production of crops for home consumption by gardeners and farmers. The population assessed for this pathway were individuals who use sludge products to produce crops for their own consumption. Ideally, the Agency would like to describe the distribution of exposures within this population. However, the available data are insufficient for such an analysis. The Agency made specific assumptions about a number of variables addressing human behavior and properties of sludge.

Plant Uptake of Metals

The slope of the line for the plant uptake was used to estimate metal concentration in plants. Plant uptake of metals was considered proportional to the cumulative application rates. An uncertainty exists whether it is appropriate to calculate plant concentration as a slope of plant uptake times an application rate. Some data on plant concentration versus application rate suggest non-linearities. EPA's assessment assumes that the linear approximation is conservative because application rates allowed under the rule are in general well in excess of test plot application rates, and metals concentration in plants is thought to reach a plateau at higher sludge application rates.

Another uncertainty in the plant uptake calculation is the use of a geometric mean value of all slopes calculated from individual sludge studies. If a distribution is lognormal, the geometric mean provides an estimate of the median (50th percentile) slope. Such a value is useful in estimating uptake for a "typical sludge". The individual sludge studies that EPA used to calculate plant uptake used sludges with higher metals concentrations than the "typical sludges" on the market today. Sludges with higher metals concentration are most likely to produce higher plant concentrations. It is possible that the geometric mean value of uptake slopes that EPA used is higher than the mean value would be if the studies used in calculations were repeated using currently produced sludge.

Another uncertainty exists as a result of the way that the geometric mean calculations were done. A value of 0.001 was used as the uptake slope from individual studies when there was no significant increase in metal uptake by the crops raised on the sludge. A geometric mean calculation is very sensitive to the inclusion of low values. From the inspection of several data sets it appears that 0.001 is substantially smaller than the upper bound on uptake that would be obtained from "no significant increase in metal uptake" studies. The use of the default slope of 0.001 may underestimate the typical slope for crop uptake.

Dietary Consumption

The pollutant limits were calculated based on population average food consumption estimates derived in a study by Pennington. These estimates are based on United States government survey data from short term food consumption reports of large surveyed populations. Such survey data is an accepted basis to estimate population average food consumption rates.

Two limitations exist with the way that the food consumption estimates were presented. First, the calculations presented address the average g/day food consumption rate. In the sludge dietary exposure assessment food consumption values are normalized for adult body weight. This does not reflect the higher food consumption rates per unit body weight of young children compared with adults. The dietary assessment does not separately consider exposures to children as a population subgroup.

A second limitation of the food consumption estimates is that they apply to the United States general population rather than individuals raising crops for home consumption. It is possible that individuals who raise a particular crop may have a higher consumption rate than individuals who only obtain the item from commercial sources. This would introduce an underestimation of the consumption rates in the population considered in the assessment. On the other hand, home gardens do not produce year-round, which may offset this bias.

Fraction of Food Raised on Sludge Treated Land.

To complete the analysis of the human food chain pathway it is necessary to estimate how much food comes from sludge treated land. USDA survey data on average percentage food consumption from home grown crops was used. While these estimates are average values for this population, EPA estimated that large garden plots are required to produce the amount of home grown crops assumed in the assessment. EPA believes that a relatively small percentage of gardens are that large. Secondly, because of seasonal factors, it may be difficult for most gardeners to produce the quantities of leafy vegetables that are assumed in the assessment. Leafy vegetables are important to the assessment as these crops tend to have high metal uptake slopes.

Plant Toxicity and Uptake

The phytotoxicity assessment was based on the relationships between sludge application rate and tissue residue, between tissue residues and reduction in growth, and between reduction in growth and reduction in yield. The relationship between reduction in growth and reduction in yield is particularly uncertain. The uncertainties will vary with chemical, crop species, and toxic endpoint; the best data were available for zinc, corn, and growth reduction. Some crops (e.g., beans) and endpoints (e.g., reproduction) may be more sensitive to the effects of sludge, although other crops (e.g. sudangrass) and endpoints (e.g., mortality) may be less sensitive. In addition, there are limited data about non-cultivated forest species and perennials, which may differ in their response to contaminants.

Phytotoxicity of metals is particularly sensitive to soil pH and the degree of binding to the sludge matrix. Most metals are more bioavailable in acidic soil, but molybdenum and selenium may be more available in alkaline soils. Since forest soils in some areas of the country may have pH below 5.5, the

assumption that the analysis represents a "reasonably worst case" may not apply to all forest land application.

While some data shows that cadmium uptake plateaus at a certain concentration in the soil, other evidence indicates copper and zinc may continue to increase. In addition, uptake varies among plant species; e.g. beets take up copper more readily than 38 other crops studied.

However, based upon results from several field studies, EPA believes that metals are bound to the sludge matrix and remain relatively unavailable biologically.

Wildlife

EPA has no standard methodology for assessing risks to wildlife. There are many uncertainties about how sludge application affects terrestrial wildlife and soil biota. The analysis presented, while utilizing available data and methodologies, only described direct toxicity to a few species. Uncertainties exist about how to extrapolate this information to other birds, mammals, amphibians, and soil invertebrates whose relative sensitivity to the compounds of concern is unknown. The ecotoxicological analyses focused on cadmium and lead because the most data are available for them. Other chemicals, particularly selenium, may also be of concern.

The criteria are based on direct toxicity, and impacts at population and community levels are not addressed. In addition, EPA used a simple linear model of bioaccumulation or bioconcentration from soil to earthworms to shrews and did not model the more complex effects of sludge contaminants on the terrestrial food chain. The analysis evaluates effects on shrews as an indicator of ecotoxicological effects, but there may be other highly exposed or sensitive organisms in the forest or field systems. Other uncertainties arise from the assumption that 33% of the shrew's diet consists of contaminated soil biota (represented solely by earthworms).

Because no standard methodologies exist, EPA did not consider how sludge amendment of forest soils or edges of agricultural fields may change the composition of species in the plant community, through either nutrient enhancement or phytotoxicity. Such changes, in turn, could change the species of herbivorous and granivorous insects, mammals, and birds with subsequent ramifications throughout the food web.

Uncertainty also exists about the impact of sludge on soil biota. The criteria are based solely on a NOAEL for the earthworm *Eisenia foetida*, which may not be the most sensitive or appropriate species to evaluate for many of the chemicals. Additionally, the analysis did not address the influence on the soil flora and fauna (nematodes, protozoa, bacteria, fungi, viruses) of adding nutrients to the soil or possible increased exposure to organisms that feed in the litter layer due to the organic matter in the sludge.

Aggregate Risk

The statistical approximations and assumptions used in the aggregate risk analysis are extensive and several are important contributors to uncertainty. While the model used for assessment of national aggregate risk has not been validated in comparison to actual exposure data, the Agency's aggregate risk assessment models generally reflect assumptions similar to those described here.

(1) The assessment assumes that population exposure is lognormally distributed before and after exposure to sludge. As the assessment addresses many low probability events in the far tail of the population distribution, a strict lognormal model may not be appropriate but no other data were available.

(2) The effect of sludge use on the distribution is assessed by making a small shift to the geometric mean of the United States population distribution without changing the geometric standard deviation. In principle, both the geometric mean and standard deviation may be expected to change. The geometric standard deviation is a highly sensitive parameter in lognormal models, so this assumption may be important in aggregate risk calculations.

(3) For lack of adequate data, the inherent variability in individual exposure to pollutants in sludge is not addressed.

Ground Water

Sensitivity analysis for the ground water model indicates that numerical criteria are very sensitive to values selected for equilibrium partition coefficients for each pollutant, and the range of plausible values for these coefficients spans several orders of magnitude. However, the Agency believes that it has chosen reasonable assumptions for the modeling, resulting in numerical criteria that are sufficiently protective of public health.

An additional source of uncertainty for partition coefficients is the speciation of metals within soils. For its calculations, the Agency used single lumped partition coefficients to represent the behavior of potential mixes of metal species within the soil. These coefficients are based on studies of sandy loam soils treated with wastewater sludge and are believed to provide appropriate and protective values for the calculations. However, under certain local conditions (e.g., highly acidic soils), differences in the speciation of metals could lead to partitioning that differs by one or more orders of magnitude from that predicted by the ground water model. They could also affect the toxicity of metals in groundwater.

EPA assumed that sludge would be uniformly mixed to a depth of 15 cm. Uneven distribution of contaminants in soil could lead to "hot spots" and variation in the amount of leaching to ground water. However, because the criteria are based on exposure averaged over many years of an individual's lifetime, the Agency believes that this variation will not significantly affect total exposure.

Monitoring Study to Address Land Application Risk Assessment Issues for Round Two Standards

Section 405 requires EPA to develop standards for sludge use or disposal which are adequate to protect public health and the environment from reasonably anticipated adverse effects of pollutants in sludge, present in concentrations that may adversely affect public health and the environment. The statute directs the Agency to promulgate these standards in two stages and to revise the standards periodically. The Agency has concluded that the standards adopted today are adequately protective based on its assessment of the available data. However, to verify its conclusions about the adequacy of today's standards, the Agency is committing to develop a comprehensive environmental evaluation and monitoring study. The results of the study will provide a useful data base for the Round Two sludge standards. Such a study will also aid the Agency in its efforts to develop a comprehensive ecological risk assessment methodology, and to correct any uncertainties in subsequent part 503 rulemakings.

As a minimum this study will address:

(1) Transport and transformation of inorganic and organic constituents of sludge considering leaching, surface runoff, and soil and sludge binding capacity (the variability in the binding capacity of different sludge/soil matrices will be considered). Ground water monitoring will be included in the study to assess whether leaching of inorganics is occurring;

(2) Variability of real-world sludge application practices;

(3) Bioavailability of sludge constituents to both plants and animals under different environmental conditions;

(4) Ecological effects of organic and inorganic constituents as well as pathogens, including effects to wildlife and non-cultivated crops and impacts on unmanaged plant and animal communities, endpoints chosen in the risk assessment for phytotoxicity and alternative endpoints;

(5) Confirmation of the distribution and variability in the concentration of constituents and binding capacity of sludge matrices; and

(6) Long-term temporal changes; for example, changes in binding capacity as sludge ages and sensitivity of the results to changes in site condition such as degradation of the sludge matrix, pH changes, and land-use changes.

EPA will develop a plan for the study and submit it to external experts for comment and refinement. The final plan including study design will be available for public comment at the time that the Round Two regulation is proposed. The Agency is seeking comment at this time on the priority of the various elements of the study and suggestions for alternative cost-effective approaches to address the uncertainties in the human health and ecological risk assessment. This information will be used in development of the study design.

As the Agency develops its ecological risk assessment methodology and as it obtains results from the monitoring study, the risk assessment decisions made in this final rule may need revision. The Agency will consider necessary revisions when the results of the monitoring study are available.

The Agency will also further evaluate the potential risks and benefits of nutrients contained in sludge in the Round Two sludge regulations. Although sludge, like other fertilizers applied to agricultural land, provides valuable nutrients needed for crop growth, over application can degrade ground and surface water quality. An extensive evaluation of the effects from nutrients in sludge was not performed in Round One. Because sewage sludge has relatively low nutrient content as compared to other unregulated commercial fertilizers, EPA did not consider nutrients a problem if sewage sludge is applied at agronomic rates.

Excessive loadings of nutrients from the use of fertilizers, both organic and inorganic, pose significant ecological risks by stimulating the over-enrichment of estuaries, lakes, reservoirs, bays, and slower streams in a process known as eutrophication. Eutrophication occurs when excess nutrients stimulate the growth of algae and alter the biological composition of ecological communities. In general, nitrogen is the limiting factor for plant growth in marine ecosystems and phosphorus is the limiting factor in fresh water. In some estuarine systems, both nitrogen and phosphorus can limit plant growth.

Nitrogen in the form of nitrate is highly mobile and moves with water. If nitrate finds its way to ground water and then to drinking water wells, it may pose a human health risk. EPA has set a drinking water standard of 10 mg/l to protect against the most sensitive health effect endpoint, methemoglobinemia (blue baby syndrome) in infants.

The Agency will consider sludge management practices in the context of risks and benefits posed by nutrients in the Round Two regulations. In addition, representatives of the U.S. Department of Agriculture have raised concerns about the standard for cadmium contained in these regulations. EPA believes, based on its current analyses, that the regulations promulgated today satisfy the requirements of Section 405 of the Clean Water Act. However, EPA welcomes additional data and analyses related to this particular sludge standard and will consider any such additional information received by the Agency within 90 days from the publication of today's rule. Should significant additional data or analyses be presented to the Agency demonstrating that a different standard is warranted, the Agency will expeditiously modify this rule.

Part VII: Risk Management Approach

Agency Risk Management Approach

Armed with the risk characterization information, the Agency can determine if a "significant" or "unreasonable" risk exists, what to do about it or what controls are necessary, and how to communicate the risk to the public and regulated community. Implicit in this analysis is that the simple identification of risk is not necessarily sufficient to justify action. In addition, non-risk factors such as the availability and effectiveness of controls, the existence of alternatives, and any benefits that would be lost or gained as a result of controls must be considered by the Agency in the process of reaching a decision. In some cases, the weight of the risk and benefits will be such that the benefits outweigh the risks. In such a case, the Agency's risk management decision may be to take no regulatory action. In other cases, risks relative to benefits are such that the reasonable action is to reduce the risk or control the environmental effect.

This process is interactive and affects earlier components in the risk assessment. Under each exposure scenario, the Agency identifies a range of control strategies and regulatory requirements that usually reduce exposure so that the risk or identified effect is put back into balance with the benefits. Using the information provided in the risk management step, the Agency can select the appropriate control strategy and means for communicating it to the public and regulated community.

Alternative Regulatory Approaches Considered in Developing the Final Rule

Introduction

This part of the preamble discusses alternatives the Agency considered in developing today's part 503 rule. EPA solicited public comments on these proposed approaches and sought suggestions for other appropriate approaches that the Agency could consider in developing its risk assessment methodology used to establish standards for the use and disposal of sewage sludge. Over the years, EPA has developed different regulatory approaches, depending on the legal requirements of a particular statute, surrounding issues, uncertainties, and information bases. Other EPA statutes covering the same pollutants or activities have very different legal requirements from section 405(d) of the CWA. The following discussion examines how different statutes mandate how EPA establishes standards under different regulatory regimes.

Title III of the 1990 Clean Air Act Amendments establishes a program to reduce emissions of hazardous air pollutants from stationary sources. Title III requires EPA to develop standards for sources of hazardous air emissions based on maximum achievable control technology for controlling these emissions. Section 112 includes a list of nearly 200 chemicals and chemical classes for which National Emission Standards for Hazardous Air Pollutants may be set. The standards promulgated under section 112 require the maximum achievable reduction in emissions, considering cost and other relevant factors. Categories and subcategories of sources are subject to regulation according to a specified schedule, with the first set of sources regulated by 1992.

EPA proposed listing sewage sludge incinerators as a category of major

sources as required under title III of the 1990 Clean Air Act Amendments (54 FR 28548, June 21, 1991). At this time, the Administrator has decided that listing this category of sources under the Clean Air Act is required by the legislation. Regulatory review of this category will take into account the final requirements being promulgated today under part 503. The regulatory review of this category is not expected to take place for seven years because comprehensive controls on this category are in the incineration subpart of the part 503 rule being promulgated today.

The EPA may promulgate additional standards, if needed, to protect health with an ample margin of safety or to prevent adverse environmental effects. Unless new legislation is enacted, health-based standards will be mandatory for categories of sources that pose an estimated cancer risk of greater than 1×10^{-6} to the most exposed individual. The schedule for these "residual risk" standards is nine years after promulgation of control technology standards for the first set of source categories and eight years post-promulgation for the remaining source categories.

Under the Safe Drinking Water Act (SDWA), the Agency first defines a goal to limit the concentration of the pollutant in drinking water (maximum contaminant level, goal—MCLG; for carcinogens, the concentration goal is zero). After setting a goal, the Agency sets an enforceable standard (maximum contaminant level) based on feasibility. Under the SDWA, the enforceable standard may not necessarily achieve the goal set for the pollutant, but it is established at a level that is safe for human health. The carcinogenic risk levels for drinking water MCLs generally range from 1×10^{-6} to 1×10^{-4}

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA) explicitly provide for balancing health and costs in decisionmaking. The carcinogenic risk levels established under FIFRA range from 1×10^{-6} to 1×10^{-4}, depending on the type of exposure involved. Applier exposure is generally in the range of 1×10^{-4} and dietary exposure is generally in the range of 1×10^{-6}. The regulatory limits under TSCA are driven by balancing economic analyses and exposure analyses, with the exposure analyses also considering adverse health effects other than carcinogenicity.

Under the Resource Conservation and Recovery Act (RCRA), Subtitle D (non-hazardous wastes), the Agency sets standards to protect human health and the environment based on the reasonable probability that municipal solid waste landfills will cause adverse effects. The standards are established considering the "practical capability" of the facilities. The Agency is requiring that States establish ground water protection standard remedies for carcinogens in the range of 1×10^{-6} to 1×10^{-4} (see, 56 *FR* 50978, October 9, 1991).

However, Subtitle C of RCRA (hazardous wastes) contains no provision to consider costs or the practical capability of a facility to meet the standards. The standards developed by the Agency under RCRA Subtitle C are necessary to protect human health and the environment. The Agency has standards that prohibit hazardous waste incinerator emissions for metals from exceeding a summed carcinogenic risk level of 1×10^{-5}.

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) directs the Agency to set standards for cleanup by considering the relative degree of risk to human health and the environment. Under CERCLA, the Agency has set standards based on carcinogenic risk levels of 1×10^{-7} to 1×10^{-4}, with 1×10^{-6} as the departure point for the analysis.

As shown, each statute is unique. Therefore, the regulatory approach and limits developed under one statute may not be appropriate for those developed under another statute. Before comparing regulatory requirements, the legal requirements of the authorizing statute must be examined.

In developing a regulatory approach, one of the principles guiding EPA is to establish reasonable standards. Section 405(d)(2)(D) of the CWA requires the Agency to establish management practices and numerical limits that are "adequate to protect public health and the environment from any reasonably anticipated adverse effects of each pollutant." EPA used exposure assessment models to derive these numerical pollutant limits. EPA determined that the exposure assessment assumptions used in its models protect individuals from events that are likely to occur and meets the statutory standard to protect public health and the environment from "reasonably anticipated adverse effects of a pollutant."

Selecting a Regulatory Approach for Part 503

In developing a regulatory approach for establishing the management practices and numerical limits (standards) that would safeguard public health and the environment, the Agency examined the use or disposal practices and the probability that individuals would be exposed to pollutants from these practices. EPA identified the type of the risks involved (e.g., breathing air with higher levels of pollutants, drinking water with pollutant levels exceeding the MCLs for drinking water, and others). It also examined the possibility of special populations at greater risk (e.g., small children playing in gardens where sewage sludge products had been applied or the effect of lead on adult males). The Agency also examined whether individuals voluntarily incurred the risks. For example, risks associated with breathing more contaminated air by individuals living in close proximity to an incinerator are involuntarily incurred and, therefore, more unacceptable than risks associated with using a properly labeled sewage sludge product in a garden. Finally, before developing alternative approaches, EPA used exposure assessment models to project the effect on an individual receiving a maximum dose throughout an average lifespan of 70 years. Aggregate effects analyses were used to project the incidence of adverse health effects from sewage sludge use or disposal on the population as a whole (i.e., the resulting number of cancer cases, carcinogenic risk, number of people exposed to lead at levels producing adverse health effects, and the number of people exposed to concentrations of non-carcinogenic pollutants above a reference dose—RfD).

In considering a regulatory approach, in the proposal EPA primarily focused on two types of risks—risks to individuals receiving the maximum dose (most exposed individual, plant or animal—MEI) and risks to the population as a whole (aggregate risk). The Agency considered four regulatory approaches for the use and disposal of sewage sludge. Each of the approaches places greater emphasis on reducing an individual or other organism's exposure to a pollutant. However, the Agency examined both the individual and aggregate effect of each alternative to balance the uncertainties in the analyses. The data available resulted in greater emphasis being placed on public health rather than environmental effects. However, where environmental effects could be identified, even qualitatively, they were considered in the determination of what constituted "adequate" protection of public health and the environment.

Opinions are divided concerning the emphasis that should be placed on individual or aggregate risk. There are some who maintain that individual cancer risk is the most, or the only,

important measure. Arguments that favor addressing individual risk assert that no individual should be at high risk and that consideration of the number of people at risk leads to acceptance of higher individual risk when few people are exposed. Furthermore, the latter approach leads to the inequity of having the acceptable risk to an individual depend on the number of people similarly exposed. The limitation of using maximum individual risk alone is that the measure does not indicate how many people may be affected. It only relates the carcinogenic risk to the MEI.

Arguments in favor of examining the aggregate risk are that incidence is an appropriate measure of total public health impact. Therefore, incidence is a good indicator of whether an approach adequately protects public health.

A rule that covers both carcinogenic and non-carcinogenic pollutants, such as today's rule, presents another disadvantage to using only an MEI or an aggregate analysis as a single measure of whether an approach adequately protects public health and the environment. Methodologies and data do not yet exist, except for lead, to correlate differing levels of exposure to non-carcinogenic pollutants with incidence of an effect. The only measure for threshold pollutants other than lead is the number of people exposed to a level above a RfD. This, in fact, may have little meaning for individual risk since risk above the RfD cannot be determined using the RfD methodology. The RfD is established such that there is a very low probability that exposure to a pollutant at or below the RfD will cause an individual health case. This also implies that there is no certainty that exposure above the RfD will cause an individual health case. Therefore, while any exposure to carcinogens can be considered a case, the same assumption can not be made for non-carcinogens.

In addition, the Agency typically weighs the aggregate effects estimates along with maximum individual or average cancer risk estimates when evaluating a particular category of like risks (i.e., the number of individuals exposed to a particular pollutant from a particular type of facility). Some observers question the relevance of adding risks, in a rule such as today's rule, when risks from different types of pollutants present different types of risks (i.e., inhalation, ingestion, and others) from different types of sources (i.e., incineration, land application for agricultural purposes, among others).

The following discussion describes the proposed alternative regulatory approaches considered by the Agency in developing the risk assessment methodology used in today's rule. The first two approaches accept the aggregate effects of current sewage sludge quality. Approach III is directed solely to protecting the MEI and Approach IV uses a combination of MEI exposure and aggregate effects of current sewage sludge quality.

Although the combination of approaches in Option IV was the Agency's selection for purposes of the part 503 proposal, it was revised for the final rule based on current Agency policy, public comment and scientific peer review.

Approach I: Use Existing Regulations (Aggregate Approach)

The first approach considered by the Agency was to use existing regulations to establish numerical limits and management practices. In establishing numerical limits for sewage sludge that is incinerated, the Agency would use the NESHAPs for mercury and beryllium in 40 CFR part 61, subparts C and E, respectively; 25 percent of the NAAQSs for lead; and the particulate limitations and monitoring requirements in 40 CFR part 60, subpart O. In addition, the Agency would have also used numerical limits for cadmium and PCBs and the pathogen reduction process requirements in 40 CFR part 257 when sewage sludge is applied to the land. Under this approach, if existing regulations did not address a particular pollutant, EPA would have used the toxicity characteristic pollutant concentrations in 40 CFR part 261 to determine if a sewage sludge was hazardous. Therefore, standards for hazardous sewage sludge would not be established in part 503. All approaches considered by the Agency similarly exclude hazardous sewage sludge from the part 503 standards. As discussed later in the preamble, for purposes of section 405, EPA is regulating hazardous sewage sludge under the requirements in 40 CFR parts 261 through 268 and sewage sludge with 50 ppm or more PCBs under the requirements in 40 CFR part 761.

The first approach was rejected immediately by the Agency because it would misuse the toxicity characteristic concentrations. The toxicity characteristic concentrations were developed to identify pollutant concentrations in wastes that, if placed in improperly managed MSWLFs have the potential to cause an unacceptably high level of ground water contamination. The regulatory thresholds do not purport to define a concentration that would be safe if used for growing food or feed crops. The toxicity characteristic concentrations, if used in the exposure assessment models, would result in concentrations exceeding the human health criteria for the disposal practice. Limiting emission levels of sewage sludge incinerators to 25 percent of the NAAQS for lead would require some incinerators to install wet electrostatic precipitators (ESPs). At present, many States are not controlling lead emissions from sewage sludge incinerators.

Approach II: Use the 98th-Percentile Pollutant Concentration (Aggregate Approach)

The second approach considered by the Agency was to use existing EPA regulations, as in the first approach. However, if existing regulations do not establish numerical limits, numerical limits would be established corresponding to the 98th-percentile pollutant concentration in the Agency's national data base on sewage sludge. The 98th-percentile pollutant concentrations would be calculated from a regression analysis of the values of each pollutant in the national data base and would be used as a cap on allowable pollutant concentrations. This would preclude potential deviations from the pollutant concentrations shown in the national data base and prevent increases in any risks associated with current use and disposal practices. In addition to management practices specified in existing regulations, such as pathogen reduction processes for the land application of sewage sludge in 40 CFR part 257, the Agency would require that labels or information sheets accompany sewage sludge products that are distributed and marketed. These would inform users about the proper use of the product.

Approach III: Use the Exposure Assessment Models for All Practices (MEI Approach)

The third approach that the Agency considered was to use the exposure assessment models in establishing numerical limits for all use or disposal practices. The exposure assessment models allow the Agency to limit not only the concentration of a pollutant in sewage sludge, but also the annual and cumulative loading rates for pollutants when sewage sludge is applied to land used for growing food-chain crops or distributed and marketed.

In the MEI approach, the target organism is a most exposed individual, plant, or animal that remains for an extended period of time at or adjacent to the site where the maximum exposure occurs. EPA used models and 14 exposure pathways to determine the

concentration of sludge-borne pollutants that may be utilized or disposed of in each use and disposal practice without exceeding human health or environmental criteria.

The human health and the environmental criteria used to protect the MEI from the adverse effects of specific pollutants were taken from criteria already published or promulgated by the Agency, from human health criteria developed by the Agency, or from plant and animal toxicity values published in scientific literature. For example, when the objective was to protect sources of drinking water, pollutant limits were developed which would ensure the Agency's maximum contaminant levels were not violated. When the objective was to protect surface water, Water Quality Criteria were used. If the Agency had not published or promulgated criteria for specific pollutants, reference doses listed in the Agency's computerized Integrated Risk Information System were used.

For carcinogens, the risk-specific doses corresponding to an incremental carcinogenic risk level of 1×10^{-5} were used for all use and disposal practices except when sewage sludge was distributed and marketed. For the distribution and marketing of sewage sludge, numerical limits were established to ensure pollutant levels do not exceed a risk-specific concentration corresponding to an incremental carcinogenic risk level of 1×10^{-6}.

For all pathways, the human MEIs were assumed to be the most sensitive individuals continuously exposed over a 70-year lifetime. Ecological MEI endpoints were also conservatively constructed, using the most sensitive species with steady-state duration and concentration of exposure over a critical life period.

Approach IV: Use the Exposure Assessment Models and the 98th-Percentile Pollutant Concentration (The Approach Used in the Part 503 Proposal)

The final approach that the Agency considered, and the one on which the Agency based the part 503 proposal, used a combination of aggregate and MEI analyses (i.e., the second and third approaches). The Agency used existing regulations, the NESHAPs for mercury and beryllium and 25 percent of the NAAQS for lead when sewage sludge is incinerated. EPA also used the exposure assessment models to establish numerical limits, as in the third approach, when individuals are likely to be exposed to high levels of pollutants in sewage sludge or when significant scientific uncertainties exist about the effect of a particular sewage sludge use or disposal practice.

However in this approach, the Agency selected an incremental carcinogenic risk target of 1×10^{-4} for sewage sludge used in the production of agricultural crops, the sale or give-away of sewage sludge products, and the disposal of sewage sludge in monofills. This target was selected because Agency analyses did not indicate a significant aggregate populational carcinogenic risk for these practices. The Agency's analyses did indicate, however, that incineration posed significantly more aggregate populational carcinogenic risk than other use or disposal methods. To reduce this aggregate carcinogenic risk, the Agency proposed regulating the incineration of sewage sludge such that the carcinogens in the emissions would not exceed an incremental unit risk of 1×10^{-5}.

The Agency did consider an incremental carcinogenic risk level of 1×10^{-6} for all practices. This option was rejected because EPA's analyses indicated that such an approach may lead to the incineration of greater volumes of sewage sludge with a potential for increased human health risks. Furthermore, considerable uncertainty remained in projecting the number of cancer cases. Since the number was already small (for other than incineration), increased uncertainty exists in projecting further reductions.

Carcinogenic risk targets were applied pollutant-by-pollutant in all use or disposal practices, except for the organic pollutants in the emissions of sewage sludge incinerators. For incinerators, the Agency set a limit on the total hydrocarbon emissions from a sewage sludge incinerator rather than on each individual organic pollutant. To do this, the Agency developed a weighted average risk-specific concentration for the carcinogenic organic compounds listed in IRIS. The Agency believed that this was comparable to setting a pollutant-by-pollutant risk-specific concentration for the metals in incinerator emissions.

When individuals were unlikely to be exposed to the pollutants in sewage sludge, the Agency proposed setting numerical limits that correspond to the 98th-percentile pollutant concentration in the Agency's national data base on sewage sludge. As in the second approach, the 98th-percentile concentration is a cap on the allowable concentration of a pollutant in sewage sludge that precludes significant deviations from the concentrations shown in the national data base to avoid increased risk from the disposal of sewage sludge.

The 98th-percentile pollutant concentration applied to the application of sewage sludge to land used for non-agricultural purposes (i.e., forests, reclaiming lands, and others), a practice on which human dietary impacts are negligible. The 98th-percentile pollutant concentration also applied to the disposal of sewage sludge on surface disposal sites, which are generally small, located away from population centers, and usually located on property owned by the treatment work. The Agency believed that little, if any, likelihood of exposure to the pollutants from these two use and disposal methods would result.

Comments on the Alternative Regulatory Approaches

The Agency received extensive scientific peer review and public comments on the proposed alternative regulatory approaches. These comments focused on the MEI exposure scenario used to determine human health impacts and on the use of the 98th-percentile technique for deriving numerical pollutant limits for sewage sludge. A description of the commenters' major concerns is presented below.

The Most Exposed Individual Approach

The risk and exposure assessment assumptions and data used in the model pathways for the MEI approach were criticized by many commenters as being inappropriate or too conservative to mirror "real world" situations. For example, many commenters took issue with the Agency's exposure assessment scenario posing an MEI who lives near a sewage sludge disposal site and is exposed continuously (i.e., 24 hours per day) for a 70-year lifetime—used to establish numerical pollutant concentrations in sewage sludge that protect public health. Commenters maintained that such exposures were unrealistic and should be considerably less than 70 years, and that few individuals would be expected to live in the same location for their entire lives. Commenters suggested that the Agency revise the MEI exposure assessment assumptions to reflect more realistic exposure conditions.

Commenters were divided on which risk levels should be used by the Agency to protect the MEI. As discussed earlier, the Agency traditionally establishes standards within a range of 1×10^{-7} to 1×10^{-4}, depending on the statute, surrounding issues, uncertainties, and information bases. Many commenters argued that the risk

levels selected by the Agency (i.e., 1×10^{-4} for all use and disposal practices, except 1×10^{-5} for incineration) were too conservative, while other commenters felt that the Agency was not stringent enough and should lower the risk level to the 1×10^{-6} to 1×10^{-7} range. Some commenters maintained that the same risk level should be used for all use and disposal practices, and that the different risk levels (i.e., 10^{-4} vs. 10^{-5}) used in the proposal were not scientifically justifiable, do not reflect an ample "margin of safety," and fail to consider non-carcinogenic effects. Other commenters suggested that the risk for all regulated pollutants destined for incineration (i.e., four metals and total hydrocarbons) be additive to allow facilities the flexibility to trade off their emissions and still meet an overall additive risk level for the five pollutants of 5×10^{-5}. Still other commenters were supportive of the proposal, stating that the risk levels selected by the Agency to protect the MEI were appropriate for the use and disposal practices regulated and that no change was needed.

Even though many commenters were critical of the risk policy decisions and exposure assessment assumptions and data (e.g., duration of exposure, use of salt/pot studies, soil ingestion rates, and others) used by the Agency in the MEI approach, none of the commenters suggested an alternative regulatory approach that they believed would be more scientifically defensible and provide an adequate level of protection of public health and the environment.

The 98th-Percentile Approach

Many commenters were critical of the 98th-percentile approach stating that the approach had scientific and technical deficiencies and either over or under regulated the use and disposal of sewage sludge, depending on the pollutants of concern and the practice. Further, the commenters maintained that the numerical limits derived from the 98th-percentile approach were not supported by adequate risk assessments and were not substantiated by field studies. These limits could not be considered a substitute for plant and animal exposure pathway analysis and subsequent calculation of numerical limitations by consideration of the pathway analysis.

In addition, may commenters felt that the 98th-percentile approach would reduce the desirability of beneficial use practices because of the increased public perception of a human health or environmental risk. Some commenters suggested that all beneficial use practices should be consistent and use the same risk assessment methodology.

Response to Comments

The Agency agrees with many of the comments provided by the public and scientific peer review committees concerning the risk assessment approach used to develop numerical limitations for the part 503 proposal. The proposed approach (a combination of MEI and 98th-percentile approaches) was necessarily constrained by the adequacy of information and data on the fate, transport and effects of sewage sludge pollutants, parameters and assumptions used in the model pathways and exposure assessment analyses, and on the use and disposal practices.

Furthermore, there is no clear guidance in section 405, which provides only that standards must be adequate to protect public health and the environment against reasonably anticipated adverse effects. There is only limited discussion of how to establish pollutant limits under section 405(d) of the Clean Water Act in the legislative history of the Act (U.S. Congress, Senate, Senator Stafford, 16 October 1986, Congressional Record S16427). Senator Stafford in debate on the legislation stated:

> * * * EPA's rules must also establish numerical limitations for each such pollutant. EPA's rules must protect public health and the environment with an ample margin of safety, and must take care to protect the health of individuals or populations which are at higher risk than the population as a whole.

EPA concluded that its statutory duty to protect against reasonably anticipated adverse effects required it to consider reasonable risks to exposed populations and not the risk associated with highly unlikely or unusual circumstances. Accordingly, the Agency decided to evaluate the risk to a highly exposed individual (HEI), instead of the most exposed individual (MEI), for the final part 503 regulation risk assessment. This more realistically reflects protection of the health of individuals or populations which are at higher risk than the population as a whole.

EPA also decided to retain a 70 year exposure for the HEI in the risk assessment for the final part 503 regulation. The Agency recognizes that the exposure assessment assumption of 70 years of continuous exposure is conservative in the context of a highly mobile society. Further, EPA is aware that the assumption constitutes a simplification of actual conditions. The decision to assume 70-year exposure for standards setting purposes represents, in part, a policy judgment by EPA. EPA believes this assumption is preferable to the less conservative alternatives suggested. Although releases of pollutants from sewage sludge use and disposal practices would reasonably be expected to change over time, such changes cannot be predicted with any degree of certainty. In lieu of discontinuing a practice, facilities may elect to replace or even expand their use or disposal practice and subsequently increase their release of pollutants to the environment. The 70-year exposure duration represents a steady-state exposure assessment assumption that is consistent with the way in which the measure of carcinogenic risk is expressed (i.e., as the probability of contracting cancer based upon a lifetime [70 year] exposure to a unit concentration). Constraining the analysis to an "average" lifetime exposure carries the implication that no one could be exposed for a period longer than the average. Since, by definition, approximately half the population would be expected to be exposed longer than the average, this assumption would tend to underestimate the possible risk to highly exposed individuals and populations.

The Agency agrees that the U.S. population, in general, is highly mobile. However, adjusting the exposure assumptions to constrain the possibility of exposure to pollutant releases from sewage sludge use and disposal practices implies that everyone has the same degree of mobility (e.g., children, the elderly and handicapped) and that exposure during the periods away from the residence are zero. EPA knows this is not the case. In addition, a less-than-lifetime exposure assumption would also have a proportional impact on the estimated risk to highly exposed individuals, suggesting that no individual could be exposed for 70 years. On balance, EPA believes that the present exposure assessment assumption of continuous exposure is consistent with (1) the steady-state nature of the analysis and with (2) the stated purpose of providing an adequate level of public health and environmental protection from any reasonably anticipated adverse effects of pollutants found in sewage sludge. In the Agency's opinion, this exposure assessment assumption, while representing in part a policy judgment by EPA, continues to be preferable to the less conservative alternatives suggested and represents an appropriate one, given the Agency's obligation to protect public health. This is true both in view of the shortcomings of such alternatives and in the absence of

compelling evidence to the contrary. Further, retaining 70-year assumption gives EPA confidence that the population of highly exposed individuals will remain extremely small.

To remedy information gaps in preparing the MEI risk assessment analyses for the part 503 proposal, the Agency used what it believed were "reasonable worst-case" assumptions. Each parameter or assumption has a "margin of safety" associated with it, depending on the accuracy of the data and information supporting it. For example, if the Agency lacked data from sludge/field studies on metals uptake in crops grown for human consumption, data from sludge/pot studies or salt/pot studies was used in the MEI risk assessment analysis. The margin of safety associated with the data from salt/pot studies is greater than the margin of safety associated with data from sludge/pot studies and far greater than the margin of safety associated with data from sludge/field studies. However, given the availability of the data at the time of proposal, the Agency believed that the use of data from salt/pot studies in the absence of data from sludge/pot or sludge/field studies was a reasonable worst-case assumption and provided an adequate level of public health and environmental protection. The problem occurs when a series of parameters and assumptions, each having a large margin of safety, are used in the same exposure pathway assessment. This results in an extremely conservative analysis where the margin of safety for each parameter and assumption has a compounding effect resulting in numerical limitations that appear to be unrealistic and could conceivably over-regulate a use and disposal practice.

A number of commenters supported the Agency's policy decision on setting the acceptable risk level to the MEI at 1×10^{-4} for all use and disposal practices except incineration, which was set at 1×10^{-5}. The Agency disagrees with commenters who proposed that the risk levels selected by the Agency may not be stringent enough, may be too conservative, or may lead to an inconsistent policy allowing different acceptable risk decisions for different use and disposal practices. For the final part 503 regulations, EPA established standards after an evaluation of risks at the same risk levels as those used for the proposed rule. Based on this evaluation, which included new information gathered during and after the public comment period for the proposal, the Agency concluded that the risk levels selected for the proposal were protective of public health, and that different human health effects levels (i.e., the different human health effects for incineration vs. other use and disposal practices) could appropriately result in different acceptable risk decisions but that the proposed risk level for incineration was unnecessarily protective and burdensome.

Information provided by the NSSS, the sludge incinerator study, the scientific peer review committees and the public was incorporated into the aggregate risk assessment for the final rule and showed minimal risk from current sludge management methods (referred to as "pre-Part 503" or "baseline" risk). Sludge incineration, which EPA had believed based on its earlier analysis posed the greatest risk to the widest population, exhibited low baseline risk. Consequently, the Agency decided to evaluate standards for the final part 503 rule that would achieve an HEI risk level no higher than 1×10^{-4} for all use and disposal practices. The Agency disagrees with commenters that argued that our assumptions in describing and protecting the HEI are not conservative enough. For example, in the incineration pathway scenario the Agency assumed that the HEI was exposed to incinerator emissions 24 hours a day for 70 years, and that the HEI was physically located where it would receive the highest annual ground level concentration of pollutant emissions for the entire exposure period. The aggregate risk assessment, which included the effects on highly exposed individuals and subpopulations (HEIs) as well as the population as a whole, was based on many conservative exposure assumptions such as these, and verified that the 1×10^{-4} risk level provided an adequate level of public health protection across all use and disposal practices including incineration. In addition to providing an adequate level of public health and environmental protection, the 1×10^{-4} risk level reduces the regulatory impact of the rule allowing the Agency to regulate the use and disposal of sewage sludge without needlessly burdening the regulated community or negatively impacting beneficial reuse.

In addition, the Agency disagrees that the risk levels for pollutants in sewage sludge that is incinerated should be additive to allow facilities the flexibility to trade-off emissions to meet a higher risk level (e.g., adding a 1×10^{-4} risk level for each of four carcinogenic metals and total hydrocarbons to establish a higher risk level for compliance of 5×10^{-4}). The Agency evaluated the potential for the summed risk of pollutants in sewage sludge to exceed the proposed risk level. Sewage sludge from 30 facilities was evaluated to determine if the total carcinogen risk of the pollutant mixture exceeded the carcinogen risk from the single highest risk pollutant found in the mixture. In all but three cases, a single pollutant dominated the risk. Therefore, the Agency believes that summing the risk would not make a significant difference in complying with the final Part 503 rule regardless of the risk level chosen. Neither does the Agency believe that it would justify the increased administrative burden it would impose on regulatory authorities and permit writers who would need to constantly readjust permits to account for varying mixtures of pollutant concentrations and for new pollutants regulated under future rulemakings.

The Agency agrees with the public and the scientific peer review committees that the 98th-percentile approach is inconsistent with the MEI approach and that numerical limitations derived from the 98th-percentile approach do not ensure protection of public health and the environment because they lack a formal pathway risk assessment.

In preparing the part 503 proposal, the Agency relied on the 98th-percentile approach because it did not have reliable exposure assessment models nor the input data and information needed to conduct a formal pathway risk assessment for certain practices. The Agency believed at the time of the proposal that the 98th-percentile approach would adequately protect public health and the environment because the 98th-percentile pollutant limitations would apply to: (1) The application of sewage sludge to land used for non-agricultural purposes (i.e., forests, reclaimed lands, and others), a practice on which human dietary impacts are negligible and other forms of human and environmental exposure appeared to be low; and (2) the disposal of sewage sludge on surface disposal sites, which are generally small, located away from populated centers and usually located on property owned by the treatment works, and therefore should present little, if any, likelihood of exposure. In addition, the 98th-percentile approach was supported by the Agency's aggregate risk assessment which showed low exposure and minimal human health impacts on the population as a whole from these use and disposal practices. This information further supported the Agency's belief that the 98th-percentile approach was protective of public health and the

environment and acceptable for purposes of proposal.

Since the proposal, the Agency has worked with experts from inside and outside EPA to develop, then refine, the modeling techniques and supporting data to conduct a formal pathway risk assessment for these practices. In addition, the public comments and scientific peer review reports have provided EPA with better data and information that improved the precision and accuracy of certain modeling parameters and assumptions used in the risk assessment to derive numerical limitations for all sewage sludge use and disposal practices. This allowed EPA to establish more realistic numerical limitations without compromising the level of protection of public health and the environment.

Final Action—Risk Assessment Methodology for the Part 503 Rule

Based on public comments, scientific peer review and the record developed in the rulemaking, EPA has selected an approach based on risk to highly exposed individuals (HEIs) and consideration of health protection for higher risk populations (aggregate risk assessment), not an unrealistic worst-case MEI approach. The Agency has decided to use a risk assessment methodology consistent with EPA guidelines and based on (or supported by—in the case of the operational standard for sludge incineration) an exposure pathway assessment using an array of assumptions and modeling parameters some of which are worst-case and others that are more reasonably based. EPA believes that this approach is consistent with the Congressional intent to establish standards "adequate to protect public health and the environment from reasonably anticipated adverse effects of each pollutant."

Thus, EPA evaluated the risk to highly exposed individuals and populations from pollutants found in sewage sludge using different exposure assessment pathways The aggregate risk assessment (which assessed risk to the HEI as well as the population as a whole) showed minimal risk from the use and disposal of sewage sludge under current (pre-part 503) sludge management methods. Therefore, the Agency concluded that if the standards developed under the final part 503 regulations protect the HEI to a cancer risk level no higher than 1×10^{-4} for all sewage sludge use and disposal practices, that risk level is considered an adequate level of public health protection.

Further, EPA also evaluated as part of its risk assessment (also using exposure assessment pathways) other non-carcinogenic health risks and environmental effects from pollutants found in sewage sludge. The risk level of 1×10^{-4} established by the Agency for this rule provided a benchmark for judging the level of protection to the HEI and populations at greater risk from carcinogenic pollutants, but did not constitute a rigid line for making the determination that such risk is adequate to protect public health and the environment from "all reasonably anticipated adverse effects." The Agency recognized early on that consideration of non-cancer risk to individuals and other environmental effects were critical in evaluating the protectiveness of standards promulgated in today's rule.

As a result, in evaluating standards for today's final rule that provide an adequate level of protection of public health and the environment, the Agency set standards not only based on cancer risk but on a series of other health and environmental effects. These include the overall incidence of other serious health effects as well as cancer within the exposed population as a whole (including average exposed and highly exposed individuals) and within special subpopulations, such as children. The Agency also considered effects on plants and animals from exposure to pollutants found in sewage sludge, science policy assumptions, estimation of uncertainties and margin of safety associated with the risk assessment parameters and assumptions, weight of the scientific evidence for human health and environmental effects, other quantified or unquantified health and environmental effects, and other impacts associated with the use and disposal of sewage sludge before selecting the final standards.

Section 405 of the CWA requires EPA to develop regulations for sewage sludge, when used or disposed of, that are protective of public health and the environment. In today's action, the Agency has selected an HEI approach with consideration of the health effects on higher risk individuals and subpopulations and the population as a whole (aggregate risk assessment) to establish numerical pollutant limitations, operational standards and management practices for the use and disposal of sewage sludge. The Agency has concluded that the numerical pollutant limitations, operational standards and management practices will provide an adequate level of protection of public health and the environment from any reasonably anticipated adverse effects of the pollutants found in sewage sludge.

As noted above, EPA employed exposure assessment models to develop risk-based numerical pollutant limits for sewage sludge when it is applied to the land or placed on a surface disposal site. EPA has determined that its statutory duty to ensure adequate protection of public health and the environment requires the Agency to add safety factors to the numerical criteria derived from the exposure assessments.

The decision to include additional safety factors in its protective numerical pollutant limitations serves a second critical objective in this rulemaking. That objective is to promote the use of sewage sludge for its beneficial properties. An important component in promoting the beneficial use of sludge is building public confidence that sewage sludge used to grow the food the public eats is safe. Adding a margin of safety to the model-derived criteria should help courage this.

There are two reasons for adding safety factors to the model-derived numerical criteria.

First, designing these models has required EPA to make a number of assumptions to characterize the exposure to an HEI. Given current modeling tools, in developing the Agency's exposure assessments, it would have been impossible to account for all of the variables in the real-world movement of pollutants from sewage sludge to environmental end points. EPA, as a consequence, made a number of assumptions to reduce the complexity of actual experience. EPA is confident that its exposure assessments (and the resulting risk-derived numerical limitations) generate numerical criteria consistent with protection of public health and the environment. At the same time, EPA recognizes that modelling is not an exact science. Of necessity, there are aspects of its exposure assessment about which the Agency has greater confidence and areas in which, because of data limitations or because the analytical tools are not highly developed, less certainty.

Second, through its exposure assessments, EPA derived numerical limitations for metals that represented the total quantity of metals that could be added to the soil. So long as the total quantity (loading) for the metal is not exceeded, the exposure assessment models predict that there will be no injury to the HEI. The model is unconcerned whether the total quantity of the pollutant is received in a single load or over time. Thus, adopting purely a cumulative loading approach could mean that sewage sludge with extremely

high metals concentrations could be applied to the land so long as the cumulative load is not exceeded.

In developing the final numerical pollutant limitations, the Agency concluded that adoption of a strictly risk-based numerical pollutant limitation may allow degradation of current sewage sludge quality. EPA's aggregate risk assessment shows only small public health effects associated with current use and disposal practices. This confirms what EPA's exhaustive review of data on sludge usage revealed, that is, sludge used at current pollutant concentration levels presents a low risk to public health and that such pollutant levels already have an inherent level of protection. However, its exposure assessment models relied, in part, on data from field studies on sewage sludge applied to agricultural land that represented a range of sewage sludge of different concentrations. The models do not look exclusively at data from the most heavily contaminated sludges or consider ecological systems impacts from sludges applied to non-agricultural lands.

In order to ensure continued protection of public health and the environment, EPA concluded that existing quality of sewage sludge that is applied to land should be "protected" and not allowed to deteriorate above current concentration levels. Implicit in EPA's numerical pollutant limits for land application (and its conclusion that such limits are safe) is the assumption that sludge with low concentrations of pollutants is safe and to downgrade the quality of sludge reduces the protective levels inherent in such limits. In these circumstances, EPA has concluded that its certainty about the protectiveness of the numerical criteria derived from its exposure assessment models for land application is increased by adding margins of safety to the numerical criteria.

Accordingly, the Agency has placed a "ceiling" on the concentration of pollutants in sewage sludge that may be applied to land at the 99th-percentile pollutant concentration from the NSSS survey. The ceiling concentration is the *higher* of the 99th-percentile pollutant concentration or risk-based pollutant limitation and acts as a trigger, dictating when sludge quality is no longer suitable for beneficial use (regardless how it is applied to the land) and must be disposed of. An important purpose of the "ceiling" is to direct the "cleanest" sludges into beneficial use practices, thereby preventing the "dirtiest" sludges from being applied to agricultural land under the veil of beneficial use. In addition, the Agency has "capped" the numerical pollutant limits for land application at the 99th-percentile pollutant concentration found in the NSSS if that concentration is *lower* than the risk-based numerical pollutant limit. The "cap" determines when sludge quality is suitable for beneficial use under the alternative pollutant limit concept or must be applied using cumulative pollutant loading rates (alternative pollutant limits and cumulative pollutant loading rates are discussed below in parts VIII and XI).

The Agency has made these risk policy decisions (i.e., the "capping and ceiling" policies) to provide an additional margin of safety to protect public health and the environment beyond the risk-based standards developed for today's rule, while maintaining sewage sludge quality to encourage sludge utilization consistent with the Agency's beneficial use policy.

In today's action, the Agency has selected an HEI approach with consideration of the health effects on higher risk individuals and subpopulations and the population as a whole (aggregate risk assessment) to establish numerical pollutant limitations, operational standards and management practices for the use and disposal of sewage sludge. It is the Agency's belief that the numerical pollutant limitations, operational standards and management practices will provide an adequate level of protection of public health and the environment from any reasonably anticipated adverse effects of the pollutants found in sewage sludge. The following part, part VIII, describes the exposure assessment methodology for each sewage sludge use and disposal practice that was an outgrowth of the public comments and scientific peer review on the proposed regulatory approach.

Part VIII: Exposure Assessment Methodology and Other Risk Management Issues for Sewage Sludge Use and Disposal Practices for the Final Rule

This part of today's preamble discusses how EPA evaluated exposure and assessed the risk in determining what pollutant limits in the final part 503 rule were needed to protect public health and the environment from pollutants in sewage sludge that is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. Included in this part is a discussion of the exposure assessment approach used to develop pollutant limits in both the proposed and final part 503 rule, as well as a discussion of the basis of other technical and non-technical assumptions used in the regulations.

Exposure Assessment Methodology and Risk Management Issues for the Proposed Rule

For the proposed rule, EPA adapted existing models and developed new models to determine the concentration of sewage sludge-borne pollutants that may be applied to the land, placed in sewage sludge-only landfills (monofills), or incinerated without exceeding human health or environmental criteria (Reference Nos. 71, 72, and 79). The models simulate the movement of pollutants into and through the environment with a series of mathematical equations or algorithms. These equations or algorithms link the pollutant disposal or release rates to the concentration of the pollutant that moves into the air, water, or land and, subsequently, reaches a target organism (i.e., plants, animals, and humans). Each algorithm in a model represents one exposure pathway through which sewage sludge-borne pollutants enter and pass through or effect an environmental medium.

The exposure pathways modeled for each use and disposal practice in the part 503 proposal were as follows:

1. Land Application to Agricultural Land
   - Sludge-soil-plant-human (Pathway 1)
   - Sludge-soil-plant-human-future use change (Pathway 1F)
   - Sludge-soil-human-future use change (Pathway 2F)
   - Sludge-soil-plant-animal-human (Pathway 3)
   - Sludge-soil-animal-human (Pathway 4)
   - Sludge-soil-plant-animal toxicity (Pathway 5)
   - Sludge-soil-animal toxicity (Pathway 6)
   - Sludge-soil-plant toxicity (Pathway 7)
   - Sludge-soil-soil biota toxicity (Pathway 8)
   - Sludge-soil-soil biota-predator of soil biota toxicity (Pathway 9)
   - Sludge-soil-airborne dust-human (Pathway 10)
   - Sludge-soil-surface water-contaminated water-toxicity to fish-toxicity to humans (Pathway 11)
   - Sludge-soil-air-human (Pathway 12A)
   - Sludge-soil-ground water-human (Pathway 12W)
2. Distribution and Marketing
   Pathway 1F, 2F, 7, 8, 9, and 11
3. Land Application to Non-Agricultural Land
   Pathway 11 and 12W
4. Monofilling
   Pathway 12A and 12W
5. Surface Disposal
   Pathway 12A and 12W
6. Incineration
   - Inhalation of incineration particulates by humans (Pathway 12A)

Both current and future exposures were considered with respect to

conversion of agricultural lands to home gardens (Pathways 1F and 2F). Future conversions of non-agricultural lands to either agricultural lands or home gardens were considered by imposing a 5-year waiting period. However, growth of practices to accommodate future increases in sludge volume or shifting between practices were not considered in establishing the numerical limits.

For all these pathways, the target organism was the most exposed individual, plant, or animal that remained for an extended period of time at or adjacent to the site where the maximum exposure occurred. The models calculate individual pollutant exposure, relying on certain fixed assumptions about the exposure route. For example, the models assumed inhalation of 20 cubic meters of air per day—an individual diet representative of extreme upper-end food consumption—and consumption of two liters of drinking water per day. Other assumptions included in the models were the location of the MEI relative to the site where the sewage sludge is placed and the source of food in the diet of the MEI. The same duration of exposure was used as that assumed in developing the applicable human health or environmental toxicological criteria (allowable doses). For example, where cancer risks were evaluated, the MEI was assumed to be continuously exposed for 70 years. Ecological MEIs were also conservatively constructed, using the most sensitive species with steady-state duration and concentration of exposure.

The Agency selected numerical values for the parameters in the algorithms of each model, translated the models into computer programs, and where appropriate, used the models to calculate the numerical limits in the proposal. The numerical limits derived from the exposure assessment models and pathways were based on human health or environmental criteria already published or promulgated by the Agency, on human health criteria developed by the Agency, or on plant and animal toxicity values published in the scientific literature. The numerical pollutant limits were designed to protect a most exposed individual (MEI) for a lifetime of exposure (except the pathway that addresses exposure of a child) to a pollutant in sewage sludge that is used or disposed. The dose that the MEI could receive for the exposure was the dose allowed by established Agency health criteria (e.g., an RfD for inorganic pollutants for a person who consumes plants grown on sewage sludge-amended soils or a threshold toxic soil concentration for an animal that grazes on sewage sludge-amended soils). Use of these values protects the MEI against the reasonably anticipated effect of a pollutant (e.g., in the case of the cadmium RfD, this represents a level in the human renal cortex not associated with significant proteinuria).

The risk level for the carcinogenic pollutants controlled in the proposed part 503 regulation varied by use or disposal practice. When sewage sludge is incinerated, the numerical limits for beryllium and mercury were based on the NESHAPs for these pollutants, and the numerical limit for lead was based on the NAAQS for lead. When the objective was to protect sources of drinking water, pollutant limits were developed which would ensure the MCLs were not violated. When the objective was to protect surface water, EPA Water Quality Criteria were used.

If the Agency had not published or promulgated criteria for specific pollutants in the proposal, EPA used reference doses listed in IRIS and risk-specific doses corresponding to an incremental carcinogenic risk level of 1×10^{-4}, except when sewage sludge was incinerated. For the incineration of sewage sludge, numerical limits were established to ensure pollutant levels did not exceed a risk-specific concentration corresponding to an incremental carcinogenic risk level of 1×10^{-5}. Terrestrial criteria designed to protect plants or animals were based on toxicity values determined from the appropriate scientific literature.

A complete description of the exposure assessment methodology and risk management issues for the proposal is found at 54 FR 5764–5791. The following sections discuss the exposure assessment pathways modeled in the final part 503 rule, the major comments received on the proposed exposure assessment approach and risk management issues, the critical modifications and risk management decisions made in developing the final exposure assessment approach for each sewage sludge use and disposal practice. A detailed discussion of the exposure assessment methodology (i.e., models, pathways, parameter values, assumptions, and others) and the risk management decisions used to develop numerical limitations for the final part 503 rule can be found in the technical support documents for each sewage sludge use and disposal practice. Information on obtaining these documents is provided in Part XIV—Availability of Technical Informational on the Final Rule.

Exposure Assessment Pathways and Risk Management Issues Evaluated for the Final Part 503 Rule

EPA evaluated 14 pathways of potential exposure to pollutants in sewage sludge for the final part 503 rule. The rule distinguishes between sewage sludge that is applied to the land for a beneficial purpose and sludge disposed of on the land. For the final regulation, EPA looked at potential exposure when sludge is used as a fertilizer or soil conditioner under two generic categories: agricultural land and non-agricultural land. Agricultural land application would include use by a farmer to grow food or feed crops, on pasture and rangeland, use by large agri-business enterprises as well as use by the home gardener. Home garden use was formerly described as "distribution and marketing" but for the final rule is "sewage sludge sold or given away in a bag or container." Non-agricultural uses include use on forest land, reclamation sites and public contact sites. In the case of agricultural land, EPA evaluated 14 pathways of exposure, for non-agricultural land, 12 of the applicable 14. EPA evaluated 2 pathways of exposure for surface disposal sites. This is the descriptive term the rule uses for sludge that is merely disposed on land either in piles or in sludge-only landfills (also referred to as monofills). For sewage sludge that is incinerated, EPA evaluated a single pathway of exposure—inhalation. Below are the 14 exposure assessment pathways evaluated in the final part 503 rule, followed by a brief description of each pathway:

1. Land Application (Beneficial Use)
   - Sludge-soil-plant-human (Pathway 1)
   - Sludge-soil-plant-home gardener (Pathway 2)
   - Sludge-soil-child (Pathway 3)
   - Sludge-soil-plant-animal-human (Pathway 4)
   - Sludge-soil-animal-human (Pathway 5)
   - Sludge-soil-plant-animal toxicity (Pathway 6)
   - Sludge-soil-animal toxicity (Pathway 7)
   - Sludge-soil-plant toxicity (Pathway 8)
   - Sludge-soil-soil biota toxicity (Pathway 9)
   - Sludge-soil-soil biota-predator of soil biota toxicity (Pathway 10)
   - Sludge-soil-airborne dust-human (Pathway 11)
   - Sludge-soil-surface water-contaminated water-fish toxicity- human toxicity (Pathway 12)
   - Sludge-soil-air-human (Pathway 13)
   - Sludge-soil-ground water-human (Pathway 14)
2. Surface Disposal
   - Sludge-soil-air-human (Pathway 13)
   - Sludge-soil-ground water-human (Pathway 14)
3. Incineration

Sludge-incineration particulate-air-human (Pathway 13)

In situations where the Agency determined that the exposure assessment pathways analyzed for a particular use or disposal practice did not yield adequately protective results, additional management practices were imposed to prevent environmental abuses and to protect public health.

For the assessment, all pathways, except Pathways 3, 5, and 7), assumed the mixing of sewage sludge with 15 centimeters (i.e., 6-inch plow depth) of the surface soil layer (having a mass of 2 million kilograms per hectare) either by mechanical incorporation or by weathering processes. This allowed conversions between pollutant concentrations in soil (in mass of pollutant per unit mass of soil), and cumulative pollutant loading rates for metals (in mass of pollutant per hectare of land) and annual pollutant loading rates for organics (in mass of pollutant per hectare of land per 365-day period).

After first determining the pollutant concentration in the soil that would be allowed (i.e., the maximum pollutant concentration in the soil that, when taken up by a plant and consumed by a target organism, does not produce undue risk) for a particular pathway, the model determines the allowable pollutant loading rate in one of two ways. For metals, the model determines the cumulative pollutant loading rate, the total quantity of metal consistent with no undue risk. This equals the allowable pollutant concentration in the soil multiplied by the mass of the soil in the top 15 centimeters of a hectare of land. The Agency assumed that metals remain in the sludge-soil matrix and that, over time, they become less biologically available to plants.

For organic pollutants, the model determines an annual pollutant loading rate (in kilograms per hectare per 365-day period) by considering the rate of pollutant loss or decay. The model assumes first order decay of organic pollutants; that is, the quantity of an organic pollutant lost per year is directly proportional to the quantity present. With continual annual applications, the concentration of a pollutant gradually approaches a plateau at which the quantity lost each year equals the quantity applied. The annual pollutant loading rate is determined such that the concentration levels off at the allowable soil concentration when sewage sludge is applied over a long period of time.

For all human exposure pathways in the final rule, the maximum allowable intake of pollutants was based on the following EPA health effects criteria: A reference dose (RfD), recommended daily allowance (RDA) or concentration (RfC) for non-carcinogens; a risk-specific dose for carcinogens based on a risk level of 1×10^{-4} for all use and disposal practices; a daily dietary intake derived from a drinking water standard; or a drinking water standard (MCL). The only exception to this is the dust inhalation pathway (Pathway 11).

In Pathway 11, the pollutant concentration in the soil is not permitted to exceed the National Institute of Occupational Safety and Health (NIOSH) workplace air quality criteria if significant quantities of soil become airborne. Assuming that the total airborne dust does not exceed the NIOSH criterion, this pathway was not a limiting pathway for any pollutant in the final rule.

Currently, 100 percent of a Maximum Contaminate Level (MCL) or other health-based standard is used as the reference point in developing numerical pollutant limits in the final part 503 rule. Because the numerical pollutant limits are based on assumptions designed to be protective of highly exposed individuals and the final part 503 regulations control sludge quality before it is used or disposed of, the Agency did not believe that MCLs or other health-based standards used in the exposure pathway assessment required any additional margin of safety beyond the margin of safety provided by parameters used in the pathway to protect against reasonably anticipated worst-case conditions. However, EPA's 1991 Ground Water Protection Strategy emphasizes prevention and recognizes that reaching an MCL or other health-based standard in ground water that is currently or reasonably expected to be used as a drinking water source is a failure of policy. Using a percentage of the MCL or health-based standard (e.g., 50 percent) as the reference point provides a margin of safety that makes the reference point consistent with the prevention policy in the 1991 Ground Water Protection Strategy (i.e., MCL is not reached).

With the publication of the final part 503 regulation, the Agency is soliciting public comment on the use of a percentage of the reference point (i.e., an MCL or other health-based standard) to develop the allowable concentration of pollutants in sewage sludge for the ground water pathway in both the land application and surface disposal risk assessments. EPA is requesting public comments within 90 days of the date of publication of the final part 503 regulation on the use of a percentage of the MCL or other health-based standard as the reference point for the ground water pathway in the land application risk assessment. The Agency will consider the public comments in future amendments to part 503 for the ground water pathway.

The following is a brief summary of each of the pathways analyzed for the final part 503 rule. As discussed previously, a more detailed description of the pathways and the entire risk/exposure assessment methodology can be found in the technical support documents for the rule.

Pathway 1

This pathway evaluates human exposure to crops grown with sludge fertilizer. It is designed to protect consumers who eat produce grown in soil using sewage sludge. The environmental endpoint is an HEI assumed to live in a region where a relatively high percentage of the available cropland receives sewage sludge applications. All crops in the diet could be presumed to be affected. However, it is assumed that the HEI ingests a mix of crops from land on which sewage sludge was applied and from land on which sewage sludge was not applied. For this pathway, 2.5 percent of a consumer's intake of grains, vegetables, potatoes, legumes, and garden fruits is assumed to be grown on sludge-enriched soil.

Pathway 1 evaluates crops grown for human consumption when sewage sludge is applied. Uptake of sewage sludge pollutants is assumed to occur through the plant roots. Direct adherence of sewage sludge or soil to crop surfaces is assumed to be minimal, and crops are assumed to be washed before consumption. The relevant practices for this pathway include agricultural use in commercial enterprises where crops for human consumption are raised, whether in pots (e.g., hothouse production) or in the field (e.g., truck farming).

The exposure evaluated for Pathway 1 in a non-agricultural setting is the exposure of a person who ingests wild berries and mushrooms grown in sludge-amended soils. The exposure to a pollutant in sewage sludge in Pathway 1 is based on (1) the uptake of a pollutant by each type of wild berry and mushroom; (2) a daily consumption of wild berries and mushrooms; and (3) the fraction of different wild berries and mushrooms grown in sewage sludge-amended soil. The HEI for Pathway 1 is a person who lives in a region where sewage sludge is applied to forest, a public contact site, or a reclamation site. The dose for this pathway is the RfD for an inorganic pollutant. Organic

pollutants were not evaluated for this pathway because they do not concentrate in wild berries and mushrooms.

Pathway 2

This pathway evaluates the case in which sludge is added to the soil in a home garden. The major difference between Pathways 1 and 2 is the fraction of food groups produced on sewage sludge-amended soil. For this pathway, as much as 60 percent of the HEI's diet of certain food groups is assumed to be grown in the home garden in which sludge is used as fertilizer.

The HEI for Pathway 2 is the home gardener who produces and consumes potatoes, leafy vegetables, legume vegetables, root vegetables, and garden fruits. These are also consumed, but not produced, by the HEI in Pathway 1. Unlike the HEI in Pathway 1, grains and cereals and peanuts are not included in the crops grown and consumed by the HEI in Pathway 2 because home gardeners do not usually consume grains and cereals and peanuts they grow themselves on sewage sludge-amended soils. For these individuals, the percentage of their diet grown on sewage sludge-amended soil is the percentage of their diet that is homegrown.

Pathway 3

This pathway assesses the hazard to a child ingesting undiluted sewage sludge. The HEI is the child who ingests sewage sludge from storage piles or from the soil surface. It is assumed that the sewage sludge is not diluted with soil when exposure occurs. The sewage sludge ingestion rate used was 0.2 grams (dry weight) per day for 5 years based on the 1989 Agency soil ingestion directive suggesting this value for children at higher risk (U.S. EPA, 1989). For this rule, EPA assumed ingestion at this level would be limited to 5 years.

In Pathway 3, EPA used the integrated uptake biokinetic model (IUBK) instead of extrapolating from cattle data, as had been done earlier for the proposal, to evaluate the effects from lead on children ingesting sewage sludge. The IUBK model used a lead blood level not to exceed 10 micrograms per deciliter, a 30 percent absorption value and a 95th-percentile population distribution to protect the HEI. Using these values in the model results in an allowable sewage sludge lead concentration of 500 parts per million (ppm) generated by the IUBK model. The lead pollutant limit calculated by the Peer Review Committee was based on the observation that body burdens (absorption) of animals fed up to 10 percent of their diet as sewage sludge did not change until the lead concentration in the sewage sludge exceeded 300 ppm. The Agency, therefore, decided to select the more conservative numerical limit for the final part 503 rule to minimize lead exposure to children and set the allowable lead concentration in sewage sludge at 300 ppm for this pathway.

Several reasons support this determination. First, setting the allowable lead concentration at 300 ppm provides an additional margin of safety with respect to lead soil contamination and any threat to the systems of developing children. Because childhood ingestion of dirt is so widespread a phenomenon and the potential consequence so severe, a high order of conservatism is warranted on this point, especially in the context of regulatory decisions authorizing the addition of a threshold pollutant like lead to the environment. In addition, a 300 ppm lead concentration in sludge is consistent with current sewage sludge quality at all but a small number of POTWs. As a result, the societal cost of an additional safety factor is small in comparison to the potential benefits.

Pathway 4

The analysis developed for this pathway is designed to evaluate human exposure from the consumption of animal products. Pollutant limits calculated for this pathway protect a highly exposed human being consuming the tissue of foraging animals that have consumed feed crops or vegetation grown on sewage sludge-amended soils. The HEI is assumed to consume daily quantities of the various animal tissue food groups. The HEI is also assumed to be exposed to a background intake of a pollutant.

Animals may consume forage and grain produced on sewage sludge-amended soil. This pathway depends on plant uptake of a contaminant being proportional to soil concentration of the contaminant. Uptake can occur through the roots with transport to shoots or other edible feedstuffs, or by volatilization from soil to above ground parts of plants.

The allowable pollutant concentration in the soil is the quotient of the allowable pollutant concentration in the feed crop and a crop uptake factor (partition coefficient). The allowable pollutant concentration in the feed crop is determined from: (1) the human intake of pollutant that can be allowed without causing undue risk, (2) typical consumption rates of various classes of animal products, (3) the percentage of each class of animal product assumed to be raised on sludge-amended soil, and (4) a set of uptake factors relating the pollutant concentration in each animal product to the pollutant concentration in the feed consumed by the animal. Forty percent of the HEI's diet of meat, dairy products and eggs is assumed to come from animals consuming feed from soil to which sludge was applied. This is especially warranted in the context of regulatory decisions involving the addition of threshold pollutants to the environment.

For Pathway 4 in a non-agricultural setting, a human consumes meat or products from wild animals that consume plants grown in sewage sludge-amended soil. The meat is assumed to be obtained from hunting wild animals (herbivores) that forage vegetation grown in sewage sludge-amended soil on forest and reclamation sites. The allowable dose for this pathway is the RfD for an inorganic pollutant adjusted for a 70 kilogram person minus the background contribution of the pollutant from air, water, and food. The exposure for this pathway is based on (1) uptake factors relating the pollutant concentration in each animal product to the pollutant concentration in the plant consumed by the wild animal, (2) typical consumption rates of various classes of animal products, and (3) the percentage of each class of animal product assumed to forage on sludge-amended soil.

Pathway 5

This pathway involves the application of sewage sludge to the land, the direct ingestion of this sewage sludge by animals, and finally, the consumption of contaminated animal tissue by humans. The analysis developed for this pathway evaluated pollutant loading limits to protect a highly exposed human consuming the tissue of foraging animals that have incidentally ingested sewage sludge. The HEI is assumed to consume daily quantities of the various animal-tissue food groups as determined by an EPA analysis of the diet. The HEI is also assumed to be exposed to a background intake of pollutant.

A grazing animal can be exposed to direct ingestion of sewage sludge by two quite different methods. The first involves direct ingestion of sewage sludge by livestock, where sewage sludge has been surface-applied to pasture crops. Livestock can ingest sewage sludge adhering to the crops or lying on the soil surface. Each year the grazing livestock are presumed to be exposed to freshly applied sewage sludge with no time for dissipation of the organic pollutants. Alternatively,

sewage sludge can be injected into the soil or mixed with the plow-layer soil, and the grazing livestock ingest the soil sewage sludge mixture. Livestock exposure will obviously be maximized when sewage sludge is directly ingested, and hence this ingestion route is considered in this analysis.

It is assumed that only a small percentage of the grazing livestock's diet is sewage sludge, and that not all of the animal tissue consumed by the HEI is derived from livestock that have been feeding on sewage sludge-amended land. Background pollutant intake by the HEI (i.e., the ingestion of pollutants from all sources other than that associated with the application of sewage sludge to the land) is taken into consideration through data derived by EPA for total background intake.

Pathway 6

This pathway evaluates what level of pollutants in sludge is protective of animals that ingest plants grown on sewage sludge-amended soil. Pathway 6 is designed to assist in setting pollutant loading limits that protect the highly sensitive/highly exposed herbivorous livestock that consumes plants grown on sewage sludge-amended soil. It is assumed that the livestock diet consists of 100 percent forage grown on sewage sludge-amended land and that the animal is exposed to a background pollutant intake. In this pathway, different animals are affected by different pollutants; thus, when a sensitive species has been identified for a pollutant, that species is used in the exposure assessment. Among the species looked at for this pathway were livestock, domestic grazing animals, birds and rodents although not all were reviewed for each pollutant.

Pathway 7

This pathway is designed to evaluate pollutant loading limits that are associated with protection of the highly sensitive/highly exposed herbivorous livestock, which incidentally consumes sewage sludge adhering to forage crops and/or sewage sludge on the soil surface. It is assumed that the percent of sewage sludge in the livestock diet is 1.5 percent and that the animal is exposed to a background pollutant intake. Again, different animals are considered in this pathway when evaluating the different pollutants; thus, when a sensitive species has been identified for a pollutant, that species is used in the exposure assessment.

Pathway 8

This pathway evaluates the risk posed by pollutants in sludge to plant growth. For the plant toxicity pathway, the Agency determined an allowable pollutant concentration in the soil that would be associated with a low probability (1×10^{-4}) of a 50 percent reduction in young plant growth. This value was derived from scientific data relating the growth of young plants and soil contaminant levels. Thus, the allowable pollutant load for this pathway is that load which, after dilution with 15 centimeters of soil, does not exceed the threshold value.

The Agency has determined that the relationship between reduction in growth and reduction in yield is particularly uncertain for metals such as chromium. Phytotoxicity resulting from metals is sensitive to changes in soil pH, plant species and to the degree of metals' binding in the sludge matrix. Based on data provided during the public comment period, EPA concluded that metals remain bound in the sludge matrix and are relatively unavailable biologically. However, the Agency determined that its data base on soil types and plant species sensitivity was limited and that pollutants regulated by this pathway should be "capped" (as discussed earlier) at the 99th-percentile pollutant concentration from the NSSS to provide an additional margin of safety to protect sensitive plant species not fully evaluated in its risk assessment.

Pathway 9

The analysis developed for this pathway is designed to assist in setting pollutant loading limits that protect the highly exposed/highly sensitive soil biota. At this time, limited sludge field data exists that indicate the level at which inorganic pollutants become toxic to soil biota. However, Hartenstein et al. (1980) routinely raised earthworms using sewage sludges, which provided a limited source of data. Evidence does not prove that they are highly sensitive species; however, because of the lack of data for other species, the criteria for this pathway have been set using earthworm data. The criteria are based on a No Observed Adverse Effect Level (NOAEL) for the earthworm *Eisenia foetida*.

Pathway 10

The analysis developed for Pathway 10 is designed to assist in setting pollutant loading limits that protect highly sensitive/highly exposed soil biota predators. Of concern in this pathway, therefore, are sensitive wildlife that consume soil biota that have been feeding on sewage sludge-amended soil. No predator has been singled out as being particularly sensitive to cadmium and lead, but rather the literature has been reviewed to identify what the Agency determined is a pollutant intake level protective of sensitive species in general. This is not the case for PCBs, where clear evidence exists that chickens are a highly sensitive species. Chronic exposure assumes that 33 percent of the sensitive species' diet is soil biota.

Pathway 11

This pathway evaluates human exposure to sludge pollutants through inhalation. The HEI for this pathway is the tractor driver tilling the field. This pathway evaluates the impact of particles that have been resuspended by the tilling of dewatered sewage sludge. The particles are inhaled by a tractor operator.

This pathway assumes that the distance from the driver to the soil surface is one meter, sewage sludge is incorporated to a depth of 15 centimeters, and sewage sludge and soil are well mixed. This HEI is not expected to be exposed to more than 10 milligrams per cubic meter (g/m^3) of total dust. At dust levels at or above this level, the American Conference of Governmental Industrial Hygienists (ACGIH) recommends that individuals work within a closed cab.

Pathway 12

The surface run-off pathway, Pathway 12, is intended to protect beneficial use of surface waters in order to protect human health and aquatic life. This pathway evaluates the risk to surface water associated with run-off of pollutants from soil on which sludge has been applied. The exposure assessment calculates the pollutant concentration in sludge-amended soil that would not result in exceeding a Water Quality Criterion for a pollutant if the soil enters a relatively small stream. The rate at which the soil enters the stream was based on the Universal Soil Loss Equation and a sediment delivery ratio. Water Quality Criteria are designed to protect human health, assuming exposure through consumption of drinking water and resident fish, and to protect aquatic life.

Pathway 13 (Land Application)

In model Pathway 13 for land application practices, the Agency evaluated the exposure of members of a farm household inhaling vapors of any volatile pollutants that may be in the sewage sludge when it is applied to the land. This pathway was considered for six pollutants: benzo(a)pyrene, bis(2-ethylhexyl)phthalate, chlordane, DDT, dimethylnitrosamine, and

polychlorinated biphenyls. These pollutants were originally selected by the Agency as pollutants of concern from the hazard indices screen because of their semi-volatile nature. The Agency did not evaluate the vapor pathway for organic pollutants like benzene, lindane, trichloroethylene, or toxaphene because these pollutants, which are highly volatile, would volatilize in wastewater treatment processes before sewage sludge disposal—either during wastewater aeration or during sludge processing and dewatering—and thus were not considered to be of concern. In addition, non-volatile metals were not evaluated in the vapor pathway.

The vapor pathway assumes that the total amount of pollutant spread in each year would vaporize during that year. Thus, the allowable annual pollutant loading rate is equal to the flux (mass of pollutant per unit area per unit time) that may be allowed to enter the atmosphere without exceeding the allowable pollutant concentration in the air. This concentration corresponds to the RfC, risk-specific dose, or an acceptable daily dose derived from an MCL. A plume model was used to relate the flux to the resulting pollutant concentration in the air. The allowable flux is determined by: (1) the allowable pollutant concentration in the air, (2) the size of the sewage sludge application site, (3) the assumed distance of an individual from the site where the air concentration must be attained, (4) the wind speed; and (5) the degree of atmospheric mixing. The wind direction is assumed never to change, so the HEI always remains in the center line of the plume.

Pathway 13 (Surface Disposal)

In exposure Pathway 13 for surface disposal sites, the Agency evaluated the exposure of an individual inhaling vapors of any volatile pollutants that may be in the sewage sludge disposed at a surface disposal site. The individual (HEI) is assumed to be living at the downwind edge of the site and is inhaling air, at a rate of 20 cubic meters per day for 70 years, that has been contaminated with volatile organic compounds from sewage sludge disposed of at the site.

Volatilization rate coefficients for uncovered cells are calculated with equations that consider constituent parameters including the Henry's Law coefficient, molecular weight and distribution coefficient. The rate of contaminant release through volatilization is estimated separately for a covered site. Contaminant loss to the vapor pathway is diluted into the total volume of air passing within two meters over the site during the period of contaminant release. This box model is used to determine the expected air concentrations to which the HEI is exposed for each unit of concentration vaporized at the downwind edge of the site. The allowable lifetime exposure to each contaminant (based on a risk level of 1×10^{-4}) is then used to back-calculate the allowable loss rate to the vapor pathway. This value is then divided by the fraction of contaminant vaporized to determine the allowable pollutant concentration at the site.

Pathway 13 (Incineration)

In model pathway 13 for incineration, the Agency evaluated the exposure of an individual living in close proximity to a sewage sludge incinerator. This individual is assumed to inhale particulates and gases from the incinerator 24 hours per day, 365 days per year for 70 years. This highly exposed individual is located at a point where the highest annual ground level concentration of incinerator emissions occurs. This pathway was evaluated for five heavy metals: arsenic, cadmium, chromium, lead and nickel and approximately 70 organics which are represented by a surrogate measure of total hydrocarbons.

Risk-specific concentrations of the four carcinogenic metals are established from cancer potency values found in IRIS. An acceptable ground level concentration of lead is established at 10 percent of the NAAQS for lead. Allowable stack emission rates for these five heavy metals are calculated by use of site-specific air dispersion models. Allowable concentrations of the five heavy metals in sewage sludge are calculated by determining the metal removal efficiency across the incinerator and air pollution control device site-specifically and considering the whole sludge feed rate to the incinerator.

Pathway 14 (Land Application)

In this pathway, the Agency evaluated the exposure of individuals who would obtain their drinking water from ground water located directly below a field to which sewage sludge had been applied. The leachate concentration formed in the sewage sludge-amended soil layer is related by a partition coefficient to the pollutant concentration in the soil. In moving down through the unsaturated zone, the peak leachate concentration is reduced by the modeled processes of vertical dispersion (primarily caused by detention of sorbed pollutant), chemical degradation, and metal precipitation.

The allowable pollutant loading rate was thus determined from the MCL that must be met at the ground water interface with no allowance for dilution, the rate of decay of a pollutant, and other factors that affect either the time period for decay or the dispersive smoothing of the peak concentration. These other factors include the recharge or infiltration rate, hydraulic characteristics of the soil, depth to ground water, and the chemical partition coefficient. For some metals, the net ground water electromotive potential (Eh) and ground water pH influence metallic species precipitation out of aqueous solution.

Pathway 14 (Surface Disposal)

In exposure Pathway 14 for surface disposal sites, the Agency evaluated the exposure of individuals who would obtain their drinking water from ground water contaminated by the surface disposal site. Exposure concentrations are predicted based on well locations 150 meters or less downgradient of the site for facilities located over a source of drinking water. Reference drinking water criteria are either MCLs or are based on a risk level of 1×10^{-4} for an HEI who consumes two liters of water per day over a 70-year lifetime.

Numerical pollutant limits for the ground water pathway are derived for both covered (sludge-only landfills—monofills) and uncovered surface disposal sites. Pollutant losses are first partitioned among the three competing loss processes: Volatilization, leaching to ground water, and on-site contaminant degradation. For surface disposal sites other than monofills, the relatively high water content of the sewage sludge received at the site results in an increased rate of seepage from the facility as compared to that estimated for monofills. Once the fraction of contaminant lost to leaching has been determined, a module is used to estimate flow and transport through the unsaturated zone and is linked to a three dimensional analytical model to depict fate and transport in the saturated zone. The linked model considers the extent to which constituent transport in the saturated zone if affected by local mounding of the water table beneath the site. The module accounts for a number of processes including advection, dispersion, adsorption, and degradation. The mass flux into the saturated zone is used as input to the model which couples this source term with aquifer characteristics to predict concentrations.

Comments on the Proposed Exposure Assessment Approach and Risk Management Issues for Land Application Practices

Land Application—Agricultural Practices

As a result of public comments and scientific peer review, many of the assumptions and data used in the exposure assessment methodology to generate numerical limitations for the proposed rule have been changed to reflect more up-to-date information and more realistic exposure scenarios describing the expected conditions on which sewage sludge will be land-applied for agricultural purposes. The following is a discussion of the major comments, responses and actions taken by the Agency in developing the final part 503 regulations for agricultural land application of sewage sludge. A complete discussion of all the comments and the Agency's responses can be found in the Response to Comments Document for the Proposed Part 503 Rule (Reference No. 109). In addition, a more detailed explanation of the Agency's scientific approach can be found in the Technical Support Document for Land Application.

Information on obtaining single copies of these documents can be found in Part XIV—Availability of Technical Information on the Final Rule.

1. Reconstructing Proposed Pathways 11 and 12

Comment: Many commenters suggested that EPA completely reconstruct the surface run-off (proposed Pathway 11), vapor (proposed Pathway 12A), and ground water (proposed Pathway 12W) exposure pathways for agricultural land application practices. They recommended that EPA incorporate better fate and transport models and different modeling assumptions into the exposure assessment (e.g., some commenters criticized the Universal Soil Loss Equation model used in Pathway 11 as too simplistic). In addition, commenters argued (1) that 100 percent of a constituent cannot be available both to volatilize from the site and simultaneously to leach into ground water and (2) that a mass balance methodology should be used to account for partitioning of pollutants across multiple pathways.

Response: The Agency agrees that proposed Pathways 11, 12A, and 12W (Pathways 12, 13, and 14 in the final rule) should be revised to make use of improved models and more realistic modeling assumptions and that a mass balance methodology should be used to account for partitioning of pollutants across these pathways. EPA has made numerous revisions to its exposure assessment pathway models for the final rule. The previous section (Exposure Assessment Approach for the Final Part 503 Rule) briefly summarizes exposure pathways 12, 13, and 14 as well as the other 11 pathways used in the final rule to calculate numerical limits for sewage sludge applied to agricultural land.

The land application exposure assessment is complex and made up of a large number of pathways and parameters. At the time of proposal, the Agency realized that the models used in assessing the risks in developing the proposed limits for the land application of sewage sludge involved a number of uncertainties and technical issues. Consequently, the proposal identified many of these issues and asked for comment. However, in the absence of data or compelling evidence to the contrary, the Agency selected the models and parameters, and constructed the pathways in the proposal to ensure protection of public health and the environment from pollutants found in sewage sludge applied to agricultural land. Based on information and data gathered during the public comment period, the Agency determined that many of the assumptions used in the exposure pathways for the proposal were overconservative, resulting in numerical pollutant limits with an unnecessarily high margin of safety.

Final Action: Exposure pathways 11, 12A and 12W were revised (Pathways 12, 13, and 14 in the final rule) and EPA developed a new methodology that accounts for the partitioning of pollutants between these pathways in response to scientific peer review and public comments. To partition contaminant losses among competing processes, all losses are treated as first-order, and a rate-loss coefficient is calculated for each. The first-order loss rate, the decay or degradation rate for a pollutant, is proportional to the concentration of the pollutant at any point in time. The higher the concentration of the pollutant, the greater the rate of loss. A first-order rate loss coefficient is calculated for each competing environmental process; soil erosion, leaching to ground water and for volatile pollutants, vaporization. Using the rate-loss coefficient a fraction of pollutant lost to each pathway is then determined.

For the land application exposure assessment, EPA partitioned pollutants based on the rate of leaching to ground water, volatilization to air, erosion to surface water, pollutant decay and retention on the land surface. The Agency did not include plant uptake in the mass balance equations since much of the contaminant taken up by plants is not actually removed from the site and may therefore remain available for leaching, erosion or volatilization. The reconstructed pathways for land application practices follow (These pathways also have been reconstructed and the mass balance methodology applied to non-agricultural land application and to surface disposal practices):

Pathway 12—Criteria for the surface water erosion pathway are determined based on the fraction of contaminant lost to surface waters, the dilution of sewage sludge-amended soil with soil from the rest of the watershed, partitioning between the aqueous and adsorbed phases in the stream, and the bioconcentration of the contaminant by aquatic species. The Universal Soil Loss Equation (USLE) is used to describe erosion for both the Sludge Management Area (SMA) and the watershed. While some commenters criticized the use of this model as too simplistic, the Agency believes that USLE provides the most accepted method for developing such a national regulation. This equation incorporates the effect of cover, land topography, support practices, and soil erodibility. USLE is implemented by assuming that land use practices and other characteristics are similar for the SMA and watershed. An allowable reference water concentration is derived based on exposure from ingestion of contaminated fish and drinking water. Criteria are designed to protect an individual who drinks 2 liters of water and eats 40 grams of fish and shellfish per day. The consumption of 40 grams per day represents the 95th-percentile weighted lifetime diet for individuals consuming fish and shellfish.

Pathway 13—The vapor pathway is designed to protect members of a farm household living at the down-wind edge of the site and inhaling volatile organic pollutants from land-applied sewage sludge. The amount of contaminant released into the air per second is estimated as the fraction of contaminant lost to the vapor pathway (determined by the mass balance model) divided by the period of release. A box model is used to dilute the pollutant releases by the amount of additional air which enters a box within 2 meters height above the site. Wind speed is assumed to be 10 miles per hour (about 4.5 meters per second). Maximum contaminant loadings are back-calculated based on a reference air concentration that corresponds to a HEI lifetime cancer risk of 1×10^{-4}.

Pathway 14—This pathway is designed to protect individuals who obtain their drinking water from ground water sources, and it assumes that a well may be located within the treated site. The model assumes that sewage sludge is incorporated into the top 15 centimeters of the surface soil layer. In addition, a reasonable worst-case depth to ground water is assumed to be 1 meter. The allowable pollutant loading is derived from the health-based standard, and it accounts for pollutant degradation and dilution within the aquifer directly below the site. The VADOFT finite element module, a fate and transport mathematical model used for this evaluation, (Reference Nos. 98 and 99) is used to estimate flow and transport through the unsaturated zone and linked to a three dimensional analytical model AT123D (Reference No. 117) to depict fate and transport in the saturated zone. AT123D is used to simulate the horizontal transport of contaminant from the entire land surface to the down-gradient edge of the site. For contaminants entering the saturated zone at the down-gradient edge, no further horizontal transport is simulated.

The Agency believes that revisions made to proposed Pathways 11, 12A, and 12W represent refinements to the models, modeling parameters and assumptions. The Agency also believes that these revisions improve exposure assessment precision and accuracy, yielding results that are consistent with protection of public health and the environment and well within acceptable risk levels established by the Agency. As has been previously noted, the effect of using very conservative assumptions for model parameters is to compound the conservatism resulting in an unreasonably worst-case approach that yields numerical pollutant limits more stringent than required to protect public health and the environment from reasonably anticipated adverse effects.

2. Human Exposure From Diet

Comment: Several commenters stated that the human dietary exposure scenario for agricultural land application and distribution and marketing (D&M—referred to as sewage sludge sold or given away in the final rule) was not properly constructed with respect to the daily dry matter intake of various food groups. Under conditions of long-term exposure, commenters felt that it was not appropriate to use data from the age and sex group having the highest daily consumption in each food group. Some commenters advocated using the approach taken in the human health aggregate risk assessment for the part 503 proposal. This approach used national averages from the Agency Dietary Risk Evaluation System (DRES) dietary data base. DRES is a computerized data base used by EPA's pesticides program to develop pesticide tolerances on crops. The system accounts for total commodity production (both vegetables and animals) in the United States. The Agency's pesticide program uses this data with census information to develop national estimates, grouped by age and sex, of commodity consumption.

One commenter objected to the Agency's assumption that 2.5 percent of the human MEI's vegetable, fruit, and grain diet was from sewage sludge-amended fields in the agricultural land practices exposure scenario. The commenter stated that the Agency estimated that approximately 0.02 percent of the nation's agricultural land was treated with sewage sludge each year. Therefore, no more than 0.02 percent of an individual's diet could originate from food grown on sewage sludge-amended soil. Since the Agency recognized that some individuals would have greater exposure than others, EPA assumed 2.5 percent of the MEI's vegetable, fruit, and grain diet was grown on sewage sludge-amended fields. The commenter maintained that this 100-fold increase based on potentially high consumption of foods grown on sewage sludge-amended fields and obtained from roadside stands was too high and, therefore, unnecessarily conservative. However, another commenter provided limited data showing potentially high consumption of foods grown on sludge-amended fields by farm families.

Response: EPA agrees that a more realistic human dietary exposure scenario should be used in calculating human food-chain risk from consuming plant or animal products that have been grown or raised on sewage sludge-amended fields.

In the proposed rule, the quantity of each of eight food groups in the human diet assumed in the analysis was taken from the Pennington data base for the age and gender group with the highest daily consumption. While the assumed diet includes an average mix of meats, fruits, legumes, grains, and dairy products, the consumption rates were higher than would be expected for a single individual over a lifetime.

In the risk assessment for the proposal, EPA used the highest consumption for all age and sex groups to represent the human diet from 0 to 70 years. As a result, the diet of the teenage male (14–16 years of age) was used to represent the consumption of grains, potatoes, root vegetables, dairy products, and dairy fat. The diet of the adult female (25–30 years of age) was used to represent lamb and lamb fat consumption. Consumption of legumes, garden fruits, beef, beef fat, poultry, poultry fat, pork, and pork fat was represented by the data for adult males (25–30 years of age). The diet of the adult male (60–65 years of age) was used to represent consumers of beef liver, beef liver fat, and eggs. Depending on whether the pollutant being evaluated was organic or inorganic, either total meat consumption or only meat fat was considered in the evaluation. It was assumed that the metals would collect in the total tissue mass, but organic pollutants would be found only in the lipid portion of the exposed animals' tissues. The Agency now believes that the additive effects of these conservative assumptions yielded an unreasonably worst-case exposure assessment approach for the proposed rule.

However, EPA disagrees with the comment that the Agency's assumption for agricultural land practices stating that 2.5 percent of the MEI's diet comes from vegetables, fruits, and grains grown on sewage sludge-amended soil is too conservative. The data from one commenter shows farm families do exist that consume a higher amount of their diet (i.e., vegetables, meat and milk) from fields fertilized with sludge. The Agency reviewed information (Reference No. 9) that estimated the percentage of total available cropland that would be required, based on nitrogen content, to dispose of the total United States sewage sludge production. Estimates for 1985 (based on 1975 data) ranged from 0.49 to 1.98 percent. This estimate could be much higher on a statewide basis, especially in areas where available cropland is small compared to the population size (such as in New Jersey). This assumption was also supported by the EPA Science Advisory Board, which recommended the Agency use 2.5 percent as a reasonably protective value. To date, the Agency has not received any study or data that would suggest a more reasonable or accurate estimate for a national regulation. The Agency believes that it can use a more reasonable assumption for the fraction of food groups grown on sludge-amended fields because other parameters in the exposure assessment for this pathway (e.g., the oral reference dose, the total background intake of pollutants from all other sources of exposure except sludge, the uptake response slope of pollutants in plant

tissue, etc.) are bounding, and to use overconservative assumptions for every model parameter compounds the conservatism beyond "reasonable" worst-case conditions. This is why the Agency did not construct exposure pathways for agricultural land application based solely on data from farm families that consume a higher amount of their diet from crops or animals raised on sludge-amended fields. The Agency believes the agricultural pathways used in the final rule adequately protect farm families because of the compounding affect bounding parameters used in the exposure pathway have on less conservative ones.

As part of EPA's exposure assessment for land application, the Agency evaluated Pathway 2, which is specifically designed to protect HEIs that consume very large portions of their diet (as much as 60 percent) from crops grown in a garden fertilized with sewage sludge. In the final land application regulation, EPA used numerical pollutant limits from Pathway 2 when those limits were more protective of human health and the environment than pollutant limits from other pathways. Therefore, the Agency evaluated each of the 14 exposure pathways for land application but only used the numerical pollutant limit from the pathway that was most protective of public health and the environment regardless of which pathway produced that limit. For example, if a pathway protecting earthworms produced a more protective (lower) pollutant limit than a pathway protecting humans, the final part 503 regulation would use the numerical pollutant limit from the earthworm pathway as the pollutant limit in the final rule. By taking the most protective pollutant limit from the most sensitive pathway, the Agency is assured of protecting both public health and the environment under a variety of reasonably worst-case exposure scenarios.

Final Action: EPA has revised its human dietary exposure scenario for agricultural land application and sewage sludge sold or given away (referred to as D&M in the proposal) to produce more realistic values representing a lifetime average consumption for both sexes analyzed for each food group. This approach is similar to the approach used in the human health aggregate risk assessment for the proposed rule and to the dietary analysis the Agency uses to evaluate risks from pesticides used on human food-chain crops.

The approach for the final rule involves integrating the consumption rates for each sex over their lifespan and calculating a weighted lifetime average value. This approach is based on the same Food and Drug Administration (FDA) data used in the proposal. However in the revised approach, each age-by-sex sample is used to assign food intakes to different age ranges of the population. These ranges are then summed to provide a lifetime average daily intake of each food group in the dietary exposure pathways.

The aggregate risk assessment for the final part 503 rule uses the Agency's DRES dietary data base. The Agency did not use the DRES system in its exposure pathway assessment to develop numerical pollutant limits for the final part 503 rule because the exposure pathways developed by the Agency for sludge required dry weights of vegetables and animal tissue consumed by the HEI and the DRES data is based on wet (fresh) weights. In order to use the DRES system in the exposure pathway assessment for sludge the Agency would have had to convert each vegetable and animal food group to dry weight, which would have introduced another area of uncertainty in the exposure assessment.

In Round Two, EPA is committed to adopting the DRES system for both the aggregate risk assessment and the exposure pathway assessment. The Agency will make the necessary changes in its exposure assessment for sludge to adopt the DRES dietary data base. The Agency is adopting the DRES system to ensure consistency between future part 503 rulemakings and other regulations being developed by the Agency but does not believe that this change will make a significant difference in the numerical pollutant limits compared to the approach used for today's final rule.

3. Fraction of Vegetable Food Groups Home-Produced with Home Garden Fertilizer Products

Comment: Many commenters maintained that the EPA's choice of values representing the fraction of vegetable food groups home-produced with home garden fertilizer products is too conservative. Several of the commenters stated that the data taken from the U.S. Department of Agriculture (USDA) 1965–1966 market-basket survey of U.S. food consumption used to calculate the values in the part 503 proposal were outdated, with the percentage of homegrown foods showing a decreasing trend over time.

One commenter contended that the availability of sewage sludge products is greater in urban areas; therefore, households in these areas have a greater opportunity to use these products in their vegetable gardens than the rural farm dweller. For this reason, the commenter felt that the urban household dweller should be used by the Agency instead of the rural farm dweller. Another commenter argued that the Agency was inconsistent—it assumed the exposed individual was a rural farm dweller growing a high percentage of his own vegetables; but the daily intake values for these vegetables were based on an urban diet. In this case, the commenter felt that either a rural or urban setting should be assumed in both cases for consistency in the final rule. One commenter suggested that the Agency use data for the rural non-farm household instead of the rural farm family because the Agency assumed that the land would be converted from agricultural to residential use in five years.

Response: The Agency agrees that its choice of values representing the fraction of vegetable food groups produced with sewage sludge home garden products was too conservative. It also agrees that it would be preferable to use more recent data to estimate these values for the final rule. The USDA 1965–1966 market-basket survey data used as the basis for the exposure assessment aggregated all U.S. households into rural farm, rural non-farm, and urban categories (Reference No. 56). To be conservative, the Agency chose the rural farm household in the exposure assessment for the proposal. The Agency now believes that this assumption was too conservative because farmers are more likely to use chemical fertilizers or sewage sludge cake rather than the typical bagged sewage sludge products distributed and marketed in commerce.

As indicated by the public comments, the rural non-farm household having a large amount of property but not operating a commercial agricultural farm business would be a more appropriate category for the exposure assessment scenario. However, the latest market-basket survey conducted in 1978 by USDA (Reference No. 57) aggregates the data differently than the 1965–1966 survey. The 1978 survey divides the U.S. population into non-metropolitan, suburban, and central city household categories. The non-metropolitan category merges the rural farm and the rural non-farm households together; but because of the way the survey data was collected, these two sub-categories cannot be easily separated for use in the exposure assessment for the final part 503 rule.

If the Agency were to use the data from the non-metropolitan category to represent the rural non-farm household,

this again would be unnecessarily conservative since the category includes rural farm households who consume a much higher percentage of homegrown food than rural non-farm families. However, data shows that 46 percent of U.S. households produce some of their own food from home gardens (Reference No. 38a), and this information could be used as a conservative method for segregating rural farm and the rural non-farm sub-categories. In addition, the Agency does not believe that the 1965–1966 survey data for urban dwellers or the 1978 survey data for suburban or central city household categories would protect public health if used in the exposure assessment scenario to protect individuals using D&M products to produce homegrown food for personal consumption. The Agency desires that data used in the exposure assessment for the final part 503 rule be suited for the purpose intended and scientifically defensible, and that the results obtained from the data adequately protective of public health and the environment.

Final Action: Based on scientific peer review and public comments, the Agency has decided to adjust the fraction of food groups from the non-metropolitan category of the 1978 USDA survey data by a multiplication factor of 2.17. This factor was derived from the fraction of U.S. households (46 percent) that produce some of their own food from home gardens; it is the basis for deriving the fraction of vegetable food groups homegrown with D&M products used in the exposure assessment for the final part 503 rule. This replaces the rural farm family exposure scenario from the USDA 1965–1966 market-basket survey (Reference No. 56) used in the proposal with the more recent 1978 USDA survey data; it uses a reasonable worst-case estimate of the fraction of vegetable food groups for non-rural farm families that was included in the non-metropolitan category.

4. Fraction of Animal Product Food Groups Derived From Sludge-Amended Soil

Comment: Several commenters argued that the values representing the fraction of meat products derived from sewage sludge-amended soil in the proposed part 503 regulations for agricultural land practices are unrealistically high and based on outdated information from the USDA 1965–1966 market-basket survey (Reference No. 56). The commenters contended that current data on food consumption by rural farm families may show a lower fraction of locally grown livestock consumed by the highest consuming households.

Response: The Agency agrees that it would be preferable to use the most recent information possible to estimate the values representing the fraction of animal product food groups derived from sewage sludge-amended soil in the exposure assessment for agricultural land practices. These values in the proposed regulations were estimated as an average percent of the annual consumption of food which is homegrown by rural farm households. These values were calculated from the USDA 1965–1966 market-basket survey data found in Table 4–14 of the proposed Land Application Methodology. The exposed individual in this assessment was conservatively assumed to consume 44 percent of meat (beef, lamb, and pork), 34 percent of dairy products, 34 percent of poultry, and 48 percent of eggs from farms raising livestock on sewage sludge-amended soil.

The USDA 1965–1966 survey data, used as the basis for estimating the values in the exposure assessment, aggregated all U.S. households into rural farm, rural non-farm, and urban categories. To be conservative, the Agency chose the rural farm household to use in the exposure assessment for the proposal. However, the latest USDA market-basket survey conducted in 1978, aggregates the data differently than the 1965–1966 survey. The 1978 survey divides the U.S. population into non-metropolitan, suburban, and central city household categories. The non-metropolitan category merges the rural farm and the rural non-farm households together; but because of the way the survey data was collected, these two sub-categories cannot be separated for use in the exposure assessment for the final part 503 rule. In addition, the Agency lacks any national information on the consumption of homegrown meat products that would enable it to adjust the data in the non-metropolitan category, previously done for vegetable food groups.

If the Agency were to use the data from the non-metropolitan category to represent the rural farm household, this would not be as conservative as the proposal since it includes rural non-farm families who are not expected to consume a significant portion of animal products raised on sewage sludge-amended lands. However, the Agency believes that using the unadjusted data from the non-metropolitan category would be adequate to protect public health, given other reasonable worst-case assumptions used in the exposure scenario. Further, the Agency does not believe that the 1978 survey data for suburban or central city households would protect public health if used in the exposure assessment to protect individuals consuming meat products from farms raising livestock on sewage sludge-amended soil. As stated earlier, the Agency believes that data, used in the exposure assessment for the final part 503 rule should be suited for the purpose intended, scientifically defensible, and protective of public health and the environment.

Final Action: The Agency has decided not to retain for the final rule the values representing the fraction of animal product food groups based on the USDA 1965–1966 market-basket survey because more recent data are available from the USDA 1978 survey. The Agency believes that while the 1978 data are not as conservative as the 1965–1966 data, they do provide a reasonable worst-case estimate of animal product food groups consumed by rural farm families and are protective of public health given other conservative assumptions used in the exposure assessment.

5. Soil Ingestion Rate for Children

Comment: In the proposal, Pathway 2F (Pathway 3 of the final part 503 rule) used an estimated soil ingestion rate for children of 0.1 grams per day to derive numerical limits for agricultural land practices and D&M. Comments were received on both sides of this issue. Some commenters stated that the rate was too high and that not all the soil ingested would be sewage sludge-amended soil, while others felt it was too low. The range of soil ingestion rates suggested by the commenters was from 0.1 to 0.5 grams per day. The values offered for percent of soil that should be considered sewage sludge ranged from 10 to 50 percent of the total soil ingested. One commenter suggested that the soil ingestion rate should be 0.2 grams per day, because this was the value given in a recent EPA health advisory (Reference No. 96).

In addition, several commenters maintained that the Agency's 10 kilogram body weight assumption is too low for a child, ages 1 to 6, ingesting sewage sludge-amended soil. The commenters felt that it was unreasonable for the Agency to assume a constant body weight of 10 kilograms for a child during a 5-year period in which the body weight usually increases drastically. The commenters maintained that a child MEI typically weighs 10 kilograms for only 1 year, and suggested that the Agency use a 15 kilogram body weight as a more realistic value that would not over estimate the average daily dose for the 5-year period of exposure.

Response: In the exposure assessment approach for the proposed rule, the Agency felt that using children exhibiting pica behavior (i.e., ingesting 0.5 to 5.0 grams of soil per day) as the MEI for the children-eating-soil pathways (Pathway 2F) was too conservative. Instead, the Agency used the average value of 0.1 grams per day as the soil ingestion rate for children. For the proposal, the Agency considered this to be a good estimate of the mean value (Reference No. 101) because all studies of soil ingestion by children were short-term measurements, with no way to estimate (long-term) time-averaged soil ingestion by a child either with pica behavior or who inadvertently ingests soil. The observed variability between children overstates the true variability of long-term exposure.

In addition, EPA did not specifically evaluate the long-term ingestion of pure sewage sludge because the Agency believed that the sewage sludge and soil would be mixed together by mechanical or natural weathering processes (i.e., a mixture ranging from 0.25 to 2.5 percent sewage sludge after dilution with 15 centimeters of soil). Therefore, long-term ingestion of 0.1 grams of sewage sludge-amended soil per day was considered a reasonable expectation.

While the use of an average soil ingestion rate of sewage sludge-amended soil, rather than the use of an ingestion rate associated with a pica child (0.5 to 5.0 grams per day) and pure sewage sludge might be construed as under-protective, other factors suggested that the Agency's analysis may be over-protective. First, the entire 0.1 grams of soil ingested per day was assumed to be composed of sewage sludge-amended soil. In real situations, only a portion of the 0.1 grams per day of soil is likely to be from sewage sludge-amended soil since children are exposed to other sources of household dust and dirt, and from sources of soil outside the home environment. Second, it is unlikely that a child would ingest 0.1 grams of a sewage sludge-soil mixture every day. Third, and possibly most important, the biological availability of sewage sludge-soil-bound pollutants was assumed to be equal to that of the pollutants in food and drinking water. However, evidence indicates that desorption from the soil particles is a very slow process, generally requiring more time than available to material that is traversing the alimentary canal. Such desorption would have to take place before the pollutant could cross the membranes into the blood stream and be transported to sites in the body where it could cause toxic effects. Fourth, because the Agency does not have RfDs for pollutants representing a short term exposure (i.e., a 5-year exposure), lifetime RfDs representing a 70-year chronic exposure were used for pollutants evaluated in this pathway. This over predicts the pollutant-dose the child receives relative to the toxic threshold (RfD) used, because the lifetime RfDs protects the child for 70 years from ingesting pollutants in sludge when in actuality the child would grow out of this "pica-like" behavior in approximately 5 years.

The Agency agrees that the 10-kilogram body weight assumption is too low and may overestimate the average daily dose for a child, ages 1 to 6, ingesting sewage sludge-amended soil. At the time of proposal, studies on blood lead concentrations in children exposed to lead-containing dusts indicate that maximum exposure via hand-to-mouth contacts occur at about 18 months of age where the child's body weight would be approximately 10 kilograms (Reference No. 101).

Final Action: Since the proposal, several groups have examined the ingestion rate and body weight issues and supported research efforts to resolve them. A recent directive from the Agency's Office of Solid Waste and Emergency Response suggested a range of soil ingestion rates of 0.1 to 0.2 grams per day (Reference No. 96) for a 16-kilogram child. For the final Part 503 rule, the Agency has selected 0.2 grams per day as a best estimate of daily sewage sludge ingestion by children with a body weight of 16 kilograms. The Scientific Peer Review Committee on land application recommended that 0.5 grams per day soil ingestion (at the 95th-percentile) would be a more reasonable worst-case exposure level for children (Reference No. 58). However, after further evaluation, the committee agreed that this is an overestimation of chronic risk associated with soil ingestion by children ages 1 to 6.

The Agency believes that using either a sewage sludge ingestion rate of 0.2 grams per day for 5 years or 0.5 grams per day for 2 years will result in the same amount of exposure and will be suitable for modeling children at higher risk. Therefore, the Agency has selected a sewage sludge ingestion rate for children of 0.2 grams per day to use in exposure Pathway 3 to derive numerical limitations for agricultural land practices in the final rule. In addition, the Agency has decided to use the 16-kilogram body weight assumption for children ingesting sewage sludge in this pathway.

6. Ingestion of Soil by Animals

Comment: Seven commenters took issue with the EPA's assumption that 8 percent of a grazing animal's diet contains sewage sludge-amended soil. The commenters considered that the 8 percent sewage sludge/soil ingestion used for Pathways 4 and 6 in the land application exposure assessment for the proposed rule was too high based on chronic sewage sludge ingestion by cattle in field studies where sewage sludge or compost was surface applied to growing pasture. They suggested that a value based on long-term grazing under average field conditions was more appropriate than assuming short-term grazing under poor field conditions. They further stated that in order for pasture-fed livestock to ingest 8 percent of their diet as sewage sludge-amended soil over a lifetime would require an extremely underdeveloped pasture as their sole source of food. In a normal pasture setting, livestock eat the ends of the grass which contains little adhering soil. Pulling up plants with roots and adhering soil attached usually occurs only when adequate developed mature grass is not available. This could occur during extreme drought conditions, but it is not likely for the entire lifespan of the animals. The commenters suggested a range from 1 to 5 percent of the grazing animals' diet be composed of sewage sludge-amended soil.

In addition, the commenters noted that in any one year, the maximum fraction of a farm treated with sewage sludge ranges from 10 to 33 percent, rather than the 100 percent assumed in the proposed exposure assessment. The commenters suggested that the Agency multiply its values by one-tenth to one-third to reflect the actual fraction of acreage set aside for sewage sludge application.

Response: The Agency agrees that the 8 percent ingestion of sewage sludge-amended soil by grazing animals considered in Pathways 4 and 6 for the land application proposed regulations was too conservative (Pathways 5 and 7 in the final rule). EPA assumed that relatively large amounts of soil would be ingested by grazing animals because some studies reviewed prior to developing the proposal had reported these or higher values. The Agency also assumed a dilution of sewage sludge with 15 centimeters of soil when the sewage sludge is applied to pastures. Since the sewage sludge applied to pastures is generally not incorporated into the soil (as it is for row crops), the Agency's assumption relied on climatic conditions and biological factors to assure mixing to the 15-centimeter

depth. The Agency feared that this assumption may underestimate grazing animals ingesting sewage sludge in even greater concentrations than those determined in the exposure assessment model because this assumption depended on incorporation through weathering.

Based on the submission of new information from a long-term study reported by Chaney et. al. (Reference No. 11), the Agency has revised its sewage sludge-amended soil ingestion assumption for grazing animals (Reference No. 58). In the study, sewage sludge ingestion was estimated from season-long analyses of feces of animals grazing in pastures receiving surface-applied liquid sludge or compost. The study concluded that the average intake of sewage sludge was 2.5 percent of a grazing animal's dry diet. Other information indicated that in any one year the maximum fraction of a farm treated with sludge was 33 percent. Therefore, the actual fraction of the grazing animals' diet which is sewage sludge would be lower than 2.5 percent if the animals are rotated among several pasture fields.

The Agency believes that exposure from surface-applied sewage sludge, as shown in the study, represents a much greater potential for ingestion than sewage sludge mixed with the top 15 centimeters of soil used in the exposure assessment pathways for the proposed rule. In addition, whole season data are more appropriate than using single highest results in the exposure assessment because prolonged exposure is usually required before toxic levels can cause adverse effects. The Agency also believes that animals are rotated among several fields and that many farms do not apply sewage sludge to 100 percent of their land in any one year. This would tend to lower the fraction of the livestock's diet affected by recent sewage sludge applications.

Final Action: Based on new information and data submitted during the public comment period, the Agency has revised the maximum fraction of a farm treated with sewage sludge and the sewage sludge-amended soil ingestion assumption for grazing animals used in exposure assessment Pathways 5 and 7 (Pathways 4 and 6 in the proposed rule). The exposure assessment for the final rule used 33 percent as the maximum fraction of a farm treated with sewage sludge and 1.5 percent sewage sludge (season-long average) in the diet of livestock grazing pastures amended 30 days before the animals enter the field. The Agency believes that over time (1) the freshly applied sewage sludge will become mixed with the previously applied sludge and soil surface and (2) grazing livestock can ingest the sewage sludge on the soil surface. The Agency believes, however, that the fraction of farmland treated and the rate of sludge ingestion is significantly less than the 100 percent and 8 percent assumptions used in the proposed rule.

7. Plant Uptake and Phytotoxicity

Comment: Many commenters recommended that Pathway 7 (Pathway 8 in the final rule) be completely removed from the land application exposure assessment model. Commenters stated that because of the complex nature of the soil-plant-sludge interacting system, pinpointing the exact cause of the crop yield response is difficult. Since sewage sludge contains a mixture of potentially toxic chemicals, predicting with a high degree of confidence that any observed adverse effect is a result of a particular pollutant acting alone or the result of synergistic effects from a combination of pollutants acting together is difficult. Furthermore, some commenters believed that this pathway should not be evaluated because it is essentially self-limiting. If a particular quality of sewage sludge caused phytotoxic effects, such as yield reductions, farmers and the public would cease using it.

In the risk assessment evaluation for the proposed rule, phytotoxicity and plant uptake data were chosen based on a selection hierarchy. This hierarchy grouped data from most preferred (i.e., "most like the conditions being regulated") to least preferred (i.e., "least like the expected conditions to be regulated"). For example, the most preferred studies from which to extract data points were performed under sludge/field conditions followed by sludge/pot conditions and the least preferred were pure organic compounds or salt/pot studies.

Numerous public comments were received on this approach. The majority stated that the use of salt or pot studies was an unreasonably worst-case situation that would drastically over-estimate plant uptake and phytotoxicity of sewage sludge pollutants. Studies using salt spikes instead of sewage sludge result in greater bioavailability of the metallic pollutants because they are not bound to an organic matrix and are, therefore, more freely taken up by plant roots.

Likewise, greenhouse studies where plants are grown in pots are known to often over predict uptake compared to field conditions. This is because pots tend to restrict the area of root growth and the small amount of contained soil tends to concentrate and retain the sewage sludge pollutants around the roots, thus accelerating uptake. Under field conditions, precipitation can disperse pollutants into the soil profile so that they are less available to the plants. In fact, numerous differences exist between the pot and field environments, such as the molecular form of the pollutant under consideration.

Response: The EPA disagrees that the phytotoxicity pathway (Pathway 8 in the final rule) should be removed from the land application exposure assessment model because it is self-limiting (i.e., farmers would not use a product that diminishes or eliminates plant productivity). The Agency believes phytotoxic effects should continue to be modeled even if they could become self-limiting. This is because the phytotoxicity effects could be harmful and cause economic losses initially before these effects could be observed. In addition, sewage sludge could be applied to areas that do not have commercially valuable plant species but could still have pollutant-sensitive plant species that exhibit phytotoxicity resulting in secondary environmental impacts, such as erosion. The Agency believes that the public should not have to determine the adverse impacts of using sewage sludge by conducting their own field trials. The potential for adverse outcomes might cause the public to stop using sewage sludge products, thus confounding the Agency's stated policy of encouraging beneficial reuse.

The Agency, however, agrees that sewage sludge/field studies should be used in place of salt or pot studies when such data is available and technically defensible. At proposal, incomplete information was available concerning sewage sludge pollutants, fate, transport and effects, and the means of sewage sludge use and disposal. However, rather than wait for more complete information in order to propose the regulations, the Agency proposed standards for those pollutants and use or disposal practices for which it had sufficient information, and solicited additional information from the public and scientific community during the public comment period. Section 405 specifically contemplates that the Agency will issue regulations based on existing information in stages and revise them periodically.

To remedy information gaps, EPA worked with experts from both inside and outside the Agency during the public comment period to review the basis of the proposal's scientific and technical data. As a result, new information obtained from the scientific

peer review experts and submissions from the public have improved the data used as the basis for the final part 503 rule, which employs mostly sewage sludge/field studies.

Final Action: In the final rule, the Agency has decided to continue to evaluate the phytotoxicity pathway (Pathway 8) as part of the exposure assessment for land application practices and to use, in all possible cases, field data derived from sewage sludge to develop the pollutant transfer co-efficients for this pathway. Much of the field data was provided by scientific peer review and public comment on the proposed rule. This approach has resulted in more realistic values and higher allowable sewage sludge application rates and higher pollutant loading rates for the actual sewage sludge-field conditions regulated. The Agency believes that continuing to evaluate Pathway 8 provides a greater degree of public health and environmental protection, and demonstrates less pollutant uptake in crops as well as a lower incidence of plant phytotoxicity.

8. Minimum Soil pH Requirements

Comment: Many commenters suggested that lack of soil pH control in the proposed rule was a gross oversight on the part of the Agency, because many studies have shown a direct relationship between pH and plant uptake of metals. The commenters maintained that if the Agency used studies conducted at certain pH levels in the exposure assessment models for agricultural land application practices, then those same pH levels should be imposed in the final part 503 rule to ensure consistency between the results predicted from the modeling analysis and those achieved in actual practice. The range of pH levels suggested for the part 503 rule varied from 5.5 to 6.5. However, some commenters objected to pH controls, arguing that higher plant uptake with lower pH is not always the case and that such controls may not be necessary for all agricultural land practices.

Response: The Agency agrees that prudence may require pH control for certain agricultural land practices to ensure that exposure assessment model assumptions and results reflect actual field conditions. In developing the exposure assessment pathways for agricultural land practices, the Agency used data on the plant species most sensitive to pollutants. Depending on the pollutant, the more sensitive species were generally leafy green vegetables, root crops, or legumes. Data taken from phytotoxicity studies generally had soil pH at 6.5 or greater because farmers generally used this condition to maximize crop productivity. A recent review of available data indicates that metal absorption by plants at a soil pH of 5.7 to 6.0 is the same as at a pH of 6.4 oz. greater (Reference Nos. 28 and 113).

The Agency recognizes that soil pH is one of the strongest influences on the capability of plants to absorb pollutants from the sewage sludge/soil matrix. However in some cases, data from low pH studies were also used in the exposure assessment model to develop the numerical limitations for agricultural land practices. Therefore, the Agency believes the numerical limits protect a majority of U.S. soil conditions without requiring pH control for all agricultural land practices regulated under the part 503 rule.

Final Action: The Agency has decided to continue to use studies conducted at pH levels that reflect a majority of U.S. soil conditions to derive the numerical limitations for agricultural land practices as part of the final part 503 rule. The Agency believes that these numerical limitations protect public health and the environment without soil pH control for all agricultural land application practices. The exposure assessment includes data that reflects low pH soil conditions so resulting numerical limits provide an adequate level of protection under a range of soil conditions. The Agency recognizes that unusual conditions not fully outside modeled parameters may not be as protected but believes that this is mitigated by the conservatism of other factors used in the exposure assessment including sensitive species. The result of not regulating minimum soil pH would simply mean that under some unreasonably worst-case conditions the numeric limitations would not be as protective as the reasonably worst-case conditions selected for the final rule.

9. Relative Effectiveness of Exposure

Comment: Several commenters objected to the Agency using a relative effectiveness of exposure value (RE) of one for all pollutants in the exposure assessment for agricultural land and D&M (referred to as "sale or give-away" in the final rule) practices. The commenters felt that sewage sludge-borne inorganic and organic pollutants do not have the same toxic effects on humans and animals when ingested from forage or food grown on sewage sludge-amended fields and that such an assumption is overconservative. Further, the commenters noted that this assumption implies that no observed differences exist in absorption among various exposure routes and that 100 percent of a pollutant from an exposure route is absorbed and taken up by the target tissue. They urged the Agency to try to develop more reasonable estimates of the RE value for the various exposure routes.

Response: The relative effectiveness of exposure value as used in the exposure assessments for agricultural or D&M practices is a unitless factor that shows the relative toxicological effectiveness of an exposure by a given route when compared with another route. (i.e., the relative effectiveness of exposure value relates the toxicological effect of a pollutant to a receiving organism through a specific exposure pathway (e.g., inhalation) instead of a reference pathway (e.g., ingestion through food) used to develop an RfD or Q* value for a pollutant.) For example, carbon tetrachloride and chloroform were estimated to be 40 and 65 percent as effective when exposure occurs, respectively, by inhalation as by ingestion. In addition to route differences, RE can also reflect differences in the exposure conditions (e.g., absorption of nickel ingested in water has been estimated to be five times greater than when ingested in food).

The Agency agrees that it should develop reasonable estimates of the RE value for the various exposure assessment pathways. However, it is widely recognized that the RE factor should only be applied where well-documented and referenced information is available on the pollutant's pharmacokinetics. When such information is not available, the Agency's policy is to conservatively set RE equal to one to ensure protection of public health and the environment. Since these data were not sufficiently well-documented at the time of the proposal, all of the RE factors used in the risk assessment were assumed to be one.

Final Action: After proposal of the part 503 regulations, the Agency undertook a more extensive literature search to identify the correct RE values for land application practices. For example, studies by Hinesly et al. (1985), in which female chickens were fed diets containing three levels of biologically incorporated cadmium, demonstrated that after 80 weeks the hens retained only 1.3, 0.98, and 0.87 percent of the total ingested cadmium (Reference No. 33). Similar results were obtained from studies with pheasant and sows (Reference Nos. 34 and 30).

Recent data from long-term field studies have shown that sewage sludge properties influence pollutant bioavailability through binding of the

pollutants by the sewage sludge itself. However, the research data base on the fate of many sewage sludge-borne pollutants is still extremely limited. As a result, uncertainties about the health effects and threshold exposures of these pollutants has made the risk/exposure assessment for these pollutants difficult. Therefore, the Agency has decided to continue to use RE values equal to one for those pollutants with limited data but has revised its RE values where sufficient scientifically defensible information was available indicating the bioavailability of the pollutant was less than 100 percent. The Agency recognizes that in some cases this may result in numerical limits that may be more protective than necessary; however, EPA believes that it is prudent to have a balance of mid-range and bounding parameters in order to protect highly exposed individuals.

10. Soil Incorporation and Density

Comment: Three commenters argued that for EPA to assume that surface-applied sewage sludge would be fully mixed in the top 15 centimeters of soil due to climatic conditions and biological factors was unrealistic. They suggested that EPA consider sewage sludge/soil incorporation of less than 15 centimeters. The commenters felt that biological and physical processes would result in some mixing of surface-applied sewage sludge so that animals and humans would not be exposed to undiluted sewage sludge, but they submitted no data to support a particular value.

One commenter criticized EPA for failing to describe how the soil incorporation depth and bulk density values were derived for the proposed rule. The commenter also questioned why these parameters were not evaluated in the proposal's sensitivity analysis.

Response: EPA disagrees that its soil incorporation assumptions are unrealistic. In the proposed rule for agricultural land and D&M practices, the Agency assumed that sewage sludge is incorporated into the top 15 centimeters of the soil. For pathways involving plant absorption of a pollutant, the actual depth of soil incorporation should make relatively little difference. This is true because the mean concentration in the root zone is likely to be more important than the distribution of the pollutant within the root zone. However, for pathways involving direct ingestion of soil by animals or children, the assumed depth of incorporation has greater importance.

EPA recognized that homeowners fertilizing their lawns are unlikely to incorporate the sewage sludge product into an already established lawn. Instead, they would just spread it on the surface where small children could be exposed. Alternatively, animals grazing on pastures may pull up shallow roots with the foliage, thereby ingesting greater concentrations of a pollutant than those assumed in the model. Nevertheless, homeowners or farmers may water the lawn after applying the sewage sludge product, causing the pollutants to migrate into the soil profile. Further dilution may occur as normal precipitation occurs or as worms and small mammals (e.g., moles) burrow into the soil. Emergent vegetation would also tend to disperse the pollutants and make direct exposure to the sludge/soil mixture more unlikely. The Agency believes that man-made and natural conditions are sufficient to ensure soil incorporation of sewage sludge and that the average soil incorporation depth of 15 centimeters is adequate to protect public health and the environment. However, for certain pathways that tend to exhibit a greater exposure to the pollutants in sewage sludge, the Agency assumed 100 percent ingestion of sewage sludge. These pathways are Pathway 3 (child ingesting sludge used in a home garden), Pathway 5 (human who consumes dairy products and meat from animals that ingest sewage sludge), and Pathway 7 (animals consuming sewage sludge adhering to forage crops or on the soil surface).

The Agency agrees that the final rule should show how the values for soil incorporation depth and soil bulk density were derived. However, a sensitivity analysis was not performed on these two parameters for the proposed rule because the Agency did not consider these parameters candidates for site-specific modeling—the test for whether site-specific modeling was appropriate. If site-specific modeling for these factors had been allowed for agricultural land practices, the Agency would have needed to establish the soil type and incorporation depth for each sewage sludge-amended field and to perform exposure assessment modelling based on these local conditions to ensure compliance. The Agency therefore rejected site-specific modelling of these factors for agricultural land practices as being too burdensome to implement and instead established national numerical limitations based on average values for soil incorporation and soil bulk density, 15 centimeters and 1.33 grams per cubic centimeters, respectively.

Final Action: In the absence of new information and data, the Agency has decided to retain the average value for soil incorporation depth (15 centimeters) except for Pathways 3, 5, and 7, and for soil bulk density (1.33 grams per cubic centimeters) in the final part 503 regulations for agricultural land practices and sewage sludge sold or given away for use in home gardens. In addition, the Technical Support Document for Land Application shows the derivation of these two parameters.

11. Background Pollutant Levels in Soil

Two commenters suggested that EPA should establish site-specific inorganic pollutant background levels in soil rather than use a single background level as input into the exposure assessment model for agricultural land practices because background levels of inorganic pollutants vary widely across geographical areas. The commenters said that establishing site-specific background levels for inorganic pollutants would provide more regulatory flexibility and foster beneficial reuse.

One commenter stated that urban soils, where D&M sludge products are widely used, contain higher background concentrations of inorganic pollutants than agricultural soils and that EPA's applying agricultural soil data to urban settings in the exposure assessment for the part 503 proposal was inappropriate.

Another commenter argued that assuming zero background levels for organic pollutants in soil underestimates risk, especially for agricultural soils which could have received heavy applications of chlorinated pesticides before sewage sludge-amendment occurred. In some cases, the background levels of these insecticides in agricultural soils (rarely found in urban settings) can approach the concentrations found in sewage sludge. The commenter suggested that the Agency use average background levels for organic pollutants in soil as the baseline for estimating exposure from further additions of organic pollutants in sewage sludge.

Response: The Agency disagrees that any of its exposure assessment assumptions concerning the background levels of inorganic and organic pollutants are inappropriate for establishing national numerical limitations for agricultural land and D&M practices.

For metals, the Agency used an estimated nationwide median concentration for agricultural lands as the background level of metals in soil. In some cases, the background concentration of a metal is a significant fraction of the maximum allowable soil concentration. In addition, for the terrestrial Pathways 1 through 9

(Pathways 1 through 10 in the final rule), the Agency assumed that once the metal is applied, it remains on the land indefinitely. Since no accounting is made for removal by (1) soil erosion, (2) leaching, (3) volatilization, or (4) absorption of the plant and removal of the harvested portion of the plant, the Agency believes that this assumption offsets the less conservative assumption of using an average value to represent background metals concentrations.

The ability of plants to absorb metals from the soil was assumed to be the same as their ability to absorb metals in sewage sludge. If higher background concentrations of metals were assumed, those numerical limits based on plant toxicity would be more stringent for copper, zinc, and nickel. However in some cases, the higher background concentrations of metals would exceed the allowable pollutant concentration in the soil. At this time, the Agency believes that selecting more stringent background levels is unnecessary and that the levels used in the final rule protect plants from metal toxicity. However, as discussed earlier in the preamble, the Agency plans to investigate the impact sludge has on plants in its monitoring study to determine what role background levels and pH play in the uptake of metals by plants grown on sludge-amended fields.

The Agency also assumed that chromium in sewage sludge and soils is generally in the trivalent, *not* hexavalent, state. According to the EPA publication, "Application of Sewage Sludge to Cropland: Appraisal of Potential Hazards of the Heavy Metals to Plants and Animals," by Council for Agricultural Science and Technology, Report No. 64, November 15, 1976, p. 25 (EPA–430/9–76–013):

> Haxavalent chromium remains as such in a soluble form in soil for a short time but is eventually reduced to trivalent chromium and then changed to forms of low solubility. Haxavalent chromium is toxic to plants, but sludges contain little, if any, haxavalent chromium because it is reduced to the trivalent state during the sewage sludge digestion process.

This conclusion is also supported by the findings of Patterson and Kodukula (JWPCF 56: 432, 1984) who determined metal distributions in activated sewage sludge systems.

For organic pollutants, the exposure assessments for agricultural land and D&M practices were performed to measure only the incremental carcinogenic risk over background levels of organic pollutants, making measuring or estimating the actual organic pollutant background levels unnecessary. In addition, the majority of organic pollutants regulated in the proposed rule have short half-lives (i.e., less than one year) and are not expected to remain in the environment for long periods of time; therefore, they should volatilize or degrade between sewage sludge applications.

Final Action: The Holmgren (1985) database, upon which the median background metal concentration levels for the proposal were based, is considered one of the most thorough analyses of national uncontaminated soils available (Reference No. 35). The Agency has decided, based on reasons discussed previously, to continue to use this database in the final rule to estimate the national median background concentrations for inorganic pollutants in soil. In addition, the Agency has decided to continue to use a zero background concentration level for organic pollutants evaluated in the final rule for agricultural land and D&M practices.

The Agency recognizes that using a national median concentration for inorganic pollutants and zero concentration for organic pollutants to represent all agricultural background pollutant levels would over predict exposure in some cases while under-predicting it in others. However, EPA believes that these assumptions, including other conservative assumptions concerning the fate and transport of metals and organic pollutants in soil, are adequate to protect public health and the environment.

Land Application—Non-Agricultural Practices

In the part 503 proposal, the Agency did not conduct a pathway exposure assessment for non-agricultural land. Instead, EPA proposed to regulate non-agricultural uses through capping sewage sludge concentrations. EPA established numerical pollutant limitations for non-agricultural land application practices using data on existing sewage sludge quality from the "40 City Study." This approach followed a preliminary risk assessment which determined that those practices did not result in high levels of human exposure. Aggregate risk analyses using the proposed numerical limitations did not show significant human health effects on the population as a whole.

The Agency's aggregate risk analysis for non-agricultural land application was based upon the assumption that sludge would be applied to non-agricultural land under the conditions provided in the rule. Among these were restrictions on growing crops and grazing animals. Consequently, these proposed management practices would eliminate any potential for exposure through many of the 14 potential pathways of exposure that had been identified for sewage sludge applied to agricultural land. Moreover, other pathways were not considered because, of their nature, they would not be applicable (e.g., protection of children in a home garden setting). Therefore, the Agency estimated aggregate effects from human exposure to pollutants in sewage sludge applied to non-agricultural land using only two pathways of exposure:

1. Sludge-Soil-Surface Water-Human (Pathway 11); and
2. Sludge-Soil-Ground Water-Human (Pathway 12W)

Using data on national application rates and the two exposure pathways, the Agency estimated that application of sewage sludge to non-agricultural land would result in a maximum individual cancer risk of 2×10^{-8} based upon the 98th-percentile pollutant concentrations shown in the "40 City Study." The 98th-percentile pollutant concentrations were calculated from a regression analysis of the values of 25 pollutants in the "40 City Study." The Agency selected the 98th-percentile concentration to prevent potential deviations from the pollutant concentrations in the "40 City Study" and to prevent increases in any risks associated with the application of sewage sludge to non-agricultural land. The Agency believed that this approach would ensure that sewage sludge quality would not get worse and, therefore, assure the continued validity of the risk assumptions underlying the Agency's regulatory control decisions.

Peer review and public comments raised a number of concerns with permitting the application of sewage sludge to non-agricultural land at 98th-percentile pollutant concentrations. Many commenters were concerned that the proposed approach was arbitrary (an artifact of the "40 City Study") and did not adequately protect public health and the environment. A complete description of the 98-percentile approach and the proposed regulations for non-agricultural land application is found in the proposal at 54 FR 5785–5789, 5798–5800, 5804–5807, 5860–5861, 5868–5871, 5879–5880, 5895.

Comment: Many commenters questioned the Agency's use of the 98th-percentile approach, stating that the approach has scientific and technical deficiencies and either over- or underregulates non-agricultural land application of sewage sludge, depending on the pollutants of concern and the practice. Some commenters stated that the proposed approach would reduce the desirability of the non-agricultural

land practices because of the increased public perception of a human health or environmental risk. Many commenters suggested that the Agency divide non-agricultural land application into different practice categories. This would allow the Agency to tailor its exposure assessment to each non-agricultural land practice category, thereby maximizing alternatives for encouraging beneficial use while protecting public health and the environment.

Many commenters were concerned that the numerical limitations derived from the 98th-percentile approach were not supported by adequate risk assessments or substantiated by field studies. In addition, commenters stated that the 98th-percentile based numerical limitations could not be considered a substitute for evaluating plant and animal exposure pathways. Some commenters stated that the approach for agricultural and non-agricultural land application practices should be consistent.

Response: The Agency agrees with public and scientific peer review comments. The Agency's objective is to encourage the beneficial use of sewage sludge wherever consonant with adequate protection of public health and the environment. To be consistent with other beneficial reuse practices within the final part 503 rule, the Agency developed numerical limitations for non-agricultural land application of sewage sludge after an exposure assessment evaluation similar to that for "agricultural" land application (see earlier discussion in this part). Based on scientific peer review and public comments, the Agency now believes that adequate data is available from direct studies of plants and animals in non-agricultural sewage sludge scenarios (or reasonably interpolated from other sludge studies) to yield valid results when evaluating risk for different non-agricultural land practice categories.

The Agency evaluated all 14 pathways assessed for agricultural land practices for their applicability to use of sewage sludge on non-agricultural land. The Agency believes that not all the pathways (or assumptions used in characterizing these pathways) for agricultural practices are appropriate for non-agricultural land practices. Thus, the Agency has deleted some of the pathways and revised the assumptions used in others to be better suited to a risk assessment for each non-agricultural land practice category. However, the Agency has determined that the new mass balance methodology and revised Pathways 11, 12A, 12W (Pathways 12, 13, and 14 in the final rule) used to establish final numerical limits for "agricultural" land application are also appropriate for non-agricultural practices and do not require further modification.

Final Action: Based on public comments and scientific peer review, the Agency has revised its exposure assessment approach for regulating sewage sludge applied to non-agricultural land (a practice covered under land application). The approach for the final part 503 rule uses an HEI exposure pathways assessment for three categories of non-agricultural land practices: (1) Forest lands, (2) soil reclamation sites (e.g., lands devastated by such situations as natural disasters, strip mined areas, construction sites), and (3) public contact sites (e.g., parks, golf courses, campuses, playgrounds, highway medians, among others).

The Agency recognizes that some of these categories differ from others regarding the method of sewage sludge application (e.g., soil reclamation sites may have only one or more high rate sewage sludge applications over a short time period while public contact sites may have many low rate sludge applications over multiple years). For this reason, the Agency conducted a separate exposure assessment for each non-agricultural land application category. In addition to meeting the numerical limitations, the application of sewage sludge must also meet specific management practices that the Agency is requiring for non-agricultural land application.

The final exposure assessment approach for non-agricultural land practices uses many of the same modeling assumptions, exposure pathways, and target organisms (i.e., HEIs) as were used for agricultural land practices. However, because the Agency recognizes that the two practices do differ, some of the exposure pathways for agricultural land application have been modified for non-agricultural land practices. In addition, different assumptions used within each non-agricultural practice category have resulted in the Agency tailoring the HEI for each exposure pathway specific to the practice category. A detailed discussion of the exposure assessment methodology (i.e., models, pathways, parameter values, assumptions, and others) used for non-agricultural land practices in the final part 503 rule can be found in the Technical Support Document for Land Application. Information on obtaining this and other technical support documents is provided in Part XIV—Availability of Technical Informational on the Final Rule.

Comments on the Proposed Exposure Assessment Approach and Risk Management Issues for Surface Disposal

Surface Disposal—All Practices Except Monofills

In the February 6, 1989, proposal, EPA proposed requirements for the disposal of sewage sludge on a surface disposal site. EPA did not perform a pathway-by-pathway exposure assessment for this method of sludge disposal for purposes of the proposal. The Agency defined "surface disposal site" as an area of land on which only sewage sludge is placed for a period of one year or longer. Surface disposal sites have no vegetative or other cover, are not part of the POTW's treatment process, and are not sites used for temporary storage of sewage sludge prior to final use or disposal. In addition, the proposal did not include monofills under the surface disposal practice and regulated the two practices separately.

As proposed, owners or operators of sewage sludge surface disposal sites would not need to comply with extensive management requirements. This is because the Agency concluded that surface disposal sites generally are small, located in rural areas on lands owned or controlled by local governments, and do not pose a significant threat to public health or the environment. The Agency proposed numerical pollutant limitations for sewage sludge disposed at surface disposal sites based on "current sludge quality" (i.e., the 98th-percentile pollutant concentration shown in the "40 City Study").

Comments/Response: For many of the same reasons explained previously (Land Application—Non-Agricultural Practices—EPA determined that it would be more appropriate to evaluate pollutants destined for use or disposal using an exposure pathway risk assessment methodology), the Agency revised its approach for regulating sewage sludge surface disposal sites. Instead of establishing pollutant limitations based on 98th-percentile sewage sludge quality, which many commenters felt was arbitrary and not adequately protective, EPA used exposure assessment models and pathways to develop numerical pollutant limitations based on risk. The EPA's revised approach for surface disposal sites is very similar to the two-tiered approach used for sewage sludge monofills. A description of the exposure assessment approach for sewage sludge monofills is provided in this part, Surface Disposal—Monofills.

Final Action: In the part 503 proposal, the Agency proposed to establish numerical pollutant limitations based on existing sewage sludge quality for sewage sludge surface disposal sites. This was because of the Agency's preliminary conclusion that such a disposal would not result in high levels of pollutant exposure to potentially exposed individuals. Further, the Agency's aggregate risk analysis did not show significant human health effects on the population as a whole from this disposal practice. To derive numerical limitations based on existing sewage sludge quality, EPA used the 98th-percentile pollutant concentrations from the "40 City Study."

Peer review and public comments suggested scientific or technical deficiencies in using the 98th-percentile pollutant concentrations. Many commenters were concerned that the proposed approach was arbitrary (an artifact of the "40 City Study") and not adequately protective of public health and the environment. As a result, today's final part 503 rule regulates both monofills and surface disposal sites in one category called "surface disposal." The rule uses an exposure assessment approach (similar to the two-tiered approach for sewage sludge monofills) for deriving numerical pollutant limitations for sewage sludge disposed of in piles or trenches at surface disposal sites.

The Agency also evaluated the potential risks to wildlife from monofills and other surface disposal practices as part of today's final rule, and found that wildlife exposure was not significant enough to develop numerical limits using the wildlife exposure pathways for these practices. The Agency has concluded that there could be exposure and potential risk to wildlife that actively forage on surface disposal sites. However, current evidence does not indicate significant levels of foraging or other biological activities that would lead to significant exposure for these practices, and that the management practices required for surface disposal by the final part 503 rule were adequate to protect wildlife. In addition, significant ecological differences generally exist between these disposal practices and land application practices where sewage sludge is applied directly into wildlife habitats and feeding areas (and for which the Agency is promulgating numerical limits and management practices under today's final rule). However, EPA has no reason to believe that exposure is significant for land application practices either, but as discussed earlier in the preamble is committed to studying these practices to ensure that the part 503 regulation protects wildlife.

The conditions within sewage sludge surface disposal sites are physically and biologically different from the conditions at land application sites. For example, because of the physical nature of these sites, active monofills and other surface disposal sites do not appear to provide a suitable habitat (i.e., a place to live) for many species. Daily disposal operations, using trucks, bulldozers, pipelines, and other types of sludge spreaders, are expected to further reduce the likelihood that individual surface disposal sites would be available for wildlife as a feeding source. Therefore, wildlife would generally have to come from habitat areas outside the surface disposal site to feed. Surface disposal sites are often at least partially separated from habitat areas by industrial activity and structures, which would impede access to these sites. Thus, wildlife are not expected to have significant exposure from these practices. Therefore, wildlife exposure pathways for surface disposal practices (including monofills) were evaluated but not used to establish numerical pollutant limitations for use in the two-tiered approach for the final part 503 rule.

Under the two-tiered approach for surface disposal sites, sludge whose concentration would not permit disposal under the first tier would be subject to alternative limitations established under the second tier. The first tier derives one set of national numerical limitations for pollutants found in sewage sludge based on a HEI exposure scenario using two exposure pathways: air, and ground water. The national numerical limitations are established for surface disposal sites without a liner. The models and assumptions used in the exposure pathways to develop the national numerical pollutant limitations are similar to those used to derive the monofill limitations, with certain modifications described below. EPA believes such an approach is reasonable in view of the similarities in likely environmental effects between disposal of sewage sludge disposed of on surface sites and in monofills.

The Agency also evaluated, using the aggregate risk assessment, a second set of national numerical limits for "lined" surface disposal practices. The Agency determined that national numerical limits for "lined" surface disposal sites including monofills were unnecessary because the aggregate risk assessment showed very low baseline risk from current sludge surface disposal methods and the exposure-based national pollutant limits for "lined" practices far exceeded pollutant concentrations found in sewage sludge from the NSSS. The Agency concluded from its evaluation that "lined" surface disposal practices provide more than an adequate level of public health and environmental protection, even in the absence of national numerical limits.

The second tier applies to "unlined" surface disposal sites receiving sewage sludge that contains any pollutant that violates the national numerical limitations established for the first tier. In addition, the second tier also applies to those "unlined" sites where the sewage sludge is disposed within 150 meters of the property line. For those surface disposal sites, the owner or operator of the site or treatment works (if different from that of the surface disposal site), would submit site-specific data to EPA to use in calculating alternative pollutant concentrations for that particular site. The owner or operator (or applicant) will use the same exposure pathways and EPA approved models to calculate alternative pollutant concentrations. A more detailed discussion of the second tier is presented below in the monofill section of this part.

The two exposure pathways modeled by the Agency for evaluating national pollutant limitations or to be used by the applicant to calculate alternative case-by-case pollutant concentrations (using site-specific data) for surface disposal sites are listed below. These pathways are similar to the reconstructed Pathways 13 and 14 (Pathways 12A and 12W in the proposed rule) used for agricultural land practices and monofills, and they employ the same mass balance methodology.

Pathway 13—In exposure Pathway 13, the Agency evaluated the exposure of an individual inhaling vapors of any volatile pollutants that may be in the sewage sludge disposed at a surface disposal site. The exposed individual (HEI) is assumed to be living at the downwind edge of the site and is inhaling air, at a rate of 20 cubic meters per day for 70 years, that has been contaminated with volatile organic compounds from sewage sludge disposed of at the site.

Volatilization rate coefficients for uncovered cells are calculated with equations that consider constituent parameters including the Henry's Law coefficient, molecular weight and distribution coefficient. The rate of contaminant release through volatilization is estimated separately for a covered and uncovered surface

disposal site. Contaminant loss to the vapor pathway is diluted into the total volume of air passing within two meters over the site during the period of contaminant release. This box model is used to determine the expected air concentrations to which the HEI is exposed for each unit of concentration vaporized at the downwind edge of the site. The allowable lifetime exposure to each contaminant (based on a risk level of 1×10^{-4}) is then used to back-calculate the allowable loss rate to the vapor pathway. This value is then divided by the fraction of contaminant vaporized to determine the allowable pollutant concentration at the site.

Calculation of criteria for surface disposal sites through this pathway is similar to the methods described later for monofills. One difference is that the equations used to model emissions are different for surface disposal sites, reflecting the fact that these facilities have a liquid surface throughout their active lifetime. Another difference is that surface disposal facilities are not assumed to receive a soil cover. As with monofills, pollutant contributions are allocated to different media using a mass-balance approach. This calculates the fraction of constituent loss caused by volatilization, leaching, and degradation.

Pathway 14—In exposure Pathway 14, the Agency evaluated the exposure of individuals who would obtain their drinking water from ground water contaminated by the surface disposal site. Numerical pollutant limits for the ground water pathway are derived for surface disposal sites with methods similar to those used for monofills.

Contaminant losses are first partitioned among the three competing loss processes: Volatilization, leaching to ground water, and on-site contaminant degradation. For surface disposal sites, the relatively high water content of the sewage sludge received at the site results in an increased rate of seepage from the facility as compared to that estimated for monofills. Once the fraction of contaminant lost to leaching has been determined, the VADOFT finite element module (a critical fate and transport model used in assessing this pathway) is used to estimate flow and transport through the unsaturated zone and is linked to a three dimensional analytical model AT123D to depict pollutant fate and transport in the saturated zone. For surface disposal sites, the linked model considers the extent to which constituent transport in the saturated zone is affected by local mounding of the water table beneath the site (i.e., increased hydroaulic pressure within the sludge pile on the water table below the site). VADOFT accounts for a number of processes including advection, dispersion, adsorption, and degradation. The mass flux into the saturated zone is used as input to AT123D which couples this source term with aquifer characteristics to predict concentrations. Exposure concentrations are predicted based on well locations 150 meters or less downgradient of the site for facilities located over a source of drinking water. Reference drinking water criteria are either MCLs or are based on a risk level of 1×10^{-4} for an HEI who consumes two liters of water per day over a 70-year lifetime.

Surface Disposal—Monofill Practice

In the part 503 proposal, EPA evaluated two exposure pathways for sludge monofills (also referred to as sludge-only landfills): (1) human exposure to sludge pollutants that infiltrate the ground water and are subsequently ingested from drinking the water (Pathway 12W); and (2) human exposure through vaporization of pollutants from the fill material and their subsequent inhalation (Pathway 12A). The analysis considered the long-term exposure that an MEI would receive from drinking two liters of ground water per day and from inhaling 20 cubic meters of air per day at the property boundary of the monofill. The Agency calculated the combined water and air exposure to the MEI and compared the combined exposure to a MCL, RfC, RfD, or pollutant risk-specific dose. As described as follows, the analytical framework for the ground water model has four components: (1) a calculation of contaminated leachate pulse duration, (2) a model of pollutant behavior and movement in the unsaturated zone, (3) an evaluation of metal solubility in ground water, and (4) a model of pollutant behavior and movement in the saturated zone.

The analysis begins with assumptions on the monofill size and fill thickness, the pollutant concentrations in the sewage sludge, the pollutant concentrations in the leachate, and the net recharge (infiltration) rate. The duration of time, T (years), over which the fill releases a metal pollutant to the unsaturated zone (leachate pulse duration) is then calculated from the following factors: the metal concentration in sewage sludge, CS (milligrams per kilogram); the sewage sludge solids content, SS (kilograms per liter); the fill thickness, D (meters); the assumed leachate concentration, CL (milligrams per liter); the ground water recharge rate, R (meters per year); and the excess liquid in the original sewage sludge volume, EL (liters per liter). The result is:

$$T = ((CS \times SS/CL) - EL) \times D/R$$

The EL term merely adjusts the recharge water budget for excess water in the sewage sludge. For degradable organic pollutants, the above calculation is modified to account for the rate of decay within the fill, as described in the support documents (Reference Nos. 72 and 102).

The above calculation of the leachate pulse duration assumes that leachate concentration remains constant over time until the sewage sludge is completely depleted of the pollutant, thereby modeling the leachate pulse as a mathematical square wave. For any particular inorganic pollutant, the leachate concentration is determined by a solid/liquid partition coefficient and the concentration CS in the sewage sludge.

The leachate pulse (i.e., the initial volume of liquid entering the unsaturated zone containing the initial concentrations of pollutants in that liquid volume from the fill) was then used in the unsaturated zone model, CHAIN (Reference No. 112). CHAIN assumes a steady rate of percolation through the unsaturated zone and calculates the concentrations in the leachate as affected by sorption to the underlying soil and decay (of organic pollutants). The effect of sorption is to reduce peak concentration of the leachate and to slow its movement through the soil. For both metals and organics, sorption to soil is determined by a solid/liquid partition coefficient. The effect of decay is to reduce the overall amount of organic pollutant in the leachate. For organic compounds, decay includes the processes of hydrolysis and anaerobic biodegradation.

In evaluating exposure to the MEI, in the proposal, the depth to ground water is assumed to be zero over Class I ground water and one meter over Class II and Class III ground water. CHAIN is bypassed in assessing exposure to an MEI for monofills located over Class I ground water, but it is used for assessing exposure to an MEI when a monofill is located over Class II or Class III ground water.

At the bottom of the unsaturated zone, the peak concentrations of metals in the leachate pulse, attenuated as calculated by CHAIN (where applicable), are then adjusted for solubility constraints, based on the calculations of MINTEQ. MINTEQ is a computer model which calculates the fraction of metals remaining in solution, and the fraction of metals precipitating out of solution

and attaching to the aquifer-rock matrix (Reference No. 20). The CHAIN model does not actually operate the MINTEQ model but rather, in an iterative manner, uses the results of previous MINTEQ calculations at various conditions of pH and Eh to calculate pollutant concentrations in the aquifer. The MINTEQ solubility adjustments are applied only to the six metals (arsenic, cadmium, copper, lead, mercury, and nickel). At the low pH and high Eh used in the proposed exposure assessment analysis, MINTEQ predicted that copper would be the only metal to precipitate in amounts that would reduce greatly the ground water concentration.

The flux of pollutants entering the aquifer in the area beneath the monofill was then input as a square wave (i.e., the entire pollutant mass or flux entering the aquifer enters it all at the same concentration) at the peak concentration to the saturated zone fate and transport model, AT123D (Reference No. 117). This model calculates the behavior and movement of the contaminant plume, as affected by advection (ground water flow), diffusion and dispersion (mixing), sorption, decay, and distance from the sewage sludge unit to the property boundary of the monofill or 150 meters (whichever is less). For Class II and Class III ground water, the MCL must be met at the property boundary of the monofill or 150 meters, whichever is less. The effect of diffusion and dispersion is to spread the pollutant plume vertically and horizontally, thereby further reducing the peak concentration. AT123D was only operated for Class II and Class III aquifers, since in Class I aquifers the leachate must meet the MCL upon entry to the aquifer.

The components of the model (leachate pulse—CHAIN—MINTEQ—AT123D) were operated in an iterative trial-and-error mode to determine the sewage sludge concentration that produced a peak concentration equal to the MCL at the point of compliance.

The Agency evaluated exposure to pollutant vapors even though dewatered municipal sewage sludge is unlikely to contain significant quantities of highly volatile material. Most volatile pollutants would vaporize before sewage sludge disposal, particularly during wastewater aeration or during sewage sludge dewatering. The model used here (Reference No. 65) has two key components: (1) Calculation of the flux of volatile pollutants into the atmosphere, and (2) determination of the peak air concentration at the property boundary.

The model is formulated so that the vaporization flux depends on the initial concentration of a pollutant in the sewage sludge and on the monofill's cover material. During the time the sewage sludge is assumed to be uncovered, the rate of vaporization is controlled by the rate of diffusion into the air (as opposed to diffusion up through the sludge). The flux is thus formulated to depend primarily on the wind speed and Henry's Law constant (concentration of the pollutant in air divided by the concentration of the pollutant in water at equilibrium).

During the time the monofill is temporarily or permanently covered, the rate of vaporization depends on the rate of diffusion up through air-filled pores in the cover material. The rate thus depends primarily on the cover material's porosity and thickness and on the Henry's Law constant.

The mean flux from the monofill is determined by considering the areas of the monofill expected to be uncovered and temporarily or permanently covered at any time. The concentration at the centerline of a plume downwind of the monofill depends on the size of the monofill, the distance to the point of compliance at the property boundary, the wind speed, and the degree of atmospheric mixing. The wind direction is assumed never to change so that the MEI always remains in the centerline of the plume. The predicted vapor exposure was combined with the predicted drinking water exposure and then compared to the exposure allowed by the MCL, RfD, or risk-specific dose.

Comment: Many commenters maintained that liners should either be required for monofills—thus making the national numerical limitations less stringent or eliminating them—or that site-specific numerical limits be established when physical parameters (e.g., synthetic liners) at the site differ from those used in the exposure assessment pathway. Other commenters advocated requiring liners and eliminating the national numerical limitations.

Response: For many of the same reasons explained previously (Land Application—Agricultural Practices), the Agency revised exposure Pathways 12A and 12W (Pathways 13 and 14 in the final rule) for calculating numerical limits for disposal of sewage sludge in monofills. The reconstructed pathways make use of improved models and more realistic modeling assumptions, and they include a mass balance methodology to account for partitioning of pollutants across the pathways. The Agency believes that these changes should improve the precision and accuracy of model outputs (i.e., numerical pollutant limits) for these pathways and satisfy many of the criticisms received from commenters.

The Agency disagrees that liners should be required for all monofills. However, the Agency agrees that national numerical limitations could be less stringent or even eliminated for sludge-only landfills that have liners provided the exposure pathway and aggregate risk assessments show that such pollutant limits are unnecessary to adequately protect public health and the environment.

A fundamental regulatory principle used in developing the proposed rule was pollution prevention. The Agency believes that it is more protective and equitable to prevent sewage sludge contamination by controlling pollutants at the source than it is to require clean-up of the contaminated ground water. Therefore, controlling the quality of the sludge being used or disposed of is an over-riding objective of the rule. By controlling the source, subsequent contamination of the ground water from sludge-only landfills is of less concern. With this principle in mind, the Agency decided to calculate the proposed national numerical concentrations of pollutants based on the monofill being unlined. However, for the proposal, the Agency did not consider whether a liner would provide such an effective means of pollution control that national numerical pollutant limits would become meaningless as a way of encouraging pollution prevention because the numerical limits would far exceed those pollutant concentrations ever found in sewage sludge. Sludge-only landfills having a minimum EPA liner are just such a case, rendering national numerical limits ineffective as a means of encouraging pollution prevention.

The EPA agrees that owner or operators (or applicants) of monofills should have the option to establish alternative (site-specific) numerical limits when certain physical and ground water quality parameters at the site differ from those used in the exposure assessment pathway. In the proposal, alternative numerical limits were established under three case-by-case circumstances when the physical parameters at a monofill site (excluding all other surface disposal practices) differed from those used in the exposure assessment models. The three circumstances (proposed only for monofills) were as follows:

Case #1—When a monofill has a sewage sludge unit that is less than 150 meters from the property boundary of the monofill, site-specific numerical limits for the pollutants in the sludge would be recalculated. The applicant

would use the actual distance to the property boundary as a factor to estimate the amount of dilution used in the EPA-approved exposure assessment model so that numerical limits would not exceed the human health criteria at the point of compliance (i.e., the property boundary).

Case #2—Numerical limits for those monofills over ground water categorized as Class III(2) could be calculated if the background ground water concentration of one or more pollutants exceeds the EPA MCLs, the risk-specific doses corresponding to an incremental carcinogenic risk level of 1×10^{-4}, or the RfDs, as appropriate. For those pollutants whose background ground water concentrations did not exceed the EPA human health criteria, the national pollutant limits in the proposal applied.

Case #3—If the concentration of one or more pollutants in the sludge exceeded the national limits, the owner or operator could submit documentation showing that site-specific data, rather than the parameters used by the Agency in the model to establish the national limits, could be used in calculating the pollutant concentrations for sewage sludge placed in the monofill. Under the proposal, the numerical limits would be recalculated for all pollutants using the site-specific data that the owner or operator substituted for the EPA parameters used in the model.

The proposal allowed site-specific modeling to derive the numerical pollutant limits for sewage sludge disposed of in monofills. This approach did not preclude the applicant from incorporating into the model the site's artificial characteristics (e.g., a synthetic liner) in addition to its natural characteristics (e.g., a natural clay liner). The applicant was thus not prevented from incorporating the effect that containment measures would have on infiltration or recharge flow rates through the fill material and on the porosity and pollutant sorption beneath the fill. For the proposal, the numerical limits were thus capable of being modified to account for the effect of containment measures such as liners.

Final Action: In order to simplify the final rule and ease the administrative burden on the regulated community, the Agency has broadened the definition of "surface disposal" to include sludge-only landfills (also referred to as monofills) and has developed one set of national numerical pollutant limitations for all "unlined" surface disposal practices.

As discussed earlier in this part, national numerical pollutant limits were evaluated for surface disposal sites with "liners" but were not included in the final rule because EPA determined that "lined" surface disposal practices provide more than an adequate level of public health and environmental protection, even in the absence of national numerical limits, and that such limits would not encourage pollution prevention. This revision condenses the regulations and retains the site-specific modeling option set forth in the proposal for monofills for "all unlined" surface disposal practices meeting certain criteria (the part 503 proposal only allowed the site-specific option for monofills).

In the final rule, EPA used exposure assessment Pathways 13 and 14 to establish national numerical limits. If the physical and ground water quality parameters at the surface disposal site differ from those used in the exposure assessment to derive the national limits, site-specific numerical limits may be recalculated for the site. There are two circumstances in which these site-specific limits are available:

Case #1—When a surface disposal site has a sewage sludge unit that is less than 150 meters from the property boundary of the site, site-specific numerical limits for the pollutants in the sludge may be recalculated. The applicant can use the actual distance to the property boundary as a factor to estimate the amount of dilution used in the EPA-approved exposure assessment model so that numerical limits would not exceed the human health criteria at the point of compliance (i.e., the property boundary).

Case #2—If the concentration of one or more pollutants in the sludge exceeds the national limits, the owner or operator can submit documentation showing that site-specific data (i.e., parameters other than the parameters used by the Agency in the model to establish the national limits) should be used in recalculating the pollutant concentrations for sewage sludge placed in the surface disposal site. In the final rule, the numerical limits may be recalculated for all pollutants using the site-specific data that the owner or operator substituted for the EPA parameters used in the model.

Using an EPA-approved model and the site-specific parameters, the owner and operator (or applicant) will calculate for Agency review and approval alternative pollutant concentrations for the surface disposal site. This approach does not preclude the applicant from incorporating into the model the site's artificial characteristics (e.g., a synthetic liner that does not meet EPA specified minimum requirements) in addition to its natural characteristics (e.g., a natural clay cover or depth to ground water). The site-specific numerical limits are thus capable of being modified to account for the effect of containment measures such as liners.

In addition, in the final rule, the Agency has established one set of national numerical limitations using two revised exposure assessment pathways (Pathways 13 and 14). The national pollutant limits are established for all surface disposal practices without an EPA specified minimum liner including sludge-only landfills without a liner. As discussed above, the final part 503 rule does not require sewage sludge to meet national numerical pollutant limits if disposed of in or on a surface disposal site with an EPA specified minimum liner. If the sewage sludge that a treatment works wishes to place in an unlined surface disposal site (i.e., a site without the EPA specified minimum liner) continues to exceed the national numerical limits or the site-specific numerical limits calculated for the site on a case-by-case basis, the treatment works must either reduce the concentration of the pollutants through more stringent local pretreatment limits, install an EPA specified minimum liner, or find an alternative way of managing the sewage sludge. The revised exposure pathways used in the final rule to evaluate and develop national numerical pollutant limits for sludge-only landfills (a practice cover under the definition of "surface disposal") are as follows:

Pathway 13—The vapor pathway is designed to protect an HEI living at the downwind edge of the site and inhaling air at a rate of 20 cubic meters per day for 70 years that has been contaminated with volatile organic compounds. Volatilization rate coefficients for uncovered or covered landfill cells are calculated with equations that consider constituent parameters, including the Henry's Law coefficient, molecular weight, and distribution coefficient. The rate of contaminant release through volatilization is estimated separately for its covered and uncovered states. Contaminant loss to the vapor pathway is diluted to the total volume of air passing within two meters over the site, during the period of contaminant release. This box model is used to determine the expected air concentrations to which the HEI is exposed for each unit of concentration vaporized. The allowable lifetime exposure to each contaminant (based on a risk level of 1×10^{-4}) is then used to back-calculate the allowable loss rate to the vapor pathway. This value is then divided by the fraction of contaminant

vaporized to determine the allowable concentration at the site.

Pathway 14—As in Pathway 13, the first step in calculations for this pathway is to partition contaminant losses among the three competing loss processes: volatilization, leaching, and contaminant degradation. This calculation requires an estimated first-order loss coefficient for leaching, calculated based on an assumed equilibrium partitioning of pollutant between adsorbed and dissolved phases within the monofill, and on an assumed rate of seepage from the facility. Once the fraction of pollutant lost to leaching has been determined, the VADOFT finite element module is used to estimate flow and transport through the unsaturated zone and is linked to a three-dimensional analytical model (AT123D) to depict fate and transport in the saturated zone. VADOFT accounts for a number of processes including advection, dispersion, adsorption, and degradation. The mass flux in the saturated zone is used as input to AT123D, which couples this source term with aquifer characteristics and chemical properties. Exposure concentrations are predicted based on well locations 150 meters or less downgradient of the site for facilities located over a source of drinking water. Reference drinking water criteria are based on either MCLs or an HEI who consumes two liters of water per day and a risk level of 1×10^{-4}.

Comments on the Proposed Exposure Assessment Approach and Risk Management Issues for Incineration

The Agency used a single exposure pathway, inhalation of sewage sludge incinerator emissions, in analyzing exposure to the MEI for the proposed rule. In developing the proposal, the Agency evaluated the inhalation of sewage sludge incinerator emissions of arsenic, beryllium, cadmium, chromium, lead, mercury, nickel, and total hydrocarbons. Total hydrocarbons were used as a surrogate for all organic pollutants.

The Agency performed air quality modeling to determine allowable concentrations in sludge that translate to pollutant emission rates (mass per unit time) that would not impose undue risks to an MEI in the vicinity of the incinerator. In the case of total hydrocarbons, the allowable emission rate determined by modeling was the numerical limit for the purpose of the proposed standard. For metals, an allowable sewage sludge concentration was derived from the allowable emission rate.

The Agency evaluated the inhalation of beryllium and mercury during development of National Emission Standards for Hazardous Air Pollutants, which specify allowable emission rates. For the proposed rule, the Agency took the NESHAPs values to be the allowable emission rates of beryllium and mercury for sludge incinerators.

The analysis of the inhalation of incinerator emissions employed atmospheric dispersion modeling to relate emission rates to ground level exposure concentrations. As discussed below, the allowable emission rate was determined from (1) the allowable ambient air quality concentration at ground level (the risk-specific concentration), (2) the stack height of the incinerator and other physical characteristics of the site, and (3) the meteorological conditions of the site. The allowable sewage sludge quality was then determined by the above allowable emission rate, the rate of sludge incineration, and emission control efficiency.

For the proposal, the allowable ambient air concentration was set to correspond to a risk-specific dose for four carcinogenic metals (arsenic, cadmium, chromium, and nickel), assuming that the MEI inhales 20 cubic meters of air per day and that indoor and outdoor air concentrations are essentially equal. Sewage sludge incinerators were allocated an air-shed contribution of lead that corresponded to 25 percent of the National Ambient Air Quality Standard.

The allowable ambient air concentration for total hydrocarbons was based on (1) statistical relationships between the concentration of total hydrocarbons and the concentrations of specific organic pollutants emitted by the four sewage sludge incinerators that were tested and (2) the assumed cancer potency of the specific organic pollutants. To develop a site-specific risk-based concentration for total hydrocarbons in the proposal, the Agency developed a weighted carcinogenic potency (referred to as Q_1* or Q*) value for the organic compounds that were projected to be in the emissions of a sewage sludge incinerator. In developing the Q* value, the Agency multiplied the Q* value of every carcinogenic organic pollutant listed in IRIS by the weighted fraction of the compound in the emissions of sewage sludge incinerators. Calculating a weighted fraction of a compound in the emission required a two step process.

First, the Agency determined the concentration in micrograms per cubic meter (ug/m^3) for the pollutant in the emissions in one of three ways. If the compound was measured in the emissions of a sewage sludge incinerator during one or more EPA tests, the 95th-percentile of the measured concentrations for the compound was used. In the case of compounds expected to be present because they are commonly found in other combustion emissions (e.g., emissions from municipal waste combustors or hazardous waste incinerators) but not detected, the concentrations of these compounds in emissions from these sources (ug/m^3) were used. Finally, for the remaining pollutants listed in IRIS and not detected in the emissions of sewage sludge incinerators, an analytical detection limit of 0.1 ug/m^3 was assigned to those pollutants. The Agency then calculated a weighted fraction for each pollutant by dividing the sum of all the pollutant concentrations into each individual pollutant concentration. Then the weighted fraction of each pollutant was multiplied by the pollutant's cancer potency value (Q*) and the resulting product was summed to give a weighted carcinogenic potency value for all carcinogenic pollutants detected or not detected.

Weighted fractions were also calculated for all non-carcinogens that have a reference dose in IRIS. However, the Agency assumed that the actual ambient air concentration of the non-carcinogens (i.e., threshold pollutants) would not exceed their inhalation RfDs and, therefore, do not contribute to the weighted Q* value or cause adverse health effects. The weighted Q* value was calculated as 0.013 (milligrams per kilogram per day)$^{-1}$.

From the Q* value, the Agency developed a risk-based concentration (RSC) for THC of 2.69 ug/m^3 used in the proposal. This value represents the lifetime average exposure to THC that would yield a risk of 1×10^{-5} for the most exposed individual. The proposal used the RSC in a simple equation to develop a site-specific numerical limit for the maximum allowable THC concentration in the facilities incinerator emissions. This calculated numerical limit is compared to the oxygen-corrected total hydrocarbon reading from the flame ionization detector to determine if the incinerator would be in compliance with the facility's permit.

Three models were used in the proposal for incineration to derive emission dispersion factors: ISCLT, LONGZ, and COMPLEX I (Reference No. 74). ISCLT is intended for urban or rural situations where the terrain elevations do not exceed the stack height. It

considers the aerodynamic effect of building downwash, which is likely to be significant for many sewage sludge incinerators with short stacks. The other two models do not evaluate building downwash but are more appropriate in situations where terrain elevations exceed the stack height. Such terrain is termed complex terrain. LONGZ is intended for complex urban terrain, while COMPLEX I is intended for complex rural terrain.

All three models require data on the incinerator, the surrounding terrain, and the meteorology of the site where the incinerator is located. Incinerator data included stack height, stack exit diameter, gas flow, and gas temperature. Meteorological data included joint frequency distributions of wind direction, wind speed, and atmospheric stability. The location of the MEI was not specified beforehand, but it was set at the location predicted by the model to have the highest long-term average ground level concentration.

In assessing the exposure to the MEI, ISCLT was used because of its ability to simulate building downwash. Since the MEI location for facilities with significant downwash tends to be close to the incinerator, the inability to simulate complex terrain accurately was not considered a serious shortcoming. Side-by-side comparisons of the three models indicated that, where downwash is significant, ISCLT predicts higher concentrations than LONGZ or COMPLEX I, even in complex terrain.

Evaluation of the effect of model parameters on the results indicated that stack height was a key parameter. Consequently, the Agency found that the dispersion factor (maximum long-term exposure concentration per unit rate of emission) varies with stack height. By modeling a number of facilities having various stack heights, the Agency was able to generate a correlation between dispersion factor and stack height. Although the stack diameter and gas velocity also varied among these facilities, these parameters were not important and had little effect on the correlation. Other parameters were held constant and were applied to all facilities: wind characteristics of Atlanta, Georgia (which had the worst combination of parameters in any U.S. city examined); flat terrain; gas temperature (38 degrees Celsius); building height (5.5 meters); and building effective diameter (39.5 meters) (Reference No. 45). The results of this analysis were presented in Table 9 of the proposal, which correlated stack heights to national dispersion factors for use in establishing numerical pollutant limits for sewage sludge incinerators (except in the case where stack height exceeded 65 meters, the proposal would have required use of a "good engineering practice" height to correlate to a dispersion factor in Table 9).

The metals emission control efficiencies assumed in assessing the exposure to the MEI corresponded to the worst 10 percent of EPA's data on sewage sludge incinerators. These control efficiencies were as follows: arsenic, 96 percent; beryllium, 99 percent; cadmium, 65 percent; chromium, 96 percent; lead, 67 percent; mercury, 0 percent; and nickel, 95 percent. Control efficiencies were not assumed for organic compounds. Instead, total hydrocarbons were used to control organic emissions.

The Agency proposed a THC operational standard of 20 ppm as one of several options it was considering for regulating sewage sludge incinerators in the November 9, 1990, notice of the NSSS. At the time, the Agency concluded that the 20 ppm THC option was acceptable for sewage sludge incinerators because it was consistent with the 20 ppm THC standard used for hazardous waste incinerators and was within the operating range for incinerators tested by the Agency. Because the Agency had only tested 9 sewage sludge incinerators and was basing its THC standard for sludge incinerators on incinerators designed to fire hazardous waste, EPA requested comment on what level the operational standard for THC should be set (i.e., 10 ppm, 20 ppm, 30 ppm, etc.).

Comments: The Agency received numerous comments on the exposure assessment approach used to establish numerical pollutant limitations for sewage sludge incinerators. Many commenters argued that EPA lacked adequate data on the scientific basis for establishing metals emission control efficiencies for sewage sludge incinerators. Commenters further stated that selecting the worst 10 percent (10th-percentile) from such limited data lacked adequate justification and was an arbitrary decision on the Agency's part. In addition, many commenters were critical of EPA's table of national air dispersion factors. The commenters cited the Agency's use of an outdated ISCLT model and inappropriate or overconservative modeling assumptions as the major problems with the analysis used to develop the dispersion factors. Several commenters felt that the table of dispersion factors was unnecessary and that the Agency should require site-specific modeling using Clean Air Act procedures to determine the air dispersion factor for a sewage sludge incinerator.

Several commenters (including the Agency's Science Advisory Board and other scientific review) took issue with the methodology used to establish THC limitations contending that too many scientific uncertainties exist in the calculation of a single weighted carcinogenic potency value representing the risk of organic compounds emitted from sewage sludge incinerators. Other commenters opposed certain other aspects of the Agency's proposed method for calculating hydrocarbon limitations, including assigning a detection limit of 0.1 $\mu g/m^3$ for both carcinogens and threshold compounds not detected in any of the incinerators tested by EPA but included in EPA's IRIS data base. Many commenters pointed out that the correlation between THC readings and the total concentration of detected organics in the four incinerators EPA tested was poor and that EPA should conduct more testing before it tries to calculate a risk for total hydrocarbon emissions.

Commenters supported a single operational standard for THC emitted from sewage sludge incinerators but questioned EPA's proposed 20 ppm THC standard as being unrealistically low and outside the normal operating range for existing sludge incinerators.

Response: The Agency has concluded that it is infeasible to establish a risk-based numerical pollutant limits for THC emissions from sewage sludge incinerators and that it should adopt an operational standard for total hydrocarbon emissions. The uncertainties identified by the Agency's SAB and commenters have convinced the Agency that site-specific, risk-related THC emission limits cannot be technically supported.

In addition, with respect to metal control limits, the Agency agrees that adequate data on sewage sludge incinerators are not available to establish national metals emission control efficiencies; and that its simplified air model (an outdated ISCLT model) and assumptions were not adequate to develop national air dispersion factors for sewage sludge incinerators. Control efficiency refers to the effectiveness of an incinerator and its air pollution control system in preventing the release of metals to the atmosphere. The air dispersion factor relates the maximum allowable emission rate of a pollutant from a sewage sludge incinerator stack to a maximum allowable increase in the ground level ambient air concentration for that pollutant at a specific distance from the incinerator. The air dispersion factor and the combined metal control efficiencies of the incinerator and the air

pollution control system are key variables in calculating safe numerical limits for pollutants in sewage sludge destined for incineration.

In the part 503 proposal, the Agency established metals emission control efficiencies and air dispersion factors to provide owners and operators of sewage sludge incinerators greater flexibility in complying with the regulations. Under the proposal, owners and operators had the option of (1) site-specific testing to determine the metal emission control efficiency and the air dispersion factor for the incinerator or (2) using the control efficiency and dispersion factor established by the Agency to calculate the maximum allowable concentrations of pollutants in the sewage sludge to be incinerated.

Further, the Agency agrees with many of the comments provided by the public and the scientific peer review committees concerning the limitations of its approach for establishing site-specific THC limitations for sewage sludge incinerators, and that an operational standard(s) for THC is more appropriate given data and scientific limitations. In the part 503 proposal, the Agency proposed to establish site-specific numerical limitations for THCs and required continuous monitoring of THC as a technique for controlling toxic organic emissions from sewage sludge incinerators. Total hydrocarbons were used as a surrogate for organic pollutants emitted from sewage sludge incinerators. The Agency proposed limiting the concentration of total hydrocarbons in the emissions in lieu of specifying the concentration of organic pollutants in sewage sludge that may be fed into the incinerator. The Agency performed air quality modeling to determine the emission rates for organic pollutants (as measured by THC) and inorganic pollutants that can be allowed without imposing undue risks to the most exposed individual in the vicinity of the incinerator. As discussed above, for organic pollutants the allowable emission rate determined by modeling is the numerical limit for THC emissions from sewage sludge incinerators. This is not the case for inorganic pollutants or metals, where the allowable emission rate was used to derive a safe inorganic pollutant concentration in the sewage sludge on a pollutant-by-pollutant basis.

EPA had originally considered controlling the concentration of organic pollutants fed into an incinerator on a pollutant-by-pollutant basis, similar to the approach proposed for metals. However, the approach was not feasible for organic pollutants because the Agency could not establish a destruction and removal efficiency (DRE) for sewage sludge incinerators. DREs of an incinerator are needed to relate the emission of an organic pollutant to its risk-specific concentration and to an allowable safe concentration of organic pollutant in the sewage sludge to be incinerated.

EPA proposed to limit the concentration of total hydrocarbons in the emissions of sewage sludge incinerators for two reasons. First, the approach controls the emission of individual organic compounds found in sludge fed into the incinerator; and second, the approach controls the emission of organic compounds that are created during the combustion process (i.e., products of incomplete combustion, PICs). The Agency recognized setting limitations on total hydrocarbons was an innovative approach that might stimulate considerable scientific debate as to its use in the proposed rule and to its applicability to other Agency incinerator programs.

Final Action: The Agency agrees with many of the findings and recommendations made during scientific review of the proposal and public comment period. As a result, the Agency has used an updated ISCLT model for exposure evaluations for the four carcinogenic metals and lead, and has revised its approach for determining air dispersion factors, control efficiencies for inorganic pollutants (i.e., metals) and its THC approach for controlling organic pollutant emissions from sewage sludge incinerators. The Agency has not established air dispersion factors and metal control efficiencies for sewage sludge incinerators because it currently lacks adequate data to establish dispersion factors and control efficiencies on a national basis. However, in the final rule the Agency has required owners and operators of sewage sludge incinerators to conduct site-specific modeling and performance tests of their facilities to calculate the air dispersion factor and the control efficiency with which the incinerators and air pollution control systems control the emissions of one or more of the pollutants listed in the final rule. The Agency has determined that the updated ISCLT model is the preferred air dispersion model for evaluating pollutants of concern for the final rule, and that the dispersion factor modeling and emission control tests are to be conducted using models and procedures specified by the permitting authority with jurisdiction over the incinerator.

In addition, the Agency has replaced its proposed THC approach with an operational standard similar (but not identical) to the technology-based Tier II approach being used by the Agency for hazardous waste combustion systems [40 CFR Parts 260, 261, 264 and 270, Standards for Emission Monitoring for Owners and Operators of Hazardous Waste Incinerators; and 40 CFR Part 260, Burning of Hazardous Wastes in Boilers and Industrial Furnaces (Reference Nos. 104 & 95)].

The CWA specifically authorizes alternatives to establishing numerical limitations for pollutants in sewage sludge in certain circumstances. Section 405(d)(3) of the CWA states:

> Alternative standards—For purposes of this subsection, if, in the judgment of the Administrator, it is not feasible to prescribe or enforce a numerical limitation for a pollutant identified under paragraph (2), the Administrator may instead promulgate a design, equipment, management practice, or operational standard, or combination thereof, which in the Administrator's judgment is adequate to protect public health and the environment from any reasonably anticipated adverse effect of such pollutant.

Congress recognized that circumstances would arise where it would *not* be feasible for EPA to prescribe numerical limits for pollutants in sewage sludge for certain sewage sludge use and disposal practices. Since a scientifically defensible methodology currently does not exist that can accurately link the concentration of organic pollutants in sewage sludge to organic pollutants emitted from the stack of a sewage sludge incinerator, EPA has concluded that establishing "site-specific" organic pollutant limits for sewage sludge incinerators is just such a case. Thus, for the final rule, the Agency has established a national operational standard for THC emissions of 100 ppm (measured as a monthly average) to ensure that good operating practices at sewage sludge incinerators achieve an adequate level of public health and environmental protection. EPA has selected a regulatory limit of 100 ppm THC (measured on a monthly average—corrected to 7 percent oxygen) for sewage sludge incinerators because: (1) it is within the range of values reported in our data base for incinerators burning sewage sludge; (2) the monthly average excursion policy ensures good operating practice at sludge incinerators on a continuous basis; and (3) the aggregate risk assessment for this practice showed low "baseline" risk to the HEI and the population as a whole.

The final part 503 approach requires owners and operators of sewage sludge incinerators to monitor continuously to ensure that the THC level does not

exceed a good operating practice-based THC limit (i.e., an operational standard for THC emissions) of 100 ppm THC. As discussed later, continuous THC monitoring is required using a flame ionization detection (FID) system over the life of the permit.

EPA has adopted an operational standard of 100 ppm for all sewage sludge incinerators because it concluded that all POTWs should achieve this emission level. Data in the record clearly establish that fluidized bed incinerator will have no difficulty in complying with this standard and that most multiple hearth units can also comply. In the case of some multiple hearth incinerators, POTWs will need to implement process and "good engineering practice" controls to meet the prescribed limits. Requiring compliance with the 100 ppm standard will require some reduction from current levels of sewage sludge incinerator emissions but the Agency cannot estimate how such changes from current practice might reduce human exposure.

The aggregate risk assessment shows that, in the case of organic emissions, current emissions represented a risk of 0.2 (based on "best estimate" emission levels) to 4 cancer case (based on 99th-percentile "worst case" emission levels) annually and a risk to a HEI of 4×10^{-4} to 7×10^{-3}. EPA concluded that any reduction in risk associated with reducing THC emissions below 100 ppm could not be justified in terms of increased protection of public health and the environment. EPA based this conclusion on the fact that the risk assessment for incinerator included very conservative assumptions. These assumptions yielded results that the Agency has concluded probably overstate the risk associated with current levels of sewage sludge incinerator organic emissions.

The risk assessment numbers are based on estimations of organic emissions from sewage sludge incinerators. In order to develop these estimations, a number of very conservative assumptions were made for both the best estimate and worst case scenarios, that probably results in overstating THC emissions for purposes of this analysis. These include assuming that *all* organic compounds that were sampled and analyzed for at seven sewage sludge incinerators—the organic compounds included in the Agency's risk assessment data base, IRIS—are present in the organic emissions of 172 POTW incinerators. In fact, the data establish that many of these compounds (including aldrin/dieldrin and hexachlorobenzene) were not detected at all in the samples. Fifty one percent of the calculated aggregate risk is based on risk associated with three compounds, not found in the sewage sludge samples and that will not be created in the process of combustion. Furthermore, organic compounds not detected in the sampling at concentrations below the detection limits were assigned emission levels that corresponded to the detection limit concentrations. This overstates THC emissions because the true level is below the detection limit and may be significantly lower or non-existent. Moreover, organic compounds that were not detected in the samples were still assumed to be emitted by an incinerator. The emission level assigned for these compounds is either the detection limit value or average values based on detection limits for other compounds. Again, this represents an assumption that results in overstatement of the level of risk.

After calculating risk associated with sewage sludge incinerator emission for THC using the assumptions discussed above, for its "worst-case" scenario, the aggregate assessment increased these estimates by a factor of 5 to account for organic emissions from the stack that have not been identified or quantified. This was done on the assumption that there are unidentified and unquantified organic emissions from sludge incinerators. EPA, in its recent report to Congress on municipal waste combustion concluded that a significant portion of organics emissions (80 percent or more) have not been identified and quantified. However, the report went on to explain that the portion of the mixture that is carcinogenic and its potency is not known. (The Municipal Waste Combustion Study Report to Congress (U.S. EPA 1987a).) Consequently, increasing the risk calculations by a factor of five overstates risk to the extent that the unaccounted for and unquantified portion of the emissions' stream does not include carcinogenic organics.

In light of this and the fact that over half the calculated risk is associated with compounds not detected in sewage sludge, EPA determined that there is no basis for limiting emissions to a level below 100 ppm. As previously explained, EPA considered requiring sewage sludge incinerators to achieve a 20 ppm emission level. However, the Agency had not considered how much variability (i.e., excursions above the THC standard) it would allow in measuring THC emissions from sewage sludge incinerators for purposes of compliance. Obviously, requiring a 20 ppm THC operational standard on a quarterly or yearly basis is significantly different from enforcing the same standard on a daily or monthly basis. For example, if the Agency used a yearly average as its excursion policy for enforcing the 20 ppm THC standard, emissions from sewage sludge incinerators could be significantly above the THC standard for periods up to six months.

However, the Agency has decided to adopt a monthly averaging period for the purpose of determining compliance. If the Agency enforced the 20 ppm THC standard on a monthly basis, such a policy would be over protective given the "baseline" aggregate risks associated with sewage sludge incinerators, and many sludge incinerators would be out of compliance (even though 20 ppm is within their operating range) because they are unable to consistently achieve that level of operation on a monthly basis. Data reviewed by the Agency established that many sewage sludge incinerators have greater variability in their THC emissions than do other waste incinerators because sewage sludge, in general, has a high moisture content and that moisture content can vary widely during operation.

Other Risk Management Issues, Comments, Responses and Final Action

A number of comments were received from commenters that are specific to various risk management aspects of the part 503 regulations. A synopsis of the major comments and the Agency's responses and final actions is given here. More comments and responses on these and other topics may be found in the Response to Comments Document for the Proposed part 503 rule (Reference No. 109). Information on obtaining single copies of this document is provided in part XIV of the preamble.

Domestic Septage

Comments on the Proposed Approach

The Agency received over 130 comments concerning the proposed treatment of septage. A majority of the commenters opposed the regulation of septage as sewage sludge. Commenters indicated the proposed regulations were too costly to implement and would have a negative effect on the environment. The commenters maintained that the regulations, if adopted as proposed, could eliminate the land application of septage or could cause illegal or reduced pumping of septage systems by homeowners or illegal dumping.

Many comments were received from small communities and septage pumpers and haulers disagreeing with

the Agency's proposed approach. They argued that applying the proposed regulations for sewage sludge from POTWs to domestic septage collected from private homes was over stringent, burdensome, and would have little or no environmental benefit. They were particularly concerned about the proposed requirements for pathogen and vector attraction reduction, and the frequency of monitoring pollutants, recordkeeping and reporting.

Response to Comments

The Agency, after reviewing the public comments, agrees that the regulations as proposed, if applied to septage, would have been exceedingly difficult to implement and therefore, unlikely to achieve the public health and environmental statutory objectives. The proposed part 503 rule regulated septage that is pumped and collected for use or disposal (septic tank pumpings) in the same manner as municipal wastewater sewage sludge. Even though a comprehensive national data base on septage quality did not exist at the time of the proposal, EPA believed that septage, like sewage sludge, had the potential to adversely impact public health and the environment because septage was suspected of having very similar properties to sewage sludge and containing the same types of pollutants and pathogenic organisms. Moreover, the legislative history of section 405 evidences Congressional intent that EPA's regulations should address domestic septage as well as sewage sludge. S. Rep. No. 50, 99th Cong., 1st Sess., p. 47 (1985). It was for these reasons that EPA decided to regulate septage in the part 503 proposal.

Under the proposed approach, the same numerical pollutant limits and management practices applicable to sewage sludge would have also applied to septage. In addition, septage would have been required to be analyzed to determine the amount and presence of inorganic and organic pollutants covered by the regulations. This information was required to allow the septage pumper or hauler to determine the appropriate use or disposal practice. If, as is generally the case, septage is to be applied to agricultural or non-agricultural land, pollutant concentration data would be needed to determine the allowable pollutant application rate or maximum pollutant concentrations for applying the septage to the land. EPA believed that concentrations of inorganic and organic pollutants in septage would be lower than concentrations of these pollutants in sewage sludge because of the septage's predominately domestic sewage nature and the lack of significant industrial wastewater contribution to it. Because septage quality should be better than sewage sludge quality, the Agency believed that it would prove easier for septage than for sewage sludge to comply with the requirements of the part 503 proposal.

Because of the comments and information EPA received on the proposal, the Agency evaluated alternative regulatory strategies that would similarly protect public health and the environment but are less complex and easier to implement. One such strategy was put forth in the 1990 notice of the NSSS (55 FR 47240–47242, November 9, 1990). This approach replaced pollutant monitoring and cumulative pollutant loading limits used for sewage sludge with a single hydraulic loading rate (30,000 gallons per acre per year) for septage applied to the land. In addition, the approach used short term lime stabilization to control pathogens and vector attraction, and other requirements such as crop, use and access restrictions to ensure adequate protection of public health and the environment. This approach received many favorable comments from reviewers.

The Agency recognized, as a result of comments on the proposal and 1990 notice, that several factors must be taken into account when regulating septage. Most septage collection businesses are small operations, usually three or fewer trucks. Each truck generally has a storage capacity of about 2,000 gallons which will contain the wastewater from, at most, two typical home septic tanks. Under these circumstances, it is readily apparent how difficult it would be to require sampling and testing of septage for organics, metals and nitrogen, and then regulate land application based on septage quality. Such an approach appears particularly onerous for small and marginal businesses in the septage service industry.

While the Agency believes domestic septage has many of the same chemical and biological constituents as sewage sludge and septage requirements must protect public health and the environment to the same degree as sewage sludge requirements, it has also concluded that septage presents less of a risk to public health and the environment than sludge may because these constituents are found at very low concentrations. Presently, a number of States and local governments regulate land application of septage by controlling the amount of septage that may be applied on a gallons per acre per year basis—a hydraulic loading rate approach similar to the approach considered in the 1990 notice.

The Agency believes the use of a hydraulic loading rate is an attractive alternative for small volumes of septage with low levels of pollutants. Such a regulatory approach is easily understood and implemented by small communities and septage pumpers and haulers. Moreover, it does not require specific testing of septage loads and land application based on the analysis of septage quality. This approach also lends itself to a simple recordkeeping system. Regulatory agencies would merely check the haulers' records which would indicate the gallons of septage hauled to a specific site.

To validate the hydraulic loading rate approach for the final rule, the Agency, using data on domestic septage quality, compared calculated reasonable hydraulic loading rates for septage to the risk-based pollutant loading rates for sewage sludge. The first step was to calculate reasonable hydraulic loading rates based on the nitrogen requirements of various crops and vegetation expected to be grown on land application sites. Based on the available nitrogen content from domestic septage and varying the crop uptake rate in pounds of nitrogen per acre per year, a range of annual septage application rates were calculated as a function of crop nitrogen requirements. Determining the annual septage application rate based on nitrogen uptake was considered reasonable because it provides only the amount of nitrogen needed to satisfy the growth requirements of crops and vegetation grown on the land application site.

To verify that hydraulic loading rates for domestic septage protect public health and the environment, the Agency reviewed the pollutant content of domestic septage from data gathered during the public comment period (Reference number 107). Using this information, the Agency calculated the cumulative pollutant loads for each pollutant in domestic septage and compared them to the risk-based cumulative pollutant loads developed for the land application of sewage sludge in the final part 503 rule. Based on this analysis the Agency concluded that a hydraulic loading rate approach for septage applied to land would provide a similar level of public health and environmental protection as cumulative pollutant loading limits provide for sewage sludge.

The Agency also evaluated the adequacy of site restrictions and pH controls as a means of protecting public health and the environment from pathogens found in and vector attraction

to domestic septage. Domestic septage contains pathogens and is capable of attracting vectors when untreated septage is applied to the land surface. Based on a university study (Ronner, A.B., Cliver, D.O. 1987. "Disinfection of Viruses in Septic Tank and Holding Tank Waste by Calcium Hydroxide." University of Wisconsin, Madison) and on several States' experience with lime stabilized septage, the Agency found that raising the pH of septage with an alkaline material to 12 or above for 30 minutes stabilizes domestic septage and equals the minimum pathogen reduction requirements for a Class B sewage sludge described in the part 503 proposal. In addition, the Agency found that (based on States' experience) the vector attraction reduction requirement for septage is also satisfied by pH control because odors are drastically reduced.

Site use and access restrictions were also evaluated as a way of protecting public health and the environment when pH control was not used to reduce pathogens and vector attraction to land applied septage. The Agency determined that use and access restrictions were an appropriate means of protecting public health and the environment in the absence of pH control by ensuring that exposure to untreated septage is minimized. Thus, for the final rule, the Agency concluded that either pH control or use and access restrictions would provide an adequate level of public health and environmental protection from land applying domestic septage.

In addition to the above changes, the Agency simplified many of the monitoring, recordkeeping, and reporting requirements for domestic septage. EPA believes that these changes result in domestic septage requirements for the final part 503 rule that are more implementable than the requirements in the proposal, and that protect public health and the environment from reasonably anticipated adverse effects of pollutants found in domestic septage.

Final Action

As a result of public comments, the Agency has revised its approach for regulating domestic septage applied to land or surface disposed for inclusion in the final part 503 rule. It is the Agency's conclusion that the revised approach will be less burdensome and still protect public health and the environment. The requirements in today's final rule apply only to *domestic* septage as defined and not to sewage sludge. These requirements also do not apply to domestic septage that is co-mingled with industrial or commercial wastewaters, sludges or greases. A description of the requirements for the final part 503 rule is provided below:

1. *Domestic septage land application rate limit.* The rate of septage applied to land would be limited to an annual septage application rate (gallons per acre per year—hydraulic loading rate) depending on the crops or vegetation grown on the land application site. The Agency has determined that limiting the hydraulic loading of septage, based on the nitrogen requirements of crops and vegetation, will adequately protect public health and the environment. This approach, based on the data on pollutant concentrations in septage reviewed by the Agency, ensures that the application of septage will not result in exceeding the cumulative pollutant loadings for metals that the Agency has found to be protective. In addition, septage applied at the appropriate hydraulic loading rate will satisfy nitrogen demands for growing crops without adversely affecting surface or ground water because available inorganic nitrogen will be taken up by the crops and organic nitrogen will be released too slowly (over a period of years) to cause contamination of surface or ground waters.

In contrast to land application, when domestic septage is disposed of on a surface disposal site, the final rule does not limit the application of septage by a hydraulic loading rate. Based on its review of data on metal concentrations in septage, the Agency has determined that a loading limitation is not required to protect public health and the environment. Metal concentrations in septage are well below safe numerical pollutant limits for sewage sludge when disposed at a surface disposal site. Moreover, the volume of domestic septage being disposed is small in comparison to sewage sludge.

2. *Pathogen and vector attraction reduction.* Short term alkaline stabilization (pH adjustment) is required to reduce pathogens and vector attraction prior to land application of septage. Short term stabilization with lime or equivalent alkaline products would be accomplished by raising the pH of septage to 12 or greater for 30 minutes. When domestic septage is disposed of at a surface disposal site, alkaline stabilization is required if the surface disposal site does not inject or incorporate the septage into the soil, or cover the septage by the end of the operating day. These requirements are similar (but not identical) to the pathogen and vector attraction reduction Criteria for Classification of Solid Waste Disposal Facilities (40 CFR part 257). The Agency has concluded that raising the pH of domestic septage reduces pathogens, indicator organisms and vector attraction and thereby decreases the risk of disease to the public. In cases where alkaline stabilization is not possible, restrictions on crops, use and access are required to protect public health and the environment.

3. *Crop restrictions.* When alkaline stabilization is not possible and domestic septage is applied to agricultural land, the planting of crops whose edible portions may contact the surface soil and of root crops grown in the soil would be prohibited after septage application for 14 and 38 months, respectively. The Agency has found that short term alkaline stabilization does not sterilize the septage but does significantly reduce the number of pathogens and indicator organisms. The 14 and 38 month planting delay would allow further die-off of these organisms from exposure to sunlight and frequent drying to levels the Agency believes is protective of public health.

4. *Use and access restrictions.* When alkaline stabilization is not possible, access to sites where the potential for public exposure is high (e.g., parks and recreational areas) is restricted for 12 months after application of domestic septage to those sites. This is the same period in the current Criteria for Classification of Solid Waste Disposal Facilities (40 CFR part 257) for septage that is applied to the land if the septage is not treated in a Process to Significantly Reduce Pathogens. The main purpose of the 12 month restriction is to protect children who may ingest septage-amended soil while playing in the areas where domestic septage is applied. The Agency believes that the 12 month period is reasonable based on pathogen die-off information for septage-amended soil. For agricultural and non-agricultural lands (i.e., forest and reclamation sites) where the potential for exposure to the septage-soil mixture is low, public access would be restricted for 30 days. In addition, animals will not be allowed to graze or feed crops harvested for a period of 30 days after the application of septage. EPA concluded that the use of different time periods for access restrictions is appropriate because those time periods reflect the potential for different exposures. The Agency also believes, based on available information, that the different time periods help protect the public from the effects of pathogens in domestic septage.

Site-Specificity for Use and Disposal Practices

Comments on the Proposed Approach

Many commenters maintained that the part 503 rule should provide greater flexibility in establishing numerical pollutant limitations and management practices for sewage sludge use and disposal by allowing for variances based on site, state or regional specific factors. The commenters argued that since site-specificity is currently a basis for EPA's National Pollutant Discharge Elimination System (NPDES) permitting program under the Clean Water Act and the part 503 regulations are an extension of this program, the same type of site-specific evaluation should be allowed for sewage sludge use and disposal. Treatment works or individuals using or disposing of sewage sludge would then have the option of complying with the national standards, or requesting a variance or waiver based on meeting state design standards or site-specific conditions. The commenters believed that this approach would increase the beneficial reuse of sewage sludge but recognized it would also increase the burden on the permitting authority. One commenter suggested that EPA allow site-specific soil testing for metals once cumulative inorganic pollutant limitations are reached in order to determine if the site-life for agricultural land practices is actually exhausted. Another commenter felt that the monofill model should be modified, on a case-by-case basis, to remove that quantity of pollutant taken up by plants and animals on the site from the quantity of pollutants available for leaching to the ground water.

Response to Comments

The Agency agrees that the part 503 regulations, to the extent feasible, given limited Agency resources, should provide the flexibility to modify the standards in appropriate circumstances. In the part 503 rule, the Agency used pollutant fate and transport models in 14 exposure assessment pathways to predict the long-term human health and environmental effects of using or disposing of sewage sludge by the practices covered in the regulations. Sensitivity analyses were performed on the models to identify those factors that were most significant in determining the model results. In conducting the sensitivity analyses for the proposal, the Agency found for certain disposal practices that varying certain parameters made a significant difference in a numerical limit for a pollutant, without causing the pollutant to exceed the human health or environmental endpoint from which the limit is calculated. However, the Agency did not find any physical parameters in the land application model made a significant difference in the pollutant limits.

For the proposal, the Agency also considered developing a "tiered" regulatory approach for treatment works that could not meet the national numerical limits and did not want to conduct site-specific exposure assessment modeling for all the parameters in the 14 exposure pathways. Such an approach would establish intermediate numerical limits based on varying a few pathways and parameters at each tier. Treatment works would submit for the appropriate tier their site-specific numerical limits, exposure pathway assessment and supporting data to the permitting authority, and the permitting authority would review and approve the data, exposure assessment and site-specific limits.

One reason the Agency rejected the "tiered" regulatory approach was its complexity. Such an approach would be inconsistent with the Agency's principle of developing a rule that could be implemented easily (i.e., a self-implementing rule). It would be impossible to include in the rule all possible variations occuring at a site. Another reason for rejecting the approach was that the Agency did not believe that treatment works would use the intermediate tiers. Rather than varying only a single parameter, the Agency felt it more likely that a treatment works would collect data on as many parameters as possible to determine if, by doing so, their sludge could meet recalculated numerical limits for their site. This would further complicate implementation of the rule, increase the burden on the permitting authority and the treatment works, and based on the Agency's analysis for the proposal, provide no significant difference in the pollutant limits for land application practices.

For the final part 503 rule, the Agency reexamined whether or not to allow site-specific pollutant limits for land application practices beneficially using sewage sludge as a fertilizer or soil amendment. As discussed above, EPA evaluated 14 exposure assessment pathways to establish national numerical pollutant limits for practices that beneficially land apply sewage sludge. The Agency considered allowing a treatment works the flexibility to conduct site-specific exposure assessments and recalculate pollutant limits for each land application site using the 14 exposure pathways evaluated in the final rule, but decided not to allow the site-specific option for land application practices for several reasons.

First, site-specific pollutant limits would have to be developed on a site-by-site basis for possibly thousands of land application sites. Given the complexity of the 14 exposure pathways and the amount of data needed to field validate and verify each exposure assessment, the Agency determined that it would not be economically practical for a treatment works to conduct as many as 14 exposure pathway assessments for each land application site. In addition, the Agency believes that the administrative burden on permitting authorities to review and approve site-specific numerical limits on a case-by-case basis for thousands of land application sites would not be feasible and is beyond the self-implementing nature of today's final rule.

Second, many of the parameters in the 14 exposure pathways are based on Agency risk policy decisions (e.g., an RfD for an inorganic pollutant). EPA does not believe that values for these parameters should be changed regardless of site-specific conditions and that any variation in these pathways or parameters could result in numerical pollutant limits that are not adequate to protect public health and the environment. Finally, if the Agency restricts which pathways and parameters can be used or varied in a site-specific exposure assessment to those that are not critical from an EPA risk policy standpoint, the Agency does not believe that the numerical limits recalculated from such a "limited" exposure assessment would result in less stringent cumulative pollutant loading rates. Therefore, conducting or evaluating a site-specific exposure assessment based on varying only a few parameters in a few pathways would not be a prudent use of limited resources since it would not make a significant difference in the numerical limits for the site.

In support of site-specific soil testing for land application practices, it is possible that inorganic pollutant concentrations measured in the soil may be less than the allowable pollutant concentrations from the exposure pathway assessment after the cumulative inorganic pollutant loading limits are reached because of losses due to leaching and plant uptake. However, EPA believes that these losses would be small and would not significantly increase site-life beyond pathway predicted values. Further, any small anticipated increase in site-life would

not justify the administrative burden of conducting and evaluating site-specific soil tests and exposure assessments. For the above reasons, the final part 503 regulations do not allow site-specific soil testing for land on which sewage sludge is applied.

The Agency also considered for the final rule whether to allow site-specific pollutant limits for surface disposal practices including sludge-only landfills. Because the part 503 surface disposal limits are based only on the results of the vapor and ground water pathways, EPA determined that site-specific pollutant limits are feasible for all surface disposal practices. However, the Agency does not believe it is feasible, on a site-specific basis or otherwise, to modify Pathway 13 (surface disposal vapor pathway) or Pathway 14 (surface disposal ground water pathway) to account for the amount of a pollutant that may be taken up by animals or vegetation on the site from the quantity of pollutant available for vaporizing to air or leaching to ground water. The Agency believes that such losses would be insignificant, if quantified, having little effect on site-specific numerical pollutant limits for those pathways.

As discussed earlier, the Agency also evaluated the potential risks to wildlife from surface disposal practices and found that wildlife exposure was not significant enough to develop numerical limits using the wildlife exposure pathways for these practices. Because of the physical nature of these sites, active surface disposal sites do not provide a suitable habitat for many plant or animal species. This is supported by current evidence that does not indicate significant levels of foraging or other biological activities that would lead to significant exposure for these practices. For these reasons, the final part 503 regulation allows site-specific pollutants limits for surface disposal practices but does not allow the exposure pathways to be modified to reduce the amount of pollutants vaporizing to air or leaching to ground water after accounting for pollutant uptake by plants and animals on the site.

Final Action

In today's rule, the option of recalculating numerical pollutant limits based on certain site-specific conditions would be available for treatment works that dispose of their sewage sludge in surface disposal sites (including monofills) on a case-by-case basis.

The final rule balances the flexibility associated with site-specific analyses against the simplicity of national numerical limits. A rule that allows exceptions for every conceivable contingency would prove difficult to understand. Moreover, implementation of such a rule would require an unwarranted commitment of the Agency's limited resources. Therefore, exceptions to national pollutant limits are based on certain site-specific conditions that would make a significant difference in the pollutant limits but not their protectiveness.

Although the Agency's preference is for treatment works to use sewage sludge for its beneficial properties, EPA's responsibility is to set standards, for each practice, that are adequate to protect public health and the environment. Section 405(e) of the CWA requires treatment works generating or treating sewage sludge, as well as persons using or disposing of sewage sludge, to comply with the technical standards. Realistically, the Agency cannot issue permits to every user of sewage sludge. Therefore, the site-specific option is not allowed for land application practices and primary responsibility is placed on treatment works for ensuring that sewage sludge meets the requirements of the rule.

The approach that the Agency is promulgating in the final rule utilizes a combination of national numerical limits and case-by-case site-specific exposure modeling for surface disposal practices. Under certain conditions the treatment works would calculate new numerical limits based on the physical and environmental conditions at the surface disposal site. The treatment works will not have to collect data on all model parameters at the site. To ensure that site-specific limits are protective of public health and the environment, the Agency will not allow the treatment works to vary long-established Agency human health or environmental criteria such as RfDs, RfCs, MCLs, etc., or other parameters that would reduce the level of protectiveness in the site-specific limit. The conditions, exposure pathway models and site-specific parameters (e.g., depth to ground water, soil type and permeability, etc.) for which a treatment works may submit site-specific data and exposure pathway assessments will be provided in supplemental guidance issued by EPA shortly after promulgation of the final part 503 rule.

Application of Sewage Sludge to Frozen or Snow-Covered Land

Comments on the Proposed Approach

Many commenters objected to EPA restricting the application of sewage sludge to frozen or snow-covered land. The commenters maintained that sewage sludge could be applied to frozen or snow-covered land in an environmentally sound manner if certain precautions were taken at the site, such as considering slope, separation distance, soil type, conservation practice, and hydraulic loading.

Response to Comments

The Agency agrees that good management practices, such as vegetative cover and run-off containment can control pollutant migration from frozen or snow-covered lands where sewage sludge is applied. In the part 503 proposal, the Agency proposed to prohibit the application of sewage sludge to frozen, snow-covered, or flooded land unless the applier could demonstrate that the sewage sludge could be applied in a manner that will not cause a discharge of pollutants into waters or wetlands in violation of any requirements set forth by the Clean Water Act. The Agency believes that sewage sludge applied to frozen, snow-covered, or flooded lands could readily be transported off the site with the first melt or rainfall into a river, stream, lake, or wetland. These uncontrolled releases could result in adverse impacts to sensitive environmental areas such as spawning habitats located in wetlands. In addition, 26 States already impose similar restrictions on the land application of sewage sludge to prevent such environmental abuse.

Final Action

The final part 503 rule prohibits the application of sewage sludge to frozen or snow-covered land if the sewage sludge will cause a discharge of pollutants into waters or wetlands in violation of Clean Water Act requirements. This requirement does not apply to sewage sludge or sewage sludge products that are sold or given away for use in home gardens. In addition, bulk sewage sludge and bulk products containing sewage sludge may not be applied to flooded land. Shortly after promulgation, the Agency will issue separate guidance explaining how appliers can demonstrate compliance with this and other Clean Water Act requirements.

Set-Back Requirements

Comments on the Proposed Approach

Several commenters requested the Agency to include in the final part 503 regulations additional set-back requirements for distances from sewage sludge land application sites to ground water, bedrock, residences, property

lines, drinking wells and surface water bodies. One commenter stated that these set-back requirements should depend on site-specific conditions, such as soil type, pH, and slope, while limiting applications during adverse conditions. Other commenters suggested set-back distances between land application sites and private and public wells of 200 and 1000 feet, respectively. One commenter felt that the 10 meter set-back used in the proposed rule was not sufficient to protect surface waters from pollutants in sewage sludge. Another commenter suggested prohibiting sewage sludge application sites where the depth to ground water is less than one meter.

Response to Comments

The Agency disagrees that the part 503 rule should include additional or more stringent set-back requirements, or prohibit the land application of sewage sludge if the depth to ground water is less than one meter. The numerical limits established by the exposure assessment models are based on "reasonable worst-case" parameters such as one meter depth to ground water and 10-meter set-back from surface water. Under these conservative conditions the Agency believes the numerical limitations are adequate to protect public health and the environment from reasonably anticipated adverse effects of pollutants found in sewage sludge that is land applied. In addition, the Agency has required other management practices and siting restrictions to further protect public health and to prevent environmental abuse.

Anyone using or disposing of sewage sludge is obligated to comply with the requirements set forth in the part 503 rule. Moreover, in the case of surface water, section 405(a) of the CWA already prohibits, except in accordance with an NPDES permit, any disposal of sewage sludge if the disposal would result in any pollutant from the sludge entering navigable waters. However, as provided in section 405(d)(5) and section 510 of the Clean Water Act, States may impose more stringent requirements than those included in the part 503 regulations. In fact, many States and local governments already have zoning and set-back requirements that address many of the concerns raised by the commenters.

Final Action

The Agency has decided to retain the proposed set-back requirements in the final part 503 regulations for all land application practices, and not to expand or increase their stringency. However, the Agency has removed the proposed set-back requirements for sewage sludge and sewage sludge products that are sold or given away (referred to as distribution and marketing in the proposal) in the final part 503 rule because data provided during the public comment period showed that distributed and marketed sludge products do not pose a significant surface water pollution problem from run-off. The Agency believes the numerical limitations derived from the exposure pathway analyses for land application practices, in addition to the set-back, siting and management practice requirements contained in the final rule are adequate to protect public health and the environment. In addition, States are free to impose more stringent requirements if needed, and in many cases already have set-back and zoning laws that address the issues identified in the public comments.

Nitrogen Limitations for Non-Agricultural Land Application

Comments on the Proposed Approach

Many commenters argued that the proposed requirement for the application of sewage sludge to non-agricultural land, which states that the amount of nitrogen applied may not exceed the nutrient needs of the vegetation grown on the site, would prevent the beneficial use of sewage sludge for many of the non-agricultural land practice categories such as forest land, soil reclamation, and other beneficial use practices. The commenters maintained that, since non-agricultural land application encompasses a number of very different practice categories each having a different nitrogen management philosophy, the Agency should revise its agronomic rates requirement.

Response to Comments

The Agency agrees that the agronomic rates requirement may not be consistent with certain beneficial non-agricultural land practices such as land reclamation. As noted, the proposal included a provision that sewage sludge could not be applied at rates in excess of the nitrogen requirements of the vegetation (e.g., trees, grasses, etc.) and at rates that would cause the excess nitrogen in the sewage sludge to leach to the ground water. The objective of such a requirement is to satisfy the removal of the nitrogen requirements for optimal plant growth and to minimize nitrate contamination of ground water.

Sewage sludge contains three to five percent nitrogen. Nitrogen may be in the form of organic nitrogen, nitrogen as ammonia, and nitrogen as nitrate. Organic nitrogen is the predominant form of nitrogen in sewage sludge and decomposes into ammonia and nitrate. Ammonia is the form of nitrogen absorbed by the plant. Ammonia not absorbed by the plant may volatilize or has the potential to oxidize and form nitrate, a water soluble anion that moves readily downward into the soil profile. High levels of nitrate in drinking water supplies may result in health problems for both infants and livestock. The drinking water standard is 10 milligrams of nitrogen as nitrate per liter of water.

The nitrogen requirements of different plants can range from 50 to over 350 kilograms per hectare (45–312 pounds per acre). The nitrogen content of the sewage sludge, cropping patterns, plant-available nitrogen in the soil, supplemental fertilizers used, climatic conditions, and method of sewage sludge application also affect the amount of nitrogen that plants can effectively absorb from the sewage sludge.

Final Action

The Agency has decided to revise the agronomic rates requirement in the final regulations for land application practices. The final part 503 rule allows the application of bulk sewage sludge at rates designed to minimize the amount of nitrogen that passes below the root zone of the crop or vegetation grown on the site to ground water. For land reclamation, the permitting authority may authorize (by permit) a variance from this requirement provided the owner or operator of the site can demonstrate that nitrogen application in excess of crop and vegetative requirements would not contaminate ground or surface water. The Agency recognizes that allowing such a variance may cause a temporary pulse of nitrogen to occur in ground water or surface water near the site. However, the Agency believes that any minor excursion granted by the permitting authority would not be of sufficient duration or magnitude to produce adverse public health or environmental effects. Any slight potential for negative impacts from a temporary nitrogen pulse would be more than offset by the beneficial effects of land reclamation such as decreased acid run-off, erosion control, attenuation of inorganic and organic pollutants, and increased soil nutrient levels.

Rather than establish a national numerical limit for nitrogen for all land application practices, the Agency is requiring that the agronomically appropriate sewage sludge application rate be established by the permitting

authority based on site-specific land management practices. Guidance is available to assist in establishing the appropriate application rate from the "Process Design Manual—Land Application of Municipal Sludge" (Reference number 61) and from County Extension Service agents, State Extension soil fertility specialists, and State and local Soil Conservation Service agents.

Part 503 Vs. Part 258

Comments on the Proposed Approach

Several commenters recommended that, in the part 503, EPA regulate monofills (now regulated with surface disposal practices) in the same way as 40 CFR part 258 regulates MSWLFs in areas such as location criteria, closure requirements, long-term care, monitoring, and financial responsibility. They felt that the proposed part 503 regulations failed to recognize the importance of these areas and of: (1) Proper liner design or other engineering measures necessary to prevent pollutant migration; (2) engineering controls that allow for efficient collection and management of leachate; (3) ground water monitoring to assure that the monofill maintains its integrity; (4) a mechanism for triggering "corrective action" when the integrity of a monofill is compromised; (5) and a financial assurance mechanism to assure that the monofill can be closed properly at the end of its useful life. Some commenters were especially concerned that the proposed part 503 rule only regulated 16 pollutants in sewage sludge while the part 258 regulations addresses monitoring requirements for over 200 constituents. Other commenters maintained that allowing sewage sludge to be co-disposed with municipal solid waste without developing the numerical limitations for the co-disposed sludge did not comply with section 405 of the Clean Water Act.

Response to Comments

The Agency disagrees that, in the part 503 regulations, EPA must regulate surface disposal practices (that now includes sludge-only landfills—monofills) in the same way it has regulated municipal solid waste landfills and include the pollution containment requirements adopted in the part 258 rule in addition to the numerical pollutant concentration limits. The 40 CFR part 258 rule is a pollutant containment rule that specifies minimum Federal criteria for municipal solid waste landfills (including landfills that accept sewage sludge along with municipal solid waste). Among these requirements are location restrictions, facility design and operating criteria, ground water monitoring, and corrective action, closure and post-closure care, along with financial assurance requirements. The part 258 rule regulates municipal solid waste landfills using all these technical considerations.

In contrast to the part 258 rule, the part 503 rule seeks to limit the addition to the environment of pollutants from sewage sludge rather than contain the pollution on site. Thus, part 503 requires a quality of sewage sludge such that there will be no unacceptable impacts from the migration of pollutants. Therefore, conservative risk and exposure models were utilized to establish numerical limitations with an adequate margin of safety for pollutants in sewage sludge so that the resulting pollutant concentrations reaching a highly exposed individual through ground water are below human health criteria (maximum contaminant levels). Ground water monitoring and corrective action would be redundant and are, therefore, not needed for this controlled release approach. This approach depends on accurately characterizing the quality of sewage sludge through monitoring and controlling the sewage sludge quality through programs such as categorical pretreatment standards and local pretreatment programs. States may, of course, impose additional requirements if they desire.

By contrast, provisions of the part 258 regulations for municipal solid waste landfills control sewage sludge that is placed in these facilities through a facility design and management practice approach. The part 503 regulations adopted today for surface disposal sites include numerical pollutant limits that are adequate to protect public health and the environment from any adverse effects from pollutants found in sewage sludge and to control the quality of sewage sludge through these limits for each use and disposal practice. By setting risk-based pollutant limits to control sewage sludge quality, the Agency ensures that public health and the environment are adequately protected for those use and disposal methods regulated in part 503.

For purposes of section 405 of the CWA, in part 503, EPA has adopted the part 258 criteria as the appropriate standard under section 405 for sewage sludge disposed of with municipal waste. EPA concluded that if sewage sludge is disposed of in a MSWLF complying with part 258 criteria, public health and the environment are protected. Although section 405 of the Clean Water Act indicates a preference for numerical pollutant concentration limits to protect public health and the environment, the statute recognizes that development of scientifically defensible pollutant limits may not always be possible for all sewage sludge use and disposal practices. Thus, section 405(d)(3) provides:

> Alternative Standards—For purposes of this subsection if, in the judgment of the Administrator, it is not feasible to prescribe or enforce a numerical limitation for a pollutant identified under paragraph (2), the Administrator may instead promulgate a design, equipment, management practice, or operational standard, or combination thereof, which in the Administrator's judgment is adequate to protect public health and the environment from any reasonably anticipated adverse effects of such pollutants (CWA 405(d)(3)).

In developing the part 258 criteria, the Agency evaluated the technical feasibility of establishing numerical limits for sewage sludge that is co-disposed with solid waste in municipal solid waste landfills. In that rulemaking, EPA determined that it is not technically feasible to establish numerical criteria for sewage sludge being disposed at these facilities since any potential environmental or human health affects clearly be dominated by the solid waste component in the disposal facility. Therefore, EPA adopted, for purposes of co-disposed sludge regulation, the part 258 design and management criteria. Sewage sludge co-disposed with solid waste at landfills meeting the requirements of part 258 will satisfy the statutory directive of the Clean Water Act because the part 258 regulations have been determined to be as protective of public health and the environment as the part 503 regulations. Even though the approaches used in parts 258 and 503 are different, both approaches accomplish their statutory directive to protect public health and the environment.

Final Action

Standards for sewage sludge that is disposed of in a landfill with municipal solid waste are established in 40 CFR part 258. Compliance by treatment works with requirements of 40 CFR part 258 constitutes compliance with section 405. The part 258 standards are jointly promulgated under the authorities of sections 4004 and 4010 of RCRA and section 405(d) of the CWA. To meet these standards, treatment works must ensure that: (1) The sewage sludge sent to MSWLFs is not hazardous, as defined by the regulatory limits in 40 CFR part 261; and (2) the sewage sludge passes the Paint Filter Liquids Test (i.e., it contains no free liquids).

In the preamble to the MSWLF rule, EPA explained its judgment that it is not technically feasible to establish numerical limitations for the pollutants which may be present in sewage sludge that is co-disposed in municipal landfills. 56 FR 50978, 50996–50997 (October 9, 1991). In lieu of such numerical limitations, EPA promulgated an extensive set of rules pertaining to the design, management practices, and engineering standards for MSWLFs which co-dispose sewage sludge. (56 FR 50978–51119, October 9, 1991). As required under CWA section 405(d)(3), EPA determined that these alternative standards were adequate to protect public health and the environment. *Id.*, at 50997.

EPA has provided a sound technical and scientific basis for its CWA section 405(d)(3) determination that numerical limitations could not be set for sludge co-disposed in municipal landfills. In the proposed part 258 rule, EPA made a tentative determination under CWA section 405(d)(3) that it was not feasible to prescribe numerical limitations for pollutants in co-disposed sludge. EPA based this determination on the conclusion that sludge constitutes only a minor portion of all waste that is disposed of in municipal landfills (e.g., 5 percent by volume) and that is not scientifically possible to separate out the fate, transport, and environmental effects of pollutants in sludge from those contaminants contained in the vast amount of other waste disposed of in the landfill. 53 FR 33314, 33320, 33322 (August 20, 1988).

In the final part 258 rule (56 FR 50978, 50996–50997), EPA explained that there were no scientifically adequate mathematical models which could be used to assess the movement of sewage sludge pollutants from disposal facilities which also accept other types of waste, such as municipal landfills. *Id.*, at 50997. EPA determined that, in contrast to disposal situations where sewage sludge is disposed of in a sludge-only facility, there were too many scientific uncertainties concerning the chemical interactions between sludge pollutants and those pollutants contained in garbage and other household waste when all were mixed in a municipal landfill. *Id.*

Given these uncertainties, EPA concluded that no existing model, including the model which had been utilized to propose numerical limitations for sludge pollutants when the sludge is used or disposed of on its own (54 FR 5764–5778 (February 6, 1989)), could track the fate of sludge pollutants in a municipal landfill. As a consequence, the Agency determined that it could not prescribe with any degree of scientific certainty the appropriate numerical limitations for such sludge pollutants in co-disposed situation. *Id.*

Moreover, EPA concluded that there was a significant absence of data on the typical levels of pollutants contained in household waste which is co-disposed with sludge in municipal landfills. *Id.* Without some knowledge about the character of the household waste component in a co-disposal facility and its effect on the potential of toxic pollutants to leach from the landfill, the Agency determined that it was "impossible to calculate limitations for the sludge pollutants." *Id.*

The information EPA considered for part 258 fully supports EPA's determination under CWA section 405(d)(3) that the operational, design, and engineering standards which are incorporated into the MSWLF rule are adequate to protect public health and the environment from any reasonably anticipated adverse effects of toxic pollutants in sewage sludge co-disposed in municipal landfills. 56 FR 50978, 50997 (October 9, 1991).

Ground Water Monitoring and Degradation

Comments on the Proposed Approach

Several commenters maintained that a mechanism to ensure ground water protection was not provided in the part 503 proposal because ground water monitoring provisions were not required for monofills. The commenters stated that the only way to guarantee compliance, and to ensure that design and construction controls work is to require ground water monitoring. Another commenter advocated requiring ground water monitoring for all sewage sludge monofills, land application sites, and surface disposal sites unless conditions warranting an exemption could be demonstrated.

Other commenters suggested that the Agency develop a national "non-degradation policy" for all ground waters underlying monofills rather than establishing national numerical limitations, and that national regulations should not allow the deliberate pollution of ground waters. However, another commenter argued that EPA does not have the statutory authority under the Clean Water Act to establish a national ground water non-degradation policy as part of the part 503 rulemaking.

Response to Comments

The Agency disagrees that it must require ground water monitoring to ensure ground water protection. Further, the EPA disagrees that a national "non-degradation policy" is needed to protect all ground waters underlying monofills or that it lacks the statutory authority under the Clean Water Act to establish such a policy if in the future the Agency determines that such a policy is necessary to protect public health and the environment.

A fundamental regulatory principle used in developing the part 503 rule is prevention of environmental harm. The Agency believes that it is more protective and cost effective to prevent sewage sludge contamination by controlling pollutants at the source than it is to require clean-up of the contaminated ground water. Therefore, controlling the quality of sewage sludge placed in the monofill is an overriding objective of the part 503 standards.

This up-front sewage sludge pollution prevention approach is different from the alternative approach taken in the "Solid Waste Disposal Facility Criteria" 40 CFR part 258 (see 56 FR 50978, October 9, 1991). The criteria for MSWLFs use location, design, and operating criteria to achieve a ground water protection performance standard. In addition to those criteria, the Agency also requires that owners or operators of MSWLFs monitor the ground water and take corrective action when necessary. This ground water monitoring serves as a method of verifying the adequacy of the design and operation of a particular MSWLF. Ground water monitoring and corrective action were mandated for the regulations by section 4010 of RCRA "as necessary to detect contamination."

Consistent with its pollution prevention objective, the part 503 rule requires that treatment works monitor the quality of sewage sludge before the sewage sludge is used or disposed of at any site. EPA's analysis based on the available scientific and technical information, indicates that if the pollutant concentrations do not exceed the limits in the part 503 regulations, the pollutants are unlikely to migrate to the ground water, especially at levels that exceed the drinking water standards. In such circumstances, the Agency believes that requiring ground water monitoring and corrective action, in addition to sewage sludge testing, is not justified or necessary to protect public health and the environment.

Final Action

The Agency has decided to retain the proposed pollution prevention approach and numerical pollutant limitations for sewage sludge quality to ensure protection of ground waters underlying sewage sludge use and disposal sites.

The Agency has not established a national non-degradation policy for all ground waters but will consider such a policy in future rulemakings if the Agency determines it is necessary to further protect public health and the environment from the use or disposal of sewage sludge.

The Agency used exposure assessment models to simulate the movement of the pollutant into and through the soil profile to the ground water. The models calculate a pollutant concentration that will not exceed an MCL at the point of compliance. For land application practices, the point of compliance is the point where the leachate enters the aquifer. For surface disposal practices, the point of compliance is immediately below the property boundary or 150 meters from the sewage sludge unit boundary, whichever is less.

The Agency's objective in establishing the pollutant limits for the use and disposal of sewage sludge is to ensure that the pollutant concentrations reaching the ground water do not exceed the drinking water standard or, if no drinking water standard exists, other appropriate human health criteria. This ground water protection standard is the basis for the Agency's determination that the pollutant limits are adequate to protect public health and the environment from any reasonably anticipated adverse effect of a pollutant.

Surface Disposal Vs. Treatment/Storage

Comments on the Proposed Approach

Numerous commenters argued that the one year cut-off for designation as a sewage sludge surface disposal site (as opposed to a treatment or storage site) is unrealistic and should be changed. Many commenters felt that interim storage and treatment should be excluded from the definition of surface disposal, and that the definition did not clearly differentiate between long and short-term storage or between treatment and disposal. Several of the commenters suggested cut-off limits for storage and treatment ranging from two to 10 years. Other commenters maintained that surface disposal sites should be regulated the same as monofills, or that exceptions should be made for facilities with adequate ground water protection such as liners.

Response to Comments

The Agency agrees that the one year time period may not adequately differentiate surface disposal from treatment or storage. As modified in the final rule, the Agency believes that the definition accurately captures the critical elements distinguishing treatment from storage. For treatment works, the final rule provides an opportunity to demonstrate that storage may require retention for a greater period than the regulatory baseline. EPA concluded that, applying these standards, regulatory authorities and permit writers can distinguish among facilities used for sewage sludge treatment, storage and disposal.

In the proposal, the Agency defined a surface disposal site as an area of land on which only sewage sludge is placed for a period of one year or longer. The one year time period was used to differentiate surface disposal from treatment or storage practices not covered under the part 503 rule.

In 1984, when the Agency initiated the part 503 rulemaking process, surface disposal sites were considered surface impoundments that were used for treatment or interim storage, not permanent disposal facilities. Subsequently, the Agency has learned that some communities use surface impoundments for extended periods of time, suggesting that the practice is, in fact, the community's method of disposal. When surface impoundments are used for the final disposal of sewage sludge, they are surface disposal sites and are subject to the CWA's requirements as a disposal method. The CWA requires the Agency to develop standards for use or disposal methods that are adequate to protect public health and the environment from any adverse effect of each pollutant.

Sewage sludge is applied to the land for use or disposal. Sewage sludge is applied to agricultural and non-agricultural land, and sewage sludge products are distributed in commerce for use in home gardens, to take advantage of the nutrient and soil conditioning properties of sewage sludge. However, surface disposal practices do not use the nutrient and soil conditioning properties for a beneficial use. Rather, many of these disposal practices use the soil simply to bind the metals and use soil microorganisms, sunlight, and oxidation to destroy the organic matter in the sludge. Disposing of sewage sludge in monofills is also a method of surface disposal that does not use the beneficial characteristics of sewage sludge.

Final Action

Based on public comment and information obtained from the National Sewage Sludge Survey, the Agency has decided to increase the one year time period used to differentiate sewage sludge surface disposal from treatment or storage to two years. The Agency believes a two year time period is appropriate for differentiating sewage sludge surface disposal from treatment and storage, and has made this change to the definition of surface disposal because certain treatment practices (e.g., composting, sludge drying beds, etc.) and storage facilities may process and store sewage sludge for periods exceeding the proposed one year time limit. The Agency believes that permit writers will be better able to distinguish between those facilities legitimately treating and storing sewage sludge and those practicing surface disposal if EPA specifies a general time limitation. For the purpose of the final rule, the Agency has also merged application of sludge to dedicated land and disposal in monofills (i.e., sludge-only landfills) under the definition of surface disposal.

The two year time limit will reduce the burden on the regulated community operating legitimate treatment and storage facilities. The yardstick permit writers must apply to distinguish between legitimate use and disposal practices is the two year time limitation. If retained and not treated for more than two years, the sewage sludge is presumed to be disposed. If the practice does not meet this simple test it is subject to the part 503 surface disposal regulations. If stored or treated the sludge is not subject to these regulations. For flexibility in cases where the facility legitimately treats or stores for periods longer than two years, the owner or operator of the facility can prepare an explanation (for review by the permitting authority, if requested) as to why treatment or storage must continue beyond the two year limit and gain relief from this requirement.

Feasibility of THC Monitoring

Comments on the Proposed Approach

Many commenters indicated that total hydrocarbon (THC) monitoring has not been shown to be practical for sewage sludge incinerators and carbon monoxide (CO) monitoring should be used instead. These commenters suggested CO monitoring since it has been demonstrated in other incinerator applications and is simpler to operate and maintain. Some commenters argued that THC monitoring is more costly than EPA estimated and would result in many sewage sludge incinerators having to install afterburners unnecessarily. Other commenters recommended that EPA should use THC monitoring to determine overall combustion efficiency of the incinerator and set minimum temperatures, or specify afterburners to

ensure complete destruction or organic pollutants.

Response to Comments

The Agency disagrees that THC monitoring is not feasible for sewage sludge incinerators or that afterburners need to be required to ensure complete destruction of organic pollutants. Because of questions raised about the feasibility and reliability of the THC monitoring of sewage sludge incinerator emissions, EPA sponsored a long-term demonstration of a heated flame ionization detection (FID) system for use as a THC monitor at the Metropolitan Waste Control Commission (MWCC), Metropolitan Wastewater Treatment Plant in St. Paul, Minnesota. The plant has six multiple hearth sludge furnaces, with wet venturi scrubbing systems and waste heat recovery boilers. A heated total hydrocarbon measuring instrument, a Beckman Model 402, was installed on incinerator No. 9 on June 19, 1989.

The MWCC plant was selected for this study because the plant's management approached the Agency about conducting a cooperative research activity and the incinerator facility has a sophisticated computer control system that allows for the collection and analysis of incinerator and air pollution control device operating data.

The objectives of the study were as follows:

1. Demonstrate the feasibility and long term reliability of an FID system on a full scale sewage sludge incinerator.
2. Determine the costs of operation and maintenance of the FID monitor.
3. Evaluate the effects of various incinerator operating parameters on THC emissions such as operating temperatures, excess air rates, transient operating conditions, and scrubber operation.
4. Correlate the organic emissions from the incinerator with the THC readings to strengthen the Agency incinerator emission data base and to further support the regulation of total organic compound emissions through the regulation of THC emissions.

The heated FID system operated satisfactorily over the two year study. Several modifications to the standard gas sampling system were made that contributed to the success of the project.

a. A 180-degree shroud was installed on the upstream side of the sintered metal stack sampling probe. This has the effect of reducing the direct impact of stack gas stream particles on the sintered metal sampling probe and is believed to greatly reduce plugging of the sampling probe.

b. The sintered metal sample probe is routinely back purged with calibration gases during the bi-weekly instrument calibration and maintenance check.

c. The temperature of the sampling system instrument was raised from 150 °C to 190 °C. At 190 °C, erratic behavior of the system ceased and stable operation was achieved. It is theorized that at the 150 °C operating temperature, moisture in the stack gas was causing the unstable operation. It appears that at least for the St. Paul incinerator system, which has a stack temperature of 90–100 °F (32–38 °C), 190 °C is necessary for successful operation. Based on this experience, each facility will be able to arrive at its own optimum operating temperature of at least 150 °C.

With these modifications of the FID system, the system performed quite well. During the study, the THC system was operational approximately 95 percent of the time. Most of the instrument down time was due to the normal maintenance shut-down of the incinerator itself.

The hot FID instrument collected data which were used in a number of analyses. For example, the THC levels in the stack have been found to correlate very well (correlation co-efficient, r^2=0.90) with the top hearth gas temperatures. Carbon monoxide instrument data do not show as good a correlation with either top hearth gas temperatures or THC data. A second heated FID system was put into operation on October 10, 1989. The readouts of both instruments correlate very well, with only a 10 percent difference between the two THC readouts. Additional parametric tests on upset operating conditions and scum burning were conducted. Also measurements of emissions of individual semi-volatile and volatile organic compounds were conducted so that EPA could better correlate THC measurements with total organic compound emissions and better understand the health risks associated with THC readings.

The operating and maintenance costs of the hot FID system at St. Paul have been documented. For the period of June 19, 1989 to December 31, 1989, 160 labor hours were spent on operation and maintenance of the system. The Agency feels that this is a reasonable effort to ensure that emissions of organic pollutants are controlled to acceptable health risk levels.

EPA conducted additional demonstrations of THC and CO monitoring on sewage sludge incinerators in fiscal years 1991 and 1992. Results of these demonstrations further showed the viability of continuous THC/CO monitoring of sludge combustion systems (Reference number 110). EPA is now convinced that THC monitoring is a viable regulatory tool.

Final Action

Based on study data, the Agency has decided to require THC monitoring using a heated flame ionization detection system to control organic emissions from sewage sludge incinerators. The results of the study demonstrate the feasibility and long term reliability of THC monitoring using a heated (150 °C) FID system. Operating and maintenance costs are competitive with other monitoring systems used in sewage sludge incinerators such as carbon monoxide monitors. In addition, THC reading from the FID system showed excellent correlation with organic pollutant emissions for the sewage sludge incinerators tested.

Incinerator Stack Height Option

Comments on the Proposed Approach

Nine commenters supported a part 503 provision that would allow owners and operators of sewage sludge incinerators the flexibility of raising their stack heights using "good engineering practice" (GEP) to meet numerical pollutant limits before requiring the installation of best available control technology (BACT) air pollution control equipment. Many of the commenters felt that this would be an appropriate provision for the risk-based part 503 rule because many existing facilities have relatively short stacks that can result in downwash exposing incinerator operators and nearby citizens to high levels of incinerator emissions. Two commenters opposed the raising of incinerator stacks arguing that deposition exposure and the overall aggregate risk from incinerator emissions would not be reduced by increasing stack height.

Response to Comments

The Agency agrees that owners and operators of sewage sludge incinerators should have the option of raising the height of their stacks using GEP (as required under 40 CFR 51.100) to meet part 503 numerical pollutant limitations before taking other corrective measures such as installing expensive air pollution equipment. In the proposal, the Agency solicited comments on whether to deny owners and operators of incinerators an opportunity to raise the height of their stacks after the effective date of the rule, as the means of complying with the numerical limits in the rule. Raising the stack height

increases the amount of dispersion, thereby reducing the concentration of the pollutants that reach the MEI. However, increasing the height of stacks does not reduce the mass emissions of the pollutants. Therefore, national cancer incidence (the number of cancer cases due to the pollutants being emitted) may not change significantly, if owners or operators choose to meet these requirements by merely increasing the height of their stacks.

The legislative history of section 405 of the CWA directs the Agency to establish numerical limits that protect the health of individuals or populations which are at higher risk than the population as a whole (Cong. Rec., S1624, October 16, 1986). If, in complying with pollutant limitations, all incinerators in the regulated universe install pollution control equipment (such as afterburners and wet electrostatic precipitators), EPA's analysis showed that in addition to protecting the HEI, reductions would occur in the total number of projected cancer cases as well as the number of projected adverse lead health effects. The Agency has concluded that allowing credit for actual stack height up to GEP stack height would protect the HEI and would not increase the projected number of cancer cases (incidence) nationwide.

Final Action

The Agency has decided to allow owners and operators of sewage sludge incinerators the flexibility of increasing the height of their stacks up to GEP height (see 40 CFR 51.100) in determining allowable numerical pollutant limits in the final part 503 rule. The Agency believes that this approach will continue to protect highly exposed individuals and will not increase the aggregate risk to the population as a whole from incinerator emissions at facilities that chose the stack height option as a means of complying with part 503 numerical pollutant limitations.

Incinerator Lead Emissions Limitation

Comments on the Proposed Approach

Commenters were divided on how the Agency should establish the lead emissions limitation for sewage sludge incinerators. Three commenters advocated setting the allowable lead emissions limit based on the ambient air lead levels at each facility. Another commenter argued that since lead emissions from other sources were being reduced by the Agency under other regulations, a lead emissions standard for sewage sludge incinerators was premature. One commenter questioned the Agency's logic for the 25 percent of the National Ambient Air Quality Standard (NAAQS) assumption used to derive the lead emissions limit. Still other commenters were supportive of the proposed lead emissions limit and agreed with the Agency's 25 percent portion of the National Ambient Air Quality Standard for lead as the basis for the incinerator lead emissions standard.

Response to Comments

A number of commenters supported the Agency's approach for establishing the lead emissions limitation for sewage sludge incinerators. However, the Agency concluded that some modifications to the proposed approach were necessary to take into account site-specific ambient lead levels in order to protect highly exposed individuals and populations from incinerator lead emissions. The Agency disagrees that a lead emissions standard for sewage sludge incinerators is premature because of lead reductions imposed by other EPA regulations, or that the Agency's logic used in establishing the lead emissions limitation is flawed.

In the proposal, EPA designed the standard to limit lead emissions from sewage sludge incinerators so that the ground level concentration of lead would not exceed 25 percent of the NAAQS for lead. The current NAAQS for lead is 1.5 micrograms per cubic meter (ug/m^3) maximum arithmetic mean averaged over a calendar quarter (see 40 CFR 50.12).

In deriving an allowable ground level concentration for lead from the incineration of sewage sludge, the Agency evaluated the following two alternatives: 10 percent of the NAAQS, the percent used in the revisions to the Hazardous Waste Incinerator regulation, and 25 percent of the NAAQS. States allocate a percentage of the NAAQS to various sources of lead emissions in non-attainment areas through State Implementation Plans (SIPs). At the time of proposal, most States had not included limits for sewage sludge incinerators in their SIPs, leading the Agency to believe that States did not consider sewage sludge incinerators a significant source of lead emissions.

However, allocation of a large quantity of the air-shed loading to sewage sludge incinerators is inconsistent with the Agency's goal to minimize lead exposure from all sources because of the significant biological changes that occur across a broad range of exposures to lead (down to very low levels). Limiting the contribution of lead from sewage sludge incinerators to 10 percent of the NAAQS level (i.e., 0.15 ug/m^3) would be consistent with this goal. However, allowing sewage sludge incinerators alone to contribute potentially up to 25 percent of the NAAQS may be excessive since allowing that increment could allow ambient lead levels in some areas to rise substantially from the present average background level of 0.1 ug/m^3. In addition, EPA's aggregate risk assessment showed lead emissions from sewage sludge incinerators to be the primary source of potential adverse health effects from lead when compared to other sludge use and disposal practices. The Agency's proposed approach to use 25 percent of the NAAQS was EPA's initial step in regulating lead from sewage sludge incinerators and to ensure that the increase in ground level ambient concentration of lead would not exceed the current lead NAAQS.

Final Action

The Agency has decided to revise its standard for limiting lead emissions from sewage sludge incinerators to 10 percent of the NAAQS for lead because the Agency's aggregate risk assessment shows lead emissions from sludge incinerators are the primary source of potential adverse health effects from lead, especially in small children, compared to other sewage sludge use and disposal practices.

In the final rule, the ground level concentration of lead contributed from the sewage sludge incinerator [exposure concentration to the highly exposed individual (HEI)] may not exceed 10 percent of the NAAQS for lead. The minimum ground level concentration of lead being contributed by a sewage sludge incinerator that must be achieved regardless of the ambient air lead concentration is 10 percent of the NAAQS for lead. However, States may wish to further limit the emission of lead from sewage sludge incinerators if it is warranted in non-attainment areas.

The 1978 NAAQS for lead was designed to ensure that 99.5 percent of the population has blood lead levels below 30 micrograms per deciliter (ug/dl), the level then judged to provide an adequate margin of safety from adverse health effects. The Agency now has data indicating that much lower blood lead levels are associated with a variety of adverse health effects in men, women, and particularly, in the very young. EPA is currently reviewing the current NAAQS for lead and will incorporate this new information. Until a new NAAQS is promulgated for lead, the current NAAQS will be the basis of the numerical limit when sewage sludge is

incinerated. When EPA revises the current NAAQS of 1.5 ug/m^3, the owner or operator of the sewage sludge incinerator is required under the part 503 regulations to revise the numerical limit for lead for the sewage sludge incinerator. The EPA believes that the revised standard used in the final part 503 rule is consistent with new information about low-level adverse health effects and the Agency's goal to minimize lead exposure from all sources.

Alternative Pollutant Limits

Comments on the Proposed Approach

Many commenters on both the proposal and the 1990 NSSS notice urged EPA to develop standards for a "clean sludge" (i.e., a sewage sludge that receives minimal regulation if the sewage sludge meets certain quality requirements).

Response to Comments

The Agency concurs in the view that protection of public health and the environment does not require the same level of regulatory control for "clean sludge." The requirements that a sewage sludge has to meet under this concept are discussed below and the reduction in regulatory requirements for that sewage sludge are discussed in the section on Final Action.

Results of the exposure pathway assessment for land application of sewage sludge provide cumulative pollutant loading rates for inorganic pollutants. These rates are the maximum amount of a pollutant that can be applied to a unit area of land consistent with protection of public health and the environment from reasonably anticipated adverse effects of pollutants in sewage sludge.

EPA also considered an alternative to a cumulative pollutant loading rate: determination of a pollutant concentration that, if not exceeded in the sewage sludge, would provide adequate protection. EPA derived the pollutant concentration from calculations using the already established cumulative pollutant loadings. Then, by applying certain conservative assumptions, EPA back-calculated to a pollutant concentration. Because the pollutant concentration is based on the cumulative pollutant loading rate and includes conservative safety factors, it provides the same degree of protection to human health and the environment as provided by the cumulative pollutant loading rate. Calculation of the pollutant concentration and the other parts of the "clean sludge concept" are discussed below.

To convert a cumulative pollutant loading rate to a pollutant concentration, two things must be done. First, the cumulative pollutant loading rate must be converted to an annual pollutant loading rate. For today's final rule, this was done by assuming that the entire cumulative load for a pollutant is applied to a hectare of land in one year. Thus, to convert the cumulative pollutant loading rates to annual pollutant loading rates, the cumulative pollutant loading rates were divided by one year. EPA believes this is a conservative assumption because it is unlikely that the cumulative load for the inorganic pollutants controlled in today's final rule will be applied to a hectare of land in one year.

Second, the annual pollutant loading rates calculated above were converted to pollutant concentrations using the following equation:

$$C = \frac{APLR}{AWSAR \times 0.001} \quad (1)$$

Where:

C = pollutant concentration in mg/kg (dry weight basis).
APLR = annual pollutant loading rate in kg/hectare/365 day period (dry weight basis).
AWSAR = annual whole sludge application rate in metric tons/hectare/365 day period (dry weight basis).
0.001 = a conversion factor.

The annual pollutant loading rate used in equation (1) is the cumulative pollutant loading rate divided by 100 years. The other variable in the equation is the annual whole sludge application rate (AWSAR).

The Agency assumed the AWSAR used in equation (1) is 10 metric tons per hectare per year for 100 consecutive years. EPA believes that the pollutant concentrations derived from this equation are conservative because it is unlikely that any one site will receive 10 metric tons of sewage sludge per hectare per year for 100 consecutive years. In addition, the nutrient requirements of crops grown on agricultural land most likely will not require that sewage sludge be applied to the land every year for 100 consecutive years. A typical AWSAR for agricultural land based on crop nutrient requirements is 7 metric tons per hectare. Typical AWSARs for a public contact site, forest, and a reclamation site are 18, 26, and 74 metric tons per hectare, respectively. Thus, for agricultural land, a public contact site, forest, or a reclamation site, the Agency has determined based on the following analysis that pollutant concentrations derived from equation (1) provide an adequate level of public health and environmental protection because sewage sludge could be applied for significantly more consecutive years than would actually occur at such sites given their nutrient requirements.

If sewage sludge is applied to agricultural land at an AWSAR of 7 metric tons per hectare; to a public contact site at an AWSAR of 18 metric tons per hectare; to forest at an AWSAR of 26 metric tons per hectare; and to a reclamation site at an AWSAR of 74 metric tons per hectare and if the sewage sludge meets the pollutant concentrations calculated using equation (1), approximately 142 years, 55 years, 38 years, and 13 years, respectively, are required before the cumulative loading rate for a pollutant is exceeded. The Agency has concluded that it is unlikely that sewage sludge will be applied to those types of land for greater than the above number of years for each type of land.

As discussed above, the Agency believes the pollutant concentrations calculated using equation (1) only should be part of the "clean sludge concept." The other parts of that concept are pathogen requirements and vector attraction requirements. To minimize the regulatory requirements for a sewage sludge that meets certain requirements, EPA believes that a sewage sludge should meet the highest quality requirements in today's final rule for pathogens. These are the Class A requirements. If Class A pathogen requirements are met, no restrictions are imposed on the site where the sewage sludge is applied.

The Agency also believes that certain vector attraction requirements should be met to minimize the regulatory requirements for a sewage sludge. This is achieved if the sewage sludge meets one of eight vector attraction requirements in the final regulations. If a sewage sludge meets the pollutant concentrations calculated using equation (1), the more stringent Class A pathogen requirements in today's regulations, and one of eight vector attraction requirements in the final rule, EPA believes that the regulatory requirements for that sewage sludge can be reduced if the sewage sludge is applied to the land. This reduction is discussed below.

Final Action

Today's final rule indicates that if a sewage sludge or material derived from sewage sludge meets the pollutant concentrations for high quality sludge in Table 3 of section 503.13, the more

stringent Class A pathogen requirements, and one of eight vector attraction requirements; the general requirements and management practices in the final regulations for land application do not apply if the sewage sludge or material derived from sewage sludge is applied to the land. The minimum frequency of monitoring, recordkeeping, and reporting requirements in the land application subpart do apply, however, if the sewage sludge or material derived from sewage sludge is applied to the land. These requirements apply because the Agency has to have information to determine whether the sewage sludge or material derived from sewage sludge meets the above three quality requirements.

The reduction in the applicability of the land application general requirements and management practices applies both to bulk sewage sludge applied to the land and to sewage sludge sold or given away in a bag or similar enclosure for application to the land. As mentioned above, it also applies to a material derived from a sewage sludge. The material in this case is derived from a sewage sludge that does not meet the three quality requirements discussed above.

The final regulations address another situation for the "clean sludge concept." That situation concerns a material derived from a sewage sludge that meets the pollutant concentrations in Table 3 of section 503.13, the Class A pathogen requirements, and one of the eight vector attraction requirements. Because the sewage sludge meets those three requirements, neither the land application standards (i.e., general requirements and management practices) the minimum frequency of monitoring requirements, the recordkeeping requirements, nor the reporting requirements in the land application subpart apply if the material derived from the sewage sludge is applied to the land. This is true for both a material applied to the land and to a material sold or given away in a bag or similar enclosure for application to the land.

Part IX: Selection of Pollutants for Regulation

The final sludge use and disposal regulations establish numerical pollutant limits for 10 metals and an operational standard for total hydrocarbons emitted from sewage sludge incinerators. The proposed regulation would have established numerical pollutant limits for 28 inorganic and organic pollutants, as well as total hydrocarbons. After further analysis of information provided on the proposal and the data from the NSSS, the Agency decided not to establish numerical pollutant limits in the final part 503 rule for certain pollutants which the Agency had proposed to regulate for the reasons explained below.

Section 405 does not direct EPA to establish use and disposal standards for all pollutants. Rather, the statute requires EPA to develop numerical pollutant standards for pollutants "which, on the basis of available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations which may adversely affect public health or the environment." 33 U.S.C. 1345. EPA applied these criteria when it identified pollutants that it evaluated and proposed for regulation. However, in the final rule, the Agency determined that certain pollutants should not be regulated because they either are not present in sludge, or if present in the sewage sludge, the potential for exposure (and consequent health or environmental risk) is small.

EPA concluded a pollutant is not present in concentrations which pose a public health or environmental risk using the following criteria:

(1) The pollutant is banned or restricted by the Agency or no longer manufactured or used in manufacturing a product. Or,

(2) The pollutant is not present in sewage sludge at significant frequencies of detection based on data gathered from the NSSS. Or,

(3) The Agency's risk assessment for the pollutant shows no reasonably anticipated adverse effects on public health or the environment at the 99th-percentile concentration found in sewage sludge from the NSSS.

Initially the Agency selected pollutants for regulation in the part 503 proposal based on a comparison of the highest observed concentration of the pollutant found in the "40 City Study" with a safe pollutant concentration derived from its screening assessment (i.e., an exposure assessment based on a very simple and over protective exposure model). If the highest observed concentration of the pollutant from the "40 City Study" was less than the pollutant concentration from the screening assessment, the pollutant was not proposed for regulation in "Round One."

As discussed in part V, the Agency determined prior to proposal that POTWs selected for analysis in the "40 City Study" were not representative of all the POTWs in the United States because the study was not statistically designed for that purpose. Moreover, the Agency concluded that pollutant concentrations from the study did not accurately represent sludge quality and that some sludges may be more contaminated than those observed. As a result of these and other deficiencies, the Agency conducted the National Sewage Sludge Survey. The NSSS was specifically designed to resolve the deficiencies in the "40 City Study" data base and to allow EPA to accurately estimate percentile concentrations of pollutants in sludge throughout the United States. However, the NSSS was not perfect in every respect.

In developing the above criteria, the Agency selected pollutant concentrations based on the 99th-percentile from the NSSS because of uncertainty in higher percentile concentrations. Because sludge quality had improved since the "40 City Study", the Agency found when it conducted the NSSS that many pollutants were at such low concentrations that they were not detectable, even using advanced analytical methods. Because of the large number of nondetectable readings for organics, extrapolation to higher concentration values for those pollutants would create a high degree of uncertainty in the pollutant concentrations. For example, N-nitrosodimethylamine was not detected in any of the samples analyzed for the NSSS. However, the calculated highest value based on use of detection limit estimates is 1,090 mg/kg. The Agency determined that the 99th-percentile pollutant concentration estimates significantly reduced this uncertainty and used this percentile in its criteria to select pollutants for regulation in the final rule.

The Agency determined that it would not establish numerical pollutant limits for any pollutant meeting one of the three criteria. For example, if a pollutant is banned from production, it is highly unlikely that it will be present in sewage sludge, and there is no consequent need to establish numerical limits for that pollutant. In the case of a number of banned and no longer manufactured pesticides that EPA had proposed to regulate, examination of the NSSS data also confirmed that these pesticides were not present in sewage sludge.

One advantage of the approach the Agency has adopted for the final rule is that it will save monitoring resources so that POTWs can focus on looking for only those pollutants of concern. Fourteen pollutants met the criteria detailed above and are no longer

regulated in the final part 503 rule: Aldrin/dieldrin, benzene, benzo(a)pyrene, bis(2-ethylhexyl) phthalate, chlordane, DDT (and its derivatives DDD and DDE), dimethyl nitrosamine, heptachlor, hexachlorobenzene, hexachlorobutadiene, lindane, polychlorinated biphenyls, toxaphene, and trichloroethylene. Further details on the analysis used in deciding not to regulate these pollutants is provided in Appendix A (Justification for the Deletion of Pollutants from the Final Standards for the Use or Disposal of Sewage Sludge) of the Technical Support Document for Land Application.

Table IX–1 lists the 11 pollutants for which the Agency is promulgating numerical limits when a particular use or disposal practice is employed.

TABLE IX–1.—POLLUTANTS FOR WHICH NUMERICAL LIMITS ARE PROMULGATED IN PART 503

Pollutants	LA	SD	I
Arsenic	X	X	X
Cadmium	X		X
Chromium	X	X	X
Copper	X		
Lead	X		X
Mercury	X		
Molybdenum	X		
Nickel	X	X	X
Selenium	X		
Total hydrocarbons [1]			X
Zinc	X		
	10	3	6

[1] Total hydrocarbon emissions encompass all organic compounds in the emissions of an incinerator.

Key:
LA—land application.
SD—surface disposal (including monofill).
I—incineration.

Part X: Aggregate Risk Assessment for the Final Part 503 Regulation

This part of the preamble discusses the aggregate risk assessment conducted to evaluate the effects of the final part 503 regulation on public health. EPA performed this evaluation by first estimating the "baseline" public health impacts of sewage sludge use and disposal without the part 503 regulation. Next, EPA assessed the public health impacts after implementing the final part 503 regulation. The difference between these two estimates is the public health "benefit" of the final part 503 regulation.

The aggregate risk assessment was designed to estimate both the expected national human health risks associated with current baseline use and disposal of sludge and the benefits of the regulation measured in terms of estimated reductions in human health risks. Methods for determining these risks differ for each of the management practices (incineration, surface disposal and land application). In general, the Agency used a sample of plants from the analytical component of the National Sewage Sludge Survey to represent the larger universe of actual facilities and used additional information on these plants from the questionnaire portion of the NSSS. EPA then developed a profile of national sewage sludge use and disposal practices based on the information obtained in the NSSS. Further, EPA also used NSSS data to assign pollutant concentrations under baseline conditions to plants in different categories.

Data describing cancer potency or other types of dose-response effects were then used to translate estimated exposure to each pollutant into measures of individual risk. Results were then aggregated to determine the likely number of individuals experiencing each relevant health effect expected per year in the affected populations as a result of exposure to sludge pollutants. For those pollutants for which dose-response relationships could not be obtained, predicted exposure was compared to risk reference doses, describing thresholds of exposure below which adverse health effects are not expected. Estimated health risks from these plants under current practices were extrapolated using weighting factors from the survey and other data describing the current inventory of sludge incinerators to calculate risks at the national level. More details on the aggregate risk assessment may be obtained from the document entitled "Human Health Risk Assessment for the Use and Disposal of Sewage Sludge: Benefits of Regulation." Information on obtaining single copies of this document is provided in part XIV.

Surface Disposal

For those plants reporting the use of surface disposal for managing their sludge, data describing the volume and quality of the sludge disposed were obtained from the NSSS. Other sources provided data describing location, topography, design and operation of surface disposal sites. These two types of data were used by the Agency to examine the possible migration of pollutants from these sites to nearby ground water or ambient air in order to determine baseline health effects. Data for the density of human populations and drinking water wells in each county containing a sampled surface disposal facility were used to determine the size of the population likely to be exposed to various levels of pollutants near the surface disposal sites. Next, the Agency estimated the likely dose of each pollutant to subgroups of exposed populations. These estimates of exposure were combined with available dose-response data and the estimated sizes of exposed populations to predict likely individual and aggregate health risks resulting from the disposal of sludge. Finally, results were extrapolated to the national level using weighting factors developed from the surveyed facilities to estimate aggregate risks from surface disposal practices under current conditions.

Results of the baseline assessment indicate less than 0.1 cancer case, less than 1 individual who exceeded a threshold blood lead level associated with adverse lead effects, and less than 1 individual experiencing lead-induced hypertension or learning disabilities associated with the placement of sewage sludge on a surface disposal site. Post-part 503 effects remain less than 0.1 cancer case, less than 1 individual who exceeds a threshold blood lead level, and less than 1 individual with a lead case from the placement of sewage sludge on a surface disposal site. This indicates a low impact on public health from placement of sewage sludge on a surface disposal site before promulgation of the rule and even a greater level of protection after implementation of the final part 503 regulation.

Land Application

For predicting the impacts from land applying sewage sludge, the Agency used average values for the concentrations of each pollutant measured in the sludge of facilities practicing land application from the NSSS. Again, the Agency used mathematical models to predict the transport of pollutants to nearby ground water and ambient air for the baseline assessment. However, additional models were used to predict the uptake of pollutants from treated soil to agricultural crops and animal tissues and to estimate contamination of surface water. Based on average population densities and assumptions about the distribution of treated produce in national markets, the Agency estimated current human exposure to and risk from each pollutant in sludge and through each relevant pathway of exposure from prototype facilities. As with surface disposal, the final step in the assessment of current risks was to extrapolate results to the national level, based on the estimated number of facilities practicing land application and the quantity of sludge applied.

As explained earlier, the basic strategy for calculating health benefits is to estimate health risks under current conditions, estimate health risk after regulation, and subtract to estimate health benefits achieved by the regulation. The above analysis was done to determine the aggregate effects before implementation of the final part 503 regulation (i.e., at baseline) and after implementation of the final part 503 regulation. The baseline assessment resulted in less than 1 cancer case, approximately 1000 individuals for whom a threshold lead concentration is exceeded, and approximately 500 individuals experiencing lead-related effects (i.e., hypertension in adult males and children with reduced Intelligence Quotient) associated with the application of sewage sludge to the land. In no case did the average exposure to the other inorganic pollutants for which limits are included in the land application exceed the reference dose for the pollutant during the baseline assessment.

Results of the aggregate risk assessment after implementation of the final part 503 land application regulations are less than 1 cancer case, less than one individual who exceeds a blood lead level, and less than one lead case. This establishes that the rule adopted today will protect public health and ensure that continued disposal of sludge will not jeopardize public health in the future.

Sewage Sludge Incineration

For those plants reporting the use of incineration for managing their sludge, data describing the volume and quality of the sludge incinerated were obtained from the NSSS. Other sources provided data describing local meteorology and likely emissions of pollutants from these facilities. These two types of data were combined as inputs for mathematical models to predict (on a site-specific basis) the fate and transport of emitted pollutants. Resulting estimates for expected concentrations of pollutants in ambient air were next combined with site-specific data describing the locations and sizes of human populations residing near the facilities sampled. By mapping predicted ground-level concentrations of each pollutant (by geographic location) onto the locations and sizes of human populations near each facility, the Agency determined the expected dose of each pollutant received by exposed individuals under current conditions.

For estimating benefits from the regulation of sewage sludge incineration, the Agency estimated expected response of individual facilities that are expected to be out of compliance with the regulation. The Agency then assumed that those facilities would choose to install and operate pollution control equipment in order to comply with the rule. Estimated emissions for each individual incinerator in the survey were adjusted for the estimated efficacy of that facility's expected control measures to estimate emissions after compliance with the part 503 regulation. After these adjustments, all calculations were repeated to determine expected exposure and risk to surrounding populations. As before, these results were extrapolated to the national level based on the estimated volume of sludge incinerated annually and results from dispersion modeling of the full inventory of known incinerators.

Results of the assessment prior to implementation of the final part 503 regulation indicated 0.3–4 cancer cases, 700 people with blood lead levels that exceed threshold levels for identified adverse health effects, and 100 people with lead-related adverse health effects because of the firing of sewage sludge in sewage sludge incinerators. Implementation of the final part 503 regulation would reduce these risks to 0.2–4 cancer cases, 90 people with blood lead levels that exceed a threshold blood lead level, and 30 people with other lead-related health effects cases because of firing of sewage sludge in a sewage sludge incinerator.

Conclusions

The aggregate risk assessment estimates that current use and disposal practices contribute 0.9–5 cancer cases annually, with a lifetime cancer risk to a highly exposed individual ranging from 6×10^{-4} for land application and surface disposal of sludge to 7×10^{-3} for incineration. The other health effects associated with sewage sludge use and disposal are primarily related to lead exposure and result in approximately 2,000 individuals who exceed a threshold blood lead level associated with adverse health effects and 700 instances of hypertension or diminished learning capacity in children. The Agency estimates that the rule reduces cancer cases by 0.09–0.7, exceedences of lead adverse health threshold by 600–2,000 and instances of lead cases by 90–600.

These results indicate that current use and disposal practices for sewage sludge pose little risk to public health. Because of uncertainties in estimated emissions of organic pollutants from incinerators, estimates of baseline risks are reported as ranges, where the lower extreme of each range is based on "best estimates" of emissions, and the higher extreme is based on "worst case" estimates. For "best estimates" of emissions, the Agency used mean reported values of emissions for each organic pollutant tested. For samples in which a particular pollutant was not detected, limits of detection were used in calculating the mean. "Worst case" estimates are based on these same values and limits of detection, except they represent a 99th-percentile confidence limit for the mean. In addition, "worst case" estimates of cancer risks have been adjusted by a factor of five to account for the possibility that up to 80 percent of the carcinogenic pollutants in organic emissions may not have been identified and quantified and could possibly pose risks comparable to those included in the study. Use of "worst case" estimates for emissions yields risk estimates about a factor of 10 higher than those based on "best estimates."

Because of uncertainties about the likely response of individual POTWs to the regulation, expected health benefits from the regulation cannot be quantified precisely. For incinerators, reductions in emissions of metals have been estimated from the assumed removal efficiencies of additional pollution control devices expected to be installed at selected incinerator facilities. For organic pollutants, however, sufficient data were not available to determine to what extent, if any, the standard for total hydrocarbons will reduce emissions. In the absence of such data, the estimated benefits are based on the assumption that emissions of organic pollutants are not reduced; if emissions are indeed reduced, benefits may have been underestimated. Similarly, sufficient data were not available for determining how the regulation will reduce human exposure and risk from land application and surface disposal. Estimates of benefits from regulating these practices therefore range from zero to 100 percent of estimated baseline risks. Even though the estimated baseline risks from all three practices are very low, the assessment shows that the adoption of the final standards for land application, surface disposal and incineration will ensure that these methods of sludge use and disposal will not pose any significant threat to public health in the future.

Part XI: Description of the Final Part 503 Regulation

Introduction

This part describes the standards EPA is promulgating in the final part 503 regulation for the use or disposal of

sewage sludge. The standards consist of general requirements, pollutant limits, management practices, operational standards, and requirements that address frequency of monitoring, recordkeeping, and reporting. Today's regulation requires that the following persons maintain certain records: Any person who generates sewage sludge or derives a material from sewage sludge, any person who applies sewage sludge to the land, any owner/operator of a surface disposal site, and any person who fires sewage sludge in a sewage sludge incinerator. The final regulation also establishes reporting requirements for Class I sludge management facilities, publicly owned treatment works (POTWs) with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more.

In the part 503 regulation, EPA uses the phrases "land application," "apply sewage sludge," and "sewage sludge applied to the land" in a more restrictive sense than their traditional meaning to delineate sharply between different regulatory requirements. As previously explained, sewage sludge is not only disposed on land as a waste material but, in many cases, also is used to condition the soil or to provide nutrients. Thus, while sewage sludge disposed on the land is obviously "applied" to the land, the part 503 regulation uses the phrase "land application", apply sewage sludge, or "sewage sludge applied to the land" only when referring to sewage sludge used for its beneficial properties. When sewage sludge is disposed by placing it on the land, the part 503 regulation refers to this disposal practice as "surface disposal."

Additionally, requirements for sewage sludge applied to the land differ depending on whether the sewage sludge is "bulk sewage sludge" or "sewage sludge sold or given away in a bag or other container." EPA employs these terms of art to distinguish the situations in which bagged sewage sludge is typically applied in small amounts in a single application (e.g., home gardens)—called in today's rule "sewage sludge sold or given away in a bag or other container"—from those in which sewage sludge may be applied in large quantities over wide areas (e.g., agricultural use and reclamation programs)—called "bulk sewage sludge" for this regulation. In the proposed rule, EPA described this small quantity sewage sludge use as "distribution and marketing" of sewage sludge (54 FR 5745 at 5880).

Further, many of the requirements in the regulation apply to the "person who prepares sewage sludge." The regulation uses this term to describe the person or entity that effectively controls the quality of the sewage sludge or material derived from sewage sludge that is ultimately either used or disposed. In cases where a treatment works' sewage sludge is used or disposed without further treatment or mixing with other materials, the treatment works that generates the sewaqe sludge is the "person who prepares the sewage sludge." In cases, for example, where a treatment works generates sewage sludge that is blended with other substances, the person blending the sewage sludge is the "person who prepares the sewage sludge" because the blender controls the quality of the material that is ultimately used or disposed.

The structure of the final part 503 regulation follows closely the structure of the proposed part 503 regulation. The final regulation includes standards for: (1) Sewage sludge applied to the land (including sewage sludge sold or given away in a bag or other container for application to the land—described in the proposed rule as "distribution and marketing"), (2) sewage sludge placed on a surface disposal site (including sewage sludge placed in a monofill), and (3) sewage sludge fired in a sewage sludge incinerator. The final part 503 regulation also contains a subpart on pathogens and vector attraction reduction.

The subpart on distribution and marketing—now described as sewage sludge sold or given away in a bag or other container—in the proposed part 503 regulation now is incorporated into the subpart on land application for the final part 503 regulation. In addition, the subpart on monofills and the subpart on surface disposal are combined in today's part 503 regulation. Further, the subpart on removal credits was moved from the part 503 regulation to the pretreatment regulations in 40 CFR part 403.

EPA incorporated the proposed subpart on distribution and marketing into the land application subpart in the final part 503 regulation to avoid confusion. Sewage sludge that is sold or given away in a bag or other container (including sewage sludge sold or given away in small quantities such as pick-up truck loads) is obviously still "applied to the land." Further, the part 503 regulation no longer employs the phrase "distribution and marketing". EPA concluded that the phrase "sold or given away in a bag or other container for application to the land" is a more accurate description of the final use of the sewage sludge. Distribution and marketing implies that the sale or give away of sewage sludge is its final use rather than application to the land.

EPA combined the subparts on monofills and surface disposal in the proposal in the surface disposal subpart in the final part 503 regulation because the differences in characteristics between surface disposal sites and monofills did not merit separate treatment. In either case, sewage sludge is placed on the land for final disposal. Both disposal practices may present essentially similar potential threats to public health and the environment.

EPA moved the subpart on removal credits from the final part 503 regulation because it logically belongs with the pretreatment requirements. Lists of pollutants eligible for a removal credit with respect to the use or disposal of sewage sludge are in the amendment to the General Pretreatment Regulations (40 CFR part 403) in today's rulemaking.

The final part 503 regulation contains frequency of monitoring requirements that are spelled out for each use or disposal practice rather than in a separate subpart as in the proposal. Each subpart similarly includes recordkeeping requirements and reporting requirements for Class I sludge management facilities, POTWs with a design flow rate equal to or less than one million gallons per day, and POTWs that serve 10,000 people or more.

The final part 503 regulation also contains two appendices. Appendix A explains how to determine the annual whole sludge application rate for sewage sludge applied to the land. This new appendix is included in the regulation because the final part 503 regulation establishes limits based on annual pollutant loading rates for sewage sludge sold or given away in a bag or other container that does not meet the pollutant concentrations for high quality sewage sludge in Table 3 of section 503.13 of the regulation. The annual pollutant loading rates are used in the procedure described in appendix A to determine the annual whole sludge application rate for the sewage sludge.

Appendix B in today's part 503 regulation contains a description of processes used to reduce pathogens in sewage sludge. These processes are similar to the pathogen reduction processes described in appendix II of 40 CFR part 257. The vector attraction reduction requirements in the process descriptions in appendix II were deleted from the process descriptions in appendix B of today's regulation. Separate requirements are included in part 503 for vector attraction reduction.

Appendix D in the part 503 proposal explained how to calculate the

maximum combustion gas flow rate. This appendix has been deleted from the final part 503 regulation because of a change in the requirements for incineration of sewage sludge.

General Provisions (Subpart A)

Purpose and Applicability (Section 503.1)

The purpose of the final part 503 regulation is to establish standards that must be met when sewage sludge is used or disposed. The standards in the part 503 regulation consist of general requirements, pollutant limits, management practices, operational standards, and requirements for frequency of monitoring, recordkeeping, and reporting. The part 503 regulation establishes standards for sewage sludge applied to the land or disposed either by placing on a surface disposal site or firing in a sewage sludge incinerator. The part 503 regulation also includes requirements for reducing organisms in the sewage sludge that cause disease (pathogens). Either the Class A or Class B pathogen requirements must be met when sewage sludge is applied to the land or placed on a surface disposal site. Further, the regulation requires reduction of vector attraction—control of those characteristics of sewage sludge that attract disease-spreading agents like flies or rats—when sewage sludge is applied to the land or placed on a surface disposal site. There are no pathogen or vector attraction reduction requirements for sewage sludge fired in a sewage sludge incinerator because pathogen and vector attraction reduction is achieved during incineration.

The Agency established limits for pollutants in sewage sludge that could adversely affect public health and the environment and for which sufficient information exists to evaluate risk associated with those pollutants and to develop numerical limits. For land application, the pollutant limits along with the management practices protect public health and the environment from the reasonably anticipated adverse effects of arsenic, cadmium, chromium, copper, lead, mercury, molybdenum, nickel, selenium, and zinc in the sewage sludge. EPA also evaluated the risks associated with organic pollutants and other inorganic pollutants applied to or placed on the land in sewage sludge and concluded that numerical pollutant limits for those pollutants are not required for the reasons explained in part IX of today's preamble.

In the case of surface disposal, the pollutant limits and management practices in this subpart protect public health and the environment from the reasonably anticipated adverse effects of arsenic, chromium, and nickel in the sewage sludge. For incineration of sewage sludge in a sewage sludge incinerator, the pollutant limits and management practices protect public health from the reasonably anticipated adverse effects of arsenic, beryllium, cadmium, chromium, lead, mercury, and nickel in the sewage sludge.

Also included in this part are operational standards for pathogen reduction and operational standards to reduce vector attraction in sewage sludge that is either land applied or placed on a surface disposal site. In addition, EPA is today establishing an operational standard for sewage sludge incinerators that limit the total hydrocarbons (THC) in the exit gas from a sewage sludge incinerator stack. The absence of rigorous analytical tools and pertinent data make the development of numerical limitations infeasible for pathogens, vector attraction reduction, and organic pollutants in sewage sludge that is incinerated.

Section 405((d)(3) authorizes the Administrator to promulgate a design, equipment, or operational standard when in the judgment of the Administrator it is not feasible to prescribe or enforce a numerical limitation for a pollutant. The Administrator concluded that it is not feasible, based on current information and the state of analytical capability, to develop numerical limitations for pathogens, vector attraction reduction, and THC at this time using the type of exposure assessment employed to develop numerical limitation for other pollutants.

In the judgment of the Administrator, the operational standards for pathogens and for vector attraction reduction protect public health and the environment from the reasonably anticipated adverse effect of pathogenic organisms (e.g., certain bacteria, enteric viruses, and helminth ova) in sewage sludge and from the characteristics (e.g., odor) of the sewage sludge that attract vectors (e.g., mosquitos and flies), respectively. In the judgment of the Administrator, the operational standard for THC protects public health from the reasonably anticipated adverse effects of organic pollutants in the exit gas from a sewage sludge incinerator stack.

The part 503 regulation also contains frequency of monitoring requirements for sewage sludge that is used or disposed and recordkeeping requirements for any person who prepares sewage sludge or applies it to the land, for the owner/operator of a surface disposal site and for any person who fires sewage sludge in a sewage sludge incinerator. In addition, reporting requirements for Class I sludge management facilities, POTWs with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more are included in the final part 503 regulation.

The recordkeeping requirements indicate who must develop and retain information, the information that must be developed, and the period that the information must be kept. These requirements are included in part 503 to make the rule self-implementing. This is discussed further in other parts of this preamble.

The final part 503 regulation requires only Class I sludge management facilities, POTWs with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more to report collected information. Other treatment works must collect and retain information for the specified period of time. Those treatment works may have to report the information to the permitting authority on request.

Some of the requirements in part 503 apply to a person who prepares sewage sludge (i.e., the person who either generates sewage sludge during the treatment of domestic sewage in a treatment works or derives a material from sewage sludge), applies sewage sludge to the land, or fires sewage sludge in a sewage sludge incinerator. Other requirements apply to the owner/operator of a surface disposal site. Still others apply to (1) sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator, (2) the exit gas from a sewage sludge incinerator stack, (3) land on which sewage sludge is applied, (4) a surface disposal site, or (5) a sewage sludge incinerator.

Compliance Period (Section 503.2)

Section 405(d)(2)(D) of the Clean Water Act, as amended, requires compliance with the part 503 regulation as expeditiously as practicable but in no case later than 12 months after publication of the final part 503 regulation, unless the final regulation requires construction of new pollution control facilities. If the final part 503 regulation requires construction of new pollution control facilities, compliance with the part 503 regulation is required as expeditiously as practicable but in no case later than two years from the date of publication of the final part 503 regulation.

The Agency chose to apply the full 12 month and two year compliance periods

to the standards in the part 503 regulation, but not to the frequency of monitoring, recordkeeping, or reporting requirements, except for total hydrocarbons. The only way to obtain information about whether the standards are met by the statutory deadline is to start monitoring the sewage sludge and keeping records before the end of the 12 month compliance period. For this reason, the part 503 regulation indicates that the frequency of monitoring, recordkeeping, and reporting requirements, except for total hydrocarbons in the exit gas from a sewage sludge incinerator stack, are effective 120 days after the effective date of the regulation (i.e., 150 days after the date of publication of the part 503 regulation).

The frequency of monitoring, recordkeeping, and reporting requirements for total hydrocarbons in the exit gas from a sewage sludge incinerator stack are effective 12 months after the date of publication of this part, unless compliance with the operational standard for total hydrocarbons in the part 503 regulation requires construction of new pollution control facilities. In that case, the frequency of monitoring, recordkeeping, and reporting requirements for total hydrocarbons are effective two years after the date of publication of the part 503 regulation.

The "date of publication" for the final part 503 regulation is the date the regulation is published in the **Federal Register.** This date is different from the "effective date" of the final regulation, which is 30 days after the date of publication of the final part 503 regulation in the **Federal Register.**

Permits and Direct Enforceability (Section 503.3)

Section 405(f) of the CWA provides that each permit issued under section 402 of the CWA to a publicly owned treatment works or to any treatment works treating domestic sewage shall include conditions to implement the part 503 regulation, unless included in permits issued under other enumerated Federal or approved State programs. In addition, the statute authorizes EPA to issue permits to treatment works treating domestic sewage solely to impose conditions to implement the regulation where none of the listed permit programs apply. Thus, the part 503 requirements may be implemented through a CWA permit, a subtitle C Solid Waste Disposal Act permit, a part C Safe Drinking Water Act permit, a Marine Protection, Research, and Sanctuaries Act permit, a Clean Air Act permit, a permit under an approved State program, or an EPA-issued "sludge only" permit. However, the requirements in part 503 must be met even in the absence of a permit for the use or disposal of sewage sludge (i.e., part 503 is self-implementing). Consequently, the responsible person must become aware of the standards in part 503, comply with the standards, monitor the sewage sludge, keep the appropriate records, and, if applicable, report information to the permitting authority even when a permit is not issued.

The standards in part 503 also are enforceable directly against any person who uses or disposes of sewage sludge through one of the practices addressed in today's final regulation. As mentioned previously, the person who uses or disposes of sewage sludge by one of the part 503 practices must become aware of the appropriate part 503 requirements and must comply with those requirements. An enforcement action can be taken against a person who does not meet those requirements even when that person does not have a permit for the use or disposal of sewage sludge.

Relationship to Other Requirements (Section 503.4)

The conditions under which sewage sludge may be disposed in a municipal solid waste landfill unit are not provided, for the most part, in part 503. These standards are established in 40 CFR part 258. In that rule, the Agency determined that public health and the environment are protected from reasonably anticipated adverse effects of pollutants in sewage sludge when sewage sludge is disposed in a municipal solid waste landfill unit that meets the criteria in part 258, as discussed earlier. Disposal of sewage sludge in a municipal solid waste landfill unit (MSWLF) that meets the part 258 criteria constitutes compliance with section 405(d) of the Clean Water Act, as amended. EPA promulgated part 258 under both the authority of section 405(d) of the CWA, as amended, and sections 1008, 2002, 4004, and 4010 of the Resource Conservation and Recovery Act of 1978 (RCRA).

Part 503 also requires that the person who prepares sewage sludge that is disposed in a municipal solid waste unit ensure that the sewage sludge meets the part 258 requirements for materials disposed in a municipal solid waste landfill unit. The sewage sludge must not be hazardous (§ 258.20) and must pass the paint filter test (§ 258.28). In addition, sewage sludge used to cover a municipal solid waste landfill unit must be suitable for that purpose (§ 258.21). Implementation of the part 258 regulations with regard to siting and operating the municipal solid waste landfill unit must be done in accordance with part 258 and subtitle D of RCRA (56 FR 50978).

Another regulation that addresses sewage sludge is EPA's storm water regulation. Even though the final part 503 regulation does not have a storm water requirement for sewage sludge that is used or disposed, the Agency concluded that it is important to recognize the storm water regulation in this preamble.

On November 16, 1990, EPA published a final rule implementing section 402(p) of the CWA, which required the Agency to establish a regulation setting forth NPDES permit application requirements for, among other sources, storm water discharges associated with industry activity. One of the 11 categories of storm water associated with industrial activity required to be controlled under this regulation is the following:

> Treatment works treating domestic sewage or any other sewage sludge or wastewater treatment device or system, used in the storage, treatment, recycling, and reclamation of municipal or domestic sewage, including land dedicated to the disposal of sewage sludge, that are located within the confines of the facility, with a design flow of 1.0 MGD or more, or required to have an approved pretreatment program under 40 CFR part 403. Not included are farm lands, domestic gardens or lands used for sludge management where sludge is beneficially reused and which are not physically located in the confines of the facility, or areas that are in compliance with section 405 of the CWA. (40 CFR 122.26(b)(14)(ix))

In establishing this category, EPA viewed facilities such as large treatment works that engage in activities that may experience spills and bubbleovers (e.g. on-site composting and storage of chemicals) as suitable candidates for storm water permits. Such treatment works are considered to be engaged in activities whose scope and size are more akin to industry activity and, hence, should be required to obtain an NPDES permit for storm water discharges. Treatment works that fit the above description are required to pursue, by the regulatory deadlines, one of the application options provided under the Agency's storm water regulation (individual applications, group application, or notice of intent to be covered under a general permit) and to comply with the terms and conditions of any permit issued to cover discharge of "storm water associated with industrial activity".

More Stringent Standards (Section 503.5)

This section of the part 503 regulation provides the permitting authority the authority to impose more stringent standards for the use or disposal of sewage sludge than the standards in the part 503 regulation or to impose additional requirements for the use or disposal of sewage sludge. To impose more stringent standards or additional requirements, the permitting authority (i.e., either EPA or a State with an EPA-approved sludge management program) must determine that the more stringent standards or additional requirements are needed to protect public health and the environment from any adverse effect of a pollutant in the sewage sludge.

One example of when a more stringent standard may be imposed by the permitting authority concerns land applied bulk sewage sludge that meets the pollutant concentrations in 503.10(b)(3), the Class A pathogen requirements in 503.32(a), and one of the vector attraction reduction requirements in 503.33(b)(1) through 503.33(b)(8). Part 503 indicates that the general requirements and management practices in the land application subpart do not apply when the bulk sewage sludge meets these three requirements. One of the management practices that, in the general case, would apply to bulk sewage sludge meeting the defined requirements is the requirement to apply the sewage sludge at an agronomic rate. The permitting authority may decide that, because of conditions at a particular site, to protect public health and the environment from the nitrogen in the bulk sewage sludge, the bulk sewage sludge should be applied to the land at an agronomic rate even though the bulk sewage sludge is not subject to this requirement. Section 503.5(a) of part 503 allows the permitting authority to impose the agronomic rate requirement on the bulk sewage sludge that is applied to the land in defined circumstances.

As provided in section 510 of the CWA, as amended, States or political subdivisions thereof or an interstate agency also may impose more stringent standards for the use or disposal of sewage sludge than the standards in today's final rule. A State or political subdivisions thereof or an interstate agency also may establish additional requirements for the use or disposal of sewage sludge as authorized by State law.

Exclusions (Section 503.6)

This section of the final regulation discusses exclusions from the part 503 regulation. These include treatment processes, selection of a sewage sludge use or disposal practice, co-firing of sewage sludge, industrial wastewater sludge, hazardous sewage sludge, sewage sludge with a high PCB concentration, incinerator ash, grit and screenings, drinking water treatment sludge, and commercial and industrial septage.

Treatment of domestic sewage and sewage sludge was addressed in the applicability section in the part 503 proposal. That discussion was moved to the section on exclusions in today's final part 503 regulation to group all exclusions in the same section.

The final part 503 regulation does not establish requirements for the treatment of domestic sewage. The standards apply to the final use or disposal of sewage sludge generated during the treatment of domestic sewage in a treatment works. For this reason, processes used to treat domestic sewage (e.g., the activated sludge process) are not subject to the part 503 requirements.

The final regulation also does not establish requirements for the treatment of sewage sludge, except in the case of those properties of sewage sludge, other than its chemical composition, that may pose a threat to public health and the environment. Thus, requirements to reduce pathogens and vector attraction are provided in subpart D. Processes used to prepare sewage sludge for final use or disposal, such as composting, are not subject to the standards in the final part 503 regulation.

The pathogen requirements in the part 503 regulation are not based on the results of an exposure assessment. Instead, the requirements are performance standards based on the demonstrated ability of treatment processes to reduce pathogens in the sewage sludge. For this reason, some of the pathogen requirements in the part 503 regulation address the treatment of sewage sludge (e.g., raise the temperature of the sewage sludge and maintain the temperature for a specific period of time).

Selection of a use or disposal practice also was addressed in the applicability section in the part 503 proposal. That discussion was moved to the section on exclusions in the part 503 regulation for the reason mentioned above.

Although EPA encourages the beneficial use of sewage sludge (e.g., through land application), the selection of a sewage sludge use or disposal practice, whether land application or some other use or disposal practice, is a local determination (e.g., the responsibility of the municipality or authority responsible for the use or disposal of sewage sludge). For this reason, the final part 503 regulation does not establish requirements for the selection of a sewage sludge use or disposal practice. However, when the selected use or disposal practice is subject to the part 503 regulation, the standards in the part 503 regulation for that practice must be met when the sewage sludge is used or disposed.

The final part 503 regulation also do not establish requirements for co-firing of sewage sludge with other wastes or to the incinerator in which sewage sludge and other wastes are co-fired. Other wastes do not include auxiliary fuel used in a sewage sludge incinerator.

Auxiliary fuel is fuel used to augment the fuel value of sewage sludge. This includes, but is not limited to, natural gas, fuel oil, coal, and other fuels such as gas generated during anaerobic digestion of sewage sludge and municipal solid waste. The municipal solid waste must be equal to or less than 30 percent of the weight of the material, including the sewage sludge, fired in the sewage sludge incinerator on a dry weight basis. When municipal solid waste is greater than 30 percent of the dry weight of the total material fired in the incinerator, the part 503 regulation does not apply to the material or to the incinerator.

The final part 503 regulation does not establish requirements for the use or disposal of sludge generated at an industrial facility during the treatment of industrial wastewater because those sludges are not sewage sludge. Sewage sludge is generated during the treatment of domestic sewage in a treatment works. The appropriate requirements (e.g., the requirements in 40 CFR part 257 when the sludge is disposed on the land) must be met when industrial sludges are used or disposed.

The Water Quality Act of 1987 expanded the applicability of section 405(d) of the CWA to industrial manufacturing and private processing facilities that treat domestic sewage combined with industrial wastewater. Although the legislative history of the 1987 Water Quality Act indicates that the Agency should impose requirements on any treatment works that treats domestic sewage, sufficient time was not available to develop standards for the use or disposal of sewage sludge generated at industrial facilities during the treatment of industrial wastewater combined with domestic sewage. EPA does not have sufficient information at this time on the number of industrial facilities that generate sewage sludge, the amount of sewage sludge generated at those facilities, and the practices through which the sewage sludge is

used or disposed to evaluate the impact of part 503 numerical limits for the sewage sludge. In addition, the Agency questions whether the models and data used to develop the numerical limits in the final part 503 regulation are appropriate for industrial sludge with a domestic sewage sludge component. For these reasons, the part 503 regulation does not establish requirements for the use or disposal of sewage sludge generated at an industrial facility during the treatment of industrial wastewater combined with domestic sewage (i.e., either domestic sewage generated at the industrial facility or domestic sewage generated off-site and transported to the industrial facility for treatment). The Agency may consider this sewage sludge in future revisions to the part 503 regulation.

The part 503 regulation does apply to sewage sludge generated at an industrial facility during the treatment of only domestic sewage. When domestic sewage generated at an industrial facility is treated at the industrial facility without combining the domestic sewage with industrial wastewater, sewage sludge generated during the treatment of the domestic sewage is subject to the part 503 requirements. Part 503 also applies to sewage sludge generated when domestic sewage generated off-site is treated only with the domestic sewage generated at the industrial facility or is treated at the industrial facility by itself.

It is important to note that all industrial wastewater treatment facilities that treat domestic sewage—whether the domestic sewage is generated on-site or off-site—are considered treatment works treating domestic sewage and may be required to apply for a permit under 40 CFR 122.21. A detailed discussion of whether an industrial wastewater treatment facility needs a permit is presented in the preamble to the sewage sludge permitting regulations promulgated on May 2, 1989 (54 FR 18716, 18725).

The part 503 regulation also does not establish requirements for sewage sludge determined to be hazardous in accordance with 40 CFR part 261. A hazardous sewage sludge must be used or disposed in accordance with the applicable requirements in 40 CFR parts 260 through 268.

The part 503 regulation does not establish requirements for the use or disposal of sewage sludge that has a concentration of polychlorinated biphenyls equal to or greater than 50 milligrams per kilogram of total solids (dry weight basis). Sewage sludge with a polychlorinated biphenyls concentration equal to or greater than 50 milligrams per kilograms of total solids (dry weight basis) must be used or disposed in accordance with the requirements of 40 CFR part 761, not the part 503 requirements.

Ash generated during the incineration of sewage sludge in a sewage sludge incinerator also is not subject to the part 503 regulation. Ash from a sewage sludge incinerator must be used or disposed in accordance with the appropriate requirements (e.g., 40 CFR part 257 when the ash is disposed on the land).

Grit (e.g., small pebbles, sand, and material with a high specific gravity) and screenings (e.g., large materials such as rags) generated during the preliminary treatment of domestic sewage in a treatment works that are used or disposed are not subject to the part 503 regulation. These materials have characteristics that are different than the characteristics of sewage sludge. Grit and screenings also must be used or disposed in accordance with the appropriate requirements (e.g., 40 CFR part 257 when the grit or screenings are disposed on the land).

Sludge generated during the treatment of either surface water or ground water used for drinking also is not subject to the part 503 regulation. That sludge is not generated during the treatment of domestic sewage in a treatment works.

The part 503 regulation does not establish requirements for the use or disposal of commercial and industrial septage, a mixture of commercial and domestic septage, or a mixture of industrial and domestic septage. Because the characteristics of domestic septage and the characteristics of commercial septage (e.g., grease from a grease trap at a restaurant) and industrial septage (e.g., liquid or solid material removed from a septic tank or similar treatment works that receives industrial wastewater) are different, the part 503 requirements for domestic septage do not apply to commercial or industrial septage. For this reason, commercial and industrial septage are excluded from the part 503 regulation.

Requirement for a Person Who Prepares Sewage Sludge (Section 503.7)

Under the final part 503 regulation, a person who prepares sewage sludge must ensure that the applicable requirements in part 503 are met when the sewage sludge prepared by the person is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The preparer could be the person who generates sewage sludge during the treatment of domestic sewage in a treatment works or a person who derives a material derived from sewage sludge. Examples of a person who derives a material from sewage sludge are a treatment works that blends sewage sludge with some other material or a private contractor who receives sewage sludge from a treatment works and then blends the sewage sludge with some other material (e.g., mixes the sewage sludge with a bulking agent). When sewage sludge is part of a material, the person derived the material from sewage sludge. Any time the quality of sewage sludge is changed, a material is derived from sewage sludge.

The purpose of this general provision is to ensure the part 503 requirements are met. The Agency concluded that the person who generates the sewage sludge or the person who derives a material from sewage sludge should be responsible for ensuring the sewage sludge is used or disposed properly. For this reason, the final part 503 regulation makes that person responsible for ensuring the applicable part 503 requirements are met when sewage sludge prepared by the person is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. This is discussed further in part XII of today's preamble.

Sampling and Analysis (Section 503.8)

This section of the final part 503 regulation requires that representative samples of sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator be collected and analyzed. The purpose of this requirement is to ensure that samples of sewage sludge that are collected are representative of the sewage sludge that is used or disposed. In some cases, grab samples may represent the sewage sludge adequately while in other cases a composite sample may have to be collected. Whatever the situation, a representative sample must be collected and that sample must be analyzed to show compliance with the part 503 requirements.

This section also contains the methods used to analyze representative samples of sewage sludge to show compliance with the part 503 requirements. Analytical methods are specified in part 503 for enteric viruses, fecal coliform, helminth ova, inorganic pollutants, *Salmonella* sp. bacteria, specific oxygen uptake rate, and total, fixed, and volatile solids. In addition, part 503 references a document that contains procedures that can be used to calculate the percent volatile solids reduction for a sewage sludge. This document, "Environmental Regulations and Technology-Control of Pathogens and Vectors, EPA–625/R–92/013, U.S.

Environmental Protection Agency, Washington, D.C., 1992, also discusses how to collect samples that are analyzed for pathogens.

Analytical methods in the final regulation are the same as the analytical methods in the part 503 proposal, except for inorganic pollutants and viable helminth ova. The numbers of the parts in "Standard Methods for the Examination of Water and Wastewater" referred to in the final regulation for various parts are different from the numbers for those parts in the proposal because a later edition of that document was referenced in the final regulation. Even though the part numbers are different, the methods are the same.

The final rule specifies that Method SW–846 be used to analyze samples of sewage sludge for inorganic pollutants. This method is used to prepare sediment, sludge, and soil samples for analysis by flame or furnace atomic absorption spectroscopy. The Agency decided to specify this method instead of the method in the proposal (i.e., Method 1620 from the Analytical Methods for the National Sewage Sludge Survey) because Method SW–846 is more widely accepted than is Method 1620, which is a draft method.

The analytical method for viable helminth ova in the final regulation is different from the analytical method for helminth ova in the proposal. EPA considers the proposed and final ova methods to be conceptually similar when floatation or similar techniques are used to separate ova from the sewage sludge. Both the proposed and final methods use microscopic ova particle visualization and characterization to enumerate the helminth ova after the sewage sludge is processed for analysis. The ova method in the final regulation was selected because it is more current that the proposed method and is more accepted in current practice.

General Definitions (Section 503.9)

Definitions included in this section of the part 503 regulation are applicable to more than one subpart in the regulation. Each subpart also includes special definitions that apply only to that subpart.

Many of the definitions in this subpart are definitions taken either directly from section 502 of the CWA or other Agency regulations. These definitions are not discussed here. The definitions developed specifically for this rule are discussed below.

Domestic septage. Domestic septage is either liquid or solid material removed from a septic tank, cesspool, portable toilet, Type III marine sanitation device, or similar treatment works that receives only domestic sewage. The term "domestic septage" is used in the final part 503 regulation instead of the term "septage", which was used in the proposed part 503 regulation, to distinguish domestic septage from liquid or solid material that contains domestic septage mixed with other materials (e.g., grease from a grease trap). These other materials are commercial or industrial septage and are not included in the definition of domestic septage.

The definition of domestic septage also makes it clear that domestic septage includes liquid and solid material removed from portable toilets or Type III marine sanitation devices. When these materials are applied to agricultural land, forest, or a reclamation site, the domestic septage requirements in the land applications subpart have to be met. When these materials are placed on an active sewage sludge unit, the appropriate requirements in the surface disposal subpart have to be met.

Domestic sewage. Domestic sewage is waste and wastewater from humans or household operations that is discharged to or otherwise enters a treatment works. This is a key definition because the standards in the part 503 regulation apply to sewage sludge generated during the treatment of domestic sewage in a treatment works. When domestic sewage is in the influent to a treatment works, even if the influent also contains industrial wastewater, sewage sludge is generated during the treatment of the domestic sewage.

Dry weight basis. Dry weight basis means calculated on the basis of having been dried at 105 degrees Celsius until reaching a constant mass (i.e., essentially 100 percent solids content). This definition is in the final part 503 regulation because all of the numerical limits and operational standards in the part 503 regulation are on a dry weight basis. The dry weight basis allows an "apples to apples" comparison of the value for a parameter in sewage sludge to the numerical limit or operational standard in the part 503 regulation for that parameter. The procedure used to convert wet weight to dry weight varies depending on the type of unit measurement. For example, to convert a wet weight concentration (i.e., milligrams per liter) to a dry weight concentration, divide the wet weight concentration by the percent solids (expressed in hundredths) in the sewage sludge. To convert an application rate (i.e., metric tons per hectare) expressed in wet weight to a dry weight application rate, multiply the wet weight rate by the percent solids (expressed in hundredths) in the sewage sludge.

Feed crops. Feed crops are crops produced primarily for consumption by animals. These include, but are not limited to, corn and grass. Note that for a crop to be considered a feed crop, it has to be produced for consumption by animals. A crop such as grass that is not produced primarily for consumption by animals (e.g., grass grown to prevent erosion or to stabilize an area or as a cover) is not a feed crop. The term animals includes domestic animals and wild animals. The key to this definition is whether the crop is produced for consumption by animals.

Fiber crops. Fiber crops are crops such as flax and cotton. This definition is included in the final part 503 regulation because products from these crops (e.g., cotton seed oil) may be consumed by humans or may be used to prepare food consumed by humans. Because of the potential exposure to the fiber crop or product of the fiber crop, the Agency concluded that the part 503 requirements should apply when sewage sludge is applied to land on which a fiber crop is grown.

Food crops. Food crops are crops consumed by humans. These include, but are not limited to, fruits, vegetables, and tobacco. Tobacco is considered a food crop, even though usually not ingested by humans, because of the potential for direct human exposure to tobacco. Because of this exposure, the Agency determined that the part 503 requirements must be met when sewage sludge is applied to land on which tobacco is grown. Food crops can be either crops grown below the land surface, crops that touch the land surface, or crops that do not touch the land surface. When a crop is consumed by humans, it is a food crop.

Ground water. Ground water is water below the land surface in the saturated zone. The saturated zone is that part of the earth's crust in which all voids in the porous materials are filled with water. The water that fills those voids is ground water.

Person who prepares sewage sludge. A person who prepares sewage sludge is either the person who generates the sewage sludge during the treatment of domestic sewage in a treatment works or a person who derives a material from sewage sludge. This definition is included in the final part 503 regulation because the regulation contains a general provision that requires any person who prepares a sewage sludge to ensure that the requirements in the part 503 regulation are met. This general provision applies only when the sewage sludge prepared by a person (i.e., the

sewage sludge generated by a person or the material derived from sewage sludge) is applied to the land, placed on a surface disposal site, fired in a sewage sludge incinerator, or placed on a municipal solid waste landfill. Other requirements for a person who prepares sewage sludge also are included in the final part 503 regulation.

Pollutant. A pollutant is an organic substance, an inorganic substance, a combination of organic and inorganic substances, or a pathogenic organism that, after discharge and upon exposure, ingestion, inhalation, or assimilation into an organism either directly from the environment or indirectly by ingestion through the food-chain, could, on the basis of information available to the Administrator of EPA, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunction in reproduction), or physical deformations in either organisms or offspring of the organisms. This definition is similar to the definition of "toxic pollutant" included in section 502(13) of the CWA, as amended.

The term "toxic pollutant" is not used in the final part 503 regulation because this generally is limited to the list of priority toxic pollutants developed by EPA. The Agency concluded that Congress intended that EPA develop the part 503 pollutant limits for a broader range of substances that might interfere with the use or disposal of sewage sludge, not just the 126 priority toxic pollutants.

Sewage sludge. The definition of sewage sludge in the part 503 regulation is similar to the definition in the proposed part 503 regulation. Besides editorial changes, the major differences between today's definition and the definition of sewage sludge in the part 503 proposal concern domestic septage and materials not considered sewage sludge.

The final part 503 regulation defines sewage sludge as solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum and solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the incineration of sewage sludge or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Domestic septage is included in the definition of sewage sludge because it is generated during the treatment of domestic sewage in a treatment works (e.g., septic tank). It also has characteristics similar to the characteristics of sewage sludge. The legislative history of section 405 reflects congressional intent that the section 405(d) requirements apply to domestic septage. S. Rep. No. 50, 99th Cong. 1st Sess. p. 47 (1985). The term "domestic septage" distinguishes domestic septage from septage, which includes commercial and industrial septage (e.g., grease from grease traps).

Scum is the material that floats on top of the wastewater in a treatment process and is removed by skimming. Scum shares many characteristics with the other residues generated during the treatment of wastewater and often is disposed with sewage sludge. For this reason, scum is included in the definition of sewage sludge.

Today's definition of sewage sludge also indicates that any material derived from sewage sludge (e.g., composted sewage sludge blended with another material) is sewage sludge. When that material is used or disposed through one of the practices regulated in the final part 503 regulation, the requirements for that practice must be met.

Ash generated during the incineration of sewage sludge is not included in today's definition of sewage sludge. Incinerator ash, which is disposed typically in landfills, is sterile and dry like other ash material. It does not have the same characteristics as other residues from wastewater treatment processes.

Grit and screenings also are not included in the definition of sewage sludge. Grit is the material, such as sand and gravel, that settles out before primary treatment. Screenings are relatively large pieces of solid material caught on bar screens at the headworks of the treatment works. These wastes are small in quantity; have characteristics that are different from the characteristics of sewage sludge; and usually are handled and disposed separately.

Storage of sewage sludge. Storage of sewage sludge is the placement of sewage sludge on land on which the sewage sludge remains for two years or less. Storage does not include placement of sewage sludge on the land for treatment.

An issue related to the definition of storage of sewage sludge concerns the length of time (i.e., two years) sewage sludge is stored before storage becomes final disposal. The length of time can be expressed in two ways. First, the period of time can be related to how long the land is used for the storage of sewage sludge. It is difficult to define storage in terms of the length of time the land is used to store sewage sludge because the land may be used to store sewage sludge for a long period of time even though a particular sewage sludge only remains on the land for a short period of time (e.g., 120 days).

The second way to express length of time for storage is the age of the sewage sludge on the unit area of land. The Agency determined that this parameter is more appropriate to use to distinguish between storage and final disposal than is the period of time the land is used to store sewage sludge. The older the sewage sludge, the higher the potential that the sewage sludge may cause an adverse impact.

The definition of storage in today's final part 503 regulation does not indicate whether the two year storage period is the period the land is used to store sewage sludge or the age of the sewage sludge. Either parameter can be used to define the storage period.

Treatment of sewage sludge. Treatment of sewage sludge is the preparation of sewage sludge for final use or disposal. This includes, but is not limited to, thickening, stabilization, and dewatering of sewage sludge. Treatment of sewage sludge is not storage of sewage sludge.

This definition is included in the part 503 regulation to distinguish treatment from final use or disposal. Requirements in the part 503 regulation apply to sewage sludge that is used or disposed. For this reason, when the sewage sludge is treated, the part 503 standards do not apply to the sewage sludge, except when treated for pathogen or vector attraction reduction, or, in the case where land is used to treat the sewage sludge, to the land on which sewage sludge is treated.

Treatment works. Treatment works is either a Federally owned, publicly owned, or privately owned device or system used to treat (including recycle and reclaim) either domestic sewage or a combination of domestic sewage and industrial waste of a liquid nature. This includes septic tanks and other types of on-site treatment systems and holding tanks because domestic sewage can be treated in these types of devices. Note that, by definition, devices or systems used to treat a combination of domestic sewage and industrial waste of a liquid nature are a treatment works. Sludge generated by the treatment works is sewage sludge.

Land Application (Subpart B)

This part of the preamble discusses the part 503 requirements for land application of sewage sludge. More

details on each of the requirements can be found in the technical support document for the part 503 land application requirements.

The final regulation recognizes two broad categories of sewage sludge applied to the land and establishes requirements for each category. For both categories, the sewage sludge must meet ceiling concentrations. If those concentrations are not met, the sewage sludge cannot be applied to the land.

The first category is bulk sewage sludge applied to the land. Bulk sewage sludge is sewage sludge that is not sold or given away in a bag or other container. Bulk sewage sludge must meet one of two pollutant limits to be applied to the land. The sewage sludge must meet pollutant concentration limits, which are in addition to the ceiling concentrations discussed above, or the amount of a pollutant applied to the land in bulk sewage sludge must not exceed a cumulative pollutant loading rate. In addition, pathogen and vector attraction reduction requirements must be met when bulk sewage sludge is applied to the land. General requirements and management practices also may have to be met when bulk sewage sludge is applied to the land depending on the quality of the bulk sewage sludge.

The second category is sewage sludge sold or given away in a bag or other container for application to the land. One of two pollutant limits also must be met when sewage sludge is sold or given away in a bag or other container. The sewage sludge must meet the same pollutant concentrations mentioned above for bulk sewage sludge, or the amount of pollutant applied to the land annually must not exceed an annual pollutant loading rate. The annual pollutant loading rates are used to calculate an application rate that is placed on a label on the bag or other container in which the sewage sludge is sold or given away. The application rate cannot be exceeded when the sewage sludge is applied to the land. In addition to meeting the pollutant limits, the sewage sludge must meet the highest quality pathogen requirements (i.e., Class A requirements) and a vector attraction reduction requirement must be met. Sewage sludge sold or given away in a bag or other container also is subject to general requirements and a management practice depending on the quality of the sewage sludge.

Applicability (Section 503.10)

The applicability section for land application in the proposed part 503 regulation indicated that the requirements apply to the application of sewage sludge to the land and to any person who applies sewage sludge to land. That section has been edited to be more explicit. The final part 503 regulation indicates that the land application requirements apply to any person who prepares sewage sludge that is applied to the land, to any person who applies sewage sludge to the land, to sewage sludge applied to the land, and to the land on which sewage sludge is applied.

Some of the requirements in this subpart apply to the sewage sludge that is land applied. These requirements address the quality of sewage sludge applied to the land and the amount of pollutants that can be applied to the land in sewage sludge.

Other requirements in this subpart apply to a person who prepares sewage sludge that is applied to the land. A person who prepares sewage sludge is either the generator of the sewage sludge or a person who derives a material from sewage sludge. Still other requirements apply to the person who applies sewage sludge to the land (e.g., recordkeeping requirements depending on which pollutant limits are met). All of these requirements are discussed in more detail later in this preamble.

As mentioned previously, the part 503 use or disposal standards include general requirements, pollutant limits, management practices, operational standards, and requirements for frequency of monitoring, recordkeeping, and reporting. For land application of sewage sludge, there are three cases where not all requirements must be met to comply with the standards. These three cases concern bulk sewage sludge applied to the land and sewage sludge sold or given away in a bag or other container for application to the land.

In the first two cases, the sewage sludge or material derived from sewage sludge must meet certain pollutant limits and certain operational standards for pathogens and vector attraction reduction. In addition, the frequency of monitoring, recordkeeping, and reporting requirements in the land application subpart must be met. The general requirements and management practices do not apply when the sewage sludge or material derived from sewage sludge meets the three quality requirements.

The rationale for not imposing the general requirements and management practices on bulk sewage sludge and sewage sludge sold or given away in a bag or other container for application to the land is that the sewage sludge that meets the three identified quality requirements is a valuable commercial product. Because of this, EPA concluded that the probability of improper application of the sewage sludge is low and the additional requirements are not necessary to protect public health and the environment. In addition, the Agency determined that over-application of the sewage sludge will not occur because over-application reduces crop yield, which nullifies the main reason to apply sewage sludge to the land in the first instance. The Agency concluded that when the sewage sludge meets the three quality requirements, it is a fertilizer material and should be treated similarly to other fertilizers. For these reasons, EPA does not require that the general requirements and management practices be met when high quality sewage sludges are applied to the land. The circumstances in which these requirements need not be met are discussed further below.

For both the first and second cases, the EPA Regional Administrator (or, in the case of a State with an approved sludge management program, the State Director) could still, acting under authority in section 405(d)(4), decide to require that any or all of the general requirements and management practices be met, on a case-by-case basis, even when a sewage sludge or bulk material derived from sewage sludge meets the three quality requirements. However, this requires a finding by the Regional Administrator that the general requirements or management practices are needed to protect public health and the environment from any reasonably anticipated adverse effect of a pollutant in the sewage sludge.

An example of a management practice that could be imposed is the requirement to apply the sewage sludge or material derived from sewage sludge to the land at a whole sludge application rate (i.e., the amount of sewage sludge that can be applied to an area of land) that does not exceed the agronomic rate. When the Regional Administrator concludes this requirement is needed to protect public health and the environment from the reasonably anticipated adverse effect of nitrogen in the sewage sludge, the Regional Administrator could impose that requirement to the bulk sewage sludge. Under this provision, the control over the site where the sewage sludge is applied, which was foregone because of the general requirements and management practices do not apply, may be re-established.

In the third case, the part 503 requirements in the land application subpart do not apply to a bulk material derived from sewage sludge when the sewage sludge used to produce the

derived material meets the pollutant concentrations in 503.13(b)(3), the Class A pathogen requirements in 503.32(a), and one of the vector attraction reduction requirements in 503.33(b)(1) through 503.33(b)(8). In this case, the sewage sludge used to produce the bulk material already meets the three quality requirements.

The final part 503 regulation does not authorize the EPA Regional Administrator or the State Director to impose the general requirements and management practices on a bulk material derived from a sewage sludge that meets the three quality requirements because the part 503 requirements do not apply to sewage sludge used to make that material once the sewage sludge meets the identified quality requirements. No records have to be kept on who receives that sewage sludge or what happens to the sewage sludge after the three quality requirements are met.

The three cases for sewage sludge sold or given away in a bag or other container for application to the land are the same as the three cases for bulk sewage sludge applied to the land. In the first two cases, the general requirements in 503.12 and the management practices in 503.14 do not apply either to sewage sludge or a material derived from sewage sludge when the sewage sludge or material is sold or given away in a bag or other container for application to the land and when the sewage sludge or material meets the pollutant concentrations for high quality sewage sludges in 503.13(b)(3), the more stringent Class A pathogen requirements in 503.32(a), and one of the vector attraction requirements in 503.33(b)(1) through 503.33(b)(8). The frequency of monitoring, recordkeeping, and reporting requirements in this subpart do apply, however, to the sewage sludge or material derived from sewage sludge.

In the third case, the final part 503 regulation indicates that the part 503 requirements do not apply to a material derived from sewage sludge that is sold or given away in a bag or other container when the sewage sludge used to derive that material meets the pollutant concentrations for high quality sewage sludges in 503.13(b)(3), the more stringent Class A pathogen requirements in 503.32(a), and one of the vector attraction requirements in 503.33(b)(1) through 503.33(b)(8). The sewage sludge used to derive that material already meets the applicable quality requirements.

The provision authorizing the imposition of the general requirements and management practices after a sewage sludge or material derived from sewage sludge meets the three quality requirements does not apply to sewage sludge sold or given away in a bag or other container for application to the land. As mentioned above, this provision in part allows control over the site where the sewage sludge is applied to be re-established. The underlying assumption for sewage sludge sold or given away in a bag or other container is that there is no direct control over the user of the sewage sludge. It is virtually impossible in the case of a widely distributed sewage sludge that is essentially equivalent to fertilizer to impose controls on the end user of the sewage sludge. When there is no control over the user initially, there is no way to re-establish that control through the imposition of general requirements or management practices. For this reason, the provision concerning re-imposing certain requirements is not applicable in this case.

Special Definitions (Section 503.11)

In this section of the final part 503 regulation, the Agency defines terms used in this subpart. Those terms include: agricultural land, agronomic rate, annual pollutant loading rate, annual whole sludge application rate, bulk sewage sludge, cumulative pollutant loading rate, forest, land application, other container, pasture, public contact site, range land, and reclamation site.

Agricultural land. Agricultural land is land on which a food crop, a feed crop, or a fiber crop is grown. This includes range land and land used as pasture. When the crop grown on the land is not consumed by humans; not produced primarily for consumption by animals; or not a fiber crop, the land on which the crop is grown is not agricultural land.

Range land and pasture are included in the definition of agricultural land because feed crops (e.g., grasses and other types of vegetation) are grown on the land. These crops are consumed by animals that graze on the land.

Agronomic rate. Agronomic rate is defined as the whole sludge application rate designed: (1) to provide the amount of nitrogen needed by the crop or vegetation grown on the land and (2) to minimize the amount of nitrogen in the sewage sludge that passes below the root zone of the crop or vegetation grown on the land to the ground water. A key aspect of this definition is the design of the whole sludge application rate. To design this rate, the nitrogen needs of the crop or vegetation grown on the land, the available nitrogen in the sewage sludge, the soil conditions at the site, and the geology of the site have to be known, among other things.

Agronomic rate is used in the final part 503 regulation to limit the amount of sewage sludge applied to the land to fertilize the crop or vegetation grown on the land. The purpose of limiting the application rate to the agronomic rate is to minimize contamination of the ground water beneath the application site by the nitrogen in the sewage sludge.

Annual pollutant loading rate. The annual pollutant loading (APLR) is the maximum amount of a pollutant that can be applied to a unit area of land during a 365-day period. In the final part 503 regulation, this rate is calculated by dividing the cumulative pollutant loading rate for an inorganic pollutant by 20 years. This is discussed further below.

Annual whole sludge application rate. The annual whole sludge application rate (AWSAR) is the maximum amount of sewage sludge on a dry weight basis that can be applied to a unit area of land during a 365-day period. This rate is for the whole sludge and not just for a single pollutant. An explanation of how to calculate an annual whole sludge application rate is in appendix A of the final regulation.

Bulk sewage sludge. Bulk sewage sludge is sewage sludge that is not sold or given away in a bag or other container for application to the land. This definition is included in the final part 503 regulation because the requirements in this subpart differ for bulk sewage sludge and for sewage sludge sold or given away in a bag or other container for application to the land.

Cumulative pollutant loading rate. A cumulative pollutant loading rate is the maximum amount of an inorganic pollutant that can be applied to an area of land. This loading rate is not an annual rate. Rather, it is the maximum amount of an inorganic pollutant that can be applied to an area of land. When the cumulative pollutant loading rate for a pollutant is reached for a particular land application site, no more of that pollutant can be applied to the site in bulk sewage sludge.

Forest. Forest is a tract of land thick with trees and underbrush. A forest includes, but is not limited to, land used for silviculture purposes and unmanaged land thick with indigenous vegetation.

Land application. Land application is the spraying or spreading of sewage sludge onto the land surface; the injection of sewage sludge below the land surface; or the incorporation of sewage sludge into the land so that the

sewage sludge can either condition the soil or fertilize crops or vegetation grown in the soil. One important aspect of this definition is "* * * so that the sewage sludge can condition the soil or fertilize crops or vegetation grown on the land." Sewage sludge is not disposed on the land in this case. Rather, the sewage sludge is used beneficially.

The definition of land application includes such things as using the sewage sludge to grow plants or flowers in a pot and using sewage sludge in the hole where a tree is planted. In such cases, the sewage sludge is used to fertilize the plant or tree even though the sewage sludge is not spread over a large area of land. Sewage sludge used for these purposes must meet the applicable requirements in the land application subpart of the final part 503 regulation.

When the sewage sludge is not used to condition the soil or to fertilize crops or vegetation grown on the land, the sewage sludge is not being land applied. It is being disposed on the land. In that case, the requirements in the subpart on surface disposal in the final part 503 regulation must be met.

Other container. The part 503 regulation differentiates between sewage sludge sold or given away in large quantities to users such as manufacturers of sewage sludge fertilizer products and sewage sold or given away in a bag or other container for direct use by the purchaser or receiver of the sewage sludge. Thus, the part 503 regulation distinguishes between bulk sewage sludge and sewage sludge sold or given away in a bag or other container. An "other container" is either an open or a closed receptacle and may include, but is not limited, to a bucket, a box, a carton, or a vehicle that has a load capacity of one metric ton or less.

An "other container" could be any type of receptacle in which sewage sludge, usually in small amounts, is sold or given away for application to the land. In most cases, the sewage sludge is used to fertilize a lawn or a home garden; to grow flowers in pots; to fertilize the ball of a tree that is planted, or for a similar type use. The sewage sludge usually is not applied to those types of land in several applications in the same year.

The Agency also chose to include in the definition of "other container" a vehicle that has a load capacity of one metric ton or less. The vehicle could be, among other things, a pick-up truck or a trailer pulled by an automobile.

A vehicle load capacity of one metric ton was chosen as the cut-off because of the assumptions EPA used to develop the standards for sewage sludge sold or given away in a bag or other container for application to the land. The Agency assumed that sewage sludge sold or given away is applied to the land in small amounts and that the sewage sludge is not applied to the land in several applications in the year.

EPA considers one metric ton of sewage sludge to be a small amount, particularly considering the types of land on which the Agency concluded that is sold or given away will be applied (i.e., a lawn, a home garden, or a public contract site). In addition, EPA does not believe that a vehicle with a load capacity of one metric ton or less will be used to haul the amount of sewage sludge needed on other types of land (e.g., agricultural land) and that such a vehicle will not be used to make several trips to the same site, particularly for several applications of sewage sludge. Most likely, a vehicle with a load capacity of one metric ton will be used to haul sewage sludge that is applied to a lawn, a home garden, or a public contact site.

Pasture. Pasture is land on which animals feed directly on feed crops such as legumes, grasses, grain stubble, or stover. For the purpose of the final part 503 regulation, pasture is considered agricultural land because a feed crop is grown on the land.

Public contact site. A public contact site is land with a high potential for contact by the public. Included in this type of land are public parks, ball fields, cemeteries, plant nurseries, turf farms, and golf courses. All of these lands have a high potential for contact by the public. This definition is included in part 503 because the final regulation contains specific requirements for sewage sludge applied to a public contact site.

Range land. Range land is open land with indigenous vegetation. This type of land differs from a forest in that range land is more open. Range land has indigenous vegetation, but is not thick with trees and underbrush.

Reclamation site. A reclamation site is drastically disturbed land that is reclaimed using sewage sludge. The drastically disturbed land may be a strip mine, a construction site, or some other land that has been cleared of most of its vegetation. Sewage sludge is applied to the land to help establish vegetation. The sewage sludge provides organic material and nutrients needed for the vegetation to grow.

General Requirements (Section 503.12)

The proposed regulation contained six general requirements for land application of sewage sludge. Two of those general requirements are addressed in the general requirements in the final regulation (i.e., meet the requirements in this subpart when sewage sludge is applied to the land and provide notice and information when the generator of the sewage sludge is not the applier of the sewage sludge), two are management practices in the final regulation (i.e., those concerning threatened and endangered species and application of sewage sludge to flooded, snow-covered, or frozen land), one is now addressed in the frequency of monitoring requirement in the final regulation (i.e., comply with the monitoring requirements), and one was deleted from the final regulation.

The proposed general requirement that was deleted from the final regulation concerns restricting the flow of a base flood, reducing the temporary storage capacity of a floodplain, or posing a hazard to human health, wildlife, or land or water resources because of sewage sludge in the runoff from the base flood. When sewage sludge is applied to the land, it is applied in large amounts over while areas. The sewage sludge is not piled high on the land in a small ares. In this case, the sewage sludge cannot restrict the flow of a base flood or reduce the temporary storage capacity of a floodplain. In addition, pollutant limits in the land application subpart are designed to protect run-off of pollutants into surface waters (i.e., the surface water pathway was evaluated during the land application exposure assessment). For these reasons and because the probability that sewage sludge will be land applied to a 100-year floodplain is low, the Agency concluded that this general requirement is not needed in the final regulation (it would be a management practice if included in the final regulation) to protect public health and the environment when sewage sludge is applied to the land.

There are 10 general requirements for land application of sewage sludge in the final part 503 regulation. The first general requirement is that no person shall apply sewage sludge to the land except in accordance with the requirements in this subpart. This general requirement is an explicit statement of obligation not to violate the requirements in this subpart when sewage sludge is applied to the land.

The second general requirement indicates that no person shall apply bulk sewage sludge subject to the cumulative pollutant loading rates in 503.13(b)(2) to land where any of the cumulative pollutant loading rates have been reached. This general requirement

establishes an explicit requirement not to exceed any of the cumulative pollutant loading rates at a land application site. It does not apply when the sewage sludge meets the pollutant concentrations in 503.13(b)(3).

The third general requirement concerns the application of domestic septage to agricultural land, forest, or a reclamation site. A person may not apply domestic septage to those types of land during a 365-day period when the annual application rate for domestic septage in 503.13(c) has been reached during that period. This general requirement does not apply to a public contact site because the final part 503 regulation prohibits the application of domestic septage to a public contact site at the annual application rate in 503.13(c).

The fourth general requirement concerns providing the concentration of total nitrogen (as N on a dry weight basis) in bulk sewage sludge to the person who applies the bulk sewage sludge to the land. The person who prepares the bulk sewage sludge is required to provide the applier written notification of the nitrogen concentration in the bulk sewage sludge, except for the bulk sewage sludge and bulk material that meet the three quality requirements discussed above. The purpose of this general requirement is to ensure that the person who applies the bulk sewage sludge is aware of the nitrogen concentration in the bulk sewage sludge. Without that concentration, the agronomic rate for the crop grown on the land application site cannot be designed properly.

The fifth general requirement requires any person who applies sewage sludge to the land to obtain the information needed to comply with the part 503 requirements. This general requirement establishes an explicit requirement for the person who applies the sewage sludge to become aware of the requirements (e.g., site restrictions when the sewage sludge meets the less stringent Class B pathogen requirements) that must be met when sewage sludge is applied to the land. This is a logical extension of the part 503 requirements because without the information a person cannot comply with those requirements.

The fifth general requirement also contains more detailed requirements for the applier when the bulk sewage sludge meets the pollutant ceiling concentrations in 503.13(b)(1) and is applied to a site under the cumulative pollutant loading rate concept in 503.13(b)(2). In that case, the applier must contact the permitting authority in the State where the bulk sewage sludge will be applied to determine whether bulk sewage sludge subject to the cumulative pollutant loading rates has been applied to the site since [insert 120 days after the effective date of this part]. Note that the purpose of contacting the permitting authority is to determine whether bulk sewage sludge subject to the above requirements has been applied to the site and not to determine the amount of each pollutant applied to the site in bulk sewage sludge.

When results of the above search indicate that bulk sewage sludge subject to the cumulative pollutant loading rates has not been applied to the site, the cumulative amount of each pollutant in Table 2 of section 503.13 of the final regulation can be applied to the site. In this case, the applier must keep a record of the amount of each pollutant in the bulk sewage sludge applied to the site by the applier.

When results of the above search indicate that bulk sewage sludge subject to the cumulative pollutant loading rates has been applied to the site since [insert 120 days after the effective date of this part], the applier must look for the records of the amount of each pollutant applied to the site in bulk sewage sludge since that date. When those records are available, the applier must use that information to determine the additional amount of each pollutant that can be applied to the site so as not to violate the cumulative pollutant loading rate for the pollutant. In this case, the applier must keep the records of the amount of each pollutant applied previously by other appliers and also must keep a record of the amount of each pollutant in the bulk sewage sludge the applier applies to the site. When the records of the amount of each pollutant applied previously cannot be found, an additional amount of each pollutant cannot be applied to the site in bulk sewage sludge because that may violate the cumulative pollutant loading rate for the pollutant.

One purpose of the last part of the fifth general requirement is to ensure that only the permissible total quantity for each pollutant is applied to a site in bulk sewage sludge after [insert 120 days after the effective date of this part]. Without knowing the previous amounts applied, this requirement cannot be met. Note that the requirements to contact the permitting authority and search for records, if appropriate, apply only when bulk sewage sludge subject to the cumulative pollutant loading rates is applied to the land. These requirements do not apply when the bulk sewage sludge that meets the high quality pollutant concentrations in 503.13(b)(3) is applied to the land.

Another purpose of the last part of the fifth general requirement is to prevent two people from applying bulk sewage sludge to the same site without either person knowing the amount of each pollutant listed in Table 2 of section 503.13 that the other person applies to the site in bulk sewage sludge. Under this general requirement, all persons who apply bulk sewage sludge subject to cumulative pollutant loading rates to a site must contact the permitting authority to determine whether bulk sewage sludge subject to that requirement has been applied to a site since [insert 120 days after the effective date of this part].

In the proposed regulation, EPA included requirements for the owner/operator of a treatment works to keep records of the amount of inorganic pollutants applied to each site (54 FR 5745 at 5895). The purpose of that requirement was to ensure that the cumulative pollutant loading rates were not violated at each land application site. The final regulation has the same requirement for the same reason: To ensure no violation of the cumulative pollutant loading rates.

In the final regulation, EPA extended the requirements to keep records of the amount of pollutants applied to a site in bulk sewage sludge to landowners who apply the bulk sewage sludge. This is a logical extension of the need for recordkeeping to prevent violations of the cumulative pollutant loading rates. The availability of the records to new owners of the land (or the prohibition on the application of bulk sewage sludge to a site in its absence) is a necessary measure to protect against exceeding cumulative pollutant loading rates on land application sites.

The sixth general requirement concerns a person who prepares bulk sewage sludge that is applied to the land by a different person. In this case, the person who prepares the bulk sewage sludge (i.e., the generator of the sewage sludge or the person who derives a material from sewage sludge) must provide notice and necessary information to the person who applies the bulk sewage sludge to the land to comply with the part 503 requirements. An example of the information that should be provided is the site restrictions that have to be met when the sewage sludge meets the less stringent Class B pathogen requirements.

The seventh general requirement, which is similar to the sixth general requirement, addresses the situation where the person who prepares sewage sludge provides the sewage sludge to another person who prepares the sewage

sludge (e.g., the person derives a material from the sewage sludge). In this case, the person who prepares the sewage sludge must provide the receiver of the sewage sludge notice and necessary information to comply with the requirements in this part. An example of when this general requirement applies is when a person receives sewage sludge from more than one person who prepares sewage sludge and then derives a material from the sewage sludges, either through mixing of the bulk sewage sludges or some other operation. In this situation, each person who prepares sewage sludge must provide the person who derives the material information (e.g., information on the quality of the sewage sludge) to comply with the requirements in this subpart.

The eighth general requirement requires the applier of the sewage sludge to provide notice and necessary information to the owner or lease holder of the land on which bulk sewage sludge is applied to comply with the requirements in the land application subpart. The land owner or lease holder has to know about requirements for the land application site (e.g., site restrictions when a sewage sludge meeting the less stringent Class B pathogen requirements is applied to the land and management practices) to ensure that those requirements are met. This general requirement ensures that the owner or lease holder of the land receives that information. It only applies, however, when bulk sewage sludge is applied to the land. It does not apply when sewage sludge sold or given away in a bag or other container for application to the land.

The ninth general requirement addresses a notice that must be provided when bulk sewage sludge, except bulk sewage sludge meeting the high quality requirements discussed above, is transported across State lines for land application in another State. When bulk sewage sludge is generated in one State (the generating State) and transferred to another State (the receiving State), the person who prepares the bulk sewage sludge must notify the permitting authority in the receiving State in which the bulk sewage sludge is proposed to be applied. The permitting authority for the receiving State is the EPA Regional Administrator or the State Director of the receiving State when that State has an approved sewage sludge program. Note that there are no approved State sludge programs as of the publication date of part 503.

EPA adopted this requirement so that the permitting authority can determine whether a permit application, or other appropriate oversight, for the land application site is needed. The notice must be given prior to transporting the sewage sludge so that the permitting authority has time to make this determination. Generally, permit applications are not required for land application sites because they are not automatically considered treatment works treating domestic sewage. In a May 2, 1989, notice, EPA stated that "under the Federal program, permits will not be required for owners or operators of land where sludge is beneficially reused such as farm lands and home gardens" (54 FR 18726)). However, the Agency went on to say that Part 122 contains a second part to the definition of treatment works treating domestic sewage that allows the Regional Administrator to designate a facility a treatment works treating domestic sewage "where necessary to protect public health and the environment from poor sludge quality, use, handling, or disposal practices, or to ensure compliance with 40 CFR part 503" (54 FR 18726)). To determine whether a permit, or other appropriate oversight is necessary, the permitting authority must first know that sewage sludge will be applied to a site.

In the proposed regulation, EPA required that the owner/operator of the treatment works to keep the location of the land application site and to submit the location to the permitting authority (54 FR 5745 at 5895). The requirement in this general requirement to notify the permitting authority when sewage sludge is applied to land in a State other than in the State where it is prepared and to provide the permitting authority the location of the land application site is a logical outgrowth of the proposed requirement to provide the permitting authority the location of the land application site.

The notice required by this general requirement is a one-time notification for each applier to any particular land application site. The notice includes information on the approximate time period sewage sludge will be applied to the site to preserve some flexibility as to exactly when sewage sludge will be applied to the site and to allow multiple applications to the same site over a period of time without requiring a separate notice for each application.

In addition to the approximate time period sewage sludge will be applied to a site, the notice must include the location of the site and information on both the person who prepares the bulk sewage sludge and the person who will apply the bulk sewage sludge. The permitting authority may request additional information or a full permit application as noted above. EPA does not expect that many permits will be issued to these land application sites. This notice requirement provides the permitting authority the flexibility to impose additional requirements, if needed, and to ensure compliance with part 503.

The last general requirement also addresses a notice that must be provided. When bulk sewage sludge subject to the cumulative pollutant loading rates is applied to the land, the person who applies the bulk sewage sludge must notify the permitting authority for the State in which the bulk sewage sludge will be applied. This must be done prior to the initial application of bulk sewage sludge to a site by each applier. The purpose of this general requirement is to ensure that a record is kept of the sites where sewage sludge subject to the cumulative pollutant loading rates is applied. Without that information, there is no way for a person who intends to apply bulk sewage sludge to know whether bulk sewage sludge has been applied to a site previously. When it is not known whether bulk sewage sludge subject to cumulative pollutant loading rates has been applied to a site, the cumulative pollutant loading rates in 503.13(b)(2) cannot be enforced. Note that this notice only provides information about whether bulk sewage sludge has been applied to a site. It does not include the amount of each pollutant applied to a site in bulk sewage sludge. Once the person who proposes to apply the bulk sewage sludge determines that bulk sewage sludge subject to cumulative pollutant loading rates has been applied to the site, that person must then contact the previous appliers to determine the amount of each pollutant applied to the site previously in bulk sewage sludge.

The notice required by the last general requirement also is a one-time notice for a land application site for each applier. Information that must be provided in the notice includes the location of the land application site and the name, address, telephone number, and National Pollutant Discharge Elimination System permit number, if appropriate, of the person who will apply the bulk sewage sludge.

Pollutant Limits (Section 503.13)

The final part 503 regulation contains ceiling concentration (Table 1), cumulative pollutant loading rates (Table 2), pollutant concentrations (Table 3), and annual pollutant loading rates (Table 4). Any sewage sludge that does not meet the ceiling concentrations

in Table 1 cannot be applied to the land. Other pollutant limits also are included in 503.13 for bulk sewage sludge and for sewage sludge sold or given away in a bag or other container. Bulk sewage sludge that is applied to the land is subject to cumulative pollutant loading rates if the sewage sludge does not meet the pollutant concentrations for high quality sewage sludge. Sewage sludge sold or given away in a bag or other container is subject to annual pollutant loading rates if it does not meet the pollutant concentrations for high quality sewage sludges.

Ceiling concentrations are included in the final part 503 regulation because EPA is concerned about the potential impact of a "dirty" sewage sludge on public health and the environment (e.g., phytotoxicity to plants). As mentioned above, if the pollutant concentrations in sewage sludge exceed the ceiling concentrations, sewage sludge cannot be applied to the land.

The ceiling concentrations in Table 1 are the less stringent of two values. They are the concentrations calculated using the cumulative pollutant loading rules from the land application exposure assessment, an assumed 100-year site life, and an assumed annual whole sludge application rate of 10 metric tons per year or the 99th percentile concentration from the National Sewage Sludge Survey (NSSS), whichever is less stringent. EPA concluded that when the pollutant concentrations in the sewage sludge do not exceed the ceiling concentrations, the potential for short-term impacts on the environment from land application of the sewage sludge are reduced greatly.

The final part 503 regulation contains two pollutant limits for bulk sewage sludge applied to the land. The first limit for bulk sewage sludge applied to the land consists of cumulative pollutant loading rates. A cumulative pollutant loading rate is the cumulative amount of an inorganic pollutant that can be applied to an area of land. Cumulative pollutant loading rates must be met when bulk sewage sludge that does not meet the pollutant concentrations for high quality sewage sludge is applied to the land.

The final part 503 regulation requires that the cumulative amount of each pollutant listed in Table 2 of section 503.13 from bulk sewage sludge applied to the land shall not exceed the cumulative pollutant loading rate for the pollutant in Table 2. To comply with this requirement, the amount of each pollutant in the bulk sewage sludge applied to a site must be known. Records have to be kept of the amount of each pollutant applied to each site. When the cumulative pollutant loading rate for any of the pollutants in Table 2 of section 503.13 is reached for a site, no more bulk sewage sludge may be applied to that site. The ceiling concentrations and cumulative pollutant loading rates may be met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

The following procedure can be used to estimate site life for a bulk sewage sludge with a particular quality and for a certain annual whole sludge application rate (AWSAR) when the cumulative pollutant loading rates are met. When either the quality of the bulk sewage sludge or the AWSAR changes, the site life for the land also changes.

Procedure

1. Measure the concentration of arsenic, cadmium, chromium, copper, lead, mercury, molybdenum, nickel, selenium, and zinc in the bulk sewage sludge.

2. Determine the AWSAR for the bulk sewage sludge. Usually, the AWSAR is equal to the agronomic rate for the bulk sewage sludge.

3. Calculate an annual pollutant loading rate (APLR) for each inorganic pollutant using equation (1) below.

$$APLR = C \times AWSAR \times 0.001 \quad (1)$$

Where:

APLR=Annual pollutant loading rate for an inorganic pollutant in kilograms-pollutant per hectare per 365-day period.

C=Measured pollutant concentration in the bulk sewage sludge in milligrams-pollutant per kilogram of total solids (dry weight basis).

AWSAR=Annual whole sludge application rate in metric tons-sewage sludge per hectare per 365-day period (dry weight basis).

0.001=A conversion factor.

4. Calculate the years an inorganic pollutant can be applied to the land by dividing the cumulative pollutant loading rate in Table 2 of the final regulation by the APLR calculated from Step 3 of this procedure.

5. Determine the lowest number of years calculated in Step 4 of this procedure. This is the period that this bulk sewage sludge can be applied to the land without causing any of the cumulative pollutant loading rates in Table 2 of section 503.13 to be exceeded.

6. This procedure is used only to estimate the number of years a bulk sewage sludge can be applied to a site. This estimate changes when the inorganic pollutant concentrations in the bulk sewage sludge change or when the annual whole sludge application rate changes.

EXAMPLE:

Given:

• Step 1—Pollutant concentrations in bulk sewage sludge (dry weight basis):

Pollutant	Concentration (mg/kg)
Arsenic	10
Cadmium	7
Chromium	850
Copper	741
Lead	134
Mercury	5
Molybdenum	9
Nickel	42
Selenium	5
Zinc	1201

• Step 2—Assume the annual whole sludge application rate for the bulk sewage sludge is 10 MT/ha/365 day period base on agronomic requirements.

• Step 3—Calculate the annual pollutant loading rates for the pollutants using equation (1):

Pollutant	Concentration (mg/kg)	APLR (kg/ha)
Arsenic	10	0.10
Cadmium	7	0.07
Chromium	850	8.50
Copper	741	7.40
Lead	134	1.30
Mercury	5	0.05
Molybdenum	9	0.09
Nickel	42	0.42
Selenium	5	0.05
Zinc	1201	12.00

• Step 4—Calculate the years an inorganic pollutant can be applied to the land:

Pollutant	CPLR (kg/ha)	APLR (kg/ha/yr)	Years (CPLR/APLR)
Arsenic	41	0.10	410
Cadmium	39	0.07	557
Chromium	3000	8.5	353
Copper	1500	7.4	202
Lead	300	1.3	231
Mercury	17	0.05	340
Molybdenum	18	0.09	200
Nickel	420	0.42	1000
Selenium	100	0.05	2000
Zinc	2800	12.0	233

• Step 5—Determine the lowest number of years calculated in Step 4:

For this example, the lowest number of years is 200 for molybdenum. Bulk sewage sludge with the inorganic pollutant concentrations given in Step 1 of this procedure can be applied to the land at an AWSAR of 10 MT/ha for 200 years. After that period, the cumulative pollutant loading rate for molybdenum is exceeded.

The values for the cumulative pollutant loading rates in the final part 503 regulation are different from the values for those rates in the proposal. They are different because values for the input parameters for the models used in the exposure assessment to develop the loading rates were updated using information received during the public comment period on the proposal and other information obtained subsequent

to the proposal. This is discussed in more detail in the land application technical support document.

The second pollutant limit for bulk sewage sludge consists of pollutant concentrations in Table 3 of section 503.13 that designate high quality sewage sludges. These concentrations were called "alternative pollutant limits (APL)" in the November 1990 National Sewage Sludge Survey notice (55 FR 47210, November 9, 1990). The Agency chose not to call the pollutant concentrations "alternative pollutant limits" in the final part 503 regulation because the other pollutant limits in the land application subpart (i.e., cumulative pollutant loading rates) also are alternative limits. Any of the alternative pollutant limits can be met when bulk sewage sludge is applied to the land. The APLs in the 1990 notice are called pollutant concentrations in the final part 503 regulation.

To develop the pollutant concentrations in Table 3 of section 503.13, the cumulative pollutant loading rates for inorganic pollutants established in the land application exposure assessment were converted to annual pollutant loading rates. Next, the calculated annual pollutant loading rates and an assumed annual whole sludge application rate (AWSAR) were used in the following equation to calculate a pollutant concentration:

$$C = \frac{APLR}{AWSAR \times 0.001} \quad (1)$$

Where:

C=pollutant concentration in mg/kg (dry weight basis).

APLR=annual pollutant loading rate in kg-pollutant/hectare/365 day period.

AWSAR=annual whole sludge application rate in metric tons/hectare/365 day period (dry weight basis).

0.001=a conversion factor.

Finally, the pollutant concentrations calculated using equation (1) were compared to the 99th percentile concentration values for the pollutants from the NSSS. The pollutant concentrations in Table 3 of section 503.13 are either the concentration calculated using equation (1) or the 99th percentile concentration, whichever is more stringent. The rationale for the use of the 99th percentile concentration is presented in part VII of today's preamble.

To convert the cumulative pollutant loading rates for inorganic pollutants to annual pollutant loading rates, the Agency assumed that the life of the site where the bulk sewage sludge is applied is 100 years. Annual pollutant loading rates were calculated by dividing the cumulative pollutant loading rates in Table 2 of section 503.13 by 100 years. EPA concluded that using a site life of 100 years is conservative because bulk sewage sludge most likely will not be applied to a site for 100 years, particularly 100 years in a row.

For the purpose of calculating the pollutant concentrations using equation (1), EPA also assumed that the AWSAR is 10 metric tons/hectare/365 day period. This rate is a conservative application rate for agricultural land based on nitrogen requirements of the crop and the nitrogen concentration in the sewage sludge.

Because the annual whole application rates for other types of land differ from the assumed rate for agricultural land, the Agency estimated the site life for the other types of land using the pollutants concentrations in Table 3 of section 503.13 and the different AWSARs in equation (1) above. An annual whole sludge application rate of 26, 18, and 74 metric tons/hectare/365 day period was used for forest, a public contact site, and a reclamation site, respectively. These rates were obtained from the NSSS.

The estimated site lives for a forest, a public contact site, and a reclamation site calculated using the above AWSARs, the pollutant concentration from Table 3 of section 503.13, and the cumulative pollutant loading rates from Table 2 of section 503.13 (i.e., cumulative pollutant loading rate divided by site life) in equation (1) are 38 years, 55 years, and 13 years, respectively. This means that when the pollutant concentrations in the sewage sludge are equal to or less than the concentrations in Table 3 of section 503.13 bulk sewage sludge can be applied to the different types of land at the above application for the above years without causing any of the cumulative pollutant loading rates in Table 2 of section 503.13 to be exceeded. The Agency concluded that it is unlikely that bulk sewage sludge will be applied to a forest for 38 years, to a public contact for 55 years, or to a reclamation site for 13 years. EPA also concluded that bulk sewage sludge will not be applied to those types of land at substantially higher application rates than 26, 18, and 74 metric tons/per hectare/365 day period for a forest, a public contact site, or a reclamation site, respectively, because of the management practice in the land application subpart that requires the sewage sludge to be applied to the land at a rate that is equal to or less than the agronomic rate.

Another reason a 13 year site life for a reclamation site is conservative is that 13 years are not needed to reclaim a site. Available information indicates that, at most, three or four years are needed to reclaim land. This does not mean that sewage sludge cannot be applied to the land after three or four years. It means that after that period, the land is no longer a reclamation site. It becomes a different type of land (e.g., agricultural land). In that case, the part 503 requirements for the other type of land have to be met when sewage sludge is applied to the land after it is reclaimed.

EPA is applying the 99th percentile concentration "cap" to designate high quality sewage sludges because certain parts of the land application subpart (i.e., general conditions and management practices) do not apply when the sewage sludge meets the pollutant concentrations and other requirements. This is the case when the sewage sludge meets the pollutant concentrations in Table 3 of section 503.13, the more stringent Class A pathogen requirements, and one of the appropriate vector attraction requirements.

Using the above approach, the concentration values for three of the pollutants in Table 3 of section 503.13 (i.e., chromium, nickel, and selenium) are "capped" at the 99th percentile value. Concentration values for the other pollutants in Table 3 of section 503.13 are the values for those pollutants calculated using equation (1).

The calculated annual pollutant loading rates for the inorganic pollutants based on a 100 year site life protect public health and the environment from reasonably anticipated adverse effects of pollutants in sewage sludge because they are derived from cumulative pollutant loading rates that provide the same protection. Pollutant concentrations (i.e., the values in Table 3 of section 503.13) based on the calculated annual pollutant loading rates provide equal protection to public health and the environment. In the case of the pollutant concentrations that are "capped", public health and the environment also are protected because those concentrations are more stringent than the pollutant concentrations calculated using equation (1).

Because the pollutant concentrations in Table 3 of section 503.13 are based on conservative site lives and typical AWSARs, the Agency concluded that records do not have to be kept of the amount of each inorganic pollutant in the bulk sewage sludge applied to a site. It is unlikely that any of the cumulative pollutant loading rates in Table 2 of section 503.13 will be exceeded at a site when the bulk sewage sludge applied to

the site meets the pollutant concentrations in Table 3 of section 503.13. The pollutant concentrations in Table 3 of section 503.13 are monthly average concentrations. The monthly average concentration of the pollutant in the sewage sludge that is applied to the land cannot exceed the value for the pollutant in Table 3 of section 503.13.

The Agency considered allowing site-specific cumulative pollutant loading rates to be developed for land application of bulk sewage sludge but decided not to allow that type of pollutant limit for several reasons. First, to develop site-specific cumulative pollutant loading rates, a site-specific exposure assessment has to be conducted. For many of the pathways in the exposure assessment, the terms in the algorithm used to calculate the allowable loading rate are based on policy decisions (e.g., the RfD for a pollutant and the soil ingestion rate). EPA does not believe that values for those terms should be changed in a site-specific assessment. For this reason, when the limiting cumulative pollutant loading rate for a pollutant is based on a pathway for which the algorithm only contains terms based on a policy decision, a site-specific cumulative pollutant loading rate could not be calculated for that pollutant. This is the case for four of the 10 inorganic pollutants for which cumulative pollutant loading rates are included in the land application subpart.

Another reason is the information that must be developed to conduct a site-specific pathway risk assessment. This includes, among other things, pollutant uptake slopes for each crop grown on each site, information on the uptake of a pollutant by a grazing animal for each application site, and variables for the ground-water pathway (e.g., depth to ground water) for each application site. Much of this information is difficult and expensive to obtain, particularly for every land application site.

A third reason the Agency decided not to allow site-specific cumulative pollutant loading rates is that site-specific cumulative pollutant loading rates have to be developed for each land application site. A person who prepares sewage sludge does not just develop one set of site-specific cumulative pollutant loading rates and use those rates for all application sites. Instead, a different site-specific cumulative pollutant loading rate has to be developed for each site. Considering the information that has to be developed to conduct site-specific exposure assessment and the cost to obtain that information, the Agency concluded that it is not feasible to conduct such an assessment for each application site.

The final part 503 regulation also contains two pollutant limits for sewage sludge sold or given away in a bag or other container for application to the land. The first group is the pollutant concentrations designating high quality sewage sludge in Table 3 of section 503.13. If the concentration of any pollutant listed in Table 3 of section 503.13 in the sewage sludge sold or given away in a bag or other container for application to the land exceeds the concentration for the pollutant in Table 3 of section 503.13, the annual pollutant loading rates have to be met.

The annual pollutant loading rates for sewage sludge sold or given away in a bag or other container are presented in Table 4 of section 503.13. The final rule requires that the product of the concentration for each pollutant listed in Table 4 of section 503.13 in sewage sludge sold or given away in a bag or other container for application to the land and the annual whole sludge application rate for the sewage sludge not cause the annual pollutant loading rate for the pollutant in Table 4 of section 503.13 to be exceeded. The procedure used to determine the annual whole sludge application rate for a sewage sludge that does not cause any of the annual pollutant loading rates in Table 4 to be exceeded is presented in appendix A of the final part 503 regulation.

The person who prepares sewage sludge that is sold or given away in a bag or other container has to determine the rate at which the sewage sludge may be applied to the land and not violate any of the cumulative pollutant loading rates in Table 2 of section 503.13. EPA has simplified that decision by calculating an annual pollutant loading rate for each pollutant using conservative assumptions, as discussed below. Using the procedure in appendix A, the person who prepares the sewage sludge calculates the rate that does not cause any of the annual pollutant loading rates in Table 4 of section 503.13 to be exceeded and places that rate on a label or information sheet.

The annual pollutant loading rates in Table 4 of section 503.13 were calculated using the cumulative pollutant loading rates in Table 2 of section 503.13 and an assumed site life of 20 years for the land where the sewage sludge is applied. The Agency concluded that 20 years is a conservative assumption because most likely sewage sludge sold or given away in a bag or other container will be applied to a lawn, a home garden, or a public contact site. EPA does not believe sewage sludge will be applied to those types of land for longer than 20 years, particularly 20 years in a row.

The annual pollutant loading rates in Table 4 of section 503.13 protect public health and the environment from the reasonably anticipated adverse effect of the pollutants in sewage sludge because they are calculated using the cumulative pollutant loading rates in Table 2 of section 503.13. The cumulative pollutant loading rates in Table 2 of section 503.13 are based on the results of the land application exposure assessment.

The final part 503 regulation contains a separate pollutant limit for domestic septage applied to agricultural land, forest, or a reclamation site. This requirement is an annual application rate.

The annual application rate for domestic septage is related to the amount of nitrogen needed by the crop grown on the application site by the following equation:

$$N = ANC \times AAR \times 8.34 \quad (2)$$

Where:

N=pounds of nitrogen needed by the crop per acre per 365 day period.
ANC=available nitrogen concentration in milligrams per liter.
AAR=annual application rate in million gallons per acre per year.
8.34=a conversion factor.

Rearranging equation (2) to solve for the annual application rate results in the following equation:

$$AAR = \frac{N}{ANC \times 8.34} \quad (3)$$

The part 503 regulation requires that the allowable annual application rate for a site be calculated using the following equation, which is equation (3) with a value substituted for ANC×8.34:

$$AAR = \frac{N}{0.0026} \quad (4)$$

The amount of nitrogen, N, needed depends on the crop grown on the land. Values for the amount of nitrogen needed by crops may be obtained from various sources (e.g., Agricultural Extension Services). Once the value for the crop grown on the land is known, that value is divided by 0.0026 to obtain the allowable annual application for a particular site. The amount of nitrogen needed could vary from year-to-year depending on the type of crop grown on the land.

As mentioned above, 0.0026 in equation (4) is the product of an

available nitrogen concentration and a conversion factor (i.e., 8.34/1,000,000). This concentration was calculated using values for Total Kjeldahl Nitrogen (TKN) and ammonia-N in domestic septage obtained from the results of the analysis of nine samples of domestic septage collected in Madison, Wisconsin. In addition, the following assumptions were made to calculate the available nitrogen concentrations:

- Domestic septage is applied to a site every year.
- The domestic septage is injected below the land surface.
- None of the ammonia-N in the domestic septage is lost through volatilization.
- Most of the organic nitrogen (i.e., TKN—ammonia) in the domestic septage becomes available over a three year period. Fifty percent is available the year domestic septage is applied to the land, 20 percent is available in the second year, and 10 percent is available in the third. The remaining organic-N, which was assumed to become available at three percent per year until no more organic-N remains, was not considered in the calculation of the available nitrogen concentration.
- "Steady state" conditions are achieved with respect to the available nitrogen concentration in the third year after application of the domestic septage.

Details for the calculation of the available nitrogen concentration used to calculate the 0.0026 value in equation (4) and the justification that the annual application rate for domestic septage protects public health and the environment from the reasonably anticipated adverse effects of pollutants in domestic septage are presented in the technical support document for the part 503 land application requirements.

EPA chose to limit the annual application rate to domestic septage for two reasons. First, available data indicate that domestic septage has pollutant concentrations that are lower than the pollutant concentrations in commercial/industrial septage (e.g., grease from grease traps). Second, the concentrations in commercial/industrial septage vary greatly. The higher pollutant concentrations and the variability of those concentrations requires that samples of commercial/industrial septage be analyzed periodically to determine the quality of the commercial/industrial septage prior to use or disposal. For these reasons, the annual application rate limit for domestic septage is not appropriate for commercial/industrial septage.

EPA also chose to allow the annual application rate to be used only when domestic septage is applied to agricultural land, forest, or a reclamation site because certain site restrictions are imposed on the site where the domestic septage is applied. EPA's determination is based on the assumption that the applier has control over the application site. Because of the difficulty of imposing site restrictions on a public contact site, a lawn, or a home garden, the Agency is prohibiting the application of domestic septage to a public contact site, a lawn, or a home garden at an annual application rate.

Management Practices (Section 503.14)

Two of the management practices for land application of bulk sewage sludge in the proposed part 503 regulation were deleted from the final part 503 regulation. One of those management practices concerned the limit on the annual amount of bulk sewage sludge that can be applied (i.e., 50 metric tons per hectare). The 50 metric ton per hectare restriction was included in the proposal because the exposure assessment models used to develop the annual pollutant loading rates could not be used for an annual whole sludge application rate greater than 50 metric tons per hectare. Subsequent to the proposal, the models were changed so that application rates greater than 50 metric tons per hectare can be used and protection of public health and the environment is still ensured. For this reason, the 50 metric ton per hectare restriction is no longer needed.

The second management practice no longer found in the land application subpart of the final part 503 regulation concerns crop and access restrictions for pathogen reduction. Those restrictions are now included in subpart D of the final part 503 regulation, which addresses both pathogen and vector attraction reduction.

The following management practices are included in the final part 503 regulation and apply when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site. These management practices do not apply when bulk sewage sludge is applied to a lawn or a home garden because EPA determined that large amounts of bulk sewage sludge will not be applied to a lawn or a home garden for several applications. For this reason, the Agency concluded the management practices are not needed to protect public health and the environment when bulk sewage sludge is applied to a lawn or a home garden. Moreover, the pollutant limits already ensure a high degree of protection. Further, the management practices in many cases have no relevance in a lawn or home garden setting. The following discussion explains the management practices EPA requires when bulk sewage sludge is applied to other than lawns or home gardens.

Part 503 requires that application of sewage sludge to the land is prohibited if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat (§ 503.14(a)). EPA will develop guidance to carry out this provision consistent with the Endangered Species Act.

Bulk sewage sludge cannot be applied to agricultural land, forest, a public contact site, or a reclamation site that is flooded, frozen, or snow-covered so that the bulk sewage sludge enters a wetland or other waters of the United States, except as provided in a permit issued pursuant to section 402 or section 404 of the Clean Water Act, as amended. This provision codifies the prohibition in section 405(a) that prohibits disposal of sewage sludge that results in pollutants in the sewage sludge entering navigable waters. This management practice does not prohibit the application of bulk sewage sludge to flooded, frozen, or snow-covered land in all cases. It only prohibits application of bulk sewage sludge to flooded, frozen, or snow-covered land when the bulk sewage sludge enters a wetland or other waters of the United States, except as provided in a section 402 or section 404 permit. EPA did not calculate pollutant limits in this subpart that protect waters of the United States from runoff from flooded, frozen, or snow-covered land on which bulk sewage sludge is applied The Agency's assessment did not model that scenario. Instead, that protection is provided through this management practice.

Section 301 of the CWA includes a prohibition against the discharge of pollutants into wetlands or other waters of the United States, unless in compliance with relevant provisions of the CWA. As mentioned above, section 405(a) of the CWA specifically prohibits discharge of pollutants in sewage sludge into navigable water, except in compliance with a permit issued under section 402. Most point source discharges of dredged or fill material into waters of the United States must be authorized by a permit issued by the U.S. Army Corps of Engineers (COE) under section 404. Other point source discharges of pollutants into waters of the United States must be authorized by a permit issued by EPA or a delegated State under section 402.

At times, it may be difficult to determine whether a particular

pollutant constitutes "fill" material subject to section 404 or a waste product more appropriately regulated under section 402. To provide guidance on this issue, EPA and the COE signed a Memorandum of Agreement Concerning Regulation of Discharges of Solid Waste Under the Clean Water Act (MOA) in 1986 (51 FR 8871, March 14, 1986). For additional guidance on this issue, contact the appropriate EPA Regional wetlands representative.

Another management practice in the land application subpart requires that bulk sewage sludge be applied to the agricultural land, forest, or a public contact site at a rate that does not exceed an agronomic rate. This requirement also applies to a reclamation site, unless the permitting authority authorizes larger amounts of bulk sewage sludge to be applied to a reclamation site.

An agronomic rate is the whole sludge application rate for a bulk sewage sludge designed: (1) To provide the amount of nitrogen needed by the crop or vegetation grown on the land and (2) to minimize the amount of nitrogen in the bulk sewage sludge that passes below the root zone for the crop or vegetation grown on the land to the ground water. The key to the definition is the design of the whole sludge application rate.

Several factors must be considered to design an agronomic rate for a land application site. These include, but are not limited to, the amount of nitrogen needed by the crop or vegetation grown on the land; the amount of organic nitrogen from previous applications of nitrogen-containing materials that becomes available each year; the type of soil at the site; and the geologic conditions of the site. As previously mentioned, the regulation includes a general requirement that requires information needed to determine the agronomic rate be provided to the appropriate person.

Note that the agronomic rate is designed to minimize the amount of nitrogen that passes below the root zone of the crop or vegetation grown on the land to the ground water. This recognizes that some of the nitrogen in the bulk sewage sludge may reach the ground water. However, the Agency concluded that by designing the rate to minimize that amount, long-term contamination of the ground water is not reasonably likely to occur because substantially all of the nitrogen is taken up by the crop or vegetation grown on the land.

The final part 503 regulation also contains one management practice for sewage sludge sold or given away in a bag or other container for application to the land. This management practice requires labelling of the bag or other container in which the sewage sludge is sold or given away or that an information sheet be provided to the person who receives the sewage sludge that is sold or given away in another container. The label or information sheet must contain the name and address of the person who prepares the sewage sludge that is sold or given away, a statement that prohibits application of the sewage sludge to the land except in accordance with the instructions on the label or information sheet, and the application rate for the sewage sludge. The requirements for the label or information sheet are minimum requirements. The person who prepares sewage sludge that is sold or given away in a bag or other container may include additional information on the label or information sheet (e.g., information required by a state or local government).

Operational Standard—Pathogens and Vector Attraction Reduction (Section 503.15)

This section indicates the class of pathogen reduction a sewage sludge must meet when applied to a certain type of land, the pathogen requirements that must be met when domestic septage is applied to agricultural land, a forest, or a reclamation site, and the alternative vector attraction reduction requirements that can be met when sewage sludge is applied to the land. The description of the different pathogen and vector attraction reduction requirements is presented in subpart D of the final part 503 regulation.

The final part 503 regulation requires that bulk sewage sludge applied to agricultural land, forest, a public contact site, or a reclamation site meet either the Class A pathogen requirements or the Class B pathogen requirements. When the sewage sludge is Class B with respect to pathogens, restrictions (e.g., growing of root crops) are imposed on the site where the sewage sludge is applied. Under this approach, the sewage sludge can be treated to reduce pathogens (Class A) or a combination of treatment and environmental attenuation (i.e. Class B with site restrictions) can be used to reduce pathogens. In the judgment of the Administrator of EPA, in either case public health and the environment are protected against the reasonably anticipated adverse effects of pathogens in sewage sludge that is applied to the land.

Bulk sewage sludge applied to a lawn or a home garden must meet the Class A pathogen requirements. The reason for this requirement is that it is not feasible to impose site restrictions on a lawn or a home garden on which bulk sewage sludge is applied. In lieu of having to impose site restrictions, which would be needed if the bulk sewage sludge only meets the Class B pathogen requirements, the bulk sewage sludge has to meet the Class A pathogen requirements. Sewage sludge sold or given away in a bag or other container for application also must meet the Class A pathogen requirements for the same reasons.

When domestic septage is applied to agricultural land, forest, or a reclamation site, either site restrictions (i.e., the same site restrictions that must be met when a Class B sewage sludge is applied to the land) must be met or a pH requirement for the domestic septage has to be met along with site restrictions concerning the harvesting of crops. The first requirement relies on the environment to reduce pathogens during the time that certain activities on the site are restricted. These restrictions prohibit harvesting of crops, grazing of animals, and public access to the site for a certain period. The second requirement relies on treatment of the domestic septage (i.e., pH adjustment) and restrictions on harvesting crops to reduce pathogens. Restrictions on harvesting of crops are part of the second requirement because the Agency does not believe adequate pathogen reduction is achieved by pH adjustment to allow crops to be harvested immediately after applying the domestic septage. These provisions are consistent with the provisions currently in 40 CFR part 257 (Criteria for Classification of Solid Waste Disposal Facilities and Practices) for septic tank pumpings applied to the land.

One of 10 vector attraction reduction requirements also must be met when bulk sewage sludge is applied to the agricultural land, forest, a public contact site, or a reclamation site. These requirements are designed to reduce the characteristics of the sewage sludge that attract vectors such as rats, mosquitos, and flies. In the judgment of the EPA, any of the 10 alternative vector attraction requirements protect public health and the environment from the reasonably anticipated adverse effects of the characteristics in sewage sludge that attract vectors. Note that the vector attraction requirement is in addition to the pathogen requirement discussed above. Both requirements must be met.

One of the first eight vector attraction reduction requirements for bulk sewage sludge applied to agricultural land, forest, a public contact site, or a reclamation site must be met when bulk

sewage sludge is applied to a lawn or a home garden. Injection of sewage sludge below the land surface and incorporation sewage sludge into the soil cannot be used to achieve vector attraction reduction in these cases. Implementation of these requirements for bulk sewage sludge applied to a lawn or a home garden would be difficult, if not impossible. For this reason, these alternative are not available for achieving vector attraction reduction when bulk sewage sludge applied to a lawn or a home garden.

One of the first eight vector attraction reduction requirements for bulk sewage sludge applied to agricultural land, forest, a public contact site, or a reclamation site also must be met when sewage sludge is sold or given away in a bag or other container for application to the land. Again, in this situation it is not feasible to inject the sewage sludge below the land surface or to incorporate the sewage sludge into the soil.

Vector attraction reduction is achieved when domestic septage is applied to agricultural land, forest, or a reclamation site when the domestic septage is injected below the surface of the land, incorporated into the soil after being applied to the land surface, or the pH of the domestic septage is raised to 12 or higher and remains at 12 or higher for 30 minutes. When vector attraction reduction is achieved by raising the pH of the domestic septage, each container (e.g., each tank truck load) of domestic septage that is applied to the land must be monitored to demonstrate compliance with that requirement. Again, these provisions are consistent with those for septic tank pumpings in 40 CFR part 257.

Frequency of Monitoring (Section 503.16)

The final part 503 regulation contains the frequency of monitoring requirements for pollutant concentrations in sewage sludge and for compliance with the pathogen density and certain vector attraction reduction requirements. Frequency of monitoring requirements, which also are included in the subparts on surface disposal and incineration, are needed to make the part 503 regulation self-implementing.

The frequency of monitoring requirements in this subpart for pollutant concentrations, pathogen density requirements, and vector attraction reduction requirements vary with the amount of bulk sewage sludge used or disposed annually. In the case of sewage sludge sold or given away in a bag or other container for application to the land, the frequency of monitoring requirements are based on the amount of sewage sludge received by the person who prepares the sewage sludge that is sold or given away in a bag or other container.

The amount of sewage sludge used or disposed was chosen as the unit of measurement on which the frequency of monitoring is based because the requirements in the final part 503 regulation apply to sewage sludge that is used or disposed. The amounts in the frequency table are based on dry weight because all of the pollutant limits in the final part 503 regulation are on a dry weight basis.

Before the derivation of the frequencies of monitoring is discussed, one other aspect of the frequencies needs to be addressed. This concerns the lowest range for the frequencies of monitoring (i.e., greater than zero but less than 290 metric tons per 365-day period). This range indicates that when sewage sludge is not used or disposed during a 365-day period, the sewage sludge does not have to be monitored for the requirements in the part 503 regulation. The sewage sludge must be monitored only when an amount is used or disposed.

The amount of sewage sludge used or disposed in the frequency of monitoring requirements is related to the flow rate for the treatment works. For example, the range of "greater than 290 metric tons per 365-day period to equal to or less than 1,500 metric tons per 365-day period" corresponds to a wastewater flow rate range of "greater than one MGD to equal to or less than five MGD". The Agency made various assumptions concerning the influent and effluent five-day biochemical oxygen demand and total suspended solids wastewater concentrations; the percent removal for total suspended solids in the primary clarifier; the percent removal of five-day biochemical oxygen demand through secondary treatment; the percent fixed solids in the sewage sludge in the influent to the stabilization process; and the percent volatile solids removed in the sewage sludge stabilization process to calculate the amount of sewage sludge used or disposed. Details of these calculations are presented in the technical support document for the part 503 land application requirements.

The final part 503 regulation allows the permitting authority to reduce the frequency of monitoring for pollutant concentrations and the pathogen density requirements for enteric viruses and viable helminth ova in 503.32(a)(5)(ii) and 503.32(a)(5)(iii), respectively, after monitoring for two years at the frequency in the final part 503 regulation. However, in no case should the frequency of monitoring be less than once per year when sewage sludge is applied to the land. Requiring the sewage sludge to be monitored at least once per year when sewage sludge is applied to the land is consistent with the frequency of monitoring requirement in EPA's state sludge management program requirement regulation (i.e., 40 CFR 501.15(b)(10)).

In deciding whether to reduce the frequency of monitoring, the permitting authority should consider the variability of the pollutant concentrations, the magnitude of the pollutant concentrations, and the frequency of detection of enteric viruses and viable helminth ova in the sewage sludge. The Agency concluded that data collected over a two-year are adequate to calculate the variability of pollutant concentrations and to determine the magnitude of the pollutant concentrations before deciding whether to change the frequency of monitoring.

As mentioned above, the frequency of monitoring for the pathogen density requirements in 503.32(a)(5)(ii) and 503.32(a)(5)(iii) may be reduced. These requirements address enteric viruses and viable helminth ova, respectively, in sewage sludge. As part of those requirements, the sewage sludge must be analyzed for enteric viruses and viable helminth ova every time the sewage sludge is monitored. After those two organisms are found in the influent to the pathogen treatment process and after the required reduction for those organisms is demonstrated through the pathogen treatment process, the sewage sludge does not have to be monitored for enteric viruses and viable helminth ova when values for the process operating parameters are consistent with the documented values for those parameters. Because the costs and complexity of the analytical methods for enteric viruses and viable helminth ova, the Agency decided to allow the permitting authority to judge whether to reduce the frequency of monitoring after monitoring at the frequency in the final part 503 regulation for two years. The Agency concluded that two years of monitoring should provide enough information to make that judgment. Note that the potential reduction in frequency of monitoring applies only to the pathogen density reduction requirements for enteric viruses and viable helminth ova mentioned above. The frequency of monitoring cannot be reduced for the other pathogen density requirements.

The final part 503 regulation requires that every container of domestic septage applied to agricultural land, forest, or a reclamation site be monitored to determine compliance with the pH

adjustment requirement when that requirement is met. Every container (e.g., each tank truck load applied to the land) must be monitored because there is no way to ensure that the domestic septage in each container meets the pH requirement by monitoring domestic septage in only a certain number of containers.

Recordkeeping (Section 503.17)

The final part 503 regulation contains recordkeeping requirements for: (1) Bulk sewage sludge that meets the pollutant concentrations for high quality sewage sludge in 503.13(b)(3), the more stringent Class A pathogen requirements in 503.32(a), and one of vector attraction reduction requirements in 503.33(b)(1) through 503.33(b)(8); a bulk material derived from sewage sludge that meets those three requirements; and sewage sludge sold or given away in a bag or other container for application to the land that meets those three requirements; (2) bulk sewage sludge applied to the land that does not meet the above requirements; (3) sewage sludge sold or given away in a bag or other container for application to the land that does not meet the above requirements; and (4) domestic septage applied to agricultural land, forest, or a reclamation site. Recordkeeping requirements are included in the final regulation to make the regulation self-implementing.

The recordkeeping requirements for bulk sewage sludge and sewage sludge sold or given away in a bag or other container for application to the land specify the information that must be developed, the person who must develop and retain the information, and the period that the information must be retained. The information that must be developed varies depending on which pollutant limits are met and on which pathogen and vector attraction reduction requirements are met. This information is needed to show that the requirements in this subpart are met.

The recordkeeping requirements for domestic septage applied to agricultural land, forest, or a reclamation site also specify the information that must be developed, the person who develops and retains the information, and the period the information has to be retained. This information indicates whether the requirements in this subpart for domestic septage are met.

The person who develops and retains the information for bulk sewage sludge that meets the pollutant concentrations for high quality sewage sludges in 503.13(b)(3), the more stringent Class A pathogen requirements in 503.32(a), and one of the vector attraction requirements in 503.33(b)(1) through 503.33(b)(8); a material derived from bulk sewage sludge that meets those requirements; or sewage sludge sold or given away in a bag or other container that meets those requirements is the person who prepares the sewage sludge. That person may be the treatment works or some other person.

The persons who develop and keep the information for bulk sewage sludge that does not meet the above requirements and is applied to agricultural land, forest, a public contact site, a reclamation site, a lawn, or a home garden are the person who prepares the bulk sewage sludge and the person who applies the bulk sewage sludge to the land. The person who prepares the bulk sewage sludge must develop certain information (e.g., pollutant concentrations in the sewage sludge) and the applier must develop other information (e.g., the record of the amount of each pollutant applied to the land). Those persons may be the treatment works, an agent of the treatment works, a private contractor, or some other person.

An example of when the person who prepares the bulk sewage sludge does not develop and keep the information is when the bulk sewage sludge meets the pollutant concentrations for high quality sewage sludge in 503.13(b)(3) and the less stringent Class B pathogen requirements. In those situations, the person who applies the bulk sewage sludge to the land must develop information concerning certain part 503 requirements (e.g., the restrictions on the application site). The Agency concluded that the person who applies the bulk sewage sludge to the land is the appropriate person to develop that information and keep the records.

For sewage sludge sold or given away in a bag or other container for application to the land, the recordkeeping responsibility lies with the person who prepares the sewage sludge that is sold or given away in a bag or other container for application to the land. For domestic septage applied to agricultural land, forest, or a reclamation site, the responsible person is the one who applies the domestic septage to those types of land.

The period that information must be retained varies depending on which pollutant limits are met. In most cases (including the requirements for domestic septage), the time is five years (i.e., the usual period for a NPDES permit). However, when cumulative pollutant loading rates are met, records for certain information have to be retained indefinitely. The reason for this requirement is that a cumulative pollutant loading rate is the cumulative amount of an inorganic pollutant that can be applied to the land. To know how much of an inorganic pollutant has been applied to the land in bulk sewage sludge, a record must be retained indefinitely.

Reporting (Section 503.18)

The final part 503 regulation requires that Class I sludge management facilities, POTWs with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more to report the information developed in the recordkeeping section, except the information developed and retained by an applier, to the permitting authority once every 365 day period. Class I sludge management facilities, POTWs with a design flow rate equal to or greater than one million gallons, and POTWs that serve 10,000 people or more must report the information on cumulative pollutant loading rates, which is developed and retained by the applier, when 90 percent or more of any of the cumulative pollutant loading rates are reached at a site. The Agency chose only to require Class I sludge management facilities, POTWs with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more to report information to the permitting authority. This was done because Class I sludge management facilities are either a publicly owned treatment works (POTW) required to have a pretreatment program or a treatment works treating domestic sewage (TWTDS) that has the potential to affect public health and the environment adversely because of the TWTDS's sewage sludge use or disposal practice.

Pretreatment POTWs are POTWs that receive industrial wastewater and, thus, are more likely to generate sewage sludge that contains the pollutants controlled in the final part 503 regulation. For this reason, the Agency concluded that those POTWs should report the information on sewage sludge use or disposal to the permitting authority at least once every 365 days. The reporting requirement also applies to TWTDS for the same reason they are classified as a Class I facility (i.e. the potential of the TWTDS's sewage sludge use or disposal practice to affect public health and the environment adversely).

The reporting requirement applies to POTW's that are not a Class I facility and either have a design flow rate equal to or greater than one million gallons per day or serve 10,000 people or more because of the potential for those POTWs to have industrial wastewater in

the influent to the POTW. Sewage sludge generated at those POTW's is more likely to have the pollutants controlled in the part 503 regulation. For this reason, the Agency concluded those POTWs also should report the information in the recordkeeping section to the permitting authority.

Surface Disposal (Subpart C)

This part of today's preamble discusses the part 503 requirements for surface disposal of sewage sludge. More details on these requirements can be found in the technical support document for the part 503 surface disposal requirements.

Applicability (Section 503.20)

The applicability section indicates that this subpart contains requirements for a person who prepares sewage sludge that is placed on a surface disposal site, the owner/operator of the surface disposal site, sewage sludge placed on a surface disposal site, and a surface disposal site. Sewage sludge is placed on an active sewage sludge unit for final disposal, not for treatment, storage, or to condition the soil or fertilize crops grown in the soil.

This subpart does not apply to sewage sludge stored or treated on the land or to the land on which the sewage sludge is stored or treated. As indicated above, sewage sludge is placed on an active sewage sludge unit for final disposal, not for storage or treatment.

This subpart also does not apply to sewage sludge that remains on the land for longer than two years when the person who prepares the sewage sludge demonstrates that the land on which the sewage sludge remains is not an active sewage sludge unit. The demonstration must explain why sewage sludge needs to remain on the land for longer than two years prior to final disposal and must discuss the approximate period the sewage sludge will be used or disposed. In addition, the person who prepares the sewage sludge must retain the information required for the demonstration for the period that the sewage sludge remains on the land. Note that the person who prepares the sewage sludge does not have to report the information in the demonstration unless requested to do so by the permitting authority.

The purpose of allowing sewage sludge to remain on the land for a period longer than two years and not having to meet the requirements in this subpart apply is to address unique situations. In such a situation, mitigating factors may justify the longer period. Without mitigating factors, EPA concluded that a two year period provides enough time to store sewage sludge for most purposes prior to final use or disposal.

Special Definitions (Section 503.21)

Definitions for the following terms are included in this subpart of the final part 503 regulation: Active sewage sludge unit, aquifer, contaminate an aquifer, cover, displacement, fault, final cover, holocene time, leachate collection system, liner, lower explosive limit for methane gas, qualified ground water scientist, seismic impact zone, sewage sludge unit, sewage sludge unit boundary, surface disposal site, and unstable area. The following discussions provide additional information on some of these definitions.

Active sewage sludge unit. An active sewage sludge unit is a sewage sludge unit that is not closed. This definition is included in the final part 503 regulation because requirements in the regulation differ for a sewage sludge unit that is active and a sewage sludge unit that is closed. To distinguish between the two sewage sludge units, the term active sewage sludge unit is used.

Aquifer. An aquifer is a geologic formation, a group of geologic formations, or a portion of a geologic formation capable of yielding ground water to wells or springs. This definition parallels the definition found in the current regulation controlling disposal of sewage sludge on the land in 40 CFR part 257. It is included in the final part 503 regulation because of the requirement in the regulation not to contaminate an aquifer.

Contaminate an aquifer. Contaminate an aquifer means to introduce a substance that causes the maximum contaminant level (MCL) for nitrate in 40 CFR 141.11 to be exceeded in ground water or that causes the existing concentration of nitrate in ground water to increase when the existing concentration of nitrate in the ground water already exceeds the maximum contaminant level for nitrate in 40 CFR 141.11. This definition is included in the final part 503 regulation because the regulation requires that sewage sludge placed on an active sewage sludge unit shall not contaminate an aquifer. Note that this requirement only applies to nitrate. The limits for the pollutant controlled in the surface disposal subpart in part 503 are designed not to cause the maximum contaminant level for the pollutants to be exceeded in the ground water. For this reason, monitoring of the ground water for these pollutants is not necessary.

Cover. Cover is soil or other material used to cover sewage sludge placed on an active sewage sludge unit. The purpose of the cover is to reduce the attraction of vectors to the sewage sludge after the sewage sludge is placed on the surface disposal site.

Holocene time: Holocene time is the most recent epoch of the Quaternary period, extending from the end of the Pleistocene epoch to the present. The most recent epoch of the Quaternary period covers approximately the last 11,000 years.

Leachate collection system. A leachate collection system is a system or device installed immediately above a liner that is designed, constructed, maintained, and operated to collect and remove leachate from a sewage sludge unit. This definition assumes that a sewage sludge unit has a liner. It is included in the final part 503 regulation because the regulation contains a management practice that requires the leachate to be collected and disposed in accordance with the applicable requirements when the sewage sludge unit has a liner and leachate collection system.

Liner. A liner is soil or synthetic material that has a hydraulic conductivity of 1×10^{-7} centimeters per second or less. The liner retards the downward movement of liquid by limiting the rate at which the liquid moves to 1×10^{-7} centimeters per second or less.

Lower explosive limit for methane gas. The lower explosive limit for methane gas is the lowest percentage of methane gas and air, by volume, that propagates a flame at 25 degrees Celsius and atmospheric pressure. This definition is included in the final part 503 regulation because of the requirement for air in any structures within a surface disposal site and air at the property line of the surface disposal site not to exceed a percentage of the lower explosive limit or the lower explosive limit, respectively.

Qualified groundwater scientist. A qualified groundwater scientist is an individual qualified to make sound professional judgments regarding groundwater monitoring, pollutant fate and transport, and corrective action. This definition is included in the final part 503 regulation because if a certification is provided to demonstrate an aquifer is not contaminated, the certification must be made by a qualified groundwater scientist.

Sewage sludge unit. A sewage sludge unit is land on which only sewage sludge is placed for final disposal. Land does not include waters of the United States, as defined in 40 CFR 122.2. When sewage sludge is placed on the land for either treatment or storage, the land is not a sewage sludge unit.

A sewage sludge unit does not include land where sewage sludge is applied to condition the soil or to fertilize crops or vegetation grown on the land. Using sewage sludge for these purposes is land application. In those cases, the requirements in subpart B (Land Application) must be met.

Sewage sludge unit boundary. The sewage sludge unit boundary is the outermost perimeter of the sewage sludge unit. This is different from the property line of the surface disposal site. This definition is needed because part 503 requires that the distance from the sewage sludge unit boundary to the surface disposal site property line be known.

Surface disposal site. A surface disposal site is a discrete area of land that contains one or more active sewage sludge units. This definition is needed because some of the requirements in this subpart apply to a surface disposal site. Other requirements in this subpart apply to active sewage sludge units in a surface disposal site.

Unstable area. An unstable area is area of land subject to natural or human-induced forces that may damage the structural components of an active sewage unit. An example of an unstable area is an area subject to earthquakes.

General Requirements (Section 503.22)

Several of the general requirements in this subpart proposed for the part 503 regulation were deleted from the final rule. They are discussed below.

The proposed regulation contained a requirement that a surface disposal site comply with National Pollutant Discharge Elimination System (NPDES) permit requirements in addition to the requirements in this subpart. The part 503 regulation does not apply to activities subject to a NPDES permit at a surface disposal site other than those that relate to the placement of sewage sludge on an active sewage sludge unit. For this reason, the proposed general requirement concerning compliance with other NPDES requirements was deleted from the final regulation. EPA notes, however, that section 405(a) prohibits the disposal of sewage sludge when it results in pollutants from the sewage sludge entering navigable waters, except in compliance with an NPDES permit.

The general requirement in the proposed regulation concerning a hazard to human health, wildlife, land, or water resources because of sewage sludge in the runoff from a base flood was deleted from the final part 503 regulation. The Agency concluded that the management practice in this subpart of the final part 503 regulation that requires the runoff from an active sewage sludge unit for a 24-hour, 25-year storm event be collected and disposed in accordance with the applicable requirements protects surface waters adequately. Similarly, as noted above, section 405(a) already prohibits the discharge of pollutants to navigable waters, except under certain circumstances.

The general requirement in this subpart of the proposal concerning a hazard to aircraft from birds was deleted from the final regulation. That general requirement was included in the proposal because of the vector attraction potential of sewage sludge placed on an active sewage sludge unit. The final regulation contains a requirement to reduce the vector attraction of sewage sludge before the sewage sludge is placed on an active sewage sludge unit or to cover the sewage sludge unit daily to reduce vector attraction. For this reason, this general requirement is no longer needed.

The general requirement in the proposed regulation concerning reduction of the temporary water storage capacity of a floodplain by a surface disposal site was deleted from the final regulation because that requirement is addressed by a management practice in the final part 503 regulation. The management practice requires that an active sewage sludge unit not restrict the flow of a base flood.

By definition, a floodplain is the lowland and relatively flat area inundated by a base flood. Not reducing the temporary water storage capacity of a floodplain means not reducing the temporary storage capacity of the area inundated by the base flood. This is the same as not restricting the flow of a base flood. Because these two requirements address the same issue, the general requirement in the proposal concerning not reducing the temporary storage capacity of a floodplain was deleted from the final regulation. As mentioned above, the requirement not to restrict the flow of a base flow is a management practice in the final part 503 regulation.

The requirements in the proposed regulation concerning threatened or endangered species, restriction of the flow of a base flood, seismic impact zone, distance from a fault or fracture, location in a wetland, and runoff from a 24-hour, 25-year storm event are classified as management practices rather than general requirements in the final part 503 regulation.

The final part 503 regulation contains four general requirements for placement of sewage sludge on a surface disposal site. The first requirement is that no person shall place sewage sludge on a surface disposal site unless the requirements for the sewage sludge and for the surface disposal site in this subpart are met. EPA concluded that, in most cases, the person who places sewage sludge on a surface disposal site will be a treatment worker. However, they may be some situations where some other person places sewage sludge on a surface disposal site. This general requirement applies to any person who places sewage sludge on a surface disposal site.

The second general requirement concerns active sewage sludge units that must close. This requirement applies to an active sewage sludge unit located within 60 meters of a fault or stress fracture with displacement in Holocene time; located in an unstable area; or located in a wetland, except as provided in a permit issued pursuant to either section 402 or 404 of the CWA, as amended. The Agency concluded that to protect public health and the environment from reasonably anticipated adverse effects of pollutants in sewage sludge, no additional amount of sewage sludge should be placed on those active sewage sludge units and that those active sewage sludge units should close by [insert one year after the effective date of this part], unless, in the case of an active sewage sludge unit located within 60 meters of a fault or stress fracture with displacement in Holocene time, otherwise specified by the permitting authority. The permitting authority may conclude after further review that an active sewage sludge unit located within 60 meters of the above fault or stress fracture need not close. One year was chosen for the time period within which the above active sewage sludge units should close because that is the compliance period for the final part 503 regulation specified in section 405(d) of the Clean Water Act, as amended.

The third general requirement in this subpart is that the owner/operator of an active sewage sludge unit must submit a written closure and post closure plan to the permitting authority 180 days prior to the date that the active sewage sludge unit closes. The plan must discuss how the active sewage sludge unit will be closed. Also included in this general requirement is the minimum information that should be included in the closure plan.

The last general requirement in this subpart of the final regulation requires the owner of the surface disposal site to provide written notification to the subsequent owner of the surface disposal site. That notification must indicate that sewage sludge was placed on the land. EPA concluded that the

subsequent owner of a surface disposal site should know that sewage sludge was placed on the land so that they can become aware of any requirements that result from placement of sewage sludge on the land (e.g., to monitor methane gas for three years after the last active sewage sludge unit in a surface disposal unit closes).

Pollutant Limits—Other Than Domestic Septage (Section 503.23)

Pollutant limits in the final part 503 regulation for sewage sludge (other than domestic septage) placed on a surface disposal site are expressed as pollutant concentrations. The pollutant concentrations protect public health and the environment from reasonably anticipated adverse effects of arsenic, chromium, and nickel in the sewage sludge. These pollutants were identified by the Agency as pollutants that affect public health and the environment adversely when sewage sludge is placed on a surface disposal site. The final rule does not establish pollutant limits for organic pollutants and some inorganic pollutants for which the Agency proposed pollutant limits. An explanation of why limits are not established in the final regulation for those pollutants are presented in the technical support document for the part 503 surface disposal requirements.

There are no pollutant limits in this subpart for domestic septage placed on an active sewage sludge unit because the Agency concluded they are not needed to protect public health and the environment when domestic septage is placed on an active sewage sludge unit. This is discussed further in the technical support document for the part 503 surface disposal requirements.

When an active sewage sludge unit does not have a liner and leachate collection system, the allowable pollutant concentrations in the sewage sludge are presented in Table 1 of section 503.23 in the final regulation. Pollutant concentrations in Table 1 of section 503.23 are based on the results of an exposure assessment for the ground-water and vapor pathways. For the ground-water pathway, the assessment assumes that the MCL for a pollutant is not exceeded 150 meters from the boundary for the active sewage sludge unit. The 150-meter distance is the distance used in the model for the ground-water exposure assessment for active sewage sludge units.

The final part 503 regulation requires that the actual distance from the active sewage sludge unit boundary to the surface disposal site property line be used to determine the allowable concentration for each pollutant listed in Table 1 of section 503.23. This applies when (1) an active sewage sludge unit does not have a liner and leachate collection system and (2) the active sewage sludge unit boundary is less than 150 meters from the property line of the surface disposal site. When the actual distance is less than 150 meters, the allowable pollutant concentrations may be different. Table 2 of section 503.23 contains the concentration for the pollutants for different unit boundary to property line distances.

The final part 503 regulation includes an alternative to the pollutant concentrations discussed above for an active sewage sludge unit that does not have a liner and leachate collection. When requested by the owner/operator of a surface disposal site at the time of permit application, site-specific pollutant limits may be developed under the final regulation for an active sewage sludge unit without a liner and leachate collection system if the existing values for site parameters specified by the permitting authority are different from the values for those parameters used to develop the pollutant limits in Table 1 of section 503.23. In addition, the permitting authority must determine that site-specific pollutant limits are appropriate for the active sewage sludge unit. An important aspect of these conditions is that the permitting authority will specify the site parameters that can be used to develop a rationale for site-specific pollutant limits. Examples of the site parameters are depth to ground water and soil type.

If the permitting authority agrees that site-specific pollutant limits are appropriate, the limits must be based on the results of a site-specific assessment, as specified by the permitting authority, or must be equal to the existing concentration of the pollutant in the sewage sludge that will be placed on the active sewage sludge unit. The lower of the above two values shall be the limit for the pollutant that cannot be exceeded in the sewage sludge.

When an active sewage sludge unit has a liner and leachate collection system, the liner retards the movement of pollutants in sewage sludge to the ground water. Results of the ground-water pathway exposure assessment for an active sewage sludge unit with a liner and leachate collection system indicate that, because of the impact of the liner, sewage sludge with essentially an unlimited concentration of the inorganic pollutants can be placed on the active sewage sludge unit. The liner ensures that the inorganic pollutants do not reach the ground water. For this reason, there are no pollutant limits for arsenic, cadmium, chromium, copper, lead, mercury, and nickel for an active sewage sludge unit with a liner and leachate collection system in the final part 503 regulation. There also are no pollutant limits for organic pollutants for sewage sludge placed on an active sewage sludge unit with a liner and leachate collection system in part 503 because all organic pollutants were deleted from the final part 503 regulation.

Management Practices (Section 503.24)

The management practices for a surface disposal of sewage sludge in the proposed part 503 regulation are included in the final part 503 regulation with some editorial changes. In addition, several new management practices were added to the final regulation.

The final regulation provides that placement of sewage sludge on an active sewage sludge unit is prohibited if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat (§ 503.24(a)). EPA will develop guidance to carry out this provision consistent with the Endangered Species Act.

The second management practice requires that an active sewage sludge unit not restrict the flow of a base flood. A base flood is a flood that has a one-percent chance of occurring in any given year (i.e., a flood with a magnitude equalled once in 100 years). Thus, an active sewage sludge unit cannot restrict the flow in an area that carries the 100-year flood. This management practice reduces the potential for the area that carries the 100-year flood to experience problems related to the location of the surface disposal site (e.g., restriction of the flow) in that area. It also protects the surface disposal site and sewage sludge placed on active sewage sludge units from the impacts of a base flood.

Flood insurance rate maps (FIRM) developed by the Federal Emergency Management Agency (FEMA) should be used to determine whether an active sewage sludge unit is located in an area that carries the base flood (i.e., the 100-year floodplain). FEMA has developed maps for approximately 99 percent of the flood-prone communities in the United States. Other sources of information on the 100-year floodplain include the U.S. Army Corps of Engineers, the Soil Conservation Service, the National Oceanic and Atmospheric Administration, the U.S. Geologic Survey, the Bureau of Land Management, the Bureau of Reclamation, the Tennessee Valley

Authority, and State and local flood control agencies.

The third management practice requires that an active sewage sludge unit be designed to withstand the maximum recorded horizontal ground level acceleration when an active sewage sludge unit is located in a seismic impact zone. One purpose of this management practice is to protect the foundation of an active sewage sludge unit from cracks caused by ground motion that could lead to collapse of the active sewage sludge unit. Maps depicting the potential seismic activity in the United States at a constant probability are available from the U.S. Geological Survey.

The fourth management practice requires that an active sewage sludge unit be located 60 meters or more from a fault that has displacement in Holocene time, unless otherwise specified by the permitting authority. The Holocene is a geologic time, known as an epoch, that extends from the end of the Pleistocene to the present (approximately the last 11,000 years).

Geologic evidence indicates that faults that moved in recent times (i.e., during the last 11,000 years) are most likely to move in the future. Faults that moved in Holocene time are easier to identify and date than are older faults because this epoch produced recognizable geological deposits. The U.S. Geological Survey mapped the location of Holocene faults in the United States in 1978. Maps of identified Holocene faults in the United States also are available from the States of California and Nevada.

EPA is prohibiting the location of an active sewage sludge unit within 60 meters of a Holocene fault, unless otherwise specified by the permitting authority, because results of studies suggest that most of deformation takes place within that distance. Effects of the deformation decrease rapidly as distance from the fault increases. The permitting authority may allow an active sewage sludge unit to be located within 60 meters of a Holocene fault after concluding that public health and the environment are protected if an active sewage sludge unit is located within that distance. This is consistent with the approach taken in 40 CFR part 258 for municipal solid waste landfills.

The fifth management practice requires that an active sewage sludge unit not be located in an unstable area. An unstable area is an area of land subject to natural or human-induced forces that may damage the structural components of the active sewage sludge. The purpose of this management practice is to protect the structural components (e.g., the foundation) of an active sewage sludge unit from forces that could damage the components. For example, when the foundation of an active sewage sludge unit fails, sewage sludge could be released and cause harm to the environment. This also is the reason that part 503 regulation requires that an active sewage sludge unit located in an unstable area close within one year of the effective date of the regulation.

To determine whether an area is unstable, the following factors should be considered, among other things: (1) Soil conditions that cause differential settling; (2) geologic or geomorphologic features such as areas prone to mass movement, Karst terrains, or fissures; (3) surface areas weakened by the withdrawal of oil, gas, or water; and (4) other features that indicate protective measures cannot be designed to withstand a natural event such as a volcanic eruption.

The management practice concerning not locating an active sewage sludge unit in an unstable area replaces the general requirement in the proposed part 503 regulation concerning location of an active sewage sludge unit in areas where adequate support exists for the structural components of the sewage sludge unit. The Agency concluded that the management practice and general requirement provide the same protection. For this reason, there in no need to have both requirements in the final part 503 regulation.

Editorial changes were made to the management practice concerning location of an active sewage sludge unit in a wetland. The final part 503 regulation requires that an active sewage sludge unit not be located in a wetland, except as provided in a permit issued pursuant to either section 402 or 404 of the CWA, as amended.

Editorial changes also were made to the management practice concerning runoff from a 24-hour, 25-year storm event. These changes clarify that the 24-hour, 25-year storm event is from a storm with a frequency of occurrence of 25 years and that the collection system must have the capacity to handle run-off from the 24-hour, 25-year storm event. The runoff from this storm event must be collected and disposed in accordance with National Pollutant Discharge Elimination System permit requirements and any other applicable requirements. This management practice protects surface waters from pollutants in the run-off. The surface water pathway was not evaluated in the exposure assessment used to develop the pollutant limits for sewage sludge placed on a surface disposal site.

The Agency chose the 24-hour, 25-year storm event for this management practice to be consistent with the requirements for hazardous waste landfills in 40 CFR 264.301(g) and the requirements for municipal solid waste landfills in 40 CFR 258.26(a)(2). Both of these provisions require that runoff from the 24-hour, 25-year storm event be collected and controlled. For the final part 503 regulation, control of the runoff means disposed in accordance with the applicable requirements.

Water that runs on an active sewage sludge unit was considered during the development of the pollutant concentrations for the ground-water pathway in the surface disposal exposure assessment. For this reason, part 503 does not have a requirement concerning water that runs on an active sewage sludge unit.

Other management practices in the final part 503 regulation address collection and treatment of leachate, concern for the build-up of methane gas in the air inside a structure within a surface disposal site and in the air at the property line of a surface disposal site, growing of crops, grazing of animals, restricting public access to a surface disposal site, and contamination of an aquifer. These are discussed below.

As mentioned above, because a liner retards the movement of pollutants in sewage sludge to the ground water, results of the ground-water pathway analysis for an active sewage sludge unit with a liner and leachate collection system indicate that sewage sludge with essentially an unlimited concentration of inorganic pollutants can be placed on an active sewage sludge unit that has a well-maintained liner and leachate collection system. For this reason, there are no pollutant limits for inorganic pollutants for an active sewage sludge unit with a liner and leachate collection system. The liner insures that the inorganic pollutants do not reach the ground water.

The part 503 regulation requires that the leachate collection system for a sewage sludge unit with a liner and leachate collection system be operated and maintained for the period that the sewage sludge unit is active and for three years after the sewage sludge unit closes. This management practice ensures that the leachate collection system is operated and maintained. Because the Agency has no pollutant limits for an active sewage sludge unit that has a liner and leachate collection system, protection of ground water obviously depends on proper operation of the unit, including the leachate collection system, to prevent pollutant build-up and in the event of liner

failure, a treat to ground water. EPA chose to require that the leachate collection system be operated and maintained for three years after the sewage sludge unit closes because that is the period that the leachate has to be collected. This is discussed further below.

The final regulation requires that the leachate from a sewage sludge unit that has a liner and leachate collection system be collected and disposed in accordance with the applicable requirements for the period the sewage sludge unit is active and for three years after the sewage sludge unit closes. This management practice is included in the final part 503 regulation to prevent damage to the liner caused by hydraulic pressure from the leachate. The pressure is reduced when the leachate is collected and removed from the active sewage sludge unit.

The three-year period after a sewage sludge unit closes during which leachate has to be collected and disposed is based on the period that methane gas must be monitored after a sewage sludge unit closes. This is discussed further below.

The final part 503 regulation contains a management practice that addresses the explosive potential of methane gas generated in a sewage sludge unit. Methane gas is generated in a sewage sludge because of the anaerobic conditions in the sewage sludge unit that result when the sewage sludge is covered. For this reason, the management practice concerning methane gas applies when a cover is placed on an active sewage sludge unit (e.g., to control vectors). When an active sewage sludge unit is not covered, the requirement to monitor methane gas does not apply.

The methane gas management practice protects public health from the explosive potential of methane gas generated during the stabilization of sewage sludge after placement on a sewage sludge unit. This is done by limiting the percent of methane gas in the air in any structure within the property line of the surface disposal site and by limiting the percent of methane gas in the air at the property line of the surface disposal site. The value for the percent of methane gas in the air in any structure within the property line of the surface disposal site is 25 percent of the lower explosive limit for methane gas, which is the lowest percent by volume of methane gas in air that propagates a flame at 25 degrees Celsius and atmospheric pressure. The value for the percent of methane gas in the air at the property line of a surface disposal site is the lower explosive limit for methane.

Methane gas also must be monitored for three years after a sewage sludge unit closes when a final cover is placed on the sewage sludge unit, unless otherwise specified by the permitting authority. This period is based on results of a study titled "Pilot Scale Evaluation of Sludge Landfilling—Four Years of Operation" conducted in 1987 by EPA's Water Research Engineering Laboratory in Cincinnati, Ohio. In this study, sewage sludge was placed in simulated landfill cells and methane production was monitored for three years and seven months. Results of this study indicate that methane production for the sewage sludge, which had been stabilized in an anaerobic digester, leveled off after approximately two years. Because the study was a laboratory simulation instead of a field study, the Agency decided to increase to the period that air must be monitored for methane gas after a sewage sludge unit closes to three years. The 10 year period for monitoring methane gas in the proposed part 503 regulation was not used in the final part 503 regulation because EPA concluded that a three year period is adequate to protect public health and the environment based on results of EPA's research. The Agency concluded that for sewage sludge that has been stabilized through either anaerobic or aerobic digestion, the 10-year period is not required.

As mentioned above, the period that methane gas must be monitored after a sewage sludge unit closes is three years, unless specified otherwise by the permitting authority. An example of when a longer monitoring period may be necessary is when a sewage sludge that has not been treated in either an anaerobic or aerobic process (e.g., a lime stabilized sewage sludge) is placed in the sewage sludge unit. In this case, the potential for methane gas generation for periods longer than three years exists. For this reason, the permitting authority may extend the period that the air in structures within a surface disposal site and at the property line of the surface disposal site must be monitored for methane gas.

Other management practices in this subpart of the final regulation address growing of crops, grazing of animals, restricting public access to a surface disposal site, and contamination of an aquifer. Unless authorized by the permitting authority, a food crop, a feed crop, and a fiber crop cannot be grown on an active sewage sludge unit. The exposure assessment on which the pollutant limits for surface disposal are based did not consider growing crops on the land where the sewage sludge is placed. This management practice protects public health and the environment by prohibiting the growing of food, feed, and fiber crops. However, in certain circumstances, the permitting authority may authorize the owner/operator of a surface disposal site to grow food crops, feed crops, and fiber crops on an active sewage sludge unit when alternative requirements (i.e., management practices) are imposed to protect public health and the environment.

The management practices concerning animals grazing on an active sewage sludge unit and public access restrictions are included in the final regulation because grazing of animals and exposure of the public to sewage sludge placed on the active sewage sludge unit (e.g., ingestion of the sewage sludge/soil mixture) were not considered in the exposure assessment used to develop the pollutant limits for surface disposal. These management practices are required, consequently, to protect public heath and the environment. In the case of grazing animals, the permitting authority may allow animals to graze on an active sewage sludge unit when the owner/operator of the surface disposal unit demonstrates that through management practices (e.g., monitor the concentration of the pollutants in animal products) public health and the environment are protected from any reasonably anticipated adverse effects of pollutants in sewage sludge when animals grazed.

Public access to a sewage sludge unit must be restricted for the period the sewage sludge unit is active and for three years after the sewage sludge unit closes. The three year period was chosen to parallel the period that air must be monitored for methane gas at a closed sewage sludge unit that receives a final cover. As mentioned above, the reason for this management practice is that the exposure assessment for the surface disposal pollutant limits did not consider contact by the public with the sewage sludge placed on an active sewage sludge unit (e.g., ingestion of the sewage sludge/soil mixture). Protection for the public is provided by restricting access to the active sewage sludge unit. In addition, this management practice keeps the public away from an area where the potential for explosions from methane gas exists (i.e., when a final cover is placed on the sewage sludge unit.

The last management practice is that the owner/operator of a surface disposal site must demonstrate that the sewage sludge does not contaminate an aquifer after placement on an active sewage sludge unit. The owner/operator may

demonstrate compliance in one of two ways. Compliance may be demonstrated through a ground-water monitoring program. Alternatively, the owner/operator may demonstrate compliance through the certification of a qualified ground-water scientist that an aquifer is not contaminated.

When the owner/operator chooses to demonstrate compliance through ground-water monitoring, EPA recommends that the owner/operator develop a formal ground-water monitoring plan. Such a plan should include the following elements: (1) A description of the location of the active sewage sludge unit; (2) a description of the ground-water monitoring system, including the number, spacing, and depths of the monitoring wells; (3) a description of how the existing level of nitrate in the ground water was determined; and (4) the frequency of sampling, sampling protocol, and sample analytical methods.

In the preamble to the proposed part 503 rule, EPA explained its approach for regulating monofills (i.e., surface disposal sites in the final part 503 regulation). EPA stated that the proposal modified and expanded the approach used in the "Criteria for Classification of Solid Waste Disposal Facilities and Practice," 40 CFR part 257. The part 257 regulation, issued under the joint authority of section 4004 of the Research Conservation and Recovery Act and section 405 of the Clean Water Act, among other things, contained a general prohibition (257.3–4) on the contamination of an underground drinking water source beyond the solid waste boundary specified in accordance with the requirements of the rule.

In the proposed part 503 rule, the Agency adopted a prevention rather than containment approach for the proposed standards for sewage sludge disposed in a monofill (i.e., surface disposal site in the final part 503 regulation). As EPA explained, this approach builds on the ground-water protection concept by establishing limits for sewage sludge on a pollutant-by-pollutant basis to ensure that the concentration of the pollutant reaching the ground water does not cause the MCL for a pollutant or other appropriate standard to be exceeded in the ground water. EPA concluded that controlling pollutants at the source was more protective and equitable to prevent sewage sludge contamination of the ground water. The proposed part 503 rule established pollutant concentration limits for 16 pollutants when sewage sludge is disposed in a monofill.

The final part 503 regulation promulgated today for sewage sludge disposed in a surface disposal site is based on the approach in the proposed part 503 rule. Based on available scientific and technical information, EPA concluded that when the pollutant concentrations in today's rule are not exceeded, the probability is small that pollutants in the sewage sludge placed on a surface disposal site will migrate to the ground water, especially at levels that cause the MCLs to be exceeded in the ground water. Consequently, the part 503 standards for surface disposal sites replace 40 CFR part 257 requirements for sewage sludge disposed on a surface disposal site, except for nitrate.

In the proposed part 503 rule, EPA requested comment on whether EPA should retain the generic prohibition on contamination of the ground water provided in part 257 as an additional protective measure and check on the efficacy of the pollutant-specific sewage sludge pollutant limits. EPA concluded that retention of the prohibition in part 257 is generally not required because the Agency has identified the pollutants that present the greatest potential for adversely affecting public health and the environment when sewage sludge is placed on active sewage sludge units. These pollutants were evaluated and assessed for determining the appropriate standards promulgated here today. However, one pollutant for which EPA has established an MCL that numerous commenters suggested may present a problem for ground-water contamination was not evaluated: Nitrate. For this pollutant, EPA decided to retain the general prohibition in part 257 on contamination of underground drinking water sources (i.e., contaminate an aquifer). The last general requirement in the surface disposal subpart incorporates the existing requirement in part 257 prohibiting nitrate contamination.

As explained above, EPA adopted a preventive policy in establishing today's surface disposal standards, which are designed to ensure that contamination of the ground water does not occur. For this reason, the part 503 rule does not require ground-water monitoring to establish the absence of contamination and, if and when contamination of the ground water is identified, does not require corrective action to clean up the ground water or to take other measures to protect public health and the environment. The proposed part 503 rule had requested comment on whether ground-water monitoring and corrective action should back-stop EPA's pollution prevention approach.

Since EPA first proposed the sewage sludge use or disposal standards, EPA has developed a formal statement of ground-water protection principles in a document titled "Protecting the Nation's Ground Water: EPA's Strategy for the 1990s" (EPA Publication 21Z–1020, July 1991). This policy addresses approaches to preventing contamination and clean-up of contaminated ground water, including early detection monitoring and recognition of the primary role of States in ground water protection. The policy concludes that development of a "Comprehensive State Ground Water Protection Program" (CSGWPP) is the most coherent current approach to draw together the many Federal ground water protection authorities administered by States and to implement these programs in a more effective, efficient and coordinated manner. At this time, EPA is in the process of preparing detailed guidance for CSGWPPs under various Federal legislative statutes addressing water quality management and ground water protection. As envisioned, under a CSGWPP, States will develop and implement ground-water protection programs tailored to their unique hydrogeologic settings and institutional arrangements, including establishing priorities for uses of ground water for drinking water supply and ecological sustainability.

At the present time, 25 States have already adopted Wellhead Protection Programs under the Safe Drinking Water Act to protect wellhead areas within their jurisdiction from contaminants that may have an adverse effect on public health. Some of these programs may include various control measures, including siting restrictions on the location of facilities. Additionally, approximately 30 States have, or are in the process of developing, a system for categorizing State ground water by use or vulnerability. EPA expects that the policies adopted in the Wellhead Protection Programs and State classification systems will be incorporated in the CSGWPPs. EPA urges those contemplating disposal of sewage sludge on surface disposal sites to contact their State authorities to determine any restrictions under State Wellhead Protection Programs or State ground-water classification schemes (or the State CSGWPP when developed) that may impose further limitations on either the siting or operation of surface disposal sites.

The standards EPA has adopted today, as noted above, include certain restrictions on the siting of surface disposal sites to protect ground water. In Round Two, EPA will consider whether also to include in the surface disposal standards an explicit requirement to comply with either State

siting, ground-water monitoring or other requirements that are part of a State's Wellhead Protection Program or applicable State CSGWPP.

Pathogens and Vector Attraction Reduction (Section 503.25)

The pathogen requirements in the final part 503 regulation for sewage sludge (other than domestic septage) placed an active sewage sludge unit are similar to the existing requirements for the disposal of sewage sludge on the land in 40 CFR part 257. Sewage sludge (other than domestic septage) placed on a surface disposal site must meet either the Class A pathogen requirements in 503.32(a) or the Class B pathogen requirements in 503.32(b), except the site restrictions in 503.32(b)(5), unless a cover is placed on the active sewage sludge unit at the end of each operating day. When a daily cover is placed on an active sewage sludge unit, the sewage sludge does not have to meet a separate pathogen requirement. The daily cover isolates the sewage sludge and allows the environment to reduce the pathogens in the sewage sludge.

The site restrictions in 503.33(b)(5) do not have to be met when the sewage sludge meets the Class B pathogen requirements because site restrictions are already imposed on an active sewage sludge unit for other than pathogen reduction. Management practices that already address site restrictions are included in this subpart because, as previously mentioned, the exposure assessment for the surface disposal pollutant limits did not address activities such as growing of crops, grazing of animals, and exposure to the sewage sludge by the public.

Domestic septage placed on a surface disposal site does not have to meet a specific pathogen requirement. The existing requirements in part 257 for septic tank pumpings indicate that septic tank pumpings applied to the land must be treated in a Process to Significantly Reduce Pathogens (PSRP) or restrictions concerning grazing of animals and access by the public must be imposed on the site where the domestic septage is applied. Because site restrictions for those two activities, as well as a restriction on the growing of crops, are imposed on all active sewage sludge units for other than pathogen reduction, the part 257 site restrictions for applying domestic septage to the land are met at every active sewage sludge unit. For this reason, domestic septage placed on an active sewage sludge unit does not have to meet an additional pathogen requirement.

The vector attraction reduction requirements in the final part 503 regulation also are similar to the part 257 vector attraction reduction requirements for sewage sludge disposed on the land. Part 257 requires that the sewage sludge be covered daily or that other appropriate techniques be used to reduce vector attraction. The final part 503 regulations requires that 1 of 10 vector attraction reduction requirements (i.e., "other techniques") be met when sewage sludge (other than domestic septage) is placed on an active sewage sludge unit or that daily cover be placed on the active sewage sludge unit. When daily cover is placed on an active sewage sludge unit, the sewage sludge does not have to meet a separate pathogen requirement. The daily cover prevents access to the sewage sludge by vectors.

Vector attraction reduction is achieved when domestic septage is placed on a surface disposal site when the domestic septage is injected below the land surface, incorporated into the soil, or the pH of the domestic septage is raised to a certain level and remains at that level for 30 minutes (i.e., "other techniques"), or when the active sewage sludge unit receives a daily cover. The "other techniques" for domestic septage are limited to injection, incorporation, and pH adjustment because the Agency does not believe that "other techniques" available for sewage sludge (e.g., volatile solids reduction and percent moisture) are feasible for each container of domestic septage placed on an active sewage sludge unit. When daily cover is placed on an active sewage sludge unit, access to domestic septage placed on the unit by vectors is prevented.

Frequency of Monitoring (Section 503.26)

The final part 503 regulation contains the frequency of monitoring requirements for pollutants in sewage sludge (other than domestic septage) placed on an active sewage sludge unit, pathogen density requirements, and vector attraction reduction requirements. The permitting authority may establish more stringent frequency of monitoring requirements, if necessary. The frequency of monitoring for sewage sludge placed on an active sewage sludge unit is based on the amount of sewage sludge placed on an active sewage sludge unit annually. Calculation of the amounts of sewage sludge in the various ranges in table 1 of section 503.26 is discussed in the section on land application in this preamble. The calculations also are discussed in the technical support document for the part 503 surface disposal requirements.

The final part 503 regulation also allows the permitting authority to reduce the frequency of monitoring for pollutants and for the pathogen density requirements in 503.32(a)(5)(ii) and 503.32(a)(5)(iii) after two years of monitoring at the frequencies in table 1 of 503.26. In deciding whether to reduce the minimum frequency of monitoring, the permitting authority shall consider, among other things, the variability of the pollutant concentrations over the two years, the magnitude of the pollutant concentrations, and the frequency of detection of enteric viruses and viable helminth ova in the sewage sludge. Note that only the permitting authority can reduce the frequency of monitoring.

As mentioned above, the frequency of monitoring for the enteric viruses density requirements in 503.32(a)(5)(ii) and the viable helminth ova density requirements in 503.32(a)(5)(iii) may be reduced. The reasons the Agency concluded the frequency of monitoring for these requirements may be reduced are discussed in the section on land application in this preamble.

The final part 503 regulation requires that each container (e.g., each tank truck load) of domestic septage placed on a surface disposal site be monitored for pH when vector attraction reduction is achieved by raising the pH of the domestic septage. Each container must be monitored because there is no other way to know whether the domestic septage meets the pH requirement.

The final regulation also requires that methane gas in all structures within a surface disposal site and at the property line of the surface disposal site be monitored continuously under certain situations. For this reason, the frequency of monitoring for methane gas for those situation is continuously.

Recordkeeping (Section 503.27)

The final part 503 regulation contains recordkeeping requirements for sewage sludge (other than domestic septage) and for domestic septage placed on a surface disposal site. The person who prepares the sewage sludge must develop certain information (e.g., the concentration of pollutants in the sewage sludge) and retain the information for five years. In addition, the owner/operator of a surface disposal site also must develop certain information (e.g., a certification that the management practices for an active sewage sludge unit are met) and retain that information for five years.

When domestic septage is placed on an active sewage sludge unit, the person

who applies the domestic septage must develop certain information and the owner/operator of the surface disposal site must develop certain information. In both cases, the information has to be retained for five years.

Recordkeeping requirements are included in this subpart because the regulation is self-implementing (i.e., the requirements apply even when a person does not receive a permit). Without the requirement to keep records, there is no way to demonstrate that the part 503 requirements are met.

Reporting (Section 503.28)

The part 503 regulation requires Class I sludge management facilities, POTWs with a design flow rate equal to or greater than 1 million gallons per day, and POTWs that serve 10,000 people or more to report the information developed in 503.27(a) for sewage sludge (other than domestic septage) to permitting authority once every 365 days. Only Class I sludge management facilities, POTWs with a design flow rate equal to or greater than 1 million gallons per day, and POTWs that serve 10,000 people or more must report information for the reasons discussed in the land application section in today's preamble.

Pathogens and Vector Attraction Reduction (Subpart D)

This section of the preamble discusses pathogen and vector attraction reduction requirements in the final part 503 regulation for sewage sludge that is applied to the land or placed on an active sewage sludge unit. More details on these requirements may be obtained from the technical support document for the part 503 pathogen and vector attraction reduction requirements.

Scope (Section 503.30)

This subpart in the final part 503 regulations establishes the requirements that must be met for a sewage sludge to classified either Class A or Class B with respect to pathogens and the alternative vector attraction reduction requirements. Either the Class A or Class B pathogen requirements must be met and one of the alternative vector attraction reduction requirements must be met when sewage sludge is applied to the land or placed on a surface disposal site. The circumstance under which either the Class A or Class B requirements must be met (e.g., sewage sludge sold or given away in a bag or other container for application to the land must meet the Class A requirements) is addressed in the part 503 subparts on land application (subpart B) and surface disposal (subpart C).

This subpart also contains site restrictions that must be met when a Class B sewage sludge is applied to the land and the pathogen requirements for domestic septage applied to agricultural land, forest, or a reclamation site. As discussed previously, there are no pathogen requirements in the final part 503 regulation for domestic septage placed on a surface disposal site.

Special Definitions (Section 503.31)

Five of the 11 special definitions in this subpart in the proposed regulation were deleted from the final part 503 regulation. Also, six new definitions were added to the final part 503 regulation and editorial changes were made to the definitions in the proposal that are included in the final regulation. Definitions for the following terms are in the final regulation: aerobic digestion, anaerobic digestion, density of microorganisms, land with a high potential for public exposure, land with a low potential for public exposure, pathogenic organisms, pH, specific oxygen uptake rate, total solids, unstabilized solids, vector attraction, and volatile solids. The definitions that were deleted from and added to the final regulation are discussed below.

The terms "food crops" and "feed crops" are defined in the general definitions in the final regulation. For this reason, the definitions for those terms are not included in this subpart of the final regulation.

The term "indicator organism" is not used in the final part 503 regulation. For this reason, the definition of indicator organism was deleted from the final regulation.

Pathogen reduction was defined in the proposed regulation as the elimination or reduction of pathogenic bacteria (*Salmonella* sp.), protozoa, viruses, and helminth ova in sewage sludge. This definition was deleted from the final regulation because the pathogen requirements in the final regulation are not expressed in terms of quantity of pathogen reduction. They are expressed in terms of values that cannot be exceeded in the sewage sludge.

In the proposed regulation, the pathogen requirements were expressed in terms of per gram of volatile suspended solids. Comments on the proposal indicated that those requirements should be expressed in terms of total solids because volatile suspended solids change in the sewage sludge during treatment. The Agency agrees with the comments and is expressing the pathogen requirements in the final regulation in terms of per gram of total solids (dry weight basis). Because the term "volatile suspended solids" is not used in the final regulation, the definition for that term was deleted from the final part 503 regulation.

The final part 503 regulation includes a definition for land with a high potential for public exposure because the site restrictions for a Class B sewage sludge that is applied to the land differ depending on the potential exposure of the public to the land. Land with a high potential for public exposure is land used frequently by the public. This includes, but is not limited to, parks, ball fields, and a reclamation site located in a populated area (e.g., a construction site). This type of land has a stringent public access restriction (i.e., one year) when a Class B sewage sludge is applied to the land.

Land with a low potential for public exposure is land used infrequently by the public. This includes, but is not limited to, agricultural land and forest. The Agency does not believe that the public will use these types of land frequently. Note that the public does not include people who apply the sewage sludge to the land or farm workers.

The final part 503 regulation also includes a definition of pathogenic organisms. Pathogenic organisms are disease-causing organisms. These include, but are not limited to, certain bacteria, protozoa, viruses, and viable helminth ova.

The definition of total solids is in the final regulation because, as mentioned above, the requirements for pathogenic organisms in sewage sludge are expressed in terms of per gram of total solids in the sewage sludge. Total solids are the materials in sewage sludge that remain as residue when the sewage sludge is dried at 103 to 105 degrees Celsius.

The final part 503 regulation includes the definition of unstabilized solids because two of the vector attraction reduction requirements in the final regulation depend on whether the sewage sludge that is used or disposed of contains unstabilized solids. Unstabilized solids are organic materials in sewage sludge that have not been decomposed biochemically or have been treated only with chemicals (e.g., lime stabilized).

Pathogens (Section 503.32)

There are several differences between the pathogen requirements in the proposed part 503 regulation and the pathogen requirements in the final regulation. These changes are discussed below.

The first change concerns the pathogen requirement for protozoa in the proposal. Protozoa are no longer included as one of the organisms subject to pathogen requirements because of the lack of an analytical method for protozoa. In addition, EPA concluded that protozoa are unlikely to survive wastewater treatment and sewage sludge treatment processes and, thus, should not cause a reasonably anticipated adverse effect in sewage sludge that is used or disposed of.

Second, the unit of measurement for density of pathogenic organisms was changed for volatile suspended solids to total solids. As mentioned previously, several commenters stated that the use of volatile suspended solids is not appropriate because the volatile suspended solids concentration changes significantly when the sewage sludge is treated. The Agency agrees and changed the unit of measurement to total solids.

A third change is not expressing the fecal coliform requirements in terms of a log reduction. Several commenters on the proposed regulation stated that requiring a log reduction may not protect public health and the environment. For example, reducing the fecal coliform from a log of 6 (i.e., 1,000,000) to a log of 4 (i.e., 10,000) is a two log reduction. A reduction for log of 4 (i.e., 10,000) to log of 2 (i.e., 100) also is a two log reduction. The final fecal coliform density is different, however, for each example (10,000 versus 100). The Agency agrees with the commenters and eliminated the log reduction requirement in the final part 503 regulation. Instead, the final regulation requires that the density of fecal coliform in the sewage sludge be equal to or less than a specific value.

Another change is the elimination of the requirement to reduce fecal streptococci in the sewage sludge. EPA concluded that the use of fecal coliform is sufficient to indicate the presence of pathogenic organisms in the sewage sludge. A requirement for both fecal streptococci and fecal coliform is redundant. Fecal coliform was selected for the final part 503 regulation because an analytical method exists for fecal coliform and because treatment works conduct fecal coliform analyses routinely.

One of the major changes in the pathogen requirements in the final regulation is that the regulation only has two classes of pathogen requirements instead of the three classes in the proposed regulation. Several commenters indicated that the requirements in the proposal for Class B and Class C are essentially the same. The Agency agrees with the commenters and only included Class A and Class B pathogen requirements in the final regulation. Changes also were made to the Class A and Class B pathogen requirements and to the site restrictions when a Class B sewage sludge is applied to the land.

The final regulation requires that the Class A pathogen requirements be met either prior to or at the same time certain vector attraction reduction requirements are met. Typically, after the Class A pathogen requirement is met, the sewage sludge is left without an adequate density of predator or competitive organisms to compete with pathogenic bacteria such as *Salmonella* sp. bacteria. As a result, regrowth of pathogenic bacteria in the sewage sludge will occur if a small number of those bacteria survive treatment or when bacteria are introduced into the sewage sludge inadvertently. When vector attraction reduction precedes treatment for pathogens, regrowth of the pathogenic bacteria can occur. When vector attraction reduction occurs after treatment for pathogens, competitive organisms are re-introduced into the sewage sludge during vector attraction reduction and regrowth of pathogenic bacteria is inhibited.

The above requirement does not apply when the vector attraction requirement concerning adjustment of sewage sludge pH is met. In that case, alkali material used to raise the pH remains in the sewage sludge after treatment. This material inhibits growth of pathogenic bacteria even when the density of predator or competitive organisms is too low to resist regrowth of the bacteria. For this reason, the order of vector attraction reduction and pathogen treatment is not relevant when the vector attraction reduction requirement is met by raising the pH of the sewage sludge to 12 or higher with alkali addition and, without the addition of more alkali, the pH of the mixture remains at 12 or higher for two hours and then remains at 11.5 or higher for an additional 22 hours.

The above requirement concerning the order of pathogen reduction also does not apply when vector attraction reduction is achieved by drying the sewage sludge to the specified percent solid values. In this case, EPA concluded that re-growth of *Salmonella* sp. bacteria is not a problem.

The requirement to reduce pathogens either prior to or at the same time as vector attraction is reduced applies only to a sewage sludge that meets the Class A pathogen requirements. A Class B sewage sludge usually has an adequate density of predator and competitive organisms even when the vector attraction reduction requirement is met before the Class B pathogen requirement is met.

The final part 503 has six alternative requirements that can be met for a sewage sludge to be classified Class A with respect to pathogens. Each alternative requirement is discussed below.

The objective of the alternative pathogen reduction requirements is to protect public health and the environment from the reasonably anticipated adverse effects of pathogens in sewage sludge that is used or disposed. The Agency concluded that the best way to meet that objective is for the sewage sludge that is used or disposed to meet certain pathogen density requirements and for that sewage sludge to meet other pathogen density requirements at the time of use or disposal. Sewage sludge generated at every treatment works and each material derived from sewage sludge should be analyzed for pathogens to show that the density of pathogenic organisms in the sewage sludge or material derived from sewage sludge are below the specified value.

The first Class A pathogen alternative in the final part 503 regulation is based on raising the temperature of the sewage sludge to a specific value and keeping the temperature at that value for a specific time. *Salmonella* sp. bacteria, enteric viruses, and viable helminth ova in the sewage sludge are expected to be reduced to acceptable levels (i.e., to below detectable levels) when the temperature and time requirements are met.

For the final part 503 regulation, the temperature and time requirements vary depending on the percent solids in the sewage sludge. When the percent solids is equal to or greater than seven percent and the sewage sludge is not heated by warmed gases or an immiscible liquid, the temperature must be 50 degrees Celsius or higher and the time period must be 20 minutes or longer. The temperature and time period are determined using equation (2) in the final regulation. The 20 minute minimum time period helps ensure uniform heating is achieved throughout the sewage sludge.

When the percent solids in the sewage sludge is equal to or greater than seven percent and the sewage sludge is heated by warmed gases or an immiscible liquid, the temperature must be 50 degrees Celsius or higher and the time period must be 15 seconds or longer. The temperature and time period in this case also are determined using equation (2) in the final regulation. Sewage sludge heated in this manner usually is

in the form of small droplets or particles (e.g., less than one millimeter in diameter) that are dispersed throughout the gas or liquid. Because of this small size, uniform heating can be achieved in a short time at a high temperature.

When the percent solids of the sewage sludge is less than seven percent and the sewage sludge is heated for 15 seconds or longer, but for less than 30 minutes, the temperature and time are determined using equation (2). Uniform heating of this sewage sludge is achieved under these conditions.

When the percent solids of the sewage sludge is less than seven percent, the temperature of the sewage sludge is 50 degrees Celsius or higher, and time period is 30 minutes or longer, the temperature and time period are determined using equation (3) in the final regulation. The Agency concluded that uniform heating of sewage sludge that has a percent solids of less than seven can be achieved at lower temperatures for shorter times. The lower percent solids allows the heat to be dispersed throughout the sewage sludge in a shorter time and not as much heat (i.e., high temperature) is needed to ensure that the temperature of the solids in the sewage sludge is raised to an adequate level.

To use the temperature and time equations, either the temperature at which the sewage sludge will be maintained or the time the temperature will be maintained has to be known. The known value is then used in the appropriate equation to obtain the other value.

In addition to the temperature and time requirements, this alternative requires that either the density of fecal coliform in the sewage sludge or the density of *Salmonella* sp. bacteria in the sewage sludge must be below a specific value at the time the sewage sludge is used or disposed, at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land, or at the time the sewage sludge is prepared to meet the requirements in 503.10 concerning sewage sludge that is not subject to the general requirements and management practices in the land application subpart. This insures that *Salmonella* sp. bacteria do not regrow in the sewage sludge subsequent to when the temperature of the sewage sludge is raised to the specific level for the specific period. EPA will provide more guidance on the terms "at the time of use or disposal", "at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land", and "at the time the sewage sludge is prepared to meet the requirements in 503.10 concerning sewage sludges not subject to the general requirements and management practices in the land application subpart".

The Agency concluded that when the temperature of the sewage sludge is raised to the value determined using equation (2) or equation (3) and maintained at that value for the specified period, the densities of *Salmonella* sp. bacteria, enteric viruses and viable helminth ova in the sewage are reduced to below detectable levels. Because enteric viruses and viable helminth ova are not expected to regrow over time, there is no requirement in this Class A alternative to measure the density of those organisms in the sewage sludge after the temperature and time requirements are met.

The second alternative in the final part 503 regulation for a sewage sludge to classified Class A with respect to pathogens also requires that the density of fecal coliform or the density of *Salmonella* sp. bacteria in the sewage sludge be below a specified level at the time the sewage sludge is used or disposed, at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land, or at the time the sewage sludge is prepared to meet the requirements in 503.10 concerning the exemption of the sewage sludge from the general requirements and management practices in the land application subpart. This requirement ensures that *Salmonella*, sp. bacteria does not regrow in the sewage sludge between the time the sewage sludge is treated and the time the sewage sludge is used or disposed.

In addition to the regrowth requirement, the second Class A alternative requires that the pH of the sewage sludge that is used or disposed be raised to above 12 and remain above 12 for 72 hours. During at least 12 hours of the 72-hour period, the temperature of the sewage sludge has to be greater than 52 degrees Celsius. At the end of the 72-hour period, the sewage sludge must be air dried to achieve a percent solids of greater than 50 percent. When these requirements are met, the Agency concluded that the density of *Salmonella*, sp. bacteria, enteric viruses, and viable helminth ova in the sewage sludge are reduced to below detectable levels.

The requirements in Alternative 2 are a generic description of a process that has been classified a Process To Further Reduce Pathogens (PFRP) by EPA. Because that process has already been classified a PFRP (i.e., a process that produces a Class A sewage sludge), the Agency concluded that sewage sludges that meet these requirements should be classified Class A. For this reason, this Class A alternative was added to the final part 503 regulation.

The third alternative in the final regulation for a sewage sludge to be classified Class A with respect to pathogens also addresses the regrowth issue by requiring that the density of either fecal coliform or *Salmonella*, sp. bacteria in the sewage sludge be below a specified value at the time the sewage sludge is used or disposed, at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land, or at the time the sewage sludge is prepared to meet the requirements in 503.10 concerning sewage sludge not subject to the general requirements and management practices in the land application subpart. In addition, this alternative requires that the sewage sludge be monitored for enteric viruses and viable helminth ova prior to being treated in a pathogen process. The number of times the sewage sludge must be monitored for those microorganisms varies, as discussed below.

As mentioned above, enteric viruses must be monitored in the sewage sludge in the influent to the pathogen treatment process during each monitoring episode for the sewage sludge. When enteric viruses are not found in influent (i.e., the density of enteric viruses is less than one Plaque-forming Unit per four grams of total solids), the sewage sludge is Class A with respect to enteric viruses until the next monitoring episode for the sewage sludge.

When the density of enteric viruses in the influent to the pathogen treatment process is equal to or greater than one Plaque-forming Unit per four grams of total solids, the density of the enteric viruses in the sewage sludge that is used or disposed (i.e., after the pathogen treatment process) must be below one Plaque-forming Unit per four grams of total solids. In addition, values for the operating parameters for the pathogen treatment process that produces the sewage sludge that meets the enteric virus density requirement must be documented. At this time, the sewage sludge is Class A with respect to enteric viruses.

For the sewage sludge to continue to be Class A with respect to enteric viruses, the values for the process operating parameters must be consistent with the values documented above at all times. Although the term "consistent with" allows the actual values for the operating parameter to be different from the documented values for the operating parameters, the Agency does not expect

there will be a large variation in those values.

The approach discussed above for enteric viruses also is part of this alternative for viable helminth ova. The sewage sludge is Class A with respect to viable helminth ova when viable helminth ova are not found (i.e., less than one per four grams of total solids) in the influent to the pathogen treatment process. When viable helminth ova are found in the influent, the density of viable helminth ova in the sewage sludge that is used or disposed must be less than one per four grams of total solids and the operating parameters for the pathogen treatment process must be documented for the sewage sludge to be Class A with respect to viable helminth ova. After the viable helminth ova reduction is demonstrated, values for the process operating parameters must be consistent with the documented values for those parameters for the sewage sludge to continue to be classified Class A with respect to viable helminth ova.

Alternative 3 is designed to reduce the analytical costs for pathogenic organisms after pathogen reduction is demonstrated for the pathogen treatment process. The Agency concluded that after pathogen reduction is demonstrated for a process, the effluent from the process (i.e., the sewage sludge that is used or disposed) does not have to be monitored for the pathogenic organisms as long as the process operating parameters are consistent with the documented values. This is similar to the temperature and time requirement in Alternative 1. In Alternative 1, as long as the temperature and time requirement is met, pathogens are reduced to acceptable levels. In this alternative, when the values for operating parameters are consistent with the documented values after pathogen reduction is demonstrated, enteric viruses and viable helminth ova are reduced to below detectable levels.

The Agency recognizes that, under this alternative, the sewage sludge may have to be analyzed for enteric viruses and viable helminth ova during each monitoring episode when enteric viruses and viable helminth ova are never found in the influent to the pathogen treatment process. The Agency also recognizes that the analyses for these organisms are costly and that only a limited number of laboratories can perform those analyses. For these reasons, the permitting authority may reduce the frequency of monitoring for those organisms in the final part 503 regulation after two years of monitoring at the specified frequency. In deciding whether to reduce the frequency of monitoring for those two microorganisms in the influent to the pathogen treatment process, the permitting authority may consider, among other things, the frequency of detection of enteric viruses and viable helminth ova during the two year period.

The fourth alternative for a sewage sludge to be classified Class A with respect to pathogens is for the sewage sludge to be monitored for fecal coliform or *Salmonella* sp. bacteria, enteric viruses, and viable helminth ova at the time the sewage sludge is used or disposed, at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land, or at the time the sewage sludge is prepared to meet the requirements in 503.10 concerning exemption from the general requirements and management practices in the land application subpart. When the density values for the above organisms in the sewage sludge are equal to or less than the values for those organisms in this alternative, the sewage sludge is Class A with respect to pathogens.

The fourth Class A pathogen alternative can be used for sewage sludges for which there is no historical knowledge about how the sewage sludge was treated. For example, when a sewage sludge has been stored for a period and is now going to be used or disposed, this alternative can be used to determine whether the sewage sludge is Class A with respect to pathogens. Because there is no information about how the sewage sludge was treated prior to storage, one of the first three Class A pathogen alternatives cannot be used to determine whether the sewage sludge is Class A. Under this alternative, samples of the sewage sludge can be collected at the time of use or disposal and analyzed to determine whether the density values for the pathogenic organisms are equal to or less than the density values for those organisms in today's regulation. When the density values for the organisms are equal to or less than the values in this alternative, the sewage sludge is Class A. The density values in this alternative for fecal coliform or *Salmonella* sp. bacteria, enteric viruses, and viable helminth ova are the same as the density values for those organisms in Alternative 3.

The fifth and sixth alternatives also address the regrowth issue by requiring that the density of either fecal coliform or *Salmonella* sp. bacteria in the sewage sludge be below a specified value at the time the sewage sludge is used or disposed, at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land, or at the time the sewage sludge is prepared to meet the requirements in 503.10 concerning sewage sludge that is not subject to the general requirements and management practices in the land application subpart. In addition, under the fifth alternative, a sewage sludge must be treated in a Process to Further Reduce Pathogens (PFRP) to be classified Class A. Processes classified PFRPs are described in appendix B. These processes are the same processes described in appendix II to 40 CFR part 257. The descriptions in Appendix B were edited to remove any requirements for vector attraction (e.g., reduce volatile solids by 38 percent). A sewage sludge must meet one of the vector attraction requirements discussed below in addition to the pathogen requirements in the final part 503 regulation.

For the sixth Class A pathogen alternative, the regrowth requirements mentioned above must be met and the sewage sludge must be treated in a process that is equivalent to a Process to Further Reduce Pathogens, as determined by the permitting authority. The Agency currently has a group that advises the permitting authority whether a process is equivalent to a PFRP. That group is the Pathogen Equivalency Committee (PEC). The final decision on whether a process is equivalent to PFRP is made by the permitting authority based on recommendations by the PEC. The sewage sludge also must meet one of the vector attraction reduction requirements discussed below in addition to this pathogen requirement.

The Class B pathogen requirements in the final part 503 regulation also are different from the Class B requirements in the proposed regulation. In the proposal, either of two requirements had to be met. First, the densities of *Salmonella* sp. bacteria and viruses in the influent to the treatment works had to be reduced to below specific values. The second requirement was that when the wastewater is treated in physical or biological processes and the sewage sludge generated in those processes is treated in a physical, biological, or chemical addition process or stored for at least one day, the densities of fecal coliform and fecal streptococci in the sewage sludge had to be below a specific value. In addition, site restrictions were imposed when a Class B sewage sludge was applied to the land.

There are three alternatives in the final part 503 regulation for a sewage sludge to be classified Class B with respect to pathogens. The first Class B alternative requires that seven samples of sewage sludge that is used or

disposed be collected each time the sewage sludge is monitored. In addition, the geometric mean of the density of fecal coliform (expressed as either Most Probable Number or Colony Forming Units) in those samples must be less than 2,000,000. A geometric mean is the anti-logarithm of the arithmetic average of the logarithms for a certain number of values (in this case, values for the seven samples).

The second Class B alternative is that the sewage sludge be treated in a Process to Significantly Reduce Pathogens (PSRP). Appendix B contains a description of processes currently classified as PSRPs. Those processes are the same as the PSRP processes described in appendix II of 40 CFR part 257 with some editorial changes. One editorial change is that the vector attraction reduction requirements in the Appendix II descriptions were deleted in today's description. As mentioned above, a sewage sludge must meet one of the vector attraction reduction requirements discussed below in addition to the pathogen requirements in the final part 503 regulation.

The third Class B pathogen alternative in the final regulation is that the sewage sludge that is used or disposed be treated in a process that is equivalent to a Process to Significantly Reduce Pathogens, as determined by the permitting authority. The Pathogen Equivalency Committee (PEC) discussed above helps the permitting authority decide whether a process is equivalent to a PSRP. The final decision on such a determination is the responsibility of the permitting authority.

The final part 503 regulation also contains site restrictions that must be met when a Class B sewage sludge is applied to the land. These restrictions provide time for the natural environment to reduce the pathogenic organisms in the sewage sludge.

Site restrictions in the final regulation for a Class B sewage sludge that is applied to the land are different from the site restrictions for that practice in the proposed regulation. These differences are discussed below.

The first site restriction pertains to food crops that touch the sewage sludge/soil mixture and are above ground totally. The proposed regulation restricted the growing of those crops for 18 months after the sewage sludge is applied to the land. The final regulation restricts the harvesting of those crops for 14 months after the application of the sewage sludge. The 14 month harvesting restriction assumes that crops will not be grown for 12 months and that the crops grow for two months before harvesting. This access restriction prevents exposure to viable helminth ova that survive for long periods in the soils on the land surface when the viable helminth ova are sheltered from sunlight and desiccation.

The second restriction pertains to food crops with harvested parts below the surface of the ground (i.e., root crops). The proposed regulation restricted the growing of those crops for five years after application of the sewage sludge. The final regulation contains two requirements for root crops depending on how long the sewage sludge remains on the land surface before incorporation into the soil.

The first requirement restricts the harvesting of food crops with harvested parts below the surface of the land for 20 months after application of the sewage sludge when the sewage sludge remains on the land surface for four months prior to incorporation into the soil. The Agency concluded that exposure of the sewage sludge to the natural environment during the four month period promotes die-off of viable helminth ova, which is the most persistent pathogen in a sewage sludge/soil mixture. This justifies the reduction in the period before a root crop can be harvested discussed below. The 20 month restriction assumes that food crops with harvested parts below the surface of the land will not be grown for 18 months and that the crops grow for two months before harvesting.

The other restriction for food crops with harvested parts below the surface of the land is that those crops cannot be harvested for 38 months after sewage sludge is applied to the land when the sewage sludge does not remain on the land surface for four months after application. In this case, the pathogenic organisms are not reduced as much by the natural environment (i.e., air and sunlight). For this reason, the restriction on harvesting root crops is 38 months to allow for die-off of viable helminth ova. This restriction assumes that the crops will not be grown for three years after application of the sewage sludge and that the crops grow for two months before they are harvested.

The site restrictions in the proposed regulation concerning the harvesting of feed crops and the grazing of animals are the same in the final regulation. Feed crops shall not be harvested and animals shall not be grazed for 30 days after application of sewage sludge to the land. The Agency concluded this is a long enough period to allow die-off of pathogens that may affect animals. This restriction also applies to the harvesting of food crops and fiber crops because the 30-day exposure to the environment is needed to allow die-off of pathogens that may affect humans.

A new site restriction concerning the harvesting of turf was added to the final regulation. The purpose of this site restriction is to prevent public exposure to turf grown on land where a Class B sewage sludge is applied. Most likely, turf grown on the land will be used on a lawn or on land with a high potential for public exposure (e.g., a public contact-site). To restrict public exposure to that turf for one year, which is the same public access restriction for land with a high potential for public exposure (see below), the final part 503 regulation requires that turf grown on land where a Class B sewage sludge is applied not be harvested for one year after application of the sewage sludge when the harvested turf is placed on a lawn or on land with a high potential for public exposure, unless otherwise specified by the permitting authority.

The public access restriction for land on which a Class B sewage sludge is applied in the proposed regulation was expanded in the final part 503 regulation. The restriction in the final regulation recognizes that the potential for exposure to the sewage sludge is not the same for all types of land.

Some lands have a high potential for exposure to the public. Those lands include, but are not limited to, parks, ball fields, and a reclamation site located in a populated area (e.g., a construction site next to a high school). When a Class B sewage sludge is applied to those types of land, the final part 503 regulation requires that public access be restricted for one year after application of the sewage sludge. This period allows the pathogenic organisms to die off in the natural environment.

Other lands have a low potential for exposure because they are used infrequently by the public. These lands include, but are not limited to, land used for silviculture purposes, agricultural land, and a reclamation site located in an unpopulated area (e.g., a strip mine). Public access to lands with a low potential for exposure has to be restricted for 30 days after application of sewage sludge to the land.

The final part 503 regulation also contains alternative pathogen requirements for domestic septage applied to agricultural land, forest, or a reclamation site. The first requirement is that the site restrictions discussed above be met. When these restrictions are met, the domestic septage does not have to meet an additional pathogen requirement.

The second requirement is to raise the pH of the domestic septage to 12 or higher by alkali addition and, without

the addition of more alkali, maintain the pH at 12 or higher for 30 minutes. In addition, the site restrictions discussed above concerning harvesting of crops must be met. The site restrictions are needed because domestic septage is not considered Class A with respect to pathogens after the pH requirement is met. Site restrictions are needed to allow die-off of pathogens through exposure to the environment before crops are harvested.

The above pH requirement is based on the results of a study conducted at the University of Wisconsin on pathogens in domestic septage (Ronner, Amy B. and Dean O. Cliver, Ph.D., "Disinfection of Viruses in Septic Tank and Holding Waste by Calcium Hydroxide (Lime)", Small Scale Waste Management Project, University of Wisconsin, Madison, Wisconsin, June 1987). The Agency concluded that when the above pH requirement is met and site restrictions concerning harvesting of crops are met, public health and the environment are protected from the pathogenic organisms in domestic septage.

Vector Attraction Reduction (Section 503.33)

The vector attraction reduction requirements in the proposed regulation are adopted in the final regulation. Editorial changes were made to several of the proposed requirements. In addition, several new vector attraction reduction requirements were added to the final part 503 regulation. The vector attraction reduction requirements in the final regulation address: the reduction in the mass of volatile solids in sewage sludge that is used or disposed; an additional reduction in the mass of volatile solids for an anaerobically digested sewage sludge that is digested anaerobically for an additional period in the laboratory; an additional reduction in the mass of volatile solids for an aerobically digested sewage sludge that is digested aerobically for an additional period in the laboratory; the specific oxygen uptake rate for a sewage sludge digested aerobically; a sewage sludge treated in an aerobic process for a specific period during which the temperature of the sewage sludge is raised; an increase in the pH of the sewage sludge; the percent solids of the sewage sludge; injection of the sewage sludge below the land surface; incorporation of the sewage sludge into the soil; cover for a surface disposal site; and pH adjustment for domestic septage. These alternative requirements are discussed below.

Not all of the vector attraction reduction requirements in the final part 503 regulation pertain to the different sewage sludge use or disposal practices. For example, when sewage sludge is sold or given away in a bag or other container for application to the land, the vector attraction reduction requirement concerning injection below the land surface does not apply. Section 503.33 (a) in the final part 503 regulation indicates which vector attraction reduction requirements pertain to which use or disposal practices.

One vector attraction reduction requirement is that the mass of volatile solids in the sewage sludge be reduced by a minimum of 38 percent. The 38 percent reduction is determined by subtracting the mass of volatile solids in the sewage sludge that is used or disposed from the mass of volatile solids in the influent to the sewage sludge digestion process and dividing that value by the mass of volatile solids in the influent to the sewage sludge digestion process. This value is then multiplied by 100 to obtain the percent reduction. By reducing the volatile solids of the sewage sludge, the "source of food" for a vector is reduced, which reduces the attractiveness of the sewage sludge to the vector.

Editorial changes were made to the proposed vector attraction reduction requirement concerning a 17 percent volatile solids reduction for anaerobically digested sewage sludge that is digested anaerobically further in the laboratory. These changes clarify that the additional anaerobic digestion should occur in a bench-scale unit in the laboratory for 40 days at a temperature between 30 and 37 degrees Celsius and that the 17 percent reduction or less is the reduction of the volatile solids in the sewage sludge at the beginning of the 40 day period. This alternative requirement is included in the final regulation because the volatile solids content of some sewage sludges is low before the sewage sludge is treated in the anaerobic digester. In this case, it is very difficult to achieve a 38 percent volatile solids reduction during digestion. The Agency concluded that when the percent volatile solids reduction after the additional digestion period is 17 percent or less, vectors will not be attracted to the sewage sludge.

The above requirement for additional treatment of a sample of the sewage sludge in the laboratory also pertains to an aerobically digested sewage sludge. A similar requirement is included in the final regulation for an aerobically digested sewage sludge.

When an aerobically digested sewage sludge cannot meet the above 38 percent volatile solids reduction requirement, a portion of the previously digested sewage sludge that has a percent solids of two percent or less can be digested aerobically in the laboratory in a bench-scale unit for 30 additional days at 20 degrees Celsius. When at the end of the 30 days, the volatile solids in the sewage sludge at the beginning of that period is reduced by less than 15 percent, vector attraction reduction is achieved for the sewage sludge.

The percent solids requirement (i.e., two percent or less) and temperature requirement are part of the above alternative because they affect the rate of digestion. When the percent solids is greater than two percent, the rate of digestion is slower than the rate of digestion when the percent solids is two percent or less. To ensure that the sewage sludge is digested fully during the 30 day period, the percent solids requirement and the temperature requirement are included in this alternative. A percent solids requirement is not included in the above alternative for additional digestion of an anaerobically digested sewage sludge because percent solids does not affect the rate of digestion during anaerobic digestion of a sewage sludge.

The percent volatile solids reduction in the above two alternative vector attraction reduction requirements is different for anaerobic digestion (i.e., 17 percent) and aerobic digestion (i.e., 15 percent). These percentages are based on experiences with the different types of digested sewage sludge.

The proposed vector attraction reduction requirement concerning the specific oxygen uptake rate (SOUR) also was changed in the final regulation. The changes are a different value for SOUR and the addition of a temperature requirement. In the final regulation, the SOUR of the sewage sludge treated in an aerobic process has to be equal to or less than 1.5 milligrams (instead of 1.0 in the proposal) of oxygen per hour per gram of total solids at 20 degrees Celsius for the sewage sludge to meet the vector attraction reduction requirement.

After reviewing the available information and comments on the proposal, the Agency concluded that vector attraction reduction can be achieved when the value for SOUR is equal to or less than 1.5. The temperature requirement is included in the SOUR vector attraction reduction requirement because the temperature of the sewage sludge affects the rate of digestion. The Agency concluded that for the sewage sludge to digested fully during aerobic digestion, the temperature of the sewage sludge should be 20 degrees Celsius.

Another vector attraction reduction requirement was added to the final

regulation for sewage sludge treated in an aerobic process. This requirement addresses the vector attraction of sewage sludges treated in processes such as composting and aerobic digestion. EPA concluded, based on available information, that when a sewage sludge is treated in an aerobic process for 14 days or longer during which time the temperature of the sewage sludge is higher than 40 degrees Celsius and the average temperature is higher than 45 degrees Celsius, volatile solids in the sewage sludge are reduced to a level that reduces the attractiveness of the sewage sludge to vectors.

The vector attraction reduction requirement in the proposal concerning raising the pH of the sewage sludge and maintaining the elevated pH for a period is the same in the final regulation. Only editorial changes were made to this requirement for the final regulation. Raising the pH of the sewage sludge reduces bacterial activity in the sewage sludge. This results in a reduction in the putrefaction of the sewage sludge, which reduces the odors from the sewage sludge. Because of the reduction in odors, vectors are not attracted to the sewage sludge.

One of the new vector attraction reduction requirements in the final part 503 regulation concerns the percent solids of the sewage sludge. In the proposal, when the percent solids of the sewage sludge was 75 or greater, based on the moisture and solids content of the sewage sludge prior to mixing with other materials, the vector attraction reduction requirement was met. The final part 503 regulation contains two percent solids requirements for vector attraction reduction.

One of the percent solids requirements is the same as in the requirement in the proposal (i.e., 75 percent). This requirement only applies, however, when the sewage sludge does not contain unstabilized solids generated in a primary wastewater treatment process. When the sewage sludge contains unstabilized solids generated in a primary wastewater treatment process, the percent solids of the sewage sludge has to be equal to or greater than 90 percent. This change was made because the Agency is concerned that regrowth of *Salmonella* sp. bacteria may occur when the sewage sludge contains unstabilized solids such as food products that *Salmonella* sp. bacteria can use for nutrients. When the percent solids of the sewage sludge is equal to or greater than 90, EPA concluded that the regrowth problem is mitigated even if the sewage sludge contains unstabilized solids.

The vector attraction reduction requirement in the proposal concerning injection of the sewage sludge below the land surface was edited and expanded in the final regulation. First, this vector attraction reduction requirement now clarifies that no significant amount of sewage sludge can be visible on the land surface within one hour after the sewage sludge is injected. Second, this requirement addresses the time during which a Class A sewage sludge has to be injected after discharge from the pathogen reduction process. Injection of a Class A sewage sludge within a specific time period was addressed in the Class A pathogen requirement in the proposal. The Agency chose to include this requirement in the section on vector attraction reduction in the final regulation to make the final part 503 regulation consistent.

In addition to changing the location of the vector attraction requirement for the injection of a Class A sewage sludge, the requirement itself was changed. The proposed regulation required that the density of fecal coliform and fecal streptococci in the Class A sewage sludge not exceed three logarithms per gram of volatile suspended solids prior to injection. EPA decided to change this requirement to "the sewage sludge shall be injected below the land surface within eight hours after the sewage sludge is discharged from the pathogen reduction process(es)". The Agency concluded that significant regrowth of *Salmonella* sp. bacteria will not occur when the sewage sludge is injected within the eight hour period.

Another vector attraction reduction requirement in the final part 503 regulation concerns incorporation of sewage sludge into the soil. EPA concluded that vector attraction reduction is minimal during the first six hours after sewage sludge is applied to or placed on the land surface. After that time, the potential for vector attraction increases. For this reason, this vector attraction reduction requirement requires that the sewage sludge be incorporated into the soil within six hours after application to or placement on the land. Incorporation into the soil reduces the opportunity for vectors to contact the sewage sludge.

The vector attraction reduction requirement concerning incorporation of the sewage sludge into the soil also requires that sewage sludge that is Class A with respect to pathogens be applied to or placed on the land within eight hours after being discharged from the pathogen treatment process. After that, the sewage sludge must be incorporated into the soil within six hours after being applied to or placed on the land. The purpose of this requirement is to ensure that regrowth of *Salmonella* sp. bacteria do not occur between the time the sewage sludge is discharged from the pathogen treatment process and the time the sewage sludge is applied to or placed on the land.

Also included in the final part 503 regulation is an alternative vector attraction reduction requirement when sewage sludge is placed on an active sewage sludge unit. When the sewage sludge is covered with soil or other material at the end of each operating day, vector attraction reduction is achieved. Vectors do not have the opportunity to contact the sewage sludge when the sewage sludge is covered. This requirement was in the subpart on monofills in the proposed part 503 regulation. Because the purpose of covering the sewage sludge is to reduce vector attraction, the Agency decided to include this requirement in the section on vector attraction reduction in the final part 503 regulation.

A new vector attraction reduction requirement concerning domestic septage also was added to the final regulation. This requirement is in response to comments that domestic septage cannot meet the vector attraction reduction requirement for sewage sludge. To meet this new requirement, the pH of the domestic septage must be raised to 12 or higher using alkali and, without the addition of more alkali, must remain at 12 or higher for 30 minutes. This requirement is based on results from the University of Wisconsin Study mentioned previously in the discussion on the pathogen requirements.

Incineration (Subpart E)

This part of today's preamble discusses the requirements in the final part 503 regulation for firing of sewage sludge in a sewage sludge incinerator. More details on these requirements may be obtained from the technical support document for the part 503 sewage sludge incineration requirements.

Applicability (Section 503.40)

The applicability section for this subpart in the final part 503 regulation is the same, with the exception of some editorial changes, as the applicability section for this subpart in the proposed regulation. This subpart applies to any person who fires sewage sludge in a sewage sludge incinerator, to a sewage sludge incinerator, to sewage sludge fired in a sewage sludge incinerator, and to the exit gas from a sewage sludge incinerator stack.

Special Definitions (Section 503.41)

Definitions for the following terms are included in this section of the final regulation: Air pollution control device, auxiliary fuel, control efficiency, dispersion factor, fluidized bed incinerator, incineration, hourly average, monthly average, risk specific concentration, sewage sludge feed rate, sewage sludge incinerator, stack height, total hydrocarbons, wet electrostatic precipitator, and wet scrubber. The definitions in this subpart discussed below amplify and reinforce the incineration requirements in the final part 503 regulation.

Auxiliary fuel. The definition of auxiliary fuel is included in the final regulation because a sewage sludge incinerator is defined as an incinerator in which sewage sludge and auxiliary fuel are fired. Auxiliary fuel is fuel used to augment the fuel value of sewage sludge. This includes, but is not limited to, natural gas, fuel oil, coal, gas generated during anaerobic digestion of sewage sludge, or municipal solid waste (not to exceed 30 percent of the sewage sludge and auxiliary fuel together by dry weight). Auxiliary fuel does not include hazardous wastes.

As mentioned above, auxiliary fuel may be municipal solid waste if the municipal solid waste is less than 30 percent by weight (dry weight basis) of the material, including sewage sludge, fired in the sewage sludge incinerator. In that case, the part 503 requirements for the incineration of sewage sludge in a sewage sludge incinerator have to be met. When 30 percent or greater of the material fired in an incinerator is municipal solid wastes, the incinerator is a municipal waste combustor and the regulations that address firing of materials in a municipal waste combustor must be met.

Control efficiency. Control efficiency is the mass of a pollutant in the sewage sludge fed to an incinerator minus the mass of that pollutant in the exit gas from the incinerator stack divided by the mass of the pollutant in the sewage sludge fed to the incinerator. The final regulation requires that control efficiency be determined from a performance test of the sewage sludge incinerator, as specified by the permitting authority.

Dispersion factor. The definition of dispersion factor in the proposed regulation is clarified in the final regulation. Dispersion factor is the increase in the ground level ambient air concentration for a pollutant at a specific distance from the sewage sludge incinerator stack because of the incineration of sewage sludge divided by the mass emission rate for the pollutant from the sewage sludge incinerator stack. The units for a dispersion factor are micrograms per cubic meter per gram per second.

Incineration. Incineration is the combustion of organic matter and inorganic matter in sewage sludge by high temperatures in an enclosed device. The phrase "controlled flame combustion" is not included in that definition because high temperatures may be achieved in an enclosed device without controlled flame combustion. Today's definition ensures that the requirements in the final regulation for incineration apply to any enclosed device in which organic material and inorganic matter in sewage sludge are combusted by high temperatures and not just to those that employ controlled flame combustion.

Hourly average. An hourly average is the arithmetic mean of the number of measurements taken during an hour. To determine an hourly average, at least two measurements must be taken during the hour. This definition is in the final regulation because this term is used in the definition of a monthly average.

Monthly average. A monthly average is the arithmetic mean of the hourly averages for the hours a sewage sludge incinerator operates during the month. Note that only the hourly averages for the hours a sewage sludge incinerator operates during the month are used to calculate a monthly average. This definition is included in the final regulation because the allowable total hydrocarbons concentration in the exit gas from a sewage sludge incinerator stack is a monthly average concentration.

Risk specific concentration. Risk specific concentration is the allowable increase in the average daily ground level ambient air concentration for a pollutant from the incineration of sewage sludge at or beyond the property line of the site where the sewage sludge incinerator is located. A risk specific concentration is either provided in the final regulation for each pollutant controlled in this subpart, except total hydrocarbons, or can be calculated using an equation in the final regulation.

Sewage sludge feed rate. The difference in the definition of sewage sludge feed rate in the proposal and the definition in the final regulation is the amount of sewage sludge fed to the incinerator. The proposed regulation indicated that the feed rate was either the average amount of sewage sludge fed to the incinerator or the design capacity of the incinerator.

In the final part 503 regulation, the feed rate is either the average daily amount of sewage sludge fired for all sewage sludge incinerators within the property line of the site where the sewage sludge incinerators are located for the number of days in a 365 day period that each incinerator operates, or the average daily design capacity for all of the sewage sludge incinerators within the property line of the site where the sewage sludge incinerators are located. When there is more than one sewage sludge incinerator located at a site, the pollutant limits for each incinerator are calculated using the same sewage sludge feed rate.

When the design capacity of the sewage sludge incinerators is not used to determine the sewage sludge feed rate, the average daily amount of sewage sludge fired in all sewage sludge incinerators is the sewage sludge feed rate. This change clarifies how the average daily amount should be determined. This rate is based on the average daily amount of sewage sludge fired for the days in a 365 period that each incinerator operates. This results in an average daily amount of sewage sludge fired based on actual operating days for each incinerator. This value would be lower if the days the incinerators do not operate (i.e., zero amount fired on those days) are considered in developing the average daily amount fired.

Sewage sludge incinerator. The definition of sewage sludge incinerator in the final part 503 regulation is an incinerator in which sewage sludge and auxiliary fuel are fired. The term "auxiliary fuel" was added to today's definition to clarify that a sewage sludge incinerator is an incinerator in which sewage sludge and auxiliary fuel are fired. As mentioned previously, hazardous wastes are not auxiliary fuel.

General Requirements (Section 503.42)

For the final part 503 rule, EPA reorganized the general requirements and management practices in the proposal for subpart E. Only one of the general requirements in this subpart for the proposal is still a general requirement in the final part 503 regulation; one is included in the general provisions in the final part 503 regulation; four are management practices in this subpart; one is included in the section on pollutant limits in this subpart; one is included in a definition in the final regulation; one is in the section on frequency of monitoring in this subpart of the final regulation; and one was deleted from the final regulation. These changes are discussed below.

The first general requirement concerns a person who fires sewage sludge in a sewage sludge incinerator. The final part 503 regulation requires that no person shall fire sewage sludge in a sewage sludge incinerator unless the requirements in this subpart are met. As mentioned above, this is the only general requirement in the incineration subpart.

The general requirement concerning access to sewage sludge fed to a sewage sludge incinerator was modified and is included in 503.8—Sampling and analysis. The general provision requires that representative samples of sewage sludge fired in a sewage sludge incinerator be collected and analyzed.

EPA proposed general requirements for this subpart concerning: (1) An instrument that measures and records the total hydrocarbons in the exit gas from a sewage sludge incinerator stack; (2) an instrument that measures and records the oxygen content in the exit gas from a sewage sludge incinerator stack; (3) an instrument that measures and records information used to determine the moisture content in the sewage sludge incinerator stack exit gas; (4) an instrument that measures and records combustion temperatures. These proposed general requirements are management practices in the final part 503 regulation.

One of the other proposed general requirements required that a sewage sludge incinerator comply with the requirements promulgated under the authority of the Clean Air Act in 40 CFR 61.30 through 61.34 for beryllium and 40 CFR 61.50 through 61.55 for mercury. These requirements are now included in the section on pollutant limits in the final part 503 regulation. This proposed general requirement also required that the requirements in 40 CFR 60.150 through 60.154 for new sources be met. The Agency decided not to include this part of the proposed general requirement in the final part 503 regulation because those requirements are not needed to protect public health and the environment from the reasonably anticipated adverse effects of pollutants in sewage sludge. Those requirements still have to be met, however. They are just not a requirement in part 503.

Another general requirement in the proposal required that the sewage sludge feed rate for all incinerators within the property line of the treatment works be used to calculate the pollutant limits for incineration of sewage sludge. Because the definition of sewage sludge feed rate in the final part 503 regulation is based on the calculation for all incinerators at the facility, the general requirement was deleted from the final regulation.

The general requirement in the proposal concerning the monitoring requirements are now included in a separate section in the final regulation. For this reason, this general requirement was deleted from the final regulation.

Another general requirement in the proposed regulation required that incinerator ash be disposed in accordance with the requirements in 40 CFR parts 257, 258, or 261 through 268, as appropriate. Because the final part 503 regulation does not apply to incinerator ash, the Agency decided not to address the disposal of incinerator ash in this subpart.

Pollutant Limits (Section 503.43)

Several changes were made in the final part 503 regulation to the proposed pollutant limits. These changes are discussed below.

In the proposed regulation, equations were presented to calculate pollutant limits for beryllium and mercury. These equations are deleted from the final regulation. Instead, beryllium and mercury in sewage sludge fired in a sewage sludge incinerator are controlled through the National Emission Standards for each of those pollutants. The final part 503 regulation requires that firing of sewage sludge in a sewage sludge incinerator shall not violate the requirements in the National Emission Standard for Beryllium in subpart C of 40 CFR part 61 and the National Emission Standard for Mercury in subpart E of 40 CFR part 61.

The proposed regulation also contained equations used to establish pollutant limits for lead, arsenic, cadmium, chromium, and nickel. Those equations are modified in the final regulation. The equation in the final regulation used to calculate the pollutant limit for lead is:

$$C = \frac{0.1 \times (NAAQS) \times 86,400}{DF \times (1 - CE) \times SF}$$

Where:

C=Allowable daily concentration of lead in milligrams per kilogram of total sewage sludge solids (dry weight basis).

NAAQS=National Ambient Air Quality Standard for lead in micrograms per cubic meter.

DF=Dispersion factor in micrograms per cubic meter per gram per second.

CE=Sewage sludge incinerator control efficiency for lead in hundredths.

SF=Sewage sludge feed rate in metric tons per day (dry weight basis).

The 0.1 value in the above equation allocates 10 percent of the NAAQS for lead to the firing of sewage sludge in a sewage sludge incinerator. This is discussed further in other parts of today's preamble.

One of the terms in the above equation is the control efficiency (i.e., percent removal of the pollutant) for the sewage sludge incinerator. The value for control efficiency could be obtained from a table in the proposed regulation (i.e., national value) or could be determined from a performance test of the incinerator (i.e., case-by-case limit). The final regulation requires that the control efficiency be obtained from a performance test of the incinerator, as specified by the permitting authority. Consequently, the table in the proposal with the control efficiencies used to calculate the national pollutant limits was deleted from the final part 503 regulation.

Another parameter in the above equation is the dispersion factor. In the proposal, the dispersion factor could be obtained from a table in the proposed regulation (i.e., used to calculate a national limit) or could be determined using an air dispersion model (i.e., used to calculate a case-by-case limit), as specified by the permitting authority. Again, like control efficiency, the final regulation requires that the dispersion factor be determined specifically for the site using either the height of the incinerator stack or the creditable stack height in an air dispersion model, as specified by the permitting authority. The final part 503 regulation does not contain values for dispersion factor.

The above changes concerning pollutant control efficiencies and dispersion factors allow the actual performance of the sewage sludge incinerator for a particular sewage sludge and the actual site conditions (e.g., actual topography) to be considered in developing the incinerator control efficiency for a pollutant and dispersion factor, respectively. The Agency concluded this is more appropriate than prescribing the pollutant control efficiencies and dispersion factors in the final part 503 regulation.

The equation in the final regulation used to calculate the pollutant limits for arsenic, cadmium, chromium, and nickel is:

$$C = \frac{RSC \times 86.400}{DF \times (1 - CE) \times SF}$$

Where:

C=Allowable daily concentration of arsenic, cadmium, chromium, or nickel in milligrams per kilogram of total sewage sludge solids (dry weight basis).

CE=Sewage sludge incinerator control efficiency for arsenic, cadmium, chromium, or nickel in hundredths.
DF=Dispersion factor in micrograms per cubic meter per gram per second.
RSC=Risk specific concentration for a pollutant in micrograms per cubic meter.
SF=Sewage sludge feed rate in metric tons per day (dry weight).

As mentioned above, values for control efficiency are determined from a performance test of the incinerator, as specified by the permitting authority. The dispersion factor is determined using either the incinerator stack height or the creditable stack height in an air dispersion model, as specified by the permitting authority. The risk specific concentration for arsenic, cadmium, and nickel is obtained from a table in this subpart of the final regulation.

In the proposed regulation, the value for the risk specific concentration for chromium was given in a table. In the final part 503 regulation, the risk specific concentration for chromium either can be obtained from a table in the final part 503 regulation or can be calculated using an equation provided in the regulation.

Different values for the risk specific concentration for chromium are presented in Table 2 of section 503.43 depending on the type of incinerator with attendant air pollution control devices used to fire the sewage sludge. These values are based on data for the different types of incinerators with attendant air pollution control devices and the percentage of hexavalent chromium in the exit gas from the sewage sludge incinerator stack. For example, available information indicates that the percentage of hexavalent chromium in the stack exit gas from a fluidized bed incinerator with a wet scrubber and a wet electrostatic precipitator is approximately 3.8 percent. This percentage was used to calculate the risk specific concentration for chromium in Table 2 of section 503.43 for that type of incinerator.

The percentage of hexavalent chromium in the exit gas from a sewage sludge incinerator is important because the hexavalent chromium has the most effect on public health. As the percentage of hexavalent chromium increases, the risk specific concentration, which is the allowable increase in the average daily ground level ambient air concentration of a pollutant from the incineration of sewage sludge, for total chromium decreases.

When the risk specific concentrations in Table 2 of section 503.43 are not used, the risk specific concentration for chromium can be calculated using equation (6) in the final regulation. The value 0.0085 in equation (6) is the risk specific concentration for chromium when the percentage of hexavalent chromium in total chromium emitted is 100 percent. To use the equation, the percent of hexavalent chromium in the exit gas from the sewage sludge incinerator stack has to be measured. That value is then used in the equation.

Operational Standard (Section 503.44)

Under the proposed rule, the allowable emissions of total hydrocarbons in the exit gas from the sewage sludge incinerator stack were controlled. This approach was adopted because EPA concluded that it is infeasible to establish a limit that protect public health for each organic pollutant in the exit gas. Consequently, EPA proposed a risk-based operational standard that limited total hydrocarbons in the exit gas using site-specific factors. In the final part 503 regulation, the pollutant limit for total hydrocarbons is similarly an operational standard. This operational standard is based, however, on the demonstrated performance of sewage sludge incinerators using available technology. The operational standard includes a THC concentration that cannot be exceeded in the exit gas from the incinerator. The total hydrocarbons concentration measured in the stack exit gas must be corrected for zero percent moisture and to seven percent oxygen using equations provided in the final regulation. The corrected value cannot exceed the monthly average concentration for total hydrocarbons specified in the final regulation.

The allowable THC concentration is a monthly average. Such an average is consistent with the assumptions made in the cancer risk assessment that supports the regulation. Implicit in the monthly average are excursions that recognize that the THC value may not be met every second of every day. This is satisfactory as long as the monthly average does not exceed 100 parts per million on a volumetric basis. EPA concluded that in the case of sewage sludge incinerators, the monthly average THC concentration is appropriate.

As mentioned above, the operational standard for THC in the final regulation is based on the performance of an incinerator with an instrument that measures a "hot" THC. For this reason, a management practice (i.e., 503.45(a)) is included in the final regulation that requires THC to be measured using an instrument that measures "hot" THC.

In the judgment of the Administrator of EPA, the operational standard for THC in the final regulation protects public health from reasonable anticipated adverse effects of organic pollutants in the incinerator stack exit gas when sewage sludge is fired in a sewage sludge incinerator. More details on how the risks associated with the total hydrocarbons operational standard were calculated are presented in part VIII of this preamble.

Management Practices (Section 503.45)

The final part 503 regulation contains seven management practices for the firing of sewage sludge in a sewage sludge incinerator. The management practices are generally intended to ensure that a sewage sludge incinerator operates within the defined parameters associated with the calculation of the pollutant limits for inorganic pollutants and with the achievement of the THC regulatory level.

The first management practice requires that an instrument that measures and records the total hydrocarbons concentration in the sewage sludge incinerator stack exit gas continuously be installed, calibrated, operated, and maintained for each sewage sludge incinerator. The total hydrocarbons instrument must employ a flame ionization detector; must have a heated sampling line maintained at a temperature of 150 degrees Celsius or higher at all times; and must be calibrated at least once every 24-hour operating period using propane. More discussion on the requirement to monitor THC continuously is presented in other parts of today's preamble.

The second management practice requires installation of an instrument that measures and records the oxygen concentration in the sewage sludge incinerator stack exit gas continuously. Such an instrument must be calibrated, operated, and maintained for each sewage sludge incinerator. This management practice is needed to obtain the information to correct the THC concentration to seven percent oxygen.

The third management practice requires the installation of an instrument that measures and records information used to determine the moisture content in the sewage sludge incinerator stack exit gas continuously. Such an instrument must be calibrated, and maintained for each sewage sludge incinerator. Information obtained through this management practice is used to correct the measured THC concentration for zero percent moisture.

The fourth management practice requires the installation of an instrument that measures and records combustion temperatures continuously.

Such an instrument must be calibrated, operated, and maintained for each sewage sludge incinerator, as specified by the permitting authority. This management practice is needed to obtain information about combustion temperatures and to ensure that the sewage sludge incinerator is operated in a manner similar to how it was operated during the performance test to determine pollutant control efficiencies.

The fifth management practice indicates that the permitting authority will specify the maximum combustion temperature for the sewage sludge incinerator. That temperature will be based on information obtained during the performance test of the incinerator to determine pollutant control efficiencies. This management practice ensures that the maximum combustion temperature does not exceed the maximum combustion temperature during the performance test.

The sixth management practice indicates that the permitting authority will specify the values for the operating parameters for the sewage sludge incinerator air pollution control device. Those values also will be based on information obtained during the performance test to determine pollutant control efficiencies. The purpose of this management practice is to ensure that the air pollution control device is operated in a manner similar to how it was operated during the performance test.

The final regulation provides that firing of sewage sludge in a sewage sludge incinerator is prohibited if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat (503.45(g)). EPA will develop guidance to carry out this provision consistent with the Endangered Species Act.

Frequency of Monitoring (Section 503.46)

This section contains the frequency of monitoring requirement that apply when sewage sludge is fired in a sewage sludge incinerator. This includes the frequency of monitoring for pollutant concentrations, total hydrocarbons concentration and oxygen concentration in the exit gas from a sewage sludge incinerator stack, information used to calculate the moisture content in the exit gas, combustion temperatures, and the air pollution control device operating parameters.

The frequency of monitoring for pollutant concentrations is based on the amount of sewage sludge fired in a sewage sludge incinerator during a 365 day period. The larger the amount fired, the more frequently the sewage sludge fed to the sewage sludge incinerator must be monitored for pollutant concentrations. A discussion of the amounts of sewage sludge in the frequency of monitoring table is presented in the section in today's preamble on land application and in the technical support document for the part 503 incineration requirements.

Part 503 also requires that the THC concentration and oxygen concentration in the exit gas from the sewage sludge incinerator stack, information used to calculate the moisture content in the exit gas, and combustion temperatures be monitored continuously. In addition, the final regulation indicates that the frequency of monitoring for the air pollution control device parameters shall be determined by the permitting authority.

The final regulation allows the permitting authority to reduce the frequency of monitoring for pollutant concentrations after two years of monitoring at the required frequency, as long as the frequency of monitoring is at least once per year when sewage sludge is fired in a sewage sludge incinerator. In deciding whether to reduce the frequency of monitoring, the permitting authority should consider, among other things, the variability of the pollutant concentrations and the magnitude of the pollutant concentrations. The Agency concluded that two years is an adequate period to collect data to make the judgment about reducing the frequency of monitoring. Note that only the permitting authority can reduce the frequency of monitoring.

Recordkeeping (Section 503.47)

The final part 503 regulation requires the person who fires sewage sludge in a sewage sludge incinerator to develop the information specified in this section and to retain the information for five years. The information that has to be developed is information needed to calculate pollutant limits for lead, arsenic, cadmium, chromium, and nickel; information needed to ensure the limits for those pollutants are met; and information needed to ensure the standards for beryllium and mercury are met. In addition, records of the total hydrocarbons and oxygen concentrations in the exit gas from a sewage sludge incinerator, the information needed to calculate moisture content of the exit gas, and information on combustion temperatures and air pollution control device operating parameters must be kept.

Reporting (Section 503.48)

Class I sludge management facilities, POTWs with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more must report the information in 503.47(b) through 503.47(h) to the permitting authority once per 365 day period. The section in today's preamble on land application explains the reasons for requiring Class I sludge management facilities, POTWs with a design flow rate of one MGD or greater, and POTWs that serve 10,000 people or more to report information.

Part XII: Implementation of 40 CFR Part 503

Clean Water Act

The 1987 amendments to the Clean Water Act included significant changes to section 405 regarding the implementation of standards for the use or disposal of sewage sludge. Prior to the 1987 amendments, the CWA required that EPA develop standards for the use and disposal of sewage sludge applicable to POTWs, but it did not specify how the standards were to be implemented, whether through permits and, if so, under what authority. Traditionally, National Pollutant Discharge Elimination System (NPDES) jurisdiction under the CWA arises when a point source discharges pollutants to navigable waters. Thus questions arose about the applicability of NPDES permits to regulate sewage sludge disposal that did not involve discharges to navigable waters. Likewise, other permits either are medium-specific (e.g., permits issued under the Clean Air Act) or regulate particular substances or methods of disposal (e.g., Subtitle D of the Resource Conservation and Recovery Act (RCRA)); therefore, they also were ill-equipped to regulate comprehensively the use and disposal of sewage sludge across all media.

The 1987 CWA amendments establish a program to protect public health and the environment from the reasonably anticipated adverse effects of pollutants in sewage sludge. In addition to requiring development of standards that establish pollutant limits and management practices for each use and disposal method, the CWA establishes requirements for inclusion of these standards in specified permits issued to treatment works treating domestic sewage. Thus, section 405(f) requires inclusion of conditions to implement the sewage sludge standards in NPDES permits, unless these conditions are included in a permit issued either under one of the listed Federal programs or by an approved State sewage sludge

program. Section 405(f)(1), as amended, provides:

> Through Section 402 Permits.—Any permit issued under Section 402 of this Act to a publicly owned treatment works or any other treatment works treating domestic sewage shall include requirements for the use and disposal of sludge that implement the regulations established pursuant to subsection (d) of this section, unless such requirements have been included in a permit issued under the appropriate provisions of subtitle C of the Solid Waste Disposal Act, part C of the Safe Drinking Water Act, the Marine Protection, Research, and Sanctuaries Act of 1972, or the Clean Air Act, or under State permit programs approved by the Administrator, where the Administrator determines that such programs assure compliance with any applicable requirements of this section * * *

Thus the CWA requires EPA to implement the standards through NPDES permits unless the standards are not included in a Clean Air Act permit, a RCRA subtitle C permit, a Marine Protection, Sanctuaries, and Research Act permit, an Underground Injection Control permit under the Safe Drinking Water Act, or an approved State program permit. It is clear that permit coverage among the programs is to be complementary, not duplicative. However, it also is clear from the statutory scheme that Congress contemplated comprehensive coverage of publicly owned treatment works and other treatment works treating domestic sewage through the permit program. No facilities are to go unpermitted merely because they fall outside the traditional jurisdiction of medium-specific programs. Thus, if a POTW or other treatment works treating domestic sewage does not have an NPDES permit, or any of the other permits listed in section 405(f)(1) that implements the sewage sludge standards, the CWA provides that EPA may issue a permit solely to implement the sewage sludge standards, commonly referred to as a "sludge-only permit." (See CWA section 405(f)(2).)

Another important provision of section 405(f)(1) allows a State to issue permits to implement the technical standards where the State permit program has been approved by the Administrator. The Administrator may approve a State program upon determining that the State program will assure compliance with the requirements of section 405. EPA interpreted the CWA to provide for optional, not mandatory, State programs, even if the State already has an approved NPDES program. In the absence of an approved State program, the appropriate EPA Regional Office will be the permit issuance authority for that State.

In addition, section 405(e) of the statute is clear that the obligation to comply with sewage sludge standards is independent of any permit or permit conditions.

> The determination of the manner of disposal or use of sludge is a local determination except that it shall be unlawful for any person to dispose of sludge from a publicly owned treatment works or any other treatment works treating domestic sewage for any use for which regulations have been established pursuant to [section 405(d)], except in accordance with such regulations.

Sewage Sludge Management Program Regulations

On May 2, 1989, EPA promulgated regulations outlining the criteria for approving State sludge permit programs and establishing permitting requirements for sewage sludge management (54 FR 18726). These regulations implement two CWA requirements: first, that permits issued to POTWs and other treatment works treating domestic sewage contain the sewage sludge standards; and second, the requirement that EPA promulgate procedures for the approval of State programs. The purpose of the State program and permitting rules is to provide the implementation framework for the sewage sludge technical standards by: (1) Providing permit conditions to incorporate the standards into permits, as well as additional requirements to track compliance with the standards; and (2) setting approval requirements for State sewage sludge programs so that States can implement the section 405 requirements.

The May 2, 1989, regulations contained three principal sections. First, the rules revised the existing NPDES permitting regulations at 40 CFR parts 122 and 124 to include sewage sludge conditions in NPDES permits and established these regulations as the basis for issuing sludge-only permits. Second, the rules contained revisions to 40 CFR part 123 for States with NPDES authority that wish to modify their existing NPDES programs to include the regulation of sewage sludge. Third, the May 2, 1989, rules contained a separate part, part 501, establishing procedures for approving State sludge management programs that are not part of a State's NPDES program. In addition, part 501 specifies the requirements for State non-NPDES sewage sludge programs. These regulations reflect the intention of CWA section 405(f) that the sewage sludge standards may be included in any of a number of permits under different programs, so long as they are addressed in a permit issued to a POTW or other treatment works treating domestic sewage. When EPA is the permitting authority (i.e., where the State has not sought and obtained approval of its sewage sludge permitting program), the sewage sludge requirements will be implemented primarily through NPDES permits, unless the requirements are contained in one of the other listed Federal permits.

Requirements Prior to Promulgation of the Technical Standards

The CWA also requires that, prior to promulgation of the technical standards, NPDES permits issued to POTWs are to contain sewage sludge conditions. Moreover, the Administrator is authorized to take other appropriate measures to protect public health and the environment from the adverse effects of sewage sludge (see CWA section 405(d)(4)). In response to this call for controls before promulgation of the technical standards, EPA developed an interim strategy for sewage sludge permitting, in a document entitled "Strategy for Interim Implementation of Sludge Requirements in Permits Issued to POTWs" (September 1989).

Now that the part 503 standards are promulgated in today's action, EPA will regulate the use and disposal of sewage sludge by those standards. The interim program, however, will continue to apply to those facilities, pollutants, and use and disposal methods not covered by today's standards. EPA retains authority to impose permit limits developed on a case-by-case basis or to take other appropriate action necessary to protect public health and the environment regarding pollutants and management practices not regulated by the part 503 standards, and to impose more stringent limits and requirements where the part 503 standards are not sufficiently protective at a particular site.

Relationship Between the Sewage Sludge Program Regulations and Today's Standards for Sewage Sludge Use or Disposal

The standards for sewage sludge use or disposal promulgated today apply to various final use or disposal practices that may be carried out by numerous parties. Before the 1987 CWA amendments, the standards applied only to POTWs. Recognizing that parties other than POTWs are likely to use or dispose of sewage sludge, Congress amended section 405(e) to make the standards applicable to any person who uses or disposes of sewage sludge. Thus, the Clean Water Act provides that

POTWs and other treatment works treating domestic sewage, as well as other users and disposers, are subject to the standards. Moreover, section 405(e) makes these standards independently enforceable even if conditions to implement the standards have not been included in a permit as provided in section 405(f).

EPA's program for implementing and enforcing today's standards follows the two-pronged approach established by the Clean Water Act. First, the standards are directly enforceable against any user or disposer of sewage sludge. POTWs and other generators of sewage sludge are users and disposers of sewage sludge even if final use or disposal is provided by some other party. Under the existing regulations and in accordance with the Interim Permitting Strategy, permits reissued to POTWs after the 1987 amendments should include conditions specifying that POTWs are expected to comply with the part 503 standards by the statutory deadlines even if the permits themselves are not modified to incorporate those standards. EPA will enforce the final part 503 standards in accordance with the Agency's existing Enforcement Management System (EMS). Second, the standards will be implemented through permits issued to POTWs and other treatment works treating domestic sewage (discussed more fully in the following section on "who must apply for a permit"). Initially, EPA will rely strongly on the direct enforceability of the standards. Over the long term, however, EPA intends that permits will become the primary mechanism for implementing the standards for POTWs and other treatment works treating domestic sewage.

The following discussion addresses several key issues related to implementation of the standards using the programmatic framework established by the permitting requirements and State program rules promulgated on May 2, 1989: (1) Who must apply for a permit, (2) permit application requirements, (3) permitting priorities, (4) requirements in the absence of a permit, (5) who issues the permit and the role of existing State programs, and (6) EPA's plans for outreach and training to foster implementation of the standards. Many of the permitting issues, as well as others related to the national sewage sludge program, are discussed in more detail in the May 2, 1989, **Federal Register** notice (54 FR 18716).

Who Must Apply for a Permit

The CWA requires today's technical standards to be included in permits issued to the key actors involved in generating, treating, and disposing of sewage sludge. Section 405(f)(1) defines the permitting universe to include POTWs and other treatment works treating domestic sewage, including facilities that are not required to obtain NPDES permits pursuant to section 402 of the CWA (section 405(f)(2)). "Treatment works treating domestic sewage" is defined at 40 CFR 122.2 to mean:

> A POTW or any other sewage sludge or waste water treatment devices or systems, regardless of ownership (including Federal facilities) used in the storage, treatment, recycling and reclamation of municipal or domestic sewage, including land dedicated for the disposal of sewage sludge. This definition does not include septic tanks or similar devices. For purposes of this definition, "domestic sewage" includes waste and waste water from humans or household operation that are discharged to or otherwise enter a treatment works. In States where there is no approved State sludge management program under section 405(f) of the CWA, the Regional Administrator may designate any person subject to the standards for sewage sludge use and disposal in 40 CFR part 503 as a "treatment works treating domestic sewage," where he or she finds that there is a potential for adverse effects on public health and the environment from poor sludge quality or poor sludge handling, use or disposal practices, or where he or she finds that such designation is necessary to ensure that such person is in compliance with 40 CFR part 503.

As explained in the preamble to the sludge permitting regulations, the purpose of this definition is to capture all those facilities that "generate sewage sludge or otherwise effectively control the quality of sewage sludge or the manner in which it is disposed (and hence its effect on the environment.)" 54 FR 18725–6 (May 2, 1989). Thus, all POTWs must have permits that implement applicable technical standards. Generally, the permit issued to the POTW must include standards applicable to sewage sludge quality as well as the other permit conditions required by 40 CFR part 122 (e.g., standard conditions and compliance monitoring requirements). In addition, the permit may include conditions related to any aspect of sewage sludge management developed on a case-by-case basis where the permitting authority determines that such conditions are necessary to protect public health and the environment. For example, today's rule does not establish standards for temporary storage of sewage sludge. The permitting authority may develop permit requirements to address potential problems at temporary storage facilities such as contamination of surface water or ground water or unrestricted public access to temporary storage locations.

The permit may also include conditions establishing a POTW's responsibilities when it sends its sewage sludge to other facilities for final use or disposal. As a general rule, a permit issued to a POTW that sends its sewage sludge to another treatment works treating domestic sewage should specify the conditions under which that POTW would be relieved of its responsibility for use or disposal of its sewage sludge in compliance with section 405(d) standards. Generally, a POTW retains responsibility for use and disposal of its sewage sludge (i.e., compliance with part 503 standards applicable to its use or disposal practices) unless it transfers its sewage sludge to another treatment works treating domestic sewage. For example, a permit issued to a POTW that sends its sewage sludge to an incinerator owned by another municipality would not necessarily include all standards applicable to incineration. The permit for the generating POTW would generally have standard conditions, while the permit issued to the incinerator would contain standard conditions and other specific conditions relating to the operation of the incinerator and the quality of sewage sludge going into the incinerator.

The scheme contemplates that facilities other than POTWs may also be required to apply for permits. Treatment works treating domestic sewage, as noted above, include facilities dedicated to the disposal of sewage sludge (i.e., surface disposal sites and incinerators). In addition, certain facilities that handle sewage sludge may be required to apply for a permit, particularly where they alter the nature of the sewage sludge before ultimate use or disposal. EPA considers that the sewage sludge has undergone a change in quality if, through processes such as stabilization, composting, digestion, or heat treatment, a change has occurred in pollutant concentrations, pathogen levels, or vector attraction properties of the sewage sludge (on a dry weight basis) sufficient to change its regulatory status under part 503. A sewage sludge also changes in quality if it is blended permanently with bulking agents (such as sawdust or wood chips) or with sewage sludge from another treatment works (as a material derived from sewage sludge, a sewage sludge product remains subject to the definition of sewage sludge under section 503.9).

EPA does not consider dewatering, of itself, to constitute a change in sludge quality. Dewatering increases the solids content of sewage sludge without

necessarily changing its dry-weight pollutant concentrations, pathogen levels, or vector attraction properties; in addition, because sewage sludge monitoring information is reported on a dry weight basis, the solids content of the sewage sludge is irrelevant to its quality under part 503. EPA also does not consider the placement of sewage sludge in a bag or other container for sale or giveaway to constitute treatment or a change in sludge quality, since the sludge has not been modified with respect to pollutant concentrations, pathogen levels, or vector attraction properties. Thus a person who simply dewaters the sewage sludge, or who places the sewage sludge in a bag or similar enclosure for sale or distribution, would not be a treatment works treating domestic sewage.

If the treatment works generating the sewage sludge transfers sewage sludge to a person who changes the quality of the sewage sludge, the entity changing the quality is a treatment works treating domestic sewage. That entity is not only subject to part 503 standards but is also required to apply for a permit. If, however, the treatment works generating the sewage sludge provides sewage sludge to a person who does not change the quality, the generating treatment works retains the responsibility for the ultimate use or disposal of the sludge and must ensure that the part 503 requirements are met.

Generally, as noted above, facilities other than POTWs that do not change the quality of sewage sludge would not be required to apply for permits. Among such facilities or operations are contract sludge haulers or land appliers. However, as previously explained, EPA retains the authority under section 405(d)(4) of the CWA to take such action as it determines is appropriate to protect public health and the environment from adverse effects from the pollutants in sewage sludge. EPA's current regulations at 40 CFR 122.1(b)(4) provide that the Regional Administrator may designate any person subject to the standards for sewage sludge use and disposal as a treatment works treating domestic sewage where necessary to protect public health and the environment from the adverse effects of sewage sludge or to ensure compliance with the sewage sludge technical standards. Exercising this authority, in special circumstances, EPA may conclude that protection of public health and the environment requires a facility or operation to apply for a permit that otherwise would not need one.

The discussion below elaborates upon the foregoing and addresses who must apply for a permit and how other users and disposers might be regulated by use and disposal practice.

Land Application

Land application, under § 503.11 of today's rule, essentially refers to the beneficial use of sewage sludge through placement in or on the soil; in a manner that utilizes the fertilizing and soil conditioning properties of the sewage sludge. The definition of land application covers a number of scenarios. Sewage sludge may be applied to the land in bulk form, directly by the treatment works or by a commercial enterprise. Land application of bulk sewage sludge may take place on land owned by the treatment works or on privately-held land. Sewage sludge may also be packaged and distributed, in some cases after further processing, for sale or give-away to the general public.

Land application may involve any or all of the following parties: The treatment works generating the sewage sludge (or other person who prepares the sewage sludge for application to the land), a distributor of the sewage sludge, a person who applies the sewage sludge to the land, and the owner or leaseholder of the land to which the sewage sludge is applied. In the simplest case, where the treatment works (or a commercial land applier that does not change the quality of the sewage sludge) applies the sewage sludge to land owned by the treatment works, the treatment works retains control over the entire process of sewage sludge generation, treatment, and application to the land. In other cases, the treatment works provides the sewage sludge to another party for further treatment (such as composting) or blending with sewage sludges from other treatment works and by so doing the treatment works at some point effectively relinquishes control over the quality of the sludge.

Subpart B of today's regulation applies to a person who applies sewage sludge to the land, to a person who prepares sewage sludge for applicetion to the land, to the sewage sludge applied to the land, and to the land on which sewage sludge is applied. Any person who generates sewage sludge or who changes the quality of sewage sludge and controls the ultimate use or disposal of sewage sludge is a treatment works treating domestic sewage and must apply for a permit containing sewage sludge conditions. Typically, owners or occupants of land on which sewage sludge is applied are not considered treatment works treating domestic sewage and need not apply for a permit. They would, however, be expected to comply with any standards that apply to management of the site after the sewage sludge is applied (e.g., any access restrictions associated with sewage sludge meeting Class B pathogen requirements).

If the treatment works is the party that applies sewage sludge to the land, the treatment works will be issued a permit that spells out the conditions for land application contained in today's rule. If the treatment works uses a commercial sewage sludge applier that does not change the quality of the sewage sludge for land application, the treatment works will still be held accountable under today's rule and through its permit for the commercial applier's compliance with the part 503 standards, since the Agency considers that the treatment works still retains control over the quality of the sewage sludge. In this case, as the generator of sewage sludge, the treatment works cannot limit its responsibility for the use and disposal of the sewage sludge in compliance with the standards merely by transferring the sludge to a commercial applier. The applier would, however, also be governed directly by the part 503 standards. If the treatment works applies its sewage sludge to the land in another jurisdiction, it may also need to apply for a State or local permit in that jurisdiction (to enable that jurisdiction to impose compliance monitoring and facilitate any necessary enforcement actions). On the other hand, if the treatment works transfers the sewage sludge to another treatment works treating domestic sewage (such as a commercial treatment facility, fertilizer manufacturer, or disposal service), that second treatment works treating domestic sewage would be required to apply for a permit that essentially picks up control where the generating treatment works' permit leaves off.

Subpart B of today's rule includes general requirements, pollutant limits, management practices, pathogen requirements, and vector attraction requirements. As described elsewhere in today's rulemaking, in certain cases a sewage sludge or sewage sludge product that meets certain minimum quality requirements is not required to meet some or all of the controls under part 503. The Agency believes that if sewage sludge (or material derived from sewage sludge) meets these requirements prior to land application, no further controls are needed on the sewage sludge or on the land where the sewage sludge is applied in order to protect public health and the environment from reasonably anticipated adverse effects of pollutants

in the sewage sludge. The rationale for not applying the general requirements and management practices is that sewage sludge that meets the three quality requirements has a comparatively higher value. Because of this, the sludge most likely will not be applied to the land inappropriately (i.e., "wasted"). In addition, the Agency does not expect over application to occur because it could reduce crop yield, which is counter to the main reason to apply sewage sludge to the land. When the sewage sludge meets the three quality requirements, it is a fertilizer material and should be regulated similarly to other fertilizers.

Under § 503.10 of today's rule, the general requirements of § 503.12 and the management practices of § 503.14 do not apply to a bulk or bagged sewage sludge if the sewage sludge meets the pollutant concentrations in § 503.13(b)(2), the Class A pathogen requirements in § 503.32(b), and one of the vector attraction requirements in 503.33(b)(1)–(8). The general requirements and management practices do not apply to a material derived from bulk or bagged sewage sludge if the material meets the minimum concentration, pathogen, and vector attraction requirements. All Subpart B standards, including monitoring, recordkeeping, and reporting requirements are inapplicable to material derived from bulk or bagged sewage sludge, if the sewage sludge used to produce that material meets the minimum concentration, pathogen, and vector attraction requirements described above. The treatment works generating the sewage sludge from which the material is derived remains responsible for any monitoring, recordkeeping, and reporting requirements, however.

After it is generated, sewage sludge generally will be land applied according to one of the following three scenarios: (1) The treatment works (or a commercial applier that does not change the quality of the sewage sludge) applies the sewage sludge to the land (i.e., under the wording of today's rule, the "person who prepares" is also the "person who applies"); (2) the treatment works provides the sewage sludge to another treatment works treating domestic sewage that further changes sludge quality and assumes responsibility for ultimate land application (i.e., the "person who prepares" provides the sewage sludge to another "person who prepares"); or (3) the treatment works demonstrates that the sewage sludge meets certain minimum quality requirements and that, as described above, no further sewage sludge management requirements (except for certain monitoring, recordkeeping and reporting requirements) apply.

An explanation for each scenario follows:

(1) If the treatment works applies its sewage sludge to the land (or sends it to a commercial applier that does not change the quality of the sludge), the treatment works retains direct control over the quality of the sewage sludge and is responsible for ensuring that the part 503 standards are met. In its permit application, the treatment works must announce its intent to apply its sewage sludge to the land either directly or through the use of a commercial applier. In the permit application, the treatment works must either identify all land application sites in advance, or submit a copy of its land application plan, which includes the geographical area covered, the site selection criteria, site management practices, and a provision for public notice (including at a minimum notice to the permitting authority and adjacent landholders) (§ 501.15(a)(2)(ix)).

The permit issued to the treatment works will contain the part 503 requirements that address the land application practices described in the permit application. EPA has determined that, when Congress amended section 405(e) to extend the obligation to comply with the sludge standards to each person using or disposing of sewage sludge, Congress did not intend to limit or transfer the responsibility of the generating POTW for ensuring compliance with the standards except insofar as the generating POTW sends the sewage sludge to another treatment works treating domestic sewage. In other words, a treatment works generating sewage sludge retains its duty to comply with the sewage sludge use and disposal standards except where it transfers its sludge to another treatment works treating domestic sewage that is itself subject to permitting requirements under section 405(f) of the CWA.

The treatment works generating the sewage sludge must apply for a permit and must identify, in the permit application, the person(s) who will apply sewage sludge to the land. In its application, the treatment works generating the sewage sludge must also identify the land application sites or submit a land application plan. EPA expects that although the treatment works generating the sewage sludge does not actually apply the sewage sludge to the land, the treatment works generating the sewage sludge will exert sufficient control over the land applier to enable the applier to comply with the part 503 standards. For this reason, § 503.12 requires the treatment works to provide the applier with the information necessary to comply with the standards.

Since under this scenario the land applier does not treat the sewage sludge or otherwise change sludge quality, the land applier is not a treatment works treating domestic sewage and is not required to apply for a permit. In this case the part 503 standards apply directly to the land applier. The permit issued to the treatment works generating the sewage sludge must contain sufficient controls to ensure that the treatment works informs the land applier of what requirements must be met, and that the treatment works is held responsible for compliance with part 503 by the land applier.

Certain part 503 requirements apply to the treatment works generating the sewage sludge, and certain requirements apply to the land applier. Generally, they can be summarized as follows:

- Under § 503.12, the generating treatment works must provide both the land applier and the site owner with the information necessary to comply with part 503.
- The generating treatment works must ensure that the sewage sludge meets the pollutant limits in § 503.13.
- The sewage sludge must be applied to the land in accordance with the management practices in § 503.14. The treatment works generating the sewage sludge will be responsible for informing the land applier of applicable management practices, and the land applier will be responsible for compliance with those management practices.
- The generating treatment works is responsible for providing all necessary treatment to meet the pathogen and vector attraction requirements in § 503.15. The land applier and site owner will together be responsible for carrying out any necessary site access restrictions.
- The generating treatment works must monitor the sewage sludge according to the requirements in § 503.16.
- The generating treatment works must keep records as required in § 503.17.
- The generating treatment works must report to the permitting authority as required in § 503.18 if it is a Class I sludge management facility or if it is required to do so in its permit. (Conceivably, a land applier could be designated by the permitting authority as Class I or otherwise subject to reporting.)

(2) Under the second scenario, the sewage sludge is not applied to the land by the treatment works generating the

sewage sludge, but it is provided to a person who provides further treatment or otherwise changes the quality of the sewage sludge (i.e., another "person who prepares"). The person who changes the quality of the sewage sludge may apply it to the land in bulk form, place it in a bag or similar enclosure for sale or distribution to the public, or provide it to another facility for further distribution and marketing.

Both the treatment works generating the sewage sludge and the person who changes the sewage sludge quality must apply for a permit. In its permit application, the generating treatment works must identify the person who will change the quality of the sewage sludge; under § 503.12, it must provide that person with the information necessary to comply with part 503. The person who changes sewage sludge quality must comply with the part 503 requirements in its permit (or, pending permit issuance, with part 503 directly).

(3) Certain part 503 requirements are inapplicable to the treatment works generating the sewage sludge if the sewage sludge meets certain minimum criteria regarding pollutant concentrations, pathogen levels, and vector attraction properties. If the sewage sludge (or the material derived from sludge) meets the pollutant concentrations in § 503.13(b)(3), the Class A pathogen reduction requirements in § 503.32(a), and one of the vector attraction requirements of § 503.33 (b) (1)–(8), the treatment works generating the sewage sludge not required to meet the general requirements of § 503.12 and the management practices of § 503.14. Furthermore, if a material is derived from a sewage sludge that meets the pollutant concentrations in § 503.13(b)(3), the Class A pathogen reduction requirements in § 503.32(a), and one of the vector attraction requirements of § 503.33 (b) (1)–(8), the material is not required to meet the subpart B requirements, including monitoring, recordkeeping, and reporting requirements.

Surface Disposal

Surface disposal, under today's regulation, is the placement of sewage sludge on an area of land dedicated to the disposal of sewage sludge and containing one or more active "sewage sludge units." A surface disposal site is, by definition, a treatment works treating domestic sewage. Subpart C of today's rulemaking applies to any person who prepares sewage sludge for placement on a surface disposal site, to the owner/operator of a surface disposal site, to the sewage sludge placed on a surface disposal site, and to a surface disposal site.

As a treatment works treating domestic sewage, a surface disposal site is subject to permitting requirements under part 122, 124 or 501. If a surface disposal site is owned or operated by the treatment works generating the sewage sludge (i.e., the "person who prepares"), the part 503 requirements for the disposal site will be contained in the permit issued to the generating treatment works. If, however, the surface disposal site is owned or operated by another party, both parties must apply for permits containing applicable part 503 requirements. Applicable requirements are in subpart C of part 503 and consist of general requirements (§ 503.22); pollutant limits (§ 503.23); management practices (§ 503.24); pathogen and vector attraction requirements (§ 503.25); and monitoring, recordkeeping, and reporting requirements (§§ 503.26–503.28).

Incineration

Subpart E of today's regulation applies to any person who fires sewage sludge in a sewage sludge incinerator, to sewage sludge fired in a sewage sludge incinerator, and to a sewage sludge incinerator. Subpart E includes general requirements (§ 503.42); pollutant limits (§ 503.43); operational standards (§ 503.44); management practices (§ 503.45); and monitoring, recordkeeping, and reporting requirements (§ 503.46 through § 503.48). Under § 503.43, site-specific variables (incinerator type, dispersion factor, control efficiency, feed rate, stack height) must be used to calculate allowable daily concentrations of arsenic, cadmium, chromium, lead, and nickel in the sewage sludge fed to the incinerator.

A sewage sludge incinerator is considered to be a treatment works treating domestic sewage under 40 CFR 122.2 and therefore must obtain a permit. If, as is mostly the case, a sewage sludge incinerator is operated by the treatment works generating the sewage sludge, the permit issued to the generating treatment works will contain the part 503 requirements applicable to its sewage sludge incinerator. In those instances where a treatment works generating sewage sludge sends its sewage sludge to another sewage sludge incinerator, the permit issued to the generating treatment works would generally contain standard conditions. The sewage sludge incinerator's permit, meanwhile, would include the sewage sludge pollutant limits, emission limits, operational standards, and management practices required by the part 503 incinerator standards.

Septage Haulers

Domestic septage is considered sewage sludge under today's rule; therefore, users and disposers of domestic septage must comply with the standards applicable to their use or disposal practices. However, EPA generally does not expect to issue permits to septage haulers because they are not considered to be treatment works treating domestic sewage (unless specifically designated by the Regional Administrator). (54 FR 18726, May 2, 1989). Instead, EPA will rely on the direct enforceability of today's rule to implement the standards with respect to septage haulers.

Septage haulers will be required to keep records of basic information about their use and disposal practices. (Note: Septage taken to a POTW for treatment is not considered use or disposal and, therefore, is not covered by today's standards.) The person applying the domestic septage to the land must comply with requirements for annual application rate (§ 503.13(c)), pathogen and vector attraction (§ 503.15 (b) and (d)), monitoring (§ 503.16(b)), and recordkeeping (§ 503.17(b)). (Alternately, the person applying the domestic septage may comply with the subpart B requirements for sewage sludge unless specifically indicated otherwise. Because the sewage sludge standards are more stringent, EPA does not expect many septage haulers to select them.)

Surface disposal of domestic septage is subject to the vector attraction requirements of subpart D. Under § 503.26, each container of domestic septage placed on a sewage sludge unit shall be monitored for compliance with the vector attraction requirement of § 503.33(b)(12), if the vector attraction requirement in § 503.33(b)(12) is met when domestic septage is placed on an active sewage sludge unit.

Permit Application Requirements

Currently, under §§ 122.22(c)(2)(i) and 501.15(d)(1)(ii)(A) of the sewage sludge permit program regulations, any POTW or other treatment works treating domestic sewage with an existing NPDES permit must submit sewage sludge permit application information when its next application for NPDES permit renewal is due, or within 120 days of promulgation of an applicable part 503 standard for sewage sludge use or disposal, whichever comes first. If a treatment works treating domestic sewage is not subject to the NPDES permitting program (i.e., it is a "sludge

only facility"), it is required under §§ 122.21(c)(2)(ii) and 501.15(d)(1)(ii)(B) to submit permit application information within 120 days of promulgation of an applicable part 503 standard or upon request of the Director. If a treatment works treating domestic sewage commences operation after promulgation of an applicable part 503 standard, it is required under §§ 122.21(c)(2)(iii) and 501.15(d)(1)(ii)(C) to submit a permit application at least 180 days prior to the date proposed for commencing operations.

EPA estimates that approximately 16,000 POTWs are in operation nationwide and that between 3,000 and 5,000 other facilities also meet the definition of treatment works treating domestic sewage because they exert control over the quality or disposal of sewage sludge. Under existing regulations, therefore, up to 20,000 POTWS and other treatment works treating domestic sewage would be expected to submit sewage sludge permit application information by June 21, 1993.

On May 27, 1992, EPA proposed a phased approach to the submittal of sewage sludge permit applications, which would reduce the number of applications received during the period immediately following promulgation of the part 503 standards. (57 FR 22197). EPA proposed this approach to manage permit applications more efficiently and to prioritize permitting activities among different types of facilities and sewage sludge use or disposal activities. EPA expects to promulgate the revised permit application requirements after promulgation of these standards.

Under the phased approach, as proposed in EPA's May 27, 1992 notice, the Agency would only require sewage sludge permit applications during the initial period following promulgation of part 503 from treatment works treating domestic sewage that are expected to have site-specific pollutant limits in their permits. Certain treatment works treating domestic sewage are required to have site-specific permit limits. Other treatment works treating domestic sewage may request site-specific permit limits under certain circumstances, as discussed below.

Site-specific permit limits are required for sewage sludge that is fired in a sewage sludge incinerator or placed on certain types of surface disposal sites. Applicants intending to incinerate sewage sludge in sewage sludge incinerators are required, under § 503.43 of today's rule, to use site-specific variables (incinerator type, dispersion factor, control efficiency, feed rate, stack height) to calculate allowable daily concentrations of arsenic, cadmium, chromium, lead, and nickel in the sewage sludge fed to the incinerator. Pollutant limits for surface disposal sites may be calculated on a site-specific basis where the site-specific parameters at the site are different from the national model (§ 503.23(b)). Under the proposed application deadline rule, requests for site-specific limits will be considered beyond the first round of permit applications only for good cause. Good cause includes instances where an applicant does not have information when the part 503 standards are promulgated to indicate that site-specific pollutant limits will be necessary (e.g., it changes use or disposal practices).

For treatment works treating domestic sewage that currently have NPDES permits and will not need site-specific pollutant limits, the sewage sludge information would be submitted when their applications for permit renewal are due. Sludge-only facilities (i.e., those without existing NPDES permits) would submit a subset of application information within one year after promulgation of an applicable part 503 use or disposal standard. Based on this information, the permitting authority would be able to determine whether additional information was needed and whether to issue a permit.

In its May 27, 1992 notice EPA also proposed to extend the time period over which permit applications must be submitted by these "first phase" facilities, from within 120 days after promulgation of part 503 to within 180 days after promulgation of part 503, to provide adequate time for applicants to compile necessary information.

Application Information Required.

Application requirements related to sewage sludge use or disposal were established by the May 2, 1989, sewage sludge permit program regulations. Section 122.21(c)(2) requires all treatment works treating domestic sewage to submit sewage sludge permit application information to the director. Section 122.21(d)(3)(ii) specifies which information must be submitted, namely, the information at § 501.15(a)(2).

Section 501.15(a)(2) requires two types of information: general facility information (paragraphs (i)–(vi)) and information on sewage sludge use and disposal practices (paragraphs (vii)–(xii)). The information requirements are as follows:

(2) *Information requirements.* All treatment works treating domestic sewage shall submit to the Director within the time frames established in paragraph (d)(1)(ii) of this section the following information:

(i) The activities conducted by the applicant which require it to apply for a permit;

(ii) Name, mailing address, and location of the treatment works treating domestic sewage for which the application is submitted;

(iii) The operator's name, address, telephone number, ownership status, and status as Federal, State, private, public, or other entity;

(iv) Whether the facility is located on Indian lands;

(v) A listing of all permits of construction approvals received or applied for under any of the following programs:

(A) Hazardous Waste Management program under RCRA.

(B) UIC program under SDWA.

(C) NPDES program under CWA.

(D) Prevention of Significant Deterioration (PSD) program under the Clean Air Act.

(E) Nonattainment program under the Clean Air Act.

(F) National Emission Standards for Hazardous Pollutants (NESHAPS) preconstruction approval under the Clean Air Act.

(G) Ocean dumping permits under the Marine Protection, Research, and Sanctuaries Act.

(H) Dredge or fill permits under section 404 of CWA.

(I) Other relevant environmental permits, including State or local permits.

(vi) A topographic map (or other map if a topographic map is unavailable) extending one mile beyond the property boundaries of the treatment works treating domestic sewage, depicting the location of the sludge management facilities (including disposal sites), the location of all water bodies, and the location of wells used for drinking water listed in the public records or otherwise known to the applicant within ¼ mile of the property boundaries;

(vii) Any sludge monitoring data the applicant may have, including available ground water monitoring data, with a description of the well locations and approximate depth to ground water, for landfills or land application sites (see appendix I to 40 CFR part 257);

(viii) A description of the applicant's sludge use and disposal practices (including, where applicable, the location of any sites where the applicant transfers sludge for treatment and/or disposal, as well as the name of the applier or other contractor who applies the sludge to land if different from the applicant, and the name of any distributors when the sludge will be disposed of through distribution and marketing, if different from the applicant);

(ix) For each land application site the applicant will use during the life of the permit, the applicant will supply information necessary to determine if the site is appropriate for land application and a description of how the site is (or will be) managed. Applicants intending to apply sludge to land application sites not identified at the time of application must submit a land application plan which at a minimum:

(A) Describes the geographical area covered by the plan;

(B) Identifies site selection criteria;
(C) Describes how sites will be managed;
(D) Provides for advance notice to the permit authority of specific land application sites and reasonable time for the permit authority to object prior to the sludge application; and
(E) Provides for advance public notice as required by State and local law, but in all cases requires notice to landowners and occupants adjacent to or abutting the proposed land application site.
(x) Annual sludge production volume;
(xi) Any information required to determine the appropriate standards for permitting under 40 CFR part 503; and
(xii) Any other information the Program Director may request and reasonably require to assess the sludge use and disposal practices, to determine whether to issue a permit, or to ascertain appropriate permit requirements.

For purposes of today's rule and permit applications triggered by promulgation of today's rule, the most significant information requirement is the requirement in paragraph (xi) to submit "any information required to determine the appropriate standards for permitting under 40 CFR part 503." The information requirements related to the part 503 standards were kept general in the May 2, 1989, rule because part 503 had not yet been promulgated. Today's rule establishes more specific information requirements for each use and disposal practice. Permit applicants must identify their chosen use and disposal practices and submit information which will enable the permitting authority either to determine compliance with the standards or to derive site-specific pollutant limits where the applicant seeks site-specific limits as provided in today's rule. EPA expects to issue additional guidance detailing what information is needed for each use and disposal practice. EPA also is in the process of revising the NPDES application form for POTWs, which will include requirements for submitting sewage sludge use and disposal information. (Prior to rulemakings affecting application forms, EPA intends to issue interim application guidance to facilitate the collection of this information.) EPA does not anticipate issuing or reissuing permits to all existing POTWs and other treatment works treating domestic sewage at one time. This approach, which was in the proposed permitting rule, was abandoned as impractical given the severe resource burden that would result. Instead, EPA expects that all permits reissued after promulgation of part 503 will contain today's standards and that other permits will be reopened to incorporate today's standards as described in the discussion below on permitting priorities. The permitting authority will use information submitted with the application (as well as from other sources, such as monitoring data submitted under the interim permitting strategy or pursuant to a POTW's pretreatment program) to determine whether to issue a permit or revoke and reissue an existing EPA-issued NPDES permit to incorporate today's standards.

As discussed later in the section on who issues the permit, EPA expects to be the permitting authority initially. Therefore, all applications should be submitted to the appropriate EPA Regional office unless the applicant is notified otherwise by EPA.

Permitting Priorities

The process of developing and issuing permits provides the permitting authority an opportunity to evaluate each facility's use and disposal practice(s) and to develop permit conditions incorporating part 503 standards as well as additional requirements, either as required by parts 122 or 501 or as tailored to site-specific circumstances (e.g., more frequent monitoring). Permit issuance also provides additional certainty to the permitted facility of its legal obligations, and compliance with permit terms may provide a defense against actions based on violations of the part 503 standards (see 40 CFR § 122.5 and preamble discussion at 54 FR 18735, May 2, 1989). Thus, permits will be the primary mechanism for implementing the national sewage sludge program in the long run.

As discussed above, EPA has determined that it is not feasible to develop and issue permits to the estimated 16,000 to 20,000 treatment works treating domestic sewage which may be subject to the part 503 standards. Consequently, EPA has proposed revisions to parts 122 and 501 to allow phased submission of permit applications over time (57 FR 22197, May 27, 1992). Permitting authorities must establish priorities for permit issuance based on consideration of the nature of the universe of facilities ultimately required to have the part 503 standards reflected in permits.

Today's rule does not establish priorities for issuance of permits to treatment works treating domestic sewage. Nonetheless, today's rule, in combination with existing policies and regulations, will allow permitting authorities to establish permitting priorities.

The Sewage Sludge Interim Permitting Strategy (September 1989) recommended that the following types of POTWs be considered priorities for purposes of interim sewage sludge permitting: Class I sludge management facilities (as defined by 40 CFR 122.2); POTWs that fire sewage sludge in a sewage sludge incinerator; and POTWs with known or suspected problems with their sewage sludge quality or sludge use or disposal practices.

EPA encourages permitting authorities to establish permitting priorities to implement part 503 standards similar to those established by the interim strategy, but modified in consideration of today's rule. In general, the general requirements, management practices, pollutant limitations, pathogen and vector requirements, and monitoring, recordkeeping, and reporting requirements in today's rule will apply in the absence of permits. The exception would be those facilities that either require or seek site-specific pollutant limitations as provided in today's rule.

EPA believes that sewage sludge permitting priorities should be established as follows. In the first round of permitting following today's rule, permitting authorities should rely to the maximum extent possible on the self-implementing aspects of the part 503 standards. Permits should be issued during the initial period after part 503 is published to those treatment works treating domestic sewage in the following high-priority categories, for which the Agency believes self-implementation is not sufficient: Sewage sludge incinerators; surface disposal sites requiring or requesting site-specific permit limits; facilities designated by the permitting authority as posing a threat to human health and the environment and that need to be fully evaluated in the context of permit development; facilities for which a permit is deemed necessary to fully support or promote beneficial use; and facilities whose NPDES permits come up for reissuance during the course of the normal five-year permit cycle.

EPA considers sewage sludge incinerators a high priority for permit issuance for two principal reasons. First, sewage sludge incinerators present a wider exposure to sewage sludge pollutants and therefore, are presumed to pose a greater potential threat to public health and the environment than other use or disposal methods. In addition, some of the requirements for sewage sludge incinerators can only be fully applied on a case-specific basis (e.g., allowable pollutant concentrations for sludge fed to incinerators must be calculated from results of air dispersion models and control efficiencies of the unit). Similarly, certain surface disposal

sites under subpart C will be required to apply for site-specific permit limits, and these are being targeted for immediate attention as part of the first phase of permit applications.

Treatment works treating domestic sewage that have been designated by the permitting authority as posing a threat to public health and the environment should also be considered a high priority for submission of application information and for permitting during the initial period following the effective date of today's rule. Although the part 503 technical standards are designed to protect public health and the environment, EPA envisions certain cases where it may be necessary for the permitting authority to work closely with the treatment works treating domestic sewage to ensure that the technical standards are properly applied and reinforced in the context of permit development and issuance. For example, where the treatment works treating domestic sewage must build new pollution control facilities to meet the standards, the permit can establish compliance schedules (see § 122.47). (Note, however, that no compliance schedule can extend the compliance deadline established under section 405(d)(2)(D) of the CWA.)

EPA believes that for certain treatment works treating domestic sewage, permit issuance will help promote beneficial use and is, therefore, establishing a high priority for addressing these facilities. For such facilities, the additional certainty provided by a permit may aid in reinforcing the requirements of the applicable technical standards and may act to reassure other parties or members of the general public that the beneficial use of sewage sludge is in strict accordance with the part 503 technical standards.

Finally, all facilities whose NPDES permits come up for reissuance during the normal permit cycle should include applicable sewage sludge standards in their permits. In addition to the above-described categories, a large number of sludge-only permits may be issued in the first permit cycle following promulgation of the part 503 standards. The priority in which these facilities are addressed will be based on the permitting authorities' determination of the threat posed to public health and the environment by these facilities' sludge use or disposal.

Requirements in the Absence of a Permit

Most requirements in today's standards are fully enforceable and can be easily understood and applied without translation into permit conditions. Compliance with the standards will be verified through the review of self-monitoring information and through inspection of facility records required to be created and maintained by the rule. However, because some standards may be established or adjusted based on site-specific factors, identification of which standards apply is necessary while development of these site-specific requirements is pending (e.g., after a permit application has been submitted but before issuance of a permit).

The part 503 standards comprise several sets of requirements for each use and disposal method: general requirements, management practices, pollutant limits, pathogen and vector attraction requirements, monitoring requirements, recordkeeping requirements, and reporting requirements. The standards applicable to each use and disposal practice are described in detail in this rule. In practice, most facilities will be able to determine from today's rule which specific pollutant concentrations apply to their use or disposal practices. In addition, facilities will be able to determine other applicable requirements such as management practices (e. g., to prevent sewage sludge applied to land from entering waters of the U.S.), monitoring requirements based on the amount of sewage sludge used or disposed, and recordkeeping designed to track the various use or disposal practices.

In the case of sewage sludge incinerators, today's rule does not establish national, uniform pollutant limits for sludge quality; instead, these limits are developed based on site specific factors. Similarly, under certain circumstances, pollutant limits for surface disposal sites must be developed based on site-specific factors. Today's rule also allows adjustment to national uniform pollutant limits for certain surface disposal practices if established in a permit. In all cases where site-specific standards are mandated or sought, the treatment works treating domestic sewage must submit a permit application with complete and accurate information supporting the site-specific pollutant limits. Submission of such applications does not relieve the applicant of the responsibility to comply with all other applicable portions of today's rule. In addition, as a matter of policy, the applicant must meet those numerical pollutant levels which appear in its application for site-specific pollutant concentrations during the period after submission of a complete permit application but prior to the issuance of a permit containing site-specific limits.

Who Issues the Permit

As discussed above, EPA is responsible for issuing permits that implement the technical standards for sewage sludge use and disposal unless those standards are implemented through certain other Federal permits or permits issued by a State with an EPA approved sludge management program. Currently, the only Federal program listed in section 405(f) with comparable permits is the Subtitle C program under RCRA. Today's rule adopts Subtitle C requirements as standards under section 405(f). Thus, sewage sludge that is a hazardous waste and facilities accepting such sludge will continue to be regulated under Subtitle C of RCRA. None of the other listed Federal permit programs is expected to implement the standards for sewage sludge use or disposal promulgated today.

As discussed previously, today's standards may also be implemented through permits issued by State programs approved by the Administrator as adequate to assure compliance with section 405 of the CWA. Under the May 2, 1989 regulations, States may seek approval of a modified NPDES program (Part 123) or a separate, non-NPDES program (Part 501). The basic requirements for either approach are essentially the same. Approved State programs will share several important features with an EPA administered program: authority to issue and enforce permits to POTWs and other treatment works treating domestic sewage that implement the Federal technical standards and other requirements for sewage sludge use and disposal; authority to enforce the technical standards against any user or disposer of sewage sludge; and general authority to take action to protect public health and the environment from any reasonably anticipated adverse effects of sewage sludge use and disposal.

Currently, no States have received EPA approval of their State sludge management programs. At least initially, EPA Regions will be responsible for implementing the technical standards promulgated today in all States using the permitting requirements and procedures in 40 CFR parts 122 and 124. Where EPA is the NPDES permitting authority, it will implement the standards through NPDES permits. Where a State has an approved NPDES program, EPA must issue a separate NPDES or sludge-only permit to implement the standards. (EPA is considering issuing guidance on joint issuance of permits in States with

approved NPDES programs). EPA may choose to issue general permits for sewage sludge use and disposal as an alternative to the requirement to impose sewage sludge conditions in individual permits. However, until States seek and apply for program approval, dual State and Federal permitting programs may be in effect. EPA encourages States to seek program approval as soon as possible and has published a State Sludge Management Program Guidance (EPA 1990) to assist their efforts.

The permitting program focuses primarily on generators of sewage sludge. Thus, in most cases the permitting authority will be the Region or State in which the treatment works treating domestic sewage is located. The sewage sludge from these facilities that is transported to another State will have to meet any part 503 requirements related to the use or disposal site unless the sludge is transferred to a treatment works treating domestic sewage. In this case, the receiving treatment works treating domestic sewage must apply for a permit and comply with part 503 standards. When a generating treatment works sends its sludge out of state to a user or disposer not defined or designated as a treatment works treating domestic sewage, the receiving State or local jurisdiction, may, but need not, issue a permit. (Some States under their own laws and programs require sludge exporters to obtain any necessary approvals from importing States, although this currently is not required by Federal regulation. Today's rulemaking does, however, require notification to the permitting authority in the receiving State in cases where bulk sewage sludge is sent out of State.)

EPA administration of the new sewage sludge permitting program will not displace existing State sewage sludge management programs (unless a State so chooses by seeking EPA approval of its program). Likewise, under section 510 of the CWA, States may impose more stringent requirements than those promulgated in today's technical standards and those in the permitting requirements and State program rule. However, more stringent State requirements generally will not be considered a part of the Federal program (i.e., they may not be Federally enforceable and would not be considered a part of an EPA-approved State sludge management program). The only exception will be where an EPA permit writer makes a determination in an individual permit proceeding that, in the particular special circumstances more stringent State requirements are necessary to protect public health and the environment as provided in section 405(d)(4) of the CWA.

EPA encourages States to adopt the part 503 standards as part of State law. The part 503 standards result from years of data gathering and analysis and represent a comprehensive and extensive evaluation of the fate and effect of sewage sludge in the environment. Today's standards have undergone extensive scrutiny by the public and scientific community. Adoption of the part 503 standards as a minimum baseline for sewage sludge use or disposal will protect public health and the environment. In addition, widespread adoption of part 503 standards would facilitate beneficial use of sewage sludge (biosolids) by establishing uniform standards from State to State.

Implementation Strategy

EPA has developed and is carrying out an overall strategy to help ensure that today's rule is implemented expeditiously and in a manner that protects public health and the environment. This strategy includes a commitment to conduct public outreach to ensure that the regulated community and the public have an opportunity to become familiar with the part 503 standards and to ask questions regarding the implementation and enforcement of the rule.

As indicated previously, the Agency will rely heavily on the self-implementing nature of the part 503 standards during the initial period after promulgation and will phase in permits incorporating the standards over a 5-year period. To familiarize affected facilities with the part 503 requirements applicable to them before standards are incorporated into their permits, EPA will mail informational material on the standards and permit application requirements directly to treatment works treating domestic sewage. Outreach will also include co-sponsoring public workshops with several national trade associations, making presentations at various other conferences, and responding to individual inquiries.

Another key element of EPA's implementation strategy will be educating EPA and State personnel on the new standards. This effort will entail training courses and issuance of guidance documents and other materials covering various aspects of implementation. For example, EPA will issue a permit writer's guidance, updating the Guidance for Developing Case-by-Case Permit Conditions for Municipal Sewage Sludge issued by EPA in 1990. The new guidance document will provide direction for incorporating the part 503 technical standards into permits. In addition, the Agency will develop and issue various documents (and, in some cases, revisions to existing materials) covering the compliance and enforcement components of its sludge implementation strategy.

Part XIII: Benefits and Costs of the Amendments to Parts 257 and 403 and the Final Part 503 Regulation

Data used to calculate estimates reported in this preamble are detailed in the Regulatory Impact Analysis (RIA). This work relies heavily on data collected during the National Sewage Sludge Survey but it is also augmented, as appropriate, by relevant data from the 1988 Needs Survey and other available sources of information.

The data presented here differ from that presented in the 1990 Notice of Data Availability for several reasons. First, the final regulatory definitions for use or disposal practices were developed after publication of the notice and these regulatory definitions are somewhat different than those definitions used in development of the survey and publication of the notice. For example, the practices of land application and distribution and marketing were combined under one definition. Second, detailed analyses conducted after publication of the notice indicated that responses meeting case by case quality control checks did not appear to be correct when considered in relation to responses at other POTWs. For example, survey responses for the amount of sewage sludge used or disposed were investigated for several POTWs after comparison of responses with those of POTWs with similar flow rates indicated a potential problem. These investigations are documented in the "Statistical Support Document for the 40 CFR part 503 Rule for Sewage Sludge Use or Disposal". Third, the statistical weighting scheme for the survey was not fully implemented when the notice was published; those summary statistics not using the weighting scheme were presented by reported flow group. Finally, the summary statistics published in the notice were based on information from the NSSS. The NSSS was only designed to cover POTWs that practice secondary and better wastewater treatment. However, this regulation also covers POTWs that only practice primary treatment, privately owned treatment works, Federally owed treatment works, and domestic septage haulers.

This part of the preamble discusses the benefits and costs of the amendments in today's rulemaking to Parts 257 and 403 and the benefits and costs of the final part 503 regulation. More details on the benefits and costs of the final part 503 regulation are presented in the Regulatory Impact Analysis for the part 503 Regulation (see Part XIV for information on how to obtain a copy).

This part of the preamble is divided into three sections. The first and second sections provide information on the generation of sewage sludge and the use or disposal of sewage sludge, respectively. The third section discusses the benefits and costs of the amendments to parts 257 and 403 and the benefits and costs of the final part 503 regulation.

Generation of Sewage Sludge

The Clean Water Act requires that municipal wastewater meet certain requirements before it can be discharged to the nation's waters. To meet those requirements, the wastewater usually must be treated. Solid, semi-solid, and liquid residues generated during wastewater treatment must be used or disposed properly. These residues must be managed properly through final use or disposal.

Municipal wastewater contains materials discharged into household drains through toilets, sinks, and tubs. These materials are domestic sewage. Components of domestic sewage include soaps, shampoos, human excrement and tissue, food stuffs, detergents, pesticides, household hazardous waste, and oil and grease. Typically, a family of four generates 300 to 400 gallons of domestic sewage wastewater per day.

Domestic sewage may be treated (or partially treated) at its source in such devices as septic tanks and portable toilets or domestic sewage may be treated in publicly owned, privately owned, or federally owned treatment works. A treatment works may treat domestic sewage alone or in combination with liquid industrial wastewater. Residues generated during the treatment of domestic sewage are, by definition, sewage sludge.

Treatment works treat municipal wastewater to a certain level of treatment (i.e., primary, secondary, or tertiary). Each level of treatment results in greater amounts of sewage sludge.

Primary treatment processes remove the solids that settle out of the wastewater by gravity. This level generates 2,500 to 3,500 liters of sewage sludge per million liters of wastewater treated. Primary sewage sludge contains 3 to 7 percent solids, 60 to 80 percent of which is organic matter. The water content of primary sewage sludge can easily be reduced by dewatering the sewage sludge.

Secondary treatment produces a sewage sludge generated by biological treatment processes. These processes (e.g., activated sewage sludge systems and trickling filters) use microbes to break down and convert the organic substances in the wastewater to microbial residue. Biological treatment processes remove up to 90 percent of the organic matter in the wastewater and produce a sewage sludge that typically contains from 0.5 to 2 percent solids. Sewage sludges produced during secondary treatment generally are more difficult to dewater than are primary sewage sludges. The organic content of secondary treatment sewage sludge ranges from 50 to 60 percent. Secondary treatment processes increase the volume of sewage sludge generated over the volume generated in primary treatment by 15,000 to 20,000 liters of sewage sludge per million liters of wastewater.

Advanced wastewater treatment processes (e.g., chemical precipitation and filtration) also increase the volume of sewage sludge to be used or disposed. In chemical precipitation, chemicals are added to the wastewater to remove organic materials and nutrients and to separate the solids from the wastewater. Characteristics of these sewage sludges vary, depending on the type of advanced treatment process used and the characteristics of the wastewater in the influent to the treatment process. The solids content of advanced treatment sewage sludges varies from 0.2 to 1.5 percent, while the organic content of the sewage sludge ranges from 35 to 50 percent.

Advanced treatment increases the volume of sewage sludge generated over the volume generated during secondary treatment by 10,000 liters of sewage sludge per million liters of wastewater. Before dewatering, sewage sludge contains from 93 to 99.5 percent water. The remaining portion is the solids and dissolved material removed from the wastewater, added in the treatment process, or cultured by the wastewater treatment process. Virtually all sewage sludges contain nutrients (e.g., nitrogen, phosphorus) and pathogens (e.g., bacteria, viruses, protozoa, and viable helminth ova). Some sewage sludges also contain more than trace amounts of organic chemicals (e.g., chloroform) and inorganic chemicals (e.g., iron). These pollutants occur in domestic sewage, industrial wastewater discharge to municipal sewers, and runoff from parking lots and other areas that enters the sewers.

Before using or disposing of sewage sludge, treatment works generally thicken, stabilize, and dewater the sewage sludge. This thickening is a process in which water from the sewage sludge is removed to achieve a volume reduction. The reduction in sewage sludge volume decreases the capital and operating costs of subsequent sewage sludge processing and use or disposal practices by decreasing the volume of sewage sludge to be processed. For example, lowering the volume of sewage sludge to be used or disposed reduces transportation costs. EPA estimates that the cost to transport sewage sludge with a 22 percent solids content over a 20-mile trip is about one-half the cost to transport sewage sludge with a 6 percent solids content over the same distance.

Treatment works frequently digest sewage sludge to reduce the level of pathogens and odors. The degree to which a sewage sludge is processed is very important when it is applied to land or placed on a surface disposal site.

Use or Disposal of Sewage Sludge

Three of the more common use or disposal practices for sewage sludge are application to the land, placement on a surface disposal site, and firing in a sewage sludge incinerator. Sewage sludge is applied to the land either to condition the soil or to fertilize crops or vegetation grown on the land. In contrast, sewage sludge is placed on the land in surface disposal for final disposal. In most cases, crops are not grown on surface disposal sites. In incineration, the organic and inorganic materials in sewage sludge are combusted in the incinerator.

As mentioned previously, the purpose of applying sewage sludge to the land is to condition the soil using the organic material in the sewage sludge or to fertilize crops or vegetation grown on the land. Approximately 33 percent of the sewage sludge used or disposed annually is applied to land. The method of applying sewage sludge to the land depends on the physical characteristics of the sewage sludge (e.g., liquid or dried) and the site conditions. Liquid sewage sludge can be applied with tractors, tank wagons, irrigation systems, or special application vehicles. Liquid sewage sludge also can be injected under the surface layer of the soil. Dewatered sewage sludge, on the other hand, typically is applied to the land by equipment similar to that used for applying limestone, animal manures, or commercial chemical fertilizers. Generally, the dewatered sewage sludge

is applied to the land surface and then incorporated by plowing or disking, except when applied to pasture. Sewage sludge is applied to areas such as agricultural land, forest, public contact sites, reclamation sites, lawns, and home gardens.

Sewage sludge is a valuable source of fertilizer when applied to agricultural land. Results of a study of sewage sludge and effluent use on selected agricultural crops in one area of Oregon found that the return per acre associated with sewage sludge application ranged from a loss of $6 to an increase of $15 per acre when compared to traditional fertilizer sources. The return per acre depended on crop rotation, previous soil management practices, soil type, and level of sewage sludge application. The savings were net savings in the cost of fertilizers, taking into account the fact that the sewage sludge was available at no cost to the farmer (Reference No. 10).

Sewage sludge has been applied to forests, at least on an experimental field-scale level, in 10 or more States. The most extensive experience with this practice is in the pacific Northwest. Liquid sewage sludge is most often sprayed from mobile equipment into established forest stands. Application of sewage sludge to forest shortens wood production cycles by accelerating tree growth, especially on marginally productive soils. Results of studies at the University of Washington on the use of sewage sludge as a fertilizer in silviculture operations show height increases of up to 1,190 percent and diameter increases of up to 1,250 percent compared with controls in certain tree species. These results have also shown that trees grow twice as fast on sewage sludge-amended soil. Thus, a tree that typically would be cut after 60 years could be cut after only 30 years.

If sewage sludge is used to stabilize and revegetate land at a reclamation site, typically large amounts of sewage sludge (usually 50 to 100 or more metric tons per hectare) are applied to the site on a short-term basis. Sewage sludge may be applied only one time or may be applied as many as two to three times. A large amount of sewage sludge is applied to a reclamation site to provide the amount of organic matter needed to establish a self-sustaining ecosystem.

Costs to reclaim land with sewage sludge are comparable to the costs of land reclamation using other commercial materials. For example, in a strip-mined area in Fulton County, IL, sites reclaimed using sewage sludge cost $3,660 an acre; costs for sites reclaimed using other commercial materials range from $3,395 to $6,290 an acre. Other examples include the use of Philadelphia's sewage sludge to reclaim more than 3,000 acres of devastated lands in Pennsylvania and the use of sewage sludge, in combination with fly ash, to revegetate contaminated soils in Palmerton, PA.

Sewage sludge may be placed on the land for final disposal. Land where the sewage sludge is placed for this purpose is a surface disposal site. The surface disposal site may contain a series of trenches, dug into the ground, into which dewatered sewage sludge is deposited. Sewage sludge also may be placed on the land surface (e.g., a sewage sludge pile). In surface disposal, usually no attempt is made to use nutrients in the sewage sludge. As mentioned previously, sewage sludge is placed on a surface disposal site for final disposal.

Approximately one-third of the sewage sludge used or disposed by POTWs (NSSS Questionnaire Survey) is landfilled with municipal solid waste. In co-disposal, the absorption characteristics of the solid waste and soil conditioning characteristics of the sewage sludge complement each other. The solid waste absorbs excess moisture from the sewage sludge and reduces leachate migration. Sewage sludge usually makes up 5 percent or less of the material in a municipal solid waste landfill.

Incineration is a disposal practice in which organic and inorganic material in sewage sludge are combusted in an enclosed device. Estimates from the NSSS Questionnaire Survey show approximately 52 percent (110) of the existing secondary and advanced treatment sewage sludge incinerators were built prior to 1973. Multiple hearth incinerators are the most common type of sewage sludge incinerator with 156 multiple-hearth incinerators (74 percent of the incinerators firing sewage sludge), 49 fluidized-bed incinerators (23 percent of the total), 3 flash-drying incinerators, and 2 electric furnaces. The estimated amount of sewage sludge fired in secondary and advanced treatment sewage sludge incinerators in 1988 was 736,000 dry metric tons, which is approximately 16 percent of all sewage sludge used or disposed by secondary or advanced treatment works. An additional 128,000 dry metric tons is estimated to be incinerated by primary treatment works. Not represented in this estimate are incinerators that fire sewage sludge with solid waste in municipal waste combustors. The Agency estimates that seven facilities practice co-incineration of sewage sludge with municipal solid waste.

Approximately 12,750 POTWs use or dispose 5.4 million dry metric tons of sewage sludge annually (NSSS Questionnaire Survey) or 47 pounds of sewage sludge (dry weight basis) for every individual in the United States.

Privately owned and federally owned treatment works also use or dispose of sewage sludge. The amount of sewage sludge used or disposed by these treatment works is unknown, but it is estimated to be no more than 0.1 million dry metric tons per year.

The volume of domestic septage used or disposed annually is significant. EPA estimates that up to 8.6 billion gallons of domestic septage are used or disposed annually, of which approximately half is discharged to POTWs and half is either land applied, placed on a surface disposal site, or placed in a lagoon for treatment.

Tables XIII–1 and XIII–2 present the amount of sewage sludge used or disposed annually by use or disposal practice for secondary and advanced treatment POTWs and for primary treatment POTWs, respectively, based on the flow rate of the POTWs as presented in the 1988 NSSS. Table XIII–3 presents the number of POTWs employing each use or disposal practice, as estimated in the 1988 National Sewage Sludge Survey for secondary and advanced treatment POTWs. The number of primary treatment POTWs employing each use or disposal practice, based on information from the 1988 Needs Survey, is presented in Table XIII–4.

TABLE XIII–1.—AMOUNT OF SEWAGE SLUDGE USED OR DISPOSED BY SECONDARY AND ADVANCED TREATMENT POTWS BY USE OR DISPOSAL PRACTICE AND FLOW RATE

[Thousands of Dry Metric Tons]

Use or disposal practice	Flow rate group				Total amount used or disposed	Use or disposal practice as percent of total
	>100 MGD	>10–100 MGD	>1–10 MGD	≤1 MGD		
Incineration	320.0	308.5	106.1	1.7	736.3	16.1
Land Application	255.0	586.7	499.9	178.1	1,519.7	33.3
Agriculture	117.8	349.3	398.6	131.3	997.0	21.9
Compost	11.5	58.7	28.5	29.3	128.0	2.8
Forests	2.3	23.1	0.3	1.0	26.7	0.6
Public Contact	47.0	53.2	36.7	4.6	141.4	3.1
Reclaimed	47.8	6.9	1.0	0.3	56.1	1.2
Sale	25.4	24.7	10.4	0.1	60.5	1.3
Undefined	3.3	70.8	24.4	11.7	110.1	2.4
Surface Disposal	39.2	240.4	110.2	81.6	471.4	10.3
Landspreading	15.3	113.5	57.6	33.9	220.4	4.8
Monofill	2.4	72.9	38.2	20.6	134.0	2.9
Other	21.5	54.0	14.5	27.1	117.0	2.6
Not Regulated	386.2	614.2	456.3	91.9	1,548.6	33.9
Unknown	141.7	143.2	0.7	0.0	285.7	6.3
Ocean Disposal*	141.7	143.2	0.7	0.0	285.7	6.3
Other	0.0	0.0	0.0	0.0	0.0	0.0
Transfer	N/A	N/A	N/A	N/A	N/A	N/A
Total	1,142.0	1,893.1	1,173.3	353.4	4,561.8	100
Percent of Total	25.0	41.5	25.7	7.7	100	

Note: Numbers may not add up to 100 percent because of rounding.
N/A indicates the value was not available.
*The NSSS data reflects use or disposal practices at the time the data was collected. The Ocean Dumping Ban Act of 1988 generally banned ocean dumping of sewage sludge by December, 1991. The last dumping ceased in June 1992.
Source: 1988 National Sewage Sludge Survey (Questionnaire), EPA.

TABLE XIII–2.—AMOUNT OF SEWAGE SLUDGE USED OR DISPOSED BY PRIMARY TREATMENT POTWS BY USE OR DISPOSAL PRACTICE AND FLOW RATE

[Thousands of Dry Metric Tons]

Use or disposal practice	Flow rate group				Total amount	Percent of total
	>100 MGD	>10–100 MGD	>1–10 MGD	≤1 MGD		
Incineration	62.9	38.0	18.7	8.8	128.4	16.1
Land Application	129.9	78.3	38.6	18.1	265.0	33.3
Surface Disposal	40.3	24.3	12.0	5.6	82.2	10.3
Not Regulated	132.4	79.9	39.3	16.5	270.0	34.0
Unknown	24.4	14.7	7.3	3.4	49.8	6.3
Total	390.0	235.2	115.8	54.4	795.4	100
Percent of Total	49.0	29.6	14.6	6.8	100	

Note: Numbers may not add up to 100 percent because of rounding.
Source: Estimated from 1988 Needs Survey and 1988 National Sewage Sludge Survey (Questionnaire), EPA.

TABLE XIII–3.—NUMBER OF POTWS USING A USE OR DISPOSAL PRACTICE AND THE AMOUNT OF SEWAGE SLUDGE USED OR DISPOSED BY SECONDARY AND ADVANCED TREATMENT POTWS

Use or disposal practice	POTWs using a practice		Sewage sludge used disposed	
	Number	Percentage of POTWs	Amount (thousands of dry metric tons)	Percentage of total amount
Incineration	327	3.0	736.3	16.1
Land Application	3,988	36.6	1,519.7	33.3
Agriculture	3,246	29.8	997.0	21.9
Compost	146	1.3	128.0	2.8
Forests	30	0.3	26.7	0.6
Public Contact	254	2.3	141.4	3.1
Reclaimed	69	0.6	56.1	1.2
Sale	199	1.8	60.5	1.3
Undefined	487	4.5	110.1	2.4
Surface Disposal	1,157	10.6	471.4	10.3
Landspreading	383	3.5	220.4	4.8
Monofill	320	2.9	134.0	2.9
Other	455	4.2	117.0	2.6
Not Regulated	2,595	23.8	1,548.6	33.9
Unknown	3,535	32.5	285.7	6.3
Ocean Disposal*	115	1.1	285.7	6.3

TABLE XIII–3.—NUMBER OF POTWS USING A USE OR DISPOSAL PRACTICE AND THE AMOUNT OF SEWAGE SLUDGE USED OR DISPOSED BY SECONDARY AND ADVANCED TREATMENT POTWS—Continued

Use or disposal practice	POTWs using a practice		Sewage sludge used disposed	
	Number	Percentage of POTWs	Amount (thousands of dry metric tons)	Percentage of total amount
Other	3,398	31.2	0	0.0
Transfer	22	0.2	N/A	N/A
Total	12,046	100	4,561.8	100

Notes: The total 12,046 indicates the total number of subpractices at the 10,893 POTWs. For Land Application and Surface Disposal practices, the numbers of subpractices do not total the number of POTWs practicing a use or disposal practice because some POTWs use more than one subpractice. Percentage of POTWs is the percentage of the 10,893 Secondary and Advanced Treatment POTWs. Numbers may not add up to 100 percent because of rounding. N/A indicates the value is not available.

*The NSSS data reflects use or disposal practices at the time the data was collected. The Ocean Dumping Ban Act of 1988 generally banned ocean dumping of sewage sludge by December, 1991. The last dumping ceased in June 1992.

Source: 1988 National Sewage Sludge Survey (Questionnaire), EPA.

TABLE XIII–4.—NUMBER OF POTWS USING A USE OR DISPOSAL PRACTICE AND THE AMOUNT OF SEWAGE SLUDGE USED OR DISPOSED BY THE POTWS PRIMARY TREATMENT POTWS

Use or disposal practice	POTWs using a practice		Sewage sludge used or disposed	
	Number	Percent of POTWs	Amount (thousands of dry metric tons)	Percent of total amount
Incineration	53	2.9	128.4	16.1
Land application	669	36.1	265.0	33.3
Surface Disposal	193	10.4	82.2	10.3
Not Regulated	395	21.3	270.0	34.0
Unknown	545	29.4	49.8	6.3
Total	1,855	100	795.4	100

Note: Numbers may not add up to 100 percent because of rounding.

Source: Estimated from 1988 Needs Survey and 1988 National Sewage Sludge Survey (Questionnaire), EPA.

Benefits and Costs of Today's Rulemaking

As mentioned previously, today's rulemaking contains an amendment to 40 CFR part 257, an amendment to 40 CFR part 403, and the final part 503 regulation (40 CFR part 503). Benefits and costs of each of these actions are presented in this part of the preamble.

Executive Order 12291 requires EPA to prepare a Regulatory Impact Analysis (RIA) for major regulations, which are defined by certain levels of costs and impacts. For example, the Executive Order specifies that a regulation imposing an annual cost and benefits to the economy of $100 million or more is considered "major" under the terms of the Order. According to the Executive Order, the RIA should contain descriptions of both potential costs and benefits.

Amendment to 40 CFR Part 257

The amendment to part 257 in today's rulemaking removes sewage sludge subject to the standards in the part 503 from the part 257 requirements. The final part 503 regulation now contains the requirements to be met if sewage sludge is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator.

The part 257 amendment in today's rulemaking has no costs because this action only amends the applicability of the part 257 regulation; therefore, the requirements in Executive Order 12291 do not apply to the amendment.

Amendment to 40 CFR Part 403

The amendment to part 403 in today's rulemaking adds two lists of pollutants to part 403 that are eligible for a removal credit with respect to the use or disposal of sewage sludge. A POTW may grant a removal credit for the pollutants on the two lists if all other applicable requirements are met.

The part 403 amendment in today's rulemaking has no costs. This amendment is expected to result in cost savings to industrial dischargers who receive a removal credit for a pollutant; therefore, the requirements in Executive Order 12291 do not apply to the amendment.

40 CFR Part 503

Based on EPA's estimate of the incremental costs of complying with the final part 503 regulation, the Agency does not consider the final part 503 regulation to be a major rule as defined in Executive Order 12291. However, EPA has prepared an extensive analysis of the benefits, costs, and other impacts associated with the final part 503 regulation. This analysis, "Regulatory Impact Analysis of the part 503 Regulation for Sewage Sludge Use or Disposal," is part of the administrative record for the final part 503 regulation. Copies of the RIA may be obtained from the National Technical Information Service (see section XIV of this preamble).

The part 503 RIA was forwarded to the Office of Management and Budget (OMB) with today's rulemaking. OMB's comments are presented in the part 503 administrative record.

As mentioned previously, the part 503 RIA contains an analysis of the benefits, costs, and economic impact associated with the final part 503 regulation. The analysis begins with an assessment of the sewage sludge use or disposal practices currently used by publicly owned, privately owned, and federally owned treatment works and by domestic septage haulers. The RIA then evaluates the impact of new or additional requirements imposed by the final part 503 regulation.

The Agency's overall approach to the RIA recognizes that, in addition to compliance costs for management practices and monitoring, record-keeping, and reporting, a POTW or other affected entity may be required to alter a current practice for sewage sludge use or disposal to achieve compliance with the final part 503 regulation. These changes could include shifts to a new or different combination of use or disposal practices or increased reliance on industrial pretreatment. The costs of these changes are evaluated for each part 503 use or disposal practice for which changes must occur. The benefits associated with complying with the regulation in the form of reduced health risks are also evaluated. The RIA presents quantitative estimates of these benefits, expressed as a reduction in the number of cancer cases and other health effects.

For the use or disposal practices subject to the final part 503 regulation, the Agency projects incremental annual compliance costs of $45.9 million annually (in 1992 dollars), or an average

of less than $1 per household served. Total annual costs include management practice costs; monitoring, record keeping, and reporting costs, and in a few cases, costs for a change in use or disposal practices.

Benefits of the final part 503 regulation are reduced effects on public health resulting from reduced exposure to pollutants in sewage sludge. EPA estimates that the benefits of the final part 503 are an annual reduction of less than 1 cancer case and 90 to 600 cases of identified adverse health effects. The final regulation also is expected to create certain environmental benefits as a consequence of improvements in managing the use or disposal of sewage sludge. Table XIII–5 presents a summary of the costs and benefits of regulating land application (subpart B), surface disposal (subpart C), and incineration (subpart E). Subpart D (pathogen and vector attraction reduction) costs are incorporated in the costs for subparts B and C, as appropriate. Benefits of subpart D are not calculated because no methodology has yet been developed to quantify the risks from pathogens in sewage sludge.

TABLE XIII–5.—ESTIMATED ANNUAL COSTS AND BENEFITS FOR ALL AFFECTED TREATMENT WORKS AND FIRMS TO COMPLY WITH THE PART 503 REGULATION

[$000]

	Benefits		
	Costs	Cancer	Non-cancer
Subpart B[a]	$14,182	0–0.5	0–500
Subpart C[a]	18,335	0–0.07	<1
Subpart E	11,703	0.09	90
Other Costs[b]	1,675		
Total Costs/Benefits	$45,895	0.09–0.7	90–600

[a] Costs for Subpart D are incorporated into the costs of meeting Subparts B and C.
[b] Costs of reading and interpreting the regulation and obtaining copies of Part 258 permits.
Source: Prepared by ERG and Abt for EPA.

The feasibility of pretreatment by industrial dischargers as a compliance alternative was evaluated as part of the final part 503 RIA. Land applying POTWs that failed the ceiling limits were analyzed to determine whether their host industries were likely to be causing high levels of the pollutant or pollutants that failed ceiling limits. In all cases, firms could be identified, based on the NSSS, that are considered likely contributors of these problem pollutants. Costs for more aggressive pretreatment programs at these firms were developed and used in the identification of the most likely compliance strategy. Where EPA determined that pretreatment was the most likely compliance strategy, the cost of pretreatment was used as the cost of compliance in the RIA. Furthermore, some POTWs practicing land application of sewage sludge currently cannot meet the part 503 pollutant concentration limits for land application of sewage sludge. Additionally, a few POTWs that fire sewage sludge in sewage sludge incinerators must install state-of-the-art pollution control equipment for metals to meet the part 503 requirements. These POTWs have a strong motivation to institute pretreatment to make the use or disposal of sewage sludge easier and less expensive.

In the RIA for the proposed part 503 regulation, the Agency conducted a limited number of case studies on the effect of industrial pretreatment on sewage sludge quality. Results of this study are presented as an appendix in the RIA for the final part 503 regulation. In this study, pollutant removals were estimated for all industrial dischargers subject to covered categorical pretreatment standards. EPA found, in these cases, that an increase in industrial pretreatment provides a significant reduction in the concentration of pollutants in sewage sludge in cases where the pollutant concentrations are high (it becomes increasingly difficult to reduce pollutant concentrations as the pollutant concentrations decline). The percentage reduction in pollutant concentrations in the case studies ranged from 6 to 96 percent. Most likely, many POTWs currently predicted to be unable to meet pollutant concentration limits in the land application subpart (and thus required to maintain records of the cumulative loadings of pollutants for each site to which sewage sludge is applied) could reduce the pollutant concentrations in the sewage sludge through a more stringent pretreatment program. This program would focus on the one or two pollutants for which the part 503 pollutant concentration cannot be met (most POTWs fail land application pollutant concentrations only for one or two pollutants).

Any reduction in pollutant concentrations because of pretreatment, however slight, achieved by POTWs firing sewage sludge in a sewage sludge incinerator that fails limits for metals could reduce the costs of compliance and make achieving compliance with subpart E of the final part 503 regulation easier overall. Without reductions in certain pollutants, several POTWs may need to monitor operations of the sewage sludge incinerator very closely to ensure that subpart E requirements are met.

The RIA for the final part 503 regulation contains some data limitations. The NSSS solved many of the data problems associated with the RIA for the proposed part 503 regulation. In addition, data gathering activities for privately and Federally owned treatment works and for domestic septage haulers that apply domestic septage to agricultural land, forest, or a reclamation site reduced some other limitations of the RIA for the proposed regulation. Some data limitations still exist, however.

Data for privately and Federally owned treatment works are still very limited. Numbers of privately owned treatment works were estimated from permits. Since only a few states collect data on use or disposal practices for privately owned treatment works, the Agency had to extrapolate the distribution of use or disposal practices using data from relatively few states to apply to the total population of privately owned treatment works.

Information on Federally owned treatment works, outside of numbers of treatment works, is unavailable. For this reason, the distribution of use or disposal practices estimated for privately owned treatment works was applied to Federally owned treatment works. In terms of flow rates, these two types of treatment works are similar. For this reason, EPA assumed that similar

sewage sludge use or disposal options are available to both types of treatment works.

Information on domestic septage haulers also is very limited. The Agency now has estimates of numbers of domestic septage haulers and typical use or disposal practices, but it has had to make estimates of the distribution of use or disposal practices based on limited information from a relatively few states where data on domestic septage haulers are collected.

Another limitation of the RIA is that, in some cases, EPA had to make assumptions about how POTWs would comply with the regulation. For example, the Agency assumed that nearly all POTWs that fire sewage sludge in a sewage sludge incinerator would elect to continue the practice of incineration. Some POTWs may decide, however, that it is less expensive to cease incineration and shift, for example, to land application. (Several POTWs that fire sewage sludge in sewage sludge incinerators generate sewage sludge that could meet the pollutant concentration limits for land application, and many could meet the cumulative limits using reasonable agronomic application rates.) For simplicity, the Agency calculated the costs of installing and operating pollution control equipment for metals needed for these POTWs to comply with the regulation, which in some cases might overstate the expense of the regulation if POTWs do decide to shift to another use or disposal practice. In all cases where simplifying assumptions such as this were made, the assumptions tended to overestimate costs of the regulation slightly, rather than underestimate costs.

A number of limitations affect the estimates of risk reduction (i.e., benefits) in the part 503 regulation. These limitations include the exclusion of certain exposure pathways, pollutants, and health effects from the estimates and the lack of ability to account for population growth and mobility.

Overall, however, EPA is confident that the compliance costs presented in the part 503 RIA reflect decisions POTWs and other entities are likely to make, as well as costs associated with these decisions. EPA also is confident that the benefits presented in the RIA are reasonable estimates of reductions in risk associated with the final part 503 regulation. In presenting the part 503 RIA, EPA divided the regulated entities into the five major groups: primary treatment POTWs, secondary and advanced treatment POTWs, privately owned treatment works, Federally owned treatment works, and domestic septage haulers. Most of the analysis focuses on secondary and advanced treatment POTWs, for which the Agency has the most information (i.e., information from the NSSS).

As noted in part III of today's preamble, data on sewage sludge quality were collected from about 200 secondary or advanced treatment POTWs during the NSSS. These data were compared to the applicable pollutant limits in the final part 503 regulation to determine whether the sewage sludge used or disposed at each POTW could meet those limits. Results of this comparison were extrapolated to the national level using the NSSS statistical weighing factors.

Any survey POTW that failed the part 503 pollutant limits given existing conditions, such as sewage sludge feed rates or land application rates, were then evaluated further to develop a compliance strategy for the POTW. Costs of the compliance strategy were then developed. A failure could be either regulatory or economic. For example, in the case of land application, if either application rates or site lives had to be reduced, a cost to deal with reductions in site lives or application rates had to be incurred. Costs to make changes to current use or disposal practices to meet part 503 requirements were then added to costs estimated for management practices, monitoring, record keeping, and reporting and then extrapolated to the national level.

To determine costs of compliance for primary treatment POTWs, the Agency determined that compliance costs for primary treatment POTWs are similar to costs for secondary or advanced treatment POTWs. This is based on the Agency's determination that pollutant concentrations in sewage sludge from primary treatment POTWs are likely to be no worse than those in sewage sludge from secondary or advanced treatment POTWs for the part 503 pollutants of concern. (SAIC 1991 Memorandum from Kathleen Stralka and Scott Henderson, to Chuck White, EPA, re: Nonparametric tests of hypothesis concerning pollutant concentrations in primary and secondary sewage sludge for 40-City Study Data, August 28). Compliance costs developed for each use or disposal practice and for each reported flow rate group investigated in the RIA (greater than 100 million MGD, greater than 10 MGD but equal to or less than 100 MGD, greater than 1 MGD but equal to or less than 10 MGD, and equal to or less than 1 MGD) were applied to the appropriate primary treatment POTWs. For example, per-POTW costs were estimated for secondary and advanced treatment POTWs with a flow rate greater than 10 MGD but equal to or less than 100 MGD that practice land application. These per-POTW costs included management practice, monitoring, record keeping, and reporting costs, as well as any compliance costs associated with sewage sludge quality. The per-POTW cost was then applied to all primary treatment POTWs with a flow rate greater than 10 MGD but equal to or less than 100 MGD and that practice land application (data on flow rate and use or disposal practice for primary treatment POTWs were estimated based on EPA's 1988 Needs Survey because the NSSS did not survey that type of treatment works).

To estimate costs of compliance for privately and Federally owned treatment works, the Agency assumed that the sewage sludge quality of these treatment works is similar to that of the smallest POTWs surveyed in the NSSS because both privately and Federally owned treatment works typically have a flow rate less than 1 MGD. The per-POTW costs developed for the smallest POTWs in the NSSS were applied, based on use or disposal practice, to the estimated number of privately and Federally owned treatment works that employ each use or disposal practice in the same way discussed previously for primary POTWs.

Compliance costs for domestic septage haulers were calculated differently because the final part 503 regulation imposes different requirements for the use or disposal of domestic septage. Part 503 does not require domestic septage applied to agricultural land, forest, or a reclamation site to meet pollutant concentration limits. Part 503, however, does require either ground-water monitoring or a certification that ground-water is not contaminated with nitrogen as a result of domestic septage placed on a surface disposal site. Because of the cost of this requirement, EPA estimates that the smallest domestic septage haulers will most likely find shifting to land application less expensive than continuing to surface dispose (EPA estimates that larger domestic septage haulers, however, will continue to practice surface disposal). Compliance costs for domestic septage haulers are estimated per-firm or per-tankload, as outlined in the discussions below, covering the impacts from the part 503 regulation for the use or disposal practice employed by a domestic septage hauler.

As mentioned previously, the RIA discusses both the benefits and the costs of the part 503 regulation. The presentation on benefits in the part 503 RIA is limited to a description of the

methodology used to estimate benefits and a summary of the results of the benefit analysis. More details on the aggregate risk assessment may be obtained from the document entitled "Human Health Risk Assessment for the Use and Disposal of Sewage Sludge: Benefits of Regulation." Information on obtaining single copies of this document is provided in part XIV.

The risk assessment for the benefits analysis follows the process outlined by the National Academy of Sciences. The assessment begins with a hazard identification and a source assessment and continues with fate and transport estimates, exposure assessments, pharmacokinetics analysis, and dose-response assessments. These components are used to estimate changes in public health, measured as morbidity and mortality.

The first step in estimating the benefits of the final part 503 regulation involves estimating the baseline public health risks of sewage sludge use or disposal. These risks are presented as cases of cancer and other adverse health effects, such as lead-related adverse effects. The key inputs for estimating baseline risks include source (POTW) information, sewage sludge pollutants, and ultimate use or disposal site characteristics.

Baseline risks from sewage sludge use or disposal practices are characterized using (1) sewage sludge quality as determined from the analytical portion of the NSSS, (2) the amount of sewage sludge used or disposed of by each POTW, and (3) the fate and transport of the pollutants subsequent to use or disposal, depending on a number of different environments that vary with each use or disposal practice.

Using the above inputs, the analysis estimates the potential pathways of human exposure and models the fate and transport of the key sewage sludge pollutants for these pathways. The analysis then estimates the potential population exposed. This information, along with dose-response data for each of the sewage sludge pollutants of concern, is used to characterize baseline public health risks.

After baseline risks were estimated, risk estimates were developed assuming the final part 503 requirements are met. The regulatory compliance strategies for the public health risk analysis assessment paralleled the strategies used to estimate the compliance cost. The same risk assessment process is used to derive the change in the baseline risk as a result of the requirements for each part 503 use or disposal practice. This change in the baseline is the measure of benefit.

Estimates of the benefits for each use or disposal practice are expressed as the number of disease cases avoided. These disease cases include cancer cases avoided and noncancer human health effects avoided. Estimated costs and benefits for the part 503 requirements for each part 503 use or disposal practice are discussed later.

Land Application

Cost and benefit analyses for the part 503 land application requirements were conducted by type of treatment works or other entity. Results of the analyses for secondary and advanced treatment works, primary treatment works, privately owned treatment works, federally owned treatment works, and domestic septage haulers are presented as follows.

For secondary and advanced treatment works, compliance with the final part 503 regulation was determined by comparing the sewage sludge quality of the POTWs in the NSSS with either pollutant concentration limits or the cumulative pollutant loading rate limits. For the cumulative pollutant loading rate limits, EPA assumed the sewage sludge application rate for a POTW is the application rate from the NSSS. The Agency also assumed that an application site has a 20-year site life (determined to be a site life that would impose no economic impacts to a POTW). Results of this analysis were extrapolated from the survey POTWs to the entire population of secondary and advanced treatment POTWs. The analysis indicated that of the 4,328 secondary and advanced treatment POTWs estimated to practice land application, 49 POTWs, or 1 percent, fail the ceiling concentrations. An additional 3,216 POTWs, or 74 percent, pass the pollutant concentretion limits. Of the remaining 1,063 POTWs, most are able to meet the cumulative pollutant loading rate limits. Nearly all of these POTWs, even though they have to meet more extensive recordkeeping requirements, are expected to comply with the land application requirements with no additional compliance costs associated with pollutant limits (i.e., the POTWs will incur no costs to shift to an alternative use or disposal practice or need to change current application rates because of the life of the application site).

Of the 49 POTWs that fail the pollutant ceiling limits, 30 are expected to institute more stringent pretreatment requirements and were estimated to continue to practice land application. The remaining 19 POTWs are expected to shift to codisposal.

The total quantity of sewage sludge that fails ceiling limits is 80,000 dmt. Of this, 63,000 dmt is expected to be shifted to codisposal. Costs to POTWs for pretreatment are $2.9 million. Total costs to POTWs for shifting to codisposal are $6.0 million. Thus, the costs associated with sewage sludge that fails to meet ceiling concentrations is estimated to be $8.9 million.

Of those POTWs whose sewage sludge meets the ceiling limits but that does not meet the pollutant concentration limits, 49 POTWs are estimated to dispose of sewage sludge that is expected to fail to meet the cumulative limits with existing application rates and a 20-year site life. However, all but two of the representative survey POTWs were out of compliance with existing state regulations at the time of the NSSS. Changes made to use or disposal practice because the POTW is out of compliance with either existing state or Federal requirements are not considered a cost of part 503. Furthermore, following discussions with one of the two surveyed POTWs that failed the cumulative pollutant loading rate limits, the Agency determined that impacts on this POTW (which represents six nationwide) would be very small because of the easy availability of large amounts of additional land for application of sewage sludge and the ability of the POTW to shift among various other use or disposal practices at virtually no incremental cost.

One other POTW whose sewage sludge is estimated to fail the part 503 land application pollutant limits (represented by one POTW in the survey) is expected to dispose of a portion of the sewage sludge that is currently land applied in a municipal solid waste landfill, a practice employed by another POTW operated by the same authority. The estimated incremental cost of shifting 1,800 dry metric tons from land application to codisposal is approximately $9,000 annually.

Total compliance costs for meeting all land application pollutant limits are estimated to be $8.9 million. The quantity of sewage sludge shifted from land application to codisposal is estimated at approximately 4 percent of the total quantity land applied.

Management practices in the land application subpart are expected to impose a negligible cost on secondary and advanced treatment POTWs. General requirements are estimated to cost $0.2 million annually. Monitoring costs based on the frequency of monitoring requirements in the part 503 regulation are expected to be $1.6 million annually. Record keeping costs are estimated to be $0.9 million

annually. Finally, reporting costs are estimated at about $20,000 annually. Thus, the total estimated compliance costs associated with land application for secondary and advanced treatment POTWs are estimated to be $11.6 million annually.

As discussed previously, per-POTW costs by flow rate for secondary and advanced treatment POTWs that land apply sewage sludge were applied to the 948 primary treatment POTWs estimated to land apply sewage sludge. These per-POTW costs ranged from $426 to $43,507 annually. Total costs for primary treatment works that practice land application are expected to be $1.9 million annually.

Per-POTW costs developed for the smallest POTWs in the NSSS that land applied sewage sludge were applied to privately owned treatment works. An estimated cost of $426 per treatment works was applied to the 1,029 privately owned treatment works to estimate the cost of the part 503 land application requirements. Total costs of the part 503 land application requirements for this group of treatment works is estimated to be $0.4 million annually.

The $426 per treatment works cost for small treatment works also was applied to 53 Federally owned treatment works to estimate the cost of the land application requirements. Estimated costs for Federally owned treatment works using the $426 per treatment works cost is $ 0.02 million annually.

Monitoring costs discussed above for the different groups of treatments works include some costs for monitoring needed to show compliance with the operational standards for pathogen and vector attraction reduction in part 503. No other costs are included for the part 503 pathogen and vector attraction reduction requirements because of the current requirements in 40 CFR part 257 for pathogen and vector attraction reduction. The requirements in part 503 are either identical to current part 257 requirements (i.e., class requirements that can include meeting PSRP) or are similar to those current requirements in part 257 but expressed differently (i.e., part 503 indicates pathogen density requirements that must be met, but properly operated PFRP processes, which can be used to meet Class A requirements, should be able to meet the limits specified). Since the part 257 requirements currently apply, no additional costs, aside from some monitoring cost, for the part 503 pathogen and vector attraction reduction requirements are expected.

Domestic septage haulers practicing land application are required either (1) to inject or incorporate the septage into the soil and meet harvesting and site access restrictions or (2) to add alkali to raise the pH of domestic septage to 12 for 30 minutes. In addition, the annual application rate for an application site is limited based on the amount of nitrogen needed by the crop or vegetation grown on the land.

Domestic septage haulers that apply domestic septage to agricultural land, forest, or a reclamation site must meet certain record keeping requirements including noting the amount of septage applied to each site. The only cost of the land application requirements for domestic septage haulers is this record keeping cost, which is estimated at $0.2 million annually.

Based on the previous figures, the Agency estimates that the total cost of complying with land application requirements in the final part 503 regulation will be $14.2 million annually.

Baseline risks associated with land application of sewage sludge (i.e., the risks associated with current practices) are estimated to be less than 1 cancer case and about 500 cases of other health effects. The benefits of complying with the final part 503 regulation are expressed as reductions in the risk—the number of baseline cases that are avoided. For land application, the benefits are estimated to be less than 1 cancer case avoided and 0 to 500 cases of other adverse health effects avoided.

Surface Disposal

The final part 503 regulation for surface disposal of sewage sludge requires that sewage sludge meet certain pollutant concentrations before being placed on an active, unlined sewage sludge unit. The pollutant concentration limits vary, depending on the distance from the site to the property boundaries. Management practices, monitoring frequency, record keeping, and reporting requirements also are included in part 503 for surface disposal of sewage sludge, regardless of whether the site is lined or unlined. Costs and benefits of the part 503 surface disposal requirements on the different groups of treatment works and other entities are discussed as follows.

Data on quality of sewage sludge placed on a surface disposal site were obtained from the NSSS and compared to the appropriate pollutant limits presented in the surface disposal subpart. The Agency made several assumptions necessary to select appropriate pollutant limits to compare sewage sludge quality.

First, EPA assumed all active sewage sludge units are located more than 150 feet from the property boundary of the surface disposal site (a reasonable worse-case assumption). Second, the Agency assumed that all active sewage sludge units are unlined (based on the finding that no monofills in the NSSS were reported to be lined). The part 503 pollutant limits for units located 150 ft. or more from the property boundary were thus determined to be the appropriate limits for comparison with pollutant concentrations from the NSSS.

Because of the expense of installing ground-water monitoring wells, the Agency determined that most POTWs reporting in the NSSS incorporated sewage sludge into the land for disposal (called dedicated land application in the NSSS) would shift to land application rather than continue to use the land strictly for disposal. The Agency identified POTWs that would shift by assuming that any POTW with an application rate that allowed it to meet the cumulative pollutant loading rates in the land application subpart, while applying the sewage sludge at an agronomic rate, would shift to land application. The Agency estimates that this assumption results in no costs to the POTWs that could meet the land application requirements (the POTW only has to be permitted for land application rather than for surface disposal). Out of 1,936 surface disposers, 526 were estimated to be permitted as land appliers. The remaining 1,410 POTWs were estimated to be permitted as surface disposers. Included in this count are 301 POTWs that store sewage sludge for more than two years. Two additional survey POTWs, representing 60 nationwide, are expected to discontinue long-term storage and codispose more of their sewage sludge. Costs for increasing the quantity of sewage sludge disposed annually are estimated to be $0.4 million.

Results of the pass/fail analysis for the 1,410 surface disposers indicate that all but eight POTWs have sewage sludge that meets the pollutants limits. The eight POTWs are expected to request site-specific pollutant limits. If site-specific pollutant limits are allowed, sewage sludge from all of the POTWs is expected to meet the site-specific pollutant limits based on the difference between the actual depth to ground water at the active sewage sludge unit and the depth to ground water assumed when the part 503 pollutant limits were developed. Thus, no surface disposers are expected to fail pollutant limits.

Costs for meeting general requirements will apply. These include a requirement to provide a closure plan when the surface disposal site closes. Based on an assumption that one-

twentieth of all surface disposal units close each year, total costs for this requirement are expected to be about $30,000 annually.

Management practice costs will also be incurred. Most of the management practice requirements are very similar to those in part 257 and are expected to result in negligible costs. However, unlined surface disposal units (which all are assumed to be) are unlikely to be certified that they will not contaminate ground water. Thus, EPA assumes ground-water monitoring must be performed. The total cost to plan the monitoring program, install monitoring wells, and sample and test ground water is expected to total $1.5 million per year.

Pathogen and vector attraction reduction requirements will have an impact on surface disposers. A number of POTWs are estimated to require further sewage sludge processing or to use daily cover in order to meet these requirements. Annual costs for all these changes are estimated at $9.6 million.

The part 503 regulation also has frequency of monitoring, record keeping, and reporting requirements when sewage sludge is placed on an active sewage sludge unit. Costs for these activities are estimated at $0.6 million annually. Total costs for secondary and advanced treatment POTWs to comply with surface disposal requirements in the final part 503 regulation are estimated at $12.1 million annually.

The per-POTW costs for placement of sewage sludge on a surface disposal site developed using the NSSS were applied to the 273 primary treatment POTWs estimated to practice surface disposal. These costs ranged from $3,925 to $96,922 per POTW. Total costs for primary treatment POTWs to meet the surface disposal requirements in the final part 503 regulations are estimated to be $1.8 million annually.

A per-POTW cost of $3,925 for the smallest POTWs in the NSSS that place sewage sludge on an active sewage sludge unit was used to estimate the costs of compliance for the 551 privately owned treatment works which place sewage sludge on a surface disposal site. The estimated cost of complying with surface disposal requirements for privately owned treatment works is $2.2 million annually.

The per-POTW cost of $3,925 for the smallest POTWs in the NSSS that place sewage sludge on an active sewage sludge unit also was used to estimate compliance costs for Federally owned treatment works which place sewage sludge on an active sewage sludge unit. Multiplying that unit cost times 28 Federally owned treatment works results in an estimated cost $110,000 annually for Federally owned treatment works to meet the part 503 surface disposal requirements.

Domestic septage placed on an active sewage sludge unit must meet only the general requirements management practices, vector attraction reduction requirements, monitoring requirements (only if alkali addition is to meet vector attraction reduction requirements), and record keeping requirements. The largest cost is for management practices, which includes ground-water monitoring. Because of this expense, 884 small domestic septage haulers are expected to shift to land application. Costs for ground-water monitoring are $1.3 million, costs for the shift to land application are $0.9 million, and costs for record keeping and reporting are $0.06 million. The total cost for the 1,360 domestic septage haulers that currently place domestic septage on an active sewage sludge unit is estimated at $2.2 million per year, costing approximately $981 to $2,798 per firm, depending on the size of the firm (in gallons per year of domestic septage pumped). The total cost of the part 503 surface disposal requirements to all types of treatment works and to other entities is estimated to be $18.3 million per year.

The baseline risks associated with surface disposal (i.e., the risks associated with current practice) are estimated to be less than one cancer or other health effects case. The benefits of complying with the surface disposal requirement, expressed as the number of baseline cases that are avoided, are estimated to be 0 to 0.07 cancer cases avoided and less than one other health effects avoided.

Sewage Sludge Incineration

The part 503 requirements for firing sewage sludge in a sewage sludge incinerator require that the allowable concentration of selected inorganic pollutants in the sewage sludge be calculated using equations in the regulation. Terms in the equation must be determined on a case-by-case basis, except for the risk specific concentration for the pollutants. The Agency developed these concentrations using a pathway risk assessment. The only pathway evaluated was the inhalation pathway. For this reason, the pollutant limits in the incineration subpart protect public health from the reasonably anticipated adverse effect of the pollutants if the pollutants are inhaled.

Also included in this subpart is an operational standard for total hydrocarbons (THC). The value for THC in the final part 503 regulation can not be exceeded in the exit gas from the sewage sludge incinerator stack. Management practices and frequency of monitoring, record keeping and reporting requirements are also included in this subpart.

The impacts of the part 503 incineration requirements on secondary and advanced treatment POTWs and primary treatment POTWs are investigated in this part of the preamble because only those groups of treatment works are believed to operate sewage sludge incinerators. However, other treatment works (both privately owned and publicly owned) transfer sewage sludge to POTWs that operate sewage sludge incinerators. Since costs of the incinerator subpart are based on costs to POTWs operating sewage sludge incinerators, cost-passthrough associated with sewage sludge transferred to treatment works operating sewage sludge incinerators is discussed in the regulatory flexibility analysis to avoid double counting of total cost.

A pass/fail analysis was conducted on the NSSS POTWs using the site-specific information necessary to calculate whether, with existing sewage sludge quality, the risk-specific concentrations in the incineration subpart could be met without any changes in feed rate, dispersion factor, or incinerator control efficiencies. Results of this analysis were extrapolated to the entire population of POTWs that operate sewage sludge incinerators nationally (these numbers are based on the analytical survey weights).

Of 185 POTWs that operate 284 sewage sludge incinerators, 171 can meet the part 503 requirements for inorganic pollutants, and all can meet the THC operational standard. Of those failing the limits on inorganic pollutants (14 POTWs), all were assumed to retrofit wet electrostatic precipitators (WESPs). When added to the existing pollution control equipment, WESPs result in pollutant control efficiencies needed without changing the existing sewage sludge quality or dispersion factor (i.e., raising stack height) and without reducing sewage sludge feed rates. The cost of retrofitting and operating WESPs is estimated to be $3.6 million annually. No cost of complying with the THC operational standard will be incurred.

Costs to test a sewage sludge incinerator for pollutant control efficiencies, costs to develop a dispersion factor, and management practice costs, which include costs to install and operate different equipment, are estimated at $7.3 million annually. Frequency of monitoring, record

keeping and reporting costs are estimated to total $0.3 million annually. Total estimated costs to comply with the part 503 requirements for firing sewage sludge in a sewage sludge incinerator for secondary and advanced treatment POTWs are $11.2 annually.

Estimated costs to comply with the part 503 incineration requirements for the NSSS POTWs range from $37,000 to $315,000 per POTW. If these costs are applied to the 11 primary treatment POTWs estimated to operate sewage sludge incinerators, the estimated cost of complying with the part 503 incineration requirements is $0.5 million annually for primary treatment POTWs. Total costs for secondary and advanced treatment works and for primary treatment works to comply with the part 503 incinerator requirements is $11.7 million annually.

Baseline risks associated with incineration (i.e., current practice risks) of sewage sludge are estimated to be 0.3 to 4 cancer cases and 100 other health effects. The benefits of complying with the part 503 incineration requirements are expressed as reductions in number of baseline cases avoided. For sewage sludge incineration, the benefits are estimated to be 0.09 cancer cases avoided and 90 other adverse health effects avoided.

A few additional costs of part 503 are not associated with the part 503 use or disposal practice employed. These costs are associated with (1) reading and interpreting the final part 503 regulation, which are assumed to be incurred whether a part 503 use or disposal practice is used for the use or disposal of sewage sludge, and (2) obtaining copies of part 258 permits, which are assumed to be needed to show that the municipal solid waste landfill meets the part 258 requirements. Costs of these activities are estimated to be $1.7 million per year.

The final part 503 regulation is expected to result in environmental benefits other than the benefits associated with reducing the incidence of adverse human health effects. These environmental benefits are an outgrowth of the general reduction in the amount and toxicity of sewage sludge used or disposed in ways that damage the environment, particularly sewage sludge that is placed in environmentally sensitive areas. These environmental benefits consist mainly of improved habitats for wildlife and other species in the areas where incineration of sewage sludge occurs.

For example, emissions reductions in the vicinities of sewage sludge incinerators may reduce particulate and other types of deposits on buildings, automobiles, and structures, reducing the extent to which these items are damaged by air pollution. Commercial farms and home gardens located in areas affected by deposits from sewage sludge incinerators may experience some increase in crop vitality because of lower levels of discharged pollutants.

The regulation may account for some cost savings as well. Many POTWs whose sewage sludge meets the pollutant concentration limits are currently practicing disposal (e.g., incineration, codisposal). EPA believes that part 503 regulation may help to ease misapprehensions about the quality of sewage sludge and that a more receptive market for high-quality sewage sludge now being disposed might develop. If the regulation helps to encourage the shift from disposal to land application for just 10 percent of all high-quality sewage sludge now disposed, a savings of nearly $1 million in fertilizer costs might be realized by farmers.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires all Federal agencies to analyze the impact of a regulation on small businesses, small governmental jurisdictions, and small organizations. The purpose of this analysis is to determine the extent to which the regulation has an impact on small entities and the nature of those impacts. For the purpose of the final part 503 regulation, the Agency defines a small entity as a POTW with a flow rate equal to or less than one MGD that corresponds to a service area of approximately 10,000 residents; a privately owned treatment works (nearly all of which have a flow rate of one MGD or less); and all domestic septage haulers, regardless of size (most domestic septage firms are operated by one self-employed person and possibly another part-time or full time employee).

Approximately 90 percent of all entities potentially subject to the final part 503 regulation are considered small by this definition. However, only a portion of small entities employ use or disposal practices covered by the part 503 regulation. Only about 40 percent of all small entities potentially subject to the part 503 regulation employ a use or disposal practice covered by part 503.

The total estimated compliance costs for the final part 503 regulation for small entities is $14.1 million, the majority of which is attributed to land application and surface disposal of sewage sludge. Of the total estimated costs for all small entities, 73 percent is attributed to entities (treatment works and septage haulers) that place sewage sludge on a surface disposal site.

Estimated compliance costs for the part 503 regulation for small publicly and privately owned treatment works are $11.0 million for direct and indirect costs including $0.4 million for cost of reading and interpreting the regulation. Thus, compliance costs for small treatment works are only about 23 percent of the total estimated compliance costs for all treatment works and firms. EPA has judged that small privately or publicly owned treatment works are not subject to substantial compliance costs under part 503 and thus focused attention on domestic septage haulers, some of which bear the largest portion of compliance costs as a ratio of revenue among small entities.

Domestic septage haulers will incur $2.4 million in compliance costs to meet the requirements in part 503. Domestic septage haulers that practice land application or surface disposal (6,120 businesses) handle about 3.1 billion gallons of domestic septage annually. Prices charged on average for domestic septage pumping are approximately $70 per 1,000-gallon septic tank. Total annual revenues for this group are thus estimated to be $217 million annually. The incremental costs of this regulation are thus only about 1 percent of the total annual revenues for this group of businesses. Total operating costs are calculated to be approximately $156.6 million for land appliers and $44.7 for surface disposers. The annual costs of complying with the part 503 regulation ($0.2 million for land appliers and $2.2 million for surface disposers) are therefore estimated to increase operating costs by about 1 percent. Only the smallest surface-disposing domestic septage haulers are considered to be potentially affected significantly by the part 503 regulation (compliance cost as a percentage of revenues are expected to be 14 percent for these firms. Most small entities are associated with ratios of one percent or less).

The Agency is not requiring domestic septage haulers to meet the more stringent and costly pathogen and vector requirements for POTWs and privately owned treatment works. Domestic septage haulers are exempted from testing domestic septage for inorganic and organic pollutants, a major cost item for POTWs and privately owned treatment works. Record keeping requirements also have been kept as simple as possible, and no reporting is required. Thus, EPA believes it has provided domestic septage haulers with the least burdensome regulation

compatible with its mandate to protect public health and the environment.

Prices charged by domestic septage pumpers vary widely by region. These prices range from $35 per septic tank to more than $200 per septic tank. If costs to comply with the part 503 requirements are passed directly through to the estimated 4.3 million homeowners who have a septic tank pumped in any one year, the pumping costs could rise by about $1.30 each. This is an increase of 0.7 percent to 4 percent (averaging 2 percent) over current prices for tank pumping. Even if prices increase to an average of $71.30, or about $36 per year per household (based on a tank pumping schedule of every two years), this is considerably less, on average, than typical per-household charges for sewage treatment at POTWs.

Domestic septage haulers that practice land application are estimated to incur $0.2 million annually to comply with part 503 requirements. All of these costs are associated with meeting the record keeping requirements. Small surface disposers, on the other hand, are expected to shift to land application and larger domestic septage haulers are expected to install ground-water monitoring wells and meet other requirements of subpart C. The major costs to these firms to shift practices are the costs to monitor ground water or to acquire additional land. The major cost to continue to surface dispose is the cost to install wells and monitor ground water. The cost to shift to land application and to monitor ground water account for nearly 97 percent of all costs to surface-disposing domestic septage haulers. Average incremental costs per firm are $48 for land appliers and $1,602 for surface disposers. Based on an analysis of net present value for the most affected small surface disposing septage haulers, EPA concludes that septage hauling firms are unlikely to close because of part 503 requirements.

Paperwork Reduction Act

The annual public reporting burden for the collection of information imposed by this final rule, averaged over a 3-year period, is estimated to be 133,198 hours for 11,056 respondents (5,088 publicly owned treatment works, 1,208 privately owned treatment works, and 4,768 domestic septage haulers) practicing land application; 65,295 hours for the 6,188 respondents (2,071 publicly owned treatment works, 547 privately owned treatment works, and 3,570 domestic septage haulers) disposing of sewage sludge on surface disposal sites; and 207,294 hours for the 186 respondents (publicly owned treatment works) which fire sewage sludge in a sewage sludge incinerator. The average time per response per respondent is estimated to be 36.4 hours. Respondent reporting and recordkeeping burden for this collection of information includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and revising the collection of information.

The information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and have been assigned control number 2040–0157.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, EPA, 401 M Street, SW. (PM–223Y), Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

Part XIV: Availability of Technical Information on the Final Rule

Availability of the Final Rule and Preamble

The final rule and preamble may be obtained by contacting: Dr. Alan Rubin, Sludge Risk Assessment Branch (WH–586), United States Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, (202) 260–1306.

Availability of Technical Support Documents

The following technical support documents are available:

(1) Technical Support Document for Land Application of Sewage Sludge—Volume I—PB93–110575
(2) Technical Support Document for Land Application of Sewage Sludge—Volume II—PB93–110583
(3) Technical Support Document for Surface Disposal of Sewage Sludge—PB93–110591
(4) Technical Support Document for Incineration of Sewage Sludge—PB93–110617
(5) Technical Support Document for Pathogen and Vector Attraction Reduction in Sewage Sludge—PB93–110609
(6) Human Health Risk Assessment for Use and Disposal of Sewage Sludge: Benefits of Regulation—PB93–111540
(7) The Regulatory Impact Analysis—PB93–110625

These documents may be ordered from: National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, ATTN: Sales, Telephone No. (703) 487–4650.

Please specify PB number when ordering.

Availability of Data and Information on the National Sewage Sludge Survey

Data and information from the National Sewage Sludge Survey are available as computer files and printed documents. These items can also be ordered from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, ATTN: Sales, telephone number (703) 487–4650. Please specify PB number when ordering.

Computer files of the database for the National Sewage Sludge Survey are available in three different formats. Persons requesting computer files, under any option, will want the National Sewage Sludge Survey: Data Element Dictionary for the Questionnaire and Analytical Databases (PB90–198961) and they may want the Data Element Dictionary for the Data Conventions Database (PB93–500403). These dictionaries contain definitions and specifications for all variables in each referenced database. The three computer file formats are as follows:

(1) ASCII Format Databases for the 1988 National Sewage Sludge Survey (PB93–500403) are available. These are IBM PC compatible files containing the Questionnaire Database, the Analytical Database, and the Data Conventions Database for the National Sewage Sludge Survey. These databases come on fourteen 3.5" 1.44 Mb floppy diskettes and approximately 20 Mb of hard drive space is required for installation.

(2) SAS format tapes (PB–90–501834) are also available. Databases available in this format include the Questionnaire Database and the Analytical Database. These are nine track tapes, written in SAS transportable code at 1600 bpi, with logical record lengths of 80 and block sizes of 8000. The tapes were written under the OS operating system, but they should also be readable by CMS, VSE, AOS/VS, PRIMOS, and VMS.

(3) Computer access to the EPA National Computer Center (NCC), which houses the reference copy of the database in the format of the SAS system for statistical analysis, is available on a fee for service basis. In order to open an account with NTIS on the NCC system, state that you wish to access the database for the National Sewage Sludge Survey. No special

passwords are required and the dataset identifiers are listed in the appropriate data element dictionaries.

Printed copies of the Analytical Database (PB90–107491), and Questionnaire Database (PB90–107509) are also available from NTIS.

Availability of Other Documents Used in Developing the Final Part 503 Rule

A copy of the documents (e.g., Response to Comments Document for the proposed part 503 Rule, Analytical Methods for the National Sewage Sludge Survey, Statistical Support Documentation for part 503, etc.) cited in the reference section of this Notice are available for review at EPA's Water Docket; 401 M Street, SW; Washington, DC 20460. The Docket is located in room L–102. For access to Docket materials, call (202) 260–3027 between 9 a.m. and 3:30 p.m. for an appointment. The EPA public information regulation (40 CFR part 2) provides that a reasonable fee may be charged for copying.

List of References Used in Preamble

1. Abron-Robinson, L.A. and L.W. Weinberger. 1984. Sewage Sludge Versus Commercial Methods for Reclaiming Strip Mine Soil. U.S. EPA, Municipal Environmental Research Laboratory and Peer Consultants. Cincinnati, OH. EPA/600/2–84/155.
2. American Petroleum Institute (API). 1983. Land Treatment Practices in the Petroleum Industry. Environmental Research and Technology, Inc., Concord, MA.
3. Anthony, R.G. and G.W. Wood. 1979. Effects of Municipal Wastewater Irrigation on Wildlife and Wildlife Habitat. Pp. 213–223. In: Sopper, William E. and Sonja N. Kerr. 1979. Utilization of Municipal Sewage Effluents and Sludge on Forest and Disturbed Land. Pennsylvania State University Press, University Park, PA.
4. Association for Utilization of Sewage Sludge. 1988. Proceedings-Second International Symposium on Land Application of Sewage Sludge. Tokyo, Japan.
5. Baxter, H.C., M. Aquiler, and K. Brown. 1983. Heavy Metals and Persistent Organics at a Sewage Sludge Disposal Site. J. Environ. Qual. 12(3):311–316.
6. Baxter, J.C., D.E. Johnson, and E.W. Kienholz. 1980. Uptake of Trace Metals and Persistent Organics Into Bovine Tissues from Sewage Sludge—Denver Project. pp. 285–309. *In* G. Bittion, B.L. Damron, G.T. Edds, and J.M. Davidson (eds.) Sludge—Health Risks of Land Application. Ann Arbor Science Publ. Inc., Ann Arbor, MI.
7. Brown, D.S., and J.D. Allison. 1987. MINTEQAI, An Equilibrium Metal Speciation Model: User's Manual. U.S. Environmental Research Laboratory, Athens, GA. EPA/600/3–87–012.
8. Brown, R.E. 1975. Significance of Trace Metals and Nitrates in Sludge Soils. J. Water Pollut. Control Fed. 47:2863–2875.
9. CAST (Council for Agricultural Science and Technology). 1976. Application of Sewage Sludge to Cropland: Appraisal of Potential Hazards of the Heavy Metals to Plants and Animals. EPA 430/9–76–013.
10. Chaney, R.L. 1973. Crop and Food Chain Effects of Toxic Elements in Sludges and Effluents. Pp. 129–141. In: Proc. of the Joint Conf. on Recycling Municipal Sludges and Effluents on Land, Champaign, IL. (July 9–13, 1973). National Assoc. State Univ. and Land Grant Colleges, Washington, D.C.
11. Chaney, R.L., R.J.F. Bruins, D.E. Baker, R.F. Horcak, J.E. Smith Jr., and D.W. Cole. 1987. Transfer of Sludge-Applied Trace Elements to the Food-Chain. Pp. 67–99. *In*: A.L. Page, T.J. Logan and J.A. Ryan (eds.). Land Application of Sludge—Food Chain Implications. Lewis Publishers, Inc. Chelsea, MI.
12. Chang, A.C. and A.L. Page. 1985. Personal Communication. Dept. of Soil and Environmental Sciences, Univ. of California, Riverside, CA. (As cited in Page, A.L., T.G. Logan, J.A. Ryan. 1987.)
13. Cohen, A. Clifford, Jr. 1959. "Simplified Estimators for the Normal Distribution When Samples are Singly Censored or Truncated." *Technometrics*. Vol. 1, No. 3 (August). 217–237.
14. Cole, D.W. 1980. Response of Forest Ecosystems to Sludge and Wastewater Applications—A Case Study in Western Washington. In: U.S. EPA. 1980. Utilization of Municipal Wastewater and Sludge for Land Reclamation and Biomass Production. Washington, D.C. EPA 430/9–81–012.
15. Cools, A., et al. 1976. Biochemical Response of Male Volunteers Ingesting Inorganic Lead for 49 Days. Int. Arch. Occup. Environ. Health 38:129–139.
16. Delos, C.G., et al. 1984. Toxic Substances. Technical Guidance Manual for Performing Waste Load Allocations, Book II–Streams and Rivers, Toxic Substances. U.S. EPA, Office of Water Regulations and Standards, Washington, D.C. EPA–440/4–84–022.
17. Dowdy, R.H., and W.E. Larson. 1975. The Availability of Sludge-Borne Metals to Various Vegetable Crops. J. Environ. Qual. 4:278–282.
18. Dowdy, R.H., et al. 1978. Growth and Metal Uptake of Snap Beans Grown on Sewage Sludge—Amended Soils, a Four-Year Field Study. J. Environ. Qual. 7:252–257.
19. Drees, L.M. 1988. Effect of Lime and Other Precipitants or Sludge Conditioners on Conversion of Chromium to the Hexavalent State When Sludge is Incinerated. Final Report. EPA Contract 68–03–3346.
20. Felmy, A.R., D.C. Girvin, and E.A. Jenne. 1984. MINTEQ—A Computer Program for Calculating Aqueous Geochemical Equilibrium. EPA–600/3–84–032.
21. Fries, G.F. 1989. Potential Polychlorinated Biphenyl Residues in Animal Products from Application of Contaminated Sewage Sludge to Land. J. Environ. Qual. 11:14–20.
22. Fries, G.G., G.S. Marrow and C.H. Gordon. 1973. Long-Term Studies of Residues in Animal Products from Application of Contaminated Sewage Sludge to Land. J. Environ. Qual. 11(1):14–20.
23. Genstle, R.W., and D.M. Albrinck. 1982. Atmospheric Emissions of Metals from Sewage Sludge Incineration. Air Poll. Control Assoc. 32(11) (November).
24. Gilliom, Robert J. and D.R. Helsel. 1986. "Estimation of Distributional Parameters for Censored Trace Level Water Quality Data. 2. Verification and Applications." *Water Resources Research*. Vol. 22, No. 2. (February). 135–146.
25. Goring, C.A.I., and J.W. Hanaker. 1972. Organic Chemicals in the Soil Environment. Vol. 1. Marcel Dekker, Inc., N.Y.
26. Guenzi, W.D., et al. (ed.). 1974. Pesticides in Soil and Water. (Listed. Soil Sci. Soc. Amer., Madison, WI.)
27. Haghiri, F. 1974. Plant Uptake of Cadmium as Influenced by Cation Exchange Capacity, Organic Matter, Zinc, and Soil Temperature. J. Environ. Qual. 3:180–183.
28. Hajjar, L.M. 1985. Effect of Soil pH and the Residual Effect of Sludge Loading Rate on the Heavy Metal Content of Tobacco and Peanut and the Effect of Cd SO_4 on the Cd Content of Various Cultivars of Grass. M.S. Thesis, North Carolina State U., Raleigh. (As Cited in: Page, A.L., T.H. Logan, and J.A. Ryan, 1987.)
29. Hallden, J.A., C.J. Pederson, and J.P. St. John. 1987. Steele Brook Pilot Study for Implementing EPA's Toxic Control Policy. Phase II Technical Analysis. U.S. EPA, Office of Water Regulations and Standards, Washington, D.C.
30. Hansen, K.G. and T.D. Hinesly. 1981. Cadmium and Soil Amended with Sewage Sludge: Effects of Residues in Swine. Environ. Health Perspect. 28:51–57.
31. Helsel, Dennis R., and R.J. Gilliom. 1986. "Estimation of Distributional Parameters for Censored Trace Level Water Quality Data. 2. Verification and Applications." *Water Resources Research*. Vol. 22, No. 2. (February). 147–155.
32. Helsel, D.R. and T.A. Cohn. 1988. "Estimation of Descriptive Statistics for Multi-Censored Water Quality Data." *Water Resources Research*. Vol. 24, No. 12. (December). 1997–2004.
33. Hinesly, T.D., L.G. Hansen, D.J. Bray and K.E. Redborg, 1985. Transfer of Sludge-Borne Cadmium Through Plants to Chickens. J. Agr. Food Chem. 33:173–180.
34. Hinesly, T.D., E.L. Ziegler, J.J. Tyler. 1976. Selected Chemical Elements in Tissues of Pheasants Fed Corn Grain from Sewage Sludge-Amended Soil. Agro/Ecosystems. 3:11–26.

35. Holmgren, G. 1985. Personal Communication to Randy Bruins, U.S. EPA. Office of Research and Development. Cincinnati, OH.
36. Honeyman, B.D., and P.H. Santschi. 1988. Metals in Aquatic Systems. Environ. Sci. Technol. 22:862.
37. Hyde, H.C., et al. 1979. Effect of Heavy Metals in Sludge on Agricultural Crops. J. Water Pollut. Control Fed. 51:2475–2486.
38. HydroQual, Inc. 1986. Technical Guidance Manual for Performing Waste Load Allocations, Book IV: Lakes, Reservoirs and Impoundments. Toxic Substances Impact. U.S. EPA, Office of Water Regulations and Standards, Washington, D.C. EPA–440/4–87–002.
38a. Kaitz, E.F. 1978. Home Gardening National Report. 1975–1977. Presented at the American Seed Trade Association, Inc., 95th Annual Convention. Kansas City, Missouri. June 1978.
39. LaGoy, P.K. 1987. Estimated Soil Ingestion Rates for Use in Risk Assessment. Risk Analysis 7:355.
40. Majima, T., et al. 1977. Studies of Pyrolysis Process of Sewage Sludge. Pp. 381–396. In: Prog. Wat. Tech. (Vol. 9). Pergaman Press, Great Britain.
41. National Center for Health Statistics. 1981. Plan and Operation of the Second National Health and Nutrition Examination Survey (1976–1980). Vital and Health Statistics Series 1(15).
42. National Well Water Association. 1985. DRASTIC: A Standardized System for Evaluating Ground Water Pollution Potential Using Hydrogeologic Settings. Ada, OK.
43. O'Connor, G.A., et al. 1989. Plant Uptake of Sludge Borne PCBs. J. Environ. Qual.
44. Page, A.L., T.G. Logan, and J.A. Ryan. 1987. Land Application of Sludge. Lewis Publishers, Inc., Chelsea, MI.
45. PEI Associates, Inc. 1987. Sewer Sludge Incineration: ISCLT Model Sensitivity Analysis. U.S. EPA, Office of Water Regulations and Standards, Washington, D.C.
46. Pennington, J.A.T. 1983. Revision of the Total Diet Study Food Lists and Diets. J. Am. Diet. Assoc. 82:166–173.
47. Peterson, M.S., L.W. Lion, and C.A. Shoemaker. 1988. Influence of Vapor-Phase Sorption and Diffusion on the Fate of Trichloroethylene in an Unsaturated Aquifer System. Environ. Sci. Technol. 22:571.
48. Pirkle, J.L., et al. 1985. The Relationship Between Blood Lead Levels and Blood Pressure and Its Cardiovascular Risk Implications. Amer. J. Epidemiol. 121(2).
49. Seaker, Eileen M., and W.E. Sopper. Reclamation of Bituminous Strip-mine Spoil Banks with Municipal Sewage Sludge. Reclamation and Revegetation Research. 3:87–100 (As cited in Seaker, Eileen M. 1985. Uses of Philadelphia Mine Mix for Strip-mine Reclamation in Western Pennsylvania. City of Philadelphia Water Department, Philadelphia, PA.)
50. Sherlock, J., et al. 1982. Assessment of Lead Intakes and Dose-Response for a Population in Ayr Exposed to a Plumbsolvent Water Supply. Hum. Toxicol. 1:115–122.
51. Singh, D. 1983. The Effect of Land Application of Sludge on Concentrations of Certain Sludge-Associated Toxic Chemicals in Michigan Soils and Crops (Report). MI Dept. of Ag., Toxic Substances Division, Lansing, MI.
52. Sopper, William E., and Sonja N. Kerr. 1980. Mine Land Reclamation with Municipal Sludge—Pennsylvania's Demonstration Program. (As cited in Cole, 1980. pp. 55–87.)
53. Strek, H.J. and J.B. Weber. 1980. Absorption and Translocation of Polychlorinated Biphenyls. Proc. South Weed, Sci, Soc. 33:226–232.
54. Taylor, D. 1988. Results of PCB Research Conducted by Madison Metropolitan Sewerage District (Madison, WI). Personal Communication to Alan Rubin. U.S. EPA. Office of Water. Washington, D.C.
55. Touchton, J.T., et al. 1976. Residual Effect of Liquid Sludge on Coastal Bermuda Grass and Soil Chemical Properties. J. Environ. Qual. 5:161–164.
56. U.S. DA. 1972. Food Consumption: Households in the United States, Seasons and Year 1965–1966. Nationwide Food Consumption Survey 1965–1966, Report No. 12.
57. U.S. DA. 1982. Food Consumption: Households in the United States, Seasons and Year 1975–1978. Nationwide Food Consumption Survey 1975–1978, Report No. H–6.
58. U.S. DA. 1989. Peer Review—Standards for the Disposal of Sewage Sludge U.S. EPA Proposed Rule 40 CFR Parts 257 and 503.
59. U.S. EPA. 1979. Process Design Manual for Sludge Treatment and Disposal. EPA 625/1–79–011.
60. U.S. EPA. 1982. Fate of Priority Pollutants in Publicly-Owned Treatment Works. Vol. I. Effluent Guidelines Division, Washington, D.C. EPA 440/1–82–303.
61. U.S. EPA. 1983. Process Design Manual for the Land Application of Municipal Sludge. Municipal Environmental Research Laboratory, Cincinnati, OH. EPA–625/1–83–016.
62. U.S. EPA. 1983. The Record of Proceedings on the OWRS Municipal Sewage Sludge Committees. Washington, D.C.
63. U.S. EPA. 1984. Environmental Regulations and Technology. Use and Disposal of Municipal Wastewater Sludge. Washington, D.C.
64. U.S. EPA. 1984. Ground-Water Protection Strategy. Washington, DC.
65. U.S. EPA. 1985. Chromium Emissions from Sewage Sludge Incinerators. Office of Air and Radiation, Emission Standards and Engineering Division.
66. U.S. EPA. 1985. Chromium Screening Study Test Report, Sewage Sludge Incinerator No. 13, Detroit Water and Sewer Department, Detroit Michigan. Office of Air Quality Planning and Standards. EMB Report 85–CHM–5.
67. U.S. EPA. 1985. Environmental Profiles and Hazard Indices for Constituents of Municipal Sludge. Washington, DC.
68. U.S. EPA. 1985. Environmental Science and Engineering. Exposure to Airborne Contaminants Released from Land Disposal Facilities—A Proposed Methodology.
69. U.S. EPA. 1985. Guideline for Determination of Good Engineering Practice Stack Height. EPA–450/4–80–023R.
70. U.S. EPA. 1986. Air Quality Criteria for Lead (volumes I–IV). Environmental Criteria and Assessment Office, Research Triangle Park, NC. EPA–600/8–83/028aF.
71. U.S. EPA. 1986. Development of Risk Assessment Methodology for Municipal Sludge Incineration. Environmental Criteria and Assessment Office, Cincinnati, OH. ECAO–CIN–486.
72. U.S. EPA. 1986. Development of Risk Assessment Methodology for Municipal Sludge Landfilling. Environmental Criteria and Assessment Office, Cincinnati, OH. ECAO–CIN–485.
73. U.S. EPA. 1986. Development of a Qualitative Pathogen Risk Assessment Methodology for Municipal Sludge Landfilling. Environmental Criteria and Assessment Office, Office of Research and Development, Washington, DC.
74. U.S. EPA. 1986. Guideline on Air Quality Models (revised). Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA–450/2–18–027R.
75. U.S. EPA. 1986. Reducing Lead in Drinking Water: A Benefits Analysis (draft final report). Office of Policy, Planning, and Evaluation.
76. U.S. EPA. 1986. Sludge Incinerator Air Quality Modeling. Office of Air Quality Planning and Standards, Research Triangle Park, NC.
77. U.S. EPA. 1986. Chromium Emissions from a Sewage Sludge Incinerator, (Draft Report). EPA Contract No. 68–03–3346.
78. U.S. EPA. 1987. Descriptive Statistics on Contaminants in Municipal Sludge Based on the EPA 40–POTW Study. Science Applications International Corporation. EPA Contract No. 68–01–6912.
79. U.S. EPA. 1987. Development of Risk Assessment Methodology for Land Application and Distribution and Marketing of Municipal Sludge. Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH. ECAO–CIN–489.
80. U.S. EPA. 1987. Integrated Risk Information System Supportive Documentation, volume I. Office of Health and Environmental Assessment, Washington, DC. EPA/600/8–86/032a.

81. U.S. EPA. 1987. Review of Technical Documents Supporting Proposed Revisions to EPA Regulations for the Disposal/Reuse of Sewage Sludge under section 405(d) of the Clean Water Act. Science Advisory Board, Environmental Engineering Committee, Washington, D.C. SAB–EEC–87–015.
82. U.S. EPA. 1987. Task Report: Cyanide Levels in Municipal Sewage Sludge In: U.S. EPA. Water Engineering Research Laboratory Monthly Report. Office of Research and Development. Cincinnati, OH.
83. U.S. EPA. 1987. The Effects of Municipal Wastewater Sludge on Leachates and Gas Production from Sludge-Refuse Landfills and Sludge Monofills. Water Engineering Research Laboratory, Office of Research and Development. Cincinnati, OH.
84. U.S. EPA. 1988. Analytical Methods for the National Sewage Sludge Survey. Washington, D.C.
85. U.S. EPA. 1988. Guidance for Writing Case-by-Case Permit Requirements for Municipal Sewage Sludge. Draft. Office of Water Experiment. Permits Division.
86. U.S. EPA. 1988. Guidelines for Ground-Water Classification Under the EPA Ground-Water Protection Strategy. Washington, D.C.
87. U.S. EPA. 1988. Location Restrictions (Subpart B) Criteria for Municipal Solid Waste Landfills (40 CFR Part 258)—Subtitle D of the Resource Conservation and Recovery Act (RCRA). Office of Solid Waste. Washington, D.C.
88. U.S. EPA. 1988. Operating Criteria (Subpart C)—Criteria for Municipal Solid Waste Landfills (40 CFR part 258)—Subtitle D of the Resource Conservation and Recovery Act (RCRA). Office of Solid Waste. Washington, D.C.
89. U.S. EPA. 1988. Personal Communication of E.P. Crumpler with Shireo Co., Dallas, TX., April 6, 1988.
90. U.S. EPA. 1988. POTW Sludge Sampling and Analysis Document (Draft). Washington, D.C.
91. U.S. EPA. 1988. Probabilistic Ground-Water Classification at the Forty-Six Currently Active Sewage Sludge Monofills. Washington, D.C.
92. U.S. EPA. 1988. Review of the National Ambient Air Quality Standards for Lead: Exposure Analysis Methodology and Validation (Draft). Washington, D.C.
93. U.S. EPA. 1988. Sampling Procedures and Protocols for the National Sewage Sludge Survey. Washington, D.C.
94. U.S. EPA. 1988. Supporting Statement for the National Sewage Sludge Survey. Washington, D.C.
95. U.S. EPA. 1989. Burning of Hazardous Waste in Boilers and Industrial Furnaces (40 CFR Part 260)—Subtitle C of the Resource Conservation and Recovery Act (RCRA). Washington, D.C.
96. U.S. EPA. 1989. Interim Final Guidance for Soil Ingestion Rates. Office of Solid Waste and Emergency Response. Washington, D.C. (January). Directive Number 9850.4.
97. U.S. EPA. 1989. Review of Proposed Sewage Sludge Incineration Rules (40 CFR Part 257 and 503). EPA–SAB–EEC–89–035.
98. U.S. EPA. 1989a. Risk of Unsaturated/Saturated Transport and Transformation Interactions for Chemical Concentrations (RUSTIC), Volume 1: Theory and Code Verification. Office of Research and Development, Environmental Research Laboratory, Athens, GA. EPA Contract No. 68–03–6304.
99. U.S. EPA. 1989b. RUSTIC Documentation, Volume II: User's Guide. Office of Research and Development, Environmental Research Laboratory, Athens, GA. EPA Contract No. 68–03–6304.
100. U.S. EPA. 1989. Technical Support Document: Incineration of Sewage Sludge (Proposal). Office of Water.
101. U.S. EPA. 1989. Technical Support Document: Land Application and Distribution and Marketing of Sewage Sludge (Proposal). Office of Water Regulations and Standards, Washington, D.C.
102. U.S. EPA. 1989. Technical Support Document: Landfilling of Sewage Sludge (Proposal). Washington, D.C.
103. U.S. EPA. 1989. Technical Support Document: Pathogens and Vectors. (Proposal). Office of Water Regulations and Standards. Washington, D.C.
104. U.S. EPA. 1989. Technical Support Document: Surface Disposal of Sewage Sludge (Proposal). Office of Water Regulations and Standards. Washington, D.C.
105. U.S. EPA. 1990. Guidance Document for Testing and Permitting Sewage Sludge Incinerators. EPA Contract No. 68–03–3533.
106. U.S. EPA. 1990. Standards for Owners and Operators of Hazardous Waste Incinerators (40 CFR Part 260, 261, 264 and 270)—Subtitle C of the Resource Conservation and Recovery Act (RCRA). Washington, D.C.
107. U.S. EPA. 1990. Supplemental Guidance on the Development and Implementation of Local Discharge Limitations Under the Pretreatment Program (Draft). Office of Water. Washington, D.C.
108. U.S. EPA. 1991. Memorandum of James A. Ryan to Alan Rubin Committee Report on 503 Regulations. Washington, D.C. March 28, 1991.
109. U.S. EPA. 1992. Response to Public Comments on the Proposed Part 503 Sewage Sludge Use and Disposal Regulations and the National Sewage Sludge Notice of Availability. Washington, D.C.
110. U.S. EPA. 1992. Sewage Sludge Incinerator Total Hydrocarbon Analyzer Evaluation. Office of Research and Development, Wastewater Research Division, Cincinnati, OH. EPA Contract No. 60–CO–0027.
111. U.S. Geological Survey. 1981. Facing Geologic and Hydrologic Hazards. Geologic Survey Professional Paper 1240–B. Washington, D.C.
112. Van Genuchten, M. 1985. Convective-Dispersive Transport of Solutes Involved in Sequential First-order Decay Reactions. J. Computers Geosci. 11:129.
113. Vlamis, J., D.E. Williams, J.E. Corey, A.L. Page and T.J. Ganje. 1985. Zinc and Cadmium Uptake by Barley in Field Plots Fertilized Seven Years with Urban and Suburban Sludge. Soil Sci. 139:81–87. (As cited in: Page, A.L., T.H. Logan, and J.A. Ryan, 1987.)
114. Water Pollution Control Federation. 1988 Incineration, Manual of Practice No. OM–11. Alexandria, VA.
115. Water Resources Council. 1977. Guidelines for Determining Flood Flow Frequency. Bulletin Number 17A.
116. Webber, L.R., and E.G. Beauchamp. 1979. Cadmium Concentrations and Distribution in Corn (*Zea mays* L.) Grown on a Calcareous Soil for Three Years After Three Annual Sludge Applications. J. Environ. Sci. Health B14(5):454–474.
117. Yeh, G.T. 1981. AT123D: Analytical Transient One-, Two-, and Three-Dimensional Simulation of Waste Transport in the Aquifer System. Oak Ridge National Laboratory, Environmental Sciences Division, Oak Ridge, TN. ORNL–5602.

Part XV: Description of the Amendments to 40 CFR Parts 257 and 403

Amendment to 40 CFR Part 257

The existing requirements in 40 CFR part 257 are applicable to all solid waste disposal facilities and practices regulated under sections 4004 and 4010 of the Resource Conservation and Recovery Act. With certain exceptions, the requirements in 40 CFR part 257 apply to all types of facilities (e.g., landfills, surface disposal sites, land application units, and waste piles) used for the disposal of solid waste and all types of non-hazardous solid wastes (i.e., municipal, industrial, commercial, agricultural, mining, and oil and gas wastes). Part 257 also applies to the disposal of sewage sludge.

Included with the 1989 part 503 proposal was a proposed amendment to part 257. The purpose of the amendment was to delete the requirements in part 257 that pertain to sewage sludge. This included deleting section 405(d) from the part 257 authority, deleting references to sewage sludge in 257.1, revising the definitions for "sludge" and "solid waste" in 257.2, deleting the reference to sections 405(d) and 405(e) from 257.3–4, and deleting paragraphs (b) and (c) from 257.3–6. These proposed changes are discussed below with respect to the final amendment to part 257 in today's rulemaking. No comments were received from the public on the proposed part 257 amendment during

the comment period for the 1989 proposal.

The final part 503 regulation contains requirements for sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. There is one case, however, that the part 503 requirements do not apply to sewage sludge used or disposed through those practices. Part 503 does not apply to the use or disposal of sewage sludge generated at an industrial facility during the treatment of industrial wastewater combined with domestic sewage generated at the industrial facility. That sewage sludge has to meet the part 257 requirements if it is disposed on the land. Because the part 257 requirements continue to apply to certain sewage sludges, today's amendment does not delete section 405(d) from the part 257 authority.

Section 257.1(b)(1) was proposed to be changed in the 1989 proposal to indicate the part 257 criteria do not apply to the use or disposal of sewage sludge under section 405(d) of the Clean Water Act. Because certain sewage sludges are subject to the part 257 requirements, today's rulemaking amends 257.1(b)(1) to indicate that part 257 contains guidelines for the disposal of sewage sludge not used or disposed through a practice regulated in 40 CFR part 503. This means that part 257 applies if sewage sludge is disposed on the land and if the sewage sludge is not used or disposed in accordance with part 503.

The 1989 proposal also proposed to amend 257.1(c)(3) and 257.1(c)(4) by deleting the last sentence in each subsection. Today's part 257 amendment deletes the final sentence in 257.1(c)(3), but does not delete the final sentence in 257.1(c)(4).

The last sentence in the current 257.1(c)(3) indicates that the part 257 criteria apply to disposal of sludges generated by treatment of domestic sewage. Because the applicability of part 257 to disposal of sewage sludge is addressed in the amended 503.1(b)(1) and in a new 503.1(c)(11), the last sentence no longer applies. For this reason, it was deleted from 257.1(c)(3).

The last sentence in 257.1(c)(4) concerning disposal of septic tank pumpings is not being deleted in today's amendment because part 257 still applies to the disposal of pumpings from septic tanks that receive commercial or industrial wastewaters. Use or disposal of pumpings from septic tanks that receive only domestic sewage (i.e., domestic septage) is addressed in part 503.

The second revision to 257.1(c) in today's amendment adds a new provision at 257.1(c)(11). This provision indicates that the part 257 criteria do not apply to the use or disposal of sewage sludge, including domestic septage, on the land when the sewage sludge is used or disposed in accordance with 40 CFR part 503. Note that domestic septage does not include pumpings from septic tanks that receive commercial or industry wastewater. As mentioned above, if those pumpings are disposed on the land, the part 257 criteria apply. The Agency decided to include this provision in 257.1(c) to make it clear that sewage sludge used or disposed in accordance with part 503 is not subject to the part 257 requirements.

Another revision to part 257 in today's rulemaking amends the definition section (i.e., 257.2). In the 1989 proposal, 257.2 was proposed to be changed by amending the terms "sludge" and "solid waste" to indicate that sewage sludge is not a sludge or a solid waste. The Agency decided not to amend those definitions in today's amendment because certain sewage sludges are still subject to the part 257 requirements. Instead, the definition of "domestic septage" and "sewage sludge" are being added to 257.2. These terms are used in the revisions to 257.1.

The final revision in today's part 257 amendment concerns 257.3–4. This subsection is being changed by adding the phrase "with respect to sewage sludge that is not used or disposed through a practice regulated in 40 CFR part 503" after "* * * a violation of section 405(e) * * * ". Section 405(e) indicates that the determination of the manner of disposal or use of sewage sludge is a local determination. However, if the selected use or disposal practice is regulated under section 405(d) of the CWA, the requirements in 405(d) have to be met. Because part 257 is promulgated under the authority of 405(d) for sewage sludges that are not regulated under part 503, section 257.3–4(b)(1) is being amended to make it clear that a party charged with a violation of section 405(e) only with respect to sewage sludge not regulated under 40 CFR part 503 may demonstrate that compliance be determined at an alternative boundary in lieu of the solid waste boundary. This amendment does not apply to a party charged with open dumping.

The proposed part 257 amendment also indicated that the Agency was considering deleting paragraphs (b) and (c) in 257.3–6. Because part 257 continues to apply to certain sewage sludge disposed on the land, EPA decided not to delete those paragraphs. Paragraphs (b) and (c) still apply if sewage sludge is disposed on the land and if that sewage sludge is not used or disposed in accordance with part 503.

Amendment to 40 CFR Part 403

Today's amendment to 40 CFR part 403 contains an appendix with two lists of pollutants eligible for a removal credit with respect to the use or disposal of sewage sludge. The first list, G–I, contains the pollutants controlled for the various use or disposal practices regulated by the part 503 regulation. If a POTW complies with the part 503 pollutant limit for a part 503 use or disposal practice and complies with the other requirements in part 503 for that practice, the pollutant is eligible for a removal credit so long as other EPA procedural and substantive requirements found at 40 CFR 403.7 are met.

For an inorganic pollutant listed in G–I to be eligible for a removal credit when present in sewage sludge that is fired in a sewage sludge incinerator, the concentration of the pollutant in the sewage sludge cannot exceed the concentration calculated using the applicable equation in part 503. In addition, part 503 requires that the National Emission Standards for Beryllium and Mercury in subparts C and D of 40 CFR part 61, respectively, and the Standards of Performance for Sewage Treatment Plants in subpart O of 40 CFR part 60 not be violated if sewage sludge is fired in a sewage sludge incinerator. These requirements must be met before a removal credit can be granted for the inorganic pollutants.

Part 503 also limits total hydrocarbon (THC) in the exit gas from sewage sludge incinerator stacks. Although the THC limit is a technology-based operational standard, in the judgment of the Administrator of EPA that limit protects public health and the environment from the reasonably anticipated adverse affects of certain organic pollutants in the incinerator stack exit gas. The 503 proposal listed all of the organic pollutants for which there were Q^* values at that time. The final part 503 regulation also includes all organic pollutants for which there are Q^* values, including those for which the values were developed after the proposal. These pollutants are eligible for a removal credit with respect to the use or disposal of sewage sludge if the THC limit is met; if the Standards of Performance for Sewage Treatment Plants in subpart O of 40 CFR part 60 are not violated; and if the other removal credit requirements are met.

The second list, G–II in the appendix, lists certain pollutants by use or disposal practice and a concentration for each pollutant. The Agency

determined that the pollutants on the second list do not pose an unreasonable risk to public health and the environment if the concentrations for those pollutants in the sewage sludge are below the concentrations for the pollutants in G–II list.

Pollutants were placed on the list in G–II for one of two reasons. First, available data, which were based in large part on the results of the 40 City Study (Fate of Priority Pollutants in Publicly Owned Treatment Works. Vol. I, Washington, DC, U.S. EPA, 1984), at the time the original list of pollutants of concern for the part 503 regulation was developed indicated that the concentrations of the pollutants in sewage sludge do not exceed the concentrations for those pollutants on the G–II list. EPA determined that, at those concentrations, the pollutants do not pose a threat to public health and the environment at the highest levels detected, and that it was not necessary to expend additional resources to determine what the highest possible "safe level" would be. EPA decided that those pollutants are eligible for a removal credit with respect to the use or disposal of sewage sludge if the concentration of a pollutant in the sewage sludge does not exceed the concentration for the pollutant in G–II and if the treatment works complies with the applicable requirements in 40 CFR 403.7.

The second reason a pollutant was placed on the list in G–II is that, after determining a risk level for the pollutant, EPA decided not to regulate it in the final part 503 regulation. The concentration for those pollutants in G–II is the concentration developed during the risk assessment for the final part 503 regulation. A removal credit is available for those pollutants with respect to the use or disposal of sewage sludge if the concentration of the pollutant in the POTW's sewage sludge is less than or equal to the concentration for the pollutant in G–II and if the treatment works complies with the applicable requirements in 40 CFR 403.7. These pollutants are designated with an asterisk on the G–II list.

Proof that the pollutant concentrations in a POTW's sewage sludge do not exceed the pollutant concentrations on the G–II list must be provided in the Sludge Management Certification portion of a POTW's removal credit application (see 40 CFR 403.7(e)(4)(v)). No further monitoring of these pollutants is required unless required by a sewage sludge permit. If subsequent monitoring reveals that the concentration of the pollutant in the POTW's sewage sludge exceeds the levels in the G–II list or any more stringent limit in the POTW's sewage sludge permit, the POTW is no longer eligible for removal credit authority for that pollutant. See 40 CFR 403.7(f)(4).

If the concentration listed in G–II is below the limit of detection for the pollutant (i.e., for N-Nitrosodimethylamine), a POTW may be granted removal credit authority for that pollutant if the POTW shows that the actual concentration in the sewage sludge is below the detection limit, unless a sewage sludge permit imposes an actual limit below the detection limit.

Today's amendment also indicates that removal credit authority can be granted to POTWs whose sewage sludge is disposed of in a municipal solid waste landfill (MSWLF) that meets the criteria in 40 CFR part 258. Any pollutant in sewage sludge for which a categorical pretreatment standard has been developed is eligible for a removal credit because disposal of sewage sludge in a MSWLF that meets the criteria in 40 CFR part 258 constitutes compliance with section 405 of the Clean Water Act, as amended. EPA published the final part 258 regulations on October 11, 1991 (56 FR 50977).

To receive removal credit authority for a pollutant, a POTW also must comply with the limits in a sewage sludge permit. A permit writer might apply such limits if site-specific circumstances vary from the assumptions underlying the pollutant limits in today's rule. The POTW also must comply with any applicable provisions of the Clean Air Act and any more stringent State or local regulations to receive removal credit authority.

The remainder of the discussion on today's amendment to part 403 reviews the options considered during the development of the appendix G lists. Implementation of today's amendment also is discussed further below.

When the proposal for part 503 regulation was published in February 1989, the Agency proposed that removal credits be available with respect to the use or disposal of sewage sludge for two groups of pollutants. The first group included pollutants regulated in part 503; removal credits would be available for POTWs that complied with the part 503 requirements for the applicable use or disposal practice. The second group included pollutants not controlled in part 503 because at the highest concentrations detected in sewage sludge, these pollutants did not present an unreasonable risk to public health or the environment.

In a Notice of Availability of Information and Data from the National Sewage Sludge Survey and Request for Comments published in the **Federal Register** in November 1990, the Agency addressed whether removal credits should be available for pollutants not addressed in the initial part 503 regulation (known as "round one" regulation). The Agency proposed and invited comment in the Notice on four options concerning the eligibility of a pollutant for a removal credit with respect to the use or disposal of sewage sludge for a second round (i.e., round two) of pollutants and for pollutants not on either the "round one" or "round two" lists. The four options were:

Option 1—A categorical pretreatment standard pollutant is eligible for a removal credit only if EPA has either established a specific numerical limit for that pollutant in part 503 or has evaluated the pollutant and concluded that it does not threaten public health and the environment in sewage sludge that is used or disposed.

Option 2—A categorical pretreatment standard pollutant not controlled in the part 503 regulation for either "round one" or "round two" becomes eligible for a removal credit with respect to the use or disposal of sewage sludge when the part 503 "round two" regulation is promulgated.

Option 3—A categorical pretreatment standard pollutant not controlled in the part 503 regulation for "round one" becomes eligible for a removal credit with respect to the use or disposal of sewage sludge if not identified by EPA in the **Federal Register** as a pollutant that may be regulated in "round two."

Option 4—A categorical pretreatment standard pollutant not controlled in the part 503 regulation for "round one" becomes eligible for a removal credit with respect to the use or disposal of sewage sludge when the "round one" regulation is promulgated.

After consideration of all of the options and the comments addressing those options, EPA selected Option 1, which is included in today's amendment to part 403. Removal credit eligibility is limited to those pollutants regulated specifically in part 503 and to pollutants that the Agency determines do not threaten public health and the environment at specified concentrations. Many commenters supported Option 1 because that option provides such a clear statement as to which pollutants are eligible for a removal credit.

As mentioned previously, section 307(b) authorizes removal credits only if the resulting industrial discharges do "not prevent sludge use or disposal by such [POTW] in accordance with section 405 * * *". Section 307(b), 33

U.S.C. 1317(b). The Third Circuit in *NRDC* v. *EPA* interpreted this language to mean that removal credits only can be granted if the comprehensive standards under section 405(d) of the CWA, as amended, are in place. Congress affirmed the Third Circuit's holding by adopting section 406(e) of the Water Quality Act. The legislative history for section 406(e) indicates that Congress wanted standards to be developed and met prior to removal credits being authorized. As Senator Stafford, one of the sponsors of the Water Quality Act of 1987, pointed out (132 Cong. Rec. S16427, daily ed. October 16, 1986):

> * * * Congress intended the existence of sludge regulations, and compliance with those regulations, to be a precondition to the granting of removal credits.

Only then can it be determined if the granting of a removal credit for a specific pollutant results in contamination of the POTW's sewage sludge.

Although section 405 does not require a limit to be developed for pollutants that do not pose a risk, section 307(b) requires compliance with a section 405 standard for a POTW to be granted removal credit authority. The Agency has resolved the potential conflict between sections 307(b) and 405 by allowing a removal credit for pollutants not controlled in the part 503 regulation provided EPA determines that regulation is unnecessary to accomplish the objective of section 405 to protect public health and the environment from the reasonably anticipated adverse effects of the pollutant. Such a determination has been made with respect to the pollutants listed by use or disposal practice on the G–II list in today's amendment to part 403.

Note: Table 22 of the proposed rule erroneously listed cyanide among the pollutants for which removal credits would be available for sludge that is land applied or distributed and marketed; EPA has not evaluated the risk of cyanide in these practices and removal credits are not available for them. To correct this error, Table G–II in the final rule does not indicate that removal credits for cyanide are available where sewage sludge is land applied. The final rule also clarifies that "total cyanide", not "cyanide", is the parameter for which removal credits may be available for surface disposal.

EPA did not select Options 2 through 4, which would have made removal credits available for additional pollutants. Those options were premised on the assumption that "round one" and "round two" regulations address substantially all the universe of pollutants in sewage sludge that may pose a threat to public health and the environment. Whether that in fact will be the case is not known at this time. EPA will consider addressing in "round two" the remaining priority pollutants controlled by categorical pretreatment standards. If those pollutants are regulated in part 503, Options 2, 3, and 4 become obsolete.

EPA cannot make removal credits available for pollutants other than those listed in appendix G at this time because the Agency has not controlled other pollutants in part 503. EPA has not analyzed all of the data to determine whether other pollutants present a risk to public health and the environment in sewage sludge that is used or disposed.

Several comments were received on the four removal credit options in the 1990 Notice. The major comments are discussed below and a response to those comments is presented.

Some commenters recommended that removal credits be abolished altogether. Various reasons were given for these recommendations including that removal credits are inconsistent with pollution prevention, erode public confidence in sewage sludge quality, and are unnecessary because industry is already required to be in compliance with categorical pretreatment standards. Others opposed removal credits for any use or disposal practice except for beneficial use practices. Others opposed removal credits if the removal credits result in any deterioration of sewage sludge quality.

The above commenters misconstrued the scope of the removal credit amendment in today's rule. Moreover, regardless of the validity of the comments, section 307(b) of the Clean Water Act, as amended, provides that the owner or operator of a POTW may revise pretreatment standards, given compliance with the statute.

One environmental group commented that EPA could not make removal credits available for any pollutant until a limit is established for the pollutant. EPA believes it is consistent with the intent of CWA sections 307(b) and 405(d) to make removal credits available for pollutants present in sewage sludge at levels that EPA has determined do not affect public health and the environment adversely. The Agency decided not to regulate pollutants for which the concentration that protects public health and the environment is above any concentration that has been detected in sewage sludge. Such regulation would result in costly monitoring for no foreseeable benefit.

This same commenter stated that EPA could not make removal credits available unless EPA subjected the pollutant to the same analysis to which regulated pollutants were subjected. The Agency does not believe it is necessary to perform an equally intensive risk assessment for every pollutant for the pollutant to be eligible for a removal credit. The resources devoted to assessing a pollutant should be increased when there is an indication that a pollutant presents an unreasonable risk to public health and the environment. Relatively little information collection and analysis may be necessary if there is little or no evidence that a pollutant presents a risk when present in sewage sludge.

The CWA, as amended, does not specify the types or amount of studies that must be performed to support a decision to regulate a pollutant under section 405. It also does not require that limits be developed for pollutants that do not present a risk to public health or the environment or are not likely ever to be present in sewage sludge in concentrations that could present such a risk. The Agency does believe, however, that for the purposes of authorizing a removal credit under section 307(b), EPA must distinguish those pollutants that do not present a risk from those for which adequate data do not exist to allow such a determination. Although it is not necessary to develop section 405 standards for every pollutant for which a removal credit may be authorized, it is necessary for EPA to consider whether section 405 requires a pollutant to be regulated. The Agency believes that it has met this requirement with respect to the pollutants listed on the G–II list in today's amendment to part 403.

Commenters argued that EPA could not make any removal credits available based on EPA's analysis of data from the 40 City Study. Removal credits are available for the pollutants listed in G–II because, at the highest values shown, EPA determined they do not present an unreasonable risk for one or more use or disposal practices. Many of the pollutant concentrations in G–II are the highest concentrations detected in the 40 City Study. At the time of the February 1989 proposal, EPA decided not to subject these pollutants to the full-scale risk assessment to which pollutants proposed for regulation were subjected. Because EPA had already determined that the pollutants do not pose a threat to public health and the environment at the highest levels detected, it was not necessary to expend additional resources to determine what the highest possible "safe level" would be. EPA decided it should instead concentrate its resources on studying those pollutants that EPA's preliminary

assessments indicated might pose a risk at existing levels.

EPA recognizes that the data from the National Sewage Sludge Survey (NSSS) is more reflective of current sewage sludge quality than the data from the 40 City Study. It may in fact be the case that EPA's analysis of the NSSS data during "round two" will indicate that certain pollutants on the G–II list are present in concentrations that merit regulation. The fact that the 40 City Study may have given an inaccurate indication of the maximum concentration of a pollutant present in any sewage sludge does not, however, change EPA's conclusion that the pollutants are "safe" at the 40 City Study levels. Examination of the NSSS data on the concentrations of these pollutants may lead to a conclusion that the "safe level" may be higher than the 40 City Study levels or may lead to a conclusion that these pollutants need to be regulated. This will not, in the absence of other information, change EPA's determination that the lower levels detected in the 40 City Study are "safe".

Also included on the G–II list are concentrations for organic pollutants based on the results of the risk assessment for the part 503 regulation. These pollutants were deleted from the part 503 regulation for various reasons after the part 503 risk assessment was completed. The concentrations for these pollutants in G–II are the concentrations based on the results of the part 503 risk assessment. If the concentration for the pollutant is below the concentration on the G–II list, public health and the environment are protected from the reasonably anticipated adverse effects of the pollutants in sewage sludge that is used or disposed. These pollutants are marked with an asterisk on the G–II list.

Some commenters argued that removal credits must be made available for any pollutant not regulated by the final part 503 regulation. The Agency believes, however, that the CWA, as amended, only allows removal credits for the pollutants in appendix G. When read together, sections 307(b) and 405 permit removal credits only when it can be determined that the increased concentrations or amounts allowed by the removal credit does not affect sewage sludge use or disposal adversely. It may in fact be the case that the use or disposal of sewage sludge is not affected adversely by some pollutants for which standards are not being promulgated today. For pollutants other than those in appendix G, it cannot be determined, however, whether pollutants were not selected for regulation because they were believed to be "safe" or because there are not adequate data to determine a "safe level". As previously noted, for example, dioxin is not a pollutant that is regulated in this rulemaking today. Dioxins, which may be present in sewage sludge, are not regulated not because they are believed safe but because at the time EPA initially screened pollutants for regulation it lacked data to evaluate dioxins for regulation.

Some commenters assumed incorrectly that the pollutants on Table III–3 in the preamble for the proposed part 503 regulation were the only pollutants for which EPA lacked adequate data to establish a "safe level". Table III–3 listed the pollutants that were recommended for further study but for which a positive determination was made subsequently that EPA lacked sufficient data to establish a safe level. There are other pollutants that may have not been recommended for study because EPA lacked data regarding the risk they presented.

In the view of some commenters, this approach excludes unfairly from removal credit eligibility pollutants that may represent little or no threat to public health and the environment simply because EPA has not evaluated them formally for environmental threat. EPA recognizes that the part 503 pollutants regulated in "Round One" generally represent those pollutants in sewage sludge with the greatest potential for threatening public health and the environment. However, it must be recognized that the decision to regulate some pollutants and not others was in part based on the availability of information on the pollutants. EPA solicited comments and data to support whether additional or fewer pollutants should be regulated but received little response. The decision not to regulate does not necessarily mean that the unregulated pollutants may not threaten public health and the environment.

EPA solicited comment on whether, in those cases where the Agency regulates 4AAP (a test measurement) as an indicator for various phenolic compounds, removal credits should be allowed for all of the compounds represented by 4AAP although only the parent compound phenol and certain other phenolic compounds were subject to environmental assessments in this rulemaking. Commenters did not provide EPA with data that 4AAP reflects the different phenolic compounds in wastewater. Therefore, removal credits only are available for the specific phenolic compounds listed on the G–II in the appendix to today's part 403 amendment.

EPA solicited comment whether a specific categorical pretreatment standard pollutant not regulated in part 503 should be eligible for a removal credit and whether the concentrations on the G–II list were appropriate. One commenter noted that the demonstration procedure is so costly and time consuming that it is unlikely that additional chemicals would be added before the deadline for categorical standards. EPA notes that the degree of information and expense required should increase with evidence of risk, but that in any case, EPA's decisions must be based on such information. The only detailed data submitted to EPA addressed the adequacy of the cap for chromium. After further analysis of all available data regarding chromium in sewage sludge, EPA decided to regulate chromium in part 503. For this reason, chromium is listed on the G–I lists rather than on the G–II list.

The concentrations listed on the G–II list are a cap for the availability of removal credits for the pollutants by use or disposal practice. EPA will study the NSSS data during "Round Two" for the part 503 regulation to determine whether these levels should be raised or if the pollutants should be regulated at some other level. If an industrial discharger believes that removal credit authority should be made available for a pollutant that is present in a POTW's sewage sludge at a higher level than the level on the G–II list, the industry should provide to EPA information on those concentrations and any information of the risk presented by such concentrations.

One commenter recommended that removal credits be available for pollutants that cannot be detected in a POTW's sewage sludge. The "safe level" might be below the detection limit for some or all test procedures. The Agency believes, therefore, that it must determine the "safe level" of a pollutant before removal credit authority can be granted for that pollutant.

This commenter listed several pollutants found rarely in sewage sludge sampled in the National Sewage Sludge Survey. EPA has not yet analyzed the data on these pollutants to determine if it is adequate to support a decision not to regulate the pollutants. Before a removal credit can be authorized, EPA has to at least establish that the highest detected levels do not present a risk. The Agency hopes to perform that analysis for the "Round Two" part 503 regulation. Before that time, removal credits only are available for the pollutants listed in G–I or G–II.

Another commenter recommended that EPA consider allowing a POTW to grant a removal credit for any pollutant that cannot be detected in the POTW's effluent. This is not within the scope of this rulemaking. The Agency notes, however, that the burden of proof is on the POTW that seeks removal credit authority to establish that it is accomplishing consistent removal of the pollutant. The methods by which consistent removal can be established is not the subject of today's rule (see 40 CFR 403.7(b)(1)).

Prior to 1986, one POTW was authorized to grant removal credits for ammonia and oil and grease. This POTW commented that EPA should clarify that removal credits are available for conventional and non-conventional pollutants. As discussed above, EPA has determined that before it can make removal credits available for a particular pollutant not regulated under Part 503, it needs to determine that regulation of that pollutant is not necessary to protect public health and the environment from the reasonably anticipated adverse effects of that pollutant. Ammonia and oil and grease are not regulated under today's final part 503 standards and EPA has not made the necessary determination that regulation is not necessary. Removal credits for ammonia and oil and grease, therefore, are not available at this time. However, as previously explained, EPA will evaluate a number of pollutants for regulation in "Round Two." Its conclusions about which pollutants may be proposed for regulation in "Round Two" must be made by late May, 1993. EPA is considering at this time not only which pollutants may be proposed for regulation but also the process for determining how to evaluate unregulated pollutants for removal credit purposes.

With respect to implementation of a removal credit, publication of the part 503 regulation does not entitle a POTW automatically to removal credit authority for a pollutant. The POTW must manage all of the sewage sludge in compliance with the use or disposal practice covered by part 503; removal credits may not be authorized before the part 503 requirements are met. To be eligible for removal credit authority, the POTW must comply, with the substantive use or disposal practice requirements and any requirement related to sewage sludge use or disposal for each pollutant for which it seeks removal credit authority. POTWs that dispose of sewage sludge in a municipal solid waste landfill that complies with the criteria in 40 CFR part 258 also may obtain removal credit authority for any categorical pretreatment standard pollutant in the sewage sludge placed in the MSWLF.

To obtain removal credit authority, a POTW must apply to EPA or to a State that has been approved to administer the Pretreatment Program. The application for removal credit authority must demonstrate that the POTW is in compliance with the removal credit regulations in 40 CFR 403.7. Only POTWs may submit the application; industrial facilities cannot apply, although they may assist the POTW in preparing an application. A POTW must have an approved pretreatment program at the time removal credit authority is granted and may extend all or part of any authorized removal credit to an industrial user.

In addition to establishing compliance with the conditions applicable to the use or disposal of sewage sludge, the POTW's removal credit application must provide data on the percentage of each pollutant removed from the wastewater consistently by the POTW. Removal credits cannot be granted if they cause the POTW to violate its NPDES permit. If the POTW is subject to combined sewer overflows, the application must establish that the POTW is taking certain actions to eliminate the combined sewer overflows. Each of these requirements is described more fully in 40 CFR 403.7.

Complete applications are reviewed by EPA or a State that has been approved to administer the Pretreatment Program. When the application is submitted to an Approved State, EPA Regions have the right to review and object to a State's approval of a submission, unless the right has been waived in the Region's Memorandum of Agreement with the State. After a period of review and public comment, removal credit authority may be granted to any POTW that complies with the procedural and substantive requirements of the removal credits regulations. Following approval, POTWs must continue to sample monthly to demonstrate continued removal of the pollutant. The POTW's demonstrated consistent pollutant removal becomes an enforceable part of its NPDES permit. Authority to grant a removal credit can be modified or withdrawn if a POTW fails to continue to achieve consistent removal, fails to comply with part 503 requirements, or no longer satisfies any other requirement of 40 CFR 403.7.

List of Subjects

40 CFR Part 257

Facilities and practices, Sewage sludge, Sludge, and Solid waste.

40 CFR Part 403

Incineration, Land application, Pollutants, Removal credits, Sewage sludge, and Surface disposal.

40 CFR Part 503

Frequency of monitoring, Incineration, Incorporation by reference, Land application, Management practices, Pathogens, Pollutants, Reporting and recordkeeping requirements, Sewage sludge, Surface disposal, and Vector attraction.

Dated: November 25, 1992.

F. Henry Habicht II,

Acting Administrator.

For reasons set out in the preamble, title 40 of the Code of Federal Regulations is amended as set forth below:

PART 257—CRITERIA FOR CLASSIFICATION OF SOLID WASTE DISPOSAL FACILITIES AND PRACTICES

1. The authority citation for 40 CFR part 257 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6944(a) and 6949(c), 33 U.S.C. 1345 (d) and (e).

2. Section 257.1 is amended by revising paragraphs (b) and (c)(3) to read as follows and by adding a new paragraph (c)(11) to read as follows:

§ 257.1 Scope and purpose.

* * * * *

(b) These criteria also provide guidelines for the disposal of sewage sludge on the land when the sewage sludge is not used or disposed through a practice regulated in 40 CFR part 503.

(c) * * *

(3) The criteria do not apply to the land application of domestic sewage or treated domestic sewage.

* * * * *

(11) The criteria do not apply to the use or disposal sewage sludge on the land when the sewage sludge is used or disposed in accordance with 40 CFR part 503.

3. Section 257.2 is amended by adding definitions in alphabetical order for "domestic septage" and "sewage sludge" to read as follows:

§ 257.2 Definitions.

* * * * *

Domestic septage is either liquid or solid material removed from a septic tank, cesspool, portable toilet, Type III marine sanitation device, or similar

treatment works that receives only domestic sewage. Domestic septage does not include liquid or solid material removed from a septic tank, cesspool, or similar treatment works that receives either commercial wastewater or industrial wastewater and does not include grease removed from a grease trap at a restaurant.

* * * * *

Sewage sludge means solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

* * * * *

4. Section 257.3–4 is amended by revising paragraph (b)(1) introductory text to read as follows:

§ 257.3–4 Ground water.

* * * * *

(b)(1) For purposes of section 1008(a)(3) of the Act or section 405(d) of the CWA, a party charged with open dumping or a violation of section 405(e) with respect to sewage sludge that is not used or disposed through a practice regulated in 40 CFR part 503 may demonstrate that compliance should be determined at an alternative boundary in lieu of the solid waste boundary. The court shall establish an alternative boundary only if it finds that such a change would not result in contamination of ground water which may be needed or used for human consumption. This finding shall be based on analysis and consideration of all of the following factors that are relevant:

* * * * *

PART 403—GENERAL PRETREATMENT REGULATIONS FOR EXISTING AND NEW SOURCES OF POLLUTION

1. The authority citation for 40 CFR part 403 continues to read as follows:

Authority: Sec. 54(c)(2) of the Clean Water Act of 1977, (Pub. L. 95–217) sections 204(b)(1)(C), 208(b)(2)(C)(iii), 301(b)(1)(A)(ii), 301(b)(2)(A)(ii), 301(b)(2)(C), 301(h)(5), 301(i)(2), 304(e), 304(g), 307, 308, 309, 402(b), 405 and 501(a) of the Federal Water Pollution Control Act (Pub. L. 92–500) as amended by the Clean Water Act of 1977 and the Water Quality Act of 1987 (Pub. L. 100–4).

2. Section 403.7 is amended by adding a sentence to the end of paragraph (a)(3)(iv) and by adding paragraphs (a)(3)(iv) (A) through (C) to read as follows:

§ 403.7 Removal credits.

(a) * * *

(3) * * *

(iv) * * * Removal credits may be made available for the following pollutants.

(A) For any pollutant listed in appendix G section I of this part for the use or disposal practice employed by the POTW, when the requirements in 40 CFR part 503 for that practice are met.

(B) For any pollutant listed in appendix G section II of this part for the use or disposal practice employed by the POTW when the concentration for a pollutant listed in appendix G section II of this part in the sewage sludge that is used or disposed does not exceed the concentration for the pollutant in appendix G section II of this part.

(C) For any pollutant in sewage sludge when the POTW disposes all of its sewage sludge in a municipal solid waste landfill unit that meets the criteria in 40 CFR part 258.

* * * * *

3. 40 CFR part 403 is amended by adding appendix G to read as follows:

Appendix G to Part 403—Pollutants Eligible for a Removal Credit

I. Regulated Pollutants in Part 503 Eligible for a Removal Credit

Pollutants	Use or disposal practice		
	LA	SD	I
Arsenic	X	X	X.
Beryllium	.....	.....	X.
Cadmium	X	.....	X.
Chromium	X	X	X.
Copper	X	.....	
Lead	X	.....	X.
Mercury	X	.....	X.
Molybdenum	X	.....	
Nickel	X	X	X.
Selenium	X	.....	
Zinc	X	.....	
Total hydrocarbons	.....	.....	X(1).

Key: LA—land application, SD—surface disposal site without a liner and leachate collection system, I—firing of sewage sludge in a sewage sludge incinerator.

(1) The following organic pollutants are eligible for a removal credit if the requirements for total hydrocarbons in subpart E in 40 CFR part 503 are met when sewage sludge is fired in a sewage sludge incinerator: Acrylonitrile, Aldrin/Dieldrin (total), Benzene, Benzidine, Benzo(a)pyrene, Bis(2-chloroethyl)ether, Bis(2-ethylhexyl)phthalate, Bromodichloromethane, Bromoethane, Bromoform, Carbon tetrachloride, Chlordane, Chloroform, Chloromethane, DDD,DDE,DDT, Dibromochloromethane, Dibutyl phthalate, 1,2-dichloroethane, 1,1-dichloroethylene, 2,4-dichlorophenol 1,3-dichloropropene, Diethyl phthalate, 2,4-dinitrophenol, 1,2-diphenylhydrazine, Di-n-butyl phthalate, Endosulfan, Endrin, Ethylbenzene, Heptachlor, Heptachlor epoxide, Hexachlorobutadiene, Alpha-hexachlorocyclohexane, Betahexachlorocyclohexane, Hexachlorocyclopentadiene, Hexachloroethane, Hydrogen cyanide, Isophorone, Lindane, Methylene chloride, Nitrobenzene, N-Nitrosodimethylamine, N-Nitrosodi-n-propylamine, Pentachlorophenol, Phenol, Polychlorinated biphenyls, 2,3,7,8-tetrachlorodibenzo-p-dioxin, 1,1,2,2,-tetrachloroethane, Tetrachloroethylene, Toluene, Toxaphene, Trichloroethylene, 1,2,4-Trichlorobenzene, 1,1,1-Trichloroethane, 1,1,2-Trichloroethane, and 2,4,6-Trichlorophenol.

II. Additional Pollutants Eligible for a Removal Credit (milligrams per kilogram—dry weight basis)

Pollutant	Use or disposal practice			
	LA	(SD)		I
		Unlined [1]	Lined [2]	
Arsenic	.....	.....	[3] 100	.....
Aldrin/Dieldrin (Total)	2.7	.....	.....	.....
Benzene	[3] 16	140	3400	.....
Benzo(a)pyrene	15	[3] 100	[3] 100	.....
Bis(2-ethylhexyl)phthtlate	.....	[3] 100	100	.....
Cadmium	.....	[3] 100	[3] 100	.....
Chlordane	66	[3] 100	[3] 100	.....

Pollutant	Use or disposal practice			
	LA	(SD)		I
		Unlined [1]	Lined [2]	
Chromium	.....	.....	[3]100	.....
Copper	.....	[3]46	[3]100	1400
DDD, DDE, DDT (Total)	1.2	2000	2000	.....
2,4 Dichlorophenoxy-acetic acid	.....	7	7	.....
Fluoride	730	.....	.....	.....
Heptachlor	7.4	.....	.....	.....
Hexachlorobenzene	29	.....	.....	.....
Hexachlorobutadiene	600	.....	.....	.....
Iron	[3]78	.....	.....	.....
Lead	.....	[3]100	[3]100	.....
Lindane	84	[3]28	[3]28	.....
Malathion	.....	0.63	0.63	.....
Mercury	.....	[3]100	[3]100	.....
Molybdenum	.....	40	40	.....
Nickel	.....	.....	[3]100	.....
N-Nitrosodimethylamine	2.1	0.088	0.088	.....
Pentachlorophenol	30	.....	.....	.....
Phenol	.....	82	82	.....
Polychlorinated biphenyls	4.6	<50	<50	.....
Selenium	.....	4.8	4.8	4.8
Toxaphene	10	[3]26	[3]26	.....
Trichloroethylene	[3]10	9500	[3]10	.....
Zinc	.....	4500	4500	4500

Key: LA—land application, SD—surface disposal, I—incineration.
[1] Sewage sludge unit without a liner and leachate collection system.
[2] Sewage sludge unit with a liner and leachate collection system.
[3] Value expressed in grams per kilogram—dry weight basis.

Subchapter O in chapter I of title 40 of the Code of Federal Regulations is amended by adding part 503, which reads as follows:

SUBCHAPTER O—SEWAGE SLUDGE

PART 503—STANDARDS FOR THE USE OR DISPOSAL OF SEWAGE SLUDGE

Subpart A—General Provisions

Sec.

Subpart B—Land Application

Subpart C—Surface Disposal

Subpart D—Pathogens and Vector Attraction Reduction

Subpart E—Incineration

Appendix A to Part 503—Procedure to Determine the Annual Whole Sludge Application Rate for a Sewage Sludge

Appendix B to Part 503—Pathogen Treatment Processes

Authority: Sections 405 (d) and (e) of the Clean Water Act, as amended by Pub. L. 95–217, Sec. 54(d), 91 Stat. 1591 (33 U.S.C. 1345 (d) and (e)); and Pub. L. 100–4, Title IV, Sec. 406 (a), (b), 101 Stat., 71, 72 (33 U.S.C. 1251 *et seq.*).

Subpart A—General Provisions

§ 503.1 Purpose and applicability.

(a) *Purpose.* (1) This part establishes standards, which consist of general requirements, pollutant limits, management practices, and operational standards, for the final use or disposal of sewage sludge generated during the treatment of domestic sewage in a treatment works. Standards are included in this part for sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. Also included in this part are pathogen and alternative vector attraction reduction requirements for sewage sludge applied to the land or placed on a surface disposal site.

(2) In addition, the standards in this part include the frequency of monitoring and recordkeeping requirements when sewage sludge is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. Also included in this part are reporting requirements for Class I sludge management facilities, publicly owned treatment works (POTWs) with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more.

(b) *Applicability.* (1) This part applies to any person who prepares sewage sludge, applies sewage sludge to the land, or fires sewage sludge in a sewage sludge incinerator and to the owner/operator of a surface disposal site.

(2) This part applies to sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator.

(3) This part applies to the exit gas from a sewage sludge incinerator stack.

(4) This part applies to land where sewage sludge is applied, to a surface disposal site, and to a sewage sludge incinerator.

§ 503.2 Compliance period.

(a) Compliance with the standards in this part shall be achieved as expeditiously as practicable, but in no case later than February 19, 1994. When compliance with the standards requires construction of new pollution control facilities, compliance with the standards shall be achieved as expeditiously as practicable, but in no case later than February 19, 1995.

(b) The requirements for frequency of monitoring, recordkeeping, and reporting in this part for total hydrocarbons in the exit gas from a sewage sludge incinerator are effective February 19, 1994 or, if compliance with the operational standard for total hydrocarbons in this part requires the construction of new pollution control facilities, February 19, 1995.

(c) All other requirements for frequency of monitoring, recordkeeping, and reporting in this part are effective on July 20, 1993.

§ 503.3 Permits and direct enforceability.

(a) Permits. The requirements in this part may be implemented through a permit:

(1) Issued to a "treatment works treating domestic sewage", as defined in 40 CFR 122.2, in accordance with 40 CFR parts 122 and 124 by EPA or by a State that has a State sludge management program approved by EPA in accordance with 40 CFR part 123 or 40 CFR part 501 or

(2) Issued under subtitle C of the Solid Waste Disposal Act; part C of the Safe Drinking Water Act; the Marine Protection, Research, and Sanctuaries Act of 1972; or the Clean Air Act. "Treatment works treating domestic sewage" shall submit a permit application in accordance with either 40 CFR 122.21 or an approved State program.

(b) Direct enforceability. No person shall use or dispose of sewage sludge through any practice for which requirements are established in this part except in accordance with such requirements.

§ 503.4 Relationship to other regulations.

Disposal of sewage sludge in a municipal solid waste landfill unit, as defined in 40 CFR 258.2, that complies with the requirements in 40 CFR part 258 constitutes compliance with section 405(d) of the CWA. Any person who prepares sewage sludge that is disposed in a municipal solid waste landfill unit shall ensure that the sewage sludge meets the requirements in 40 CFR part 258 concerning the quality of materials disposed in a municipal solid waste landfill unit.

§ 503.5 Additional or more stringent requirements.

(a) On a case-by-case basis, the permitting authority may impose requirements for the use or disposal of sewage sludge in addition to or more stringent than the requirements in this part when necessary to protect public health and the environment from any adverse effect of a pollutant in the sewage sludge.

(b) Nothing in this part precludes a State or political subdivision thereof or interstate agency from imposing requirements for the use or disposal of sewage sludge more stringent than the requirements in this part or from imposing additional requirements for the use or disposal of sewage sludge.

§ 503.6 Exclusions.

(a) *Treatment processes.* This part does not establish requirements for processes used to treat domestic sewage or for processes used to treat sewage sludge prior to final use or disposal, except as provided in § 503.32 and § 503.33.

(b) *Selection of a use or disposal practice.* This part does not require the selection of a sewage sludge use or disposal practice. The determination of the manner in which sewage sludge is used or disposed is a local determination.

(c) *Co-firing of sewage sludge.* This part does not establish requirements for sewage sludge co-fired in an incinerator with other wastes or for the incinerator in which sewage sludge and other wastes are co-fired. Other wastes do not include auxiliary fuel, as defined in 40 CFR 503.41(b), fired in a sewage sludge incinerator.

(d) *Sludge generated at an industrial facility.* This part does not establish requirements for the use or disposal of sludge generated at an industrial facility during the treatment of industrial wastewater, including sewage sludge generated during the treatment of industrial wastewater combined with domestic sewage.

(e) *Hazardous sewage sludge.* This part does not establish requirements for the use or disposal of sewage sludge determined to be hazardous in accordance with 40 CFR part 261.

(f) *Sewage sludge with high PCB concentration.* This part does not establish requirements for the use or disposal of sewage sludge with a concentration of polychlorinated biphenyls (PCBs) equal to or greater than 50 milligrams per kilogram of total solids (dry weight basis).

(g) *Incinerator ash.* This part does not establish requirements for the use or disposal of ash generated during the firing of sewage sludge in a sewage sludge incinerator.

(h) *Grit and screenings.* This part does not establish requirements for the use or disposal of grit (e.g., sand, gravel, cinders, or other materials with a high specific gravity) or screenings (e.g., relatively large materials such as rags) generated during preliminary treatment of domestic sewage in a treatment works.

(i) *Drinking water treatment sludge.* This part does not establish requirements for the use or disposal of sludge generated during the treatment of either surface water or ground water used for drinking water.

(j) *Commercial and industrial septage.* This part does not establish requirements for the use or disposal of commercial septage, industrial septage, a mixture of domestic septage and commercial septage, or a mixture of domestic septage and industrial septage.

§ 503.7 Requirement for a person who prepares sewage sludge.

Any person who prepares sewage sludge shall ensure that the applicable requirements in this part are met when the sewage sludge is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator.

§ 503.8 Sampling and analysis.

(a) *Sampling.* Representative samples of sewage sludge that is applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator shall be collected and analyzed.

(b) *Methods.* The materials listed below are incorporated by reference in this part. These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The materials are incorporated as they exist on the date of approval, and notice of any change in these materials will be published in the **Federal Register**. They are available for inspection at the Office of the Federal Register, 7th Floor, suite 700, 800 North Capitol Street, NW., Washington, DC, and at the Office of Water Docket, room L-102, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC. Copies may be obtained from the standard producer or publisher listed in the regulation. Methods in the materials listed below shall be used to analyze samples of sewage sludge.

(1) *Enteric viruses.* ASTM Designation: D 4994–89, "Standard Practice for Recovery of Viruses From Wastewater Sludges", 1992 Annual Book of ASTM Standards: Section 11—Water and Environmental Technology, ASTM, 1916 Race Street, Philadelphia, PA 19103–1187.

(2) *Fecal coliform.* Part 9221 E. or Part 9222 D., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW., Washington, DC 20005.

(3) *Helminth ova.* Yanko, W.A., "Occurrence of Pathogens in Distribution and Marketing Municipal Sludges", EPA 600/1–87–014, 1987. National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (PB 88–154273/AS).

(4) *Inorganic pollutants.* "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods", EPA Publication SW–846, Second Edition (1982) with Updates I (April 1984) and II (April 1985) and Third Edition (November 1986) with Revision I (December 1987). Second Edition and Updates I and II are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161 (PB–87–120–291). Third Edition and Revision I are available from Superintendent of Documents, Government Printing Office, 941 North Capitol Street, NE., Washington, DC 20002 (Document Number 955–001–00000–1).

(5) *Salmonella sp. bacteria.* Part 9260 D., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW., Washington, DC 20005; or

Kenner, B.A. and H.P. Clark, "Detection and enumeration of *Salmonella* and *Pseudomonas aeruginosa*", Journal of the Water Pollution Control Federation, Vol. 46, no. 9, September 1974, pp. 2163–2171. Water Environment Federation, 601 Wythe Street, Alexandria, Virginia 22314.

(6) *Specific oxygen uptake rate.* Part 2710 B., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW., Washington, DC 20005.

(7) *Total, fixed, and volatile solids.* Part 2540 G., "Standard Methods for the Examination of Water and Wastewater", 18th Edition, 1992, American Public Health Association, 1015 15th Street, NW., Washington, DC 20005.

§ 503.9 General definitions.

(a) *Apply sewage sludge or sewage sludge applied to the land* means land application of sewage sludge.

(b) *Base flood* is a flood that has a one percent chance of occurring in any given year (i.e., a flood with a magnitude equalled once in 100 years).

(c) *Class I sludge management facility* is any publicly owned treatment works (POTW), as defined in 40 CFR 501.2, required to have an approved pretreatment program under 40 CFR 403.8(a) (including any POTW located in a State that has elected to assume local program responsibilities pursuant to 40 CFR 403.10(e)) and any treatment works treating domestic sewage, as defined in 40 CFR 122.2, classified as a Class I sludge management facility by the EPA Regional Administrator, or, in the case of approved State programs, the Regional Administrator in conjunction with the State Director, because of the potential for its sewage sludge use or disposal practice to affect public health and the environment adversely.

(d) *Cover crop* is a small grain crop, such as oats, wheat, or barley, not grown for harvest.

(e) *CWA* means the Clean Water Act (formerly referred to as either the Federal Water Pollution Act or the Federal Water Pollution Control Act Amendments of 1972), Public Law 92–500, as amended by Public Law 95–217, Public Law 95–576, Public Law 96–483, Public Law 97–117, and Public Law 100–4.

(f) *Domestic septage* is either liquid or solid material removed from a septic tank, cesspool, portable toilet, Type III marine sanitation device, or similar treatment works that receives only domestic sewage. Domestic septage does not include liquid or solid material removed from a septic tank, cesspool, or similar treatment works that receives either commercial wastewater or industrial wastewater and does not include grease removed from a grease trap at a restaurant.

(g) *Domestic sewage* is waste and wastewater from humans or household operations that is discharged to or otherwise enters a treatment works.

(h) *Dry weight basis* means calculated on the basis of having been dried at 105 degrees Celsius until reaching a constant mass (i.e., essentially 100 percent solids content).

(i) *EPA* means the United States Environmental Protection Agency.

(j) *Feed crops* are crops produced primarily for consumption by animals.

(k) *Fiber crops* are crops such as flax and cotton.

(l) *Food crops* are crops consumed by humans. These include, but are not limited to, fruits, vegetables, and tobacco.

(m) *Ground water* is water below the land surface in the saturated zone.

(n) *Industrial wastewater* is wastewater generated in a commercial or industrial process.

(o) *Municipality* means a city, town, borough, county, parish, district, association, or other public body (including an intermunicipal Agency of two or more of the foregoing entities) created by or under State law; an Indian tribe or an authorized Indian tribal organization having jurisdiction over sewage sludge management; or a designated and approved management Agency under section 208 of the CWA, as amended. The definition includes a special district created under State law, such as a water district, sewer district, sanitary district, utility district, drainage district, or similar entity, or an integrated waste management facility as defined in section 201(e) of the CWA, as amended, that has as one of its principal responsibilities the treatment, transport, use, or disposal of sewage sludge.

(p) *Permitting authority* is either EPA or a State with an EPA-approved sludge management program.

(q) *Person* is an individual, association, partnership, corporation, municipality, State or Federal agency, or an agent or employee thereof.

(r) *Person who prepares sewage sludge* is either the person who generates sewage sludge during the treatment of domestic sewage in a treatment works or the person who derives a material from sewage sludge.

(s) *Place sewage sludge or sewage sludge placed* means disposal of sewage sludge on a surface disposal site.

(t) *Pollutant* is an organic substance, an inorganic substance, a combination of organic and inorganic substances, or a pathogenic organism that, after discharge and upon exposure, ingestion, inhalation, or assimilation into an organism either directly from the environment or indirectly by ingestion through the food chain, could, on the basis of information available to the Administrator of EPA, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunction in reproduction), or physical deformations in either organisms or offspring of the organisms.

(u) *Pollutant limit* is a numerical value that describes the amount of a pollutant allowed per unit amount of sewage sludge (e.g., milligrams per kilogram of total solids); the amount of a pollutant that can be applied to a unit area of land (e.g., kilograms per hectare); or the volume of a material that can be

applied to a unit area of land (e.g., gallons per acre).

(v) *Runoff* is rainwater, leachate, or other liquid that drains overland on any part of a land surface and runs off of the land surface.

(w) *Sewage sludge* is solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to, domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

(x) *State* is one of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Commonwealth of the Northern Mariana Islands, and an Indian Tribe eligible for treatment as a State pursuant to regulations promulgated under the authority of section 518(e) of the CWA.

(y) *Store or storage of sewage sludge* is the placement of sewage sludge on land on which the sewage sludge remains for two years or less. This does not include the placement of sewage sludge on land for treatment.

(z) *Treat or treatment of sewage sludge* is the preparation of sewage sludge for final use or disposal. This includes, but is not limited to, thickening, stabilization, and dewatering of sewage sludge. This does not include storage of sewage sludge.

(aa) *Treatment works* is either a federally owned, publicly owned, or privately owned device or system used to treat (including recycle and reclaim) either domestic sewage or a combination of domestic sewage and industrial waste of a liquid nature.

(bb) *Wetlands* means those areas that are inundated or saturated by surface water or ground water at a frequency and duration to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.

Subpart B—Land Application

§ 503.10 Applicability.

(a) This subpart applies to any person who prepares sewage sludge that is applied to the land, to any person who applies sewage sludge to the land, to sewage sludge applied to the land, and to the land on which sewage sludge is applied.

(b)(1) *Bulk sewage sludge.* The general requirements in § 503.12 and the management practices in § 503.14 do not apply when bulk sewage sludge is applied to the land if the bulk sewage sludge meets the pollutant concentrations in § 503.13(b)(3), the Class A pathogen requirements in § 503.32(a), and one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8).

(2) The Regional Administrator of EPA or, in the case of a State with an approved sludge management program, the State Director, may apply any or all of the general requirements in § 503.12 and the management practices in § 503.14 to the bulk sewage sludge in § 503.10(b)(1) on a case-by-case basis after determining that the general requirements or management practices are needed to protect public health and the environment from any reasonably anticipated adverse effect that may occur from any pollutant in the bulk sewage sludge.

(c)(1) The general requirements in § 503.12 and the management practices in § 503.14 do not apply when a bulk material derived from sewage sludge is applied to the land if the derived bulk material meets the pollutant concentrations in § 503.13(b)(3), the Class A pathogen requirements in § 503.32(a), and one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8).

(2) The Regional Administrator of EPA or, in the case of a State with an approved sludge management program, the State Director, may apply any or all of the general requirements in § 503.12 or the management practices in § 503.14 to the bulk material in § 503.10(c)(1) on a case-by-case basis after determining that the general requirements or management practices are needed to protect public health and the environment from any reasonably anticipated adverse effect that may occur from any pollutant in the bulk sewage sludge.

(d) The requirements in this subpart do not apply when a bulk material derived from sewage sludge is applied to the land if the sewage sludge from which the bulk material is derived meets the pollutant concentrations in § 503.13(b)(3), the Class A pathogen requirements in § 503.32(a), and one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8).

(e) *Sewage sludge sold or given away in a bag or other container for application to the land.* The general requirements in § 503.12 and the management practices in § 503.14 do not apply when sewage sludge is sold or given away in a bag or other container for application to the land if the sewage sludge sold or given away in a bag or other container for application to the land meets the pollutant concentrations in § 503.13(b)(3), the Class A pathogen requirements in § 503.32(a), and one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8).

(f) The general requirements in § 503.12 and the management practices in § 503.14 do not apply when a material derived from sewage sludge is sold or given away in a bag or other container for application to the land if the derived material meets the pollutant concentrations in § 503.13(b)(3), the Class A pathogen requirements in § 503.32(a), and one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8).

(g) The requirements in this subpart do not apply when a material derived from sewage sludge is sold or given away in a bag or other container for application to the land if the sewage sludge from which the material is derived meets the pollutant concentrations in § 503.13(b)(3), the Class A pathogen requirements in § 503.32(a), and one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8).

§ 503.11 Special definitions.

(a) *Agricultural land* is land on which a food crop, a feed crop, or a fiber crop is grown. This includes range land and land used as pasture.

(b) *Agronomic rate* is the whole sludge application rate (dry weight basis) designed:

(1) To provide the amount of nitrogen needed by the food crop, feed crop, fiber crop, cover crop, or vegetation grown on the land; and

(2) To minimize the amount of nitrogen in the sewage sludge that passes below the root zone of the crop or vegetation grown on the land to the ground water.

(c) *Annual pollutant loading rate* is the maximum amount of a pollutant that can be applied to a unit area of land during a 365 day period.

(d) *Annual whole sludge application rate* is the maximum amount of sewage sludge (dry weight basis) that can be applied to a unit area of land during a 365 day period.

(e) *Bulk sewage sludge* is sewage sludge that is not sold or given away in a bag or other container for application to the land.

(f) *Cumulative pollutant loading rate* is the maximum amount of an inorganic pollutant that can be applied to an area of land.

(g) *Forest* is a tract of land thick with trees and underbrush.

(h) *Land application* is the spraying or spreading of sewage sludge onto the land surface; the injection of sewage sludge below the land surface; or the incorporation of sewage sludge into the soil so that the sewage sludge can either condition the soil or fertilize crops or vegetation grown in the soil.

(i) *Monthly average* is the arithmetic mean of all measurements taken during the month.

(j) *Other container* is either an open or closed receptacle. This includes, but is not limited to, a bucket, a box, a carton, and a vehicle or trailer with a load capacity of one metric ton or less.

(k) *Pasture* is land on which animals feed directly on feed crops such as legumes, grasses, grain stubble, or stover.

(l) *Public contact site* is land with a high potential for contact by the public. This includes, but is not limited to, public parks, ball fields, cemeteries, plant nurseries, turf farms, and golf courses.

(m) *Range land* is open land with indigenous vegetation.

(n) *Reclamation site* is drastically disturbed land that is reclaimed using sewage sludge. This includes, but is not limited to, strip mines and construction sites.

§ 503.12 General requirements.

(a) No person shall apply sewage sludge to the land except in accordance with the requirements in this subpart.

(b) No person shall apply bulk sewage sludge subject to the cumulative pollutant loading rates in § 503.13(b)(2) to agricultural land, forest, a public contact site, or a reclamation site if any of the cumulative pollutant loading rates in § 503.13(b)(2) has been reached.

(c) No person shall apply domestic septage to agricultural land, forest, or a reclamation site during a 365 day period if the annual application rate in § 503.13(c) has been reached during that period.

(d) The person who prepares bulk sewage sludge that is applied to agricultural land, forest, a public contact site, or a reclamation site shall provide the person who applies the bulk sewage sludge written notification of the concentration of total nitrogen (as N on a dry weight basis) in the bulk sewage sludge.

(e)(1) The person who applies sewage sludge to the land shall obtain information needed to comply with the requirements in this subpart.

(2)(i) Before bulk sewage sludge subject to the cumulative pollutant loading rates in § 503.13(b)(2) is applied to the land, the person who proposes to apply the bulk sewage sludge shall contact the permitting authority for the State in which the bulk sewage sludge will be applied to determine whether bulk sewage sludge subject to the cumulative pollutant loading rates in § 503.13(b)(2) has been applied to the site since July 20, 1993.

(ii) If bulk sewage sludge subject to the cumulative pollutant loading rates in § 503.13(b)(2) has not been applied to the site since July 20, 1993, the cumulative amount for each pollutant listed in Table 2 of § 503.13 may be applied to the site in accordance with § 503.13(a)(2)(i).

(iii) If bulk sewage sludge subject to the cumulative pollutant loading rates in § 503.13(b)(2) has been applied to the site since July 20, 1993, and the cumulative amount of each pollutant applied to the site in the bulk sewage sludge since that date is known, the cumulative amount of each pollutant applied to the site shall be used to determine the additional amount of each pollutant that can be applied to the site in accordance with § 503.13(a)(2)(i).

(iv) If bulk sewage sludge subject to the cumulative pollutant loading rates in § 503.13(b)(2) has been applied to the site since July 20, 1993, and the cumulative amount of each pollutant applied to the site in the bulk sewage sludge since that date is not known, an additional amount of each pollutant shall not be applied to the site in accordance with § 503.13(a)(2)(i).

(f) When a person who prepares bulk sewage sludge provides the bulk sewage sludge to a person who applies the bulk sewage sludge to the land, the person who prepares the bulk sewage sludge shall provide the person who applies the sewage sludge notice and necessary information to comply with the requirements in this subpart.

(g) When a person who prepares sewage sludge provides the sewage sludge to another person who prepares the sewage sludge, the person who provides the sewage sludge shall provide the person who receives the sewage sludge notice and necessary information to comply with the requirements in this subpart.

(h) The person who applies bulk sewage sludge to the land shall provide the owner or lease holder of the land on which the bulk sewage sludge is applied notice and necessary information to comply with the requirements in this subpart.

(i) Any person who prepares bulk sewage sludge that is applied to land in a State other than the State in which the bulk sewage sludge is prepared shall provide written notice, prior to the initial application of bulk sewage sludge to the land application site by the applier, to the permitting authority for the State in which the bulk sewage sludge is proposed to be applied. The notice shall include:

(1) The location, by either street address or latitude and longitude, of each land application site.

(2) The approximate time period bulk sewage sludge will be applied to the site.

(3) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) for the person who prepares the bulk sewage sludge.

(4) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) for the person who will apply the bulk sewage sludge.

(j) Any person who applies bulk sewage sludge subject to the cumulative pollutant loading rates in § 503.13(b)(2) to the land shall provide written notice, prior to the initial application of bulk sewage sludge to a land application site by the applier, to the permitting authority for the State in which the bulk sewage sludge will be applied and the permitting authority shall retain and provide access to the notice. The notice shall include:

(1) The location, by either street address or latitude and longitude, of the land application site.

(2) The name, address, telephone number, and National Pollutant Discharge Elimination System permit number (if appropriate) of the person who will apply the bulk sewage sludge.

§ 503.13 Pollutant limits.

(a) Sewage sludge. (1) Bulk sewage sludge or sewage sludge sold or given away in a bag or other container shall not be applied to the land if the concentration of any pollutant in the sewage sludge exceeds the ceiling concentration for the pollutant in Table 1 of § 503.13.

(2) If bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site, either:

(i) The cumulative loading rate for each pollutant shall not exceed the cumulative pollutant loading rate for the pollutant in Table 2 of § 503.13; or

(ii) The concentration of each pollutant in the sewage sludge shall not exceed the concentration for the pollutant in Table 3 of § 503.13.

(3) If bulk sewage sludge is applied to a lawn or a home garden, the concentration of each pollutant in the

sewage sludge shall not exceed the concentration for the pollutant in Table 3 of § 503.13.

(4) If sewage sludge is sold or given away in a bag or other container for application to the land, either:

(i) The concentration of each pollutant in the sewage sludge shall not exceed the concentration for the pollutant in Table 3 of § 503.13; or

(ii) The product of the concentration of each pollutant in the sewage sludge and the annual whole sludge application rate for the sewage sludge shall not cause the annual pollutant loading rate for the pollutant in Table 4 of § 503.13 to be exceeded. The procedure used to determine the annual whole sludge application rate is presented in appendix A of this part.

(b) Pollutant concentrations and loading rates—sewage sludge.

(1) Ceiling concentrations.

TABLE 1 OF § 503.13.—CEILING CONCENTRATIONS

Pollutant	Ceiling concentration (milligrams per kilogram)[1]
Arsenic	75
Cadmium	85
Chromium	3000
Copper	4300
Lead	840
Mercury	57
Molybdenum	75
Nickel	420
Selenium	100
Zinc	7500

[1] Dry weight basis.

(2) Cumulative pollutant loading rates.

TABLE 2 OF § 503.13.—CUMULATIVE POLLUTANT LOADING RATES

Pollutant	Cumulative pollutant loading rate (kilograms per hectare)
Arsenic	41
Cadmium	39
Chromium	3000
Copper	1500
Lead	300
Mercury	17
Molybdenum	18
Nickel	420
Selenium	100
Zinc	2800

(3) Pollutant concentrations.

TABLE 3 OF § 503.13.—POLLUTANT CONCENTRATIONS

Pollutant	Monthly average concentrations (milligrams per kilogram)[1]
Arsenic	41
Cadmium	39
Chromium	1200
Copper	1500
Lead	300
Mercury	17
Molybdenum	18
Nickel	420
Selenium	36
Zinc	2800

[1] Dry weight basis.

(4) Annual pollutant loading rates.

TABLE 4 OF § 503.13.—ANNUAL POLLUTANT LOADING RATES

Pollutant	Annual pollutant loading rate (kilograms per hectare per 365 day period)
Arsenic	2.0
Cadmium	1.9
Chromium	150
Copper	75
Lead	15
Mercury	0.85
Molybdenum	0.90
Nickel	21
Selenium	5.0
Zinc	140

(c) Domestic septage.

The annual application rate for domestic septage applied to agricultural land, forest, or a reclamation site shall not exceed the annual application rate calculated using equation (1).

$$AAR = \frac{N}{0.0026} \quad \text{Eq. (1)}$$

Where:

AAR=Annual application rate in gallons per acre per 365 day period.

N=Amount of nitrogen in pounds per acre per 365 day period needed by the crop or vegetation grown on the land.

§ 503.14 Management practices.

(a) Bulk sewage sludge shall not be applied to the land if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat.

(b) Bulk sewage sludge shall not be applied to agricultural land, forest, a public contact site, or a reclamation site that is flooded, frozen, or snow-covered so that the bulk sewage sludge enters a wetland or other waters of the United States, as defined in 40 CFR 122.2, except as provided in a permit issued pursuant to section 402 or 404 of the CWA.

(c) Bulk sewage sludge shall not be applied to agricultural land, forest, or a reclamation site that is 10 meters or less from waters of the United States, as defined in 40 CFR 122.2, unless otherwise specified by the permitting authority.

(d) Bulk sewage sludge shall be applied to agricultural land, forest, a public contact site, or a reclamation site at a whole sludge application rate that is equal to or less than the agronomic rate for the bulk sewage sludge, unless, in the case of a reclamation site, otherwise specified by the permitting authority.

(e) Either a label shall be affixed to the bag or other container in which sewage sludge that is sold or given away for application to the land, or an information sheet shall be provided to the person who receives sewage sludge sold or given away in an other container for application to the land. The label or information sheet shall contain the following information:

(1) The name and address of the person who prepared the sewage sludge that is sold or given away in a bag or other container for application to the land.

(2) A statement that application of the sewage sludge to the land is prohibited except in accordance with the instructions on the label or information sheet.

(3) The annual whole sludge application rate for the sewage sludge that does not cause any of the annual pollutant loading rates in Table 4 of § 503.13 to be exceeded.

§ 503.15 Operational standards—pathogens and vector attraction reduction.

(a) *Pathogens—sewage sludge.*

(1) The Class A pathogen requirements in § 503.32(a) or the Class B pathogen requirements and site restrictions in § 503.32(b) shall be met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

(2) The Class A pathogen requirements in § 503.32(a) shall be met when bulk sewage sludge is applied to a lawn or a home garden.

(3) The Class A pathogen requirements in § 503.32(a) shall be met when sewage sludge is sold or given away in a bag or other container for application to the land.

(b) *Pathogens—domestic septage.*

The requirements in either § 503.32 (c)(1) or (c)(2) shall be met when domestic septage is applied to agricultural land, forest, or a reclamation site.

(c) *Vector attraction reduction—sewage sludge.*

(1) One of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(10) shall be met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

(2) One of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) shall be met when bulk sewage sludge is applied to a lawn or a home garden.

(3) One of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) shall be met when sewage sludge is sold or given away in a bag or other container for application to the land.

(d) *Vector attraction reduction—domestic septage.* The vector attraction reduction requirements in § 503.33(b)(9), (b)(10), or (b)(12) shall be met when domestic septage is applied to agricultural land, forest, or a reclamation site.

§ 503.16 Frequency of monitoring.

(a) *Sewage sludge.* (1) The frequency of monitoring for the pollutants listed in Table 1, Table 2, Table 3 and Table 4 of § 503.13; the pathogen density requirements in § 503.32(a) and in § 503.32(b)(2) through (b)(4); and the vector attraction reduction requirements § 503.33 (b)(1) through § 503.33(b)(8) shall be the frequency in Table 1 of § 503.16.

TABLE. 1 OF § 503.16.—FREQUENCY OF MONITORING—LAND APPLICATION

Amount of sewage sludge[1] (metric tons per 365 day period)	Frequency
Greater than zero but less than 290.	Once per year.
Equal to or greater than 290 but less than 1,500.	Once per quarter (four times per year).
Equal to or greater than 1,500 but less than 15,000.	Once per 60 days (six times per year).
Equal to or greater than 15,000.	Once per month (12 times per year).

[1] Either the amount of bulk sewage sludge applied to the land or the amount of sewage sludge received by a person who prepares sewage sludge that is sold or given away in a bag or other container for application to the land (dry weight basis).

(2) After the sewage sludge has been monitored for two years at the frequency in Table 1 of § 503.16, the permitting authority may reduce the frequency of monitoring for pollutant concentrations and for the pathogen density requirements in § 503.32 (a)(5)(ii) and (a)(5)(iii), but in no case shall the frequency of monitoring be less than once per year when sewage sludge is applied to the land.

(b) *Domestic septage.* If either the pathogen requirements in § 503.32(c)(2) or the vector attraction reduction requirements in § 503.33(b)(12) are met when domestic septage is applied to agricultural land, forest, or a reclamation site, each container of domestic septage applied to the land shall be monitored for compliance with those requirements.

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§ 503.17 Recordkeeping.

(a) *Sewage sludge.* (1) The person who prepares the sewage sludge in § 503.10(b)(1) or (e) shall develop the following information and shall retain the information for five years:

(i) The concentration of each pollutant listed in Table 3 of § 503.13 in the sewage sludge.

(ii) The following certification statement:

"I certify, under penalty of law, that the Class A pathogen requirements in § 503.32(a) and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in § 503.33(b)(1) through § 503.33(b)(8)] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the pathogen requirements and vector attraction reduction requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(iii) A description of how the Class A pathogen requirements in § 503.32(a) are met.

(iv) A description of how one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) is met.

(2) The person who derives the material in § 503.10 (c)(1) or (f) shall develop the following information and shall retain the information for five years:

(i) The concentration of each pollutant listed in Table 3 of § 503.13 in the material.

(ii) The following certification statement:

"I certify, under penalty of law, that the Class A pathogen requirements in § 503.32(a) and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8)] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the pathogen requirements and the vector attraction reduction requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(iii) A description of how the Class A pathogen requirements in § 503.32(a) are met.

(iv) A description of how one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) is met.

(3) If the pollutant concentrations in § 503.13(b)(3), the Class A pathogen requirements in § 503.32(a), and the vector attraction reduction requirements in either § 503.33 (b)(9) or (b)(10) are met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:

(i) The person who prepares the bulk sewage sludge shall develop the following information and shall retain the information for five years.

(A) The concentration of each pollutant listed in Table 3 of § 503.13 in the bulk sewage sludge.

(B) The following certification statement:

"I certify, under penalty of law, that the pathogen requirements in § 503.32(a) have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the pathogen requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(C) A description of how the pathogen requirements in § 503.32(a) are met.

(ii) The person who applies the bulk sewage sludge shall develop the following information and shall retain the information for five years.

(A) The following certification statement:

"I certify, under penalty of law, that the management practices in § 503.14 and the vector attraction reduction requirement in [insert either § 503.33 (b)(9) or (b)(10)] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the management practices and vector attraction reduction requirements have been met. I am aware that there are significant penalties for false certification including fine and imprisonment."

(B) A description of how the management practices in § 503.14 are met for each site on which bulk sewage sludge is applied.

(C) A description of how the vector attraction reduction requirements in either § 503.33(b)(9) or (b)(10) are met for each site on which bulk sewage sludge is applied.

(4) If the pollutant concentrations in § 503.13(b)(3) and the Class B pathogen requirements in § 503.32(b) are met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:

(i) The person who prepares the bulk sewage sludge shall develop the following information and shall retain the information for five years:

(A) The concentration of each pollutant listed in Table 3 of § 503.13 in the bulk sewage sludge.

(B) The following certification statement:

"I certify under, penalty of law, that the Class B pathogen requirements in § 503.32(b) and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) if one of those requirements is met] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the pathogen requirements [and vector attraction reduction requirements if applicable] have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(C) A description of how the Class B pathogen requirements in § 503.32(b) are met.

(D) When one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) is met, a description of how the vector attraction reduction requirement is met.

(ii) The person who applies the bulk sewage sludge shall develop the following information and shall retain the information for five years.

(A) The following certification statement:

"I certify, under penalty of law, that the management practices in § 503.14, the site restrictions in § 503.32(b)(5), and the vector attraction reduction requirements in [insert either § 503.33 (b)(9) or (b)(10), if one of those requirements is met] have been met for each site on which bulk sewage sludge is applied. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the management practices and site restrictions [and the vector attraction reduction requirements if applicable] have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(B) A description of how the management practices in § 503.14 are met for each site on which bulk sewage sludge is applied.

(C) A description of how the site restrictions in § 503.32(b)(5) are met for each site on which bulk sewage sludge is applied.

(D) When the vector attraction reduction requirement in either § 503.33 (b)(9) or (b)(10) is met, a description of how the vector attraction reduction requirement is met.

(5) If the requirements in § 503.13(a)(2)(i) are met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site:

(i) The person who prepares the bulk sewage sludge shall develop the following information and shall retain the information for five years.

(A) The concentration of each pollutant listed in Table 1 of § 503.13 in the bulk sewage sludge.

(B) The following certification statement:

"I certify, under penalty of law, that the pathogen requirements in [insert either § 503.32(a) or § 503.32(b)] and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) if one of those requirements is met] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the pathogen requirements [and vector attraction reduction requirements] have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(C) A description of how the pathogen requirements in either § 503.32 (a) or (b) are met.

(D) When one of the vector attraction requirements in § 503.33 (b)(1) through (b)(8) is met, a description of how the vector attraction requirement is met.

(ii) The person who applies the bulk sewage sludge shall develop the following information, retain the information in § 503.17 (a)(5)(ii)(A) through (a)(5)(ii)(G) indefinitely, and retain the information in § 503.17 (a)(5)(ii)(H) through (a)(5)(ii)(M) for five years.

(A) The location, by either street address or latitude and longitude, of each site on which bulk sewage sludge is applied.

(B) The number of hectares in each site on which bulk sewage sludge is applied.

(C) The date and time bulk sewage sludge is applied to each site.

(D) The cumulative amount of each pollutant (i.e., kilograms) listed in Table 2 of § 503.13 in the bulk sewage sludge applied to each site, including the amount in § 503.12(e)(2)(iii).

(E) The amount of sewage sludge (i.e., metric tons) applied to each site.

(F) The following certification statement:

"I certify, under penalty of law, that the requirements to obtain information in § 503.12(e)(2) have been met for each site on which bulk sewage sludge is applied. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the requirements to obtain information have been met. I am aware that there are significant penalties for false certification including fine and imprisonment."

(G) A description of how the requirements to obtain information in § 503.12(e)(2) are met.

(H) The following certification statement:

"I certify, under penalty of law, that the management practices in § 503.14 have been met for each site on which bulk sewage sludge is applied. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the management practices have been met. I am aware that there are significant penalties for false certification including fine and imprisonment."

(I) A description of how the management practices in § 503.14 are met for each site on which bulk sewage sludge is applied.

(J) The following certification statement when the bulk sewage sludge meets the Class B pathogen requirements in § 503.32(b):

"I certify, under penalty of law, that the site restrictions in § 503.32(b)(5) have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the site restrictions have been met. I am aware that there are significant penalties for false certification including fine and imprisonment."

(K) A description of how the site restrictions in § 503.32(b)(5) are met for each site on which Class B bulk sewage sludge is applied.

(L) The following certification statement when the vector attraction reduction requirement in either § 503.33 (b)(9) or (b)(10) is met:

"I certify, under penalty of law, that the vector attraction reduction requirement in [insert either § 503.33(b)(9) or § 503.33(b)(10)] has been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the vector attraction reduction requirement has been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(M) If the vector attraction reduction requirements in either § 503.33 (b)(9) or (b)(10) are met, a description of how the requirements are met.

(6) If the requirements in § 503.13(a)(4)(ii) are met when sewage sludge is sold or given away in a bag or

other container for application to the land, the person who prepares the sewage sludge that is sold or given away in a bag or other container shall develop the following information and shall retain the information for five years:

(i) The annual whole sludge application rate for the sewage sludge that does not cause the annual pollutant loading rates in Table 4 of § 503.13 to be exceeded.

(ii) The concentration of each pollutant listed in Table 4 of § 503.13 in the sewage sludge.

(iii) The following certification statement:

"I certify, under penalty of law, that the management practice in § 503.14(e), the Class A pathogen requirement in § 503.32(a), and the vector attraction reduction requirement in [insert one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8)] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the management practice, pathogen requirements, and vector attraction reduction requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(iv) A description of how the Class A pathogen requirements in § 503.32(a) are met.

(v) A description of how one of the vector attraction requirements in § 503.33 (b)(1) through (b)(8) is met.

(b) *Domestic septage.* When domestic septage is applied to agricultural land, forest, or a reclamation site, the person who applies the domestic septage shall develop the following information and shall retain the information for five years:

(1) The location, by either street address or latitude and longitude, of each site on which domestic septage is applied.

(2) The number of acres in each site on which domestic septage is applied.

(3) The date and time domestic septage is applied to each site.

(4) The nitrogen requirement for the crop or vegetation grown on each site during a 365 day period.

(5) The rate, in gallons per acre per 365 day period, at which domestic septage is applied to each site.

(6) The following certification statement:

"I certify, under penalty of law, that the pathogen requirements in [insert either § 503.32(c)(1) or § 503.32(c)(2)] and the vector attraction reduction requirements in [insert § 503.33(b)(9), § 503.33(b)(10), or § 503.33(b)(12)] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the pathogen requirements and vector attraction reduction requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(7) A description of how the pathogen requirements in either § 503.33 (c)(1) or (c)(2) are met.

(8) A description of how the vector attraction reduction requirements in § 503.33 (b)(9), (b)(10), or (b)(12) are met.

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§ 503.18 Reporting.

(a) Class I sludge management facilities, POTWs (as defined in 40 CFR 501.2) with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more shall submit the following information to the permitting authority:

(1) The information in § 503.17(a), except the information in § 503.17 (a)(3)(ii), (a)(4)(ii) and in (a)(5)(ii), for the appropriate requirements on February 19 of each year.

(2) The information in § 503.17 (a)(5)(ii)(A) through (a)(5)(ii)(G) on [insert the month and day from the date of publication of this rule] of each year when 90 percent or more of any of the cumulative pollutant loading rates in Table 2 of § 503.13 is reached at a site.

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Subpart C—Surface Disposal

§ 503.20 Applicability.

(a) This subpart applies to any person who prepares sewage sludge that is placed on a surface disposal site, to the owner/operator of a surface disposal site, to sewage sludge placed on a surface disposal site, and to a surface disposal site.

(b) This subpart does not apply to sewage sludge stored on the land or to the land on which sewage sludge is stored. It also does not apply to sewage sludge that remains on the land for longer than two years when the person who prepares the sewage sludge demonstrates that the land on which the sewage sludge remains is not an active sewage sludge unit. The demonstration shall include the following information, which shall be retained by the person who prepares the sewage sludge for the period that the sewage sludge remains on the land:

(1) The name and address of the person who prepares the sewage sludge.

(2) The name and address of the person who either owns the land or leases the land.

(3) The location, by either street address or latitude and longitude, of the land.

(4) An explanation of why sewage sludge needs to remain on the land for longer than two years prior to final use or disposal.

(5) The approximate time period when the sewage sludge will be used or disposed.

(c) This subpart does not apply to sewage sludge treated on the land or to the land on which sewage sludge is treated.

§ 503.21 Special definitions.

(a) *Active sewage sludge unit* is a sewage sludge unit that has not closed.

(b) *Aquifer* is a geologic formation, group of geologic formations, or a portion of a geologic formation capable of yielding ground water to wells or springs.

(c) *Contaminate an aquifer* means to introduce a substance that causes the maximum contaminant level for nitrate in 40 CFR 141.11 to be exceeded in ground water or that causes the existing concentration of nitrate in ground water to increase when the existing concentration of nitrate in the ground water exceeds the maximum contaminant level for nitrate in 40 CFR 141.11.

(d) *Cover* is soil or other material used to cover sewage sludge placed on an active sewage sludge unit.

(e) *Displacement* is the relative movement of any two sides of a fault measured in any direction.

(f) *Fault* is a fracture or zone of fractures in any materials along which strata on one side are displaced with respect to strata on the other side.

(g) *Final cover* is the last layer of soil or other material placed on a sewage sludge unit at closure.

(h) *Holocene time* is the most recent epoch of the Quaternary period, extending from the end of the Pleistocene epoch to the present.

(i) *Leachate collection system* is a system or device installed immediately above a liner that is designed, constructed, maintained, and operated to collect and remove leachate from a sewage sludge unit.

(j) *Liner* is soil or synthetic material that has a hydraulic conductivity of 1×10^{-7} centimeters per second or less.

(k) *Lower explosive limit for methane gas* is the lowest percentage of methane gas in air, by volume, that propagates a flame at 25 degrees Celsius and atmospheric pressure.

(l) *Qualified ground-water scientist* is an individual with a baccalaureate or

post-graduate degree in the natural sciences or engineering who has sufficient training and experience in ground-water hydrology and related fields, as may be demonstrated by State registration, professional certification, or completion of accredited university programs, to make sound professional judgments regarding ground-water monitoring, pollutant fate and transport, and corrective action.

(m) *Seismic impact zone* is an area that has a 10 percent or greater probability that the horizontal ground level acceleration of the rock in the area exceeds 0.10 gravity once in 250 years.

(n) *Sewage sludge unit* is land on which only sewage sludge is placed for final disposal. This does not include land on which sewage sludge is either stored or treated. Land does not include waters of the United States, as defined in 40 CFR 122.2.

(o) *Sewage sludge unit boundary* is the outermost perimeter of an active sewage sludge unit.

(p) *Surface disposal site* is an area of land that contains one or more active sewage sludge units.

(q) *Unstable area* is land subject to natural or human-induced forces that may damage the structural components of an active sewage sludge unit. This includes, but is not limited to, land on which the soils are subject to mass movement.

§ 503.22 General requirements.

(a) No person shall place sewage sludge on an active sewage sludge unit unless the requirements in this subpart are met.

(b) An active sewage sludge unit located within 60 meters of a fault that has displacement in Holocene time; located in an unstable area; or located in a wetland, except as provided in a permit issued pursuant to section 402 of the CWA, shall close by [insert date one year after the effective date of this Final rule], unless, in the case of an active sewage sludge unit located within 60 meters of a fault that has displacement in Holocene time, otherwise specified by the permitting authority.

(c) The owner/operator of an active sewage sludge unit shall submit a written closure and post closure plan to the permitting authority 180 days prior to the date that the active sewage sludge unit closes. The plan shall describe how the sewage sludge unit will be closed and, at a minimum, shall include:

(1) A discussion of how the leachate collection system will be operated and maintained for three years after the sewage sludge unit closes if the sewage sludge unit has a liner and leachate collection system.

(2) A description of the system used to monitor for methane gas in the air in any structures within the surface disposal site and in the air at the property line of the surface disposal site, as required in § 503.24(j)(2).

(3) A discussion of how public access to the surface disposal site will be restricted for three years after the last sewage sludge unit in the surface disposal site closes.

(d) The owner of a surface disposal site shall provide written notification to the subsequent owner of the site that sewage sludge was placed on the land.

§ 503.23 Pollutant limits (other than domestic septage).

(a) Active sewage sludge unit without a liner and leachate collection system.

(1) Except as provided in § 503.23 (a)(2) and (b), the concentration of each pollutant listed in Table 1 of § 503.23 in sewage sludge placed on an active sewage sludge unit shall not exceed the concentration for the pollutant in Table 1 of § 503.23.

TABLE 1 OF § 503.23.—POLLUTANT CONCENTRATIONS—ACTIVE SEWAGE SLUDGE UNIT WITHOUT A LINER AND LEACHATE COLLECTION

Pollutant	Concentration (milligrams per kilograms [1])
Arsenic	73
Chromium	600
Nickel	420

[1] Dry weight basis.

(2) Except as provided in § 503.23(b), the concentration of each pollutant listed in Table 1 of § 503.23 in sewage sludge placed on an active sewage sludge unit whose boundary is less than 150 meters from the property line of the surface disposal site shall not exceed the concentration determined using the following procedure.

(i) The actual distance from the active sewage sludge unit boundary to the property line of the surface disposal site shall be determined.

(ii) The concentration of each pollutant listed in Table 2 of § 503.23 in the sewage sludge shall not exceed the concentration in Table 2 of § 503.23 that corresponds to the actual distance in § 503.23(a)(2)(i).

TABLE 2 OF § 503.23.—POLLUTANT CONCENTRATIONS—ACTIVE SEWAGE SLUDGE UNIT WITHOUT A LINER AND LEACHATE COLLECTION SYSTEM THAT HAS A UNIT BOUNDARY TO PROPERTY LINE DISTANCE LESS THAN 150 METERS

Unit boundary to property line	Pollutant concentration [1]		
Distance (meters)	Arsenic (mg/kg)	Chromium (mg/kg)	Nickel (mg/kg)
0 to less than 25	30	200	210
25 to less than 50	34	220	240
50 to less than 75	39	260	270
75 to less than 100	46	300	320
100 to less than 125	53	360	390
125 to less than 150	62	450	420

[1] Dry weight basis.

(b) Active sewage sludge unit without a liner and leachate collection system—site-specific limits.

(1) At the time of permit application, the owner/operator of a surface disposal site may request site-specific pollutant limits in accordance with § 503.23(b)(2) for an active sewage sludge unit without a liner and leachate collection system when the existing values for site parameters specified by the permitting authority are different from the values for those parameters used to develop the pollutant limits in Table 1 of § 503.23 and when the permitting authority determines that site-specific pollutant limits are appropriate for the active sewage sludge unit.

(2) The concentration of each pollutant listed in Table 1 of § 503.23 in sewage sludge placed on an active sewage sludge unit without a liner and leachate collection system shall not exceed either the concentration for the pollutant determined during a site-specific assessment, as specified by the permitting authority, or the existing concentration of the pollutant in the sewage sludge, whichever is lower.

§ 503.24 Management practices.

(a) Sewage sludge shall not be placed on an active sewage sludge unit if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat.

(b) An active sewage sludge unit shall not restrict the flow of a base flood.

(c) When a surface disposal site is located in a seismic impact zone, an active sewage sludge unit shall be designed to withstand the maximum recorded horizontal ground level acceleration.

(d) An active sewage sludge unit shall be located 60 meters or more from a fault that has displacement in Holocene

time, unless otherwise specified by the permitting authority.

(e) An active sewage sludge unit shall not be located in an unstable area.

(f) An active sewage sludge unit shall not be located in a wetland, except as provided in a permit issued pursuant to section 402 or 404 of the CWA.

(g)(1) Run-off from an active sewage sludge unit shall be collected and shall be disposed in accordance with National Pollutant Discharge Elimination System permit requirements and any other applicable requirements.

(2) The run-off collection system for an active sewage sludge unit shall have the capacity to handle run-off from a 24-hour, 25-year storm event.

(h) The leachate collection system for an active sewage sludge unit that has a liner and leachate collection system shall be operated and maintained during the period the sewage sludge unit is active and for three years after the sewage sludge unit closes.

(i) Leachate from an active sewage sludge unit that has a liner and leachate collection system shall be collected and shall be disposed in accordance with the applicable requirements during the period the sewage sludge unit is active and for three years after the sewage sludge unit closes.

(j)(1) When a cover is placed on an active sewage sludge unit, the concentration of methane gas in air in any structure within the surface disposal site shall not exceed 25 percent of the lower explosive limit for methane gas during the period that the sewage sludge unit is active and the concentration of methane gas in air at the property line of the surface disposal site shall not exceed the lower explosive limit for methane gas during the period that the sewage sludge unit is active.

(2) When a final cover is placed on a sewage sludge unit at closure, the concentration of methane gas in air in any structure within the surface disposal site shall not exceed 25 percent of the lower explosive limit for methane gas for three years after the sewage sludge unit closes and the concentration of methane gas in air at the property line of the surface disposal site shall not exceed the lower explosive limit for methane gas for three years after the sewage sludge unit closes, unless otherwise specified by the permitting authority.

(k) A food crop, a feed crop, or a fiber crop shall not be grown on an active sewage sludge unit, unless the owner/operator of the surface disposal site demonstrates to the permitting authority that through management practices public health and the environment are protected from any reasonably anticipated adverse effects of pollutants in sewage sludge when crops are grown.

(l) Animals shall not be grazed on an active sewage sludge unit, unless the owner/operator of the surface disposal site demonstrates to the permitting authority that through management practices public health and the environment are protected from any reasonably anticipated adverse effects of pollutants in sewage sludge when animals are grazed.

(m) Public access to a surface disposal site shall be restricted for the period that the surface disposal site contains an active sewage sludge unit and for three years after the last active sewage sludge unit in the surface disposal site closes.

(n)(1) Sewage sludge placed on an active sewage sludge unit shall not contaminate an aquifer.

(2) Results of a ground-water monitoring program developed by a qualified ground-water scientist or a certification by a qualified ground-water scientist shall be used to demonstrate that sewage sludge placed on an active sewage sludge unit does not contaminate an aquifer.

§ 503.25 Operational standards—pathogens and vector attraction reduction.

(a) *Pathogens—sewage sludge (other than domestic septage).* The Class A pathogens requirements in § 503.32(a) or one of the Class B pathogen requirements in § 503.32 (b)(2) through (b)(4) shall be met when sewage sludge is placed on an active sewage sludge unit, unless the vector attraction reduction requirement in § 503.33(b)(11) is met.

(b) *Vector attraction reduction—sewage sludge (other than domestic septage).* One of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(11) shall be met when sewage sludge is placed on an active sewage sludge unit.

(c) *Vector attraction reduction—domestic septage.* One of the vector attraction reduction requirement in § 503.33 (b)(9) through (b)(12) shall be met when domestic septage is placed on an active sewage sludge unit.

§ 503.26 Frequency of monitoring.

(a) *Sewage sludge (other than domestic septage).*

(1) The frequency of monitoring for the pollutants in Tables 1 and 2 of § 503.23; the pathogen density requirements in § 503.32(a) and in § 503.32 (b)(2) through (b)(4); and the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) for sewage sludge placed on an active sewage sludge unit shall be the frequency in Table 1 of § 503.26.

TABLE 1 OF § 503.26.—FREQUENCY OF MONITORING—SURFACE DISPOSAL

Amount of sewage sludge [1] (metric tons per 365 day period)	Frequency
Greater than zero but less than 290.	Once per year.
Equal to or greater than 290 but less than 1,500.	Once per quarter (four times per year).
Equal to or greater than 1,500 but less than 15,000.	Once per 60 days (six times per year).
Equal to or greater than 15,000.	Once per month (12 times per year).

[1] Amount of sewage sludge placed on an active sewage sludge unit (dry weight basis).

(2) After the sewage sludge has been monitored for two years at the frequency in Table 1 of § 503.26, the permitting authority may reduce the frequency of monitoring for pollutant concentrations and for the pathogen density requirements in § 503.32 (a)(5)(ii) and (a)(5)(iii), but in no case shall the frequency of monitoring be less than once per year when sewage sludge is placed on an active sewage sludge unit.

(b) *Domestic septage.* If the vector attraction reduction requirements in § 503.33(b)(12) are met when domestic septage is placed on an active sewage sludge unit, each container of domestic septage shall be monitored for compliance with those requirements.

(c) *Air.* Air in structures within a surface disposal site and at the property line of the surface disposal site shall be monitored continuously for methane gas during the period that the surface disposal site contains an active sewage sludge unit on which the sewage sludge is covered and for three years after a sewage sludge unit closes when a final cover is placed on the sewage sludge.

(Approved by the Office of Management and Budget under control number 2040–0157)

§ 503.27 Recordkeeping.

(a) When sewage sludge (other than domestic septage) is placed on an active sewage sludge unit:

(1) The person who prepares the sewage sludge shall develop the following information and shall retain the information for five years.

(i) The concentration of each pollutant listed in Table 1 of § 503.23 in the sewage sludge when the pollutant concentrations in Table 1 of § 503.23 are met.

(ii) The following certification statement:

"I certify, under penalty of law, that the pathogen requirements in [insert § 503.32(a), § 503.32(b)(2), § 503.32(b)(3), or § 503.32(b)(4) when one of those requirements is met] and the vector attraction reduction requirements in [insert one of the vector attraction

reduction requirements in § 503.33(b)(1) through § 503.33(b)(8) when one of those requirements is met] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine the [pathogen requirements and vector attraction reduction requirements if appropriate] have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(iii) A description of how the pathogen requirements in § 503.32 (a), (b)(2), (b)(3), or (b)(4) are met when one of those requirements is met.

(iv) A description of how one of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) is met when one of those requirements is met.

(2) The owner/operator of the surface disposal site, shall develop the following information and shall retain that information for five years.

(i) The concentration of each pollutant listed in Table 2 of § 503.23 in the sewage sludge when the pollutant concentrations in Table 2 of § 503.23 are met or when site-specific pollutant limits in § 503.23(b) are met.

(ii) The following certification statement:

"I certify, under penalty of law, that the management practices in § 503.24 and the vector attraction reduction requirement in [insert one of the requirements in § 503.33 (b)(9) through (b)(11) if one of those requirements is met] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the management practices [and the vector attraction reduction requirements if appropriate] have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(iii) A description of how the management practices in § 503.24 are met.

(iv) A description of how the vector attraction reduction requirements in § 503.33 (b)(9) through (b)(11) are met if one of those requirements is met.

(b) When domestic septage is placed on a surface disposal site:

(1) If the vector attraction reduction requirements in § 503.33(b)(12) are met, the person who places the domestic septage on the surface disposal site shall develop the following information and shall retain the information for five years:

(i) The following certification statement:

"I certify, under penalty of law, that the vector attraction reduction requirements in § 503.33(b)(12) have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the vector attraction requirements have been met. I am aware that there are significant penalties for false certification including the possibility of fine and imprisonment."

(ii) A description of how the vector attraction reduction requirements in § 503.33(b)(12) are met.

(2) The owner/operator of the surface disposal site shall develop the following information and shall retain that information for five years:

(i) The following certification statement:

"I certify, under penalty of law, that the management practices in § 503.24 and the vector attraction reduction requirements in [insert § 503.33(b)(9) through § 503.33(b)(11) when one of those requirements is met] have been met. This determination has been made under my direction and supervision in accordance with the system designed to ensure that qualified personnel properly gather and evaluate the information used to determine that the management practices [and the vector attraction reduction requirements if appropriate] have been met. I am aware that there are significant penalties for false certification including the possibility of fine or imprisonment."

(ii) A description of how the management practices in § 503.24 are met.

(iii) A description how the vector attraction reduction requirements in § 503.33(b)(9) through § 503.33(b)(11) are met if one of those requirements is met.

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§ 503.28 Reporting.

Class I sludge management facilities, POTWs (as defined in 40 CFR 501.2) with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve 10,000 people or more shall submit the information in § 503.27(a) to the permitting authority on February 19 of each year.

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Subpart D—Pathogens and Vector Attraction Reduction

§ 503.30 Scope.

(a) This subpart contains the requirements for a sewage sludge to be classified either Class A or Class B with respect to pathogens.

(b) This subpart contains the site restrictions for land on which a Class B sewage sludge is applied.

(c) This subpart contains the pathogen requirements for domestic septage applied to agricultural land, forest, or a reclamation site.

(d) This subpart contains alternative vector attraction reduction requirements for sewage sludge that is applied to the land or placed on a surface disposal site.

§ 503.31 Special definitions.

(a) *Aerobic digestion* is the biochemical decomposition of organic matter in sewage sludge into carbon dioxide and water by microorganisms in the presence of air.

(b) *Anaerobic digestion* is the biochemical decomposition of organic matter in sewage sludge into methane gas and carbon dioxide by microorganisms in the absence of air.

(c) *Density of microorganisms* is the number of microorganisms per unit mass of total solids (dry weight) in the sewage sludge.

(d) *Land with a high potential for public exposure* is land that the public uses frequently. This includes, but is not limited to, a public contact site and a reclamation site located in a populated area (e.g, a construction site located in a city).

(e) *Land with a low potential for public exposure* is land that the public uses infrequently. This includes, but is not limited to, agricultural land, forest, and a reclamation site located in an unpopulated area (e.g., a strip mine located in a rural area).

(f) *Pathogenic organisms* are disease-causing organisms. These include, but are not limited to, certain bacteria, protozoa, viruses, and viable helminth ova.

(g) *pH* means the logarithm of the reciprocal of the hydrogen ion concentration.

(h) *Specific oxygen uptake rate (SOUR)* is the mass of oxygen consumed per unit time per unit mass of total solids (dry weight basis) in the sewage sludge.

(i) *Total solids* are the materials in sewage sludge that remain as residue when the sewage sludge is dried at 103 to 105 degrees Celsius.

(j) *Unstabilized solids* are organic materials in sewage sludge that have not been treated in either an aerobic or anaerobic treatment process.

(k) *Vector attraction* is the characteristic of sewage sludge that attracts rodents, flies, mosquitos, or other organisms capable of transporting infectious agents.

(l) *Volatile solids* is the amount of the total solids in sewage sludge lost when the sewage sludge is combusted at 550 degrees Celsius in the presence of excess air.

§ 503.32 Pathogens.

(a) *Sewage sludge—Class A.* (1) The requirement in § 503.32(a)(2) and the requirements in either § 503.32(a)(3), (a)(4), (a)(5), (a)(6), (a)(7), or (a)(8) shall be met for a sewage sludge to be classified Class A with respect to pathogens.

(2) The Class A pathogen requirements in § 503.32 (a)(3) through (a)(8) shall be met either prior to meeting or at the same time the vector attraction reduction requirements in § 503.33, except the vector attraction reduction requirements in § 503.33 (b)(6) through (b)(8), are met.

(3) *Class A—Alternative 1.* (i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of *Salmonella* sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in § 503.10 (b), (c), (e), or (f).

(ii) The temperature of the sewage sludge that is used or disposed shall be maintained at a specific value for a period of time.

(A) When the percent solids of the sewage sludge is seven percent or higher, the temperature of the sewage sludge shall be 50 degrees Celsius or higher; the time period shall be 20 minutes or longer; and the temperature and time period shall be determined using equation (2), except when small particles of sewage sludge are heated by either warmed gases or an immiscible liquid.

$$D = \frac{131{,}700{,}000}{10^{0.1400t}} \quad \text{Eq. (2)}$$

Where,
D=time in days.
t=temperature in degrees Celsius.

(B) When the percent solids of the sewage sludge is seven percent or higher and small particles of sewage sludge are heated by either warmed gases or an immiscible liquid, the temperature of the sewage sludge shall be 50 degrees Celsius or higher; the time period shall be 15 seconds or longer; and the temperature and time period shall be determined using equation (2).

(C) When the percent solids of the sewage sludge is less than seven percent and the time period is at least 15 seconds, but less than 30 minutes, the temperature and time period shall be determined using equation (2).

(D) When the percent solids of the sewage sludge is less than seven percent; the temperature of the sewage sludge is 50 degrees Celsius or higher; and the time period is 30 minutes or longer, the temperature and time period shall be determined using equation (3).

$$D = \frac{50{,}070{,}000}{10^{0.1400t}} \quad \text{Eq. (3)}$$

Where,
D=time in days.
t=temperature in degrees Celsius.

(4) *Class A—Alternative 2.* (i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of *Salmonella* sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in § 503.10 (b), (c), (e), or (f).

(ii) (A) The pH of the sewage sludge that is used or disposed shall be raised to above 12 and shall remain above 12 for 72 hours.

(B) The temperature of the sewage sludge shall be above 52 degrees Celsius for 12 hours or longer during the period that the pH of the sewage sludge is above 12.

(C) At the end of the 72 hour period during which the pH of the sewage sludge is above 12, the sewage sludge shall be air dried to achieve a percent solids in the sewage sludge greater than 50 percent.

(5) *Class A—Alternative 3.* (i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of *Salmonella* sp. bacteria in sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in § 503.10 (b), (c), (e), or (f).

(ii) (A) The sewage sludge shall be analyzed prior to pathogen treatment to determine whether the sewage sludge contains enteric viruses.

(B) When the density of enteric viruses in the sewage sludge prior to pathogen treatment is less than one Plaque-forming Unit per four grams of total solids (dry weight basis), the sewage sludge is Class A with respect to enteric viruses until the next monitoring episode for the sewage sludge.

(C) When the density of enteric viruses in the sewage sludge prior to pathogen treatment is equal to or greater than one Plaque-forming Unit per four grams of total solids (dry weight basis), the sewage sludge is Class A with respect to enteric viruses when the density of enteric viruses in the sewage sludge after pathogen treatment is less than one Plaque-forming Unit per four grams of total solids (dry weight basis) and when the values or ranges of values for the operating parameters for the pathogen treatment process that produces the sewage sludge that meets the enteric virus density requirement are documented.

(D) After the enteric virus reduction in paragraph (a)(5)(ii)(C) of this section is demonstrated for the pathogen treatment process, the sewage sludge continues to be Class A with respect to enteric viruses when the values for the pathogen treatment process operating parameters are consistent with the values or ranges of values documented in paragraph (a)(5)(ii)(C) of this section.

(iii)(A) The sewage sludge shall be analyzed prior to pathogen treatment to determine whether the sewage sludge contains viable helminth ova.

(B) When the density of viable helminth ova in the sewage sludge prior to pathogen treatment is less than one per four grams of total solids (dry weight basis), the sewage sludge is Class A with respect to viable helminth ova until the next monitoring episode for the sewage sludge.

(C) When the density of viable helminth ova in the sewage sludge prior to pathogen treatment is equal to or greater than one per four grams of total solids (dry weight basis), the sewage sludge is Class A with respect to viable helminth ova when the density of viable helminth ova in the sewage sludge after pathogen treatment is less than one per four grams of total solids (dry weight basis) and when the values or ranges of values for the operating parameters for the pathogen treatment process that produces the sewage sludge that meets the viable helminth ova density requirement are documented.

(D) After the viable helminth ova reduction in paragraph (a)(5)(iii)(C) of this section is demonstrated for the pathogen treatment process, the sewage

sludge continues to be Class A with respect to viable helminth ova when the values for the pathogen treatment process operating parameters are consistent with the values or ranges of values documented in paragraph (a)(5)(iii)(C) of this section.

(6) *Class A—Alternative 4.* (i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of *Salmonella* sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in § 503.10 (b), (c), (e), or (f).

(ii) The density of enteric viruses in the sewage sludge shall be less than one Plaque-forming Unit per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in § 503.10 (b), (c), (e), or (f), unless otherwise specified by the permitting authority.

(iii) The density of viable helminth ova in the sewage sludge shall be less than one per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or give away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in § 503.10 (b), (c), (e), or (f), unless otherwise specified by the permitting authority.

(7) *Class A—Alternative 5.* (i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of *Salmonella*, sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or given away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in § 503.10(b), (c), (e), or (f).

(ii) Sewage sludge that is used or disposed shall be treated in one of the Processes to Further Reduce Pathogens described in appendix B of this part.

(8) *Class A—Alternative 6.* (i) Either the density of fecal coliform in the sewage sludge shall be less than 1000 Most Probable Number per gram of total solids (dry weight basis), or the density of *Salmonella*, sp. bacteria in the sewage sludge shall be less than three Most Probable Number per four grams of total solids (dry weight basis) at the time the sewage sludge is used or disposed; at the time the sewage sludge is prepared for sale or given away in a bag or other container for application to the land; or at the time the sewage sludge or material derived from sewage sludge is prepared to meet the requirements in § 503.10(b), (c), (e), or (f).

(ii) Sewage sludge that is used or disposed shall be treated in a process that is equivalent to a Process to Further Reduce Pathogens, as determined by the permitting authority.

(b) *Sewage sludge—Class B.* (1)(i) The requirements in either § 503.32(b)(2), (b)(3), or (b)(4) shall be met for a sewage sludge to be classified Class B with respect to pathogens.

(ii) The site restrictions in § 503.32(b)(5) shall be met when sewage sludge that meets the Class B pathogen requirements in § 503.32(b)(2), (b)(3), or (b)(4) is applied to the land.

(2) *Class B—Alternative 1.*

(i) Seven samples of the sewage sludge shall be collected at the time the sewage sludge is used or disposed.

(ii) The geometric mean of the density of fecal coliform in the samples collected in paragraph (b)(2)(i) of this section shall be less than either 2,000,000 Most Probable Number per gram of total solids (dry weight basis) or 2,000,000 Colony Forming Units per gram of total solids (dry weight basis).

(3) *Class B—Alternative 2.* Sewage sludge that is used or disposed shall be treated in one of the Processes to Significantly Reduce Pathogens described in appendix B of this part.

(4) *Class B—Alternative 3.* Sewage sludge that is used or disposed shall be treated in a process that is equivalent to a Process to Significantly Reduce Pathogens, as determined by the permitting authority.

(5) *Site Restrictions.* (i) Food crops with harvested parts that touch the sewage sludge/soil mixture and are totally above the land surface shall not be harvested for 14 months after application of sewage sludge.

(ii) Food crops with harvested parts below the surface of the land shall not be harvested for 20 months after application of sewage sludge when the sewage sludge remains on the land surface for four months or longer prior to incorporation into the soil.

(iii) Food crops with harvested parts below the surface of the land shall not be harvested for 38 months after application of sewage sludge when the sewage sludge remains on the land surface for less than four months prior to incorporation into the soil.

(iv) Food crops, feed crops, and fiber crops shall not be harvested for 30 days after application of sewage sludge.

(v) Animals shall not be allowed to graze on the land for 30 days after application of sewage sludge.

(vi) Turf grown on land where sewage sludge is applied shall not be harvested for one year after application of the sewage sludge when the harvested turf is placed on either land with a high potential for public exposure or a lawn, unless otherwise specified by the permitting authority.

(vii) Public access to land with a high potential for public exposure shall be restricted for one year after application of sewage sludge.

(viii) Public access to land with a low potential for public exposure shall be restricted for 30 days after application of sewage sludge.

(c) *Domestic septage.* (1) The site restrictions in § 503.32(b)(5) shall be met when domestic septage is applied to agricultural land, forest, or a reclamation site; or

(2) The pH of domestic septage applied to agricultural land, forest, or a reclamation site shall be raised to 12 or higher by alkali addition and, without the addition of more alkali, shall remain at 12 or higher for 30 minutes and the site restrictions in § 503.32 (b)(5)(i) through (b)(5)(iv) shall be met.

§ 503.33 Vector attraction reduction.

(a)(1) One of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(10) shall be met when bulk sewage sludge is applied to agricultural land, forest, a public contact site, or a reclamation site.

(2) One of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) shall be met when bulk sewage sludge is applied to a lawn or a home garden.

(3) One of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(8) shall be met when sewage sludge is sold or given away in a bag or other container for application to the land.

(4) One of the vector attraction reduction requirements in § 503.33 (b)(1) through (b)(11) shall be met when sewage sludge (other than domestic

septage) is placed on an active sewage sludge unit.

(5) One of the vector attraction reduction requirements in § 503.33 (b)(9), (b)(10), or (b)(12) shall be met when domestic septage is applied to agricultural land, forest, or a reclamation site and one of the vector attraction reduction requirements in § 503.33 (b)(9) through (b)(12) shall be met when domestic septage is placed on an active sewage sludge unit.

(b)(1) The mass of volatile solids in the sewage sludge shall be reduced by a minimum of 38 percent (see calculation procedures in "Environmental Regulations and Technology—Control of Pathogens and Vector Attraction in Sewage Sludge", EPA–625/R–92/013, 1992, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268).

(2) When the 38 percent volatile solids reduction requirement in § 503.33(b)(1) cannot be met for an anaerobically digested sewage sludge, vector attraction reduction can be demonstrated by digesting a portion of the previously digested sewage sludge anaerobically in the laboratory in a bench-scale unit for 40 additional days at a temperature between 30 and 37 degrees Celsius. When at the end of the 40 days, the volatile solids in the sewage sludge at the beginning of that period is reduced by less than 17 percent, vector attraction reduction is achieved.

(3) When the 38 percent volatile solids reduction requirement in § 503.33(b)(1) cannot be met for an aerobically digested sewage sludge, vector attraction reduction can be demonstrated by digesting a portion of the previously digested sewage sludge that has a percent solids of two percent or less aerobically in the laboratory in a bench-scale unit for 30 additional days at 20 degrees Celsius. When at the end of the 30 days, the volatile solids in the sewage sludge at the beginning of that period is reduced by less than 15 percent, vector attraction reduction is achieved.

(4) The specific oxygen uptake rate (SOUR) for sewage sludge treated in an aerobic process shall be equal to or less than 1.5 milligrams of oxygen per hour per gram of total solids (dry weight basis) at a temperature of 20 degrees Celsius.

(5) Sewage sludge shall be treated in an aerobic process for 14 days or longer. During that time, the temperature of the sewage sludge shall be higher than 40 degrees Celsius and the average temperature of the sewage sludge shall be higher than 45 degrees Celsius.

(6) The pH of sewage sludge shall be raised to 12 or higher by alkali addition and, without the addition of more alkali, shall remain at 12 or higher for two hours and then at 11.5 or higher for an additional 22 hours.

(7) The percent solids of sewage sludge that does not contain unstabilized solids generated in a primary wastewater treatment process shall be equal to or greater than 75 percent based on the moisture content and total solids prior to mixing with other materials.

(8) The percent solids of sewage sludge that contains unstabilized solids generated in a primary wastewater treatment process shall be equal to or greater than 90 percent based on the moisture content and total solids prior to mixing with other materials.

(9)(i) Sewage sludge shall be injected below the surface of the land.

(ii) No significant amount of the sewage sludge shall be present on the land surface within one hour after the sewage sludge is injected.

(iii) When the sewage sludge that is injected below the surface of the land is Class A with respect to pathogens, the sewage sludge shall be injected below the land surface within eight hours after being discharged from the pathogen treatment process.

(10)(i) Sewage sludge applied to the land surface or placed on a surface disposal site shall be incorporated into the soil within six hours after application to or placement on the land.

(ii) When sewage sludge that is incorporated into the soil is Class A with respect to pathogens, the sewage sludge shall be applied to or placed on the land within eight hours after being discharged from the pathogen treatment process.

(11) Sewage sludge placed on an active sewage sludge unit shall be covered with soil or other material at the end of each operating day.

(12) The pH of domestic septage shall be raised to 12 or higher by alkali addition and, without the addition of more alkali, shall remain at 12 or higher for 30 minutes.

Subpart E—Incineration

§ 503.40 Applicability.

(a) This subpart applies to a person who fires sewage sludge in a sewage sludge incinerator, to a sewage sludge incinerator, and to sewage sludge fired in a sewage sludge incinerator.

(b) This subpart applies to the exit gas from a sewage sludge incinerator stack.

§ 503.41 Special definitions.

(a) *Air pollution control device* is one or more processes used to treat the exit gas from a sewage sludge incinerator stack.

(b) *Auxiliary fuel* is fuel used to augment the fuel value of sewage sludge. This includes, but is not limited to, natural gas, fuel oil, coal, gas generated during anaerobic digestion of sewage sludge, and municipal solid waste (not to exceed 30 percent of the dry weight of sewage sludge and auxiliary fuel together). Hazardous wastes are not auxiliary fuel.

(c) *Control efficiency* is the mass of a pollutant in the sewage sludge fed to an incinerator minus the mass of that pollutant in the exit gas from the incinerator stack divided by the mass of the pollutant in the sewage sludge fed to the incinerator.

(d) *Dispersion factor* is the ratio of the increase in the ground level ambient air concentration for a pollutant at or beyond the property line of the site where the sewage sludge incinerator is located to the mass emission rate for the pollutant from the incinerator stack.

(e) *Fluidized bed incinerator* is an enclosed device in which organic matter and inorganic matter in sewage sludge are combusted in a bed of particles suspended in the combustion chamber gas.

(f) *Hourly average* is the arithmetic mean of all measurements, taken during an hour. At least two measurements must be taken during the hour.

(g) *Incineration* is the combustion of organic matter and inorganic matter in sewage sludge by high temperatures in an enclosed device.

(h) *Monthly average* is the arithmetic mean of the hourly averages for the hours a sewage sludge incinerator operates during the month.

(i) *Risk specific concentration* is the allowable increase in the average daily ground level ambient air concentration for a pollutant from the incineration of sewage sludge at or beyond the property line of the site where the sewage sludge incinerator is located.

(j) *Sewage sludge feed rate* is either the average daily amount of sewage sludge fired in all sewage sludge incinerators within the property line of the site where the sewage sludge incinerators are located for the number of days in a 365 day period that each sewage sludge incinerator operates, or the average daily design capacity for all sewage sludge incinerators within the property line of the site where the sewage sludge incinerators are located.

(k) *Sewage sludge incinerator* is an enclosed device in which only sewage sludge and auxiliary fuel are fired.

(l) *Stack height* is the difference between the elevation of the top of a sewage sludge incinerator stack and the

elevation of the ground at the base of the stack when the difference is equal to or less than 65 meters. When the difference is greater than 65 meters, stack height is the creditable stack height determined in accordance with 40 CFR 51.100 (ii).

(m) *Total hydrocarbons* means the organic compounds in the exit gas from a sewage sludge incinerator stack measured using a flame ionization detection instrument referenced to propane.

(n) *Wet electrostatic precipitator* is an air pollution control device that uses both electrical forces and water to remove pollutants in the exit gas from a sewage sludge incinerator stack.

(o) *Wet scrubber* is an air pollution control device that uses water to remove pollutants in the exit gas from a sewage sludge incinerator stack.

§ 503.42 General requirements.

No person shall fire sewage sludge in a sewage sludge incinerator except in compliance with the requirements in this subpart.

§ 503.43 Pollutant limits.

(a) Firing of sewage sludge in a sewage sludge incinerator shall not violate the requirements in the National Emission Standard for Beryllium in subpart C of 40 CFR part 61.

(b) Firing of sewage sludge in a sewage sludge incinerator shall not violate the requirements in the National Emission Standard for Mercury in subpart E of 40 CFR part 61.

(c) *Pollutant limit—lead.*

(1) The daily concentration of lead in sewage sludge fed to a sewage sludge incinerator shall not exceed the concentration calculated using Equation (4).

$$C = \frac{0.1 \times NAAQS \times 86,400}{DF \times (1 - CE) \times SF} \quad \text{Eq. (4)}$$

Where:

C=Daily concentration of lead in sewage sludge in milligrams per kilogram of total solids (dry weight basis).

NAAQS=National Ambient Air Quality Standard for lead in micrograms per cubic meter.

DF=Dispersion factor in micrograms per cubic meter per gram per second.

CE=Sewage sludge incinerator control efficiency for lead in hundredths.

SF=Sewage sludge feed rate in metric tons per day (dry weight basis).

(2)(i) When the sewage sludge stack height is 65 meters or less, the actual sewage sludge incinerator stack height shall be used in an air dispersion model specified by the permitting authority to determine the dispersion factor (DF) in equation (4).

(ii) When the sewage sludge incinerator stack height exceeds 65 meters, the creditable stack height shall be determined in accordance with 40 CFR 51.100(ii) and the creditable stack height shall be used in an air dispersion model specified by the permitting authority to determine the dispersion factor (DF) in equation (4).

(3) The control efficiency (CE) in equation (5) shall be determined from a performance test of the sewage sludge incinerator, as specified by the permitting authority.

(d) Pollutant limit—arsenic, cadmium, chromium, and nickel.

(1) The daily concentration for arsenic, cadmium, chromium, and nickel in sewage sludge fed to a sewage sludge incinerator each shall not exceed the concentration calculated using equation (5).

$$C = \frac{RSC \times 86,400}{DF \times (1 - CE) \times SF} \quad \text{Eq. (5)}$$

Where:

C=Daily concentration of arsenic, cadmium, chromium, or nickel in sewage sludge in milligrams per kilogram of total solids (dry weight basis).

CE=Sewage sludge incinerator control efficiency for arsenic, cadmium, chromium, or nickel in hundredths.

DF=Dispersion factor in micrograms per cubic meter per gram per second.

RSC=Risk specific concentration in micrograms per cubic meter. *S*

F=Sewage sludge feed rate in met,ric tons per day (dry weight basis).

(2) The risk specific concentrations for arsenic, cadmium, and nickel used in equation (6) shall be obtained from Table 1 of § 503 .43.

TABLE 1 OF § 503.43.—RISK SPECIFIC CONCENTRATION ARSENIC, CADMIUM, AND NICKEL

Pollutant	Risk specific concentration (micrograms per cubic meter)
Arsenic	0.023
Cadmium	0.057
Nickel	2.0

(3) The risk specific concentration for chromium used in equation (5) shall be obtained from Table 2 of § 503.43 or shall be calculated using equation (6), as specified by the permitting authority.

TABLE 2 OF § 503.43.—RISK SPECIFIC CONCENTRATION—CHROMIUM

Type of incinerator	Risk specific concentration (micrograms per cubic meter)
Fluidized bed with wet scrubber	0.65
Fluidized bed with wet scrubber and wet electrostatic precipitator	0.23
Other types with wet scrubber	0.064
Other types with wet scrubber and wet electrostatic precipitator	0.016

$$RSC = \frac{0.0085}{r} \quad \text{Eq. (6)}$$

Where:

RSC=risk specific concentration for chromium in micrograms per cubic meter used in equation (5).

r=decimal fraction of the hexavalent chromium concentration in the total chromium concentration measured in the exit gas from the sewage sludge incinerator stack in hundredths.

(4)(i) When the sewage sludge incinerator stack height is equal to or less than 65 meters, the actual sewage sludge incinerator stack height shall be used in an air dispersion model, as specified by the permitting authority, to determine the dispersion factor (DF) in equation (5).

(ii) When the sewage sludge incinerator stack height is greater than 65 meters, the creditable stack height shall be determined in accordance with 40 CFR 51.100(ii) and the creditable stack height shall be used in an air dispersion model, as specified by the permitting authority, to determine the dispersion factor (DF) in equation (5).

(5) The control efficiency (CE) in equation (5) shall be determined from a performance test of the sewage sludge incinerator, as specified by the permitting authority.

§ 503.44 Operational standard—total hydrocarbons.

(a) The total hydrocarbons concentration in the exit gas from a sewage sludge incinerator shall be corrected for zero percent moisture by multiplying the measured total hydrocarbons concentration by the correction factor calculated using equation (7).

$$\text{Correction factor (percent moisture)} = \frac{1}{(1-X)} \quad \text{Eq. (7)}$$

Where:

X=decimal fraction of the percent moisture in the sewage sludge incinerator exit gas in hundredths.

(b) The total hydrocarbons concentration in the exit gas from a sewage sludge incinerator shall be corrected to seven percent oxygen by multiplying the measured total hydrocarbons concentration by the correction factor calculated using equation (8).

$$\text{Correction factor (oxygen)} = \frac{14}{(21-Y)} \quad \text{Eq. (8)}$$

Where:

Y=Percent oxygen concentration in the sewage sludge incinerator stack exit gas (dry volume/dry volume).

(c) The monthly average concentration for total hydrocarbons in the exit gas from a sewage sludge incinerator stack, corrected for zero percent moisture using the correction factor from equation (7) and to seven percent oxygen using the correction factor from equation (8), shall not exceed 100 parts per million on a volumetric basis when measured using the instrument required by § 503.45(a).

§ 503.45 Management practices.

(a)(1) An instrument that measures and records the total hydrocarbons concentration in the sewage sludge incinerator stack exit gas continuously shall be installed, calibrated, operated, and maintained for each sewage sludge incinerator, as specified by the permitting authority.

(2) The total hydrocarbons instrument shall employ a flame ionization detector; shall have a heated sampling line maintained at a temperature of 150 degrees Celsius or higher at all times; and shall be calibrated at least once every 24-hour operating period using propane.

(b) An instrument that measures and records the oxygen concentration in the sewage sludge incinerator stack exit gas continuously shall be installed, calibrated, operated, and maintained for each sewage sludge incinerator, as specified by the permitting authority.

(c) An instrument that measures and records information used to determine the moisture content in the sewage sludge incinerator stack exit gas continuously shall be installed, calibrated, operated, and maintained for each sewage sludge incinerator, as specified by the permitting authority.

(d) An instrument that measures and records combustion temperatures continuously shall be installed, calibrated, operated, and maintained for each sewage sludge incinerator, as specified by the permitting authority.

(e) The maximum combustion temperature for a sewage sludge incinerator shall be specified by the permitting authority and shall be based on information obtained during the performance test of the sewage sludge incinerator to determine pollutant control efficiencies.

(f) The values for the operating parameters for the sewage sludge incinerator air pollution control device shall be specified by the permitting authority and shall be based on information obtained during the performance test of the sewage sludge incinerator to determine pollutant control efficiencies.

(g) Sewage sludge shall not be fired in a sewage sludge incinerator if it is likely to adversely affect a threatened or endangered species listed under section 4 of the Endangered Species Act or its designated critical habitat.

§ 503.46 Frequency of monitoring.

(a) *Sewage sludge.*

(1) The frequency of monitoring for beryllium and mercury shall be specified by the permitting authority.

(2) The frequency of monitoring for arsenic, cadmium, chromium, lead, and nickel in sewage sludge fed to a sewage sludge incinerator shall be the frequency in Table 1 of § 503.46.

TABLE 1 OF § 503.46.—FREQUENCY OF MONITORING—INCINERATION

Amount of sewage sludge[1] (metric tons per 365 day period)	Frequency
Greater than zero but less than 290.	Once per year.
Equal to or greater than 290 but less than 1,500.	Once per quarter (four times per year).
Equal to or greater than 1,500 but less than 15,000.	Once per 60 days (six times per year).
Equal to or greater than 15,000	Once per month (12 times per year).

[1] Amount of sewage sludge fired in a sewage sludge incinerator (dry weight basis).

(3) After the sewage sludge has been monitored for two years at the frequency in Table 1 of § 503.46, the permitting authority may reduce the frequency of monitoring for arsenic, cadmium, chromium, lead, and nickel, but in no case shall the frequency of monitoring be less than once per year when sewage sludge is fired in a sewage sludge incinerator.

(b) Total hydrocarbons, oxygen concentration, information to determine moisture content, and combustion temperatures.

The total hydrocarbons concentration and oxygen concentration in the exit gas from a sewage sludge incinerator stack, the information used to measure moisture content in the exit gas, and the combustion temperatures for the sewage sludge incinerator shall be monitored continuously.

(c) Air pollution control device operating parameters.

The frequency of monitoring for the sewage sludge incinerator air pollution control device operating parameters shall be specified by the permitting authority.

(Approved by the Office of Management and Budget under control number 2040–0157)

§ 503.47 Recordkeeping.

(a) The person who fires sewage sludge in a sewage sludge incinerator shall develop the information in § 503.47(b) through § 503.47(n) and shall retain that information for five years.

(b) The concentration of lead, arsenic, cadmium, chromium, and nickel in the sewage sludge fed to the sewage sludge incinerator.

(c) The total hydrocarbons concentrations in the exit gas from the sewage sludge incinerator stack.

(d) Information that indicates the requirements in the National Emission Standard for beryllium in subpart C of 40 CFR part 61 are met.

(e) Information that indicates the requirements in the National Emission Standard for mercury in subpart E of 40 CFR part 61 are met.

(f) The combustion temperatures, including the maximum combustion temperature, for the sewage sludge incinerator.

(g) Values for the air pollution control device operating parameters.

(h) The oxygen concentration and information used to measure moisture content in the exit gas from the sewage sludge incinerator stack.

(i) The sewage sludge feed rate.

(j) The stack height for the sewage sludge incinerator.

(k) The dispersion factor for the site where the sewage sludge incinerator is located.

(l) The control efficiency for lead, arsenic, cadmium, chromium, and nickel for each sewage sludge incinerator.

(m) The risk specific concentration for chromium calculated using equation (6), if applicable.

(n) A calibration and maintenance log for the instruments used to measure the total hydrocarbons concentration and oxygen concentration in the exit gas from the sewage sludge incinerator stack, the information needed to determine moisture content in the exit gas, and the combustion temperatures

(Approved by the Office of Management and Budget under control number 2040–0157)

§ 503.48 Reporting.

Class I sludge management facilities, POTWs (as defined in 40 CFR 501.2) with a design flow rate equal to or greater than one million gallons per day, and POTWs that serve a population of 10,000 people or greater shall submit the information in § 503.47(b) through § 503.47(h) to the permitting authority on February 19 of each year.

(Approved by the Office of Management and Budget under control number 2040–0157)

Appendix A to Part 503—Procedure to Determine the Annual Whole Sludge Application Rate for a Sewage Sludge

Section 503.13(a)(4)(ii) requires that the product of the concentration for each pollutant listed in Table 4 of § 503.13 in sewage sludge sold or given away in a bag or other container for application to the land and the annual whole sludge application rate (AWSAR) for the sewage sludge not cause the annual pollutant loading rate for the pollutant in Table 4 of § 503.13 to be exceeded. This appendix contains the procedure used to determine the AWSAR for a sewage sludge that does not cause the annual pollutant loading rates in Table 4 of § 503.13 to be exceeded.

The relationship between the annual pollutant loading rate (APLR) for a pollutant and the annual whole sludge application rate (AWSAR) for 1a sewage sludge is shown in equation (1).

$$APLR = C \times AWSAR \times 0.001 \quad (1)$$

Where:

APLR=Annual pollutant loading rate in kilograms per hectare per 365 day period.

C=Pollutant concentration in milligrams, per kilogram of total solids (dry weight basis).

AWSAR=Annual whole sludge application rate in metric tons per hectare per 365 day period (dry weight basis).

0.001=A conversion factor.

To determine the AWSAR, equation (1) is rearranged into equation (2):

$$AWSAR = \frac{APLR}{C \times 0.001} \quad (2)$$

The procedure used to determine the AWSAR for a sewage sludge is presented below:

Procedure:

1. Analyze a sample of the sewage sludge to determine the concentration for each of the pollutants listed in Table 4 of § 503.13 in the sewage sludge.

2. Using the pollutant concentrations from Step 1 and the APLRs from Table 4 of § 503.13, calculate an AWSAR for each pollutant using equation (2) above.

3. The AWSAR for the sewage sludge is the lowest AWSAR calculated in Step 2.

Appendix B to Part 503—Pathogen Treatment Processes

A. Processes to Significantly Reduce Pathogens (PSRP)

1. Aerobic digestion—Sewage sludge is agitated with air or oxygen to maintain aerobic conditions for a specific mean cell residence time at a specific temperature. Values for the mean cell residence time and temperature shall be between 40 days at 20 degrees Celsius and 60 days at 15 degrees Celsius.

2. Air drying—Sewage sludge is dried on sand beds or on paved or unpaved basins. The sewage sludge dries for a minimum of three months. During two of the three months, the ambient average daily temperature is above zero degrees Celsius.

3. Anaerobic digestion—Sewage sludge is treated in the absence of air for a specific mean cell residence time at a specific temperature. Values for the mean cell residence time and temperature shall be between 15 days at 35 to 55 degrees Celsius and 60 days at 20 degrees Celsius.

4. Composting—Using either the within-vessel, static aerated pile, or windrow composting methods, the temperature of the sewage sludge is raised to 40 degrees Celsius or higher and remains at 40 degrees Celsius or higher for five days. For four hours during the five days, the temperature in the compost pile exceeds 55 degrees Celsius.

5. Lime stabilization—Sufficient lime is added to the sewage sludge to raise the pH of the sewage sludge to 12 after two hours of contact.

B. Processes to Further Reduce Pathogens (PFRP)

1. Composting—Using either the within-vessel composting method or the static aerated pile composting method, the temperature of the sewage sludge is maintained at 55 degrees Celsius or higher for three days.

Using the windrow composting method, the temperature of the sewage sludge is maintained at 55 degrees or higher for 15 days or longer. During the period when the compost is maintained at 55 degrees or higher, there shall be a minimum of five turnings of the windrow.

2. Heat drying—Sewage sludge is dried by direct or indirect contact with hot gases to reduce the moisture content of the sewage sludge to 10 percent or lower. Either the temperature of the sewage sludge particles exceeds 80 degrees Celsius or the wet bulb temperature of the gas in contact with the sewage sludge as the sewage sludge leaves the dryer exceeds 80 degrees Celsius.

3. Heat treatment—Liquid sewage sludge is heated to a temperature of 180 degrees Celsius or higher for 30 minutes.

4. Thermophilic aerobic digestion—Liquid sewage sludge is agitated with air or oxygen to maintain aerobic conditions and the mean cell residence time of the sewage sludge is 10 days at 55 to 60 degrees Celsius.

5. Beta ray irradiation—Sewage sludge is irradiated with beta rays from an accelerator at dosages of at least 1.0 megarad at room temperature (ca. 20 degrees Celsius).

6. Gamma ray irradiation—Sewage sludge is irradiated with gamma rays from certain isotopes, such as Cobalt 60 and Cesium 137, at room temperature (ca. 20 degrees Celsius).

7. Pasteurization—The temperature of the sewage sludge is maintained at 70 degrees Celsius or higher for 30 minutes or longer.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122, 123, and 501

[FRL–4515–7]

National Pollutant Discharge Elimination System Sewage Sludge Permit Regulations; State Sludge Management Program Requirements

AGENCY: Environmental Protection Agency.

ACTION: Final rule; technical amendment.

SUMMARY: Under existing regulations that establish sewage sludge permitting and State sewage sludge program requirements, approximately 20,000 publicly owned treatment works and other treatment works treating domestic sewage are required to submit permit applications within 120 days after the promulgation of standards applicable to their sewage sludge use or disposal practice(s). The final sewage sludge use and disposal standards will be published in the **Federal Register** on or near the same date as this final rule. To facilitate the management of these applications, on May 27, 1992, EPA proposed to revise these rules to stagger the submission of permit applications. Additionally, EPA proposed to extend the time period during which the initial set of applications must be submitted from 120 days to 180 days after promulgation of the technical standards. In response to comments received on the May 27, 1992, proposal, EPA is issuing a final rule which requires permit applications in phases and extends the time period in which the initial applications are due following the publication of the final use or disposal standards.

On July 28, 1986, EPA promulgated final regulations for application requirements for facilities that discharge only non-process wastewater, which resulted in internal recodification of § 122.21. Conforming changes were not made to § 123.25(a)(4) which refers to the relevant portions of section 122. These technical corrections are being made as part of this rule.

EFFECTIVE DATE: The effective date of this final rule is March 22, 1993.