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 commonly 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	63.2	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, clover-leaf 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 dces 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-chloroanline).	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 mircroenvironments 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,