• What are wastewater sources and discharge volumes?

• Are wastewater discharges continuous or intermittent (depending on facility operations, rainfall, or other event)?

• What is the current level of treatment in place?

• One source of contaminated wastewater at PBST facilities is water that accumulates at the bottom of product tanks, known as tank bottom water. How are PBSTs currently managing this wastewater (hauled off-site for contract disposal, mixed with accumulated stormwater and treated on-site, or other means)? What determines how a PBST will dispose of its tank bottom waters? How do PBST facilities manage and treat contact stormwater?

• What is the extent of pollution prevention/recovery practices in place?

• How have EPA's stormwater regulations impacted PBST discharges?

B. EPA requests information on the industries for which the Agency states that there is incomplete data available for analysis (*i.e.*, industrial point source categories with existing effluent guidelines identified with ''(4)'' in the column titled ''Rationale'' in Tables VI–1 and industrial point source categories with no existing effluent guidelines identified with ''(3)'' in the column titled ''Rationale'' in Tables VIII–1). EPA will need to collect more information for the next biennial plan. Specifically, EPA hopes to gather the following information:

• What toxic pollutants are discharged from these industries in non-trivial amounts on an industry and per-facility basis?

• What raw material(s) or process(es) are the sources of these pollutants?

• What technologies are available (technically and economically) to control or prevent the generation and/or release of these pollutants.

C. EPA solicits comments on whether EPA used the correct evaluation factors, criteria and data sources to develop this proposed plan. Please see the record for a more detailed discussion of EPA's analysis supporting this proposal (DCN 00548, section 3.0). Also see the record for more information on how EPA's analysis differed from the analytical framework described in the draft Strategy for National Clean Water Industrial Regulations (DCN 00553, section 3.0). EPA invites comment on the appropriateness of and to suggest improvements to its approach, its identification of relevant data sources and its uses of these data.

D. EPA solicits comments on whether, and if so how, should the Agency provide EPA Regions and States with permit-based support instead of revising effluent guidelines (*e.g.*, when the vast majority of the hazard or risk is associated with one or a few facilities).

E. EPA solicits comment on how to improve its impairment analysis to better characterize and quantify relationships between industrial point sources and impaired waters.

F. EPA solicits comment on the sources of data EPA might use to document industry efforts to voluntarily reduce pollutant discharges. EPA invites commenters to provide any information they have documenting voluntary pollution reductions by any of the industry categories regulated (or potentially regulated) by effluent limitation guidelines.

G. EPA solicits comment on the methodology for grouping industries for review and prioritization and the factors and measures EPA should consider for determining if discharges are trivial.

H. Process additives in use in the steam electric power generation point source category have changed over time. Starting in the early 1990s, some power plants began converting from the use of chlorinated compounds to brominated compounds. However, many of these plants report only total residual oxidant (TRO) as part of their NPDES permit requirements. What additional data sources are available to quantify the amount and type of brominated compounds discharged from this industry?

I. EPA solicits comment on implementation issues related to existing effluent guidelines.

Dated: December 23, 2003.

G. Tracy Mehan III,

Assistant Administrator for Water.

[FR Doc. 03–32214 Filed 12–30–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7605–8]

Standards for the Use or Disposal of Sewage Sludge; Final Agency Response to the National Research Council Report on Biosolids Applied to Land and the Results of EPA's Review of Existing Sewage Sludge Regulations

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is publishing the results of its review of regulations under the Clean Water Act (CWA) governing the use and disposal of sewage sludge. The Clean Water Act requires that EPA review the sewage sludge regulations for the purpose of identifying additional toxic pollutants and promulgating regulations for such pollutants consistent with the requirements. As part of this review, EPA commissioned the National Research Council (NRC) of the National Academy of Sciences to independently review the technical basis of the chemical and microbial regulations applicable to sewage sludge that is applied to land. In July 2002, the NRC published a report entitled ''Biosolids Applied to Land: Advancing Standards and Practices'' in response to the EPA's request.

In April 2003 EPA announced and requested public comments on a preliminary strategy explaining how EPA planned to respond to the NRC report recommendations. Today, the Agency is announcing its final response, also known as the final action plan, to the NRC report. EPA is also presenting the results of its review of existing sewage sludge regulations to identify additional toxic pollutants in sewage sludge for potential future regulations. Based on a screening assessment of chemical pollutants for which EPA had adequate data (*e.g.*, human health benchmark values, and information on fate and transport in the environment), as well as concentration data in sewage sludge for those pollutants, EPA has identified 15 pollutants for possible regulation. This list constitutes the final results of EPA's current review of existing sewage sludge regulations as required by the CWA. These pollutants will undergo a more refined risk assessment and risk characterization which may lead to a notice of proposed rulemaking under the Clean Water Act. In this notice, the term ''biosolids'' is used interchangeably with ''sewage sludge,'' which is defined in the regulations and used in the statute.

ADDRESSES: The public record for this action has been established under Docket ID No. OW–2003–0006. Materials are available for public viewing at the Water Docket in the EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: Rick Stevens, U.S. Environmental Protection

Agency, Office of Water, Health and Ecological Criteria Division (4304T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. (202) 566–1135. *stevens.rick@epa.gov*.

SUPPLEMENTARY INFORMATION:

General Information

A. Interested Entities

Entities potentially interested in this notice are those who prepare sewage sludge, apply sewage sludge to land, dispose of sewage sludge in a surface disposal unit, or incinerate sewage sludge in a sewage sludge incinerator. Categories and entities include:

Category	Examples of interested entities
State/Local/Tribal Government	Publicly owned treatment works and other treatment works that treat domestic sewage, prepare sewage sludge and/or apply sewage sludge to the land, place sewage sludge in a surface disposal unit, or incinerate sewage sludge.
Federal Government	Federal Agencies with treatment works that treat domestic sewage, prepare sewage sludge and/or apply sewage sludge to the land, place sewage sludge in a surface disposal unit, or incinerate sewage sludge.
Farmers, Ranchers and Home Gardeners	Individuals who apply sewage sludge to land.
Industry	Privately-owned treatment works that treat domestic sewage, as well as persons who receive sewage sludge and change the quality of the sewage sludge before it is applied to the land, place sewage sludge in a surface disposal unit, or incinerate sewage sludge.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this action. This table lists the types of entities that EPA is now aware could potentially be interested in this action. Other types of entities not listed in the table could also be interested. To determine whether your facility is affected by this action, you should carefully examine today's notice. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under Docket ID No. OW–2003–0006. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

2. *Electronic Access*. You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section B.1. Once in the system, select ''search,'' then key in the appropriate docket identification number.

C. Abbreviations and Acronyms Used

AMSA—Association of Metropolitan Sewerage Agencies
ASTM—American Society for Testing and Materials
CDC—Centers for Disease Control and Prevention
CFR—Code of Federal Regulations
CPE—Cytopathic Effects
CWA—Clean Water Act
EMS—Environmental Management System
EPA—U.S. Environmental Protection Agency
FQPA—Food Quality Protection Act
HQ—Hazard Quotient
ICC–PCR—Integrated cell culture—polymerase chain reaction
ICMA—International City/County Management Association
IRED—Interim Reregistration Eligibility Decision
IRIS—Integrated Risk Information System
ISG—Information Sharing Group
LGEAN—Local Government Environmental Assistance Network
NBP—National Biosolids Partnership
NPDES—National Pollutant Discharge Elimination System
NODA—Notice of Data Availability
NRC—National Research Council
NSSS—National Sewage Sludge Survey
OPP—Office of Pesticide Programs
OW—Office of Water
PCBs—Polychlorinated biphenyls
PCDDs/Fs—Polychlorinated dibenzo-p-dioxins/dibenzofurans
PCR—polymerase chain reaction
PCS—Permit Compliance System
PEC—Pathogen Equivalency Committee
PFRP—Process to Further Reduce Pathogens
POTW—Publicly Owned Treatment Works
PPCPs—Pharmaceutical and Personal Care Products
PSRP—Processes to Significantly Reduce Pathogens
QA/QC—Quality Assurance/Quality Control
QMRA—Quantitative Microbial Risk Assessment
RED—Reregistration Eligibility Decision
RME—Reasonable Maximum Exposure
SOP—Standard Operating Procedure
SSI—Sewage Sludge Incinerator
TBD—Technical Background Document
UA—University of Arizona
USDA—United States Department of Agriculture
VOC—volatile organic compounds
WEF—Water Environment Federation
WERF—Water Environment Research Foundation

Table of Contents

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

In section 405 of the CWA, Congress, for the first time, set forth a comprehensive program designed to reduce potential health and environmental risks and maximize the beneficial use of sewage sludge. As amended, section 405(d) of the CWA requires EPA to establish numerical limits and management practices that protect public health and the environment from the reasonably anticipated adverse effects of chemical and microbial pollutants in sewage sludge. Section 405(e) prohibits any person from disposing of sewage sludge from publicly owned treatment works (POTWs) or other treatment works treating domestic sewage except in compliance with regulations promulgated under section 405.

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

EPA did not meet the section 405(d) timetable for promulgating the first round of regulations, and a citizen's suit was filed to require EPA to fulfill this mandate. *See Gearhart* v. *Reilly*, Civ. No. 89–6266–HO (D. Ore.). A consent decree was entered by the court in this case, establishing schedules for both rounds of sewage sludge rules. EPA promulgated the first rule (''Round One'') on February 19, 1993 (40 CFR part 503, 58 FR 9248). The consent decree required the Administrator to sign a notice proposing Round Two regulations no later than December 15, 1999, and to sign a notice taking final action on the proposal no later than December 15, 2001.

For the second round (''Round Two''), EPA identified 31 pollutants and pollutant categories not regulated in Round One that EPA was considering for regulation. In November 1995, EPA narrowed the original list of 31 pollutants to two pollutant groups for the second round rulemaking: polychlorinated dibenzo-p-dioxins/dibenzofurans (PCDDs/Fs) and dioxin-like coplanar polychlorinated biphenyls (PCBs) (USEPA, 1996).

On December 15, 1999, the Administrator signed a proposal to establish numerical limits for chlorinated dibenzo-p-dioxin, chlorinated dibenzofurans, and co-planar PCBs (''dioxins'') in sewage sludge that is applied to the land and proposed not to regulate dioxins in sewage sludge that is disposed of in a surface disposal unit or fired in a sewage sludge incinerator. 64 FR 72045 (December 23, 1999). On December 21, 2001, the Administrator gave final notice of EPA's determination that numerical standards or management practices are not warranted for dioxins in sewage sludge that is disposed of at a surface disposal unit or a sewage sludge incinerator. 66 FR 66228 (December 21, 2001). The consent decree in *Gearhart* v. *Whitman* was amended to extend the deadline for final action on the land application Round Two rulemaking from the original date of December 15, 2001, to a new date of October 17, 2003.

On June 12, 2002, EPA published a Notice of Data Availability (NODA) containing new information relating to dioxins in land-applied sewage sludge and requested public comments. 67 FR 40554. On October 17, 2003, the Administrator signed a notice for publication in the **Federal Register** announcing EPA's decision that regulation of ''dioxins'' in land-applied sewage sludge was not needed to adequately protect human health and the environment. 68 FR 61084 (October 24, 2003).

Section 405(d)(2)(C) requires EPA to biennially review existing sewage sludge regulations for the purpose of identifying and regulating additional toxic pollutants in sewage sludge to adequately protect human health and the environment from the reasonably anticipated effects of such pollutants. The Agency commissioned the NRC to independently review the technical basis of the chemical and microbial regulations governing land application to help address the human health concerns raised by the public and to fulfill the requirement for periodic reassessment of the Standards for Use or Disposal of Sewage Sludge. The NRC study took place between January 2001 and June 2002. In July 2002, the NRC published a report entitled, ''Biosolids Applied to Land: Advancing Standards and Practices'' in response to EPA's request. The NRC identified a need to update the scientific basis of part 503 and provided approximately 60 recommendations.

EPA entered into an agreement with the parties in *Gearhart* v. *Whitman*, to publish a notice in the **Federal Register** describing how the Agency intends to respond to the NRC report recommendations and to seek public comment on its planned response. EPA also agreed to review publicly available information to identify additional toxic pollutants in sewage sludge and to publish a notice and seek public comment on the results of the review. Fulfilling these commitments, EPA published a notice in the **Federal Register** on April 9, 2003 (68 FR 17379). EPA also agreed to publish its final response to the NRC recommendations and the final results of its review under section 405(d)(2)(C). Today's Notice fulfills this agreement.

II. What Requirements Are Included in the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503)?

CWA section 405(d)(2)(A) required the first round of regulation to be based on ''available information on [the] toxicity, persistence, concentration, mobility, or potential for exposure'' of toxic pollutants in sewage sludge. EPA published the Round One standards (40 CFR part 503) on February 19, 1993, establishing requirements for the final use or disposal of sewage sludge when it is: (1) Applied to the land for a beneficial purpose, including in home gardens, (2) placed in a surface disposal site, including sewage sludge-only landfills, or (3) incinerated.

For land application, EPA set numerical limits for nine metals in sewage sludge, established operational standards (described later in this notice) to reduce or eliminate pathogens in sewage sludge and to reduce vector attraction, and required management practices to restrict the application rate and placement of sewage sludge on the land. For surface disposal in sewage sludge-only units, part 503 includes numerical limits for three metals in sewage sludge, requirements for the placement and management of a surface disposal site, and operational standards

to reduce or eliminate pathogens in sewage sludge and to reduce vector attraction. For incineration in a sewage sludge incinerator (SSI), EPA establishes limits for five metal pollutants in sewage sludge fired in a SSI and adopted standards under the Clean Air Act for two additional metal pollutants. The Agency has also established performance standards for SSIs through an operational standard for total hydrocarbons or carbon monoxide emissions that controls numerous organic compounds found in the emissions of sewage sludge incinerators. Part 503 also allows disposal of sewage sludge in a municipal solid waste landfill that meets the requirements of 40 CFR part 258. In addition, the final rule requires monitoring, record keeping, and reporting. Standards apply to publicly and privately-owned treatment works that generate or treat domestic sewage sludge and to anyone who uses or disposes of sewage sludge.

The Part 503 Standards consist of seven elements designed to work together to protect human health and the environment. These elements are:

(1) General requirements,

(2) Numerical limits for certain pollutants,

(3) Management practices,

(4) Operational standards,

(5) Monitoring,

(6) Recordkeeping, and

(7) Reporting.

An example of a general requirement in the standards is the provision, applicable to all land-applied sewage sludge, for sewage sludge preparers to obtain information on the nutrient content of the sewage sludge and pass this information to land appliers so that the land appliers can comply with the requirement to apply the sewage sludge at a suitable agronomic rate. Numerical pollutant limitations for certain pollutants in land-applied sewage sludge are expressed as pollutant concentrations in sewage sludge or as cumulative or annual loading rates of pollutants applied on receiving soils. Management practices prescribe how the sewage sludge is to be placed on the land or otherwise managed in the environment. For example, one management practice prohibits the application of sewage sludge to land closer than 10 meters from waters of the United States. Operational standards are technology requirements such as process descriptions and performance requirements to reduce or eliminate pathogens from sewage sludge and to reduce vector attraction. These technology-based requirements, together with required crop harvesting restrictions and site controls, constitute the approach for the control of pathogens in sewage sludge.

Under part 503, monitoring of chemical and microbial pollutants in sewage sludge and certification of certain actions by the preparer or land applier must be performed at a frequency commensurate with the annual amount of land-applied sewage sludge. Sewage sludge preparers and land appliers must keep records of these monitoring and certification activities. Finally, sewage sludge preparers and land appliers must report this information to the permitting authority (EPA or States authorized to administer the program) at least annually.

EPA has amended part 503 several times since its initial publication in February 1993. Following promulgation of the Round One rule, several petitions were filed that challenged various aspects of the rule. In one petition, mining and chemical concerns successfully challenged the land application molybdenum limits. EPA amended the numerical standards for molybdenum to delete the cumulative loading rate, annual loading rate, and the pollutant concentration in sewage sludge to be land-applied. 59 FR 9095 (February 25, 1994). The Agency retained the ceiling concentration value for molybdenum. Also, in the same **Federal Register** notice, EPA added to the sewage sludge incinerator requirements continuous monitoring of carbon monoxide as an alternative to continuous monitoring of total hydrocarbons. In addition, the court remanded several of the land application requirements as a result of petitions for review challenging various other land application standards (*Leather Industries of America* v. *EPA*, 40 F.3d 392 (D.C. Cir. 1994)). EPA deleted all numerical standards for chromium in sewage sludge to be land-applied and adjusted the limit for selenium as a result of that decision. 60 FR 54764 (October 25, 1995). In August 1999, EPA amended part 503 to make a number of technical amendments, provide regulatory flexibility, and make the sewage sludge incinerator standards self-implementing. 64 FR 42552 (August 4, 1999).

For a detailed discussion of the part 503 rule, see *A Plain English Guide to the EPA Part 503 Biosolids Rule (1994).* A copy of the Plain English Guide is available at the EPA Web site at *http://www.epa.gov/owm/mtb/biosolids/503pe/index.htm*.

III. What Is the Purpose of Today's Notice?

In today's **Federal Register** notice, the Agency describes its final action plan to address the NRC recommendations. In addition, EPA is stating the final results of its review under section 405(d)(2)(C) of the CWA and is identifying 15 additional toxic pollutants in sewage sludge that will be further evaluated for potential regulation. As described later, EPA has considered public comments and other factors in developing its action plan and in identifying additional toxic pollutants in its review of existing regulations under section 405(d)(2)(C).

IV. What Was EPA's Charge to the National Research Council?

EPA asked the NRC to evaluate the scientific basis of EPA's current regulations and standards for chemical pollutants and microbial pollutants (pathogens) in sewage sludge that is land-applied. Specifically, EPA asked the NRC to focus on the adequacy and appropriateness of the risk assessment methods and data that the Agency used in setting regulatory requirements to protect human health. The NRC convened the Committee on Toxicants and Pathogens in Biosolids Applied to Land (''the Committee''), which conducted the evaluation and prepared a final report. The Statement of Tasks included the following:

1. Review the risk assessment methods and data used to establish concentration limits for chemical pollutants in biosolids to determine whether they are the most appropriate approaches.

2. Review the current standards for pathogen reduction or elimination in biosolids and their adequacy for protecting public health.

3. Explore whether approaches for conducting pathogen risk assessment can be integrated with those for chemical risk assessment.

The April 9, 2003, notice (68 FR 17379) contains additional details regarding EPA's charge to the NRC.

V. What Were the National Research Council's Major Findings and Recommendations Concerning Land Application of Sewage Sludge?

The NRC Committee concluded that ''There is no documented scientific evidence that the part 503 rule has failed to protect human health. However, additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to [sewage sludge].'' The Committee recognized that land application of sewage sludge is a widely used, practical option for managing the large volume of sewage sludge generated at waste water treatment plants that otherwise would

be disposed of at landfills or by incineration. The Committee also identified a need to update the scientific basis of part 503 to ensure that the current chemical and microbial standards are supported by current scientific data and risk assessment methods. They also recommended that the EPA demonstrate effective enforcement of part 503 and validate the effectiveness of sewage sludge management practices.

The NRC report contains four overarching recommendations: (1) Use improved risk assessment methods to better establish standards for chemicals and pathogens, (2) conduct a new national survey of chemicals and pathogens in biosolids, (3) establish an approach to human health investigations, and (4) increase the resources devoted to EPA's biosolids program. These four overarching recommendations are discussed in detail and supplemented by around 56 individual recommendations contained in Chapters 2–6 of the NRC report. The April 9, 2003 notice (68 FR 17379) contains additional details regarding these findings.

VI. What Process Did EPA Use To Address the NRC Recommendations?

The April 9, 2003, **Federal Register** notice (68 FR 17379) contains details concerning this process. To summarize, upon release of the NRC report, EPA established a committee to respond to the recommendations in the report. The committee includes EPA representatives from a cross-section of offices that are involved or interested in the sewage sludge program. The committee identified and prioritized each NRC recommendation, and developed a preliminary strategy to carry out the activities identified in response to the NRC recommendations. In section VII of the April 9, 2003, **Federal Register** notice (68 FR 17384), EPA presented its preliminary strategy for responding to the NRC recommendations. The section presented three main objectives for attaining a better understanding of sewage sludge and reducing the potential for, or reducing the uncertainty related to, human health impact: (1) Update the scientific basis of part 503 by conducting research in priority areas, (2) strengthen the biosolids program by evaluating results of completed, ongoing, or planned studies both within and outside EPA, and (3) continue ongoing activities for enhancing communications with outside associations and with the public.

EPA then presented responses to the NRC recommendations and a planned strategy by specific categories: (1) Survey; (2) exposure; (3) risk assessment; (4) methods development; (5) pathogens; (6) human health studies; (7) regulatory activities; and (8) biosolids management *See* section VIII of the April 9 notice, 68 FR 17384–17393.

The format of today's notice differs from the April 9, 2003, notice. In today's notice, EPA is presenting a final action plan that includes specific projects that are an outgrowth of the categories presented in the April 9, 2003, notice, in response to many comments that the Agency was too vague in its presentation of preliminary strategies. EPA weighed several factors in determining its final action plan: (1) Major concerns presented in public comments received on the April 9, 2003, notice; (2) the findings of the Water Environment Research Foundation (WERF) Research Summit in July 2003; (3) EPA's existing research commitments in response to areas in the NRC report; and (4) feasibility of responding to specific areas given available resources.

VII. EPA's Final Action Plan To Address NRC Recommendations

A. Background

On April 9, 2003, EPA published a preliminary strategy in the **Federal Register** (68 FR 17379) to prioritize projects to respond to the NRC recommendations and to add value to the Agency's sewage sludge program. The notice summarized the NRC recommendations by category and presented EPA's evaluation of the recommendations and planned responses, and requested public comments. EPA received nearly 100 comments from States, citizens, the sewage treatment and land application industries, environmental groups, and academia. Comments ranged from support for Agency commitments and its preliminary response strategy to seeking a complete overhaul of EPA's sewage sludge program as well as for EPA to implement all of the NRC's recommendations. All comments and the Agency responses are included in the docket in a separate *Response to Public Comments Document* (USEPA, 2003d).

In the time since the NRC issued its report in 2002, EPA has taken steps to enhance its research program to improve the sewage sludge program and to begin implementing recommendations by the NRC. Much of EPA's research complements work being done by others outside the Agency, such as the research projects and the research issues identified at the July 2003 Biosolids Research Summit sponsored by the Water Environment Research Foundation (WERF). EPA plans to participate in and/or use, as appropriate, outside research, in conjunction with EPA-specific research, in order to make the most of the Agency's limited resources and to enhance the part 503 program. EPA's research program includes projects that will be initiated or completed in the near term (*i.e.*, through 2005).

The Agency does not have sufficient resources to implement all of the NRC recommendations, but we do agree that certain projects can help reduce the persistent uncertainty related to exposure to sewage sludge. EPA plans to review and evaluate completed research projects, both inside and outside EPA, as well as complete or begin other projects, to improve the basis for conducting risk assessments and upgrading the basis for the part 503 regulations or improving management practices. Therefore, EPA has developed this final action plan in response to the NRC recommendations with consideration of public comments on the April 9, 2003, preliminary strategy, information gathered from broad stakeholder input received through the WERF Research Summit, and Agency priorities and resource availability. This final action plan is based on fiscal year (FY) 2004 estimated resources. For planning purposes, the Agency has assumed the same level of funding (*i.e.*, at the estimated FY 2004 level) for future years; however, EPA recognizes that funding for FY 2005 and thereafter is subject to final appropriations.

There are two projects in the Agency's preliminary strategy (68 FR 17379), re-evaluation of the risk assessment used for pollutants regulated or evaluated in Round One and a molecular pathogen tracking exposure study, that EPA has decided not to do given all ongoing studies presented in this action plan, changing priorities, and limited resources. In addition, the latter project was intended to focus on individuals who have received medical attention and who suspect that they have been affected by sewage sludge application practices to potentially isolate causative agents. The Agency believes that such a study may still have merit, but in order to respond to reported incidences of human illnesses and adverse health effects alleged to have been caused by land application of sewage sludge, EPA believes that it should include various stakeholders who have had experiences with incidences related to sewage sludge, stakeholders who may be interested in participating, and those

who have the expertise and should take part in helping to develop such a program. For this reason, EPA will participate in an incident tracking workshop to bring these stakeholders together and determine the next steps. See Project 6 later in this notice.

B. Near-Term Projects (FY 2004 through FY 2005)

The Agency expects to complete or begin the following activities, presented in this notice as ''projects,'' within the next two to three years, with the goal of strengthening the sewage sludge use and disposal program. The sewage sludge program encompasses regulatory and non-regulatory components, as described in these projects.

Project 1: Biennial Review Under CWA Section 405(d)(2)(C)

As described above, the CWA requires EPA to review existing sewage sludge regulations at least every two years for the purpose of identifying additional pollutants for possible regulation under the CWA section 405(d)(2)(C).

This project relates to Category G, Regulatory Activities, in the April 9, 2003, notice. See 68 FR 17390. It also relates to major short-term and major long-term goals of continuing program implementation outlined in that notice. For the current biennial review, EPA has assessed available data on chemical pollutants that have been detected in sewage sludge and that have not been regulated or previously assessed in Rounds One and Two. EPA collected and conducted a preliminary review of publicly available information on chemical toxicity, environmental properties (*e.g.*, mobility and persistence), and concentration; identified chemical pollutants for which appropriate analytical methods and human health benchmarks are available; made preliminary determinations regarding sufficiency of information; and conducted an exposure and hazard-based screening assessment. Details are presented in Sections VIII through X of this notice.

In addition to any regulatory amendments that EPA may propose as a result of the current review, EPA is planning to assess the need and appropriate levels for new numerical limitations for molybdenum in land-applied sewage sludge. See Project 13 later in this notice.

Subsequent reviews will be conducted every two years as required by the CWA. EPA will review any new peer-reviewed research and other relevant information to determine whether to identify any additional toxic pollutants for regulatory consideration. This biennial review process may also be useful for identifying toxic pollutants that may warrant further research.

Project 2: Compliance Assistance and Enforcement Actions

As indicated in the Agency's preliminary strategy of April 9, 2003 (*see* 69 FR 17391), and this final action plan, EPA will continue to provide compliance assistance to individuals, municipalities, or other entities on matters pertaining to sewage sludge use and disposal and will take enforcement actions, as appropriate. This project relates to Category H, Biosolids Management Activities, in the April 9, 2003, notice. *See* 68 FR 17391.

EPA has maintained an active presence in biosolids compliance and enforcement activities. EPA's enforcement and compliance activities are tracked in the Integrated Compliance Information System (ICIS) and Permit Compliance System (PCS) databases. Specifically, the ICIS database documents the following Federal enforcement actions taken to address biosolids: 391 administrative orders for FY 1995–2002, 119 administrative penalty orders for FY 1995–2002, and one civil judicial action in FY 1997. The PCS database documents 382 regional and state biosolids inspections for FY 2000–2002.

Furthermore, EPA Regions and States have the responsibility to address situations where compliance assistance and enforcement actions to address biosolids are appropriate and necessary. Regional responsibilities for the biosolids program include actively following up on phone calls and complaints received from the public, and, where appropriate as demonstrated by the data, initiating Agency enforcement actions. EPA has taken enforcement actions and/or appropriate administrative remedies to address biosolids violations of 40 CFR part 503 and will continue to take such actions, including instances where biosolids pose an imminent and substantial endangerment to human health or the environment.

To assist the States and Regions in their oversight of the biosolids program, EPA has, either in place or in development, tools to assist and promote compliance with biosolids regulatory requirements. The National Pollutant Discharge Elimination System (NPDES) Compliance Inspection Manual, which is used by EPA and State inspectors to perform inspections in the field, includes a ''Sludge (Biosolids)'' chapter. EPA is currently revising and updating the manual, which is expected to be complete in 2004. The Clean Water Act/NPDES Computer Based Inspector Training CD-ROM, including a module specific to biosolids inspections, was finalized in August 2003. EPA plans to make both of these tools available on the EPA Web site.

Additionally, there are two compliance assistance Web sites, which are available for biosolids compliance studies, information and tools, and for links to other sites with pertinent biosolids compliance information. One is the National Environmental Compliance Assistance Clearinghouse at: *http://cfpub.epa.gov/clearinghouse/*. This site is a searchable clearinghouse of compliance assistance materials. The second Web site is the Local Government Environmental Assistance Network (LGEAN) at *http://www.lgean.net.* This online compliance assistance center, which focuses on local government environmental requirements, is operated by the International City/County Management Association (ICMA), and has six other partners representing local government.

EPA is also working to improve its data reporting and management system that supports compliance oversight. EPA is continuing to work with States as it modernizes the Permit Compliance System (PCS) to allow for more effective program oversight. As part of the PCS modernization, a separate workgroup (including States and EPA) was devoted to the data needed to manage the biosolids program. Based upon the recommendations of this workgroup, the PCS Executive Council decided to add data elements to PCS to improve tracking and oversight of the biosolids program, and the draft detailed design was distributed for review. The detailed design document was finalized in September 2003, which served as the basis for the software development. The anticipated implementation date for the modernized PCS is December 2005, provided adequate funding is committed to this project.

The land application of sewage sludge in compliance with EPA's regulations is an appropriate choice for communities. The NRC concluded that ''There is no documented scientific evidence that the part 503 rule has failed to protect human health. However, additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids.'' Thus, EPA has directed its water enforcement and compliance resources to focus on risks posed by wet weather issues and untreated pollutants, including raw sewage and wastes associated with storm water, sanitary sewer overflows, combined sewer

overflows, and concentrated animal feeding operations. Both agriculture and urban runoff/storm sewers are listed in the top four sources of impaired river miles in the 2000 National Water Quality Inventory Report to Congress (section 305(b) report). Given the complexity and magnitude of addressing potential human exposures to pathogens and chemicals from untreated human and animal wastes from wet weather and the present scientific knowledge of the relative risks associated with biosolids, there is an appropriate level of resources allocated to biosolids compliance and enforcement activities.

Project 3: Methods Development, Optimization, and Validation for Microbial Pollutants in Sewage Sludge

EPA's sewage sludge regulations are designed to protect human health and the environment by requiring treatment of sewage sludge to reduce or eliminate pathogens (also referred to as microbial pollutants) when land-applied (40 CFR part 503, subpart D). The regulations require that land-applied sewage sludge meet either Class A or Class B requirements to treat sewage sludge using one of various treatment processes. There are six alternative methods, one of which must be met to be classified as Class A sewage sludge. In addition, in order to be classified as Class A sewage sludge, the pathogen reduction treatment must occur prior to or in conjunction with vector attraction reduction measures, except for vector attraction reduction by alkali addition or drying. To be classified as Class B sewage sludge, one of three alternative treatment methods must be met. Because these three Class B treatment methods do not reduce pathogens to the same extent as the Class A methods, Class B sewage sludge is also subject to site restrictions, such as restrictions on crop harvesting, animal grazing and public access.

EPA recently published a document entitled *Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge* (USEPA, 2003e). This document provides information concerning federal requirements under subpart D of part 503, a description of different treatment processes, vector attraction reduction issues, sampling and analysis protocols for pathogens, the process for applying for equivalency, and the kind of support EPA's Pathogen Equivalency Committee (PEC) can provide to permitting authorities. This publication not only serves to assist the user community and to link researchers with their clients, but also has been produced as part of the Agency's strategic long-term research plan for preventing and reducing risks from pollution that threaten human health and the environment.

The NRC recommended that EPA undertake a new national sewage sludge survey to look for pathogens in sewage sludge. In addition, the NRC report identified standardization and validation of methods for detection and enumeration of indicator organisms and specific pathogens as essential for oversight and compliance testing. Raw sewage, anaerobically and aerobically digested sewage sludge, and wastewater are known to contain numerous residual microorganisms that can cause disease in humans and animals. These include viruses, bacteria, protozoans and helminth ova. As described in the April 9, 2003, notice, EPA agrees that pathogens deserve further attention, and the Agency had sponsored a workshop in 2001 and initiated a number of studies (*see* Project 11). Pathogen projects relate back to Category D, Methods Development, and Category E, Pathogens, in the April 9, 2003, FR notice. See 68 FR 17388.

Several commenters stated that there is an urgent need for EPA to develop and validate methods for detection and enumeration of bacteria and viruses in sewage sludge, soil, water and air. EPA agrees and recognizes that reliable analytical methods are critical to measuring pathogens in sewage sludge, whether ''raw'' or ''finished.'' Therefore, one of the Agency's priority microbial agent research areas is the development or improvement of analytical methodology. The following sections describe the available methods for helminth ova, viruses, and bacteria, each of which are in need of improvement to increase analytical specificity, sensitivity, and accuracy.

It was also suggested that EPA propose a vigorous study program to determine whether or not Class B sludge site restrictions are protective against infectious diseases. The greatest number of pathogen-related comments were directed to the issue of EPA's response regarding risk assessment, treatment efficacy, and site-specific restrictions for both Class A and B Sewage sludge. Some recommended the sewage sludge industry be involved in study efforts because of their experience in the area, while others recommended against industry involvement because of their potential bias. EPA plans to improve the methods and procedures for determining the effectiveness of these pathogen reduction or elimination treatment processes.

In addition to developing and improving the microbial analytical methods described below, WERF and EPA are funding research termed quantitative microbial risk assessment (QMRA), as described in ''A Dynamic Model to Assess Microbial Health Risks Associated with Beneficial Uses of Biosolids' (WERF, 2003). *See* Project 8 later in this notice for a description of the QMRA project.

Project 3a: Optimization of the Method for Detecting, Enumerating, and Determining the Viability of Ascaris Ova in Sewage Sludge

The goal of this project is to optimize the helminth ova method for the detection in the various sewage sludge matrices in order to assess the effectiveness of treatment practices meant to inactivate ova. The helminth (*Ascaris*) ova assay described in *Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge* (USEPA, 2003e) has been used a number of times, it is time consuming, and it has never been fully optimized and validated for the various sewage sludge matrices.

The first stage will optimize the assay for various sewage sludge matrices. The next stage will be a single laboratory validation followed by multi-laboratory validation of the assay. We anticipate that this research will be conducted over the next three years. Products include publication of one or more scientific papers characterizing the *Ascaris* ova assay for the various sewage sludge matrices and a standard operating procedure (SOP) detailing the optimal method for laboratory validation studies by 2007.

Project 3b: Improved Methods for Detecting Viruses in Sewage Sludge

EPA will develop improved virus detection methods for evaluating treatment technology efficacy. Some members of EPA's PEC, an ongoing committee charged with making recommendations on the adequacy of new sewage sludge treatment processes, and the NRC have questioned the reliability of existing virus methods for analysis of sewage sludge matrices. The PEC has recommended research that would improve the reliability of available analytical methods.

40 CFR 503.8(b) specifies methods that must be used when analyzing for various pathogens. The publication *Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge* (USEPA, 2003e) lists the required pathogen methods, along with complete references for these methods. The appropriate method to test for enteric

viruses when monitoring is required, according to this publication, is the American Society of Testing and Materials (ASTM) Method D4994–89. Although Method D4994–89 was validated in a multi-laboratory study, the Method achieves only partial recovery of virus from sewage sludge and laboratories are sometimes allowed to use their own standard virus plaque assays. This results in wide variations in virus levels and types recovered from various sewage sludge samples, calling into question the utility of the method. Furthermore, Method D4994–89 is labor intensive, making it difficult for many laboratories to undertake.

Several groups have proposed simpler methods which may yield higher virus recoveries than Method D4994–89. However, limited data are available to evaluate these methods. EPA supports the concept of performance-based methods, and the PEC would accept data from simpler methods, if shown to be at least as effective as Method D4994–89. Therefore, the Agency has developed a research plan to improve analytical methods for viruses and anticipates this work to be completed in 2005. The goal is to have improved methods with higher sensitivity, specificity, and accuracy for detecting viruses in sewage sludge. One objective in this plan is to demonstrate whether other methods are comparable to Method D4994–89. Methods will be compared for their ability to recover viruses that are naturally present in sewage sludge in addition to their ability to recover seeded viruses.

The plaque assay was used for virus detection in the initial round-robin testing of Method D4994–89. This quantitative assay relies upon the development of virus-induced plaques within cell culture monolayers. A most probable number (MPN)-based method for measuring cytopathic effect (CPE) in cell cultures may prove a more useful assay as this is reported capable of detecting viruses at 2-to 100-fold lower concentrations than plaque assays, with the higher sensitivities observed for environmental water samples.

The plaque assay and the MPN-based CPE assays are limited because it fails to detect many of the most important human enteric viral pathogens. Thus, they may provide limited data on whether viral pathogens are inactivated by sewage sludge treatment processes. A new assay has been developed that combines the advantages of cell culture (*e.g.*, detection of infectious particles only) and polymerase chain reaction (PCR) techniques for rapid detection of important human viral pathogens. The Agency will evaluate this integrated cell culture—PCR (ICC–PCR) assay to determine whether previously undetectable human enteric viral pathogens are present in sewage sludge.

Method validation will be accomplished by comparing Method D4994–89 using plaque, MPN, and ICC–PCR assays for seeded and unseeded sewage sludge types. EPA will develop standard operating procedures (SOP) to be further tested on a wide variety of sewage sludge types.

The final objective will be to determine the appropriate virus type to use in seeding viruses in sewage sludge. Utilizing the method described in the SOP, virus recoveries will be compared using a range of virus types, including poliovirus, coxsackievirus, echovirus, and others to be determined. If possible, the Agency will determine recoveries before and after a sewage sludge treatment process. It is estimated that this project will take two years. Products include publication of scientific papers describing the method comparisons and a SOP detailing the optimal method for validation studies.

Project 3c: Development and Validation of Analytical Methods for Fecal Coliform in Sewage Sludge

Fecal coliform bacteria are used as indicators of treatment process effectiveness in the production of Class A and Class B sewage sludge. This ongoing project identifies available methods for enumerating fecal coliforms in sewage sludge, selects the most appropriate methods, determines minimum performance characteristics that must be met, and evaluates these methods in quantifying such organisms using multiple laboratories.

EPA will use multiple laboratories to update and evaluate protocols for assaying fecal coliforms in sewage sludge using multiple tube fermentation techniques and test the method on treated sewage sludge samples using independent laboratories. Samples of Class A and B sewage sludge from full-scale wastewater treatment facilities will be assayed with and without known amounts of *Escherichia coli,* a species of fecal coliform. The Agency will compare the relative performance of individual laboratories performing such tests and develop acceptable standards. The final product, anticipated to be completed in 2005, will be a draft EPA Method 1680 entitled ''Fecal Coliforms in Treated Sewage Sludge by Multiple-Tube Fermentation Procedures.''

Project 3d: Development and Validation of Analytical Methods for *Salmonella* in Sewage Sludge

Many serovars of *Salmonellae* can cause gastroenteritis and typhoid fever. *S. enterica* serovar Typhi is the causative agent for typhoid fever. These bacteria may be used to demonstrate treatment effectiveness of Class A sewage sludge. This project will identify available methods for enumerating *Salmonella* in treated sewage sludge, select the most appropriate methods, evaluate minimal performance characteristics that must be met, and evaluate these methods in quantifying such organisms using multiple laboratories. EPA will develop and test the method on treated sewage sludge samples.

The Agency will update and evaluate protocols for assaying *Salmonella* in sewage sludge using multiple tube fermentation techniques among multiple laboratories. Samples of Class A sewage sludge from full-scale wastewater treatment facilities will be assayed with and without known amounts of *Salmonella.* EPA will compare the relative performance of individual laboratories performing such tests and develop acceptable standards. The final product, to be completed in late FY 2004, will be a draft EPA Method 1682 titled ''*Salmonella* in Sewage Sludge by Modified Semisolid Rappaport-Vassiliadis (MSRV) Medium.''

Project 4: Field Studies of Application of Treated Sewage Sludge

EPA will initiate field studies to evaluate management techniques for treated sewage sludge in order to determine whether the pathogen and chemical requirements of part 503 are being met. These studies, that relate to certain categories discussed in the Agency's preliminary strategy of April 9, 2003, notice (68 FR 17385–17386, 17388–17390), will measure selected indicators of microbial, chemical, and particulate emissions from sewage sludge land application sites and will study the fate of contaminants in the soil to which biosolids are applied. Data resulting from these studies may also be appropriate for inclusion in future risk assessments of biosolids application scenarios.

EPA plans to work with State, Regional, USDA, and other partners to conduct field studies of land application practices at up to five sewage sludge land application sites. Field sampling at actual application sites will involve a variety of media and methods to characterize airborne and soil-bound

contaminants resulting from land application of sewage sludge. Depending on resources, items that will be investigated include, but are not limited to: (1) Quantification of aerosol components such as pathogens, endotoxins, particulate matter, odor compounds, and volatile organic compounds (VOCs); (2) quantification of sewage sludge components such as pathogens and metals, and (3) effects of these components on the soil to which the sewage sludge is applied. Quality Assurance (QA) and specific research plans are being developed. EPA plans to initiate peer review on this research plan in 2004 and field work will not begin until the plan has been peer reviewed. The Agency plans to complete the study and draft a report two years after the QA plan has been approved.

Project 5: Targeted National Survey of Pollutants in Sewage Sludge

As EPA described in the April 9, 2003, **Federal Register** notice, EPA has concluded that undertaking a targeted survey is at present more useful than conducting a comprehensive survey modeled on the 1988–89 National Sewage Sludge Survey (NSSS) (68 FR 17385). Some commenters liked the targeted survey approach, but most commenters requested that EPA consider another national full-scale survey and made suggestions as to which pollutants should be included, or excluded, from such a survey.

Pending results of ongoing research projects and regulatory review, EPA will design and conduct a targeted survey of select chemical pollutants. Microbial pollutants (pathogens) in sewage sludge may also be included, depending on availability of resources and adequacy of methods. A survey may provide feedback for updating the science and technology of sewage sludge applied to land, disposed of in a surface disposal unit, or incinerated. The new concentration data would be used to assess human and ecological risk of identified, unregulated pollutants found in sewage sludge and identify pollutants for potential regulation.

EPA is committed in FY 2005 to starting a limited analytical survey of chemical pollutants found in sewage sludge. EPA expects this survey to address the pollutants identified by the exposure and hazard screening assessment as presenting a potential hazard, as identified in the current section 405(d)(2)(C) biennial review. The Agency will evaluate the extent to which methodology will allow expansion of the survey scope within available resources to include additional pollutants (*e.g.*, the survey may also include metals regulated in Round One using improved methods while surveying for new metals identified as presenting a potential hazard in the current review). *See* section X of this notice for a list of these pollutants.

Furthermore, the results of current research projects may help determine the scope of a survey. The survey design and pollutants to be included in the survey may be influenced based on factors that include:

- Whether to survey pollutants that were not previously detected in sewage sludge, but where new or improved methods are available and other data may indicate a potential for hazard,
- Whether to survey pollutants with reported occurrences in sewage sludge from other countries only (*i.e.*, not studied in U.S. sewage sludge),
- Whether to include pathogens, and
- Whether to include pollutants with a high indication of potential hazard when the scientific basis of the human health benchmarks in IRIS or OPP databases for these pollutants is in the process of reassessment.

EPA will design the survey starting in FY 2005. The Agency will seek stakeholder involvement in the design and implementation of the survey.

Project 6: Participate in an Incident Tracking Workshop

One of the highest research priorities identified by the NRC and participants at the July 2003 WERF Biosolids Research Summit is the need for rapid response investigations of reported health effects potentially resulting from land application practices. EPA also received many public comments urging development of an incident tracking and response process. The Agency agrees that developing an incident tracking program is important. However, the Agency believes that it should not develop an incident monitoring program on its own, but should include various stakeholders who have had experiences with incidents related to sewage sludge, stakeholders who may be interested in participating, and those who have the expertise and should take part in helping to develop such a program.

As stated above, stakeholders who have had experiences with reported incidents related to land application of sewage sludge should be consulted. A program of incident monitoring and investigation could be modeled after an existing program. Once such organization that has experience with such incidents is the State of North Carolina (NC). The North Carolina Department of Environment and Natural Resources is responsible for environmental programs in the state, including biosolids and residuals management. One purpose of the program is to assure timely and meaningful response to perceived and actual environmental incidents. The experiences of NC and others could be helpful in developing such a program and determining the next steps.

In order to respond to reported incidents of human illnesses and adverse health effects alleged to have been caused by land application of sewage sludge, and to determine the appropriate next steps in the process, EPA believes that local and State health agencies, in addition to other Federal health agencies, such as the Center for Disease Control and Prevention (CDC), are positioned best and have the necessary expertise to respond to allegations of adverse health effects following use or disposal of sewage sludge. However, EPA is committed to participating in activities related to this issue and plans to participate in the incident tracking workshop with WERF and other stakeholders in developing the research concepts and methods, and in interpreting and summarizing results.

The first step in the process will take place when WERF assembles stakeholders in a workshop to be held in 2004. EPA will participate in the workshop, which will begin evaluating the next steps for investigating adverse human health allegations following land application of sewage sludge. Ultimately, the objective is to determine whether such reported symptoms of illness can be attributed to the land application of sewage sludge.

The Cornell Waste Management Institute (CWMI) has collected over 300 incidents over the past several years in which residents living near sites where sewage sludge has been applied have reported illness (Cornell Waste Management Institute, 2003; Harrison and Oakes, 2002). However, the CWMI states that it has not been confirmed by scientific investigation that illnesses have resulted from land application of sewage sludge. The information provided by the CWMI may be useful as stakeholders begin to plan for a workshop to address such incidents.

This process, starting with the multi-stakeholder workshop, will take place at least through FY 2005. Additional activities beyond that time frame will depend on the outcome of the workshop, work with local, State and Federal agencies, as well as other stakeholders and availability of resources. Additional activities may include participating in subsequent stakeholder meetings or workshops and

deciding on additional activities and next steps.

Project 7: Conduct Exposure Measurement Workshop

The purpose of this workshop is to identify exposure-related research priorities. This workshop is meant to compliment the objectives of the WERF workshop (*see* Project 6) or be a related follow-up activity that is structured around issues and ideas identified in the WERF workshop. Workshop discussions will focus on exposure measurement tools that researchers or health agencies can use to investigate reports of adverse human health effects from land application of sewage sludge. The discussions and tools will focus on scientific uncertainties related to: (1) Which particular sewage sludge contaminants or combinations of contaminants may be potentially responsible for disease outbreaks; (2) how affected individuals are exposed to these contaminants; (3) how sewage sludge treatment and management practices can reduce potential risks; and (4) how good analytical methods and monitoring have to be to obtain satisfactory answers. The workshop will explore such topic areas for identifying research priorities as methods development, ambient measurements (including spatial and temporal monitoring requirements), fate and transport modeling, and exposure measurements, including identifying the specific exposure routes (*e.g.*, oral and inhalation), exposure pathways (*e.g.*, eating food, drinking water), and contaminants.

Workshop participants would include representatives from EPA; other Federal, State and local agencies; academia; wastewater utilities; environmental groups; industry; and citizen groups. Participants would identify and possibly prioritize what, when, and where measurements should be taken, and how they should be taken during rapid response investigations. EPA will develop a report to summarize discussions and identify the exposure research tools needed to investigate reported incidents of exposure. Pending the results from a similar effort being sponsored by WERF and in which EPA will participate (Project 6), we expect to hold this workshop in 2004.

Project 8: Assess the Quality and Utility of Data, Tools and Methodologies to Conduct Microbial Risk Assessments on Pathogens

The NRC recommended that EPA develop risk assessment methods to apply to pathogenic risks from land application of sewage sludge. While numerical limits for chemical pollutants in sewage sludge are based on assessment of risk, EPA currently regulates pathogens in sewage sludge through technology-based operational standards. In issuing part 503 in 1993, the Agency acknowledged that it lacked essential tools and data to conduct microbial risk assessments on sewage sludge. As the NRC noted, while methods for assessing risks from pathogens have advanced since 1993, there are still obstacles with respect to available data, analytical methods, and exposure and risk assessment modeling.

EPA is working on a number of areas related to risk assessments of pathogens. There are two examples of projects that are ongoing and that will be assessed as part of this broader effort. One is a conceptual framework for assessing the risks of human disease following exposure to waterborne pathogens, as described in ''Revised Framework for Microbial Risk Assessment'' (International Life Sciences Institute, 2000). The second is a quantitative microbial risk assessment (QMRA), as described in ''A Dynamic Model to Assess Microbial Health Risks Associated with Beneficial Uses of Biosolids'' (WERF, 2003).

In the first example, the International Life Sciences Institute (ILSI), in cooperation with EPA, developed a framework that provides a useful and proven tool for conducting microbial risk assessments. The framework emphasizes the dynamic and iterative nature of the risk assessment process, and that future efforts need to be directed toward the examination of methods for estimating risk and ways to improve the estimates. Areas for further evaluating the assumptions in the framework model, described in the ILSI framework, include understanding the relationship between infection and subsequent illness, impact of critical susceptibility factors such as age and immune status, secondary transmission of diseases, and heterogeneous distributions of microorganisms and the potential changes in concentration of microorganisms in the environment.

In the second example, WERF and EPA are funding Quantitative Microbial Risk Assessment (QMRA) research. In addition to WERF and EPA, other organizations involved in this research include the University of California at Berkeley and Eisenberg, Olevieri and Associates. The document describing this research also presents a methodology for assessing exposure and risks to human health from pathogens in biosolids. The present methodology provides initial screening for a given scenario, identifies broad conditions for high and low risk situations, and estimates where more data are needed. Future work (beyond 2004) may focus on applying this methodology to more refined scenarios. Such validation activities will assist EPA in ultimately developing microbial risk assessment guidelines.

EPA will inventory and assess data, methods, and tools for risk assessment on pathogens in sewage sludge (such as the two examples discussed above as well as others) to better inform research activities in sewage sludge and microbial risk assessment. In conducting this assessment, EPA will review information gathered from others doing research on this issue, some of which was described in the April 2003 draft response (68 FR 17379). This project will start with a problem formulation step to identify the key elements in assessing pathogen risks in land-applied sewage sludge. During the second phase, EPA will develop a plan to identify the available and appropriate methods and data to perform the risk assessment defined in problem formulation. An expert panel will review the material and EPA will address panel comments in the final document. This project will serve as a vehicle to better define the deficiencies in microbial risk assessment and better identify research needs for microbial risk assessment in sewage sludge matrices. The final product in FY 2005 will be a peer-reviewed plan for future analysis.

Project 9: Support Pathogen Equivalency Committee

In its April 9, 2003, notice, EPA described the work of the Pathogen Equivalency Committee (PEC), which has been operating since 1985. Public comments mentioned the PEC Committee a number of times, and there was a generally favorable opinion of the Committee. Most commenters recommended that the PEC be fully recognized and authorized by EPA to approve new part 503 processes. Supporting comments by some agreed with both the Haas report (Haas, 2001) and the NRC conclusions that the PEC has an important mission. A few comments indicated that, if the PEC were further legitimized, it should be expanded to include industry and academic experts outside of the EPA.

EPA plans additional support for the PEC, including resources to help address the increasing number and complexity of requests for guidance regarding the regulatory requirements for reducing pathogens, as well as development of alternative treatment technologies. The NRC report affirmed

the importance of the Committee's mission to regulators and the regulated community. The states and the Office of the Inspector General have also identified the Committee's work as a high priority. Public comments also reflected a desire to see the PEC adequately supported by EPA. All stressed the need for the PEC to have the resources it needs to fulfill its mission.

EPA created the PEC in 1985 to make recommendations to EPA management on applications for Processes to Significantly Reduce Pathogens (PSRP) and Processes to Further Reduce Pathogens (PFRP) equivalency under part 257 and later part 503. The PEC also provides guidance to applicants on the data necessary to determine equivalency, and to permitting authorities and members of the regulated community on issues (*e.g.*, sampling and analysis) related to meeting subpart D (pathogen and vector attraction reduction) requirements of part 503. If the PEC recommends that a process is equivalent to PSRP or PFRP, the operating parameters and any other conditions critical to adequate pathogen reduction are specified. The PEC consists of members with expertise in bacteriology, virology, parasitology, environmental engineering, medical and veterinary sciences, statistics, and sewage sludge regulations. It includes representatives from EPA's Offices of Research and Development, Office of Water, and Regional Offices, and the Centers for Disease Control and Prevention.

Project 10: Development and Application of Analytical Methods for Detecting Pharmaceutical and Personal Care Products in Sewage Sludge

The purpose of this project is to develop and apply analytical methodologies for detecting pharmaceutical and personal care products (PPCPs) in sewage sludge. The NRC Report specifically identified PPCPs as one category of diverse compounds that has not been studied in sewage sludge and that is especially likely to be present in domestic sewage sludge. The NRC report indicated that there is a need for a new hazard assessment of sewage sludge to expand the suite of chemicals evaluated.

EPA's preliminary strategy in the April 9, 2003, notice indicated that while study emphasis is being placed on pathogens to address areas of uncertainty and public interest, selected chemicals are also being addressed to help determine significant issues and identify information gaps that remain to be addressed in these areas. *See* 68 FR 17385. Chemical pollutants in pharmaceutical and personal care products are among those that EPA intends to study.

In FY 2004 through FY 2005, chemical analysis methods developed in-house previously for PPCPs (*e.g.*, antibiotics and musks) would be adapted for sewage sludge. In FY 2006, EPA may finish methods development, convert them to 40 CFR part 136 methodology, and publish methodologies. Subsequently, the methods may be applied to a limited number of real-world samples for a pilot-scale survey of PPCPs in sewage sludge.

Project 11: Publish the Proceedings of USEPA-USDA Workshop on Emerging Infectious Disease Agents and Issues Associated with Animal Manures, Biosolids, and Other Similar By-Products

As mentioned in connection with Project 3 (Methods for Microbial Pollutants), the NRC Report called for more information on the risks of disease associated with pathogens and how to analyze for them. It also called for more information on how to better disinfect sewage sludge.

In June 2001, EPA and USDA sponsored a workshop on ''Emerging Pathogen Issues in Biosolids, Animal Manures, and Other Similar By-Products'' (USEPA in press). The workshop brought together experts in sewage sludge management and animal wastes to review the state of the science, exchange ideas on how to deal with unresolved issues and suggest areas where the scientific community should focus its efforts. Participants discussed:

- Viruses, bacteria, protozoa, prions, fungi, and helminth ova;
- Migration of pathogens to groundwater and air from recycling and treatment operations;
- Qualitative identification and detection methods for pathogens; the fate of antibiotics in animal and human wastes;
- Pathogen resistance to antibiotics; and
- Susceptibility of people with immuno-suppressed conditions to pathogens.

As stated in Category E (Pathogens) of the preliminary strategy dated April 9, 2003 (68 FR 17389), EPA will make available the information produced at this workshop on pathogens in sewage sludge and animal wastes by publishing the proceedings of the workshop. The proceedings from the workshop have been peer reviewed by national and international experts, and the report will be published in early 2004.

Project 12: Support ''Sustainable Land Application Conference''

The purpose of this conference will be to address soil reactions of constituents in treated sewage sludge, manures, and other non-hazardous wastes, and to further environmentally friendly management of wastes in a sustainable manner. This January 2004 conference in Lake Buena Vista, Florida will address soil constituents (chemicals and microorganisms) reactions with constituents in treated sewage sludge, wastewater treatment plant effluents, manures, and other non-hazardous wastes. Further, this international conference is expected to have about 300 participants discussing metals, pathogens, organics, nutrients, and the interface between science and real-world applications by:

- Reviewing fundamental and specific soil reactions of non-hazardous waste constituents (nutrients, organics, metals and pathogens);
- Improving our understanding of contaminant reactions in soils, emphasizing the commonalities of soil reactions among wastes;
- Synthesizing multi-disciplinary information and characterizing the state-of-the-science for land application (''what do we know?'');
- Identifying high-priority and critical research needs (''what do we need to know?''); and
- Promoting intra- and inter-disciplinary approaches to solving problems of sustainable waste disposal and utilization.

Papers and presentations will be both invited and volunteered. All papers will be refereed and EPA will use conference findings, as appropriate, in future refinements of part 503.

Project 13: Review Criteria for Molybdenum in Land-applied Treated Sewage Sludge

One of the NRC's recommendations was that EPA should propose molybdenum standards to replace those that EPA rescinded following a legal challenge to numerical limitations promulgated in the Round One rule. Also, some commenters believe that EPA should reassess the molybdenum standard. The preliminary strategy in the April 9, 2003, notice indicated that EPA would determine the applicability of new information as the basis for re-proposing molybdenum standards for land-applied sewage sludge. *See* 68 FR 17391. This activity is included in the Agency's final action plan, as stated below.

In 2000, EPA held a workshop to update toxicity and environmental

properties for molybdenum in sewage sludge. Based on that workshop, EPA intends to assess the need and appropriate level for a numerical standard for molybdenum in sewage sludge using a summary of workshop results and conclusions (O'Connor *et al.*, 2001), supplemented with additional data developed since 2000. EPA expects to complete this assessment in 2005.

Project 14: Improve Stakeholder Involvement and Risk Communication

The NRC recommended that stakeholders should be involved in the risk assessment process and to examine biosolids management practices to ensure that the underlying risk assessment principles are effectively translated into practice. As stated in its preliminary strategy in the April 9, 2003, notice, the Agency's policy is to involve stakeholders at various stages of policy development. The Agency intends to consider how consultation with stakeholders should be included in developing future sewage sludge risk assessments. See 68 FR 17386. EPA received many comments on its preliminary strategy of April 9, 2003, urging the Agency to involve stakeholders more widely in the many aspects of the sewage sludge program.

EPA is committed to working with stakeholders who are concerned with the application or disposal of sewage sludge (the general public, State and local agencies, and private groups). In addition, the Agency will consider how it can implement the NRC's recommendations to involve stakeholders in updating and strengthening the scientific credibility of the sewage sludge regulations.

The Agency's risk communication programs are aimed at improving public awareness of the issues and achieving pollutant exposure reductions. Embodied in all of the projects is not only a need to foster public awareness of the issues surrounding sewage sludge use and exposure, but also a recognition of the advances in problem-solving that can be achieved through collaboration and cooperation.

Through the activities and organizations described in this project, EPA will participate in improving the effectiveness of risk communication methods at national, regional, and local levels. States have their own oversight programs, some of which are quite comprehensive. There is a total of about 150 full time equivalent State employees assigned to their respective biosolids programs. Five States have been authorized by EPA to administer the part 503 program, and 15 additional States are at various stages in the authorization process. National coordination of State, regional and Headquarters biosolids programs are achieved via an annual State and Regional biosolids coordinators meeting. EPA plans to continue to work closely with State and Regional biosolids coordinators and plans to support the annual workshop for sharing the latest information about biosolids management and oversight. Other organizations and activities that are designed to promote stakeholder involvement include the following:

An *Information-Sharing Group* (ISG) has been established based upon the concepts developed in WERF studies concerning joint fact-finding research. The ISG includes concerned citizens, health scientists, municipal operators, farmer representation, biosolids managers, and input from State and Federal regulatory agencies. The ISG has been established to work jointly with about 25 scientific experts in a large cooperative study of odor, particulates, pathogens, and endotoxins in the air around biosolids and animal manure land application sites. WERF has efforts underway to expand the use of such information-sharing in various research projects.

The *National Biosolids Partnership* (NBP) is an alliance formed in 1997 with the Association of Metropolitan Sewerage Agencies (AMSA), the Water Environment Federation (WEF), and EPA. The goal of the NBP is to advance environmentally sound and accepted sewage sludge management practices through partnerships with producers, service contractors, users, regulatory agencies, universities, the farming community, and environmental organizations.

The NBP is developing a voluntary *Environmental Management System* (EMS) for sewage sludge to help wastewater agencies improve their sewage sludge management programs beyond the regulatory minimums. The EMS involves environmental improvement, public involvement, and independent third party review of the facility applying for EMS status. Fifty-three wastewater agencies in the U.S. are participating in this voluntary program. Several of these municipalities are ready or will be ready for third-party audit of their EMS programs in 2004. Participating municipalities report benefits, such as more efficient operation, reduced odors in sewage sludge, less intrusive transport of the sewage sludge to land application sites, better communication, and meaningful involvement by the public.

In order for a wastewater facility to be admitted and certified to the Partnership EMS program, it must meet five requirements established by the NBP:

1. Document responsibility for the Biosolids Value Chain-pretreatment, treatment, and all biosolids management practices;
2. Commit to 10 principles in the NBP's Code of Good Practice;
3. Meet all NBP requirements;
4. Complete a fully independent third-party audit of its EMS that has been verified by a NBP's accredited audit company; and
5. Demonstrate their commitment to continual improvements in their EMS for environmental performance, regulatory compliance, public participation, and quality biosolids management practices.

Recently, the NBP recognized the Orange County Sanitation District (OCSD) in Fountain Valley, California, as the first wastewater agency in the Nation to be admitted to the Partnership EMS for biosolids programs. The EMS certification signifies that OCSD meets the NBP's requirements for the EMS program and that it supports excellence in sewage sludge management practices, exceeds regulatory compliance obligations, and provides meaningful opportunities for public participation.

The NBP recognized the City of Los Angeles Department of Public Works as the second wastewater agency in the Nation to be admitted to the Partnership EMS for sewage sludge program. A third-party audit of the City's Biosolids EMS program led to certification on September 4, 2003. EPA continues to support the development of EMS programs for wastewater agencies and the goals of improved communication and addressing public concerns in a more timely manner.

The NBP also announced release of its 2003 *Environmental Management System for Biosolids ''Self Help'' Training Program* intended to help wastewater agencies that are interested in starting their own EMS. The Agency plans to continue supporting NBP activities and to work with municipalities to expand their use of EMS and other programs in biosolids management. Two NBP Web sites present relevant sewage sludge information: *http://www.biosolids.org* and *http://biosolids.policy.net/emsguide/manual/goodpractmanual.vtml.*

In conclusion, EPA believes these 14 projects and associated activities will strengthen the biosolids program by improving our ability to:

- Measure pollutants of interest;

- Determine the risks posed by contaminants identified as potentially hazardous;
- Bring various stakeholder groups together via a workshop to begin development of a national incidence tracking system to ultimately determine health effects following land application of sewage sludge;
- Better understand and characterize the odors, volatile chemicals, and bioaerosols that may be emitted from land application sites;
- Better understand the effectiveness of sewage sludge processes and management practices to control pathogens;
- Improve the Agency's inspection and compliance initiatives; and
- Improve stakeholders' involvement in EPA's sewage sludge program.

C. Other Projects

Projects that are longer term in nature are those that EPA anticipates will be initiated after 2005. Initiation of longer-term projects will depend on the outcome of the research projects listed in section B, results of research being conducted by others outside the Agency, and availability of sufficient resources.

In addition to EPA directed research and activities, there is also considerable relevant work being conducted by others outside the Agency in academia, other State and Federal agencies, and trade groups, among others, that will address issues raised by the NRC recommendations. For example, WERF's sewage sludge research projects include identifying emergent trends in pathogen detection, assessing microbial health risks, identifying and controlling odors, and better understanding the fate, effects, and bioavailability of metals and certain chemicals in sewage sludge after land application. Two WERF Web sites that address relevant sewage sludge information and research are *http://www.werf.org/Collection/biosolids_chart.cfm#table1* and *http://www.werf.org/press/winter03/default.cfm.*

One WERF project involves ''Biosolids Public Perception & Participation'' (WERF, In Press). The project team included members from the New England Biosolids and Residuals Association, the Northwest Biosolids Management Association, the Center for Environmental Communication, and BioCycle, as well as two review panels consisting of biosolids stakeholders and academics. The study concludes that positive public relationships with stakeholders starts by developing public participation and thus earning public trust. Building success with stakeholders involves two way communication with the public, not only through the use of brochures, fact sheets, television spots and radio talk shows, but also by having a complaint hotline, tours, open houses, door-to-door contact, and community advisory groups. The final report from this study should be available by the end of winter 2004.

The University of Arizona (UA), Department of Soil, Water and Environmental Science, investigates physical, chemical, and microbial processes that affect the quality of surface and subsurface waters. Some of the UA's research projects deal with sewage sludge land application and utilization (*e.g.*, agricultural land application and mine tailing stabilization), sewage sludge management (*e.g.*, pathogen reduction in solar drying beds), health protection (*e.g.*, fate and transport of pathogens within sewage sludge, fate of *Staphylococcus aureus* in sewage sludge and evaluation of odors from land-applied sewage sludge), and rapid response to emerging issues (*e.g.*, antibiotic-resistant bacteria and endotoxins in land-applied sewage sludge, endocrine-related effects, and fate and transport of SARS virus). In one recent study at the UA, scientists are studying *Staphylococcus aureus* in sewage sludge after it had been processed at full-scale treatment plants (Rusin *et al.*, 2003).

Much of the work being done outside of EPA, including the research described above, that relates directly to NRC recommendations is being used to improve the Agency's sewage sludge program. EPA plans to review and evaluate studies external to EPA to determine if they are useful for conducting risk assessments and improving the basis for the part 503 regulations or improving management practices. The Agency will review these studies in accordance with the Information Quality Guidelines (see ''Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency'' USEPA, 2002). These guidelines stress that information disseminated by EPA should adhere to a basic standard of quality, including objectivity, utility, and integrity.

VIII. Process To Review Part 503 Regulations Under the CWA Section 405(d)(2)(C)

As previously described, section 405(d)(2)(C) of the CWA requires that EPA review the sewage sludge regulations for the purpose of identifying additional toxic pollutants and promulgating regulations for such pollutants consistent with the requirements of section 405(d). In 1993, EPA promulgated regulations in 40 CFR part 503 setting numerical standards for certain toxic pollutants in sludge, requirements for pathogen and vector attraction reduction, and operational standards for emissions from sewage sludge incinerators.

As explained in section IV, EPA commissioned the NRC study of existing sewage sludge land application regulations to strengthen its scientific review under section 405(d)(2)(C). EPA agreed with the parties in *Gearhart* v. *Whitman* to publish a preliminary notice seeking public comment and a final notice, stating the results of its section 405(d)(2)(C) review.

In fulfilling this commitment, EPA first collected and conducted a preliminary review of publicly available information on the occurrence of chemicals in sewage sludge. This information consists of concentration data found in national and international literature sources published between 1990 and 2002 and the 1989 National Sewage Sludge Survey (NSSS); data on environmental properties such as mobility and persistence; and available human health benchmarks (HHBs). EPA compiled a list of 799 chemical pollutants for which such information was found and described this list of candidate pollutants for ongoing sewage sludge evaluation in the April 2003 **Federal Register** notice. EPA placed the full list of candidate pollutants in the docket for public review and comment (USEPA, 2003a). EPA made minor corrections to the list, which resulted in slightly revising the list from 799 candidate pollutants to 803 candidate pollutants. See Table 1 in Appendix O of the Technical Background Document (TBD) (USEPA, 2003b).

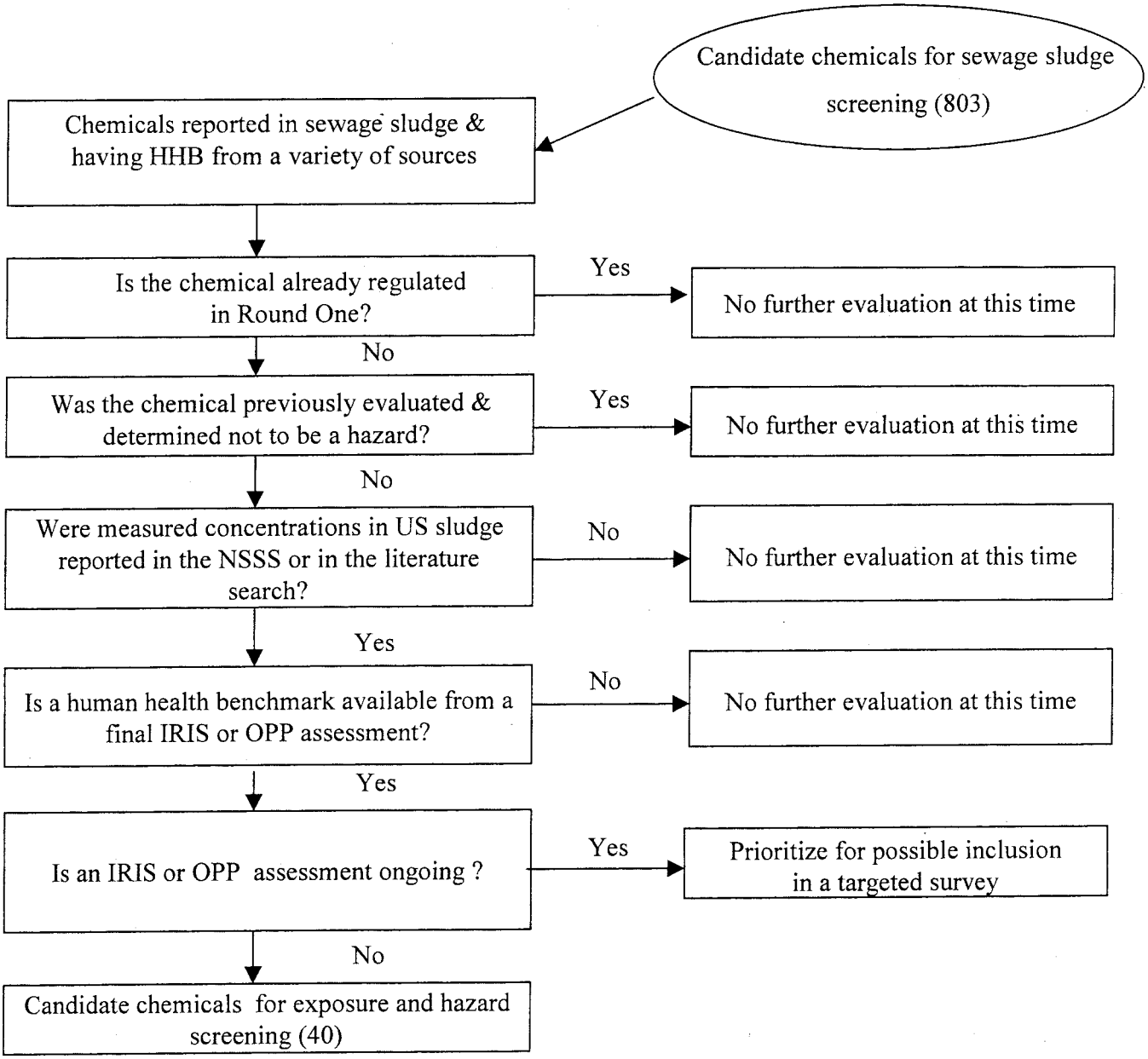
EPA then used a human health-based data evaluation and pollutant selection process to determine whether the existing data were sufficient for each of these 803 pollutants to proceed with an exposure and hazard screening assessment. This process involved identifying the pollutants for which EPA peer-reviewed final HHBs are available, and for which there are data on concentrations in U.S. sewage sludge for those pollutants with HHBs, either in the NSSS or reported in the literature.

In summary, a pollutant was selected from the list of 803 pollutants for an exposure and hazard screening assessment if it met two criteria: (1) It has measured concentrations in U.S. sewage sludge based on the literature, or it had been measured in the 1989 NSSS;

and (2) it has a HHB from one of two sources that was not undergoing reevaluation as of October 1, 2003. The sources for HHBs were EPA's Integrated Risk Information System (IRIS) health assessments and EPA's Office of Pesticide Programs (OPP) Reregistration Eligibility Decisions (REDs) or Interim Reregistration Eligibility Decisions (IREDs). Figure 1 depicts the steps involved in this process.

BILLING CODE 6560–50–P

Figure 1. Human Health-Based Pollutant Selection Process



BILLING CODE 6560–50–C

Applying this process resulted in a list of 40 pollutants that merited exposure and hazard screening. These 40 pollutants are listed in Table 1.

TABLE 1.—CANDIDATE POLLUTANTS FOR EXPOSURE AND HAZARD SCREENING

Chemical	CASRN
Acetone	67–64–1
Acetophenone	98–86–2
Anthracene	120–12–7
Azinphos methyl	86–50–0
Barium	7440–39–3
Benzoic acid	65–85–0

TABLE 1.—CANDIDATE POLLUTANTS FOR EXPOSURE AND HAZARD SCREENING—Continued

Chemical	CASRN
Beryllium	7440–41–7
Biphenyl, 1,1-	92–52–4
Butyl benzyl phthalate	85–68–7
Carbon disulfide	75–15–0
Chloroaniline, 4-	106–47–8
Chlorobenzene; Phenyl chloride	108–90–7

TABLE 1.—CANDIDATE POLLUTANTS FOR EXPOSURE AND HAZARD SCREENING—Continued

Chemical	CASRN
Chlorobenzilate	510–15–6
Chlorpyrifos	2921–88–2
Cresol, o-; 2-Methylphenol	95–48–7
Diazinon	333–41–5
Dichloroethene, 1,2-trans-	156–60–5
Dichloromethane; Methylene chloride	75–09–2
Dioxane, 1,4-	123–91–1
Endrin	72–20–8
Ethyl p-nitrophenyl phenylphosphorothioate; EPN; Santox	2104–64–5
Fluoranthene	206–44–0
Hexachlorocyclohexane, alpha-	319–84–6
Hexachlorocyclohexane, beta-	319–85–7
Isobutyl alcohol	78–83–1
Manganese	7439–96–5
Methyl ethyl ketone	78–93–3
Methyl isobutyl ketone (MIBK); Methyl-2-pentanone, 4-	108–10–1
Naled	300–76–5
Nitrate	14797–55–8
Nitrite	14797–65–0
N-Nitrosodiphenylamine	86–30–6
Phenol	108–95–2
Pyrene	129–00–0
Silver	7440–22–4
Trichlorofluoromethane	75–69–4
Trichlorophenoxy propionic acid, 2-2,4,5-; Silvex	93–72–1
Trichlorophenoxyacetic acid, 2,4,5-; 2,4,5-T	93–76–5
Trifluralin	1582–09–8
Xylenes (mixture)	1330–20–7

Data collection and evaluation, along with the results for determining sufficiency of data to proceed with an exposure and hazard screening assessment for a pollutant, are available in detail in appendix O of the TBD (USEPA, 2003b).

As described by Figure 1, EPA did not include pollutants for which the scientific basis for the HHBs is currently being reassessed. This applied to certain chemicals with HHBs in IRIS or OPP's IREDs and REDs. EPA has not included these chemicals in the list of chemicals to consider for exposure and hazard screening assessment at this time because these HHBs are critical to determining whether, and at what level, pollutants might be of potential hazard in sewage sludge. Because, under section 405(d)(2)(C), EPA is required to review the sewage sludge regulations for identification of additional toxic pollutants every two years, EPA has deferred chemicals with ongoing health assessments for a future review when the assessment is complete. EPA believes that the HHB reassessments will provide valuable information relevant to possible further regulation of sewage sludge once they are complete and that it would be premature to include these pollutants in a hazard screening process at this time.

At the same time, EPA recognizes that some of the chemical pollutants which are undergoing HHB reevaluation may be of concern in sewage sludge, and that it may be prudent to include such pollutants in the planned targeted survey (*i.e.*, section VII.B, Project 5) so that concentration values in sewage sludge may be obtained and used in future section 405(d)(2)(C) reviews. Therefore, EPA used a simple estimate of potential hazard to prioritize chemicals with ongoing health assessments for possible inclusion in the targeted survey.

The simple estimate involved calculating a theoretical hazard quotient (THQ) for each of the 20 chemicals with ongoing IRIS or OPP health assessments using existing oral human health benchmarks. The THQ is the ratio of the theoretical average daily intake (TADI), for a 1–3 year old child, one of the most highly exposed population groups on a kg body weight basis, to the oral critical dose (OCD), where the OCD (in milligrams/kilograms/day, or mg/kg/day) is the lowest of the reference dose, population adjusted dose, or dose for 10^{-5} cancer risk.[1] On this basis, a prioritization scale was established for the 20 chemicals with ongoing IRIS or OPP health assessments, which have existing oral human health benchmarks. Using this priority scale and results of the exposure screening assessment, EPA decided which chemicals to consider high priority for potential health concern and, subject to the availability of adequate budgetary resources, to include in the targeted survey to be initiated in FY 2005. These are benzo[a]pyrene, PCB congeners and Aroclors (excluding coplanar PCB congeners already included in the 2001 dioxins survey), di(2-ethylhexyl) phthalate, thallium, antimony, carbon tetrachloride and fluoride. This prioritization strategy is further described in appendix O of the Technical Background Document (USEPA, 2003b). These pollutants are not being identified at this time for purposes of further regulatory consideration as part of EPA's current review under section 405(d)(2)(C).

As mentioned above, the 40 pollutants listed as a result of the selection process depicted in Figure 1 were next analyzed through an exposure and hazard screening process. The principal objective was to evaluate whether the Agency should consider any of these as additional toxic pollutants for regulation in sewage sludge under section 405(d) of the CWA. As discussed in section X, the screening assessment identified 15 pollutants with hazard quotient (HQ) values equal to or greater than one.

IX. Hazard-Based Screening Assessment

EPA used a probabilistic hazard assessment model with appropriately conservative assumptions to analyze the 40 pollutants identified as a result of the data evaluation and pollutant selection process. This section describes the data and analyses EPA used in this screen for the 40 pollutants listed in Table 1. The two major questions addressed in this assessment were:

- Which environmental pathways are of concern?
- What is the potential hazard associated with each pollutant?

The Technical Background Document (TBD) (USEPA, 2003b) contains the rationale behind the relationships addressed and the methods, data gaps, and uncertainties associated with the data and models. The TBD also contains details about properties of sewage sludge, regional climate, soil characteristics, farm size, exposure routes and pathways, toxicity values, source models and other modeling parameters and assumptions related to the screening assessment.

A. Sewage Sludge Management Practices Modeled

The exposure and hazard screening assessment evaluated the 40 chemicals for three sewage sludge management practices:

- Disposal in sewage sludge lagoons (surface disposal units),
- Application of sewage sludge to pastureland and cropland, and
- Sewage sludge fired in a sewage sludge incinerator.

Below is a summary description of the screening scenarios and key assumptions for the three sewage sludge management practices.

1. Sewage Sludge Lagoon Scenario

The lagoon scenario was the surface disposal unit chosen for the model

[1] The NRC recommended that EPA evaluate risks based on ''reasonable maximum exposure'' (RME). Therefore, in the hazard screening assessment, EPA uses a risk level of 1E–5 to calculate the RME to a subpopulation of highly exposed individuals, rather than a 1E–6 risk level to calculate risk to the general population. A risk level of 1E–5 is consistent with setting such a risk level for, and being protective of, the RME in the sewage sludge regulations. Members of the subpopulation defined as subject to RME are farm families assumed to live on a farm and consume farm-raised foods where land-applied sewage sludge is used as fertilizer or a soil amendment and, therefore, are more highly exposed to sewage sludge than the general population.

because sewage sludge disposed in such an impoundment is likely to have the greatest potential to cause groundwater contamination of the various surface disposal configurations. For the sewage sludge lagoon scenario, EPA assumed that sewage sludge is managed in a lagoon or surface impoundment that holds the sludge for disposal. For this hazard assessment, the lagoon modeled was a non-aerated surface impoundment. Exposure to pollutants via sewage sludge in lagoons occurs through the drinking water and ambient air. We assumed that no food chain exposures occur from sewage sludge in this surface lagoon scenario because EPA has no data indicating that food is grown or raised in close proximity to surface disposal units. The surface impoundment was assumed to operate for 50 years (*i.e.*, sewage sludge is surface-disposed in the lagoon over that time period) after which it was closed. Surface impoundments were modeled based on a nationally representative sample of non-aerated, non-hazardous waste surface impoundments. See appendix A of the TBD (USEPA, 2003b).

It was assumed that these impoundments are located in a rural industrial setting where residents live within a distribution of distances relatively close to the lagoon, where they might be exposed to ambient air contaminated by sludge pollutants and where they might ingest drinking water from residential groundwater wells. These modeled residents also use their residential wells as a source of drinking water and for other household uses, such as showering. More details of the sewage sludge lagoon screening assessment are available in the TBD (USEPA 2003b).

2. Land Application Scenario

For the agricultural land application scenario, EPA assumed that sewage sludge is applied to both pastureland and cropland that are used to raise food for human consumption. The farmer was assumed to apply sewage sludge to pastureland and cropland at the appropriate agronomic rates. For this exposure and hazard screening assessment, the following assumptions were used to reflect a distribution of typical agricultural practices common throughout the United States:

- Sewage sludge is applied at a rate of 5 to 10 metric tons per hectare per application (uniform distribution).
- Applications occur once every 2 years.
- Applications are limited to a maximum of 40 years (20 applications).
- Cropland is tilled to a depth of 20 cm at application and at two additional times during the year.
- Pastureland is not tilled, but the sludge is assumed incorporated to a depth of 2 cm by bioturbidation.

Application to both row crops and pasture includes runoff into two water-bodies types. The first is an ''index reservoir'' using the Shipman City Lake in Shipman, Indiana as a model for drinking water exposures. This reservoir covers 13 acres, is 9 ft deep, and has a watershed area of 427 acres. The ratio of drainage area to capacity (volume of water in the lake) is approximately 12 for the index reservoir in this assessment. These areas remain constant in this assessment, and the same index reservoir was assumed to occur in each of the 41 climate regions. Also, in the screening assessment, it was assumed that the 427-acre watershed area contains other farms that also apply sewage sludge occupying 10 to 80 percent of the watershed in aggregate (in addition to the modeled farm).

The second water-body type is a farm pond and was used to evaluate ecological exposure, and human exposure from fish consumption. It was assumed that the pond had the farm area as its total drainage basin and to have a drainage area to capacity ratio of five. The farm pond depth is assumed to be constant at 9 feet. The area of the pond is proportional to the area of the farm. EPA also assumed that there is no buffer between the amended agricultural land and the farm pond; thus, EPA assumes that the erosion and runoff from the agricultural land go directly to the farm pond. Additional details of the screening assessment for the land application scenario are available in the TBD (USEPA 2003b).

3. Sewage Sludge Incinerator Scenario

For the sewage sludge incinerator scenario, EPA assumed that the modeled receptor resides and inhales ambient air in the shadow of a sewage sludge incinerator's emissions plume. To estimate maximum exposure to ground-level concentrations of pollutants to which the modeled individual would be exposed, we used the following parameters in exposure modeling:

- Sewage sludge feed rate (SF) in the units of dry metric tons of sewage sludge fed into the incinerator per second.
- An emission factor (EF) in the units of grams of pollutant emitted at the incinerator stack per dry metric ton of sewage sludge fed into the incinerator.
- A dispersion factor (DF) obtained by air modeling in the units of micrograms of pollutant per cubic meter of ambient air at ground level per grams of pollutant emitted at the incinerator stack per second.

Multiplication of these three factors together yields an estimated maximum ground level concentration of a pollutant in units of micrograms of pollutant per cubic meter of ambient air. Additional details of the screening assessment for the incinerator scenario are available in the incineration pathway analysis (USEPA 2003c).

B. Receptors

The exposure pathways by which humans and ecological species (*i.e.*, those humans and wildlife that are exposed to components in sewage sludge) for the three sewage sludge management practices are described in the TBD, section 1.7. In summary, families living near sewage sludge incinerators and sewage sludge lagoons, as well as farm families consuming food produced on sewage sludge-amended soil, were considered the affected populations in this exposure screening assessment. Ecological receptors were assessed for exposure to contaminated habitat, food and feed following agricultural land application of sewage sludge.

For the agricultural land application scenario, human members of the subpopulation defined as subject to reasonable maximum exposure (RME) are members of a farm family assumed to live on a farm and consume farm-raised foods where land-applied sewage sludge is used as fertilizer or a soil amendment. These individuals are more highly exposed to sewage sludge than the general population. Much of the information for the RME for the agricultural land application scenario comes from the EPA Exposure Factors Handbook, a peer-reviewed source of data for use in risk assessments (USEPA, 1997). A higher percentage of the farm family's diet consists of food grown on sewage sludge-amended soil. EPA assumed that adults and children on the farm consume fish caught from a nearby waterbody (a pond) and that the farm family also raised a significant portion of its fruit and vegetable diet on sewage sludge amended soils. In addition, the farm family is exposed through drinking water or showering in either untreated surface water from an index reservoir or groundwater from a residential well.

For the incineration scenario, EPA defined RME as exposure to a rural family living in proximity to a sewage sludge incinerator. These individuals were assumed to be exposed by direct inhalation of emissions from a sewage sludge incinerator.

For the surface disposal scenario, EPA defined RME as exposure to a rural family living near a sewage sludge lagoon. EPA assumed these individuals are exposed to constituents of sewage sludge through ingestion of groundwater from a nearby residential well and by inhalation from showering.

Affected wildlife included invertebrate and vertebrate animals that may be exposed to contaminants through land application of sewage sludge. It was assumed that the ecological receptors, both aquatic and terrestrial, are exposed in the crop and pasture and in and around a farm pond. The representative terrestrial and aquatic wildlife species were selected based on their living, feeding, and foraging habitat. We included animals that derive a significant portion of their diet from a farm, as well as those that live in or feed in and around farm ponds.

The Agency did not assess exposure pathways for wildlife in the sewage sludge lagoon scenario (as a surface disposal unit) or the incineration scenario, only the land application scenario. EPA estimates that less than one percent of the sewage sludge produced annually in the United States is disposed of in surface disposal units and approximately 17 percent is disposed of by combustion in sewage sludge incinerators. Thus, these disposal methods involve a relatively small proportion of total sewage sludge produced compared to land application of sewage sludge. In addition, surface disposal sites generally are areas with poor ecological habitat. Most of the sewage sludge produced in the U.S. goes to land application to fertilize crop or as a soil amendment. Therefore, the Agency did not assess aquatic and terrestrial wildlife exposure associated with surface disposal or incineration for this screen. We deem the land application scenario, which includes the treated agricultural crop and pasture land and farm pond, to be more representative of wildlife habitat, and thus, where ecological exposures are most likely to happen. Therefore, EPA believes that the agricultural land application scenario is a good indicator of ecological hazard.

C. Exposure Assessment Modeling

Human exposures may occur as a result of sewage sludge disposal in a lagoon or incinerator, or as the result of application of sewage sludge to agricultural land. The human exposure pathways modeled for the sewage sludge lagoon scenario are presented in Table 2. It was assumed that a resident family lives near a facility with a sewage sludge lagoon and breathes the ambient air at that location. It was also assumed that the family has a residential well that supplies tap water to the household for drinking water and showering. Ambient air exposures and the inhalation of contaminants during showering were estimated by the average daily air concentrations of vapors to which an individual might be exposed. Exposure via drinking water was estimated by multiplying the modeled concentrations of the pollutants in groundwater by the drinking water consumption rate of the individual.

TABLE 2.—HUMAN EXPOSURE PATHWAYS FOR THE SEWAGE SLUDGE LAGOON SCENARIO

Receptor	Inhalation of ambient air	Inhalation of shower air (groundwater source)	Ingestion of drinking water (groundwater source)
Adult Resident	x	x	x
Child Resident	x	x	x

In the agricultural land application scenario, more exposure routes are considered in the assessment. The exposure pathways considered for the farm family are presented in the Table 3.

TABLE 3.—HUMAN EXPOSURE PATHWAYS FOR THE AGRICULTURAL LAND APPLICATION SCENARIO

Receptor	Inhalation of ambient air	Inhalation of shower indoor air (groundwater or surface water)	Ingestion of drinking water (groundwater or index reservoir)	Ingestion of soil	Ingestion of produce	Ingestion of beef and dairy products	Ingestion of fish (farm pond)
Adult Farmer	x	x	x	x	x	x	x
Child Farm Resident	x	x	x	x	x	x	x

Although all of the ingestion pathways (ingestion of food and water) were aggregated in the exposure model to estimate total ingestion hazards to humans in this screening assessment, EPA did not aggregate the ingestion and inhalation pathways. The Agency aggregates oral and inhalation pathways under certain circumstances (*e.g.*, as required by the Food Quality Protection Act, OPP adds together the ingestion and inhalation pathways for pesticides that have similar toxicological endpoints for both pathways). For purposes of this screening assessment, a pathway providing exposure approximately three orders of magnitude lower than the predominating pathway (*i.e.*, ingestion, and in particular ingestion of drinking water) need not be aggregated. In this screening assessment for sewage sludge, exposure to humans via inhalation for the pollutants that have reference concentration (RfC) values is negligible, as shown by the results of the TBD. The inhalation HQs are several orders of magnitude lower than ingestion HQs; thus, aggregating these two pathways would not add meaningful results.[2]

For the ecological screening assessment, exposure concentrations were calculated for both direct contact and ingestion pathways. The exposure pathways assessed include direct contact with treated sewage sludge applied to agricultural land and indirect exposure through ingestion of contaminated food and soil or ingestion of, or contact with, surface water that

[2] There were no ingestion pathways considered for the sewage sludge incineration scenario.

receives runoff from a sewage sludge-amended field. Table 4 shows the affected wildlife and exposure pathways in the ecological screening assessment. It was assumed that exposure concentrations in sediment and soil were the maximum annual average modeled concentrations. For exposure through surface water contact, exposure concentrations were calculated to match benchmark exposure durations. For example, if the benchmark for aquatic organisms was derived from a toxicological study in which fish were exposed to the contaminant for 96 hours, then the 4-day (96-hour) maximum modeled concentration was selected as the exposure concentration. For chronic benchmarks intended to reflect long-term or lifetime exposure, the maximum annual concentration was used in the assessment.

TABLE 4.—EXPOSURE PATHWAYS FOR WILDLIFE SPECIES

Receptor	Direct contact	Direct contact medium	Ingestion
Fish	x	Surface water (farm pond)	
Aquatic Invertebrates	x	Surface water (farm pond)	
Aquatic Plants	x	Surface water (farm pond)	
Amphibians	x	Surface water (farm pond)	
Aquatic Community	x	Surface water (farm pond)	
Sediment Biota	x	Sediment (farm pond)	
Soil Invertebrates	x	Soil (agricultural field)	
Mammals			x
Birds			x

The exposure dose of the ingestion pathway for terrestrial and aquatic species was calculated as a function of the combination of concentrations in each receptor's diet items and receptor-specific ingestion rates, body weight, and bioconcentration factors. The dietary compositions were based on species-specific data on foraging and feeding behavior and reflected a year-round adult diet. Diet items were grouped by category, including different types of vegetation (*e.g.*, fruits, forage, grain, roots) and several types of prey (*e.g.*, small birds, small mammals, invertebrates, fish).

Each species' diet was modeled using the midpoint of dietary percentages for each diet item, beginning with the item with highest midpoint value and proceeding through the diet items until a full diet (100 percent) was accumulated. In this example, a robin's diet would consist of 50.5 percent soil invertebrates and 49.5 percent fruits.

The species-specific exposure factors (ingestion rates and body weights) were taken from EPA's Wildlife Exposure Factors Handbook (USEPA, 1993) and are presented in the Technical Background Document (USEPA, 2003b).

D. Screening Criteria Development

1. Human Health Benchmarks

As indicated in the data collection and evaluation steps, we used in the screening assessment human toxicity values (or HHBs) that are available in EPA's IRIS, RED, or IRED. These toxicity values include chronic reference doses (RfDs), chronic population adjusted doses, inhalation reference concentrations (RfCs), oral cancer slope factors, air unit risk factors, and oral doses and air concentrations at specified cancer risk levels. The HHBs used in this assessment are critical doses for ingestion pathways or critical concentrations used as an air pathway criterion. For air exposures to pollutants, the critical concentration is the lower value of the RfC or concentrations in air associated with an excess cancer risk of E–5 (1 in 100,000), based on the air unit risk factor. For ingestion, the critical dose is the lower of the RfD, population adjusted dose, or dose for an excess cancer risk of E–5, based on oral cancer slope factor over a lifetime.

2. Ecological Benchmarks

The benchmarks used for ecological hazard assessment are effects or toxicity values expressed in terms of media concentration (*e.g.*, mg/l for surface water or mg/kg for soil) for the direct contact pathway and in terms of dose (mg/kg-d) for the ingestion pathway. Because there is no single repository for EPA-approved ecological benchmarks analogous to EPA's IRIS or OPP RED and IRED documents, ecological benchmarks from EPA, other government reports, and from toxicological studies in the published literature were considered for the ecological screening assessment. General criteria for selecting ecological benchmarks, as well as a hierarchy of data sources, used in the screening assessment are included in Appendix P of the TBD (USEPA 2003b).

The ecological hazard screening assessment addresses the potential for adverse effects to terrestrial and aquatic wildlife, which EPA believes are the receptors which are anticipated to experience the highest exposure to pollutants in sewage sludge. The potential for pollutants to bioaccumulate in wildlife receptors is specifically addressed through the assessment of the ingestion pathway. The assessment includes receptors exposed through ingestion of both aquatic and terrestrial food items and thus addresses the potential for bioaccumulation of pollutants from soil, surface water, and sediment.

3. Hazard Characterization

The potential hazard to human and ecological receptors is expressed in terms of hazard quotients (HQs). An HQ equal to or greater than one indicates a potential for adverse effects to occur and the need to conduct a more detailed or refined risk assessment and risk characterization. For chemicals with a human health benchmark (HHB) for ingestion, the results of the screening assessment are a ratio of the estimated average daily dose or lifetime average daily dose to a critical dose for each pollutant. For chemicals with an HHB for inhalation, the average daily air concentration is compared with the critical concentration for these pollutants. If either of these ratios exceeds one at the 95th exposure percentile, the pollutant fails the screen.

A similar comparison is performed for ecological benchmarks. If the HQs equal or exceed one for any pollutant, that pollutant also fails the screen. For the direct exposure pathway, HQs are calculated as the ratio of the exposure concentration to the relevant toxicity value. For example, we calculate the HQ for fish as the ratio of the surface water concentration to the fish 96-hour toxicity value. For the ingestion pathway, HQs are the ratio of the exposure dose to the relevant

benchmark. The screening assessment was neither designed nor intended to provide definitive risk estimates. The assessments simply indicate the potential for adverse ecological effects to a variety of wildlife and provide information on the ongoing assessment of ecological risks associated with the agricultural application of sewage sludge. Additional details concerning the screening assessment are presented in sections 2 and 3 of the TBD.

X. Results of the Review of the Part 503 Regulations Under CWA Section 405(d)(2)(C)

Of the 40 pollutants for which EPA conducted its exposure and hazard screening assessment, 15 have hazard quotients (HQs) [3] that either exceed one for human receptors, or equal or exceed one for ecological receptors. We considered these 15 pollutants to have failed the screen, and, therefore, constitute the final results of EPA's current review under section 405(d)(2)(C) of the CWA. The details of screening results for all pollutants in this screening analysis are found in the TBD (USEPA, 2003b).

The results of the human and ecological exposure and hazard assessments contained in this section are intended to identify those pollutants that warrant further consideration for rulemaking. These results also indicate which exposure pathway or pathways should be the focus of further consideration with respect to these pollutants.

EPA expects to complete a more refined risk assessment and characterization for these 15 pollutants for purposes of determining whether, and if so for which, of these 15 pollutants EPA will propose rule amendments under section 405(d). Upon completion of additional assessments, if indicated, EPA will initiate a proposed rulemaking under section 405(d). Any proposed regulations may take the form of numerical limits, best management practices, or other controls and limitations needed to protect the environment and human health. The results of EPA's review described in today's notice (*i.e.*, the identified 15 pollutants) do not mean that EPA has concluded that these pollutants in sewage sludge adversely affect human health or the environment. Some, or perhaps even all, of these pollutants may not be present in concentrations that warrant regulation; or a refined risk assessment may indicate that there is insufficient risk to human health or the environment to warrant regulation. The results of EPA's review mean that EPA will obtain updated concentration data for these pollutants and will conduct a refined risk assessment using the new concentration data to determine whether to propose amendments to part 503 in order to regulate any of these pollutants under section 405(d) of the CWA.

A. Results of Human Health Screening Assessment

EPA performed a human health exposure and hazard screening assessment using both cancer and non-cancer endpoints. None of the chemicals with cancer end-points had HQs equal to or greater than one, or were considered to have failed the screen, for either the land application, surface disposal, or incineration scenarios. Also, no pollutant with a non-cancer endpoint failed the screen on the basis of inhalation exposure, either from incineration or indirectly from land application or surface disposal. Thus, EPA has identified no additional pollutants to consider for rulemaking for sewage sludge that is disposed of by incineration in a sewage sludge incinerator. However, as explained below, some pollutants failed the screen for non-cancer risks when screened for the land application and surface disposal scenarios. Table 5 presents the results for the pollutants that had HQs greater than one for the agricultural land application scenario, and Table 6 presents the results for the pollutants that had HQs greater than one for the sewage sludge lagoon scenario. Values are presented for pollutants at the 95th percentile exposure scenario of the HQ distribution.

TABLE 5.—HUMAN HAZARD QUOTIENT VALUES GREATER THAN ONE BY PATHWAY FOR THE AGRICULTURAL LAND APPLICATION SCENARIO AT THE 95TH PERCENTILE OF THE HQ DISTRIBUTION

CASRN	Chemical	Pathway receptor	HQ
14797–65–0	Nitrite	Ingestion of Surface Water: Child	1.1
		Total Ingestion: Child	1.3
7440–22–4	Silver	Ingestion of Milk:	
		Adult	3.8
		Child	12.0
		Total Ingestion:	
		Adult	4.0
		Child	12.3

TABLE 6.—HUMAN HAZARD QUOTIENT VALUES GREATER THAN ONE BY PATHWAY FOR THE SEWAGE SLUDGE LAGOON SCENARIO AT THE 95TH PERCENTILE OF THE HQ DISTRIBUTION

CASRN	Chemical	Pathway receptor	HQ
7440–39–3	Barium	Drinking Water from Groundwater:	
		Adult	1.5
		Child	3.5
106–47–8	4-Chloroaniline	Drinking Water from Groundwater:	
		Adult	2.7
		Child	6.4
7439–96–5	Manganese	Drinking Water from Groundwater:	
		Adult	32
		Child	76

[3] Exposure at or below the HHB values are considered protective of human health. Hence, the HQ values greater than one are considered to have failed the human health screen. Exposure at or above the ecological benchmarks or values are considered to exceed a level considered to be protective of wildlife species and the environment. Hence, the HQ values equal to or greater than one are considered to have failed the ecological screen.

TABLE 6.—HUMAN HAZARD QUOTIENT VALUES GREATER THAN ONE BY PATHWAY FOR THE SEWAGE SLUDGE LAGOON SCENARIO AT THE 95TH PERCENTILE OF THE HQ DISTRIBUTION—Continued

CASRN	Chemical	Pathway receptor	HQ
14797–55–8	Nitrate	Drinking Water from Groundwater:	
		.	
		Adult	9.2
		Child	23
14797–65–0	Nitrite	Drinking Water from Groundwater:	
		Adult	14
		Child	34

Nitrite had HQs greater than one in both the agricultural land application and sewage sludge lagoon scenarios. Silver had HQs greater than one for the agricultural land application only. Barium, manganese, and nitrate had HQs greater than one for the sewage sludge lagoon scenario only. The only organic chemical that had an HQ greater than one was 4-chloroaniline, also in the sewage sludge lagoon scenario. Complete human health screening assessment results are available in appendix Q of the TBD (USEPA, 2003b).

B. Results of Ecological Screening Assessment

The ecological screen was performed by either comparing environmental concentrations to which the ecological species are exposed to comparable ambient media benchmarks for direct contact (surface water, sediment, or soil) or by comparing exposure via ingestion (food, forage, water, and incidental ingestion of soil or sediment) to comparable ingestion benchmarks. The ecological screening was performed only for the agricultural scenario, since this was considered the higher exposure scenario. Table 7 shows the pollutants that had HQs equal to or greater than one for terrestrial wildlife via the direct contact pathways. There are no ingestion hazards for any aquatic or terrestrial wildlife species from any of the chemicals, based on the results presented in the TBD. Because there are many wildlife receptors, EPA grouped the receptors and listed only the highest HQ for each receptor group in Table 7. See appendix R of the TBD for a complete listing of HQs for each receptor group.

TABLE 7.—HAZARD QUOTIENT VALUES EQUAL TO OR GREATER THAN ONE FOR AQUATIC AND TERRESTRIAL WILDLIFE VIA DIRECT CONTACT PATHWAYS FOR THE 95TH PERCENTILE OF THE HQ DISTRIBUTION

CASRN	Chemical	Receptor [1]	HQ
67–64–1	Acetone	Sediment Biota	356.2
120–12–7	Anthracene	Sediment Biota	2.9
7440–39–3	Barium	Aquatic Community	235.7
7440–41–7	Beryllium	Aquatic Community	7.8
75–15–0	Carbon disulfide	Sediment Biota	1.9
106–47–8	4-Chloroaniline	Aquatic Invertebrates	1.3
333–41–5	Diazinon	Sediment Biota	1.1
206–44–0	Fluoranthene	Aquatic Community	10.7
		Sediment Biota	4.2
7439–96–5	Manganese	Aquatic Community	13.9
78–93–3	Methyl Ethyl Ketone	Sediment Biota	5.8
108–95–2	Phenol	Sediment Biota	102.4
129–00–0	Pyrene	Aquatic Community	41.9
		Sediment Biota	21.1
		Soil Biota	4.5
7440–22–4	Silver	Aquatic Community	246.6
		Aquatic Invertebrates	28.2
		Fish	4.8

[1] Sediment biota organisms include sediment invertebrates; aquatic community organisms include fish, aquatic invertebrates, aquatic plants, and amphibians; soil biota organisms include soil invertebrates.

Values presented in Table 7 are at the 95th exposure percentile of the HQ distribution for direct contact. The screening showed that thirteen pollutants had HQs greater than one via direct contact with surface water, sediment, or soil. These consisted of four metals and nine organic pollutants. These results indicate that a more refined risk assessment and risk characterization are warranted. Full results for all pollutants and receptors assessed are presented in appendix R of the TBD (EPA, 2003b).

C. Summary

The results of the hazard screening assessment contained in this section identify those pollutants which EPA is considering for rulemaking under section 405(d). These results also indicate which exposure pathway or pathways should be the focus of further consideration with respect to these pollutants. EPA has identified 15 pollutants in its review under section 405(d)(2)(C). The results of EPA's review do not mean that EPA has concluded that these pollutants in sewage sludge adversely affect human health or the environment. The magnitude of the hazard indices discussed previously do not indicate the absolute risk for a pollutant/pathway. The results of EPA's review mean that EPA will obtain updated concentration data and conduct a refined risk assessment using the data to determine whether to propose amendments to part

503 in order to regulate any of these pollutants under section 405(d) of the CWA.

In summary, of the 40 pollutants evaluated in the screen, 15 pollutants have HQs that either exceed one for human health or are equal to or greater than one for wildlife species (*see* Tables 5 through 8), as summarized in Table 8:

TABLE 8.—SUMMARY TABLE OF THE 15 POLLUTANTS WITH HQS THAT EITHER EXCEED ONE FOR HUMAN HEALTH OR ARE EQUAL TO OR GREATER THAN ONE FOR ECOLOGICAL RECEPTORS

Chemical	Receptor	Sewage sludge scenario		
		Agricultural land application	Surface disposal	Incinerator [1]
Acetone	Sediment biota	x		
Anthracene	Sediment biota	x		
Barium	Aquatic community	x		
	Adult		x	
	Child		x	
Beryllium	Aquatic community	x		
Carbon disulfide	Sediment biota	x		
4-Chloroaniline	Aquatic invertebrates	x		
	Adult		x	
	Child		x	
Diazinon	Sediment biota	x		
Fluoranthene	Aquatic community	x		
	Sediment biota	x		
Manganese	Aquatic community	x		
	Adult		x	
	Child		x	
Methyl ethyl ketone	Sediment biota	x		
Nitrate	Adult		x	
	Child		x	
Nitrite	Adult		x	
	Child	x	x	
Phenol	Sediment biota	x		
Pyrene	Aquatic community	x		
	Sediment biota	x		
	Soil biota	x		
Silver	Aquatic community	x		
	Aquatic invertebrates	x		
	Fish	x		
	Adult	x		
	Child	x		

[1] No chemical with cancer or non-cancer end-points failed the screening assessment from incineration. In addition, no chemical with cancer end-points failed the screening assessment by either the land application or the surface disposal scenarios.

EPA will design and conduct a targeted national survey of pollutants in sewage sludge in 2005 through 2007. The results of the survey will provide pollutant concentration values that EPA will then use in a more refined risk assessment and risk characterization. Based on the results of these refined analyses, EPA will propose as soon as practicable new regulations under section 405(d) for any pollutants which it determines may be present in sewage sludge in concentrations which may adversely affect public health or the environment.

XI. References

Cornell Waste Management Institute. 2003. *Clustering of Biosolid Land-Application Reported Health Incidents by Locality. http://cwmi.css.cornell.edu/sludge/incidents.htm* (Revised November 8, 2003).

Haas, C.N. 2001. *Assessment of the PEC Process.* Drexel University. January 2, 2001.

Harrison, E.Z. and S.R. Oakes. 2002. *Investigation of Alleged Health Incidents Associated with Land Application of Sewage Sludges.* New Solutions, Vol. 12 (4): 387–408 (2002).

International Life Sciences Institute. 2000. *Revised Framework for Microbial Risk Assessment.* An ILSI Risk Science Institute Workshop Report. Washington, DC.

NRC, 2002. *Biosolids Applied to Land; Advancing Standards and Practices*, National Research Council of the National Academies. The National Academies Press. Available online at *http://search.nap.edu/books/0309084865/html.*

O'Connor, G.A., R.B. Brobst, R.L. Chaney, et al. 2001. *A modified risk assessment to establish molybdenum standards for land application of biosolids.* J. Environ. Qual. 30:1490–1507.

Rusin, P.A., S.L. Maxwell, J.P. Brooks, et al. 2003. *Evidence for the Absence of Staphylococcus aureus in Land Applied Biosolids,* Environ. Sci. Technol. 2003, Vol. 37, No. 18, 4027–4030.

USEPA, 1994. *A Plain English Guide to the EPA Part 503 Biosolids Rule.* 190 pages. Office of Water, Office of Wastewater Management. Available online at: *http://www.epa.gov/owm/mtb/biosolids/503pe/index.htm.*

USEPA, 1996. *Technical Support Document for the Round Two Sewage Sludge Pollutants.* EPA–822–R–96–003. Office of Water. Washington, DC.

USEPA, 2000. *National Water Quality Inventory Report to Congress* (section 305(b) report).

USEPA, 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency.* EPA

260R–02–008. Office of Environmental Information. Washington, DC. October 2002. Available online at *http://www.epa.gov/oei/qualityguidelines.*

USEPA, 2003a. *Candidate Pollutants for Ongoing Sewage Sludge Evaluation.* 15 pages. Office of Water, Office of Science and Technology. Washington, DC. (EPA Docket for 68 FR 17379).

USEPA, 2003b. *Technical Background Document for the Sewage Sludge Exposure and Hazard Screening Assessment.* Office of Water. RTI Project No. 08317.001.024.005.

USEPA, 2003c. *Methodology and Results of the Screening Analysis for Pollutants Managed by Incineration.* Office of Air. Washington, DC.

USEPA, 2003d. *Responses to Public Comments Document.* Office of Water. Office of Science and Technology. Washington, DC.

USEPA, 2003e. *Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge.* EPA/625/R–92/013–2003.

WERF, 2003. *Dynamic Model to Assess Microbial Health Risks Associated with Beneficial Uses of Biosolids.* Cooperative Agreement No. CR–825237. Alexandria, VA.

WERF, In Press. *Biosolids Public Perception & Participation.* Ned Beecher, New England Biosolids & Residuals Association, Principal Investigator. Alexandria, VA.

Dated: December 23, 2003.

G. Tracy Mehan III,

Assistant Administrator, Office of Water.

[FR Doc. 03–32217 Filed 12–30–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–OW–FRL–7605–4]

Notice of Availability of Draft Aquatic Life Criteria Document for Copper and Request for Scientific Views

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and request for scientific views.

SUMMARY: This notice informs the public about the availability of a draft document containing updated aquatic life criteria for copper and requests scientific views. The Clean Water Act (CWA) requires EPA to develop and publish, and, from time to time, revise criteria for water quality that accurately reflect the latest scientific knowledge. EPA's recommended water quality criteria provide guidance for States and authorized Tribes to establish water quality standards under the CWA to protect human health and aquatic life.

DATES: EPA will accept scientific views on the draft *2003 Draft Updated of Ambient Water Quality Criteria for Copper* document on or before March 1, 2004.

ADDRESSES: Scientific views may be submitted electronically, by mail or through hand-delivery/courier. Follow the detailed instructions as provided in section I.C. of the **SUPPLEMENTARY INFORMATION** section. Electronic files may be e-mailed to: *OW-Docket@epa.gov.* Scientific views may be mailed to the Water Docket, Environmental Protection Agency, Mailecode: 4101T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, Attention Docket ID No. OW–2003–0079. Instructions for couriers and other hand delivery are provided in section I.C.3. The Agency will not accept facsimiles (faxes).

FOR FURTHER INFORMATION CONTACT: Cindy Roberts, Health and Ecological Criteria Division (4304T), U.S. EPA, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460; (202) 566–1124; *roberts.cindy@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Interested Entities

Entities potentially interested in today's notice are those that produce, use, or regulate copper. Categories and entities interested in today's notice include.

Category	Examples of interested entities
State/Local/Tribal Government.	States, Tribes and municipalities.
Industry	Mining, fabricated metal products, electric equipment.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this notice. This table lists the types of entities that EPA is now aware could potentially be interested in this notice. Other types of entities not listed in the table could also be interested.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this notice under Docket ID No. OW–2003–0079. The official public docket consists of the documents specifically referenced in this notice, any scientific views received, and other information related to this notice. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. To view these materials, we encourage you to call ahead to schedule an appointment. Every user is entitled to copy 266 pages per day before incurring a charge. The docket may charge 15 cents a page for each page over the 266-page limit plus an administrative fee of $25.00.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view the scientific views, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket, but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available