

of the complete application. To receive EPA approval, a State or Tribe must demonstrate that its program is at least as protective of human health and the environment as the Federal program, and provides for adequate enforcement (section 404(b) of TSCA, 15 U.S.C. 2684 (b)). EPA's regulations (40 CFR part 745, subpart Q) provide the detailed requirements a State or Tribal program must meet in order to obtain EPA authorization.

A State may choose to certify that its lead-based paint activities program meets the requirements for EPA authorization, by submitting a letter signed by the Governor or the Attorney General stating that the program meets the requirements of section 404(b) of TSCA. Upon submission of such certification letter, the program is deemed authorized until such time as EPA disapproves the program application or withdraws the program authorization.

In accordance with 40 CFR 745.324(d), "Program Certification," the Governor of North Dakota submitted a self-certification letter to the EPA Administrator on September 26, 2002, certifying that the State program meets the requirements contained in 40 CFR 745.324(e)(2)(i) and (e)(2)(ii). Included in the application was a letter from the Attorney General of North Dakota, certifying that the laws and regulations of the State provided adequate legal authority to administer and enforce TSCA section 402.

Notice of North Dakota's application, a solicitation for public comment regarding the application was published in the **Federal Register** of January 8, 2003 (68 FR 1059) (FRL-7282-8). As determined by EPA's review and assessment, North Dakota's application successfully demonstrated that the State's Lead-Based Paint Activities Program achieves the protectiveness and enforcement criteria, as required for Federal authorization. Furthermore, no public comments were received regarding North Dakota's application. Therefore, as of September 26, 2002, the State of North Dakota is authorized to administer and enforce the lead-based paint program under TSCA section 402.

II. Federal Overfiling

TSCA section 404(b) (15 U.S.C. 2684(b)) makes it unlawful for any person to violate, or fail or refuse to comply with, any requirement of an approved State or Tribal program. Therefore, EPA reserves the right to exercise its enforcement authority under TSCA against a violation of, or a failure or refusal to comply with, any

requirement of an authorized State or Tribal program.

III. Withdrawal of Authorization

Pursuant to TSCA section 404(c), the Administrator may withdraw a State or Tribal lead-based paint activities program authorization, after notice and opportunity for corrective action, if the program is not being administered or enforced in compliance with standards, regulations, and other requirements established under the authorization. The procedures EPA will follow for the withdrawal of an authorization are found at 40 CFR 745.324(i).

IV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before certain actions may take effect, the agency promulgating the action must submit a report, which includes a copy of the action, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this document in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

Environmental protection, Hazardous substances, Lead, Reporting and recordkeeping requirements.

Dated: March 28, 2003.

Robert E. Roberts,

Regional Administrator, Region VIII.

[FR Doc. 03-8657 Filed 4-8-03; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL -7478-7]

Standards for the Use or Disposal of Sewage Sludge; 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, with request for comment.

SUMMARY: The Environmental Protection Agency is providing notice and requesting public comment on the Agency's preliminary review of

regulations under the Clean Water Act governing the use and disposal of sewage sludge. 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 pathogen 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.

Today, the Agency is also announcing a strategy explaining how EPA plans to respond to the recommendations in the NRC report. Today's notice explains the rationale for the strategy and solicits public comments on the strategy.

In addition, EPA is announcing the preliminary results of its review of existing sewage sludge regulations under the Clean Water Act. At this time, EPA has not identified any additional toxic pollutants that warrant regulation in sewage sludge. The next step in identifying chemicals that may warrant regulation is to conduct a screening analysis of those chemicals for which adequate data and analytical methods are available and for which there is evidence that they may occur in sewage sludge. EPA plans to complete this screening analysis by January 2004. The terms "sewage sludge" and "biosolids" are used interchangeably in this notice.

DATES: EPA requests comments on all aspects of this notice. If you wish to submit comments on this action, you must do so by July 8, 2003.

ADDRESSES: Send your comments to: Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OW-2003-0006. Comments may also be submitted electronically or through hand delivery/courier. Follow the detailed instructions for providing comments in section B of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Arleen Plunkett, U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division (4304T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. (202) 566-1119. plunkett.arleen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Additional Docket Information

A. 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 are 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.

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/fedrgrstr/>.

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 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. 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. 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 A.1.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or

other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

B. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider late comments.

1. Electronically

If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification,

EPA may not be able to consider your comment.

i. EPA Dockets

Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in Docket ID No. OW-2003-0006. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. E-mail

Comments may be sent by electronic mail (e-mail) to ow-docket@epa.gov, Attention Docket ID No. OW-2003-0006. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. Disk or CD ROM

You may submit comments on a disk or CD ROM that you mail to the mailing address identified in section B.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send your comments to: Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OW-2003-0006.

3. *By Hand Delivery or Courier.* Deliver your comments to: EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC 20460, Attention Docket ID No. OW-2003-0006. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section A.1.

C. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate a potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Abbreviations and Acronyms Used

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

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

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

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

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

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

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

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

that numerical standards or management practices are not warranted for dioxins in sewage sludge that are disposed of at a surface disposal unit or incinerated in a sewage sludge incinerator. 66 FR 66228 (December 21, 2001). In that notice, EPA also announced that a final action on the proposal to amend the Standards for the Use or Disposal of Sewage Sludge for sewage sludge that is applied to the land would be published at a later date. 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 at 67 FR 40554, EPA published a Notice of Data Availability (NODA) containing new information relating to dioxins in land-applied sewage sludge and requested public comments. Currently, EPA is evaluating the public comments received on the NODA and will consider these comments in formulating a final action on dioxins in land-applied Sewage sludge by October 17, 2003.

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

As noted above, 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. These regulations established requirements for the final use and 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 biosolids-only landfills, and (3) incinerated.

For land application, Part 503 set numerical limits for nine heavy metals in sewage sludge, established operational standards (described below) 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. Regarding surface disposal, Part 503 set numerical limits for three metals in sewage sludge, established requirements for the placement and management of a surface disposal site, and established operational standards to reduce or eliminate pathogens in sewage sludge and to reduce vector attraction. For incineration in a sewage sludge incinerator (SSI), Part 503 establishes

limits for five metallic pollutants in sewage sludge fired in a SSI and adopted standards under the Clean Air Act for two additional metallic 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 in accordance with 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 six elements designed to work together to protect human health and the environment. These elements are (1) numerical limits for certain pollutants, (2) management practices, (3) operational standards, (4) monitoring, (5) record keeping, and (6) reporting.

As an example, the land application provisions require a sewage sludge preparer to gather information on the nutrient content of the sewage sludge and pass this information along to the land applier in order for the land applier to be able to apply the sewage sludge at a suitable agronomic rate. Numerical limitations for land-applied sludge are pollutant concentrations in sewage sludge or cumulative or annual loading rates, based on multi-pathway exposure analyses and risk assessments to protect public health. Management practices include requirements, such as how the sewage sludge is to be placed on the land or otherwise managed in the environment. An example is the prohibition against applying 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 reduce vector attraction. These, together with required crop harvesting restrictions and site controls, constitute the approach for the control of pathogens in sewage sludge.

Monitoring of chemicals and pathogens 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. Records must be kept of these monitoring and certification activities at the locations where the

monitoring/certifications have occurred. Finally, the larger sewage sludge preparers and land appliers must report this information to the permitting authority 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 for review were filed challenging various aspects of the rule. In one petition, several mining and chemical concerns challenged the land application molybdenum limits. EPA amended the part 503 numerical standards for molybdenum to delete the cumulative loading rate, annual loading rate, and the pollutant concentration for molybdenum in sewage sludge to be land-applied. 59 FR 9095 (February 25, 1994). The ceiling concentration value for molybdenum was retained. Also, in that **Federal Register** notice, EPA added continuous monitoring of carbon monoxide as an alternative to continuous monitoring of total hydrocarbons in the sewage sludge incinerator requirements. In another case, *Leather Industries of America v. EPA*, 40 F.3d 392 (D.C. Cir. 1994), the court remanded several of the land application requirements. As a result of that decision, EPA deleted all numerical standards for chromium in sewage sludge to be land-applied and adjusted the Table 3 limit for selenium. 60 FR 54764 (October 25, 1995). EPA is considering further amendments to address the issues remaining from the partial remand, as well as other issues. EPA most recently 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), which is available as stated in the **ADDRESSES** section of the preamble. A copy of the Plain English Guide is available at the website address <http://www.epa.gov/owm/mtb/biosolids/503pe/index.htm>.

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

Section 405(d)(2)(C) of the CWA calls on EPA to review the existing sewage sludge regulations in part 503 at least every two years for the purpose of identifying additional toxic pollutants in sewage sludge and promulgating regulations for such pollutants consistent with the requirements of section 405(d). Over the past decade, questions have been raised over the

adequacy of the chemical and pathogen standards for protecting human health. To help address the human health concerns and the requirement for periodical reassessment of the Standards for Use or Disposal of Sewage Sludge, the Agency commissioned the NRC to independently review the technical basis of the chemical and pathogen regulations. 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. For a copy of the full NRC report, visit our Web site at <http://www.epa.gov/ost/biosolids/nas/complete.pdf>. The NRC identified a need to update the scientific basis of Part 503 and provided approximately 60 recommendations.

In an agreement with the parties in *Gearhart v. Whitman*, EPA agreed to publish a notice in the **Federal Register** stating how it will respond to the NRC report recommendations and to seek public comments on its planned response. EPA also agreed to review publicly available information for the purpose of identifying additional toxic pollutants in biosolids and to publish a notice providing the results of the review and seek public comment. Today's notice fulfills this agreement.

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

EPA asked the NRC to conduct an independent evaluation of the regulations and standards for chemical pollutants and pathogens in biosolids that are land-applied. Specifically, the NRC was asked to focus on the adequacy and appropriateness of the risk assessment methods and data used by the Agency 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 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. Consider the NRC's previous (1996) review and determine whether that report's recommendations have been appropriately addressed. Consider (a) how the relevant chemical pollutants were identified, (b) whether all relevant exposure pathways were identified, (c) whether exposure analyses, particularly from indirect exposures, are realistic, (d) whether the

default assumptions used in the risk assessments are appropriate, and (e) whether the calculations used to set pollutant limits are appropriate.

2. Review the current standards for pathogen reduction or elimination in biosolids and their adequacy for protecting public health. Consider (a) whether all appropriate pathogens were considered in establishing the standards, (b) whether enough information on infectious dose and environmental persistence exists to support current control approaches for pathogens, (c) risks from exposure to pathogens found in biosolids, and (d) new approaches for assessing risks to human health from pathogens in biosolids.

3. Explore whether approaches for conducting pathogen risk assessment can be integrated with those for chemical risk assessment. If appropriate, recommend approaches for integrating pathogen and chemical risk assessments.

The NRC report, "Biosolids Applied to Land: Advancing Standards and Practices," described the work of the committee, stating that "the committee searched for evidence on human health effects related to biosolids exposure" in its review of the risk assessments and technical data used by EPA to establish the chemical and pathogen standards and the management practices contained in part 503. The report noted that "the committee did not attempt to determine whether the approaches used by EPA to set the 1993 biosolids standards were appropriate at the time of their development, and the committee's findings and recommendations should not be construed as either criticism or approval of the standards issued at that time."

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

The NRC committee concluded that "there is no documented scientific evidence to indicate that the part 503 rule has failed to protect human health," but additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids. The committee recognized that land application of biosolids is a widely used, practical option for managing the large volume of biosolids generated at waste water treatment plants that otherwise would need to be disposed of at landfills or by incineration. The committee also identified a need to update the scientific basis of part 503 to (1) ensure that the

chemical and pathogen standards are supported by current scientific data and risk assessment methods, (2) demonstrate effective enforcement of part 503, and (3) validate the effectiveness of biosolids management practices. The NRC report focused on identifying how current risk assessment practices and knowledge regarding chemical pollutants and pathogens in biosolids can be used to update and strengthen the scientific basis and credibility of EPA's biosolids regulations.

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 53 individual recommendations contained in Chapters 2-6 of the NRC report.

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

Upon the release of the report, EPA established an Intra-Agency Committee (IAC) to respond to the recommendations in the NRC report and begin review of the existing Part 503 regulations to identify additional toxic pollutants that may warrant future regulation, pursuant to section 405(d)(2)(C). The IAC is comprised of EPA representatives from a cross-section of environmental program offices that are involved or interested in the biosolids program.

The IAC first developed an approach for responding to the NRC report and conducting the section 405(d)(2)(C) review of existing regulations. Activities for responding to the NRC report included developing a matrix to identify and track each recommendation, grouping the recommendations into eight categories based on subject area, evaluating the recommendations individually and establishing priorities, drafting initial responses by category, and developing a strategy to carry out the activities identified in response to the NRC recommendations. The approach for reviewing existing regulations to identify additional toxic pollutants that may warrant regulation, pursuant to section 405(d)(2)(C), is described in Section IX of this notice.

As stated above, the IAC first prepared a matrix (Compilation of National Research Council (NRC) Recommendations on Biosolids and

EPA Responses and Activities, USEPA 2002a) of all of the recommendations contained in the NRC report (NRC 2002). The matrix ensured that all recommendations were identified. Once in the matrix, recommendations that were found to be similar in subject matter and intent were placed in a framework to facilitate evaluation.

The Agency categorized the 57 recommendations (four overarching and 53 specific) into eight categories: (1) Survey, (2) Exposure, (3) Risk Assessments, (4) Methods Development, (5) Pathogens, (6) Human Health Studies, (7) Regulatory Activities, and (8) Biosolids Management. EPA's response and planned activities are presented on a category-by-category basis.

VII. EPA's Strategy for Responding to the NRC Recommendations?

EPA has identified three main objectives for attaining a better understanding of biosolids 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 communication with outside associations and with the public.

Major Short-Term Goals and Priority Actions During FY03 and FY04

Over the next two years, subject to available resources, the Agency proposes to pursue biosolids activities in the following priority areas:

1. Continue program implementation (regulatory, compliance, and enforcement).
2. Evaluate the state-of-the-science and revise risk assessment methodologies, as appropriate.
3. Review available data, track ongoing studies by researchers outside of EPA, and identify information gaps. Initiate further field studies as needed.
4. Continue ongoing/planned activities relative to exposure, risk assessment, biosolids management, and analytical methods development.
5. Determine what pollutants, if any, warrant further regulation under the CWA.
6. Design and begin conducting a targeted survey that uses information obtained from published pollutant occurrence and effects data, State occurrence data bases, and input received during the public comment period.

7. Conduct a dialogue with other health-based Federal agencies, such as CDC, on the possibility of cooperatively tracking incident reports and investigating whether adverse human health outcomes can be associated with biosolids exposure. The results could help the Agency identify research gaps and, if appropriate, the need for a more comprehensive research plan.

These activities would be aimed at implementing NRC recommendations for reducing the potential for public health impact and updating the scientific basis of Part 503.

Major Longer-Term Goals and Future Priorities (FY05 and Beyond)

The Agency's proposed long-term biosolids activities depend on results of activities conducted in FY03/FY04 and available resources. The following priority areas are aimed at implementing recommendations for reducing the potential for public health impact:

1. Continue program implementation (regulatory, compliance, and enforcement).
2. Update the scientific basis of Part 503 by using FY03/04 research or by conducting research in priority areas.
3. Strengthen the biosolids program by incorporating results of completed, ongoing, or planned research activities both within and outside EPA to possibly include:
 - Quantitative microbial risk assessment.
 - Improved understanding of exposure pathways/scenarios.
 - Molecular tracking study.
4. Continue activities to establish partnerships and communicate more effectively with other public health-based agencies, outside associations and the public.

There is considerable relevant work being conducted by others outside of EPA that may help inform and respond to the NRC recommendations. Much of the external work that relates directly to certain NRC recommendations is discussed in this notice and is being used to improve the Agency's biosolids program.

The Agency's approach also includes promoting policy and procedural guidance for ensuring and maximizing the quality of the information disseminated. Completed studies and ongoing research, once compiled, will be reviewed and evaluated for their contribution to EPA's biosolids program in accordance with Information Quality Guidelines (expressed in "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by

the Environmental Protection Agency" USEPA 2002b). These guidelines stress that information disseminated by EPA should adhere to a basic standard of quality, including objectivity, utility, and integrity.

EPA has developed this notice using its best estimate of FY 2003 resources, which are not finalized, and based on the President's FY 2004 budget. The Agency has assumed the same level of funding for future years, as is typically done.

VIII. EPA Responses to the NRC Recommendations by Category

A. Survey

1. Summary of Survey-Related NRC Report Recommendations

The NRC recommended that the Agency conduct a new national survey of chemicals and pathogens in biosolids. A survey may provide feedback for updating the science and technology of biosolids applied to land. These data would then be used to identify pathogens and additional chemicals for potential regulation and possibly deregulate those that are not, or no longer, found. The NRC recommended several components in designing a new national survey, including collecting data from State program databases, determining the adequacy of analytical detection methods and limits to support risk assessment, evaluating chemicals eliminated previously due to lack of data (e.g., toxicity or exposure) and new chemical categories (e.g., odorants, surfactants and pharmaceuticals) not previously evaluated.

Further, the NRC recommended monitoring environmental media, surveying for pathogens in both raw sewage sludge and treated sewage sludge managed through the various processes recommended in Part 503, assessing multiple species of certain metals (e.g., mercury and arsenic) that have different toxicity profiles for human health, including infants and children, and analyzing a broad spectrum of pathogens in biosolids or environmental media adjacent to final use or disposal sites.

In addition, the NRC recommended that the Agency verify the adequacy of treatment and management practices. For example, to verify that Class A and B (as described in Part 503) treatment processes perform as assumed by engineering and design principles, EPA could determine pathogen density and elimination across treatment processes in biosolids and environmental media over time and examine management practices to ensure that risk-assessment

principles are effectively translated into practice.

2. The Agency's Response to the Survey Category

How EPA Plans To Address NRC Survey Recommendations

The Agency believes that a comprehensive survey of pollutants in biosolids may provide useful information, but it is not likely the most pragmatic survey option available at this time. EPA has developed a proposed survey approach based on experience gained from the 1988 National Sewage Sludge Survey (NSSS), limitations of available analytic methods, knowledge of effects and routes of exposure, and suggestions by the NRC, among other factors (see Planned Strategy for the Survey Category below). The 1988 NSSS was ultimately limited in utility by shortcomings in available analytical methods and limited information of pollutant effects and/or means of exposure. While some advances in these areas have been made since 1988, these same limitations still exist for many pollutants, especially for pathogens and many of the new or emerging chemicals identified by the NRC. Therefore, EPA has concluded that a less comprehensive, more targeted, survey, to help fill data gaps and inform decisions regarding further studies, may be more useful to address uncertainties highlighted by the NRC. Information developed by national and international experts on pathogens and toxic chemicals may help produce a better informed survey design. The Agency believes that using such information may produce more valuable results than conducting a comprehensive national survey at this time. EPA is first planning to develop and initiate a targeted survey after considering the following sources of information:

Available data: The Agency has conducted a biosolids literature search and is reviewing the information for relevant data on chemicals and pathogens in biosolids. The literature search includes topics related to a survey of chemicals and pathogens in biosolids, management practices, and treatment efficacy. This information obtained may also assist EPA in responding to other NRC recommendations. For example, the Agency plans to use available information to prioritize future research and, if necessary, modify biosolids management practices to reduce risk.

Other sources of data include studies conducted by EPA regional offices, States, and universities. For example, EPA Region 8 is conducting a long-term

study of biosolids addition to soil and the potential effects on soil microbiology. The University of Arizona is conducting research on airborne pathogen exposure at various times and distance from biosolids application sites. Within the next six to nine months, the Agency plans to review and assess such studies for their contribution in determining the potential for exposure and adverse human health impact from land-applied biosolids.

Studies: Ongoing EPA studies address many technical uncertainties related to pollutants in biosolids. For example, the adequacy of current analytical methods for selected priority pathogens and the development and/or validation of new methods are also being studied. In addition, field studies are being used to provide site-specific occurrence data.

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.

Planned Strategy for Designing a Targeted Survey

During the next fiscal year the Agency plans to initiate or continue Studies devoted to:

1. Methods development and/or validation studies for enteric viruses and helminth ova (see Methods Development).
2. Continuation and/or expansion of field studies to determine environmental contaminant occurrence at selected sites (see Methods Development and Pathogens Categories).

In addition, during the next 18 to 24 months, EPA is proposing to design a targeted approach for a survey of pollutants that occur in sewage sludge. New and existing information from sources such as relevant published pollutant occurrence and effects data, State occurrence databases, and input received during the public comment period will be used to help in the development of the proposed survey.

To ensure the survey provides meaningful results and the effective use of limited resources, EPA is considering restudying some of the pollutants that were studied in the 1988–1989 NSSS. EPA is also considering including some new and emerging chemicals, taking into account the availability of adequate analytical methods and their associated analytical costs. As a result, the Agency may only be able to measure a limited number of pollutants.

B. Exposure

1. Summary of Exposure NRC Recommendations

The NRC made recommendations on how current exposure information and updated conceptual exposure models can be used to update and strengthen the scientific basis of the chemical and technology-based pathogen standards. This category also includes recommendations to evaluate exposure for the reasonable maximum exposure (RME) individual, updating fate and transport models that might affect exposure estimates, and conducting pre-planned exposure studies under certain situations for specific exposure groups.

2. The Agency's Response to the Exposure Category

How EPA Plans To Address NRC Exposure Recommendations

Understanding human exposure to chemicals and pathogens, including the concentrations and fate and transport through important exposure pathways, is key for risk assessments supporting the Part 503 rule. As discussed below in the Risk Assessment category, the Agency plans to use a risk assessment framework to evaluate the priorities for reassessing or updating underlying components (including exposure assumptions) of previously conducted risk assessments. The Agency plans to use this information to determine if new exposure and risk calculations may be warranted for pollutants not previously assessed. Such an evaluation would include a review of the exposure information used in the Round 1 and Round 2 rules in light of new exposure information.

To conduct this activity, the Agency plans to first collect and review currently available exposure information from published literature, Federal and State databases, the NRC report, and other relevant sources. The Agency anticipates that some of the NRC recommendations regarding exposure may be addressed in newly available information, while others may require completion of ongoing studies. The Agency plans to review currently available exposure information to help identify data gaps and to inform decisions about future risk assessments and the need for additional exposure studies.

In the mid-1990's, EPA conducted research on the land application of biosolids to disturbed and contaminated sites requiring reclamation or remediation. These studies, which focused on the ability of biosolids to help improve soil properties and

establish sustainable vegetation cover on disturbed and highly contaminated sites, also included identification and determination of metals bioavailability in biosolids. The research was conducted to strengthen our understanding of the potential health impacts of metals, a particular focus during the development of the 1993 regulations. Results of this work showed that assumptions regarding metals availability used in earlier metals risk assessments were conservative. The Agency plans to reevaluate these findings in context with current practices and policies regarding exposure to metals in biosolids.

Exposure research: As part of a broader set of field studies, EPA recently initiated, in partnership with USDA and the State of Pennsylvania (PA), the planning of exposure-related research at five biosolids production and/or application sites. These studies are intended to gather site-specific information on current practices in biosolids production and application, and to identify and evaluate the fate of pollutants following biosolids application. Other objectives for this research, depending on the site, include (1) characterization of treated and untreated sludge (biological, physical, and chemical characterization), along with sampling and analysis during land application, (2) assessing the presence of pathogens, nitrogen, sulfur, volatile organic compounds and particulates in air, (3) determining how well the sewage sludge is disinfected as it moves through the different stages of processing, and (4) determining pathogen content in Class B sludge, once applied and following a period of natural attenuation. Other related work is being conducted by the University of Arizona's Water Quality Center.

Planned work is expected to begin in mid 2003. The plan is for facility operations for these sites to be documented, including the operation and performance of treatment process used to process sewage sludge and produce Class A and Class B biosolids. Pathogen and chemical occurrence data will also be collected at these sites. Proposed measurements over time for the production and land application processes may include total and volatile solids, pH, temperature, odor, appearance (e.g., color, paste, liquid, powder), fecal coliforms, *Salmonella* spp., *Staphylococcus aureus*, enteric viruses, and helminth ova.

Because of concern over bioaerosols, air samples will be taken prior to, during, and following land application at the point of application and the fence line, for up to thirty days. Air sampling

will be conducted in collaboration with USDA to address pathogens, chemicals, endotoxins, and particulates occurrence. Chemical and pathogen concentrations in air represent an initial step towards understanding the potential exposure of nearby communities. A description of the proposed studies can be found in the Pathogens category.

CAFO research: EPA is also conducting research on microorganisms and chemicals at animal manure land application sites, composting sites, and concentrated animal feeding operations (CAFOs). These include studies on the concentrations of airborne pathogens, toxic organic compounds, odorants, and particulates. The CAFO studies are important, because pathogen and chemical air transport and fate for animal manures resemble those for biosolids. The ongoing and proposed studies are described in the Methods Development category in this notice.

Planned Exposure Activities

EPA plans to continue its research partnership with USDA and the State of PA and to study an additional five field application sites.

The Agency is exploring a plan to conduct a molecular pathogen tracking exposure study as a follow-up to the PA/USDA/EPA study. This study would focus on individuals who have received medical attention and who suspect that they have been affected by biosolids application practices. This study would analyze human biological monitoring samples (e.g., feces, blood, or swabs from skin, ears, eyes, or throat) to isolate potential causative agents, and genetic characterization would be used to identify the potential source(s).

C. Risk Assessment

1. Summary of Risk Assessment NRC Recommendations

The NRC recommended that the Agency use improved risk assessment methods to better assess risks and establish standards for chemicals and pathogens under Part 503, since methods for conducting risk assessments have evolved substantially since the 1993 regulations were established. The recommendations also include reassessing standards for chemicals currently in the Part 503 regulation using the latest science. The NRC suggested that future risk assessments incorporate new information on exposure, dose-response relationships, pathogen survival, quantitative microbial risk assessment techniques, and consideration of site-specific factors that may affect risk management practices (e.g., odor).

Recommendations were also made to involve stakeholders in the risk assessment process and to examine biosolids management practices to ensure that the underlying risk assessment principles are effectively translated into practice.

2. The Agency's Response for the Risk Assessment Category

How EPA Plans To Address NRC Risk Assessment Recommendations Current and Planned Risk Assessment Activities

For this notice, risk assessment is defined as the process of identifying the potential adverse health effects associated with environmental exposures to pollutants in biosolids, their severity, and likelihood. Previously, EPA used a risk based approach for estimating risks to human health and developing management practices to reduce risks and set protective standards. When they were conducted, EPA's assessments were based on state-of-the-science methods, information and management practices. The NRC recommended areas where new or updated health and exposure information, models, and risk assessment methods may strengthen the Agency's assessments for land-applied biosolids.

Consistent with the recommendations of the NRC, EPA plans to address the potential health hazards and exposures associated with land application of biosolids using state-of-the-science risk approaches. Specifically, EPA plans to reassess methods and data used for previously evaluated pollutants, and apply these methods to new pollutants. For example, risks from pollutants not previously assessed due to a lack of toxicity, environmental fate, or exposure information, will be reevaluated if new information is available. This effort is expected to take place in FY03 and FY04. The Agency has assessed risks to children and sensitive populations, and will continue that approach in future assessments and reassessments.

The NRC also recommended that representative stakeholders could be included in the risk assessment process to help identify exposure pathways, local conditions that could influence exposure, and possible adverse health outcomes. 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.

EPA, in conjunction with States and other Federal agencies, has already been addressing local biosolids issues in a

few areas, and has used these opportunities to include stakeholders in the process to further evaluate and improve the assessment and management of biosolids. For example, stakeholders were involved in the scenario development and regulatory processes of a recent study in Pennsylvania. As part of this study, an informal information sharing group was formed that included concerned citizens, local officials, and contractors to assist the Agency in identifying stakeholder concerns and ensuring transparency in the field study process.

For the ongoing Round Two land application rulemaking, EPA conducted a revised risk assessment in response to public and peer review comments on the 1999 Round Two proposal. This revised assessment used a probabilistic approach instead of a deterministic approach to yield information on the sources of variability and uncertainty in the final risk estimates. The probabilistic approach used estimated values for certain input variables over the range of observed data to estimate the risks for the highly exposed population. This revised risk assessment also used new inputs, which included a redefined "highly exposed individual," new pathways and mechanisms of exposure, new exposure factors adopted from the latest EPA Exposure Factors Handbook, a sensitivity analysis to determine the relative importance of the input variables, and updated scientific information on the chemicals of concern, dioxins. EPA redefined the "highly exposed individual" as a member of a farm family that consumes 50 percent of his/her diet from home-produced crops and animal products grown on his/her own biosolids-amended land. EPA plans to use the Round Two risk assessment approach as a starting point for evaluating the NRC's recommendations, including the use of the reasonable maximum exposed (RME) individual for improving future risk assessments.

EPA is currently funding and conducting research related to risk assessment of biosolids. EPA is sponsoring research or has awarded grants to the Water Environment Research Foundation (WERF) and others to develop quantitative pathogen risk assessment methods and approaches. EPA plans to conduct a comprehensive evaluation and peer review of these results and, if deemed appropriate for use in assessing risk from pathogens found in biosolids, the Agency would incorporate these new risk assessment methods into any new or updated risk assessment and update the part 503 rule as necessary.

Other studies and related activities that EPA is conducting or sponsoring include the development of dose-response models for quantitative risk assessment of selected pathogens and the development of transmission models of pathogens and disease. These models are currently being developed for drinking water and, EPA plans to evaluate and, if appropriate, modify applicable models to be used in analyzing pathogens in biosolids. In addition, research is being conducted with USDA and various States on the extent of airborne concentrations of pathogens, toxic compounds, odorants, particulates and bioaerosols. EPA plans to evaluate the results of these studies for use in refining and improving future biosolids exposure and risk assessments. Further descriptions of these studies are provided in the pathogen section and the action plan.

To further the state of the knowledge surrounding all aspects of sewage sludge use and disposal, including improved risk assessments, EPA is supporting a workshop scheduled for January of 2004 on the "state of the science" on land application of municipal and industrial wastewater effluents, sewage sludge, and animal manures. This workshop is being coordinated by the University of Florida and will have numerous contributors from the Agricultural Research Service of USDA, and academia, among other groups. New and additional information on biosolids toxicities and environmental properties may emerge from this workshop; once evaluated, this information may be used in future risk assessment updates of the Part 503 Rule. The Web site <http://www.conference.ifas.ufl.edu/landapp/> contains information concerning the upcoming workshop, as well as other relevant information.

As discussed previously, EPA may use the risk assessment paradigm to provide both a focused reassessment of certain previously addressed pollutant risks, exposure pathways and risk assessment approaches, as well as assessing pollutants which have not been previously evaluated to effectively address the NRC risk assessment related recommendations and the review required by Section 405(d)(2)(C) of the CWA. These risk assessment activities will be initiated this year. This effort will be developed and outlined by an interdisciplinary workgroup within EPA and include external review of the analysis plan.

For this risk analysis, EPA is planning to focus on an evaluation of those key pollutants and pathways which are likely to be of greatest concern or where

the new scientific developments may have the greatest impacts. This may result in later updating the Round One risk assessment models and re-evaluating selected pollutants, pathways and endpoints and/or new pathways and endpoints not previously addressed.

EPA is planning a two-step process for addressing the NRC recommendations with respect to risk assessments for pollutants in sewage sludge. The first step would be to conduct a problem formulation which would re-evaluate or assess methods, approaches and pollutants considered in the Round One determinations, and any new qualitative information for future pollutants. This problem formulation step would include the development of exposure/risk assessment scenarios that would be used to identify critical/key stressors, routes of exposure, model application and data gaps. The primary focus of this effort will be on areas having the greatest potential risks and uncertainties (e.g. pathogens). The problem formulation will serve to eliminate those stressors, scenarios, routes of exposure, and endpoints that need not be evaluated further. It would retain those areas which are potentially significant or require more study. The problem formulation would also result in a research analysis plan that would not only identify risk assessment activities but also prioritize research to address exposure and risk management.

The second step would be to conduct quantitative risk assessments and risk characterizations for key pollutants identified and prioritized by the scenario/conceptual models, as appropriate. These assessments would initially be screening level risk assessments. More refined assessments would be conducted only on those pollutants and pathways for which the screening-level assessment indicate significant potential for risk. In conducting any risk assessments, screening or comprehensive, EPA will, as appropriate, apply the most up-to-date scientific information and risk assessment methodologies. In addition, EPA proposes to continue its efforts to evaluate and develop new methods for pathogen risk assessments and improved models for exposure assessments.

EPA's proposed activities are to continue to track development of methods for QMRAs and develop guidelines for assessing risk from pathogens. In addition, EPA also plans to continue work on the evaluation of data and models for improving exposure assessments. EPA may also evaluate and

assess data and information related to multiple exposures, potential contaminant interactions, and potential effects on sensitive sub-populations, to the extent the state-of-the-science is available.

D. Methods Development

1. Summary of Methods Development NRC Recommendations

The NRC recommended that the Agency develop and standardize methods for measuring pathogens and emerging chemicals in biosolids and bioaerosols. Standardized methods could be used to provide measures of performance and to verify that the Agency's management practices and standards are reliable.

Specifically, the NRC recommended developing, standardizing, and validating methods for pathogens in biosolids and bioaerosols (*e.g.*, airborne pathogens). In addition, research that uses improved pathogen detection technology, round-robin laboratory testing to establish method accuracies and precision for pathogen concentrations in raw and treated biosolids, mechanisms for incorporating new methodologies into the verification process, and measures of performance that can be monitored (*e.g.*, concentrations of selected chemicals in exposure media and human biological monitoring such as blood or urine of workers and residents) could be considered useful in conducting and interpreting future risk assessments and used to develop applicable risk-assessment technologies.

2. The Agency's Response to Methods Development

How EPA Plans To Address NRC Methods Development Recommendations

For the methods development category, the Agency plans to focus its resources on pathogens and chemicals associated with biosolids. Validated analytical methods are necessary to support exposure assessments for toxic pollutants and pathogens. Methods are needed for determining the reliability of treatment processes, assaying pathogens and chemicals in raw and treated biosolids, incident follow-up, sampling environmental media, and human biological monitoring. Ongoing or planned methods development activities in the Agency that address the NRC recommendations follow.

Method Development Activities

Recently initiated EPA methods development work includes field studies at five biosolids production and

application sites. Currently available analytical methods are being identified or in some cases adapted for this study. A description of these field studies has been provided in the preceding Exposure subsection of this notice. Additionally, EPA is conducting field studies at animal manure land application sites, composting sites, and concentrated animal feeding operations (CAFOs). This research includes measurements of pathogens, toxic organic compounds, odorants and particulates in the air near CAFOs. Both the biosolids and CAFO studies include evaluation and adaptation of analytical methods for selected pathogens and chemicals. Results of these studies should assist the Agency in determining the need for additional methods development research.

Open-path Fourier Transform Infrared (FTIR) spectrometry will be used to measure volatile organic compounds from land application sites. EPA is validating analytical methods for microorganisms cited in 40 CFR Part 503. Fecal coliform methods have been validated, whereas Salmonella methods are being validated. Methods and validation studies for these two agents are expected to be published in 2004.

Planned Method Development Activities

As part of its field study programs, EPA plans to work with USDA to investigate methods for measuring bacteria and viruses in air upwind and downwind of biosolids land application sites. EPA is considering developing and validating analytical methods for enteric viruses and helminth ova, as well as chemical analytical methods for emerging chemicals of potential concern in biosolids (*e.g.* pharmaceuticals).

E. Pathogens

1. Summary of Pathogen NRC Recommendations

The NRC recommended that the Agency review approaches for developing microbial analytical methods and conducting microbial risk assessments (Quantitative Microbial Risk Assessments) to analyze sensitivity and to ascertain what critical information is needed to reduce uncertainty about the risks from exposure to pathogens in biosolids. According to the NRC, research activities that might improve EPA's pathogen standards and reduce risk, or uncertainties concerning risk, from pathogens following exposure to biosolids include development, standardization and validation of detection and quantification methods

for pathogens and indicator organisms, conducting research on vectors carrying pathogens and bioaerosols, and conducting studies to determine whether site restrictions for Class B achieve intended effects for pathogen levels. The NRC also recommended that EPA not allow provisions for distributing Class A biosolids in bags or other containers (weighing less than one metric ton) when they do not meet pollutant concentration limits (*i.e.*, all biosolids sold or given away should be exceptional quality).

Other NRC recommendations include considering additional indicator organisms (*e.g.*, *Clostridium perfringens*) for use in regulations, as well as funding, supporting and officially sanctioning the Pathogen Equivalency Committee (PEC) as part of the Federal program. National field and laboratory surveys to verify that Class A and Class B treatment processes for pathogens perform as assumed by their engineering and design principles could also be conducted. Determinations could be made of pathogen density and elimination across the various accepted treatment processes and in the biosolids or environmental media over time, applying geographic and site-specific conditions that affect pathogen fate and transport to determine the effectiveness of site restrictions, buffer zones, and holding periods for Class B biosolids. EPA may also consider further refining, and directly correlating, stabilization controls to outcomes using metabolic techniques (*e.g.*, sour test, carbon dioxide metabolic release, methane metabolic release).

2. The Agency's Response to the Pathogen Category

How EPA Plans To Address NRC Pathogen Recommendations

EPA currently uses a technology and management practices based approach to minimize pathogen exposure. The Agency is considering studies to better understand the measurement, control, and fate of pathogens during the production and land application of sewage sludge. Such studies include improved analytical methods, evaluation of treatment and application processes, site-specific pathogen occurrence studies, potential human health impacts, exposure assessment, and risk assessment.

Certain pathogen studies are discussed in the Methods Development subsection of this notice. Where other studies address several pathogen issues (*e.g.*, field studies, management, treatment, site restrictions), they are briefly described below.

Research: EPA has an ongoing biosolids research program focused on selected pathogens, and is expanding this program during this fiscal year. Future pathogen research will be determined by the results of ongoing studies that will inform the Agency about significant issues and information gaps that require additional work. Presently, the Agency is considering research in at least three general areas: (1) Development of improved pathogen analytical techniques; (2) assessment of exposure and risk for critical pathways and pollutants, and (3) evaluation of sewage sludge processing and land application methods and site restrictions. Results of such research will assist the Agency in determining where improvements may be needed.

Pathogen Activities

In June 2001, EPA and USDA sponsored a workshop on "Emerging Pathogen Issues in Biosolids, Animal Manures, and Other Similar By-Products" (USEPA 2003 in press). The workshop assembled experts in biosolids and animal waste management to review the state-of-the-science, resolve persistent and complex issues, and provide suggestions for research. The workshop considered: 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 immunosuppressed conditions to pathogens.

A discussion of recently initiated EPA work concerning pathogens at five biosolids and three animal manure production and/or application sites is provided in the previous Exposure category.

The Agency has completed and is conducting additional studies on exposure and occurrence of disease which are described in the Risk Assessment and Human Health subsections of this Section VII. In a collaboration with Duke University, EPA has also published a report on the relationship between odor from animal and waste water residuals processing facilities and land application sites and potential health effects (Journal of Agromedicine, Volume 7(1), 2000, ISSN: 1059-924X). The report summarizes the state of knowledge on ambient odor health effects with emphasis on animal manure and biosolids odor emissions. Potential mechanisms for health symptoms, methods for validating health symptoms, presence of odor, and

efficacy of odor management are discussed. The importance of health effects was found to be dependent upon a number of factors, and health impacts may be minimized using odor remediation methods.

The University of Arizona's, National Science Foundation, Water Quality Center (<http://www.wqc.arizona.edu>) has conducted, and is planning to conduct, pathogen studies in biosolids including: (1) Air transmission of pathogens from land application, (2) potential occurrence of *Staphylococcus aureus*, (3) fate and transport of pathogens, and (4) risk assessments for pathogens in land applied biosolids. These studies will evaluate various application sites, terrain, climate, and potentially affected nearby populations. The researchers involved in this study plan to model the transmission of pathogens to estimate exposure for nearby human populations, which may ultimately allow the development of predictive risk assessment protocols. EPA will monitor these studies as they develop over at least the next two years to determine their relevance to the National biosolids program.

EPA's Pathogen Equivalency Committee (PEC): The Agency formed and has supported the PEC since 1985. PEC members provide guidance to applicants, permitting authorities and members of the regulated community on sampling and analysis issues related to meeting the subpart D requirements of part 503 (pathogen and vector attraction reduction). The PEC currently consists of representatives from EPA and the Centers for Disease Control and Prevention (CDC). The members have expertise in bacteriology, virology, parasitology, wastewater engineering, medical and veterinarian sciences, statistics, and sludge regulations. The PEC evaluates and supports development of alternative treatment technologies by consulting with local communities, States, industry and others stakeholders. The PEC provides information on biosolids processes, contaminant occurrences, and exposure, and assists EPA regions, States, and the regulated industry with questions about equivalency for Processes to Significantly Reduce Pathogens (PSRP) and Processes to Further Reduce Pathogens (PFRP) under 40 CFR part 257 and 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 Water Environment Research Foundation (WERF), with contributions from EPA, is funding a diverse research

program to support the wastewater treatment industry. An important part of their program has been supporting research on biosolids that has been aimed at reducing uncertainties and hence is significant with respect to the NRC recommendations. Treatment plant residuals and biosolids, including pathogen issues, have consistently ranked among the top five priorities for WERF subscribers over the past decade. WERF biosolids research entails more than 40 basic and applied projects to reduce uncertainties, better manage biosolids, assess public perception of risks, and develop strategies for biosolids treatment and management. Much of WERF's research is focused on the beneficial uses of biosolids. The Research of particular interest includes methods for rapidly detecting pathogens. EPA plans to continue to review and evaluate such research projects as they are completed to determine their relevancy to the national biosolids program.

Other studies supported by WERF are intended to determine biosolids land application rates. Phosphorus overload in animal manure and biosolids is a particular concern. These studies are evaluating phosphorus bioavailability and Class A and Class B pathogens to determine potential impact on groundwater and other environmental media. WERF is convening a biosolids research summit in the summer of 2003. A WERF pre-summit will provide training about mutual gains activities and joint fact finding, and will develop a protocol for guiding the assistance of an information sharing group (comprised of the concerned citizens, as well as stakeholders) in recommending WERF-sponsored research and oversight needs. EPA plans to collaborate with WERF and the USDA to sponsor an international conference on sustainable land application for municipal and industrial effluents, manures, biosolids and other non-hazardous wastes. The conference, scheduled for January 2004, will provide information and perspectives on research gaps and needs. Detailed information on the WERF biosolids research program may be accessed at <http://www.werf.org>.

Planned Pathogen Activities

Quantitative Microbial Risk Assessment (QMRA): EPA and WERF are funding research termed "QMRA", as described in "A Dynamic Model to Assess Microbial Health Risks Associated with Beneficial Uses of Biosolids" (WERF 2003, Cooperative Agreement No. CR-825237). The organizations involved in this research include WERF, 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 developing microbial risk assessment guidelines, subject to available resources.

Potential future pathogens activities will include analytical methods development, exposure and risk assessment. The Agency is also considering continuing site-specific evaluations of current treatment and land application processes, studies of wastewater treatment sludge stabilization during biosolids production to reduce odors and vectors, and the use of pilot-scale treatment units to optimize sludge treatment techniques for pathogen and chemical control.

F. Human Health Studies

1. Summary of Human Health NRC Recommendations

The NRC recommended that the Agency conduct response incident investigations, targeted exposure surveillance, and well-designed epidemiological investigations of exposed populations. Data from these studies would be used to provide a means of documenting whether health effects exist that can be linked to biosolids exposure.

The NRC also recommended that preplanned exposure assessment studies characterize exposure of workers and the general public who come into contact with biosolids either directly or indirectly. Such studies could include the identification of microorganisms and chemicals, the selection of measurement methods for field samples, and the collection of adequate samples in appropriate scenarios.

Further, the NRC recommended that epidemiological studies of biosolids use be designed to provide evidence of a causal association, or lack thereof, between biosolids exposure and adverse human health effects. These studies could include an assessment of the occurrence of disease and an assessment of potential exposures. Because large scale and comprehensive epidemiological studies are expensive and require extensive data analysis,

priority could be given to studies that can help reduce uncertainty.

2. The Agency's Response to the Human Health Studies Category

How EPA Plans To Address NRC Human Health Studies Recommendations

At this time, the Agency does not plan to conduct an epidemiological study, as discussed in the NRC report. As noted by the NRC, comprehensive epidemiological studies are complex, time consuming, and require substantial additional funding. The Agency may assess the future need for epidemiological studies, but believes targeted human health studies (*e.g.*, those of focused scope, such as exposure to pollutants via aerial transport and incident investigations) over the short-term might better address potential human health impact and persistent uncertainties surrounding exposed populations. These studies could help assess the potential airborne exposure to pollutants and could help determine whether incidents are occurring following biosolids exposure. Targeted exposure and human health studies could also help inform the design of any future epidemiological studies, should they prove necessary. Results from targeted studies would also allow the Agency to communicate with other public health-based federal agencies regarding human health exposure and epidemiological studies.

Planned Human Health Activities

Targeted Human Health Investigations: The Agency's primary objective is to characterize pollutants and microbial agents present in biosolids, as well as any associated human exposure pathways, that may have the greatest potential to adversely impact human health. Specifically, the NRC sees an immediate need for a systematic approach for investigating claims of disease or illness following biosolids exposure. Regulators, sewage sludge processors, and land appliers must be capable of responding rapidly to such reports. The Agency is investigating the possibility of developing a process for timely notification, recording, and tracking incident reports in collaboration with the Centers for Disease Control and Prevention (CDC). The Agency has initiated preliminary discussions with the CDC to discuss possible mechanisms for recording and tracking biosolids related disease incidents.

The University of Arizona's National Science Foundation, Water Quality Center, may also join cooperatively in

the USDA/EPA/State of PA study to evaluate risk from exposure to pathogens, particulates, endotoxins, and odors from farm fields and other agricultural and silvicultural settings upon which biosolids, animal manures, and other organic amendments have been applied. These cooperative studies will evaluate various application sites, terrain, climate, placements of receptor populations and downwind ambient air concentrations of pathogens and volatile organic chemicals near residents. The Agency plans to evaluate if the collected data can be used to develop models for estimating exposure of human populations downwind of these sites, which might then be used in predictive risk assessment applications.

G. Regulatory Activities

1. Summary of Regulatory NRC Recommendations

The NRC recommended that EPA revise or develop regulatory criteria for biosolids in a timely fashion and identify additional regulatory mechanisms to better protect human health and the environment from the exposure to land-applied biosolids. This recommendation includes the following components: a review of biosolids protocols used by other nations, adoption of national standard treatment design criteria, a refinement of stabilization controls correlated to outcomes using metabolic techniques, development of molybdenum standards, development of a quantitative microbial risk assessment (QMRA) to establish regulatory criteria for pathogens, studies to determine whether the management practices specified in the Part 503 rule achieve their intended effect, provisions for the distribution of Class A biosolids weighing less than 1 metric ton (*i.e.*, the NRC recommends that all biosolids sold should be exceptional quality (EQ)), and the elimination of exemptions for nutrient management and site restrictions for land-applied EQ biosolids.

The NRC also recommended that EPA consider additional risk-management practices when revising the part 503 rule. Considerations should include limitations on holding or storage practices, slope restrictions, soil permeability and depth to groundwater, and setbacks to residences or businesses, surface water, and drinking water supplies.

2. The Agency's Response to the Regulatory Category

How EPA Plans To Address NRC Regulatory Recommendations

Ongoing Regulatory Activities

New Standards: As previously mentioned in Section II above, EPA vacated the numeric standards for molybdenum in sewage sludge as a result of litigation. EPA has conducted a literature search of new environmental properties information for molybdenum in land-applied biosolids. Following review of this new information, EPA will determine its applicability as the basis for re-proposing molybdenum standards for land-applied sewage sludge. EPA is planning to complete this review in 2003.

EPA also has information indicating that virtually no biosolids products are sold or given away in bags or other containers unless they comply with the pollutant concentrations for the nine metals currently regulated and the pathogen and vector attraction reduction requirements, which allows these products to be classified as exceptional quality (EQ) as described in the EPA guidance (USEPA, 1994). EPA plans to evaluate the data during the current year to determine whether to amend part 503 to eliminate the non-EQ Table 4 alternative for selling and distributing biosolids products that are sold or given away in bags or other containers weighing less than one metric ton.

Standardized Management Practices: Part 503 is designed to protect public health through compliance not only with numerical criteria for pollutants found in biosolids, but also with operational standards for pathogen and vector attraction reduction. These operational standards are performance based, based on operational goals for specified reduction, to enable elimination of pathogens and vector attraction reductions in sewage sludge through various engineering designs, processes and equipment. EPA believes that such means are appropriate for achieving environmental performance while encouraging efficient, cost-effective, and innovative systems and approaches.

The establishment of national standard treatment design criteria may not result in application of the most efficient site-specific practices for protecting public health. The additional management practices recommended by the NRC are linked to site-specific, or local-level, conditions. Examples include topography, soil characteristics, climate, population density, land-use,

depth to groundwater, and proximity to surface waters. States and local jurisdictions will have better knowledge of local conditions, and are in a better position to establish additional management practices to augment the protectiveness of the part 503 Standards. However, EPA also plans to evaluate such practices to determine if additional requirements or improvements in the Part 503 Rule are warranted.

Regulations from Other Nations: EPA generally considers relevant and available information and protocols from other nations to augment and inform its decisions. When standards are available, such as the Canadian standards for sewage sludge, these have provided the Agency with valuable new perspectives and insights into the scientific, technical, and societal basis for the development and implementation of sewage sludge regulations. However, there are fundamental scientific and programmatic differences between certain international sewage sludge standards and EPA's standards for the use or disposal of sewage sludge in 40 CFR part 503.

The Part 503 Standards are based on information for pollutants found in sewage sludge, and are risk-based as directed by section 405(d) of the Clean Water Act. As such, the Part 503 Standards consist of numerical limits with adequate margins of safety to protect public health and the environment. The Part 503 numerical standards are based on a conservative set of exposure pathway and risk assessment assumptions.

In contrast, international sewage sludge standards are based on differing legal frameworks. Therefore, sewage sludge regulation promulgated by some other countries may not be comparable to EPA's authority or standards under section 405 of the CWA. However, numerous other countries have supported the quantitative risk assessment approach and have often adopted Part 503 limits for regulating biosolids.

Planned Regulatory Activities

Studies: As part of its field studies in 2004, EPA is planning to evaluate certain Class B disinfection processes including the natural attenuation of pathogens that occurs while the sludge is on or in the soil for the site restriction periods stated in the current regulations (40 CFR 503.32(b)(5)). Treatment processes that are expected to be evaluated include anaerobic digestion and lime addition. Site restrictions to be studied include limitations on how soon

agricultural activities can occur after biosolids application. In determining the efficacy of current management practices, ways to improve them may also be identified. This research will be initiated in 2003.

H. Biosolids Management

4. Summary of Biosolids Management NRC Recommendations

The NRC recommended that the Agency increase the resources devoted to its biosolids program and expand biosolids management activities. Specific recommendations were made to increase funding to States to implement programs, fund, support, and officially sanction EPA's Pathogen Equivalency Committee (PEC) as part of the EPA biosolids program, and strike a balance between expending resources on new site-specific data collection and expending resources to model and assess risk using existing information.

The NRC also recommended biosolids management activities in the following areas: expand and strengthen the oversight program, track allegations and sentinel events of adverse health effects from exposure to land-applied biosolids, and conduct studies to determine whether the management practices specified in Part 503 achieve their intended effect.

Furthermore, the NRC recommended that the Agency develop a procedural framework to implement human health investigations and to verify that (1) treatment technologies for pathogen control are effective (quality control), (2) chemical standards are met (compliance audits), and (3) unanticipated hazards are identified.

2. The Agency's Response to the Biosolids Management Category

How EPA Plans To Address NRC Biosolids Management Recommendations

Biosolids Management Activities

Overview: At EPA Headquarters, the biosolids regulatory staff within the Office of Water has been increased recently. The new staff positions will be devoted to regulatory development, Part 503 updates, and implementation activities. There is also an enforcement or compliance presence in each of the EPA Regional Offices for following up on phone calls and complaints received from the public, and initiating Agency enforcement actions, as appropriate.

States have their own oversight programs, some of which are quite comprehensive. There are 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 points in the authorization process. National coordination of State, regional and Headquarters biosolids programs are achieved via an annual national meeting.

EPA continues to meet its statutory obligations under the Clean Water Act (CWA) pertaining to sewage sludge. The Agency continues to believe that land application of biosolids is an appropriate choice for communities, when conducted in compliance with EPA regulations. Given present scientific knowledge, EPA has based the allocation of resources to biosolids compliance and enforcement on its assessment of the relative risks to public health and the environment that are posed by biosolids.

Regions and States have the flexibility and responsibility to address situations where compliance assistance and enforcement actions to address biosolids are appropriate and necessary. EPA has taken enforcement actions and/or appropriate administrative remedies to address biosolids violations of 40 CFR part 503 and will continue to take actions to address instances where biosolids pose an imminent and substantial endangerment to human health or the environment. EPA will reconsider resources devoted to biosolids if additional research and science demonstrate greater risk.

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 (Chapter 10). This manual has just undergone major revisions and updating by a Headquarters and regional workgroup; the Manual is being distributed as a final draft for regional and program office review. Electronic training modules, including a module for biosolids inspections, are planned to be available shortly after the release of the revised manual, in Summer 2003.

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 on-line 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.

In the area of data systems, EPA is continuing to work with States as it modernizes the Permit Compliance System (PCS) to allow for more effective program oversight. While PCS is the national data system for the NPDES permit program, it currently requires only limited biosolids data. As part of the PCS modernization, a separate workgroup (including States and EPA) was devoted to the data needed to manage the biosolids program. This workgroup examined data in State systems, Biosolids Data Management System (BDMS) and PCS, and considered incorporating BDMS into PCS. The recommendations of this workgroup, endorsed by the PCS Executive Council, was not to incorporate or link BDMS, but rather to add data elements to PCS to improve tracking and oversight of the biosolids program.

The BDMS is another source of biosolids data. It was developed in the late 1990s by Region VIII to track biosolids quantity, quality, use, and disposal practices in the Region VIII states. While not the national system of record for biosolids, BDMS is a tool for municipalities in which they can enter data themselves and use the BDMS to develop reports for states, EPA and for citizen review. The BDMS is also a valuable management tool and can be used to record information about reported incidences associated with biosolids land application. The BDMS is available at: <http://www.treeo.ufl.edu/water/bdmsQuestionnaire.asp>. Current BDMS users include some EPA Regional offices, States, users of biosolids, contract land appliers, and POTWs throughout the U.S. and Canada. EPA is continuing to assess the potential of upgrading BDMS as a management tool that can link with established states and the Federal PCS system.

Research by the Water Environment Research Foundation (WERF) is described in the Pathogen and the Human Health Studies categories. WERF also supported a study by the New England Biosolids and Residuals Association (NEBRA) looking at the importance of establishing relationships among researchers, federal government and concerned citizens. This research

included a survey on public perceptions and what people know about biosolids, what their concerns are and whether their concerns are being addressed adequately. The study's aim is to suggest ways that regulators and people can work together. A report is due out by mid 2003.

This and other projects will help the Agency gain a better understanding of public perception issues, values, and expectations. EPA can then identify the most effective communication approaches to ensure understanding of the importance of, and need for, proper biosolids management

Science and Public Outreach: Because of varying resources and diverse local circumstances, risk communication practices vary widely throughout the United States. The Agency's risk communication programs are aimed at improving public awareness of the issues and to achieve exposure reductions where needed. Embodied in all of the priorities for action described in this biosolids strategy is a need to foster public awareness of the issues surrounding biosolids use and exposure. Through the activities and organizations mentioned below, EPA is committed to improving the effectiveness of risk communication methods at national, regional, and local levels.

An Information-Sharing Group (ISG) has been established based upon the concepts developed in WERF studies concerning joint fact-finding research. The ISG is comprised of concerned citizens, health scientists, municipal operators, a farmer, 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. Currently the researchers are from EPA, USDA, the State of PA, and several other organizations. WERF has efforts underway to expand the use of such information-sharing in other research projects.

The National Biosolids Partnership (NBP) is a 48 member alliance formed in 1997 with AMSA (Association of Metropolitan Sewerage Agencies), WEF (Water Environment Federation, and EPA (U.S. Environmental Protection Agency). Through partnering with producers, service contractors, users, regulatory agencies, universities, the farming community, and environmental organization, the goal of the NBP is to advance environmentally sound and accepted biosolids management practices.

Through a voluntary Environmental Management System (EMS), being developed for biosolids by the National Biosolids Partnership (NBP), EPA continues to provide the public with educational information, based on the best science, about the recycling and disposal of biosolids. EPA strongly supports the ongoing efforts of the NBP to develop the EMS and to provide correct and timely information and community-friendly practices that could be followed via its new communications system. The EMS program supports local agencies to find ways to meet and go beyond what is required in state and federal regulations. About 45 municipalities are now pilot-testing their biosolids EMS programs based upon a blueprint developed by the NBP. Several of these municipalities will be ready to undergo an independent third party audit of the EMS program later this year (2003). Municipalities involved in the voluntary EMS program are reporting benefits they have achieved. They report that their participation in the EMS program has resulted in more efficient operation, reduced odors in biosolids, less intrusive transport of the biosolids to land application sites, better communication, and meaningful involvement of the public. The Agency plans to continue supporting NBP activities and working with municipalities on expanding the use of EMS programs in biosolids management. Two NBP Web site address that present relevant biosolids information are <http://www.biosolids.org> and <http://biosolids.policy.net/emsguide/manual/goodpractmanual.vtml>.

The EPA's Pathogen Equivalency Committee was discussed in the Pathogens subsection. The PEC is instrumental in the development and evaluation of regulatory-related initiatives. EPA will continue to support and evaluate the activities of the PEC.

State Regulations: 40 CFR part 503 sets minimum standards for the use or disposal of sewage sludge. State requirements may be more restrictive or administered in a manner different from the Federal regulation. In all cases, users and disposers of biosolids must comply with the most restrictive portions of both the Federal and State rules. In most cases, the part 503 rule is self-implementing; users must comply with part 503 rule, even if they have not been issued a permit covering sewage sludge use or disposal. EPA or States can take enforcement actions directly against persons who violate part 503 requirements. In situations where States and others are addressing such issues,

EPA plans to use those opportunities to further evaluate and develop the tools to improve the assessment and management of sewage sludge.

Planned Biosolids Management Activities

The priority activities for biosolids presented in this response were evaluated in the larger context of other Agency priorities. The purpose of listing planned activities is to illustrate the Agency's future direction based on current information. Given the activities spelled out in this response, EPA's goal over the next two years is to complete studies and other activities, follow external research, and review available information. The Agency's longer-term goal is to assess results from completed and ongoing activities to determine further research needs. Implementation of various activities will be considered by the relevant EPA Offices and Regions in future priority setting activities.

IX. How Did EPA Conduct the Review of Part 503 Regulations Under the CWA Section 405(d)(2)(C)?

Section 405(d)(2)(C) of 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" of section 405(d). EPA has promulgated regulations in 40 CFR part 503 setting numeric 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 above, EPA commissioned the NRC study of existing sewage sludge land application regulations for the purpose of strengthening the scientific basis of its review under section 405(d)(2)(C). In an agreement with the parties in *Gearhardt v. Whitman*, EPA agreed to publish a notice seeking public comment on its proposed response to the NRC recommendations and the results of its 405(d)(2)(C) review. In conducting this review, EPA committed to review and evaluate publicly available information, such as sampling data, scientific studies, and other analysis and information taken from a wide range of national and international public and private sources.

In fulfilling this commitment, EPA has performed a comprehensive assessment of the availability of data on chemicals that have been detected in or in some way linked to sewage sludge. EPA reviewed Rounds One and Two screening histories; collected and

conducted a preliminary review of publicly available information on chemical toxicity, environmental properties such as mobility and persistence, and concentration; identified chemical pollutants for which appropriate analytical methods and human health benchmarks are available; and made preliminary determinations regarding sufficiency of information for risk-based screening analyses. The results of this review are available in the docket (USEPA, 2003e).

At this time, EPA has not identified any additional toxic pollutants that warrant regulation in sewage sludge. The next step in identifying toxic pollutants that may warrant regulation is to conduct a screening analysis of those chemicals for which adequate data and analytical methods are available and for which there is evidence that they may occur in sewage sludge. EPA plans to complete this screening analysis by January 2004. In addition, EPA is continuing to seek additional information to fill data gaps for those chemicals for which adequate data for the screening analysis is not yet available and would welcome any relevant data from commenters.

The Agency began its review under section 405(d)(2)(C) by first reviewing the complete list of pollutants that were considered in developing the Round One rule and Round Two proposal. For Round One, EPA conducted a National Sewage Sludge Survey (NSSS) in 1988–1989, which included an analysis of 411 pollutants. These 411 pollutants included, among others, every organic chemical including pesticide, dibenzofuran, dioxin and PCB analytes for which EPA had gas chromatography and mass spectrometry (GC/MS) standards (58 FR 9268–9269). Of the original 411 pollutants, EPA promulgated numeric standards in Round One for 10 pollutants (metals) in land-applied sewage sludge, three pollutants (metals) in sewage sludge placed in surface disposal units, seven pollutants in sewage sludge fired in sewage sludge incinerators (SSIs), and an operational standard for total hydrocarbons (or alternatively carbon monoxide) emitted from SSIs.

These same 411 pollutants were the starting point in 1995 for identifying pollutants for developing a Round Two regulation. EPA conducted a preliminary screening analysis which resulted in an identification of 31 pollutants for potential regulation in Round Two. These 31 pollutants were the subject of a comprehensive hazard identification study, which narrowed the list to dioxin, dibenzofurans and

coplanar polychlorinated biphenyls (PCBs).

Many of the original 411 pollutants were eventually eliminated for consideration in Round One or Round Two rulemakings; 254 were eliminated because they were not detected in any or in fewer than one percent of the sewage sludge samples surveyed in the NSSS, and others were dropped because of a lack of sufficient information on their toxicity and environmental properties. In particular, 44 of the 411 pollutants, though detected at a frequency of greater than one percent, were dropped from further consideration because of lack of data on human health benchmarks and/or environmental properties. For a more detailed description of the process for Round One and Two, see USEPA, 2002c.

For the current review, EPA again started with the 411 pollutants initially identified for Round One consideration; As mentioned above, 254 of these pollutants were detected at a frequency rate of less than one percent in the 1988–89 NSSS and therefore were dropped from further consideration in both the Round One and Round Two rulemakings. Because the low detection rates for these 254 pollutants could have been due to the limits of the analytical and sampling methodology employed in 1988–89, EPA included these pollutants in the current review for potential addition to the Part 503 Standards. A literature search was performed on these pollutants to identify (1) human health benchmarks, (2) environmental properties, and (3) their presence or concentrations in sewage sludge.

As previously mentioned, 44 of the 411 pollutants considered in the Round One and Round Two rulemaking processes were detected at a frequency of greater than one percent, but were dropped from further consideration because of lack of data on human toxicity and/or environmental properties. EPA has preliminarily determined that 23 of the 44 are either non-toxic or non-persistent in the environment, but is continuing to evaluate them.

Next, EPA conducted a literature search of publicly available information to identify information on pollutants in sewage sludge since 1990, including information on pollutants that were not among the 411 originally identified pollutants. EPA has collected 459 scientific papers from national and international government entities, universities, non-profit and other private entities for the time period of 1990–2002, the date of the last NSSS to the present (USEPA, 2002d). Of these

459 papers, 216 papers concern either the Round One or Round Two pollutants only. The balance of these papers, 243, concern or potentially concern pollutants that were not the subjects of Rounds One or Two. Subsequently, these 243 papers were reviewed to verify which of the papers do in fact concern pollutants which were not the subjects of Rounds One and Two. In addition, these papers were reviewed for human health benchmarks, environmental properties, and presence or concentrations of these pollutants in sewage sludge.

EPA also collected information from EPA databases and several other existing databases with respect to human health benchmarks, and found 170 pollutants with some human health benchmarks among these databases (USEPA, 2002e). These databases include: EPA's Integrated Risk Information System, EPA's Superfund Technical Support Center Provisional Toxicity Values, EPA Health Assessment Documents, California Environmental Protection Agency Chronic Inhalation Reference Exposure Levels and Cancer Potency Factors, Agency for Toxic Substances and Disease Registry Minimal Risk Levels, and Health Effects Assessment Summary Tables.

The next step in this process was to ascertain whether analytical methods exist for detecting and quantifying each of these pollutants in sewage sludge (USEPA, 2002f, USEPA, 2002g, USEPA, 2002h). Although the accuracy, precision, and limits of detection of analytical methodologies for chemical pollutants in the sewage sludge matrix have significantly improved since the 1988–89 NSSS, there are still many pollutants for which no validated analytical methods exist.

In summary, EPA evaluated publicly available information with respect to presence in sewage sludge, toxicity (including human health benchmarks), persistence, mobility and potential for exposure for the pollutants contained in each of the four groups of pollutants described above: (1) The 254 pollutants with a low frequency of detection in the 1988–89 NSSS, (2) the 44 toxic pollutants that were detected at a frequency of greater than one percent in the 1988–1989 NSSS, but that had insufficient information to be able to perform subsequent evaluation, (3) the pollutants that were not the subject of Rounds One or Two but are covered in the 243 papers that turned up in the literature search, and (4) the 170 pollutants for which some health benchmark exists in the literature. These four groups of pollutants as

described above were compared to eliminate any duplicates. Finally, EPA evaluated all of these pollutants to determine whether there are sufficiently accurate and precise analytical methodologies with adequate detection limits for these pollutants in the sewage sludge matrix. These results are available in detail in the docket for this notice (USEPA, 2003b).

These preliminary results will be further analyzed, leading to a risk-based screening analysis. The criteria for determining whether to proceed to a screening analysis for any pollutant are whether there are: (1) Adequate and reliable data regarding concentration of the pollutant in sewage sludge, (2) a current human health benchmark, (3) adequate information on environmental properties, such as persistence and mobility, and (4) an appropriate analytical method for the pollutant. In evaluating item 2 above, EPA will focus initially on chemicals for which there is a current peer-reviewed human health benchmark developed by EPA. EPA will next determine the adequacy of the available environmental properties data for use in the risk-based screening analysis.

The results of this screening analysis will serve as a basis for determining whether additional toxic pollutants should be considered for regulation in sewage sludge under section 405(d) of the Clean Water Act. As noted above, EPA has not yet identified any additional pollutants for regulation. Inclusion in the results presented today does not mean that a pollutant has been determined to be present in sewage sludge in concentrations that may adversely affect human health or the environment. Some, or even all, of these chemicals that have been detected in sewage sludge may only be present infrequently or in trace amounts, and may not present a risk of adverse effects to human health or the environment. Also, the properties or degree of toxicity of such chemicals may make their presence, even in higher amounts, of little risk to human health or the environment. As noted above, the NRC concluded that while there are significant data gaps, there is currently no documented scientific evidence that the existing Part 503 regulations have failed to protect public health. These results, however, are an important step forward in that they identify chemicals for which sufficient new information exists to proceed to a risk-based screening analysis, as well as data gaps that must be filled for other chemicals before such a screening analysis can be conducted.

EPA expects to complete its risk-based screening analysis of chemicals for which adequate information is currently available by January 2004. At that time EPA will identify those pollutants, if any, for which EPA plans to initiate a rulemaking under section 405(d). EPA requests comment on the methodology and results to date of its review under section 405(d)(2)(C) of the CWA. EPA also requests information that may help to fill data gaps for those chemicals for which sufficient information is not yet available to conduct a risk-based screening analysis.

X. What Are the Primary Issues for Public Comment?

While the EPA is requesting comments on all of the information discussed in this Notice, the Agency hopes that the public comment will also focus specifically on the following aspects of this Notice:

1. The Agency's preliminary strategy for responding to the NRC Recommendations, given that the Agency's biosolids program does not have sufficient resources to implement all of the recommendations.
2. EPA requests comment on its review under section 405(d)(2)(C) of the CWA. EPA also requests information that may help to fill data gaps for those chemicals for which sufficient information is not yet available to conduct a risk-based screening analysis.
3. EPA's plan to investigate the possibility of developing a process for timely notification, recording, and tracking incident reports in collaboration with other health-based Federal agencies, such as the Centers for Disease Control and Prevention.
4. The Agency's plan to begin designing a survey using information obtained from published pollutant occurrence and effects data, State occurrence data bases, and input received during the public comment period.

XI. References

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Dated: April 2, 2003.

G. Tracy Mehan III,

Assistant Administrator, Office of Water.

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FEDERAL COMMUNICATIONS COMMISSION

[MM Docket No. 98-204; DA 03-1046]

Interim Policy Concerning Placement of Equal Employment Opportunity Public File Report in a Broadcaster's Public File

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Commission gives notice of its interim policy concerning the deadline for placement of Equal Employment Opportunity public file reports in stations' public files. This document also gives notice of groups that have filed petitions for reconsideration in this matter regarding requirement modifications.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Lewis Pulley (202) 418-1456, or Roy Boyce (202) 418-1438, Policy Division, Media Bureau.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Public Notice, MM Docket No. 98-204, adopted and released March 31, 2003. The complete text of this Public Notice is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY-A257, 445 12th Street, SW., Washington, DC and may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street SW., Room CY-B-402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898, or via email qualexint@aol.com.

Synopsis of Public Notice

1. By this Public Notice the Media Bureau establishes an interim policy concerning the enforcement of the requirement of the Equal Employment Opportunity ("EEO") rule—§ 73.2080—that a broadcaster that is part of an employment unit with five or more full-