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BIOSOLIDS APPLIED TO LAND: ADVANCING STANDARDS AND PRACTICES

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National Research Council

July 2002

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BIOSOLIDS APPLIED TO LAND: ADVANCING STANDARDS AND PRACTICES

Committee on Toxicants and Pathogens in Biosolids Applied to Land

Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

National Research Council

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Preface

In this report, biosolids are defined as sewage sludge that has been treated to meet the regulatory requirements for land application set out in the Code of Federal Regulations, Title 40 (Part 503). The U.S. Environmental Protection Agency (EPA) established the Part 503 rule and is responsible for overseeing the national biosolids program. The land-application requirements include concentration limits and loading rates for chemical pollutants, treatment and use requirements for controlling and reducing pathogens and the attraction of vectors, and management practices. The requirements are intended to protect public health and the environment from any reasonably anticipated adverse effects. Over the past decade, questions have been raised about the adequacy of the chemical and pathogen standards for protecting public health. To help address the questions and the requirement for periodic reassessment of the Part 503 rule, EPA asked the National Research Council (NRC) to independently review the technical basis of the chemical and pathogen regulations for biosolids, focusing only on human health.

In this report, the NRC's Committee on Toxicants and Pathogens in Biosolids Applied to Land (membership and biographical information provided in Appendix A) searched for evidence on human health effects related to biosolids exposure and the technical methods and approaches used by EPA to establish its human-health-based chemical and pathogen standards for biosolids. The NRC and the committee are aware that some interested parties were anticipating that this report might make a determination of whether EPA should continue to promote land application of biosolids. However, such a determination was not part of the committee's charge. The committee agrees that regulations must be adequate to protect human health and the environment and that they must be complied with and enforced. The committee was asked to focus its review on approaches for identifying human health hazards, for assessing exposure to those hazards, and for assessing risk from the exposures. This report offers numerous recommendations to update and strengthen the scientific credibility of the biosolids regulations and to ensure their consistent implementation.

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report: Robert Cooper, BioVir Laboratories, Inc., Benicia, California; Alison Cullen, University of Washington, Seattle, Washington; Charles Henry, University of Washington, Seattle, Washington; Cecil Lue-Hing, Cecil Lue-Hing & Associates, Inc., Burr Ridge, Illinois; Philip Landrigan, Mount Sinai School of Medicine, New York, New York; Aaron Margolin, University of New Hampshire, Durham, New Hampshire; Penny Newman, Center for Community Action and Environmental Justice,

Riverside, California; George O'Connor, University of Florida, Gainesville, Florida; Robert Southworth, Marshall, Virginia; Alan Stern, New Jersey Department of Environmental Protection, Trenton, New Jersey; Willy Verstraete, University of Gent, Gent, Belgium; and William Yanko, Big Bear City, California.

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Michael Kavanaugh, Malcolm Pirnie, Inc., Emeryville, California, and Ronald Estabrook, University of Texas Southwestern Medical Center, Dallas, Texas. Appointed by the NRC, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

The committee gratefully acknowledges the individuals who made presentations to the committee at its public meetings. A list of those individuals is provided in Appendix B. The committee also wishes to thank EPA staff members Alan Hais, Robert Bastian, Alan Rubin, James Smith, and Charles White for their assistance in providing documents and information.

The committee is grateful for the assistance of the NRC staff in preparing the report. It particularly wishes to acknowledge the contributions of Susan Martel, project director, who coordinated the project and contributed to the committee's report. Other staff members who contributed to this effort are James J. Reisa, director of the Board on Environmental Studies and Toxicology; Roberta M. Wedge, program director for risk analysis; Mark Gibson, program officer (Water Science and Technology Board); Ruth E. Crossgrove, editor; Mirsada Karalic-Loncarevic, research assistant; and Jessica Brock, senior project assistant.

Finally, I would especially like to thank all the members of the committee for their efforts throughout the development of this report.

Thomas A. Burke, Ph.D.
Chair, Committee on Toxicants and
Pathogens in Biosolids Applied to Land

CONTENTS

Abbreviations

CFR	Code of Federal Regulations
CFU	colony forming units
CWA	Clean Water Act
EQ	exceptional quality
HEI	highly exposed individual
MEI	most exposed individual
MPN	most probably number
MT	metric tons
NIOSH	National Institute for Occupational Safety and Health
NRC	National Research Council
NSSS	National Sewage Sludge Survey
OIG	EPA Office of Inspector General
PCBs	polychlorinated biphenyls
PEC	Pathogen Equivalency Committee
PFRP	process to further reduce pathogens
PFU	plaque-forming unit
POTW	publicly owned treatment works
PSRP	process to significantly reduce pathogens
QMRA	quantitative microbial risk assessment
RME	reasonable maximum exposure
TEF	toxicity equivalency factor
TS	total solids

ABBREVIATIONS

AMSA	Association of Metropolitan Sewerage Agencies
CFR	Code of Federal Regulations
CFU	colony forming units
CWA	Clean Water Act
DAF	dilution attenuation factor
EQ	exceptional quality
HEI	highly exposed individual
MEI	most exposed individual
MPN	most probable number
MT	metric tons
NIOSH	National Institute for Occupational Safety and Health
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PFRP	process to further reduce pathogens
PFU	plaque-forming unit
POTW	publicly owned treatment works
PSRP	process to significantly reduce pathogens
QMRA	quantitative microbial risk assessment
RME	reasonable maximum exposure
TEF	toxicity equivalency factor
TEQs	toxic equivalents
TS	total solids
UC	uptake coefficient
WEF	Water Environment Federation

Summary

Wastewater treatment in the United States is a major cornerstone of efforts to keep the nation's waters clean. Sewage sludge is the solid, semisolid, or liquid residue generated during treatment of domestic sewage. Since the early 1970s, the U.S. Environmental Protection Agency (EPA) and the wastewater treatment industry have promoted recycling of sewage sludge. With the prohibition of ocean disposal of wastewater residuals in 1992, the use of sewage sludge as soil amendments (soil conditioners or fertilizers) or for land reclamation has been increased to reduce the volume of sewage sludge that must be landfilled, incinerated, or disposed of at surface sites. Approximately 5.6 million dry tons of sewage sludge are used or disposed of annually in the United States; approximately 60% of that is used for land application. Depending on the extent of treatment, sewage sludge may be applied where little exposure of the general public is expected to occur on the sites, such as on agricultural land, forests, and reclamation sites, or on public-contact sites, such as parks, golf courses, lawns, and home gardens. EPA estimates that sewage sludge is applied to approximately 0.1% of available agricultural land in the United States on an annual basis.

The regulation governing land application of sewage sludge was established by EPA in 1993 in the Code of Federal Regulations, Title 40 (Part 503), under Section 405 (d) of the Clean Water Act. The regulation is intended to protect public health and the environment. The Part 503 rule established management practices for land application of sewage sludge, concentration limits and loading rates for chemicals, and treatment and use requirements designed to control and reduce pathogens and attraction of disease vectors (insects or other organisms that can transport pathogens). In this report, the term *biosolids* refers to sewage sludge treated to meet the land-application standards in the Part 503 rule or any other equivalent land-application standards.

The chemical and pathogen land-application standards in the Part 503 rule were developed differently. For chemicals, EPA conducted extensive risk assessments that involved identifying the chemical constituents in biosolids judged likely to pose the greatest hazard, characterizing the most likely exposure scenarios, and using scientific information and assumptions to calculate concentration limits and loading rates (amount of chemical that can be applied to a unit area of land). Nine inorganic chemicals in biosolids are currently regulated, and EPA is considering the addition of a class of organic chemicals (dioxins) to its regulation. Monitoring data on some of the regulated inorganic chemicals indicate a decrease in their concentrations over the past decade, due in part to the implementation of wastewater pretreatment programs. Thus, the chemical limits for biosolids can be achieved easily. In contrast to the chemical standards, the pathogen standards are not risk-based concentration limits for individual pathogens but are technologically based requirements aimed at reducing the presence of pathogens and potential exposures to them by treatment or a combination of treatment and use restrictions. Monitoring biosolids is required for indicator organisms (certain species of organisms believed to indicate the presence of a larger set of pathogens).

THE COMMITTEE'S TASK

In response to the Clean Water Act requirement to reassess periodically the scientific basis of the Part 503 rule and to address public-health concerns, EPA asked the National Research Council (NRC) to conduct an independent evaluation of the technical methods and approaches used to establish the chemical and pathogen standards for biosolids, focusing specifically on human health protection and not ecological or agricultural issues. The NRC convened the Committee on Toxicants and Pathogens in Biosolids Applied to Land, which prepared this report. The committee was asked to perform the following tasks:

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 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.

MAJOR FINDINGS AND RECOMMENDATIONS

The committee recognizes that land application of biosolids is a widely used, practical option for managing the large volume of sewage sludge generated at wastewater treatment plants that otherwise would largely need to be disposed of at landfills or by incineration. In responding to its charge, the committee searched for evidence on human health effects related to biosolids exposure, reviewed the risk assessments and technical data used by EPA to establish the chemical and pathogen standards, and reviewed the management practices of the Part 503 rule. 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. The committee found that EPA has not yet addressed certain recommendations of the 1996 NRC report that pertain to the scope of the present study. The committee is aware that some interested parties were anticipating that this report might make a determination of whether EPA should continue to promote land application of biosolids. However, such a determination was not part of the committee's charge. Nor was the committee asked to judge the adequacy of the individual standards in protecting human health. The

committee's report instead is focused on identifying how current risk-assessment practices and knowledge regarding chemicals and pathogens in biosolids can be used to update and strengthen the scientific basis and credibility of EPA's biosolids regulations.

In this report, the committee documents numerous findings and a number of recommendations for addressing public-health concerns, uncertainties, and data gaps about the technical basis of the biosolids standards. To delineate issues needing the greatest attention, the committee identified the following overarching findings and recommendation based on its review and synthesis of the specific findings and recommendations of each chapter.

Overarching Findings

There is no documented scientific evidence that the Part 503 rule has failed to protect public health. However, additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids. There have been anecdotal allegations of disease, and many scientific advances have occurred since the Part 503 rule was promulgated. To assure the public and to protect public health, there is a critical need to update the scientific basis of the rule to (1) ensure that the chemical and pathogen standards are supported by current scientific data and risk-assessment methods, (2) demonstrate effective enforcement of the Part 503 rule, and (3) validate the effectiveness of biosolids-management practices.

Overarching Recommendations

- **Use improved risk-assessment methods to better establish standards for chemicals and pathogens.** Risk-assessment methods for chemicals and pathogens have advanced over the past decade to the extent that (1) new risk assessments should be conducted to update the scientific basis of the chemical limits, and (2) risk assessments should be used to supplement technological approaches to establishing regulatory criteria for pathogens in biosolids.
- **Conduct a new national survey of chemicals and pathogens in sewage sludge.** The committee endorses the recommendation of a previous NRC committee that a new national survey of chemicals be performed. The committee further recommends a survey of pathogen occurrence in raw and treated sewage sludges. The survey should include a careful examination of management practices to ensure that risk-assessment principles are effectively translated into practice. Data from the survey should be used to provide feedback for continuous improvement in the science and technology of biosolids applied to land.
- **Establish a framework for an approach to implement human health investigations.** A procedural framework should be established to implement human health investigations, including short-term investigations of unusual episodes of release, exposure, or disease and large-scale preplanned studies of exposures and their association, if any, with disease. The framework should have mechanisms to document state-of-the-art successes, both technological and administrative, in preventing or remediating exposure to pathogens and toxicants and their adverse health outcomes. Further, the framework should include a means for tracking allegations and sentinel events (compliance, management, or health based),

investigations, and conclusions. Such tracking should be systematic and developed in cooperation with states.

- **Increase the resources devoted to EPA's biosolids program.** To remedy the deficiencies and to implement the recommendations described in this report, more funding and staff resources are needed for EPA's biosolids program. EPA should support and facilitate greater delegation of authority to states to administer the federal biosolids regulation. Resources are also needed for conducting needed research and to revise the regulation as appropriate and in a timely fashion.

These recommendations are discussed in greater detail below and in the following chapters.

Health Effects

Toxic chemicals, infectious organisms, and endotoxins or cellular material may all be present in biosolids. There are anecdotal reports attributing adverse health effects to biosolids exposures, ranging from relatively mild irritant and allergic reactions to severe and chronic health outcomes. Odors are a common complaint about biosolids, and greater consideration should be given to whether odors from biosolids could have adverse health effects. However, a causal association between biosolids exposures and adverse health outcomes has not been documented. To date, epidemiological studies have not been conducted on exposed populations, such as biosolids appliers, farmers who use biosolids on their fields, and communities near land-application sites. Because of the anecdotal reports of adverse health effects, the public concerns, and the lack of epidemiological investigation, the committee concluded that EPA should conduct studies that examine exposure and potential health risks to worker and residential populations. Studies of wastewater treatment workers exposed to raw sewage sludge should not be used as substitutes for studies of populations exposed to biosolids. The types and routes of exposure to sewage sludge and biosolids constituents can be quite different, and there are major differences in the populations exposed. For example, exposures to biosolids go beyond the wastewater treatment plant to other worker populations, such as appliers and farmers, and to the general public, such as communities living near land-application sites and consumers of crops grown on biosolids-amended soils. Exposed populations may also include sensitive subpopulations, such as children, immunocompromised individuals, and the elderly, who are unlikely to be prevalent in the workplace.

Findings: There is a lack of exposure and health information on populations exposed to biosolids. Therefore, although the land application of biosolids has occurred for many years with little, if any, systematic documented evidence of adverse effects, there is a need to gather epidemiological data and to investigate allegations of health incidents. EPA needs to study more rigorously the exposure and health risks, or the lack thereof, in worker and community populations exposed to biosolids.

Recommendations: Although routine human health surveillance of all populations exposed to biosolids is impractical, the committee recommends that EPA promote and support response investigations, targeted exposure surveillance studies, and a few well-designed epidemiological investigations of exposed populations. This recommendation is intended to

provide a means of documenting whether health effects exist that can be linked to biosolids exposure. The committee recommends the following types of studies:

- *Studies in response to unusual exposures and unusual occurrences of disease.* Occasionally, the occurrence of unusual events can provide information on the agents of disease. For example, an outbreak or a symptom of disease might occur following a known exposure or an unusual exposure scenario. In both instances, exposure and health outcomes should be determined.
- *Preplanned exposure-assessment studies.* Such studies should characterize the exposures of workers, such as biosolids appliers and farmers, and the general public who come into contact with constituents of biosolids either directly or indirectly. The studies would require identification of microorganisms and chemicals to be measured, selection of measurement methods for field samples, and collection of adequate samples in appropriate scenarios. A possible exposure-assessment study would be to measure endotoxin exposure of workers at biosolids production and application sites and of communities nearby.
- *Complete epidemiological studies of biosolids use.* These studies should be conducted to provide evidence of a causal association, or a lack thereof, between biosolids exposure and adverse human health effects. They should include an assessment of the occurrence of disease and an assessment or measurement of potential exposures. An example of a longitudinal epidemiological study would be an evaluation of health effects in a cohort of biosolids appliers These workers should be characterized by duration and level of exposure, and given appropriate follow-up. Because complete epidemiological studies are expensive and require extensive data analysis, priority should be given to studies that can address serious or widespread problems and help reduce uncertainty.

Chemical and Pathogen Standards

EPA's 1993 chemical and pathogen standards for biosolids were based on the scientific and technical information available at that time and the expectation that the prescribed biosolids-management practices specified in the Part 503 rule would be effective in preventing harmful exposure to biosolids constituents. To assure the public that the standards are protective of human health, it is important that EPA demonstrate that its chemical limits and pathogen-reduction requirements are supported by current scientific data and risk-assessment methods. Management practices (e.g., 10-meter setback from water bodies) are designed to control the potential risks; therefore, it is important to verify the effectiveness of the practices. In addition, EPA must demonstrate that the Part 503 rule is being enforced.

Findings: The committee found that no substantial reassessment has been done to determine whether the chemical or pathogen standards promulgated in 1993 are supported by current scientific data and risk-assessment methods. In addition, EPA does not have an adequate program to ensure compliance with the biosolids regulations and has not documented the effectiveness of its prescribed management practices. Although there is no documented scientific evidence that the Part 503 rule has failed to protect public health, there is a need to address scientific and management questions and uncertainties that challenge EPA's biosolids standards.

Recommendations: EPA should expand its biosolids oversight activities to include procedures for (1) assessing the reliability of the biosolids treatment processes, (2) monitoring compliance with the chemical and pathogen standards, (3) conducting environmental hazard surveillance, and (4) studying human exposure and health. The committee recommends that Figure S-1 be used by EPA as a framework for establishing such a program. The central part of the figure presents the general process by which biosolids are produced and used for land application. Depicted on the left side of the figure are opportunities for conducting environmental hazard surveillance. At these stages, biosolids or environmental samples should be collected and analyzed 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. An important part of this verification process is a review of the management practices required for land application, because the practices are predicated on the assumption that exposure to hazardous agents is further reduced by the implementation of such practices. Studies should be conducted to determine whether the management practices specified in the Part 503 rule achieve their intended effect. Additional risk-management practices should be considered in revising the Part 503 rule. Considerations should include setbacks to residences or businesses, setbacks to private and public water supplies, limitations on holding or storage practices, slope restrictions, soil permeability and depth to groundwater or bedrock, and greater distance to surface water.

The right side of the figure depicts the various points in the process where human exposures can occur. Field research should be conducted to assess potential exposure to biosolids constituents of concern. Results from this research could be used to identify populations that should be monitored or studied at particular times and locations for abnormal health conditions and potential biosolids exposure (see earlier recommendations for response and epidemiological studies). Studying environmental samples and reports of adverse health outcomes can provide feedback to support or improve the risk-assessment and risk-management processes.

The major aspect of the framework studied by the committee was the technical basis of the 1993 chemical and pathogen land-application standards of the Part 503 rule. Recent EPA guidance recommends that risk assessment of complex mixtures ideally be based on studies of the mixture rather than on selected individual components. Such an approach is not feasible for biosolids, however, because studies of biosolids as complex mixtures are lacking. Furthermore, although methods for conducting risk assessments of chemical mixtures are available, no work has been done on risks from pathogen mixtures, much less chemical-pathogen mixtures.

Finding: Because of data gaps and lack of risk-assessment methods for complex mixtures, it is not possible at this time to integrate pathogen risk assessment with chemical risk assessment. Thus, it remains necessary to use a component-based approach to assessing risks from chemicals and pathogens in biosolids. There have been substantial improvements in conducting risk assessments since the Part 503 rule was promulgated, and guidance for using these improved methods to update and strengthen the scientific basis of the chemical and pathogen standards is provided below.

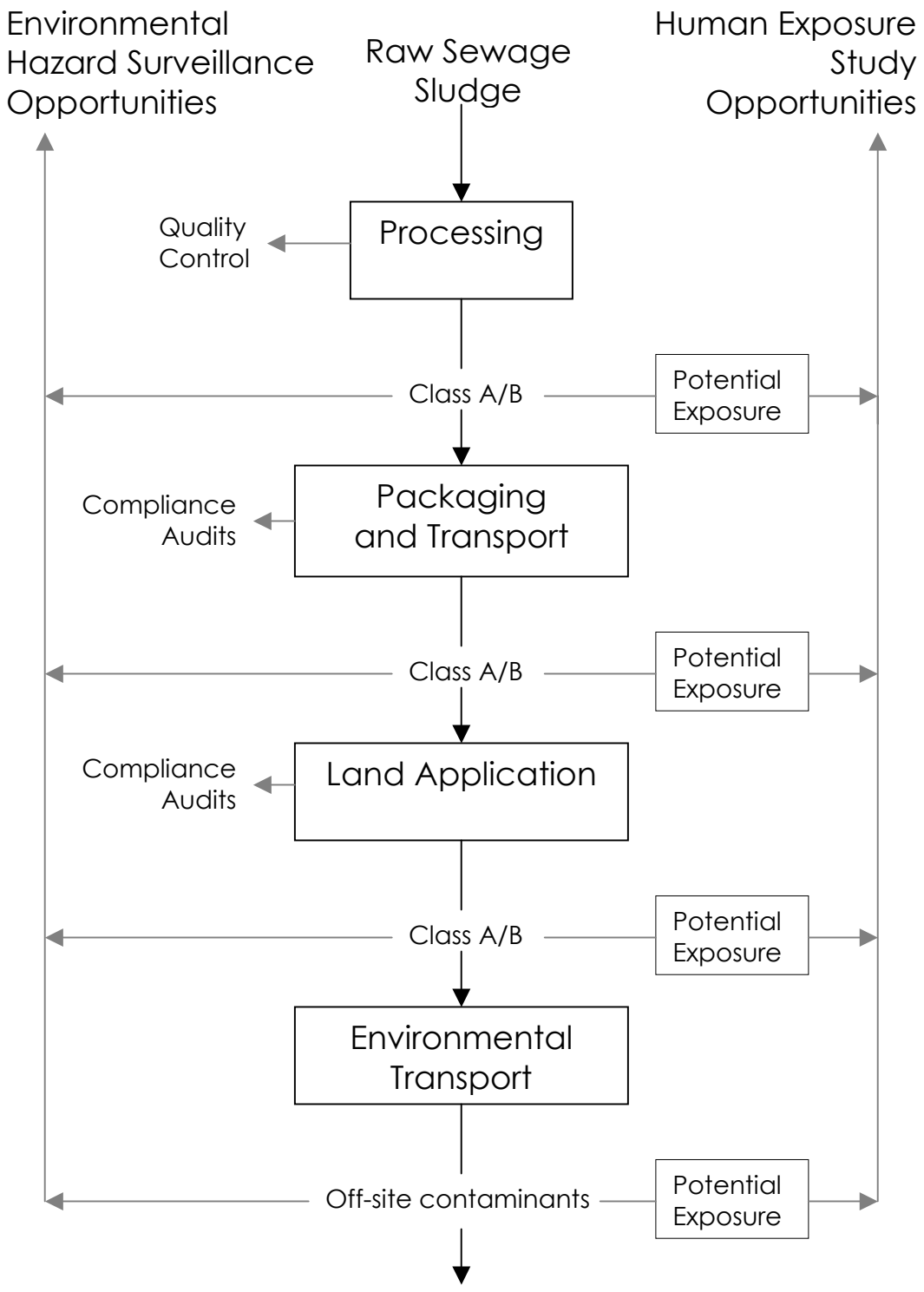

FIGURE S-1 Processing, transport, and land application of biosolids with options for hazard surveillance and studies of human exposures.

Chemical Standards

In developing the original (1993) Part 503 rule, EPA selected 10 inorganic chemicals (arsenic, cadmium, chromium,[1] copper, lead, mercury, molybdenum,[2] nickel, selenium, and zinc) to regulate for land application. Risk assessments were conducted on each chemical to establish concentration limits and loading rates. However, methods for conducting risk assessments have evolved substantially since the 1993 regulations were established. One of the major developments has been a growing recognition of the need to include stakeholders in the risk-assessment process. Stakeholders are groups who are potentially affected by the risk, groups who will manage the risk, and groups who will be affected by efforts to manage the source of the risk. Stakeholders can provide information and insights into how biosolids are used in practice and the nature of potential exposures to chemicals and pathogens. Involving stakeholders throughout the risk-assessment process provides opportunities to bridge gaps in understanding, language, values, and perspectives and to address concerns of affected communities. Other important developments in risk assessment in recent years include improvements in measuring and predicting adverse health effects, advancements in measuring and predicting exposure, explicit treatment of uncertainty and variability, and improvements in describing and communicating risk.

In developing its 1993 chemical standards, EPA selected chemicals, exposure conditions, and risk-assessment assumptions that were intended to be representative and conservative enough to be applicable to all regions of the United States and to all land-application sites, including agricultural fields, forests, and reclamation sites. Thus, the standards were expected to account for possible variations in biosolids composition, geographic and environmental conditions, or application and management practices. EPA relied heavily on its 1988-1989 National Sewage Sludge Survey (NSSS) to identify chemicals to regulate, using percent detection and concentration values to exempt some chemicals from regulation and to establish ceiling-concentration limits for others. A 1996 NRC report (*Use of Reclaimed Water and Sludge in Food Crop Production*) questioned the reliability of the results of the NSSS because of limitations in sampling analyses and data-reporting methods. Improvements in industrial wastewater pretreatment processes and changes in chemical uses have occurred over the past decade. Chemicals not included in the NSSS analyses have since been identified as potential concerns, and data gaps on toxicity and fate and transport characteristics that prevented risk assessment from being performed on some chemicals a decade ago might now be filled. In addition, the committee found no adequate justification for EPA's decision to eliminate from regulation all chemicals detected at less than 5% frequency in the NSSS (or 10% frequency in subsequent reanalysis). It should be noted that there are still data gaps that will continue to limit risk-assessment capability on many of the chemicals, including those newly identified as potential concerns.

[1] Chromium was deleted from the regulation in 1995. This amendment was the result of a petition seeking review of the pollutant limits for chromium filed in 1993 by the Leather Industries of America, Inc., to the U.S. Circuit Court of Appeals for the District of Columbia Circuit. The court remanded the request to EPA for additional justification or modification of its chromium regulations in the Part 503 rule. The agency subsequently determined that there was insufficient support for regulating chromium in biosolids.

[2] Standards for molybdenum were dropped from the original regulation. Currently, only a ceiling-concentration limit is available for molybdenum, and a decision about establishing new pollutant limits for this metal has not been made.

EPA considered 14 major exposure pathways in setting the 1993 limits for the nine regulated chemicals. Nine of the pathways resulted in exposure to humans, two to animals, two to soil organisms, and one to plants. The pathways were evaluated for agricultural and nonagricultural application scenarios. For all nine of the regulated chemicals, agricultural scenarios produced the lowest limits that were subsequently used in the regulation. EPA elected to evaluate the human exposure pathways for a theoretical, highly exposed individual (HEI) (i.e., a hypothetical individual assumed to remain for an extended period of time at or adjacent to the site where maximum exposure occurs). The degree of realism for the HEI varied among the exposure pathways, and it was not clear to the committee whether exposure estimates were comparably conservative for all pathways. Moreover, each pathway was evaluated independently, and no consideration was given to exposure from multiple pathways.

Current risk-assessment practice is to perform comprehensive, multipathway risk assessments that estimate aggregate exposures for each receptor population (i.e., groups with potential exposure to contaminated media). Such risk assessments are based on a conceptual site model that identifies the biosolids sources (e.g., biosolids tilled into soil or applied to the surface for agricultural soil), the pathways by which biosolids constituents might be released and transported, and the nature of human contacts with the constituents. General practice has changed from using the HEI as the receptor of concern, because such an individual is unlikely to exist, to using an individual with reasonable maximum exposure (RME). An RME individual is a hypothetical individual who experiences the maximum exposure that is reasonably expected to occur (i.e., an upper-bound exposure estimate). RMEs should be based on receptor populations of concern, such as a farm family living adjacent to and downhill from a land application site.

A number of risk algorithms were used to calculate the 1993 chemical limits. The general algorithms are still valid, but some fate and transport models and exposure parameter assumptions used in the calculations have advanced since 1993, and some alternative assumptions have been supported by new studies. Chemical limits should be based on an integrated evaluation of all exposure pathways that might affect the identified receptors.

Findings: The committee found the technical basis of the 1993 chemical standards for biosolids to be outdated. EPA has not reevaluated its chemical standards since promulgation, so the data and methods used for the original regulations are well over a decade old. There have been substantial advances in risk assessment since then, and there are new concerns about some adverse health outcomes and chemicals not originally considered. Because of the diversity of exposed populations, environmental conditions, and agricultural practices in the United States, it is important that nationwide chemical regulations be based on the full range of exposure conditions that might occur. Furthermore, there is a need to investigate whether the biosolids produced today are similar in composition to those used in the original assessments.

Recommendations: Using current risk-assessment practices, EPA should reassess the standards for the regulated chemicals and conduct another chemical selection process to determine whether additional chemicals should be considered for regulation. On the basis of the revised risk assessments and chemical selection, EPA can determine whether the standards or risk-management process should be revised and whether additional chemicals should be regulated. Because the land-application standards are to be relevant nationally, it is important that the revised risk assessments reflect regional variations in climate, hydrology, and biosolids use and characteristics, and that standards are protective of populations reflecting reasonable

estimates of maximum exposure. The chemical standards should be reevaluated and updated periodically to ensure that they are supported by the best available scientific data and methods. Important elements for updating the risk assessments are the following:

- As recommended by an earlier NRC committee, a new national survey of chemicals in biosolids should be conducted. EPA should review available databases from state programs in designing a new survey. Other elements that should be included in the survey are an evaluation of the adequacy of detection methods and limits to support risk assessment; consideration of chemical categories, such as odorants and pharmaceuticals, that were not previously evaluated; and assessment of the presence of multiple species of certain metals, such as mercury and arsenic, that have different toxicity end points. Data from this survey should be used to identify any additional chemicals for potential regulation.
- Aggregate exposure assessments should be performed. A conceptual site model should be used to identify major and minor exposure pathways for various application scenarios. Special consideration should be given to identifying the application practices and environmental conditions that are likely to result in the greatest human exposure. Risks from long-term low-level exposures, as well as short-term episodic exposures, such as those that can occur with volatile chemicals, should be evaluated.
- An RME individual, rather than an HEI, should be evaluated for each exposure pathway. Use of the RME is a more informed and reasonable estimate of exposure than the HEI because it reduces reliance on the subjective application of default assumptions and reflects improved methods of characterizing population exposure. When the RME individual is likely to be exposed by more than one pathway, exposures should be added across pathways.
- Fate and transport models and exposure parameter assumptions used in the risk assessment should be updated to reflect the most current information on the RME individual for each exposure pathway.
- Representatives of stakeholders should be included in the risk-assessment process to help identify exposure pathways, local conditions that could influence exposure, and possible adverse health outcomes.

Pathogen Standards

Pathogens are disease-causing microorganisms. The two land-application classifications for biosolids, Class A and Class B, are based on pathogen content. Class A biosolids have pathogen densities below specified detection limits, whereas Class B biosolids have pathogen densities above those limits. No risk assessments were conducted to establish the 1993 pathogen standards for these classes. Instead, EPA established technologically based requirements to reduce the presence of pathogens by treatment or a combination of treatment and use restrictions. To meet Class A requirements, demonstration of pathogen reduction is required by using one of several prescribed treatments. Monitoring of indicator organisms is required of Class A biosolids at the time of use, distribution, or land application to verify that treatment processes have reduced pathogen concentrations as expected (i.e., below the specified detection limits). Class B biosolids must also undergo treatment to reduce the presence of pathogens but, unlike Class A biosolids, Class B biosolids may have detectable concentrations of pathogens. Because of that, site restrictions are required to minimize contact with the biosolids until environmental factors (e.g., heat and desiccation) have further reduced the presence of pathogens. Site restrictions

include restrictions on crop harvesting, animal grazing, and public access for designated periods of time. However, there is no requirement that on-site measurements be taken at Class B application sites to confirm that the treatment and the use restrictions resulted in below-detection pathogen concentrations. Such on-site measurements would help to estimate potential risks and the efficacy of site-management requirements.

EPA considered a spectrum of bacteria, viruses, protozoa, and helminths in setting its 1993 pathogen standards. New information on some of these and other organisms are now available for updating hazard identification. Humans may be exposed to pathogens in biosolids from ingestion of contaminated food, water, or soil; dermal contact; and inhalation of bioaerosols (aerosolized biological particles). There is also the potential for humans to be exposed via secondary transmission from exposure to pathogens shed from infected individuals either by direct contact or by routes through the environment. Some exposure pathways, such as the inhalation pathway, were not adequately evaluated by EPA in the development of the 1993 Part 503 pathogen requirements. EPA also did not address sufficiently the potential for surface-water contamination by runoff, groundwater contamination, and secondary transmission of disease.

The reliability of biosolids treatment processes in reducing pathogens is essential for public-health protection. There is a need to better document the reliability of EPA's prescribed treatment processes and to establish that management controls intended to reduce pathogens by natural attenuation are effective. An important consideration in making these determinations is ensuring that the pathogen detection methods used are accurate and precise. Substantial advances in detection and quantification of pathogens in the environment have been made since the 1993 promulgation of the 503 rule. For example, new molecular techniques for detecting pathogens (e.g., polymerase chain reaction) are now available. In addition, new approaches to environmental sample collection and processing are available. However, improved standardized methods for measuring pathogens in biosolids and bioaerosols need to be developed.

As with the chemical standards, EPA based its 1993 pathogen standards on selected pathogens and exposure conditions that were expected to be representative and conservative enough to be applicable to all areas of the United States and all types of land applications. This includes the recognition that pathogen survival in soils can range from hours to years, depending on the specific pathogens, biosolids application methods and rates, initial pathogen concentrations, soil composition, and meteorological and geological conditions. Little is know about pathogen transport and survival in bioaerosols.

Quantitative microbial risk-assessment (QMRA) methods similar to those used in chemical assessments have been developed for microbial agents in drinking water and food. These methods are not as well established as those for chemicals, and there are important differences between the two. One of the major differences is that microbial risk assessment must include the possibility of secondary transmission of disease, either through person-to-person contact or from transmission of the pathogen to others through air, food, or water. The importance of secondary transmission depends in part on the level of acquired immunity to the pathogen in the community, a phenomenon that has no analog in chemical risk assessment.

Findings: Given the variety of pathogens that have the potential to be present in biosolids, the committee supports EPA's approach to establishing pathogen reduction requirements and monitoring indicator organisms. However, the reliability of EPA's prescribed treatment techniques should be better documented using current pathogen detection technology, and more research on environmental persistence and dose-response relationships are needed to

verify that current management controls for pathogens are adequate to maintain minimal exposure concentrations over an extended period of time. QMRA methods have developed sufficiently to provide better risk information that should be used to establish or support existing regulatory criteria.

Recommendations:

- EPA should conduct a national survey of pathogen occurrence in raw and treated sewage sludges. Important elements in conducting the survey include use of consistent sampling methods, analysis of a broad spectrum of pathogens that could be present in sewage sludge, and use of the best available (preferably validated) pathogen measurement techniques**.**
- QMRAs should be developed and used to establish regulatory criteria (treatment requirements, use restrictions, and monitoring) for pathogens in biosolids. For example, EPA could stipulate an acceptable risk level for a particular pathogen. QMRA could then be used to estimate the concentration of that pathogen in biosolids either at the point of application (where there is immediate potential for exposure) or following any required holding period. EPA could then determine experimentally based relationships between the maximum acceptable pathogen concentration and the process conditions (e.g., time, temperature, pH, chemical doses, and holding times) and/or the pathogen indicator concentrations (either density or reduction through treatment). On the basis of those relationships, regulatory criteria and monitoring for land application can be updated or developed to ensure consistent attainment of target pathogen concentrations. To conduct QMRAs, a conceptual site model should be used to identify all potential routes of exposure; additional input data (e.g., dose-response and pathogen-survival data) should be collected; and consideration should be given to potential secondary transmission of infectious disease. QMRAs also can be used to analyze sensitivity and to ascertain what critical information is needed to reduce uncertainty about the risks from exposure to pathogens in biosolids. The pathogen standards should be reevaluated and updated periodically to ensure that they are supported by the best available scientific data and methods and to ensure that anecdotal information is not being used for the predication of past, current, or future regulations.
- EPA should foster development of standardized methods for measuring pathogens in biosolids and bioaerosols.
- EPA should promote research that uses improved pathogen detection technology to better establish the reliability of its prescribed pathogen treatment processes and biosolids-use controls to achieve and maintain minimal exposure over time. In setting pathogen treatment requirements, it might be useful to establish metrics for typical (mean) treatment performance and concentrations not to be exceeded.
- Research should be conducted to assess whether other indicator organisms, such as *Clostridium perfringens*, could be used in regulation of biosolids. Such indicators, along with traditional indicators and operational parameters, may be suitable for monitoring day-to-day regulatory compliance.

1

Introduction

Land application of treated sewage sludge (often referred to as biosolids) for soil-amendment and land-reclamation purposes has increased over the past decade as a result of the ban on ocean dumping of wastewater residuals (Ocean Disposal Ban Act of 1988) and as an alternative to other disposal options, such as landfilling or incineration. Recycling sewage sludge has been practiced for many decades. In 1993, EPA promulgated Standards for the Use or Disposal of Sewage Sludge (Code of Federal Regulations Title 40, Part 503), which set pollutant limits, operational standards for pathogen and vector-attraction reduction, management practices, and other provisions intended to protect public health and the environment from any reasonably anticipated adverse effects from chemical pollutants and pathogenic organisms. Many of the regulations (commonly referred to as the Part 503 rule) were based on risk assessments conducted to identify and characterize risks associated with the use or disposal of sewage sludge. In this report, the National Research Council's (NRC's) Committee on Toxicants and Pathogens in Biosolids Applied to Land reviews the nature of the human health risks from chemicals and pathogens in biosolids; evaluates the scientific approaches that EPA used to establish its human-health-based land-application pollutant limits and pathogen reduction techniques; provides an overview of the advances in risk assessment since the establishment of those standards; and, in light of the advancements, recommends risk-based strategies for reevaluating the human-health-based land-application standards of the Part 503 rule.

This chapter briefly reviews why biosolids are a public-health concern, states the task addressed by the committee, sets forth the committee's activities and deliberative process in developing the report, and describes the organization of the report.

BIOSOLIDS

Definitions and Use

Sewage sludge is defined in the Part 503 rule as the solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works. The term biosolids is not used in the Part 503 rule, but EPA (1995) defines biosolids as "the primarily organic solid product yielded by municipal wastewater treatment processes that can be beneficially recycled" as soil amendments. Use of the term biosolids has been controversial because of the perception that it was created to improve the image of sewage sludge in a public-relations campaign by the sewage industry (Rampton 1998). For the purposes of this report, the committee considers sewage sludge to be the solid, semi-solid, or liquid residue generated during treatment of domestic sewage, and biosolids to be sewage sludge that has been treated to meet the land-application standards in the Part 503 rule or any other equivalent land-application standards.

It is estimated that approximately 5.6 million dry tons of sewage sludge are used or disposed of annually in the United States, of which approximately 60% are used for land-application or public distribution (see Chapter 2). On the basis of data from EPA (1999a) and

USDA (1997), EPA estimates that approximately 0.1% of available agricultural land in the United States is treated with biosolids. Biosolids are a complex mixture that may contain organic, inorganic, and biological pollutants from the wastewaters of households, commercial establishments, and industrial facilities and compounds added or formed during various wastewater treatment processes. Such pollutants include inorganic contaminants (e.g., metals and trace elements), organic contaminants (e.g., polychlorinated biphenyls [PCBs], dioxins, pharmaceuticals, and surfactants), and pathogens (e.g., bacteria, viruses, and parasites). Sewage-sludge treatment processes are intended to reduce the volume and organic content of biosolids and to reduce the presence of pathogens but retain beneficial properties for soil-amendment and land-reclamation purposes. Figure 1-1 provides a simplified schematic of how biosolids are produced and illustrates how the content of biosolids can vary depending on the wastewater streams and the variations in treatment processes. See Figures 2-1 and 2-2 in Chapter 2 for more detailed diagrams of wastewater and sewage sludge treatment.

BOX 1-1 Definitions

Sewage sludge: the solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works.

Biosolids:

- EPA's definition: the primarily organic solid product yielded by municipal wastewater treatment processes that can be beneficially recycled (whether or not they are currently being recycled).
- Committee's definition: sewage sludge that has been treated to meet the land-application standards in the Part 503 rule or any other equivalent land-application standards or practices.

Biosolids are applied to agricultural and nonagricultural lands as soil amendments, because they can improve the chemical and physical properties of soils and they contain nutrients and trace elements important for plant growth. Agricultural lands include sites where food crops (for human or animal consumption) and nonfood crops are grown. Nonagricultural lands include forests, rangelands, and public contact sites (e.g., public parks, golf courses, and cemeteries). Severely disturbed lands, such as strip mines and gravel pits, can be reclaimed with biosolids.

Biosolids are divided into two classes on the basis of pathogen content: Class A and Class B. Class A biosolids are treated to reduce the presence of pathogens to below detectable levels and can be used without any pathogen-related restrictions at the application site. Class A biosolids can also be bagged and sold to the public, if other requirements are met. Class B biosolids are treated to reduce pathogens but still contain detectable levels of them. Class B biosolids have site restrictions that seek to minimize the potential for human and animal exposure until environmental factors, such as heat, sunlight, and desiccation, have reduced pathogens further. Class B biosolids cannot be sold or given away in bags or other containers or used at sites with public use.

Sewage sludge that is not treated to meet land-application standards is usually disposed of at landfills or surface disposal sites that contain only sewage sludge or are incinerated. Regulations pertaining to these disposal practices are contained in the Part 503 rule. Review of disposal regulations is, however, outside the scope of the committee's task.

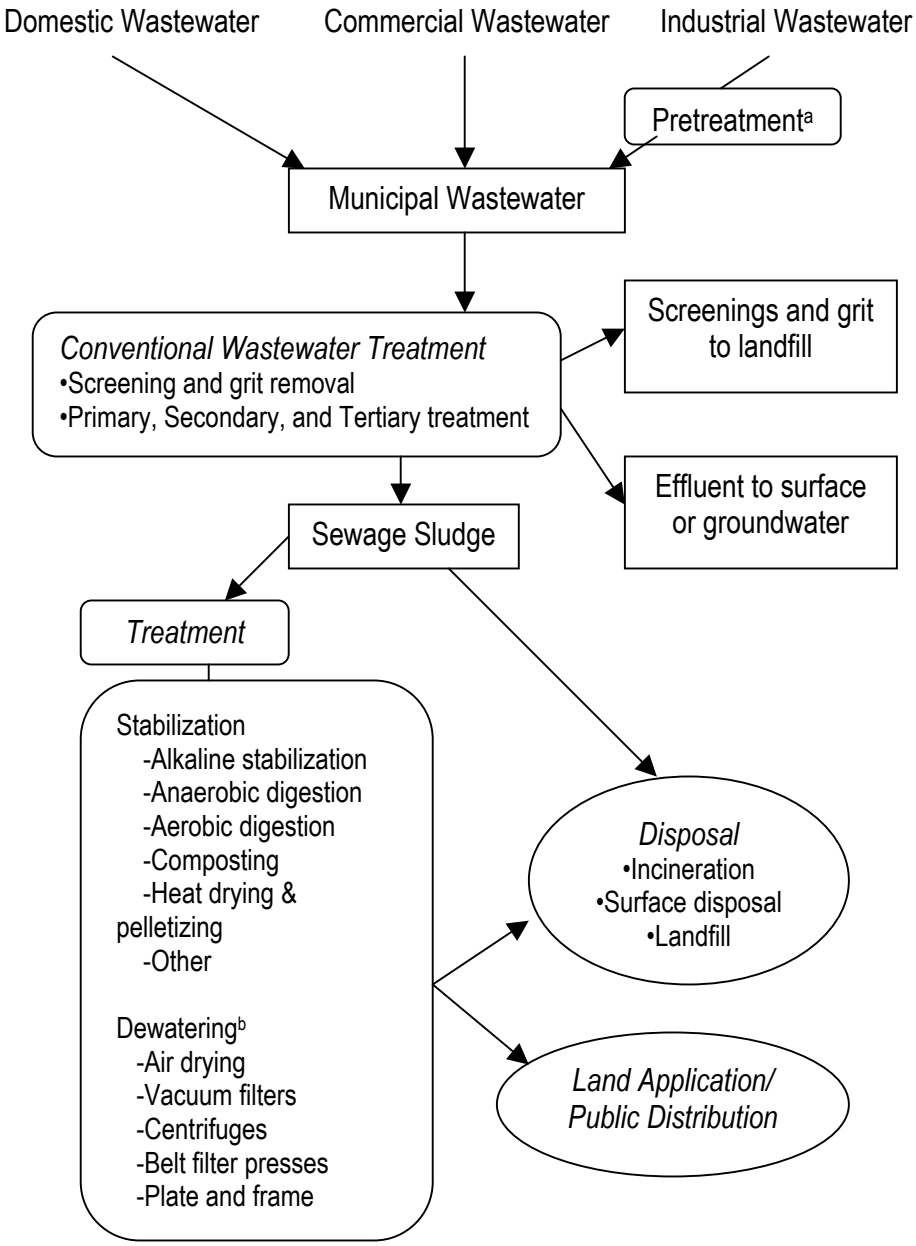

FIGURE 1-1 Biosolids production.
[a]Required by federal and state agencies.
[b]Prior to dewatering, sewage sludge is conditioned and thickened by adding chemicals (e.g., ferric chloride, lime, or polymers).

Pollutant Standards

Different methods were used to establish the chemical pollutant and pathogen standards in the Part 503 rule. For the chemical pollutant limits, sewage-sludge surveys (EPA 1982, 1990) and risk assessments (EPA 1992a,b) were used to identify and characterize risks from chemical pollutants in sewage sludge. The risk assessments considered a variety of pathways by which humans, animals, plants, and soil organisms could be exposed to biosolid pollutants. Chemical standards (i.e., ceiling concentrations (mg/kg), cumulative pollutant loading rates (kg/hectare), pollutant concentration limits (mg/kg), and annual pollutant loading rates (kg/hectare/365-day period) were originally established for 10 inorganic chemicals, using the most limiting exposure pathway. These chemicals are arsenic, cadmium, chromium,[1] copper, lead, mercury, molybdenum,[2] nickel, selenium, and zinc. Standards for five of the currently regulated chemicals (arsenic, cadmium, lead, mercury, and selenium) are based on potential adverse human health effects. Most standards are only for eight chemicals; only a ceiling concentration is currently established for molybdenum, as described in the footnote.

In December 1999, EPA issued a proposal to amend the Part 503 rule for land-applied biosolids by adding a risk-based concentration limit for dioxins, a category of organic compounds that includes 29 specific congeners of polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans, and coplanar polychlorinated biphenyls (PCBs) (EPA 1999b). (More details about this proposal are presented in Chapters 2 and 5.)

EPA established operational standards for pathogens in biosolids rather than risk-based standards, although it conducted a preliminary set of risk assessments for viruses (EPA 1992c), bacteria (EPA 1991a), and parasites (EPA 1991b). The operational standards are pathogen-reduction requirements, the goal of which is to reduce the presence of pathogens (including enteric viruses, bacteria, parasites, and viable helminth ova) in biosolids to levels that are unlikely to pose a threat to public health and the environment under specific use conditions. Because of the variety of different pathogens that might be present in sewage sludge and the impracticality of testing for all of them, EPA requires analyses of "indicator organisms." An indicator organism is a particular species of microorganism whose presence is used to indicate that a certain set of pathogenic organisms might also be present. The Part 503 rule specifies operational standards for fecal coliforms, *Salmonella* sp. bacteria, enteric viruses, and viable helminth ova.

Earlier NRC Review

In 1996, the NRC published the report *Use of Reclaimed Water and Sludge in Food Crop Production*, which reviewed the practice of using wastewater and biosolids for agricultural

[1] Chromium was deleted from regulation in 1995. This amendment was the result of a petition filed in 1993 by the Leather Industries of America, Inc. to the U.S. Circuit Court of Appeals for the District of Columbia Circuit seeking review of the pollutant limits for chromium. The court remanded the request to EPA for additional justification or modification of its chromium regulations in the Part 503 rule. The Agency subsequently determined that there was "an insufficient basis at this time for the regulation of chromium in sewage sludge that is applied to land" (EPA 1995).

[2] Standards for molybdenum were dropped from the original regulation. Currently, only a ceiling-concentration limit is available for molybdenum, and a decision about establishing new pollutant limits for this metal has not been made.

purposes. That report focused specifically on issues related to food-crop production and evaluated the regulations for chemicals and pathogens in the Part 503 rule; reviewed the impacts on soil, crops, and groundwater; and considered the economic, legal, and institutional issues of the practice. The current report is different from the earlier one in that it encompasses all land-application uses (not only food-crop production), is focused only on human health risks, and provides an in-depth assessment of the methods used to assess those risks.

The 1996 report concluded that "While no disposal or reuse option can guarantee complete safety, the use of [municipal wastewater and biosolids] in the production of crops for human consumption, when practiced in accordance with existing federal guidelines and regulations, presents negligible risk to the consumer, to crop production, and to the environment. Current technology to remove pollutants from wastewater, coupled with existing regulations and guidelines governing the use of reclaimed wastewater and sludge in crop production, are adequate to protect human health and the environment." However, the report also highlighted limitations and inconsistencies in EPA's risk evaluation and made recommendations for additional research. Excerpts of the major recommendations of that report are presented in Box 1-2.

One of the major concerns with respect to EPA's risk evaluation was the reliability of the National Sewage Sludge Survey (EPA 1990), which served as the basis for many of the decisions made in the Part 503 rule, including EPA's decision to exempt organic pollutants from regulation. Inconsistencies were found in the survey's sampling and data-reporting methods that undermined the reliability of the data. Therefore, it was recommended that EPA conduct another national survey of pollutants in biosolids. To date, no comprehensive survey has been performed.

The 1996 NRC report also examined the adequacy of EPA's pathogen requirements and made recommendations to improve them (Box 1-1). EPA[3] has indicated that it plans to develop better analytical protocols for detecting pathogens, including *Salmonella*, as resources permit. It notes that, in general, most biosolids producers continue to demonstrate Class A quality by relying on the fecal coliform tests rather than the *Salmonella* test. EPA also plans to develop monitoring protocols for specific pathogens.

EPA[3] has not decided whether to reevaluate the 30-day waiting period required before grazing is allowed on biosolids-amended pastures. A decision will be based on EPA's review of a workshop held in June 2001 titled Emerging Pathogen Issues in Biosolids, Animal Manures and Other Similar By-products and a microbial risk-assessment model currently being developed by researchers at the University of California at Berkeley for the Water Environment Research Foundation.

HUMAN HEALTH AND RISK-ASSESSMENT ISSUES

A number of potential human health and risk assessment issues were brought to the committee's attention. Some of the major human health issues include the following:

[3] Responses to follow-up questions from U.S. House Science Committee Hearing on Biosolids, March 22, 2000. Submitted to the committee by Elizabeth M. Sokul, Oversight Counsel, Committee on Science, U.S. House of Representatives.

BOX 1-2 Recommendations in NRC (1996) Report

Adequacy of Existing Regulations for Pathogens in Reclaimed Water and Biosolids

- Until a more sensitive method for the detection of *Salmonella* in biosolids is developed, the present test should be used for support documentation, but not be substituted for the fecal coliform test in evaluating biosolids as Class A.
- EPA should continue to develop and evaluate effective ways to monitor for specific pathogens in biosolids.
- EPA should re-evaluate the adequacy of the 30-day waiting period following the application of Class B biosolids to pastures used for grazing animals.

Adequacy of Existing Regulations for Harmful Chemicals in Reclaimed Water and Biosolids

- A more comprehensive and consistent survey of municipal wastewater treatment plants is needed to show whether or not toxic organic compounds are present in biosolids at concentrations too low to pose a risk to human and animal health and to the environment. In conducting a second NSSS, EPA should strive to improve the integrity of the data by using more consistent sampling and data-reporting methods. The EPA should not exclude chemicals from regulatory consideration based solely on whether or not those chemicals have been banned from manufacture in the United States (e.g., PCBs) since they are still found in sewage sludge from many wastewater treatment plants.

Marketing Biosolids Products to the Public

- The Part 503 rule should be amended to more fully assure that only biosolids of exceptional quality, in terms of both pathogen and chemical limits, is marketed to the general public so that further regulation and management beyond the point of sale or give-away would not be necessary.

Soil, Crop, and Ground Water Effects

- When determining biosolids and fertilizer application rates, an analysis of the rates of organic nitrogen mineralization should be performed in order to avoid buildup of excess nitrate-nitrogen. Nitrate-nitrogen that is not taken up by plants may contribute to excess fertilization and leaching. Where excess phosphorus is of concern, soil phosphorus levels should be monitored and biosolids application rates should be adjusted to correspond to crop phosphorus rather than nitrogen needs.
- As more croplands are treated with biosolids and reach their regulatory limit of chemical pollutant loading from biosolids applications, additional information will be needed to assess potential, long-term impacts of biosolids on ground water quality and on the sustainability of soils for crop production.

Economic, Legal, and Institutional Issues

- Any payment program designed to promote agricultural use of treated effluents or biosolids should be carefully structured to avoid the creation of incentives to apply reclaimed water or biosolids at rates in excess of agronomic rates, and to avoid undermining farm management practices needed to protect public and occupational health and the environment.
- States and municipalities that wish to implement a beneficial-use program need to address public concerns and provide assurances that the new uses of biosolids and wastewater do not endanger health or the environment in application areas. The public and local officials should be involved in the decision-making process at an early stage.
- The operators and municipal wastewater treatment facilities and the parties using biosolids and wastewater should implement visible, stringent management and self-regulation measures, including monitoring and reliable reporting by farmers, and should support vigilant enforcement of appropriate regulations by local or state agencies. Implementation of these measures will be credible means of preventing nuisance risks and harm to people, property, and highly valued nearby resources.
- The municipal utility should carry out demonstration programs for public education, and to verify the effectiveness of management and self-regulatory systems. In addition, the utility should be prepared to indemnify farmers against potential liabilities when farmers' financing by banks or other lenders may hinge on this assurance.
- Management of biosolids for beneficial use should be more visibly linked to existing regulations governing its disposal. Program credibility may be improved and public concern reduced if federal, state, and municipal regulators clearly assign authority to local governments for responding to any reports of adverse consequences related to beneficial use of biosolids, such as ground water contamination, odor, attraction of vermin, or illnesses. The public should be aware that state and local units of government have the necessary regulatory authority to take corrective actions against parties who have violated rules and guidance.

- Differences in the extent of health complaints. There are several allegations of deaths caused by exposure to biosolids and anecdotal reports of illnesses ranging from acute to chronic problems, including headaches, respiratory problems, and gastrointestinal illnesses. Most health complaints appear to be concentrated in specific locales. Other locales receive few or no complaints.
- Citizen complaints. Odors from biosolids are the principal complaint from citizens living near biosolids land-application sites. Citizens have also complained of attraction of vectors (e.g., insects, birds), declines in property values, and damage to property and public roads by the heavy trucks used to transport biosolids. These type of complaints have sometimes been categorized as nuisance problems or aesthetic issues, but concerns have been raised that odors and vector attraction could have health impacts.
- Differences in public confidence in enforcement and compliance with the Part 503 rule. A variety of alleged incidents were brought to the committee's attention, including improper application of biosolids, inadequate public-access restrictions at Class-B application sites, and violations of the 30-day waiting period before allowing grazing on treated pastures. It was beyond the scope of the committee's task to investigate or verify these allegations, but an audit of the national biosolids program by EPA's Office of Inspector General concluded that "EPA does not have an effective program for ensuring compliance with the land application requirements of Part 503. Accordingly, while EPA promotes land application, EPA cannot assure the public that current land application practices are protective of human health and the environment" (EPA 2000).

In addition to health issues, questions have been raised about the risk-assessment approaches used to establish the biosolids standards. Major issues include the following:

- Regional and site-specific considerations. Biosolids content, use practices, and application-site characteristic (e.g., geology and climate) vary greatly among and within regions. It is important that these variations are considered in the risk assessment used to establish the biosolids standards.
- Difficulties in conducting risk assessments when the available database is poor. Major gaps in the biosolids data include need for updated characterization of biosolids constituents, exposure information, and understanding of relevant health effects.
- Challenge of assessing risks from a complex mixture. Biosolids are a mixture of organic and inorganic chemicals and biological agents. Risk-assessment procedures typically quantify risks from single chemicals and assume additivity when multiple chemicals are present. Although much thought has been given to evaluating risks from chemical mixtures, strategies for considering risks from exposure to complex mixtures are still in development.

THE COMMITTEE'S TASK

The Clean Water Act requires EPA to periodically reassess the scientific basis of the Part 503 rule, including the option of adding pollutants to the regulation. Several advances and improvements in conducting risk assessments have occurred since the promulgation of the rule in 1993. Some researchers have questioned the scientific basis and data used in establishing EPA's biosolids standards, noting data gaps, nonprotective policy choices, and more stringent standards

set by other countries. In addition, there is increasing concern among communities near land-application sites about the health risks from exposure to biosolids. For these reasons, EPA asked the NRC to conduct an independent evaluation of the technical basis of the Part 503 rule land-application standards.

In response to this request, the NRC convened the multidisciplinary Committee on Toxicants and Pathogens in Biosolids Applied to Land. The committee was asked to review information on the land application of biosolids and to evaluate the methods used by EPA to assess human health risks from chemical pollutants and pathogens in biosolids. Specifically, the committee was asked to:

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 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 COMMITTEE'S APPROACH

To accomplish its task, the committee held five meetings between March 2001 and May 2002. The first two meetings involved data-gathering sessions that were open to the public. The committee heard from EPA, the National Institute for Occupational Safety and Health, industry representatives, environmental and community groups, and academics. Many concerned members of the public attended the meetings and were given the opportunity to address the committee. Citizens living near land-application sites voiced concerns about odors, health effects, lack of investigation into health complaints, and application practices that do not comply with the regulations. At its second meeting, the committee also visited an agricultural field in Riverside County, California, where Class B biosolids were being applied. The purpose of the visit was to observe techniques used to apply biosolids to an agricultural field. The committee also reviewed a large body of written material on biosolids. The committee relied on peer-reviewed publications as its primary source of information, but unpublished data (submitted by various sources, including industry representatives and the public) were sometimes used to supplement existing information or when no other information was available.

The committee is aware that some readers expect this report to cover all aspects of biosolids use and determine whether EPA should continue to promote its use. That expectation goes well beyond the committee's charge. Therefore, it is important to clarify what this report addresses and what it does not address.

This report focuses on the land application of Class A and Class B biosolids. It does not consider risks from sewage treatment processes (including composting), storage, or transporting, nor does it cover risks from disposal practices of landfilling, surface disposal, or incineration.

The committee was asked to devote its efforts to evaluating existing biosolids regulations (as of July 1, 2000) in 40 CFR Part 503. Because the regulations cover only chemical (specifically inorganics) and pathogenic pollutants, radioactive contaminants were not included in the committee's assessment, even though the committee is aware that radioactive compounds may be present in biosolids. The committee's assessment also excluded an in-depth evaluation of EPA's risk assessment and proposed regulations for dioxins, because they were not finalized at the time of writing. However, the committee did evaluate the scientific basis of EPA's original decision not to regulate organic pollutants in biosolids.

Although the Part 503 rule considers risks to both human and environmental health, the committee was asked to focus its evaluation on human health risks and not on plant, animal, or ecological risks. The committee interpreted this task to include an evaluation of relevant occupational health, in addition to public health. It is also important to emphasize that the primary purpose of this report is to provide an evaluation of the risk-assessment methods and approaches used to establish the biosolids land-application standards and is not an investigation into the validity of allegations of biosolids-related illnesses. Risk assessment is the characterization of potential adverse health effects resulting from exposure to environmental hazards. It is a process separate from risk management, which is the term used to describe the process by which risk-assessment results are integrated with other information (e.g., social, economic, and engineering factors) to make decisions about the necessity, method, and extent of risk reduction.

REPORT ORGANIZATION

The remainder of this report is organized into six chapters. Chapter 2 describes the history of the biosolids regulations, treatment processes, use practices, compliance issues, and risk-management practices in the United States. It also provides a brief overview of biosolids regulations and practices in Europe. Chapter 3 reviews the available evidence on human health effects from exposure to biosolids. Chapter 4 presents developments in risk assessment since the Part 503 rule was established and discusses current risk-assessment practices used by EPA. Chapter 5 reviews EPA's risk-assessment approach to setting limits for chemical pollutants in biosolids. EPA's pathogen-reduction standards are reviewed in Chapter 6, along with new developments in the area of risk assessment for microbial agents. Chapter 7 explores whether it is possible to use an integrated approach to assess the risks from a complex mixture of chemical and biological agents.

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2

Biosolids Management

Wastewater treatment necessarily produces two end products: effluent and sewage sludge. All wastewater generated in homes, businesses, industries, and other venues that is conveyed to wastewater treatment plants is treated to allow effluent discharge back into the surface and groundwaters of the United States. Sewage sludge is likewise treated in the wastewater process, generally through aerobic or anaerobic microbial activity for specified time periods and temperatures. Both effluent and sewage sludge require treatment to ensure that their release into the environment is protective of human health and the environment as required by the Clean Water Act (CWA). Sewage sludge is defined as the solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works, and biosolids are defined in this report as sewage sludge that has been treated to meet standards for land application under Part 503 of the CWA or any other equivalent land-application standards.

Of the nation's estimated 263 million people in 1996, 190 million of them or 72% contributed wastewater directly through a sewerage system to approximately 16,000 publicly owned treatment works (POTW) (EPA 2000a). The remaining 73 million people discharged wastewater to some form of onsite treatment system or holding tank, more than half of which also is ultimately discharged to a POTW (Razvi 2000). Each person discharging human waste to a wastewater treatment system produces approximately 47 dry pounds (21 kilograms) of sewage sludge each year (EPA 1993). As the population of the United States increases, the percentage of the population directly discharging to POTWs is projected to increase to 88% by 2016 (EPA 2000a). The ability to effectively treat and return wastewater and sewage sludge to the environment in a protective manner is of paramount importance from both a public-health and an environmental perspective. In partial recognition of this fact, Congress passed the CWA of 1972 and the federal government has contributed $61.1 billion in grants and $16.1 billion in low-interest loans to municipal and local governments between 1972 and 1999 for capital construction costs to provide necessary support for wastewater and sewage-sludge treatment and disposition of biosolids (EPA 2000a). Approximately 40% of that amount has been used for sewage sludge treatment and disposition of biosolids (Peavy et al. 1985). Sewage sludge is generated in several treatment processes that generally include primary (from primary clarification) and secondary (from secondary clarification) sewage sludge. The general process of treating wastewater and sewage sludge is illustrated in Figures 2-1 and 2-2.

EPA is responsible under Section 405 of the CWA to promulgate regulations for sewage sludge use or disposal. The CWA Amendments of 1987 (CWA 1987) added special provisions that required EPA to identify toxic pollutants and set sewage-sludge standards that are "adequate to protect public health and the environment from any *reasonably anticipated* adverse effect of each pollutant" (emphasis added). Recognizing that sewage-sludge production will continue to increase and that sewage sludge possesses many potential beneficial properties for agricultural production, federal and state agencies have long advocated the recycling of them as biosolids through land application (EPA 1981, 1984, 1991). The other primary options for sewage sludge

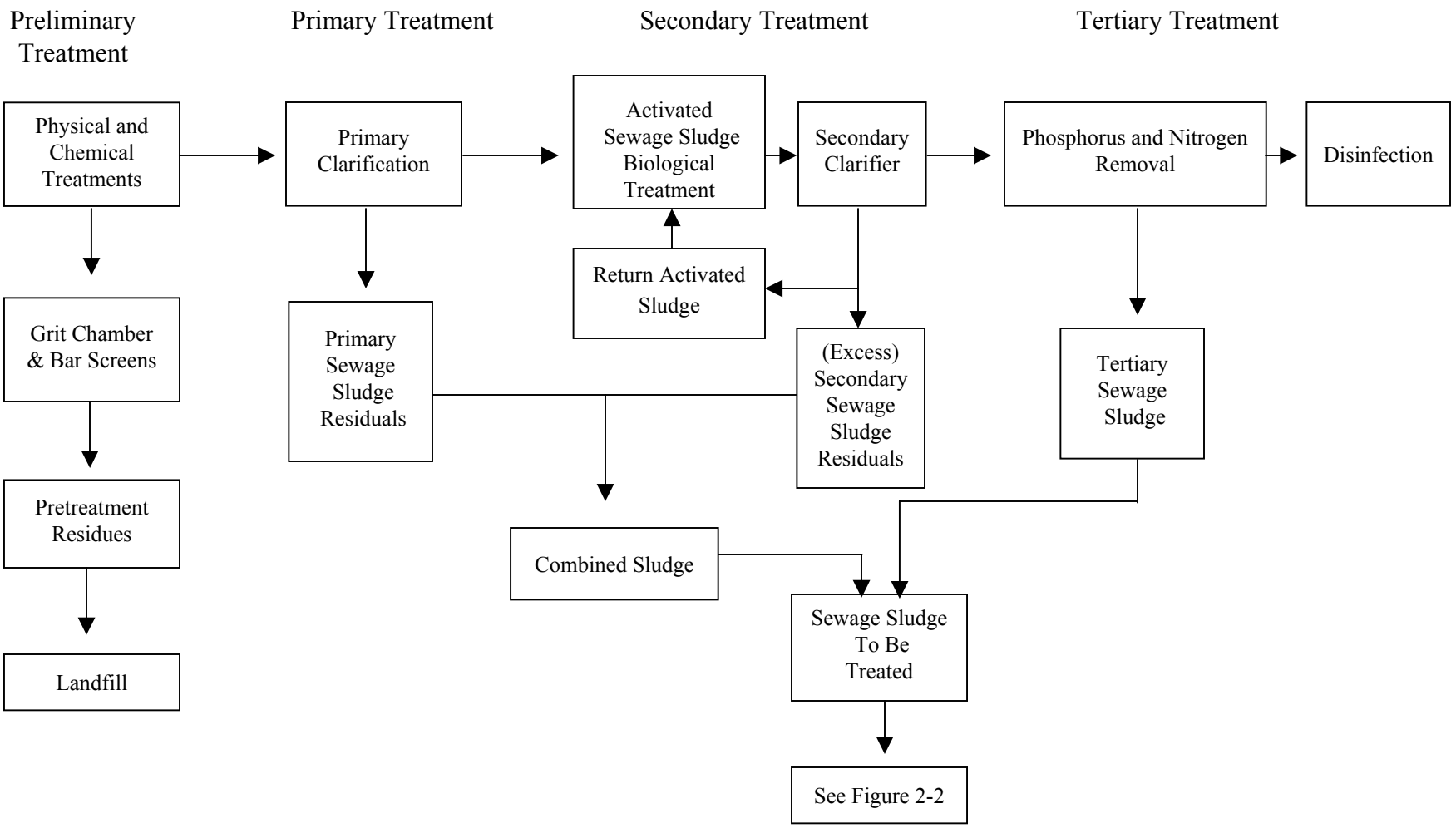


FIGURE 2-1 The process schematic delineating water and wastewater treatment along with the sewage sludge stream

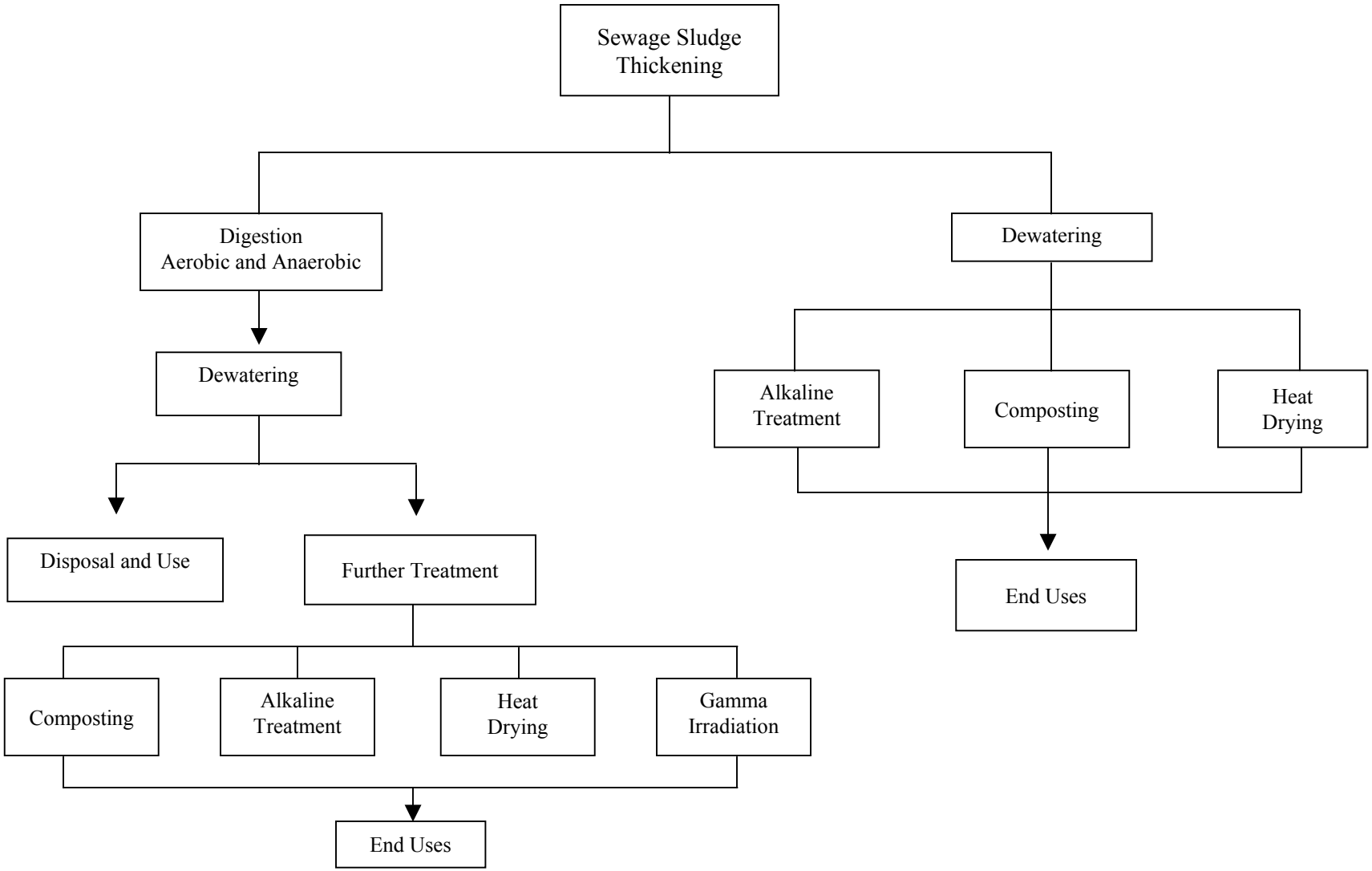


FIGURE 2-2 Sewage sludge treatment alternatives

disposition are to bury it in a landfill or to incinerate it. Although these latter options possess inherent risks and environmental difficulties, they are beyond the scope of this report (see Chapter 1).

Of the 16,000 POTWs in the United States, approximately 8,650 generate sewage sludge that must be used or disposed of at least annually (Wisconsin Department of Natural Resources, unpublished data, 2001). Based on data from 37 states, approximately 5,900 of these sewage sludge generators (68%) either land apply or publicly distribute over 3.4 million dry tons of biosolids each year (see also End Use Practice section of this chapter). Most of this recycling use is conducted without public opposition and with no documented adverse health effects. However, recent allegations of adverse health effects have received media and congressional attention. Chapter 3 assesses the epidemiological evidence and approach for health effects associated with biosolids production and application, but does not systematically investigate these allegations. Rather, the report examines the process by which the regulations were established and determines whether advances in risk-assessment methods warrant a revisiting of the process.

This chapter briefly examines the development of the Part 503 rule, certain related issues, and what EPA has done to implement the rule since promulgation. It also reviews how states implement the rule, whether or not they have explicit delegated authority from EPA. An examination of biosolids regulations and practices in Europe is then used to compare and contrast these practices. An overview of the acceptable pathogen treatment controls and land application site restrictions, is presented, as well as associated methods for stabilization to reduce the attraction to vectors, such as rodents. Issues are raised that relate to the verification of the efficacy of treatment. Finally, this chapter examines end-use practices in the United States, biosolids quality achieved, data on nonregulated pollutants, risk-management practices inherent to land application of biosolids (primarily Class B) and to the risk-assessment process, and compliance and enforcement strategies and action taken by EPA or states.

FEDERAL BIOSOLIDS REGULATIONS AND CURRENT STATE OF PROGRAM

History

The current biosolids standards became effective in Part 503 of Chapter 40 of the Code of Federal Regulations (40 CFR 503) on March 22, 1993 (EPA 1993). More specifically, the regulations are established as General Requirements, Pollutant Limits, Management Practices, Operational Standards, Frequency of Monitoring Requirements, Record Keeping, and Reporting. The requirements apply to each of the three major methods of ultimate disposition of sewage sludge or biosolids: recycling and public distribution, burial in a municipal solid-waste landfill or a surface disposal site, or incineration. Enforceable standards are established for all three options, but this report focuses only on land application and public distribution. The standards were developed over more than 10 years and received both public and private input. From September 13, 1979, until 40 CFR 503 was published, standards for the land application of biosolids were set in 40 CFR Part 257 (EPA 1979). Research focusing on the beneficial micro- and macronutrients present in treated sewage sludge had been conducted at numerous universities before the publication of the 1979 regulations (e.g., Keeney et al. 1975). Indeed,

Wisconsin statutes specifically encouraged the responsible recycling of biosolids through use on agricultural land beginning in 1973 (Wisconsin Statutes Assembly Bill 128, 1973).

Because POTWs typically have industrial contributors to their wastewater collection systems, wastewater pretreatment regulations became effective through 40 CFR Part 403 on June 26,1978, with a stated objective to:

a. prevent the introduction of pollutants into POTWs which will *interfere* with the operation of a POTW, including interference with its use or disposal of municipal biosolids;
b. prevent the introduction of pollutants into POTWs which will *pass through* the treatment works or otherwise be incompatible with such works; and
c. improve opportunities to recycle and reclaim municipal and industrial wastewaters and biosolids (EPA 1999a).

These regulations to control pollution dramatically reduced the concentrations of selected pollutants discharged to applicable sewerage systems and therefore also the concentrations in the resultant biosolids (see also Characterization of Biosolids section).

Federal Policy

EPA has had a long-standing policy of promoting the beneficial use of biosolids, and a regulatory mandate to review and revise related regulations periodically as new research warrants. In January 1981, EPA published a statement of federal policy and guidance with the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) for the proper management and necessary controls of land application of biosolids for the production of fruits and vegetables. EPA (1984) further formalized its policy of promoting beneficial use and developing a comprehensive regulatory approach as mandated by the CWA in the *Federal Register* on June 12, 1984. EPA again clarified that position through the publication of an interagency policy, which with six other federal agencies promoted the beneficial use of biosolids in the *Federal Register* on July 18, 1991 (EPA, USDA, U.S. Department of Defense, U.S. Department of Energy, U.S. Department of the Interior, FDA, and the Tennessee Valley Authority, 1991).

Section 402 of the CWA sets provisions for permitting discharges, including sewage sludge, to waters of the United States. As authorized by the CWA, the National Pollutant Discharge Elimination System (NPDES) permit program has been in place since 1972 and regulates point sources of water pollution, such as pollutants discharged from pipes or ditches. Many states consider the land application of biosolids to be a point-source discharge to groundwater and regulate this practice under the permit program. Individual homes that are connected to a municipal system, use a septic system, or do not have a surface discharge do not need an NPDES permit; however, industrial, municipal, and other facilities must obtain permits if their discharges go directly to surface waters. In most cases, the NPDES permit program is administered by authorized states. Chapter 40 of CFR 501 was published in 1989 to set a regulatory framework for states seeking delegated authority to implement a biosolids program under permits in compliance with Section 402. At present, there are five states that have received delegation (Oklahoma, Utah, Texas, Wisconsin, and South Dakota) and about 20 that are seeking such authority. Conversely, 44 states have received delegated implementation authority for the NPDES effluent permit program (EPA 1999a). Notably, delegation for the

effluent permit program is funded, and delegation for and implementation of the biosolids program is not.

Proposed Regulation

40 CFR 503 was published for public comments on February 6, 1989. EPA's original risk assessment (see Chapter 5 for further information) defined the at-risk population as the most exposed individual (MEI). The MEI is a person who is maximally exposed to a pollutant in biosolids for a lifetime. EPA conducted an aggregate public-health risk assessment that estimated the risk from land application of biosolids in the absence of any regulation. That aggregate assessment found that the risk would be less than one cancer case per year and that approximately 1,000 persons would exceed a threshold lead concentration and 500 would experience some lead-related health effects. With the final regulation in place, the resultant risk was predicted to be less than one cancer case, less than one person exceeding a threshold blood lead level, and less than one person experiencing adverse lead effects (EPA 1993). In addition, this risk would present itself only at such time as all assumptions in the risk assessment were fulfilled.

The Cooperative State Research Service Technical Committee W-170, composed of university researchers, organized a Peer Review Committee (PRC) from academia, EPA, environmental groups, and units of state and local government to provide expert and extensive comments to EPA on the proposed rule (Cooperative State Research Service Technical Committee W-170 1989). Two critical points were raised during the public comment period by the PRC: (1) The MEI was modeled with multiple layers of conservative exposures that could not exist in reality, and this contradicted the notion of reasonably anticipated adverse effects; and (2) the research for metal uptake was based on metal salts and pot studies in greenhouses rather than field research. They also recommended a risk-based approach to pathogens. Although EPA had an official policy to promote beneficial use of biosolids, the proposed regulation would have substantially curtailed such use, thus encouraging increased surface disposal and incineration.

As a result of this extensive peer review, EPA initiated additional research and substantially modified the risk assessment and ultimately the regulation. For example, EPA decided to use a highly exposed individual (HEI) rather than an MEI in the risk assessment. The HEI is a person who remains for an extended period at or adjacent to the site where maximum exposure occurs. The HEI represented a more reasonable case of exposure and still provided multiple safety factors of protection (EPA 1993, 1995a).

Final Regulations

There are three major categories of requirements establishing biosolids quality and site-management criteria for land application. Each of these categories is further divided into two sections. When biosolids meet the strictest section in all three categories, it is considered exceptional quality (EQ). Management-practice requirements establish site restrictions and limit application rates on agricultural land for the remaining non-EQ biosolids. The three requirement categories that establish biosolids quality are as follow:

- Pollutant concentrations versus ceiling concentrations;
- Class A pathogen criteria versus Class B pathogen criteria that include management practices.
- Process-control criteria to reduce attraction to vectors versus physical barriers from vectors.

Biosolids that meet the requirements to be deemed EQ can be publicly distributed without further regulation under 40 CFR 503. (If biosolids do not meet the pollutant concentration limits and the other requirements, they can still be publicly distributed as long as an information sheet is included that specifies a maximum annual application rate.) It is further stipulated that biosolids must be land applied at an "agronomic rate" to not exceed the nitrogen requirements for the crop grown. This stipulation is to avoid loss from the root zone to the groundwater and to avoid excessive nitrogen buildup that may ultimately run off to surface water.

The Part 503 federal regulations for pathogen and vector attraction control are and have been technologically based instead of risk based. That is in part due to unreliable pathogen assays and insufficient and variable data with respect to the fate and transport of pathogens in the natural environment (see Chapter 6 for more details).

Pollutant Concentrations

Specific pollutant concentrations were derived for nine metals (EPA 1995a). The risk assessment examined 14 pathways of exposure and a maximum cumulative loading rate was determined for the most limiting pathway for each pollutant. These values are shown in column 2 of Table 2-1.

TABLE 2-1 Pollutant Concentration Limits and Loading Rates for Land Application in the United States

Pollutant	(1) Ceiling Concentration Limit (mg/kg)[a]	(2) Cumulative Loading Rate Limit (kg/ha)[a]	(3) Pollutant Concentration Limit (mg/kg)[a]	(4) Annual Pollutant Loading Rate for Distributed Biosolids Exceeding Column 3 (kg/ha/y)[a]
Arsenic	75	41	41	2.0
Cadmium	85	39	39	1.9
Copper	4,300	1,500	1,500	75
Lead	840	300	300	15
Mercury	57	17	17	0.85
Molybdenum	75	-	-	-
Nickel	420	420	420	21
Selenium	100	100	100	5
Zinc	7,500	2,800	2,800	140
Applies to:	All biosolids that are land applied	Bulk biosolids	Bulk or bagged[b] biosolids	Bagged[b] Biosolids where at least one element does not meet column 3

[a] Dry weight basis.
[b] Bagged biosolids are sold or given away in a bag or container containing less than 1 metric ton (MT).
Source: Adapted from 40 CFR, Part 503.

Assumptions were then made that a site was used for 100 consecutive years at a loading rate of 10 MT/hectare per year. Next, a back calculation was used to determine a maximum concentration in the biosolids that would not allow the maximum cumulative loading rate to be attained. The pollutant concentration limits are intended to define biosolids that can be land applied without requiring the applier to track cumulative pollutant loadings. The methods used by EPA to identify the pollutant concentration limits are described in Chapter 5. That concentration became the pollutant concentration limit in all but two cases (see below). The current pollutant concentration limits are shown in column 3 of Table 2-1.

A National Sewage Sludge Survey (NSSS) was conducted by EPA (1990) for the purpose of gathering needed data on sewage sludge quality in the nation. The ceiling limit was set at the 99 percentile level found in the NSSS or the risk-based number, whichever was greater. The current ceiling limit concentrations are shown in column 1 of Table 2-1. The risk-derived number became the ceiling limit only for chromium (which was later deleted from regulation; see discussion later in this chapter), selenium, and nickel[1]. In those cases, the 99% value became the pollutant concentration limit. Currently, both the ceiling concentration and pollutant concentration limits are risk based for nickel and selenium.

Thus, land-applied biosolids that contain chemical concentrations less than those shown in column 3 of Table 2-1 do not need to track cumulative loadings to sites, because it is assumed that loadings will never approach the limits shown in column 2. If land-applied biosolids have any chemical concentrations between the values of column 3 and column 1, then cumulative loading records must be kept for any such bulk application.

It is important to note that when biosolids are sold or given away in a bag or container that weighs less than 1 MT, it must meet the strictest standards for pathogen and vector control but does not need to meet the pollutant concentration limits shown in column 3 of Table 2-1. As noted previously, if it does not meet the column 3 limits, an information sheet must be supplied or instructions printed on the bag that prescribe loading rates that will not exceed annual loading rates shown in column 4. Because of the perceived infrequent use of this exception and the difficulty with tracking its use, the committee concluded that it would be simpler to require that all biosolids sold or given away be EQ.

Pathogen Control

Biosolids are divided into Class A and Class B on this basis of their pathogen content and control. Class A biosolids must undergo more extensive treatment than Class B biosolids (described below) to reduce pathogens, including bacteria, enteric viruses, and viable helminth ova, to below detectable amounts. Once these goals are achieved, Class A biosolids can be land applied without any pathogen-related restrictions at the site. Biosolids having the least further restrictions on land application are those meeting the Class A pathogen requirements, the vector control requirements, and the high-quality pollutant concentration limits for metals. If all these requirements are met, the biosolids can be used with no more restrictions than any other fertilizer or soil-amendment product.

The Class B pathogen requirements were developed from the 1979 40 CFR 257 regulations for processes to significantly reduce pathogens (PSRP). In the initial development of

[1] The risk-based number and 99-percentile level found in the NSSS were the same for nickel.

those requirements, a PSRP was defined as a process that reduces pathogenic viruses, *Salmonella* bacteria, and indicator bacteria (fecal coliform) by at least 1 log (90%) (EPA 1989).

The Class B biosolids requirements are intended to ensure that pathogens in biosolids have been reduced to amounts that are protective of public health and the environment under the specific use conditions. As a central element of the Class B criteria, site restrictions designed to minimize potential for human and animal contact apply until environmental factors have further reduced pathogens to low amounts. Thus, packaged Class B biosolids cannot be sold or given away for land application at public-contact sites, lawns, and home gardens but can be used in bulk quantities at appropriate types of land-application sites, such as agricultural lands, forests, and mine reclamation sites, provided the biosolids meet limits on pollutants, vector-attraction reduction, and other management requirements of Part 503 (EPA 1993). In addition, biosolids can be used as municipal-solid-waste (MSW) landfill cover in compliance with 40 CFR Part 258.

Class A Pathogen Requirements

The Class A pathogen criteria require that both treatment-process control requirements and prescribed densities of either fecal coliform or *Salmonella* are satisfied. Pathogen criteria must be met at the same time or before the vector-attraction reduction requirements are met. One of the following organism density requirements listed below must be satisfied for all Class A alternatives:

Fecal Coliform Density Requirements: The fecal coliform density must be less than 1,000 most probable number (MPN) per gram (g) of total solids (TS), and that must be satisfied immediately after the treatment process is completed. If the material is bagged or distributed at that time, no retesting is required. If the material is bagged, distributed, or land applied at a later time, it must be retested and the density requirement satisfied to ensure that regrowth of bacteria has not occurred.

***Salmonella* Density Requirements:** The *Salmonella* density must be less than 3 MPN per 4 g of TS, and that must be satisfied immediately after the treatment process is completed. If the material is bagged or distributed at that time, no retesting is required. If the material is bagged, distributed, or land applied at a later time, it must be retested and the density requirement satisfied to ensure that regrowth of bacteria has not occurred.

In addition, one of the following treatment processes listed must be met to be designated Class A biosolids (EPA 1999b). The goal of these processes is to reduce pathogen densities below specified detection limits for three types of organisms: *Salmonella* sp. (<3 MPN [most probable number] per 4 grams total solids), enteric viruses (<1 PFU [plaque-forming unit] per 4 grams total solids), and helminths (<1 viable organism per 4 grams total solids).

Alternative 1—Temperature and Time Process: These criteria were based on a time-temperature relationship related to pasteurization studies and to composting data. This alternative has been and is still used for aerobic digestion and anaerobic digestion. An increased sewage-sludge temperature must be maintained for a prescribed period according to the guidelines summarized in Table 2-2.

TABLE 2-2 Guidelines for Temperature Treatments

Total Solids	Temperature	Time	Equation, D = Time in Days, t = temp in °C	Notes
≥ 7%	≥ 50°C	≥ 20 min	$D = \frac{131{,}700{,}000}{10^{0.14t}}$	No heating of small particles by warmed gases or immiscible liquid
≥ 7%	≥ 50° C	≥ 15 s	$D = \frac{131{,}700{,}000}{10^{0.14t}}$	Small particles heated by warmed gases or immiscible liquid
< 7%	> 50° C	≥ 15 s to < 30 min	$D = \frac{131{,}700{,}000}{10^{0.14t}}$	
< 7%	≥ 50° C	≥ 30 min	$D = \frac{50{,}070{,}000}{10^{0.14t}}$	

Note: Temperatures calculated using the appropriate equation must never be less than 50°C. The time values are not used in the calculations, but are provided to indicate the prescribed duration that temperature must be maintained. Source: EPA 1999b.

Alternative 2—Alkaline Treatment Process: The pH of the sewage sludge must be raised to greater than 12 for at least 72 hours (h). During this time, the temperature of the sewage sludge must be greater than 52° C for at least 12 h. In addition, after the 72-h period, the sewage sludge must be air dried to at least 50% total solids.

Alternative 3—Prior Test for Enteric Virus and Viable Helminth Ova: The sewage sludge must be analyzed for the presence of enteric viruses and viable helminth ova. If the sewage sludge is analyzed before pathogen-reduction processing and found to have densities of enteric virus of less than 1 plaque-forming unit (PFU) per 4 g of TS and viable helminth ova of less than 1 per 4 g of TS, the sewage sludge is considered Class A biosolids with respect to enteric virus and viable helminth ova until the next monitoring event. If the sewage sludge is analyzed before pathogen-reduction processing and found to have densities of enteric virus greater than or equal to 1 PFU/4 g of TS or viable helminth ova of more than 1 per 4 g of TS and is tested again after processing and found to have densities of enteric virus of less than 1 PFU/4 g of TS and viable helminth ova less than 1 per 4 g of TS, the sewage sludge is considered Class A biosolids when the treatment process is operated under the same conditions that successfully reduced enteric virus and helminth ova.

Alternative 4—Post-Test for Enteric Virus and Viable Helminth Ova Process: If the sewage sludge is not analyzed before pathogen-reduction processing for enteric viruses and viable helminth ova, the sewage-sludge density of enteric viruses must be less than 1 PFU/4 g of TS, and the density of viable helminth ova must be less than 1 per 4 g of TS at the time the sewage sludge is used, disposed of, or prepared for sale or giveaway in a bag or container or when the biosolids meets EQ requirements.

Alternative 5—Processes to Further Reduce Pathogens (PFRP):

Alternative 5a—Composting Process: Compost the sewage sludge using either within-vessel or static-aerated-pile composting methods and maintain the temperature of the sewage sludge at 55°C or higher for 3 days, or compost the sewage sludge using windrow composting methods and maintain the temperature of the sewage sludge at 55°C or higher for 15 days or longer. During this period, a minimum of five windrow turnings are required.

Alternative 5b—Heat Drying Process: Dry the sewage sludge by direct or indirect contact with hot gases to reduce the moisture content of the sewage sludge to 10% or lower. Either the temperature of the sewage-sludge particles must exceed 80°C or the wet bulb temperature of the gas in contact with the sewage sludge leaving the dryer must exceed 80°C.

Alternative 5c—Heat Treatment Process: Heat liquid sewage sludge to a temperature of 180°C or higher for 30 min.

Alternative 5d—Thermophilic Aerobic Digestion Process: Agitate liquid sewage sludge with air or oxygen to maintain aerobic conditions. The mean cell residence time for the sewage sludge must be 10 days at 55°C to 60°C.

Alternative 5e—Beta Ray Irradiation Process: Irradiate the sewage sludge with beta rays from an accelerator at a dose of at least 1.0 megarad at room temperature.

Alternative 5f—Gamma Ray Irradiation Process: Irradiate the sewage sludge with gamma rays from certain isotopes, such as cobalt 60 and cesium 137, at a dose of at least 1.0 megarad at room temperature.

Alternative 5g—Pasteurization Process: Maintain the temperature of the sewage sludge at 70°C or higher for 30 min or longer.

Alternative 6— Process Equivalent to Process to Further Reduce Pathogens (PFRP): Treat the sewage sludge in a process that is equivalent to PFRP, as approved by the permit authority. To obtain a Class A biosolid rating, the process must reduce *Salmonella* species or fecal coliforms to below Class A criteria and must operate under the specified conditions used in its application demonstration to the EPA Pathogen Equivalency Committee (see below).

Class B Pathogen Requirements

In addition to management-practice requirements, including site restrictions, the Class B pathogen control requirements mandate that one of the following be satisfied before land application:

Fecal Coliform Limitation: Compliance with the fecal coliform limitation for Class B biosolids must be demonstrated by calculating the geometric mean of at least seven separate samples. (TS analysis must be done on each sample.) The geometric mean must be less than 2,000,000 MPN or colony-forming units (CFU) per g of TS.

Aerobic Digestion: Agitate the sewage sludge with air or oxygen to maintain an aerobic condition for a mean cell residence time and temperature between 40 days at 20°C and 60 days at 15°C. (This process cannot be satisfied during the winter in most of the northern United States without additional measures being taken to maintain adequate temperatures.)

Anaerobic Digestion: Treat the sewage sludge in the absence of air for a specific mean cell residence time at a specific temperature. Values for the mean cell residence time and temperature must be between 15 days at 35°C to 55°C and 60 days at 20°C. Straight-line interpolation to calculate mean cell residence time is allowable when the temperature is between 35°C and 20°C.

Lime Stabilization: Add sufficient lime to the sewage sludge to raise the pH to 12 after 2 h of contact.

Air Drying: Dry the sewage sludge on sand beds or in paved or unpaved basins for a minimum of 3 months. During 2 of the 3 months, the ambient average daily temperature must be above 0°C.

Composting: Compost the sewage sludge using either within-vessel, static-aerated-pile, or windrow composting methods and raise the temperature of the sewage sludge to 40°C or higher for 5 days. For 4 h at some point during each of the 5 days, the temperature in the compost pile must exceed 55°C.

Process Equivalent to Process to Significantly Reduce Pathogens (PSRP): Treat the sewage sludge in a process that is equivalent to a PSRP, as approved by the permit authority.

Over the past 15 years, two processes have been approved as PSRP equivalents by the EPA Pathogen Equivalency Committee (PEC). These are the N-Viro alkaline stabilization process and the Synox OxyOzone process. Both processes have been upgraded to PFRP status in more recent studies. Specifically, the N-Viro process meets the Class B equivalency criteria for alkaline stabilization, and the Synox OxyOzone process meets the criteria of pathogen monitoring from influent to effluent.

Reduction of Vector Attraction

Vector-attraction reduction may be classified as long-term or short-term stabilization or may be accomplished through physical barriers. Long-term stabilization is defined as the biological degradation of the putrescible organics and results in a reduction of vector attraction. One of 10 options may be used to satisfy vector control. The first five options below are considered long-term stabilization, and the next three are considered short-term stabilization (inhibit biological activity before application) and must be demonstrated at the time of use to ensure that the criteria are satisfied. It should be stressed that when biosolids are applied to land, the vector-attraction-reduction requirements must be satisfied. This can be a potential issue with the short-term options since they are reversible. It should also be noted that treatment should be complete prior to land application so that further reaction does not occur in the field, which may result in the release of odorants. One of the following eight vector control requirements may be used to qualify as EQ biosolids:

Volatile Solids Reduction: The mass of volatile solids in the sewage sludge shall be reduced by a minimum of 38%.

Specific Oxygen Uptake Rate: The specific oxygen uptake rate (SOUR) for aerobic sewage sludge shall be equal to or less than 1.5 milligrams (mg) of oxygen per hour per gram of total solids on a dry-weight basis, corrected to 20° C.

Anaerobic Bench-Scale Test: Demonstrate through additional digestion in a bench-scale test that additional volatile solids reduction for anaerobically digested sewage sludge is less than 17%. This can be demonstrated by anaerobically digesting a portion of the previously digested sewage sludge in the laboratory in a bench-scale unit for 40 additional days at a temperature between 30°C and 37°C. This requirement is satisfied when at the end of the test, volatile solids have been reduced by less than 17%, as measured from the beginning to the end of the test.

Aerobic Bench-Scale Test: Demonstrate through additional digestion in a bench-scale

test that additional volatile solids reduction for aerobically digested sewage sludge is less than 15%. This can be demonstrated by aerobically digesting a portion of the previously digested sewage sludge at a concentration of 2% solids or less in the laboratory in a bench-scale unit for 30 additional days at a temperature of 20°C. Sewage sludge with a higher percentage of solids must be diluted with effluent down to 2% at the start of the test. This requirement is satisfied when at the end of the test, volatile solids have been reduced by less than 15%, as measured from the beginning to the end of the test.

Aerobic Process (for Compost): The sewage sludge must be treated in an aerobic process for 14 days or longer. During that time, the temperature of the sewage sludge must be higher than 40°C and the average temperature of the sewage sludge must be higher than 45°C.

pH Adjustment: The pH of the sewage sludge must be raised to 12 or higher by alkali addition and, without the addition of more alkali, remain at 12 or higher for 2 h and then at 11.5 or higher for an additional 22 h.

Drying Without Primary Solids: The percent solids of sewage sludge that does not contain unstabilized solids generated in a primary wastewater treatment process shall be equal to or greater than 75% based on the moisture content and total solids prior to mixing with other materials.

Drying with Primary Solids: The percent solids of sewage sludge that contains unstabilized solids generated in a primary wastewater treatment process shall be equal to or greater than 90% based on the moisture content and total solids prior to mixing with other materials.

In place of the process-based requirements, one of the following two requirements may be utilized during or after land application and are considered physical barriers to vector attraction:

Injection: No significant amount of the biosolids can be present on the land surface within 1 h of biosolids injection.

Incorporation: The biosolids must be incorporated within 6 h of surface application or as approved by the permit authority.

Table 2-3 summarizes the above requirements.

Treatment Design Standards

Sewage sludge treatment technology not only provides the primary mechanism for pathogen reduction and the necessary stabilization to reduce biosolids attraction as a food source for vectors but also provides the means to reduce odors and related public nuisance and public health concerns. Although 40 CFR 503 provides prescriptive standards for treatment process control, the Great Lakes-Upper Mississippi River Board of State and Provincial Public Health and Environment Managers (GLUMB 1997) report *Recommended Standards for Wastewater Facilities* (commonly referred to as the "Ten States Standards") is used as a basis for minimum

TABLE 2-3 Summary of Requirements for Vector Attraction Reduction Under Part 503

Requirement	What Is Required?	Most Appropriate for:
Option 1 503.33(b)(l)	At least 38% reduction in volatile solids during sewage sludge treatment	Sewage sludge processed by –Anaerobic biological treatment –Aerobic biological treatment –Chemical oxidation
Option 2 503.33(b)(2)	Less than 17% additional volatile solids loss during bench-scale anaerobic batch digestion of the sewage sludge for 40 additional days at 30°C to 37°C (86°F to 99°F)	Only for anaerobically digested sewage sludge
Option 3 503.33(b)(3)	Less than 15% additional volatile solids reduction during bench-scale aerobic batch digestion for 30 additional days at 20°C (68°F)	Only for aerobically digested sewage sludge with 2% or less solids
Option 4 503.33(b)(4)	SOUR at 20°C (68°F) is $\leq$1.5 mg of oxygen/h/g total sewage sludge solids	Sewage sludges from aerobic processes (should not be used for composted sewage sludges)
Option 5 503.33(b)(5)	Aerobic treatment of the sewage sludge for at least 14 days at over 40°C (104°F) with an average temperature of over 45°C (113°F)	Composted sewage sludge (Options 3 and 4 are likely to be easier to meet for sewage sludges from other aerobic processes)
Option 6 503.33(b)(6)	Addition of sufficient alkali to raise the pH to at least 12 at 25°C (77°F) and maintain a pH $\geq$12 for 2 h and a pH $\geq$11.5 for 22 more hours	Alkali-treated sewage sludge (alkalies include lime, fly ash, kiln dust, and wood ash)
Option 7 503.33(b)(7)	Percent solids $\geq$75% prior to mixing with other materials	Sewage sludges treated by an aerobic or anaerobic process (i.e., sewage sludges that do not contain unstabilized solids generated in primary wastewater treatment)
Option 8 503.33(b)(8)	Percent solids $\geq$90% prior to mixing with other materials	Sewage sludges that contain unstabilized solids generated in primary wastewater treatment (e.g., any heat-dried sewage sludges)
Option 9 503.33(b)(9)	Biosolids are injected into soil so that no significant amount of sewage sludge is present on the land surface 1 hour after injection, except Class A biosolids which must be injected within 8 h after the pathogen reduction process	Biosolids applied to the land or sewage sludge placed on a surface disposal site; domestic septage applied to agricultural land, a forest, or a reclamation site or placed on a surface disposal site
Option 10 503.33(b)(10)	Biosolids are incorporated into the soil within 6 h after application to land or placement on a surface disposal site, except Class A biosolids, which must be applied to or placed on the land surface within 8 h of the pathogen reduction process	Biosolids applied to the land or sewage sludge placed on a surface disposal site; domestic septage applied to agricultural land, forest, or a reclamation site or placed on a surface disposal site
Option 11 503.33(b)(11)	Sewage sludge placed on a surface disposal site must be covered with soil or other material at the end of each operating day	Sewage sludge or domestic septage placed on a surface disposal site
Option 12 503.33(b)(12)	pH of domestic septage must be raised to $\geq$12 at 25°C (77°F) by alkali addition and maintained at $\geq$12 for 30 min without adding more alkali	Domestic septage applied to agricultural land, a forest, or a reclamation site or placed on a surface disposal site

Source: Adapted from EPA 1999b.

design requirements in many states but does not require the minimum criteria for many of the PSRPs. The committee concludes that tightening the minimum treatment design standards by control agencies and GLUMB to reflect and be consistent with the requirements of 40 CFR 503 would accomplish much in the area of compliance and odor abatement. Since odors are a primary source of public complaints, adequacy of treatment cannot be over-emphasized. Odors are a function of treatment quality and are minimized with effective treatment and management.

Rule Modifications

Two lawsuits were brought shortly after the 1993 rule promulgation, involving three chemical pollutants (chromium, selenium, and molybdenum) that caused modifications to the land application section of 40 CFR 503. The first lawsuit centered on the fact that the pollutant concentrations for chromium and selenium were not based on risk, and the petition argued that EPA was required under the CWA to establish such limits based only on risk. The court agreed and required that the risk-based values become the pollutant concentrations in all cases. This meant that the ceiling concentrations in those cases would also be the risk-based number. (The pollutant limit for selenium was therefore increased from 36 [99%] to 100 milligrams per kilgram [mg/kg] [risk based].) The suit also charged that the research used to assess phytotoxicity as the limiting pathway for chromium was based on pot studies and not field research, which showed no such effects. The court again agreed, but EPA chose not to replace the standard with the next limiting pathway, because it would set the limit at 12,000 mg/kg. Determining that no biosolids would have chromium concentrations that high, chromium was deleted from regulation under 40 CFR 503 (EPA 1995b).

The second lawsuit asserted that the research used to determine the limiting pathway for molybdenum (animal ingesting feed grown on biosolids-treated fields) was not scientifically supportable, and calculated amounts of molybdenum that plants take in (e.g., plant uptake slopes) were based on highly contaminated sewage sludge. EPA agreed to conduct more research to better establish risk levels. At this time, the cumulative loading limit and pollutant concentration limits have been deleted for molybdenum and only the ceiling concentration remains (see Table 2-1) (EPA 1994b). O'Connor et al. (2001) conducted a modified risk assessment and recommended values for the deleted tables. However, EPA has not acted to revise the molybdenum standard.

Revision of Regulations

EPA was court-ordered to promulgate a second round of 40 CFR 503 regulations by December 15, 2001. In response, EPA conducted a pollutant screening hazard identification exercise and subsequently determined that the only pollutants posing a potential risk that were not regulated in the first round were dioxin and dioxin-like compounds. On December 23, 1999, EPA published proposed risk-based regulations for 7 dioxin, 10 furan, and 12 coplanar PCB congeners (EPA 1999c). Once again, EPA received numerous comments on the proposal representing an array of perspectives. As a result of the public comments received, EPA contracted for a new biosolids survey to evaluate biosolids concentrations of the congeners of interest, contracted for a new risk assessment using probabilistic or Monte Carlo simulation

methods rather than the deterministic methods used for the proposed rule, and engaged a peer-review panel. Agreement was recently reached between all parties to extend the deadline for the Round 2 land-application rule until October 17, 2003. EPA (2002a) published a Notice of Data Availability on June 12, 2002 that summarizes new data and a revised risk assessment.

Public Issue Forums

A number of public forums have been critical of the Part 503 final regulations or of EPA's commitment to oversight in implementing the regulation. The criticisms include the following:

- After promulgation of the 503 regulations in 1993, EPA decided that the land application of biosolids was a low risk to public health and therefore the biosolids oversight program was given a low priority in its annual budget. That decision was based on the aggregate risk assessment, which showed negligible adverse effects even without regulation. However, the decision has had far-reaching negative consequences and forced the agency and state programs to operate in a conflict resolution mode rather than in an efficient proactive mode. As a result, resources are expended only after a problem is identified rather than working to avoid the problem in the first place. This policy decision provides little flexibility for dealing with perceived effects or emerging issues.
- A committee of the National Research Council (NRC) was convened in 1993 to examine the science behind the federal biosolids regulations and the use of biosolids on food-chain crops. The NRC (1996) report concluded that "if the regulations are properly adhered to, the use of [biosolids] on food-chain crops for human consumption is protective of human health." The report also recommended that additional research be conducted in certain areas, particularly in pathogen control, and that EPA take steps to ensure that the regulations were followed (see also Chapter 1 and Box 1-1 for more detail on that committee's recommendations.)
- There have been several allegations of human deaths and illnesses caused by land application of biosolids. However, there has been no documented scientific evidence to substantiate those claims.
- There have also been several allegations of animal deaths caused by land application of biosolids (e.g., cases in Colorado and Georgia). Supporting evidence to substantiate these allegations has not been documented in the scientific literature, but EPA did investigate them and have produced reports on their findings.[2,3] It found no substantiation for the allegations.
- The National Institute for Occupational Safety and Health (NIOSH) published a Hazard ID 10 (NIOSH 2000) in August 2000 based on a Health Hazard Evaluation Report (Burton and Trout 1999). The reports were based on an investigation of worker health effects at the LeSourdsville, Ohio, wastewater treatment facility, owned and operated by the Butler County Health Department. The workers were involved in the treatment, storage, and land application of sewage sludge. There was a lapse between the time of the workers becoming ill and the involvement of NIOSH. At the time of the illnesses, LeSourdesville had operating difficulties, and the sewage sludge produced did not meet the Class B biosolids requirements (Lodor 2001).

[2] D.H. Gould, G.H. Loneragan, Integrated Livestock Management Group; G.K. Beck, and H.D. Fraleigh, Colorado State University; and R.B. Brobst, EPA, unpublished data, no date.
[3] J.W. Gaskin and E.W. Tollner, University of Georgia, unpublished data, no date.

For example, the sewage sludge had fecal coliform densities more than 4 times the allowed limit. At the time of the NIOSH inquiry in 1999, coliform densities were well below the limit. However, it was also found that good hygiene protocol was not generally followed by the biosolids workers, thus precluding any relevant correlations. NIOSH recently released guidance for controlling potential risks to workers exposed to Class B biosolids (NIOSH 2002). This document supercedes the Hazard ID 10 document.

- A congressional hearing before the Committee on Science chaired by Congressman F. James Sensenbrenner, Jr., was held on March 22, 2000, to hold EPA accountable for how it dealt with criticism and the public in general regarding its biosolids program. (The hearing was not intended to question the science behind the existing regulations; see also Kester 2000a.)
- An independent program audit by the EPA Office of the Inspector General (OIG) (EPA 2000b) requested by the EPA Office of Water (OW) concluded that there was a significant lack of oversight and resources committed by the EPA Office of Enforcement and Compliance Assurance (OECA), Office of Wastewater Management (OWM), Office of Science and Technology (OST), and the Office of Research and Development (ORD). Therefore, EPA could not guarantee that land-application and public-distribution practices were conducted in compliance with the CWA regulations and thus protective of public health and the environment. Notably, the Inspector General did not claim that the regulations were not protective but rather criticized EPA's inability to confirm compliance. However, OW and OECA officially declined to take action on many of the OIG's recommendations due to budgetary constraints and other program priorities (EPA 2000c, 2001a). The OIG subsequently sent a letter stating that OW's and OECA's formal response was inadequate. The OIG suggested alternative means for fulfilling the report recommendations and broadly criticized the lack of commitment to the biosolids program and the absence of consensus regarding program implementation within EPA (EPA 2001b). They also requested a timeline from OW and OECA for establishing a new biosolids goal and identifying needed resources to accomplish it under the Government Performance and Results Act (GPRA). The OW and OECA responded with a letter (EPA 2002) stating that to fulfill the OIG recommendations would require budget and staff resources the agency simply did not have. Thus, the OW and OECA position continues to be that the biosolids are a low risk to human health and the environment. Given the ongoing need for OW and OECA to set priorities among its many programs concerning public health and environmental protection, they maintain that their limited resources are better allocated elsewhere.
- In late 2000, EPA requested and sponsored an NRC study to review information on the land application of biosolids and re-examine the risk-assessment methods used in developing the Part 503 regulations in light of recent research findings and advances in risk assessment to determine whether the standards were still adequately protective of human health. This study is also reviewing pathogen control, whether a risk-based approach for pathogens should be pursued, and whether chemical and pathogen risk-assessment approaches can be integrated. This report is the product of that committee.
- The EPA OIG released a status report of EPA's biosolids program in March 2002 (EPA 2002b). The major findings of the report were:
    - EPA places a low priority on the biosolids program and the number of program staff assigned to it have been declining.
    - EPA has delegated authority of the biosolids program to only five states. EPA cannot be certain that all citizens in non-delegated states are provided at least the same level of protection as in the federal program.

- There can be wide variation in how states manage biosolids.
- EPA has no formal process for tracking health complaints. Of 21 complaints that were brought to the OIG's attention, 14 were investigated by EPA or a state agency, five were not report to EPA or the state, and two were not related to biosolids.
- EPA has no plans for conducting a comprehensive evaluation and monitoring study to address risk assessment uncertainties. More research on pathogen testing appears to be needed.
- In reviewing EPA's relationship with the Water Environment Federation (WEF), OIG found that 96% of the $12.9 million given to WEF and its research organization over a 3-year period was Congressionally mandated and EPA had no discretion in awarding the funds.
- The general public has concerns about the effects on biosolids on health, quality of life, and natural resources. Public perception of land application of biosolids has a significant impact on the implementation of the program.

EPA Resources

The committee notes that it has long been recognized by those within EPA working in the biosolids field and state agencies required to implement the biosolids program that EPA disinvestment in the program has caused an inability to adequately ensure that the regulations are followed. Although more than 40% of the capital cost and the operation and maintenance expense of wastewater treatment is expended on biosolids treatment and management (much of which is from federal dollars in the form of grants and low-interest loans), less than one-tenth of 1% of EPA's budget is devoted to the biosolids program. Of EPA's $7.8 billion budget in FY 2001, only about $4 million or 0.05% was devoted to biosolids staff and the program (J. Walker, EPA, presentation at Biosolids Regulator Workshop, Potomac, Maryland, June 28, 2001).

The Wisconsin Department of Natural Resources (WDNR) represents all state environmental protection agencies to EPA, including the EPA Biosolids Program Implementation Team (BPIT), on a number of biosolids issues. In this capacity, the WDNR has sent five letters to EPA between 1998 and 2001 seeking program support (Meyer 1998; Kester 2000b,c; 2001a,b). The areas of most critical need include technical support on biosolids treatment for pathogen and vector-attraction controls and staffing. The Pathogen Equivalency Committee (PEC) comprises agency experts who primarily serve as volunteers to provide technical support regarding the adequacy of treatment technology with respect to pathogen control. Each of the 10 EPA Regions have between 0.2 and 2 full-time employees (FTEs), and a total nationwide of 8.8 FTEs, working in all areas of biosolids management. The EPA ORD has 2 FTEs devoted to the program, and EPA headquarters has 4.8 FTEs (J. Walker, EPA, presentation at Biosolids Regulator Workshop, Potomac, Maryland, June 28, 2001). In addition to these obvious staff shortages, consideration should be given to train new experts in the field to replace existing staff, many of who are approaching retirement.

State Programs

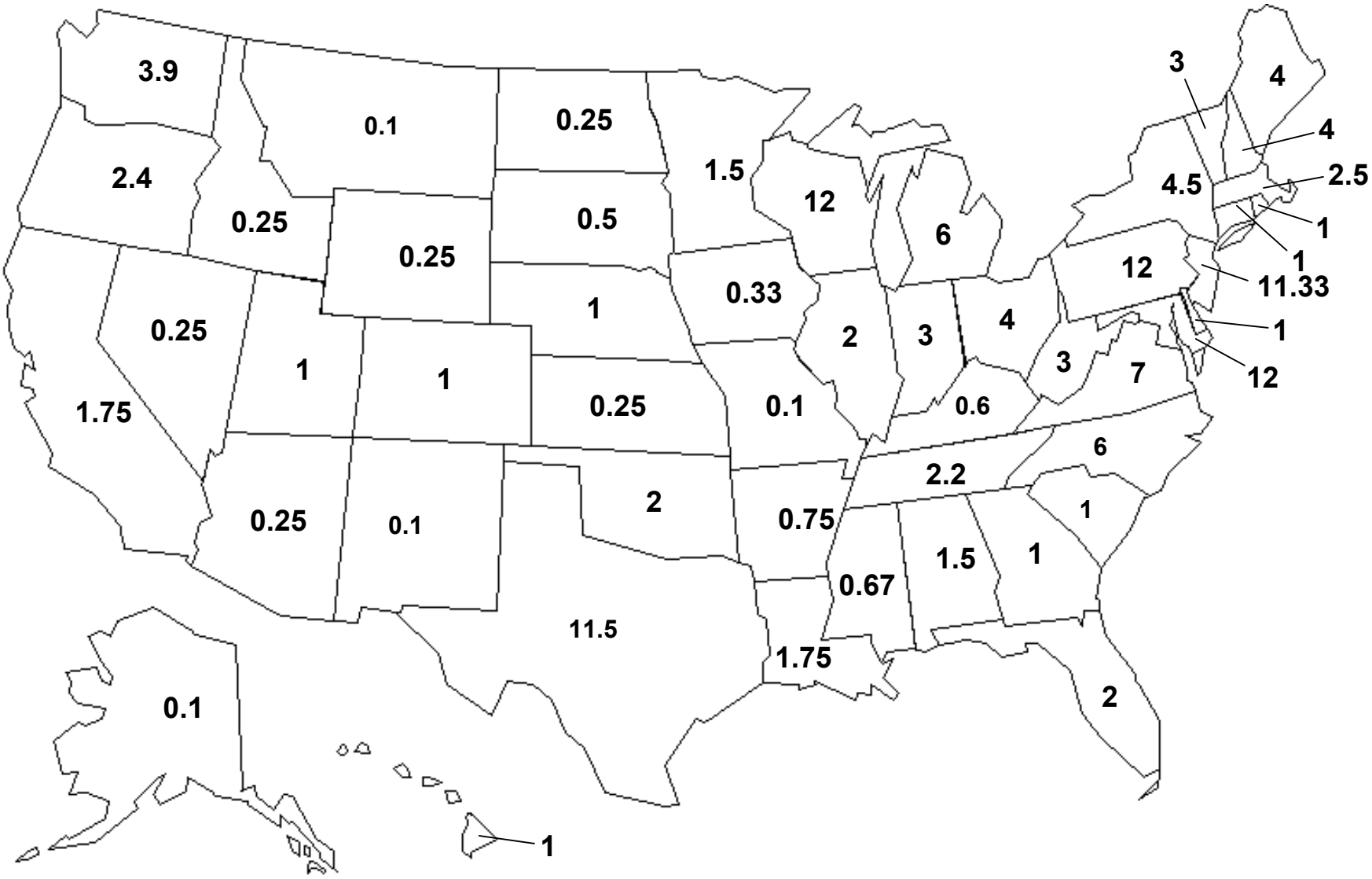
Many states are responsible for implementing biosolids programs by their own statutes and regulations. In those states, biosolids application falls under both EPA and state rules, with federal rules being required minimum standards. Some municipalities (or local units of government) in the United States have adopted local ordinances pertaining to land application. The authority of a municipality, and thus the scope that a local ordinance can address, varies between the states (Harrison and Eaton 2001). Thus, the ability of a local ordinance to withstand legal challenge depends on the state. As noted previously, only five states (Oklahoma, Utah, Texas, Wisconsin, and South Dakota) have received official delegated authority from EPA to administer the federal regulations for biosolids. Several states have submitted requests for delegated authority but in many cases, experience long waiting periods for a review of that request (e.g., Vermont and Iowa) or encounter other legal or technical roadblocks. For example, Colorado, Indiana, and South Carolina have had legal issues with self-audit protection laws, which are inconsistent with federal requirements. North Carolina has issues with implementing agreements compliant with endangered species protection administered through the U.S. Fish and Wildlife Service, and Michigan has potential issues with authority over non-Native American wastewater generated or used on Native American land. Nevertheless, all states have varying degrees of commitment for biosolids program administration. Figure 2-3 shows the number of full-time employees working for state biosolids programs. This figure is based on direct communication between the WDNR and each state (WDNR, unpublished data, 2001).

EUROPEAN BIOSOLIDS MANAGEMENT

The management of biosolids in Europe varies from country to country, as do the standards applied, their derivation, and their enforcement. This situation is readily apparent when U.S. regulations and their varying levels of enforcement are compared with those of European countries. Some of the substantial differences in the contaminant standards between Europe and the U.S. are, in part, due to differences in approaches to environmental protection and regulatory intent (public health and environmental protection). For example, some European countries have taken the approach of minimizing any accumulation of metals beyond background environmental levels, whereas other European countries and the U.S. have performed risk assessments to determine land-application concentrations that are protective of reasonably anticipated adverse effects. Even the latter approach has lead to substantially different standards between some countries. A variety of factors influence the outcomes of risk assessment (discussed in Chapter 5), but the major contributing factor to different risk-based standards between countries is the country's selection of target organism (humans, animals, plants, soil organisms) to protect. While it was beyond the scope of this report to prepare a comprehensive evaluation of differences between U.S. standards and those of other countries, it is important that the differences be acknowledged and the bases for those differences used to inform future risk assessments. This section provides an overview of how different European countries have approached the management of biosolids for land application.

The European Union is composed of 15 member nations. The Council of European Communities (1986) published the Sewage Sludge Directive (86/278/EEC). All members had to promulgate their own version of the directive as national regulations by 1989. The directive

FIGURE 2-3 Number of FTEs dedicated to state biosolids programs. Figures do not include septage staff.
Source: EPA 2002c.



included a recommended range of pollutant concentration values for seven constituents in biosolids for member nations to use in adopting their standards (see Table 2-4). However, individual nations could choose to adopt more stringent standards than those recommended in the directive. New regulations were proposed but might not be adopted until 2005 (Luca Marmo, European Commission, Brussels, personal communication, 2002).

TABLE 2-4 European Union Limit Values for Concentrations of Heavy Metals in Biosolids for Use on Land

	Limit Values (mg/kg dm)	
Elements	Directive 86/278/EEC	Proposed
Cadmium	20-40	10
Chromium	-	1,000
Copper	1,000-1,750	1,000
Mercury	16-25	10
Nickel	300-400	300
Lead	750-1,200	750
Zinc	2,500-4,000	2,500

Source: Adapted from Council of the European Communities 1986.

A comprehensive review of biosolids use and disposal practices was published by the International Association on Water Quality (IAWQ), International Water Association (IWA), the Water Environment Federation (WEF), and the European Water Pollution Control Association (EWPCA) (Matthews 1996). Selected information from that review and other references has been presented with appropriate updates when available (Council of the European Communities 1986; EPA 1990, 1995a,b, 1999b; Gendebien et al. 1999; European Union 2000a,b; and European Communities 2001). Accordingly, representative data from Europe to complement U.S. information have been assembled to provide a basis for comparison and some determination of the current and future status of biosolids management.

An assessment of the status of disposal and recycling within the European Community (European Communities 2001) reviewed existing legislation and regulations and provided an analysis of stakeholder positions, motivations, and constraints, as well as solutions for reducing constraints and encouraging the use of biosolids. Analysis of existing legislation indicated that specific requirements focus principally on the use of biosolids in agriculture both nationally and in Europe. The EEC directives, which have the strongest influence on biosolids use, are directive 91/271/EEC on urban wastewater treatment and 86/278/EEC on the use of biosolids in agriculture (Council of the European Communities 1986). Requirements set by the latter directive are a crucial element in the management of biosolids produced in the member states and some member states have introduced provisions that go beyond the requirements of the directive. In particular, the limit values for concentrations of heavy metals in biosolids are lower than those specified in the directive in a majority of the countries.

As indicated in Table 2-5, the countries in which the limitations on heavy metal concentrations are the most stringent are Belgium (Flanders region), Denmark, Finland, the Netherlands, and Sweden. Greece, Luxembourg, Ireland, Italy, Portugal, and Spain have set limit values similar to those in the directive; values for Poland, an accession country, are also lower than the European Union standards. The United Kingdom legislation differs by not providing any limit values for heavy metals in biosolids but rather specifies the maximum annual average loads of heavy metals to soil that are similar to the directive (Table 2-6). In addition, the regulations on biosolids use include limit values for pathogens in France, Italy, and Luxembourg and, for organic compounds in Austria, Belgium-Flanders, Denmark, France, Germany, and Sweden, neither of which are included in the directive (Tables 2-7 and 2-8).

In all member states, regulations on the use of biosolids specify limit values for heavy metals in soil that are similar in most cases to the requirements set in the directive (Table 2-9). Some countries have defined limit values for several categories of soil pH or limit the maximum load of heavy metals to agricultural lands on a 10-year basis. Maximum quantities of biosolids that can be applied on land have been set between 1 metric ton by the Netherlands for grasslands and 10 metric tons by Denmark per hectare and per year.

The debate on biosolids recycling and disposal differs in intensity and resolution throughout the European community. An analysis of stakeholder groups (European Communities 2001), including the farming community, landowners, industries, water and wastewater plants and companies, local authorities, national authorities, and citizens and consumer groups, indicated a significant diversity of opinion ranging from opposition to advocacy as shown below:

- The regulatory requirements in the Netherlands and Flanders region of Belgium have prevented almost all use of biosolids in agriculture since 1991 and 1999, respectively.
- In countries such as Denmark and the United Kingdom, new regulations are considered sufficiently strict to reduce risks to an acceptable level (Denmark), and agreement in 1998 between water and sewage operators and retailers as well as farmers' associations and government (United Kingdom) led to the joint adoption of a "safe sludge matrix" providing for additional restrictions on the use of biosolids on agricultural land as well as the categories of crops on which biosolids may not be used.
- In Sweden, a voluntary agreement was signed in 1994 between the Swedish Environmental Protection Agency, the Swedish Federation of Farmers (LRF) and the Swedish Water and Waste Water Association concerning quality assurances relating to the use of biosolids in agriculture. However, in October 1999, the LRF recommended that its members stop using biosolids because of quality concerns.
- Public opinion in Germany has recently swung in favor of agricultural land application, mainly because this practice is considered economically viable and that the potential risks are sufficiently reduced by the existing legislation, which is now being reviewed.
- In Austria, France, and the Walloon region of Belgium, national (or regional) agreements have been considered, and in France, such an agreement was supported on the condition that additional quality controls and an insurance fund be developed. One party to the agreement (farmers' union) asked for a ban on biosolids because current methods used are not considered sufficient to address the perceived risks related to the agricultural cycling of biosolids.
- In Finland and Luxembourg, the farming community is generally hostile toward the use of biosolids for land application, mainly because of the pressure to use animal manure (e.g., the

TABLE 2-5 European Union Limit Values for Heavy Metals in Biosolids, milligrams per kilogram of dry matter (DM) (Shaded cells represent limit values below those required by directive 86/278/EEC.)

	Cd	Cr	Cu	Hg	Ni	Pb	Zn	As	Mo	Co
Directive 86/278/EEC	20-40	---	1,000-1,750	16- 25	300-400	750-1,200	2,500-4,000	--	--	--
Austria	2[a] 10[b] 10[c] 4[d] 10[e] 0.7-2.5[f]	50[a] 500[b] 500[c] 300[d] 500[e] 70-100[f]	300[a] 500[b] 500[c] 500[d] 500[e] 70-300[f]	2[a] 10[b] 10[c] 4[d] 10[c] 0.4-2.5[f]	25 100[b] 100[c] 100[d] 100[e] 25-80[f]	100[a] 400[b] 500[c] 150[d] 500[c] 45-150[f]	1,500[a] 2,000[b] 2,000[c] 1,800[d] 2,000[c] 200-1,800[f]	20[c]	20[c]	10[a] 100[c]
Belgium (Flanders)	6	250	375[f]	5	100	300	900[f]	150	--	--
Belgium (Walloon)	10	500	600	10	100	500	2,000		--	--
Denmark - dry matter basis - total phosphorus basis	0.8 100	100	1,000	0.8 200	30 2,500	120[g] 10,000[g]	4,000	25[h]	--	--
Finland	3 1.5[i]	300	600	2 1[i]	100	150 100[I]	1,500	--	--	--
France	20[j]	1,000	1,000	10	200	800	3,000	--	--	--
Germany	10	900	800	8	200	900	2,500	--	--	--
Greece	20-40	500	100 -1,750	16-25	300-400	750-1,200	2,500-4,000	--	--	--
Ireland	20	--	1,000	16	300	750	2,500	--	--	--
Italy	20	--	1,000	10	300	750	2,500	--	--	--
Luxembourg	20-40	1,000- 1,750	1,000-1,750	16-25	300-400	750-1,200	2,500-4,000	--	--	--
Netherlands	1.25	75	75	0.75	30	100	300	--	--	--
Portugal	20	1000	1,000	16	300	750	2,500	--	--	--
Spain - soil pH <7 - soil pH >7	20 40	1,000 1,750	1,000 1,750	16 25	300 400	750 1,200	2,500 4,000	--	--	--
Sweden	2	100	600	2.5	50	100	800	--	--	--
United Kingdom	--	--	--	--	--	--	--	--	--	--
Accession countries										
Estonia	15	1,200	800	16	400	900	2,900	--	--	--
Latvia	20	2,000	1,000	16	300	750	2,500	--	--	--
Poland	10	500	800	5	100	500	2,500	--	--	--

[a] Lower Austria (grade II);
[b] Upper Austria;
[c] Burgenland;
[d] Vorarlberg;
[e] Steiermark;
[f] Carinthia;
[g] These values will be reduced to 125 (Cu) and 300 (Zn) from December 31, 2007; [h] For private gardening, lead value is reduced to 60 mg/kg of dry matter (DM) or 5000 mg/kg P;
[i] For private gardening;
[I] Target limit values for 1998;
[j] 15 mg/kg of DM from January 1, 2001 and 10 mg/kg of DM from January 1, 2004.
Abbreviations: As, arsenic; Cd, cadmium; Co, cobalt; Cr, chromium; Cu, copper; Hg, mercury; Mo, molybdenum; Ni, nickel; Pb, lead; Zn, zinc.
Source: Adapted from European Communities 2001.

TABLE 2-6 European Union Limit Values for Amounts of Heavy Metals That May Be Added Annually to Soil, Based on a 10-Year Average

	Limit Values (g/ha/y)	
Elements	Directive 86/278/EEC	Proposed
Cadmium	150	30
Chromium	-	3,000
Copper	12,000	3,000
Mercury	100	30
Nickel	3,000	900
Lead	15,000	2,250
Zinc	30,000	7,500

Note: The component authority may decide to allow an increase in the loading rate for copper and zinc on a case-by-case basis for those plots of land that are copper- or zinc-deficient and if it has been proved by qualified expert advice that there is a specific agronomic need for the crops.
Abbreviation: g/ha/y, gram per hectare per year.
Source: Adapted from Council of the European Communities 1986; European Union 2000b.

TABLE 2-7 European Limit Values for Pathogens Concentrations in Biosolids

	Salmonella	Other Pathogens
France	8 MPN/10 g of DM	Enterovirus: 3 MPCN/10 g of DM Helminths eggs: 3/10 g of DM
Italy	1,000 MPN/g of DM	
Luxembourg		Enterobacteria: 100/g No egg of worm likely to be contagious
Poland	Biosolids cannot be used in agriculture if it contains *Salmonella*	"Parasites": 10/kg of DM

Abbreviations: DM, dry matter; MPN, most probable number; MPCN, most probable cytophatic number.
Source: Adapted from European Communities 2001.

TABLE 2-8 European Limit Values for Organic Compounds in Biosolids (milligrams per kilogram of dry matter)

	Dioxins and Furans (PCDD, PCDF) ng/TE/kg of DM	PCBs	AOX	LAS	DEHP	NPE	PAH	Toluene
Austria	100[a,b,c] 50[e]	0.2[a,b,c] 1[e]	500[a,b,d]	--	--	--	6[d]	--
Belgium (Flanders)[e]								
Denmark from 1/07/2000 from 1/07/2002	--	--	--	2,600 1,300 1,300	100 50 50	50 30 10	6 3 3	--
France	--	0.8[f]	--	--	--	--	2-5[g] 1.5-4[h]	--
Germany	100	0.2[i]	500	--	--	--	--	--
Sweden	--	0.4		--	--	100	3	5

[a]Lower Austria.
[b]Upper Austria.
[c]Vorarlberg.
[d]Carinthia.
[e]Limit values for approximately 30 organic compounds.
[f]Sum of seven principal PCBs (PCB 28, 52, 101, 118, 138, 153, 180).
[g]Fluoranthene.
benzo[*b*]fluoranthene, benzo[*a*]pyrene.
[h]When used on pasture land.
[i]For each one of the six congeners.
Abbreviations: AOX, sum of organohalogenous compounds; DEPH, di(2-ethylhexyl)phthalate; LAS, linear alkyl-benezene sulfonates; NPE, nonylphenol and nonylphenolethoxylates; PAH, polyaromatic hydrocarbons; PCBs, polychlorinated biphenyls; PCDD, polychlorodibenzodioxins; PCDF, polychlorodibenzofurans; TE, 2,3,7,8-tetrachloro-*p*-dioxin toxicity equivalents.
Source: Adapted from European Communities 2001.

TABLE 2-9 European Union Limit Values for Heavy Metals in Soil (milligrams per kilogram of dry matter)
(Shaded cells represent limit values below those required by Directive 86/278/EEC.)

	Cd	Cr	Cu	Hg	Ni	Pb	Zn	As	Mo	Co
Directive 86/278/EEC (6<pH<7)	1-3	--	50-140	1-1.5	30-75	50-300	150-300	--	--	--
Austria	1.5[a] 1[b] 2[c] 2[d] 2[e] 0.5-1.5[f]	100[a] 100[b] 100[c] 100[d] 100[e] 50-100[f]	60[a] 100[b] 100[c] 100[d] 100[e] 40-100[f]	1[a] 1[b] 1.5[c] 1[d] 1[e] 0.2-1[f]	50[a] 60[b] 60[c] 60[d] 60[e] 30-70[f]	100[a] 100[b] 100[c] 100[d] 100[e] 50-100[f]	200[a] 300[b] 300[c] 300[d] 300[e] 10-200[f]	--	10[e]	50[e]
Belgium (Flanders)	0.9	46	49	1.3	18	56	170	22	--	--
Belgium (Walloon)	2	100	50	1	50	100	200	--	--	--
Denmark	0.5	30	40	0.5	15	40	100	--	--	--
Finland	0.5	200	100	0.2	60	60	150	--	--	--
France	2	150	100	1	50	100	300	--	--	--
Germany	1.5	100	60	1	50	100	200	--	--	--
Greece	1-3	--	50-140	1-1.5	30-75	50-300	150-300	--	--	--
Ireland	1	--	50	3	30	50	150	--	--	--
Italy	1.5	--	100	1	75	100	300	--	--	--
Luxembourg	1-3	100-200	50-140	1-1.5	30-75	50-300	150-300	--	--	--
Netherlands	0.8	100	36	0.3	35	85	140	--	--	--
Portugal									--	--
-soil pH <5.5	1	50	50	1	30	50	150			
-5.5< soil pH <7	3	200	100	1.5	75	300	300			
-soil pH >7	4	300	200	2	110	450	450	--		
Spain										
- soil pH <7	1	100	50	1	30	50	150	--	--	--
- soil pH >7	3	150	210	1.5	112	300	450	--	--	--
Sweden	0.4	60	40	0.3	30	40	100-150	--	--	--
United Kingdom										
-5 < soil pH 5.5	3	--	80	1	50	300	200	--	--	--
-5.5 < soil pH <6	3	--	100	1	60	300	250			
-6≤ soil pH ≤7	3	--	135	1	75	300	300			
-soil pH >7	3	--	200	1	110	300	450			
Estonia	3	100	50	1.5	50	100	300	--	--	--
Latvia	0.3-1	15-30	10-25	0.1-0.15	8-30	15-30	35-100	--	--	--
Poland	1-3	50-100	25-75	0.8-1.5	20-50	40-80	80-180	--	--	--

[a] Lower Austria (grade II);
[b] Upper Austria;
[c] Burgenland;
[d] Vorarlberg;
[e] Steiermark;
[f] Carinthia.
Abbreviations: Cd, cadmium; Cr, chromium; Cu, copper; Hg, mercery; Ni, nickel; Pb, lead; Zn, zinc; As, arsenic; Mo, molybdenum; Co, cobalt.
Source: Adapted from European Communities 2001.

Finnish Union of Agricultural Producers requested a ban on the use of biosolids for land application, and have renewed its stand against the use of biosolids in agriculture in 2001).

- In Ireland and Portugal, farmers tend to support the agricultural use of biosolids for economic and for agronomic (organic matter and phosphorus content) reasons, although biosolids use in these countries has been relatively recent.
- In Spain, Italy and Greece, available information indicates that there is little debate on use of biosolids.

The analysis of stakeholders' positions (European Communities 2001) indicates that the main areas of concerns on sewage sludge disposal and biosolids recycling are that the growing quantities of sewage sludge must be treated with the aim of keeping both environmental and economic costs as low as possible. Similarly, improving practices of treatment and use of biosolids is now considered essential. Moreover, within the context of uncertainties concerning the potential impacts on human health and the environment of the various disposal and recycling options, additional research is needed to increase confidence in the use of biosolids in agriculture.

Some strategies suggested by the recent European Union biosolids-management assessment for reducing constraints and encouraging recycling of biosolids include the following (European Communities 2001):

- Certify the treatment process involved, the quality of biosolids, and recycling practices.
- Develop a trust fund or insurance system to cover any loss of profits, damages, or other costs related to the use of biosolids in agriculture together with legal provisions to regulate producer liability.
- Standardize science-based laws and regulations.
- Enhance mutual confidence and communication and transfer of information between stakeholders.
- Diminish uncertainty over risks to human health and environment, and extend the assessment and dissemination of information beyond heavy metals to include organic pollutants and pathogens.
- Develop codes of practice for the recycling of biosolids, the possible use of labels for quality assurance, and associated training programs and outreach activities for stakeholders.

When European Union biosolids-management practices are compared with those of the U.S., it is apparent that European and U.S. contaminant limits apply largely to heavy metals and are based on (1) the concentration of the biosolids itself; (2) the loading or total amount of metal that can be added and how quickly it can be applied; and (3) the maximum concentration of metals in soil allowed to build up after biosolids application.

According to an analysis of regulations in the United States and some European countries by McGrath et al. (1994), three basic approaches to setting limits were distinguished: (1) analyzing the pathways of pollutant transfer to selected target organisms and an assessment of the likely harmful effects that metals might have on the target; (2) setting limits consistent with the lowest-observed-adverse-effect concentrations, which are actual cases of effects due to metals but not necessarily derived from studies that involved applications of biosolids; and (3) attempting to match the metal inputs to soils to the small losses of metals due to crop removal, soil erosion, and leaching (metal balance approach). These approaches were considered

responsible for the widely different numerical limits for metals arising either from a policy decision to reach zero impact (metals balance) and associated low levels or from approaches that allow some increase in metal concentrations in soils based on target organisms and use of associated models and sparse toxicity data. Thus, the practice of implementing vastly different regulations for biosolids application to land in the United States and within European Union member nations create differing social, economic, technological, and environmental impacts that beg consensus resolution in the scientific, technical, and regulatory communities.

Within the European Union, the intended goal and most widely applied biosolids disposition option is agricultural use. However, the selection of an option and its implementation according to European Commission directives is affected by local or national circumstances. Thus, the degree of flexibility varies. Some indication of the production and disposal of domestic sewage sludge and biosolids in Europe as of 1992 is included in Table 2-10. Notably, ocean disposal has been phased out, so that the principal disposal options now include agricultural use, landfill, and incineration. As in the United States, the European Commission has developed regulatory limits (Sewage Sludge Directive 86/278/EEC) when biosolids are used in agriculture. The Sewage Sludge Directive requires member states to apply maximum limit values for certain heavy metals in the biosolids and in the soil to which it is applied; to pretreat sewage sludge; and to restrict its use, including the frequency and quantity of application, on certain soils.

These regulations establish conditions relating to pretreatment, nutrient needs, quality of soil, protection of surface waters and groundwaters, and compliance with concentration limits of heavy metals in soil. Use of biosolids is prohibited on specified categories of land within defined periods prior to harvesting and where concentrations of heavy metals in the soil exceed specified limit values. Records must be kept and made available to the competent authorities on the quantities, composition, use, treatment, and results of analysis on biosolids, the names and addresses of recipients of biosolids, and the places where biosolids are to be used (European Union 2000a). Accordingly, member states have performed biosolids surveys to comply with the reporting requirements, such as the U.K. Sludge Survey for 1996-1997 (Gendebien et al. 1999). Summary reports indicating biosolids quality and ultimate disposition quantities are to be submitted to the European Union every 5 years (e.g., UK. Department of the Environment 1993).

A part of the implementation of the directive is that application for biosolids use is made in advance of the operation, and conditions are applied to the methods and type of biosolids used. Consideration is given to the links between biosolids use and potential transmission of pathogens to the human food chain and into water courses or supplies through nutrient leaching. In addition, biosolids producers are obliged to provide details of biosolids composition to owners of land where biosolids will be applied (see Box 2-1). Analytical methods, sampling frequencies, monitoring procedures, and record-keeping requirements are also prescribed (see Box 2-2).

Proposed revisions are included in the European Union Working Document on Sludge (European Union 2000b), and changes in limit values are being considered for heavy metals and organic compounds on the basis of biosolids concentrations and soil characteristics. The use of biosolids in soils where the concentrations of heavy metals exceed the limit values suggested in Table 2-11 would be allowed only on a case-specific basis, and member states would have to ensure that those limit values are not exceeded as a result of the use of biosolids. If the concentrations of one or more heavy metals in biosolids are higher than the concentration limits suggested in Table 2-4 or if the concentrations of one or more organic compounds in biosolids are higher than the concentration limits proposed in Table 2-12, the use of biosolids should not

take place. Compliance with Tables 2-4 and 2-12 is assumed if 90% of samples in a 12-month period are less than the standards and if 10% of samples exceed the standards by less than 50%. The maximum annual quantities of heavy metals indicated in Table 2-6 that may be added to the soil because of use of biosolids should not be exceeded. These limit values are intended to be reviewed every 6 years with a view toward achieving medium- and long-term concentrations for pollution prevention.

TABLE 2-10 Production and Disposal of Domestic Sewage Sludge and Biosolids in European Community in 1992 (1,000 metric tons of dry matter per year), (%)

Member State	Quantity	Agriculture	Landfill	Incineration	Ocean	Other[a]
Austria	170 (2.3)	30.6 (18)	59.5 (35)	57.8 (34)	-	22.1 (13)
Belgium	59.2 (0.8)	17.2 (29)	32.5 (55)	8.9 (15)	-	0.6 (1)
Denmark	170.3 (2.3)	92 (54)	34 (54)	40.9 (24)	-	3.4 (2)
Finland	150 (2.0)	37.5 (25)	112.5 (75)	-	-	-
France	865.4 (12.0)	502 (58)	233.5 (27)	130 (15)	-	-
Germany	2,681.2 (2.3)	724 (27)	1,448 (54)	375.2 (14)	-	134 (5)
United Kingdom	1,107 (15.0)	488 (44)	88.6 (8)	77.4 (7)	322 (30)	121 (11)
Greece	48.21[b] (0.6)	4.8 (10)	43.4 (90)	-	-	-
Ireland	36.7 (0.5)	4.4 (12)	16.6 (45)	-	12.8 (35)	2.9 (8)
Italy	816 (11.0)	269.2 (33)	449 (55)	16.2 (2)	-	81.6 (10)
Luxembourg	8 (0.1)	1 (12)	7 (88)	-	-	-
Netherlands	335 (4.5)	87 (26)	171 (51)	10 (3)	-	67 (20)
Norway	95 (1.3)	53.2 (58)	41.8 (44)	-	-	-
Portugal	25 (0.3)	2.7 (11)	7.3 (29)	-	0.5 (2)	14.5 (58)[c]
Spain	350 (4.7)	175 (5)	122.5 (35)	17.5 (5)	35 (10)	-
Sweden	200 (2.7)	80 (40)	120 (60)	-	-	-
Switzerland	270 (3.6)	121.5 (45)	81 (30)	67.5 (25)	-	-
Total	7,387 (100.0)	2,690.1 (36.4)	3,066.2 (41.6)	801.4 (10.9)	380.3 (5.19)	447.1 (6)

[a]Recultivation, forestry, and so forth; [b]Other estimates at 200,000 metric tons of dry matter per year; [c] Surface water.
Source: Adapted from Matthews 1996.

BOX 2-1 Examples of Regulatory Controls

One European Union member state (United Kingdom) operates a prenotification system through its competent authority. This system is designed to ensure that biosolids are given suitable treatment before spreading on agricultural land and has led to the setting of legal limits for metals in soil according to the requirements of the directive. In addition, the UK has set limits for 10-y average rates of application for metals in biosolids and requires that producers identify suitable sites. A code of practice for the agricultural use of biosolids in agriculture has been issued, and there is a separate code dealing with the agricultural use of biosolids in forests. The responsibility for undertaking sampling and analysis lies with the biosolids producers who must support their activities by maintaining records and supplying data to the Environment Ministry. Sampling and analytical procedures are in accordance with the code of practice, which incorporates the directive's requirements and specifies restrictions to minimize risks to health.

The Sewage Sludge Directive has been incorporated into the legislation of another member state (Sweden) through an order issued by the Environment Ministry. This order governs the monitoring of biosolids quality and the spreading of biosolids on arable land. It also lays down limit values for inputs of nutrients to arable soil via biosolids, limit values for metals in arable soils, and limit values for inputs of metals to arable soil. A separate ordinance specifies limit values for metal concentrations in biosolids intended for agricultural use. Biosolids must be treated before being used in agriculture and producers of biosolids must supply a declaration of contents to those who will use the biosolids. Similarly, the operation of sewage plants in that state requires authorization from national and regional authorities.

In a third member state (Portugal) the national law sets limit values for heavy metal concentrations in the soil and the quantity of biosolids per hectare.

BOX 2-2 Examples of Monitoring Procedures

In one member state (United Kingdom) monitoring is undertaken in accordance with the directive, whereby soil is analysed on first application and at least every twentieth year whilst biosolids are spread to determine its pH and metals levels. Biosolids are analysed at least every six months and every time significant changes occur in the quality of the biosolids treated at the works. Analysis is the responsibility of the biosolids producer but records must be kept and made available to the Environment Ministry. The analytical methods used are in accordance with the directive. The parameters analysed conform to the directive and there are a number of additional ones.

In another Member State (Portugal) the national law requires sampling of both the biosolids and the soil. The biosolids are analysed by the user, who has the burden of proof that it complies with the legally established limits. The results are then made available to the Institute of Waste (INR), Regional Directorates of the Environment (DRAs) or General Inspectorate of Environment (IGA), who give the final approval. The analyses of the soil are to be undertaken before biosolids are applied, although there is no specification of sampling frequency after the biosolids are spread. The results must be kept for five years.

In another Member State (Sweden) the producer of biosolids is responsible for carrying out sampling and analysis of biosolids in respect of dry matter and loss on ignition; pH; total phosphorus; total nitrogen; ammonium nitrogen; lead, cadmium, copper, chromium, mercury, nickel and zinc. The order that requires this also lays down detailed rules on sampling and analysis methods. The frequency of sampling and analysis is determined according to the treatment capacity of the plant. As a minimum, the sampling and analysis must be done on an annual basis. Permitting authorities are responsible for supervision and inspection.

Source: Adapted from European Union 2000a.

TABLE 2-11 European Union Limit Values for Concentrations of Heavy Metals in Soil

	Limit Values (mg/kg dm)			
Elements	Directive 86/278/EEC 6<pH<7	Proposed 5 ≤ pH<6	Proposed 6 ≤ pH<7	Proposed pH ≥ 7
Cadmium	1-3	0.5	1	1.5
Chromium	-	30	60	100
Copper	50 -140	20	50	100
Mercury	1-1.5	0.1	0.5	1
Nickel	30 -75	15	50	70
Lead	50-300	70	70	100
Zinc	150-300	60	150	200

Note: When the concentration value of an element in a specific land area is higher than the concentration limit set in the table, the competent authority may still allow the use of biosolids on that land on a case-by-case basis after evaluation of the following aspects: (1) intake of heavy metals by animals, (2) uptake of heavy metals by plants, (3) groundwater contamination, and (4) long-term effects on biodiversity, particularly on soil biota. The areas of land with higher metal concentrations will be monitored and the possibility of using biosolids will be subject to a periodical assessment by the competent authority.

Source: Adapted from European Union 2000b.

TABLE 2-12 Proposed Limit Values for Concentrations of Organic Compounds and Dioxins in Biosolids for Use on Land

Organic Compounds	Proposed Limit Values (mg/kg DM)
AOX[a]	500
LAS[b]	2,600
DEHP[c]	100
NPE[d]	50
PAH[e]	6
PCB[f]	0.8

Dioxins	Proposed Limit Values (ng/TE/kg DM)
PCDD/PCKF[g]	100

[a]Sum of halogenated organic compounds; [b]Linear alkylbenzene sulfonates; [c]Di(2-ethylhexyl)phthalate; [d]It comprises the substances nonylphenol and nonylphenolethoxylates with 1 or 2 ethoxy groups; [e]Sum of the following polycyclic aromatic hydrocarbons: acenapthene, phenanthrene, fluorene, flouranthene, pyrene, benzo(b+j+k)fluoranthene, benzo(a)pyrene, benzo(ghi)perylene, indeno(1,2,3-c,d)pyrene; [f]Sum of the polychlorinated biphenyl congeners number 28, 52, 101, 118, 138, 153,180; [g]Polychlorinated dibenzodioxins and dibenzofurans. Abbreviations: DM, dry matter; TE, 2,3,7,8-tetrachloro-*p*-dioxin toxicity equivalents.
Source: Adapted from European Union 2000b.

PATHOGEN ISSUES AND TREATMENT CONTROLS

EPA sponsored the Workshop on Emerging Infectious Disease Agents and Issues Associated with Animal Manures, Biosolids, and Other Similar By-Products in Cincinnati, Ohio, in June 2001. This workshop was attended by over 100 participants from around the world, who raised general concerns with respect to bacteria, viruses, and parasites in these materials. Although animal manures are generally land applied and untreated and contain pathogens of concern, only biosolids are addressed in this report. Concerns for pathogen control in Classes A and B biosolids were expressed. For example, because Class B biosolids are only partially disinfected through treatment, further disinfection of land-applied Class B biosolids is related to management and treatment by natural attenuation. Workshop participants agreed that more data are needed on rates of pathogen survival in soil or on crops after application of biosolids. As discussed earlier, the criteria of at least seven samples with a geometric mean of less than 2×10^6 MPN or CPU of fecal coliform per gram of dry weight as a control is one of the means for determining Class B treatment adequacy. Better documentation is needed to correlate that or any number to treatment efficiency.

The process control requirements for Classes A and B designations are essentially identical to those established in 40 CFR 257, the 1979 regulations preceding 40 CFR 503. The treatment controls were based on an assumed log reduction of at least 1 for each option (EPA 1985, 1989). The fecal density requirement established in 40 CFR 503 was assumed to correlate to a roughly 2-log reduction (EPA 1985, 1992). However, as early as 1981, it was recognized that additional research was necessary to better document the presence of pathogens and other organisms in raw sewage sludge and their fate through the various treatment regimes in the regulations, and a comprehensive literature review of all relevant publications between 1940 and 1980 was conducted (Pedersen 1981).

Based on limited analyses in EPA's National Risk Management Research Laboratory (NRMRL) in Cincinnati and more complete data collected in Wisconsin between 1998 and 2000, fecal coliforms appear to be present at very low densities in biosolids and perhaps even in raw sewage sludge. That is also true of *Ascaris* eggs and enteric virus (J. Smith, EPA, personal communication, 2002; WDNR, unpublished data, 2000). These data raise the question of the validity of relying on numeric standards for various organisms because it is unclear what they represent. For example, enteric virus and helminth ova are used to measure treatment efficiency for Class A biosolids because of their hardiness and resistance to treatment, but they are also used as indicators of Class A treatment in Alternatives 3 and 4 (discussed previously). Thus, numeric standards are not necessarily incorrect, but there is a need to better define their regulatory meaning and adequacy. Another point of concern raised at the EPA workshop was assay development. For example, with the measurement of *Ascaris*, there is no proper protocol for sampling, pretreatment, and purification before the assay and the appropriate quality-assurance and quality-control (QA and QC) protocols for the spike to be used in the assays. The assays for the other parasites and protozoan oocysts are also unreliable and underdeveloped. The analytical methods for other parasites, protozoan oocysts, and even fecal coliform in biosolids are also suspect, and method development and validation are needed (EPA 2001c). Table 2-13 provides a partial list of possible organisms that may be used as measures of treatment efficiency and that was discussed at the EPA 2001 conference.

TABLE 2-13 Process Criteria For Class B

Bacterial Inactivation				
Process	Temperature	Critical Parameter	Time	Possible Measure of Efficiency
Air drying	>0°C	Desiccation by-products	2-3 mo	*E. coli,* fecal coliform, *Clostridium perfringens*
Alkaline stabilization	Ambient	Ammonia, pH	2 h	*Clostridium perfringens*
Aerobic digestion	15-20° C	Endogenous microbial activity	60-40 d	Fecal coliform, *E. coli*
Anaerobic digestion	20-35° C	Endogenous microbial activity, organic by-products	60-15 d	*Clostridium perfringens*
Composting	40-55° C	Organic by-products	5 d at 40° C, 4 h at 55° C	*Clostridium perfringens*

Source: EPA 2001c.

Many organisms of concern have been known to be present in sewage sludge, and regulations have been developed with the intent to maximize their elimination and minimize the potential transport to humans. This was evident in the initial sewage sludge (40 CFR 257) regulations promulgated in 1979. Nevertheless, new organisms of concern have been identified, and new research should be initiated to reconfirm the level of disinfection achieved through various pathogen process controls. Bacteria such as *E. coli* 0157:H7, *Listeria,* and *Helicobacter* have emerged as potential public-health problems (see Chapter 6 for more details). Table 2-14 lists these and other bacteria of potential regulatory concern, including ones that represent a change in concern from low to high or are newly recognized. In addition, it is necessary to understand the mechanisms responsible for pathogen reduction and time required to meet the control-process requirements. For these reasons, it is necessary to validate the rate of elimination of pathogens through various treatment regimes. Research in this area is currently underway (J. Smith, EPA, personal communication, May 2002).

TABLE 2-14 Bacterial Pathogens of Potential Concern in Biosolids

Major Concern—Classic[a]	New Issues—Changes[b]
Salmonella	*E. coli* 0157:H7
Shigella	*Listeria*
Enteropathogenic *E. coli*	*Helicobacter*
Yersinia enterocolitica	*Mycobacteria*
Campylobacter jejuni	*Aeromonas*
Vibrio cholera	*Legionella*
Leptospira	*Burkholderia*
	Endotoxins
	Antibiotic resistance

[a]Kowal 1985; [b]EPA 2001c.

In the area of virology, the conference raised several issues concerning viruses, such as coxsackievirus, echovirus, adenoviruses, rotaviruses, and reovirus (to name a few). Their potential impact on public health is included in Table 2-15. For pathogen monitoring, the virologists discussed using enteroviruses and coliphages for process disinfection efficacy, but suggested *E. coli*, fecal coliforms, enterococci, and *Clostridium perfringens* for field monitoring. As a result of the workshop deliberations, the consensus opinion of the participating virologists was that Class-B-treatment processes should yield the reductions summarized in Table 2-16 if the processes are properly conducted and maintained and the site's climate, geology, and soil characteristics enable natural attenuation.

Regarding the assessment of helminth eggs and protozoan oocysts, the efficacy of existing Class B disinfection processes for inactivating parasites remains a concern, but the processes should be effective for protozoan oocysts. However, little information is available on treatment efficiency of helminth eggs. There are also concerns with analytical methods for the detection and identification of helminth eggs of the species noted in Table 2-17. Therefore, research is needed to develop reliable assays to measure helminth eggs and to assess the efficacy of Class B processes for inactivating helminths (e.g., *Taenia* and *Toxicara*) where fecal coliforms have traditionally been the only means of monitoring pathogen-inactivation performance. The

TABLE 2-15 Principal Viruses of Concern in Municipal Wastewater and Sewage Sludge

Virus	Diseases of Public Health Concern
Poliovirus	Poliomyelitis
Coxsackievirus	Meningitis, pneumonia, hepatitis, fever, etc.
Echovirus	Meningitis, paralysis, encephalitis, fever, etc.
Hepatitis A virus	Infectious hepatitis
Rotavirus	Acute gastroenteritis with sever diarrhea
Norwalk agents	Epidemic gastroenteritis with severe diarrhea
Reovirus	Respiratory infections, gastroenteritis

Source: Kowal 1985.

TABLE 2-16 Class B Virus Reduction for Biosolids Disinfection Process

Process	Virus Log Reduction	Time
Lagoon storage	1-2	6-12 mo
Mesophilic anaerobic digestion	1-2	15-30 d
Mesophilic aerobic digestion	1-2	15-30 d
Alkaline stabilization pH = 11 to 12	1-3	1 d
Air drying <3% solids	<1	2- 3 mo
Air drying >3% solids	3-4	2- 3 mo
Heat drying 55-60°C	3-4	~1 h
Composting 40-55°C	3-4	6 wk

Source: EPA 2001c.

TABLE 2-17 Principal Parasites of Concern in Municipal Wastewater and Sewage Sludge

Helminth Worms	Symptoms or Diseases
Ascaris lumbricoides	Digestive disturbances, abdominal pain
Ascaris suum	Coughing, chest pain, or asymptomatic
Trichuris trichiura	Abdominal pain, diarrhea, anemia, weight loss
Toxocara canis	Fever, abdominal discomfort, and muscle aches
Taenia sasginata	Nervousness, insomnia, anorexia
Taenia solium	Nervousness, insomnia, anorexia
Necator americanus	Hookworm disease
Hymenolepis nana	Taeniasis

Source: Kowal 1985.

workshop participants expressed interest in using *Clostridium perfringens* as a indicator organism when noncharged biocides are the major agent for inactivation and for anaerobic digestion, lagoon storage, composting, and alkaline stabilization. The existing Part 503 regulation states that the Class A disinfected biosolids are far less a concern as a result of *Ascaris* egg controls along with the temperature factors. In the current Class A requirements, monitoring is required for *Salmonella* or fecal coliform in addition to meeting one of several treatment control processes, which include several nationally approved processes designated equivalent to a process to further reduce pathogens (PFRP) (listed in Table 2-18).

Concerns for Class A processes were also elucidated at the EPA workshop. However, there was less concern with pathogen contamination and more with the confirmation of the efficiency of Class A processes. (Approved mechanisms of pathogen control for Class A treatment for bacteria, viruses, and parasites are summarized in Table 2-19.) Issues of concern included regrowth of pathogens with short-term stabilized biosolids and possible emission of odors. Others were specification of treatment process versus product control and the appropriate point in the treatment process to obtain pre-treatment samples and whether to use an indicator organism to predict pathogen survival and recontamination. However, the major problem discussed at the workshop was the Class A process criteria that do not take into account potentials for regrowth. Regrowth of pathogens can occur in Class A biosolids but generally not with Class B biosolids. To prevent pathogen regrowth, a fairly stable background population of microorganisms are needed. Relevant research on composting indicate the need for 10^4 to 10^5 microorganisms per gram of dry weight of solid (Burnham et al. 1992). With such background levels, as would be common with Class B biosolids, pathogen regrowth is inhibited by competition with the existing microbial ecosystem. Class A disinfection processes generally eliminate these competing microorganisms, requiring retesting of Class A biosolids if used in bulk quantities more than 3 weeks or so after production.

Bioaerosol generation is a concern with the processes of aerobic digestion, anaerobic digestion, composting, alkaline stabilization, and combinations. The concerns are bacterial species, viruses, and bacteria in bioaerosols but probably not parasites due to their greater size and weight.

In summary, several pathogen-related issues and research needs were identified at the EPA workshop and in related literature:

- Further information regarding pathogen survival in processing or emission during the process.
- Research on vectors carrying pathogens and toxins.
- Assessment of bioaerosols and other chemical aerosols.
- Test-method development and validation for various organisms in sewage sludge and biosolids.
- Field verification of efficacy of Class A and Class B treatment processes (including data to directly relate process controls to initial and final pathogen and indicator densities).
- Development of indicator pathogens for assessment of impact and attenuation in field situations.

TABLE 2-18 Processes Recommended as Equivalent to PFRP

Process	Criteria for Approval
CBI Walker, Inc. Aurora, Illinois	Two-stage aerobic digestion process utilized time-temperature control with resulting mesophilic aerobic digestion for stabilization
Fuchs Gass and Wasserteckink Mayen, Germany	Two-stage autothermophilic aerobic digestion process utilizing time-temperature control with resulting mesophilic aerobic digestion for stabilization.
International Process Systems, Inc. Glastonbay, Connecticut	In-vessel composting process related to time-temperature disinfection followed by compost maturation for stabilization
K-F Environmental Technologies, Inc. Pompton Plains, New Jersey	Indirect drying process utilizing the PSRP (process to significantly reduce pathogens) heat drying process criteria and short-term stabilization at less than 10% moisture content
Lyonnaise des Eaux Pecz-Sur-Seine, France	Two-phase thermophillic and mesophilic anaerobic digestion where pathogen criteria used to demonstrate PFRP (process for the further reduction of pathogens) criteria with mesophilic stabilization
AJW, Inc. Santa Barbara, California	Thermophilic alkaline stabilization used pasteurization criteria with short-term stabilization related by pH
N-Viro Toledo, Ohio	Advance alkaline stabilization that has various alternatives for disinfection and alkaline composting for disinfection. They used the pathogen criteria and alternative 2
Synox Corporation Jacksonville, Floride	OxyOzonation process is an acid-oxidizing process that utilizes a pathogen criteria from influent and effluent in alternative 3
Ultra Clear, Inc. Marlboro, New Jersey	Microbiological composting and drying process which is a time-temperature process equivalency

Source: EPA 1999b.

TABLE 2-19 Class A Inactivation of Pathogens

Process	Inactivation	Concerns
Aerobic digestion (thermophilic)	Time, Temperature	Oxygen transfer, solids content, bioaerosols
Anaerobic digestion (thermophilic)	By-products, time, temperature	Solids content, odor, bioaerosols, pH
Composting (thermophilic)	By Products, time, temperature	Solids content, odor, bioaerosols, pH
Alkaline stabilization	Ammonia, time-temperature	Solids content, odor, aerosols, pH
Heat drying (>80°C)	Time-Temperature	Explosions, odors, aerosols
Irradiation (gamma, beta)	>1 megarad	Solids content, stablization
Combinations		
Digestors Lagoons Drying beds	Time-Temp, by-products	Solids content, odors, bioaerosols

Source: Reimers et al. 1986a,b, 1999, 2001; EPA 2001c.

PATHOGEN EQUIVALENCY COMMITTEE

A critical function in the regulation of sewage sludge and biosolids is fulfilled by the Pathogen Equivalency Committee (PEC) established in 1985. The PEC is composed of experts within EPA, who evaluate treatment technologies to determine whether they are equivalent in treatment efficiency to either recognized PSRP (Class B) or PFRP (Class A) as defined in 40 CFR 503. Determination of several such treatment technologies expected within a few years are vermicomposting, microwave technology, infrared irradiation technology, alkaline stabilization, anaerobic digestion, and aerobic digestion. The equivalency criteria could be related to treatment alternatives 1 through 6 for Class A or alternatives 1 through 3 for Class B.

The long-term responsibilities of PEC include integrating and developing methods for microbial assays, gross biosolids parameters, analysis of metals, and analytical techniques for organics, many of which are included in *Standard Methods*, manuals published by the American Society for Testing and Materials, and agricultural analysis. In developing microbial assays, protocol development and workshops to train EPA and other professionals are needed. The same issues relate to vector-attraction tests, which need to be compiled and refined for new stabilization techniques. Due to the major problems arising with manure in nonpoint source pollution, USDA and EPA should collaborate on method development. However, EPA does not have a formal coordinated group that handles these important issues, and there has been no logical protocol to resolve these questions. Even so, the committee believes that this ongoing problem could be resolved with appropriate action from EPA.

In the fall of 2000, Haas (2001) conducted an independent assessment of the pathogen equivalency process. That report focused on the determination of equivalency for both PSRP and PFRP process assessment. Overall, the report found that the members of the PEC need assistance to better conduct their duties. The report's short-term recommendations to support the PEC were as follows:

- The PEC members should have a formal portion of their time allocated to PEC responsibilities.
- Travel funds should be put at the disposal of the PEC to enable meeting attendance and visits to selected sites of petitioners.
- There is a perception on the part of PEC members that EPA's Cincinnati laboratories do not include biosolids as a formal part of their mission statement. This needs to be clarified and rectified.
- A formal procedure for designation of backup members should be devised.

The report also includes a protocol for formally handling a PEC application and recommended that it be developed via a formal approval route. Overall, the report found that the diverse background of EPA staff serving on the PEC is a well-rounded forum and should be continued.

IMPLEMENTATION AND END-USE PRACTICES

Overview

There are three major alternatives for final disposition of sewage sludge: (1) recycling as biosolids to agricultural land as a fertilizer or soil amendment or selling or giving away to the public for use on home gardens or lawns; (2) burying in a municipal solid-waste landfill or a surface disposal site; or (3) burning in an incinerator. When assessing any of these practices, they should be evaluated holistically for risk. For instance, if all land application should cease, how would the overall risk be altered if additional landfills, surface disposal sites, and incinerators were constructed and operated to accommodate the additional volumes? In response to EPA's beneficial-use policy, the publication of risk-based regulations and the general trend toward recycling, numerous states began to encourage POTWs to use their biosolids in the late 1980s and 1990s. This policy was further aided by philosophical shifts away from, and political and legal difficulties associated with siting and constructing incinerators and landfills.

Management Practices

Biosolids are applied to land through one of three methods:

- Injection: Injection vehicles directly inject liquid biosolids at a depth of 6 to 9 inches into the soil. The injectors may simultaneously disc the field or include fine injection tubes for minimal soil breakup, depending on the type of farm-management practices used. This method is considered the most effective for odor control and minimizes the risk of runoff to surface

waters. However, it is not possible to use injection when applying to hay crops or frozen ground. Application is usually prior to planting or after harvest. Vehicles range from 1,500 to 5,000-gallon capacity. Injection is considered a physical-barrier option for satisfying vector-control requirements.

- Incorporation: Biosolids are applied to the surface of the soil and then physically worked into the field within 6 h or as specified by the permit authority. This method is common for cake solids that cannot be injected and is used either prior to planting or after harvest. Biosolids are generally incorporated at a depth of 6 to 9 inches. Incorporation is also considered a physical-barrier option for satisfying vector-control requirements.
- Surface Application: Either liquid or cake solids are applied to the soil surface but are not incorporated into the soil until normal farming practices disturb the soil. This method is common for hay crops and application during winter months. Surface application does not satisfy vector-control requirements, and stabilization must be accomplished through treatment prior to surface application.

The federal regulations for managing a land-application site include the following prescriptions:

- Biosolids shall not be applied to land if it is likely to adversely affect a threatened or endangered species or its critical habitat.
- Biosolids must not be applied to land that is frozen, flooded, or snow covered, so that biosolids cannot enter any wetland or waters of the United States, except as provided in an National Pollutant Discharge Elimination System (NPDES) permit.
- Biosolids must not be applied to land at a distance of less than 10 meters (33 feet) from any waters of the United States, unless otherwise specified in a NPDES permit.
- Biosolids must be applied at a rate equal to or less than the agronomic nitrogen need of the crop to be grown.

Some states require more stringent site criteria including greater distances from surface waters, maximum slope restrictions, minimum depths to groundwater and bedrock, minimum and maximum soil permeability rates, minimum distances to residences or recreation areas, and minimum distances to private or public water-supply wells. For example, Table 2-20 compares the criteria required by Wisconsin with those of the Part 503 rule.

TABLE 2-20 Wisconsin Requirements for Biosolids Applied to the Land in Bulk

Site Criteria	Surface	Incorporation	Injection	Part 503 Requirements
Depth to bedrock	3 ft	3 ft	3 ft	
Depth to high groundwater	3 ft	3 ft	3 ft	
Allowable slopes	0-6%	0-12%	0-12%	
Distance to wells				
- Community water supply or school	1000 ft	1000 ft	1000 ft	
- Other[a]	250 ft	250 ft[a]	250 ft[a]	
Minimum distance to residence, business or recreation area	500 ft	200 ft	200 ft	
Minimum distance to residence or business with permission	250 ft	100 ft	100 ft	
Distance to rural schools and health care facilities	1000 ft	1000 ft	500 ft	
Distance to property line	50 ft[b]	25 ft[b]	25 ft[b]	
Minimum distance to streams, lakes, ponds, wetlands, or channelized waterways connected to a stream, lake, or wetland				33 ft
- Slope 0 to <6 %	200 ft	150 ft	100 ft	
- Slope 6 to <12 %	Not allowed	200 ft	150 ft	
Minimum distance to grass waterways, or dry run with a 50 ft range grass strip[c]				
- Slope 0 to <6 %	100 ft	50 ft	25 ft	
- Slope 6 to <12 %	Not allowed	100 ft	50 ft	
Soil permeability range (in/h)	0.2-6.0	0-6.0	0-6.0	

[a]Separation distances to non-potable wells used for irrigation or monitoring may be reduced to 50 ft. if the biosolids are incorporated or injected and the department does not determine that a greater distance to the wells is required to protect the groundwater; [b]The distances to property lines may be reduced with the written permission of both property owners; [c]Separation distances not required if grass waterway or dry run with grass strip is contained within a site or field for the purpose of erosion control. Source: Adapted from Wisconsin Administrative Code 1996.

Inherent in the concept of developing two classes of pathogen-control criteria are management-practices and site-restriction requirements to equalize the two standards. EPA imposed limitations regarding minimum time durations between application of Class B biosolids and the harvesting of certain crops, the grazing of animals, and public access to the site. Those limitations are summarized in Table 2-21. If the limitations are followed, EPA concluded that the level of protection from pathogenic organisms in Class B biosolids was equal to the protection provided by the unregulated use of Class A biosolids.

Three factors affect the potential dietary exposure to pathogens via crops through land application (EPA 1999b): (1) pathogens must be in the biosolids; (2) the application of biosolids to food crops must transfer the pathogens to the harvested crop; and (3) the crop must be ingested before it is processed to reduce the pathogens. If all three factors are not present, potential exposure is eliminated. The production of Class A biosolids reduces the pathogens in biosolids to below detectable concentrations and may be used without further restriction if it is also deemed exceptional quality (EQ). In contrast, Class B biosolids may contain reduced but still measurable densities of pathogenic bacteria, viruses, protozoans, and viable helminth ova.

TABLE 2-21 Minimum Duration Between Application and Harvest/Grazing/Access for Class B Biosolids Applied to the Land

Criteria	Surface	Incorporation	Injection
Food crops whose harvested part may touch the soil/biosolids mixture (beans, melons, squash, etc.)	14 mo	14 mo	14 mo
Food crops whose harvested parts grow in the soil (potatoes, carrots, etc.)	20/38 mo[a]	38 mo	38 mo
Food, feed, and fiber crops (field corn, hay, sweet corn, etc.)	30 d	30 d	30 d
Grazing of animals	30 d	30 d	30 d
Public access restriction			
High potential[b]	1 yr	1 yr	1 yr
Low potential	30 d	30 d	30 d

[a]The 20 month duration between application and harvesting applies when the biosolids that are surface applied stays on the surface for 4 months or longer prior to incorporation into the soil. The 38 month duration is in effect when the biosolids remain on the surface for less than 4 months prior to incorporation; [b]This includes application to turf farms which place turf on land with a high potential for public exposure. Source: Adapted from 40 CFR Part 503.

The site restrictions are imposed to allow for further reduction of the pathogenic populations through natural attenuation processes. The restrictions are based primarily on the survival rate of helminth ova, which are considered the hardiest pathogens that might be present in biosolids. Some of the factors that influence pathogen survival are sunlight, moisture, pH, temperature, cations, presence of soil microflora, and organic material content. Potential pathways of exposure are also considered in setting the time restrictions. For instance, pathogen die-off is much different when crops are exposed on their surfaces compared with crops grown underground. Helminth ova can survive on top of soil or within soil for months to years depending on climate; thus, longer waiting periods are required for food crops either grown in the biosolids-amended soil or in contact with the soil-biosolids mixture. In practice, far less than 1% of biosolids-amended land is used for the production of unprocessed food-chain crops (WDNR, unpublished data, 2001). Of 27 states responding to an inquiry on this topic by the Wisconsin DNR, 25 reported no such use and two reported less than 1% such use. Based on these results, this finding can be reasonably expected in the remaining 23 states.

Other management practices are intended to minimize the introduction of biosolids to surface water (primarily because of phosphorus and solids concerns) or the leaching of biosolids to groundwater (primarily because of nitrate concerns). To this end, for Class B and other non-EQ biosolids, EPA requires minimum setback distances of 10 meters from surface waters, although at least 21 states have increased their minimum setback distance between 50 and 300 feet. Such factors as slope, buffer strips, method of biosolids application, and the designated uses of nearby surface waters may be considered by states in setting setback distances. EPA also requires that application of non-EQ biosolids be limited to accommodate the nitrogen requirements of the crop to be grown. Notably, federal statutes do not include groundwater in the definition of waters of the United States, and thus no minimum depth to groundwater or bedrock is included in federal regulations. However, at least 23 states include such requirements and at least 10 have prohibited land application of biosolids during winter months. While recognizing that there are vast differences in topography, weather, and soil conditions across the country, EPA would be well advised to include more specific site requirements in its biosolids

regulations, including minimum depth to groundwater, controls on winter application, and setback distances from residences.

In addition, stockpiling of biosolids in fields should only be done with fully stabilized and treated biosolids, for very short durations (generally for no more than 72 h), and in a manner that ensures there is no runoff to surface water or adjacent land. Storage at treatment plants or off-site engineered facilities should be considered to avoid the need to land apply during inclement weather conditions.

Most states mimic the federal requirements for limiting land-application rates to accommodate the nitrogen requirements of the intended crops. Nitrogen is the limiting factor in assessing application rates. The application rate must be based on the nitrogen needs of the crop to be grown. Available nitrogen should be assessed based on mineralization rates for the organic nitrogen and method of application for the ammonium-nitrogen. Nitrogen supplied from all other sources must also be taken into account. This should be implemented through communication between the land applier and the farmer. Because of these nitrogen limitations, biosolids are the most regulated fertilizer or soil amendment used on agricultural land. However, a small but growing number of states are also limiting the application rate based on the phosphorus needs of the crop or some other phosphorus index. As animal waste becomes further regulated based on phosphorus content, phosphorus consideration is likely to have an impact on the biosolids program as well. (Animal waste has not to date been regulated to address pathogen or nutrient control.) Excess phosphorus often becomes a water-quality problem after it reaches surface waters, because it promotes accelerated algae growth and eutrophication. For these reasons, wastewater treatment plants are increasingly being forced to limit the phosphorus in their effluent discharge to surface waters. Therefore, the phosphorus concentration in sewage sludge is necessarily increasing. Although the Part 503 rule does not address phosphorus, many states require setback distances, slope restrictions, and winter prohibitions to minimize the potential for runoff and the associated problems with phosphorus.

End-Use Practices

The Wisconsin DNR has worked with all states to gain information regarding biosolids-use practices, quality, pathogen control, and vector-attraction reduction. The following data from 37 states represent the best estimation of current biosolids use in the United States (WDNR, unpublished data, 2001):

- 5.6 million dry tons of biosolids are used or disposed of. Of this,
- 3.4 million dry tons of biosolids are used as soil amendments and/or fertilizer in the United States, representing 61% of the total amount used or disposed of.
  - 2.4 million dry tons of biosolids are land applied, representing 43% of the total amount used or disposed of.
  - 1 million dry tons of biosolids are land applied or publicly distributed as EQ biosolids, representing 18% of the total amount used or disposed of.
- 0.95 million dry tons of biosolids are disposed of in licensed municipal solid waste landfills, representing 17% of the total amount used or disposed of.
- 0.08 million dry tons of biosolids are disposed of in surface disposal units, representing

1% of the total amount used or disposed of.

- 1.1 million dry tons of biosolids are burned through incineration, representing 20% of the total amount used or disposed of.

CHARACTERIZATION OF BIOSOLIDS

Several national surveys of biosolids quality have been conducted by EPA and the Association of Metropolitan Sewerage Agencies (AMSA) to quantify concentrations of pollutants and nutrients in biosolids. In addition, states have collected data on biosolids as part of their biosolids program management and compliance monitoring for many years. Compliance is tracked largely through state programs and through the federal Biosolids Data Management System (BDMS) and Permit Compliance System (PCS). For chemicals, monitoring is required for total percent solids, the nine regulated inorganic compounds, total nitrogen, and total nitrogen ammonium. For pathogens, the pathogen density requirements for Class A and Class B biosolids (discussed earlier in this chapter) are monitored. Vector attraction reduction requirements are also monitored. Minimum monitoring requirements are specified in 40 CFR 503 based on the quantity of biosolids used or disposed of (see Table 2-22).

TABLE 2-22 Frequency of Monitoring and Land Application and Landfilling

Amount of Biosolids (dry metric tons per 365 days)	Amount of Biosolids (dry U.S. tons per 365 days)[a]	Frequency of Monitoring
$0 < X < 290$	$0 < X < 320$	Once per yr
$290 \leq X < 1{,}500$	$320 \leq X < 1{,}654$	Once per quarter
$1{,}500 \leq X < 15{,}000$	$1{,}654 \leq X < 16{,}540$	Once per 60 d
$15{,}000 \leq X$	$16{,}540 \leq X$	Once per mo

[a]Amount that is land applied or landfilled on a dry weight basis.
[b]Metric tons = U.S. tons x 0.907
Source: 40 CFR 503

The current 503 regulations require that monitored biosolids must be representative of what is actually going to be used or disposed of. Whenever the biosolids are changed so that their characteristics change, new sampling must take place.

The success of the pretreatment program is illustrated in the reduced concentrations of selected inorganic pollutants in biosolids since the implementation of regulations on non-domestic discharges to sewerage systems. The data for biosolids show significant reductions in some of the regulated inorganic chemicals from the inception of the pretreatment program until the mid-1990s when the concentrations leveled off. For example, data collected in Pennsylvania from 1978 to 1997 showed large decreases in cadmium, copper, lead, mercury, nickel, and zinc, and smaller rates of decreases for arsenic, selenium, and molybdenum (Stehouwer et al. 2000). Wisconsin and New Jersey have extensive biosolids monitoring data, and will be used for illustrative purposes. Tables 2-23 and 2-24 show pollutant concentrations over time. The numbers presented are state averages. The Wisconsin data include any outlier data, and nondetects are considered at the detection limit. Data from Portland, Oregon (Portland 2002), Seattle metropolitan area (King County 2000), and Milwaukee metropolitan area (MMSD 2001) depict similar trends.

TABLE 2-23 Wisconsin Data (all values are in mg/kg dry weight)

Element	1979	1982	1985	1988	1991	1994	1997	2000
As	17.4	6.5	6.0	8.4	9.1	7.4	9.8	11.2
Cd	23.7	18.8	28.8	17.7	11.2	7.2	6.3	6.0
Cr	1053	699	777	363	247	117	73	89
Cu	821	792	873	702	586	573	575	540
Pb	326	310	248	182	130	95	77	63
Hg	3.4	5.2	8.2	4.2	3.9	3.8	2.6	3.4
Mo					36	22	21	20
Ni	131	130	92	83	52	41	43	36
Se					4.5	5.5	8.6	10.9
Zn	1881	2045	1631	1360	1054	921	892	847

Source: WDNR, unpublished data, 2001

TABLE 2-24 New Jersey Data (all values are in mg/kg dry weight)

Element	1981-1983	1989-1994	1997
As	2.7	2.85	4.33
Cd	9.4	5.6	3.5
Cr	93	39	26
Cu	825	679	628
Pb	210	100	65
Hg	3.6	2.3	1.9
Mo		15	13
Ni	46	31	23
Se		2.0	4.9
Zn	1110	826	810

Source: New Jersey Department of Environmental Protection, unpublished data, 2001

In addition to the regulated pollutants within EPA's biosolids program, the pretreatment program is charged with controlling the 126 "priority pollutants," as well as any other incompatible pollutants from industries that discharge into the sewer systems, as described in the Clean Water Act (EPA 1999a). There are four criteria under the pretreatment program as described earlier. These criteria are directed towards ensuring compliance with permits. Selected contaminants in their wastewater are monitored by industries to which the pretreatment program or local ordinance limits apply and also in the effluent discharge of the POTWs covered by the pretreatment program. Toxic organic chemicals discharged to a POTW may be volatilized, degraded, deposited in the sewage sludge or passed through to the effluent. Monitoring of the wastewater effluent may be required for the 126 priority pollutants, but there is no federal requirement to test sewage sludge for them, nor federal limits on most of their concentration in biosolids. One issue with monitoring for these constituents is that on the rare occasion that one or more of them are detected, there are no established criteria levels of concern for many of them. Reliable data on the impact of pretreatment programs on the concentration of toxic organic chemicals in biosolids are not currently available.

PCBs were considered a group of related organic compounds in the initial development of the 503 regulations but ultimately were not regulated because their production had already been banned in the United States. However, 12 coplanar PCBs are still under consideration for regulation in Part 503. A 2000 survey of 50 biosolids samples in Wisconsin found detected concentrations of total PCBs in 40% of the samples when the analysis was performed on an aroclor basis (Wisconsin DNR, unpublished material 2000). A further analysis of a subset of the 50 samples (samples with detectable aroclors, six with nondetectable aroclor samples, and one

resample) on a congener-specific basis found detectable concentrations in 100% of the samples. A similar 2001 EPA survey of 101 biosolids samples from across the nation also found detectable concentrations of coplanar PCBs (EPA 2002a). The total PCB concentration mean in the Wisconsin survey was 0.23 mg/kg for the aroclor analyses and 0.3 mg/kg for the congener-specific analyses. Current regulations in 40 CFR 761 state that land-applied biosolids with concentrations of total PCBs at less than 50 mg/kg are regulated under 40 CFR 503, and sewage sludge with concentrations greater than 50 mg/kg cannot be land applied and are subject to provisions within that regulation (EPA 1998). Furthermore, 40 CFR 257 requires industrial sludge with concentrations of total PCBs at greater than 10 mg/kg to be injected or incorporated when land applied.

EPA's stated purpose in their sampling survey of 2001 was to determine toxicity equivalent concentrations (TEQs) for the 29 congeners of dioxins, furans, and coplanar PCBs which they proposed to add to 40 CFR 503. The mean TEQ value for total dioxin and dioxin-like compounds was 31.60 nanograms per kilogram (ng/kg) DM, when non-detect measurements were summed at one-half the detection limit (EPA 2002a). AMSA also conducted a survey of member and nonmember facilities in late 2000 (Alvarado et al. 2001). A total of 197 biosolids samples were collected from 170 facilities and mean and median TEQ concentrations of 48.5 and 21.7 ng/kg were reported, respectively. The TEQ values ranged from 7.1 to 256 ng/kg with a single outlier of 3,590 ng/kg. Notably, these TEQ concentrations are lower than those reported in a similar survey conducted in 1994 (Green et al. 1995). This finding may be due to fewer medical-waste incinerators in operation and other reduced combustion sources of dioxin but may in large part be explained by improved analytical techniques. In all three surveys, nondetectable congeners were summed at one-half the detection concentration. As detection concentrations continue to decrease, so too do the added values of nondetections.

The State of Vermont recently reported the results of a survey of the 17 dioxin and furan congeners (but excluded coplanar PCBs) in a sampling of 20 POTWs and 3 comingling EQ generating facilities (Kelley 2000). A total of 28 samples were collected in November and December 1996 and in August 1998. The mean and median TEQ concentrations were 11.22 and 8.55 ppt, respectively, and the range was from 1.32 to 59.44 ppt. One important difference in the Vermont survey data compared with the EPA and AMSA data is that nondetectable congeners were summed as zero rather than one-half the detection limit.

COMPLIANCE ASSISTANCE AND ENFORCEMENT

Perhaps the most common and vocal complaint of EPA's biosolids program is the lack of federal presence to ensure compliance with the existing regulations. In the absence of that assurance, and as the report of the Office of the Inspector General (OIG) concluded (EPA 2000b), EPA cannot claim that the regulations are followed and that public health and the environment are protected as required by the CWA. States do, however, implement their own biosolids programs to some greater or lesser extent and actively participate in both compliance assistance and enforcement.

State regulators report substantial compliance is prevalent when assessed. EPA's Office of Enforcement and Compliance Assistance has taken a formal position that biosolids are a low public-health and environmental priority, and thus no formal program policy in place. However, according to EPA, all 10 regional offices will take appropriate action as required if a case is

brought to their attention (D. Regas, EPA, personal communication to OIG, June 11, 2001). Although some EPA regions are more aggressive and involved than others, little enforcement action is taken at the federal level. Furthermore, enforcement strategies differ between states and EPA; states tend to favor stepped enforcement that focuses on compliance assistance and education, and EPA is likely to levy monetary penalties with less discussion.

EPA recently established an incident-response team to address and investigate critical allegations of sewage sludge and biosolids violations and public-health threats, as part of the Biosolids Program Implementation Team. A problem this team has faced is that they are not notified of situations in a timely manner. There is currently no process for registration or follow-up on complaints and alleged violations. An administrative framework is necessary to track such allegations, investigations, and outcomes.

FINDINGS AND RECOMMENDATIONS

EPA provides insufficient support and oversight to the biosolids program. EPA gives low priority to its biosolids program, because it contends that risks from exposure to chemicals and pathogens in biosolids are low and that land-application programs generally function as intended and in compliance with the regulations. This contention should be better substantiated.

Recommendations

- *EPA should strengthen its biosolids-oversight program by increasing the amount of funding and staff (technical and administrative) devoted to it.*
- *EPA should provide additional funds (not diverted funds) to states to implement biosolids programs and facilitate delegation of authority to states to administer the federal biosolids regulations.*
- *Resources are also needed for conducting research into emerging issues and to revise the regulations as appropriate and in a timely fashion (e.g., molybdenum standards should be proposed).*
- *A process should be established to track allegations and sentinel events (compliance, management, or health based), investigations, and conclusions. Such tracking should be systematic, developed in cooperation with states, and document both positive and negative outcomes.*

The Pathogen Equivalency Committee (PEC) performs invaluable technical support and process assessment.

Recommendations

- *The PEC should be funded, supported, and officially sanctioned as an integral part of the federal biosolids program. The following are important in supporting the PEC:*
- *The PEC members should have a formal portion of their time allocated to PEC responsibilities.*
- *Travel funds should be put at the disposal of the PEC to enable meeting attendance and visits to selected sites of petitioners.*
- *There is a perception on the part of PEC members that EPA's Cincinnati laboratories*

do not include biosolids as a formal part of their mission statement. This needs to be clarified and rectified.

- *A formal procedure for designation of backup members should be devised.*

Biosolids risk-management practices are an integral component of the risk assessment and technological criteria that were used to establish the standards of the Part 503 rule. They are therefore an important component of the regulations for chemicals and pathogens.

Recommendations

- *Studies should be conducted to determine whether the management practices specified in the Part 503 rule (e.g., 10-meter setback from waters) achieve their intended effect.*
- *Additional risk-management practices should be considered in future revisions to the Part 503 rule, including setbacks from residences or businesses, setbacks from private and public-water supply wells, slope restrictions, soil permeability and depth to groundwater or bedrock, and reexamination of whether a greater setback distance to surface water is warranted.*
- *Provisions for allowing distribution Class A biosolids in bags or other containers (weighing less than 1 metric ton) should not be allowed when they do not meet pollutant concentration limits (i.e., all biosolids sold or given away should be EQ).*
- *Exemptions from nutrient management and site restrictions for land application of bulk EQ biosolids should be eliminated.*

There are several prescribed treatment processes that can be used to meet regulatory requirements for classifying biosolids as Class A or Class B. However, the efficacy of the treatment processes need verification, and the stabilization regulations need to be refined for consistent control of vector attraction.

Recommendations

- *EPA should conduct national field and laboratory surveys to verify that Class A and Class B treatment processes perform as assumed by their engineering and design principles. Determinations should be made of pathogen density and elimination across the various accepted treatment processes and in the biosolids or environmental media over time.*
- *Standard treatment design criteria should be adopted nationally to ensure compliance with existing biosolids regulations.*
- *Stabilization controls need to be further refined and directly correlated to metabolic Techniques (e.g., SOUR test, carbon dioxide metabolic release, methane metabolic release).*

The available methods for detecting and quantifying pathogens in biosolids have not been validated. There have been a number of advances in detection and quantification of pathogens in the environment and in approaches to environmental sample collection and processing. However, no consensus standards have been developed for pathogen measurements in biosolids.

Recommendation

EPA should support development, standardization, and validation of detection and quantification methods for pathogens and indicator organisms regulated under the Part 503 rule. The sufficiency of these methods and their results should be considered in conducting and

interpreting future risk assessments and used to develop applicable risk-management technologies.

The CWA requires EPA to establish biosolids regulations based on risk; however, it is important to acknowledge and consider other approaches to regulating land application of biosolids.

Recommendation

As part of the process of revising the Part 503 rule, EPA should review biosolids protocols used by other nations. This could provide valuable new perspectives and insights into the scientific, technical, and societal bases for the development and implementation of biosolids regulations.

EPA and the U.S. Department of Agriculture co-sponsored a workshop on emerging pathogens in June 2001 with international experts in the field. The committee supports the major research recommendations from that workshop (listed below).

Recommendations

Research is needed on the following topics:

- *Pathogen survival in processing or emissions during the treatment process.*
- *Vectors carrying pathogens and toxins.*
- *Bioaerosols and other chemical aerosols.*
- *Test-method development and validation for various organisms in sewage sludge and biosolids.*
- *Field verification of efficacy of Class A and Class B treatment processes (including data to directly relate process controls to initial and final pathogen and indicator densities).*
- *Development of indicator pathogens for assessment of impact and attenuation in field situations.*

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3

Epidemiological Evidence of Health Effects Associated with Biosolids Production and Application

This chapter reviews the epidemiological literature concerning workers and community residents potentially exposed to biosolids in their production and application. This literature is valuable for four reasons: (1) It may provide documentation of human-health consequences of exposure to biosolids under the circumstances of their production, application, and use; (2) it may provide information on routes of exposure, such as airborne transmission or ingestion; (3) it may provide information on a dose-response relationship; and (4) it may identify gaps in the literature. Recognition of gaps is essential to distinguish between no evidence of effect and evidence of no effect. Finally, even though all prediction is based on logical extension from available information, an epidemiological review can provide an assessment of the strength of the knowledge foundation from which predictions are made.

The committee was apprised of various human-health allegations associated with biosolids exposure from news articles, written submissions from the public, and citizens who attended its public meetings. It was beyond the committee's charge to investigate or verify these allegations. Thus, the committee limited review to studies published in the peer-reviewed literature and reports from government agencies. The review included studies that investigated health effects or provided biomonitoring data (evidence of biological absorption, i.e., chemical absorption into the body) and excluded studies limited to human exposure without evidence of biological absorption or human health effects. Although the committee was asked to focus on public health, the review includes epidemiological studies involving production and application of biosolids by workers, in addition to assessments of health effects in community residents. The rationale for inclusion of information on worker exposure is that occupational exposure, which for many toxicants is usually higher in exposed workers than in residents exposed from the general environment, often provides a substantial basis for extrapolating risk assessment from higher occupational concentrations to lower environmental concentrations.

The committee also considered potential risks from odors and disease vectors, but did not find any epidemiological studies of these types of risks related to biosolids. Odors and disease vectors have often been categorized as nuisance or aesthetic issues, but odors can have adverse physiological and psychological effects (see Chapter 5) and vectors can transmit disease (see Chapter 6). These are issues that need careful consideration, as there appears to be a fine line between when odors or disease vectors are merely nuisance issues and when they are health issues.

DESCRIPTION OF THE LITERATURE

The committee evaluated 23 studies relevant to the assessment of human health effects associated with biosolids exposure and divided them into six major focus populations: (1) biosolids users (e.g., farmers and home gardeners), (2) populations near agricultural application

sites, (3) workers involved in biosolids production and application, (4) populations near sewage treatment plants, (5) workers in sewage treatment plants, and (6) compost workers. Few epidemiological studies were conducted specifically for biosolids exposure. There are substantially more studies of workers in sewage treatment plants and populations living near them. Although those studies do not involve exposure to biosolids per se, they were included because they provide valuable information about hazards to sewer workers and others exposed to raw sewage that could be used to identify potential hazards from biosolids. However, an exhaustive review of the literature on exposures from sewage treatment plants was not conducted.

Table 3-1 provides the details of the studies that the committee evaluated. A summary of the populations studied, the observed outcomes, and the committee's assessment is provided below.

Exposed Populations

- **Biosolids users.** One study documents chemical exposure from avocational gardening use of biosolids (Baker et al. 1980). This single investigation, conducted before current regulatory requirements for biosolids were initiated, demonstrates the possibility of chemical contamination from biosolids. No other studies of farm or nonfarm biosolids users were found.
- **Populations near agricultural application sites.** One study of a population near a biosolids land-application site was found (Dorn et al. 1985). That study reported no differences in symptoms or serological conversion between farm residents living near the application site and a comparison group.
- **Workers in biosolids production and/or application industry.** One study by the National Institute for Occupational Safety and Health (NIOSH) reported a history of gastrointestinal illness in workers handling Class B biosolids (Burton and Trout 1999). Environmental assessment found potential worker exposure to enteric bacteria. After the study was issued, Lodor (2001) reported that the biosolids to which the workers were exposed did not meet Class B requirements. NIOSH (2002) subsequently released a guidance document for controlling potential risks to workers exposed to Class B biosolids, that supercedes its earlier Hazard ID document on Class B biosolids.
- **Populations near sewage treatment plants.** The committee evaluated four studies of populations living near sewage treatment plants. These studies cover a wide spectrum of outcomes and exposures and include one to a few studies of any particular area. Increases in gastrointestinal and respiratory illnesses (Fannin et al. 1980), an increase in diarrhea (Camann et al. 1980), and decrease in school absenteeism (Camann et al. 1980) were reported. However, these studies are not sufficient to evaluate the safety of populations near sewage treatment plants.
- **Sewage treatment plant workers.** Fourteen studies of sewage treatment plant workers were evaluated. These studies reported both increases (Brugha et al. 1998; Weldon et al. 2000) and no increases (Trout et al. 2000) in hepatitis A infection; increased complaints of nasal irritation, tiredness, and diarrhea, which were considered compatible with exposure to endotoxin (Rylander et al.1977); increased prevalence of gastroenteritis (Khuder et al. 1998); a confirmed outbreak of Pontiac fever (Gregersen et al. 1999); evidence of pesticide absorption

TABLE 3-1 Summary of Human Health Studies on Biosolids and Biosolids-related Exposures

Study type	End points evaluated	Findings	References
Biosolids Users			
Cross-sectional	Evaluation of PCB exposure and health effects in (1) biosolids users (n = 89) in Bloomington, Indiana, exposed to biosolids directly from application to gardens or indirectly from foods grown in biosolids-amended soils; (2) workers occupationally exposed to PCBs (n = 18, only 1 exposed via biosolids); (3) family members of workers occupational exposed to biosolids (n = 19), and (4) individuals with no known exposure to PCBs (n = 22). (PCBs were discharged into the municipal sewage system by a electrical capacitor manufacturing plant.)	Mean serum concentrations of PCBs were 17.4 ppb in biosolids users; 75.1 ppb in PCB-exposed workers; 33.6 ppb in worker family members; and 24.4 ppb in nonexposed individuals. For biosolids users, PCB serum concentrations were associated positively with the percentage of garden care ($p = 0.035$) and negatively with wearing gloves while gardening ($p = 0.021$) but were not significantly associated with the amount of biosolids used or the duration of exposure. No overt symptoms of PCB toxicity were observed, and no correlations were found between PCB exposure and tests of hematological, hepatic, or renal function. Plasma triglyceride concentrations were found to increase with serum PCB concentrations, suggesting that PCBs might alter lipid metabolism.	Baker et al. 1980
Populations Near Agricultural Application Sites			
Prospective	Three-year health survey of farm residents (n = 164) and domestic animals at farm application sites in Ohio. Residents also underwent tuberculin and serological testing. Results were compared with residents of farms that do not apply biosolids (n = 130).	No significant differences in the following parameters were found between residents at land-application sites and control sites: respiratory illness, gastrointestinal illness, or general symptoms; disease occurrence in domestic animals; and serological conversions to 23 viruses and the frequency of associated illnesses. No conversions from positive to negative tine test results were found after sewage sludge application.	Dorn et al. 1985
Workers in Biosolids Production and/or Application Industry			
Cross-sectional	Interviews with employees (n = 5) loading, unloading, and applying Class B biosolids and environmental monitoring, including breathing-zone air samples for bacteria, endotoxins, VOCs, and trace metals.	History of gastrointestinal illness among workers. Enteric bacteria were detected in the air and bulk samples. Endotoxin levels at or below levels found in wastewater treatment facilities. Various metals and VOCs were low. After this study was issued, it was reported that the biosolids to which the workers were exposed did not meet Class B requirements.	Burton and Trout 1999; Lodor 2001

Table 3-1 Continued

Study type	End points evaluated	Findings	References
Populations Near Sewage Treatment Plants			
Retrospective	Acute illnesses and symptoms reported between 1965 and 1971 by community in Tecumseh, MI (n = 4,889). Community was divided into concentric rings radiating out in multiples of 600 m from an activated sewage sludge treatment plant.	Greater than expected occurrence of respiratory and gastrointestinal illnesses in community living within 600 m of the plant. Limitations in interpreting the results were identified by the investigators as confounding by a demographically heterogeneous population (low socioeconomic population), lack of exposure and meteorological data, and relatively low volume of the exposure source.	Fannin et al. 1980; Jakubowski 1986
Retrospective	Monitoring of microorganisms in the air upwind and downwind of a plant in Tigard, OR, and comparison of absenteeism rates in a nearby school before and after the plant opened.	Absenteeism at the school decreased during the 2 yr after the plant began operations compared with attendance data collected over 7 yr before the plant opened.	Camann et al. 1980; Jakubowski 1986
Prospective	Health survey of community (n = 4,300) in Schaumburg, IL, between 1974 and 1976, which covered a period before and after an activated sewage sludge treatment plant was operational. Serological tests and isolation of pathogens from clinical specimens were also performed on a subset of the community (n = 226).	Significant ($p < 0.01$) increases were found in the reported incidence of skin disease, chest pain, diarrhea, weakness, nausea, and vomiting in the population living within 2 m of the plant. Diarrhea was the only symptom for which there were uniform reports throughout the reporting period, increasing from 4.1% before the plant opened to 7.6% after the plant opened. There were no increases in the isolation of *Pseudomonas*, *Salmonella*, or parasites in fecal samples after the plant opened, and a significant decrease in *Proteus* isolations were observed during the operational period. Increases in *Streptococcus* and *Staphylococcus* isolates in throat swabs were observed after plant opening, but regression analyses found no relationship with exposure to the plant. Similarly, there were increases in virus isolates in fecal samples during the operational period, but those increases were not found to be related to the plant. Antibody tests for enteric viruses found no evidence of increased exposure from the plant, and aerosol monitoring results indicated that levels of microorganisms in the air in the residential areas in the vicinity of the plant were similar to background concentrations.	Johnson et al. 1980; Jakubowski 1986

Table 3-1 Continued

Study type	End points evaluated	Findings	References
Prospective	Eight-month health survey of a population (n = 2,378) living in the vicinity of a plant in Skokie, IL. Analyses of blood, throat, and fecal specimens were tested in subsets of the population. Microbial aerosol monitoring and meteorological data were also collected.	Regression analyses performed between total particle exposure indices and self-reported illness rates, pathogenic bacteria isolation rates, prevalence rates of virus antibody, and virus antibody titers were negative. Regression analyses were also negative when illness rates and exposure indices were run with reference to length of residence, age, smoking, presence of young children, chronic respiratory disease, and chronic gastrointestinal illness.	Northrop et al. 1980; Jakubowski 1986
Sewage Treatment Plant Workers			
Cross-sectional	Health survey of workers at a sewage treatment plant in Toronto, Canada (n = 50). Lung function tests and analyses of PCBs in blood samples were also conducted. (The plant received controlled discharges of PCBs from an electrical manufacturing company.)	The most common symptoms reported by workers included cough, sputum production, wheezing, sore throat, and skin complaints. Workers tended to have slightly reduced lung function. Serum concentrations of PCBs could not be related to symptoms or clinical findings.	Nethercott and Holness 1988
Cross-sectional	A saliva test was used to detect antibodies to hepatitis A virus (anti-HAV) in workers at wastewater plants serving Columbus, OH (n = 163). Results were compared with those from workers not exposed to wastewater (n = 139).	Forty-two wastewater workers and 17 control workers tested positively for anti-HAV. After controlling for confounding effects of age and race, no association was found between wastewater work and an increased prevalence of anti-HAV (prevalence ratio = 1.3; 95% confidence interval 0.7 to 2.4). In an evaluation of wastewater workers alone, no statistically significant occupational risk factors for anti-HAV was found.	Trout et al. 2000
Cross-sectional	Workers (n = 34) from eight sewage treatment plants in Sweden completed health questionnaires and underwent spirometry and airway tests. Results were compared with those of nonsewage workers (n = 35).	Reports of nasal irritation, tiredness, and diarrhea were significantly higher in sewage workers compared with controls. Airway responsiveness was increased among sewage workers, but there were no differences in spirometry results. The authors suggested that the symptoms were likely caused by endotoxin, which was detected between 3.8 and 32,170 ng/m^3.	Rylander 1999

Table 3-1 Continued

Study type	End points evaluated	Findings	References
Cross-sectional	Workers (n = 189) from 16 sewage treatment plants in New York were surveyed for working habits, life style, and symptoms of illness. Results were compared with workers at a water treatment plant (n = 82).	The frequency of headache, dizziness, sore throat, skin irritation, and diarrhea was significantly higher among the sewage workers.	Scarlett-Kranz et al. 1987
Cross-sectional	Patients (n = 5) repairing a decanter for sewage sludge concentration developed illnesses consistent with Pontiac fever.	Serological confirmation of Pontiac fever in all five workers and recovery of *Legionella pneumophila* from sewage sludge.	Gregersen et al. 1999
Cross-sectional	Wastewater workers (n = 359) and drinking-water workers (n = 89) were examined for anti-HAV.	Anti-HAV was detected in 28.4% of wastewater workers and in 23.6% of drinking-water workers. After adjustment for age and other variables, the odds ratio for anti-HAV was 2 (CI: 1-3.8). Additional risk factors included years in industry, never wearing face protection, and skin contact.	Weldon et al. 2000
Cross-sectional	Study of employees in water and sewage company (n = 241).	Exposure to raw sewage was a risk factor for HAV infection (odds ratio 3.7 (CI: 1.5-9.4); 60% of workers reporting exposure to raw sewage had HAV infection.	Brugha et al. 1998
Cross-sectional	Urine assay for pesticide among wastewater treatment workers processing effluent from pesticide plant and among comparison workers in water system.	69% of exposed workers exceeded urine cut-off value compared with 10% in comparison plant. Shift changes were consistent with occupational exposure.	Elia et al. 1983
Cross-sectional	Examination of sewage treatment plant workers (n = 145) after hexachlorocyclopentadiene was dumped into a municipal sewage system.	Examination of 41 employees showed proteinuria and increased serum lactic dehydogenase levels 3 d after the plant was closed. These findings were not found 3 wk later.	Morse et al. 1979
Prospective	Twelve-month study of infection rates in experienced and inexperienced workers (n = 336) exposed to wastewater and nonexposed workers in Cincinnati, Chicago, and Memphis.	No significant differences were found in illness rates by worker category or city, in virus or bacterial isolation rates, or in serological analyses. Higher rates of gastrointestinal illness were reported by inexperienced workers but could not be related to a specific agent or exposure.	Clark et al. 1980; Jakubowski 1986
	Serological analysis for rotavirus, Norwalk agent, and *Prototheca wickerhamii* from serum archived from the worker population above.	No association between wastewater exposure and antibodies to either rotavirus or *Prototheca*. Inexperienced workers had higher levels of antibodies to Norwalk agent.	

Table 3-1 Continued

Study type	End points evaluated	Findings	References
	Evaluation of 815 death certificates from former wastewater workers in Chicago.	Deaths from leukemia ($p = 0.04$) and pneumonia ($p = 0.02$) were greater than expected.	
Cross-sectional	Comparison of protozoan parasitic infection among sewer workers (n = 126) in France compared with 363 food handlers (n = 363).	Rates of infection were higher among sewer workers for all 6 yr. Foreign travel was considered but no other possible differences were found among exposed and comparison groups.	Schlosser et al. 1999
Retrospective	Historical cohort study of wastewater treatment workers (n = 242) and comparison group of college maintenance workers (n = 54) followed for 12 mo.	Significantly higher prevalence of gastroenteritis and gastrointestinal symptoms ($p < 0.05$) and headaches ($p < 0.05$) but not respiratory symptoms. No difference was found between high and low exposure categories.	Khuder et al. 1998
Cross-sectional	Health survey and clinical tests of workers at six sewage treatment plants (n = 199) in Sweden compared with control workers at a drinking water plant (n = 41).	Reports of skin disorders, diarrhea, and other gastrointestinal symptoms were significantly greater among the sewage-treatment workers. No differences were found in white-blood-cell count or serum Ig concentrations between the groups, except for slightly increased IgM concentrations among sewage workers. The most likely cause of symptoms was toxins from gram-negative bacteria.	Lundholm and Rylander 1983
Cross-sectional	Workers in sewage treatment plant (n = 30) compared with age-matched blood donors.	Environmental measurement of dust and airborne bacteria conducted. Elevations in IgA, thrombocytes, leukocytes, endotoxin antibodies, c-reactive proteins considered consistent with endotoxin exposure.	Rylander et al. 1977
Compost Workers			
Cross-sectional	Heath complaints and diseases of compost workers (n = 58) in Hamburg, Germany compared with control subjects (n = 40).	Significantly more symptoms and diseases of the airways ($p = 0.003$) and skin ($p = 0.02$) were reported by compost workers than controls. Antibody concentrations to fungi and actinomycetes were significantly increased in compost workers.	Bünger et al. 2000

Table 3-1 Continued

Study type	End points evaluated	Findings	References
Prospective	Infection rates among compost workers in Camden, NJ, Philadelphia, PA, Beltsville, MD, and Washington, DC, with high exposure (n = 98) and intermediate exposure (n = 157) and workers not involved in composting (n = 133). Study period was between 1979 and 1981.	Eye and skin irritation was reported more frequently among compost-exposed groups. *Aspergillus fumigatus* was detected in nasal and throat swabs (70% in high-exposure group, 20% in intermediate-exposure group, and 5% in low-exposure group), but there was no consistent increase in antibodies to the fungal spores. There were no differences in levels of antibodies to *Legionella pneumophila* between exposure groups, and no antibodies to *Histoplasma capsulatum* were detected. Compost workers had greater IgG antibody levels against compost-derived endotoxin, elevated C3 and hemolytic complement levels, and higher white-blood-cell and eosinophilic counts. In pulmonary function tests, vital forced capacity was greater at the end of the week than at the beginning of the week for compost workers.	Clark et al. 1984

Abbreviations: CI, confidence interval; PCBs, polychlorinated biphenyls; VOCs, volatile organic compounds; ppb, parts per billion; m, meter; ng, nanogram; HAV, hepatitis A virus; Ig, immunoglobulin.

(Elia et al. 1983); no differences in illnesses rates, nor isolation of virus or bacteria (Clark et al. 1984); increased rates of protozoan infection (Scholsser et al. 1999); increased rates of reports of skin disorders, diarrhea, and gastrointestinal symptoms (Lundholm and Rylander 1983). These studies are sufficient to suggest transmission of specific infectious diseases to sewage treatment plant workers (e.g., Pontiac Fever). However, no firm conclusions can be drawn at this time.

- **Compost workers.** Studies of compost workers have reported significant increases in diseases of the airways and skin and evidence of increased exposure to fungi and actinomycetes (Bünger et al. 2000) and eye and skin irritation and fungal colonization but no serological evidence of infection (Clark et al. 1984). These two studies provide suggestive evidence of colonization of compost workers with fungi.

Observed Health Outcomes

- **Toxic exposures.** Two studies (Baker et al. 1980; Morse et al. 1979) documented the potential for industrial chemicals to be present in wastewater. Sewage workers can be exposed, as can those who use biosolids for agriculture or other land-application purposes. Morse et al. (1979) investigated occupational exposure resulting from a one-time contamination of the wastewater, and Baker et al. (1980) studied occupational and residential exposure resulting from an ongoing contamination of wastewater. These two studies demonstrate that workers and community residents can be exposed to chemical hazards that enter into the municipal waste stream.

The epidemiological literature on exposure to toxic substances in biosolids provides no information by which to gauge two issues. The first issue concerns the adequacy of routine monitoring of wastewater in order to capture common toxicants and toxicants that might be idiosyncratic to the industrial processes in a particular locale. Although wastewater is periodically examined for chemical contamination, the number of chemicals sought is much less compared with the number of chemicals used commercially. Second, the periodicity of testing and the periodicity of discharge will determine the probability of identification of a hazardous chemical in a sample of effluent.

- **Viral infection.** The potential for viral infection of wastewater workers was documented in several studies (Brugha et al. 1998; Weldon et al. 2000) and not in others (Clark et al. 1980; Northrop et al. 1980). One study documented the absence of serological evidence of viral infection among populations near application sites (Dorn et al. 1985). No study examined viral infection among workers in biosolids production or application sites.

The epidemiological literature provides no evidence for or against the potential for biosolids to serve as a vehicle for viral infection. The probability that biosolids are a potential vector for infection might be revealed by other lines of research, such as environmental viral studies.

- **Bacterial and protozoan infection.** Some studies have documented complaints of gastrointestinal illness related to sewage sludge (Fannin et al. 1980; Johnson et al. 1980; Burton and Trout 1999) and others have not (Dorn et al. 1985). Similarly, some studies have detected enteric bacteria in air and bulk samples (Burton and Trout 1999), and others have not (Johnson et al. 1980). One study found evidence of protozoan infection among sewer workers (Schlosser et al. 1999).

For bacterial and protozoan infection, there is neither evidence of infection nor evidence of no infection. Evidence of viable organisms in biosolids would strengthen the biological plausibility of a causal association, as would demonstration of the potential for exposure during specific aspects of production and application of biosolids.

- **Irritation and allergic reaction.** Several studies reported allergy or irritation among sewer workers (Rylander 1999) and workers in compost production (Clark et al. 1984; Bünger et al. 2000). The role of endotoxin in these observations is strengthened by demonstration of endotoxin content of biosolids but is weakened by lack of evidence showing a relationship between level of exposure and effect.

Assessment of Causality

Assessment of causality requires judgment of epidemiological and other information. Conclusions that an association is causal rest on demonstration of such factors as consistency of findings in independent studies, strength of association, temporal sequence, and biological plausibility (demonstration of dose-response relationships) (Bradford-Hill 1966). There is a small body of epidemiological literature on the potential adverse health effects of biosolids. The literature is even more sparse considering the varying populations that are potentially exposed to biosolids, including wastewater treatment, biosolids production, occupational exposure during application, and community exposure.

For some exposures, such as chemical exposure, it is fairly clear that chemical contamination of sewage with industrial chemicals can result in product contamination leading to exposure of workers and community residents. It is unclear whether the system for preventing chemical contamination of sewage and monitoring sewage is sufficient to ensure protection from chemical exposures.

Although there is evidence of infection of sewage workers, it is unclear, based on design criteria for production of biosolids or based on sampling for detection of viable organisms, whether viral, bacterial, or protozoal infection of workers or community residents exposed to biosolids is plausible. There is a relative absence of evidence documenting infection, and limited evidence documenting the lack of infection from biosolids. A similar assessment can be made for the evidence of a causal relationship of symptoms of irritation and allergy and exposure to endotoxins.

Some have contended that there is evidence of lack of health hazard from occupational exposure in wastewater treatment plants and that by extrapolation risk from biosolids must be negligible. This reasoning is problematic for several reasons. First, as described earlier in this chapter, the knowledge base regarding wastewater treatment workers is thin and contradictory. Secondly, the exposure characteristics will be quite different in the wastewater treatment industry compared with biosolids land-application. For example, potential exposure to airborne contaminants from wet sewage sludge is quite different from those from dried biosolids. Thirdly, the routes of exposure may be different between populations exposed to raw sewage sludge compared with those exposed to biosolids. Fourthly, the populations exposed to biosolids may not be equivalent to the occupational population exposed to sewage sludge. Farm families and community residents will include subpopulations unlikely to be found in the workplace, such as children and individuals with respiratory diseases. Thus, lack of compelling evidence of

adverse health effects among wastewater treatment workers should not be used to infer that there will be a lack of adverse health effects from exposure to biosolids.

There are two types of health studies that will reduce uncertainty regarding health effects of biosolids exposure—response studies and preplanned studies. Response studies are initiated rapidly on notification that there has been either an unusual exposure or occurrence of disease among workers or community residents exposed to biosolids. Such studies are intended to assess and attempt to relate measures of exposure with measures of disease. Response studies should be conducted in a short time frame (weeks to months). Whether response studies are conducted by state or federal agencies or academia on behalf of EPA, a priority setting mechanism must be established so that limited resources are used to maximize the probability that the response studies will effectively contribute to the sparse information on the health consequences of exposure of workers and/or residents to biosolids in their production and manufacture.

Preplanned studies, on the other hand, are conducted to test a specific hypothesis. The hypothesis might be generated by researchers who compete for research funding, or more specific questions may be formed by EPA or other agencies. Preplanned studies must be well designed and conducted to reduce uncertainty concerning issues of importance. For example, a preplanned epidemiological study must be sufficiently large, characterize exposure, include an adequate interval between exposure and observation to allow for occurrence of disease if it were to occur, measure confounders, and be able to delineate adverse outcomes and evidence of their occurrence.

There are two types of preplanned studies—exposure assessment and complete epidemiological studies. In exposure assessment studies, the goal is to define the distribution and determinants of exposure to an agent or chemical of interest. This information may then be used in formal risk assessments.

The second type of preplanned study is the complete epidemiological study. The goal of this study is to assess the association of the occurrence and distribution of disease with measurement of prior exposure (provided through a concurrent or prior exposure assessment). The purpose of preplanned studies is to determine if exposure is related to increased occurrence of disease, or its corollary.

In contrast with response studies, preplanned studies are more expensive because they are larger, require more effort in planning, involve more extensive data analysis, and more effort in assessment of exposure. Consequently, more effort will be expended in setting priorities in preplanned studies. Priorities should include probability of the study reducing uncertainty, seriousness of the disease outcome, incidences of the disease outcome, a priori level of uncertainty, and importance of the results in protecting against adverse health consequences.

It is also important to recognize that worker populations and communities are not homogenous in their susceptibility to disease or subsequent adverse consequences. Thus, in response and preplanned studies, it is important to include all or a sample of the potential susceptible subpopulations. Examples of susceptible subpopulations include children, the elderly, pregnant women, and individuals with chronic disease.

In addition, stakeholders should be involved in review of the design, conduct, and interpretation of studies. Stakeholders may include representatives of workers and management, community representatives, health care providers, and victims of disease.

FINDINGS AND RECOMMENDATIONS

The committee concludes that because of lack of epidemiological study and the need to address the public's concerns about potential adverse health effects, EPA should conduct studies that examine exposure and potential health risks to worker and community populations. Studies of wastewater treatment workers should not be used as substitutes for studies of actual biosolids exposure. While routine human health surveillance of all populations exposed to biosolids is impractical, the committee recommends that EPA promote and support a research effort to reduce uncertainty about the possible health consequences of exposure to biosolids. Stakeholders should be involved in review of the design, conduct, and interpretation of studies. The types of studies the committee recommends include:

Response Studies

- *Studies in response to unusual exposure and unusual occurrence of disease.* On occasion, unplanned events occur that can provide information on the agents of disease. An example might be an outbreak or a symptom of disease following a known exposure or an unusual exposure scenario. In both instances, exposure and health outcomes should be determined.

Preplanned Studies

- *Biosolids exposure-assessment studies.* Such studies should characterize the exposures of workers, such as biosolids appliers and farmers, and the general public who come into contact with constituents of biosolids either directly or indirectly. The studies would require identification of microorganisms and chemicals to be measured, selection of measurement methods for field samples, and collection of adequate samples in appropriate scenarios. A possible exposure-assessment study would be to measure endotoxin exposure of workers at biosolids production and application sites and of communities nearby.
- *Complete epidemiological studies of routine biosolids use.* These studies should be conducted to provide evidence of a causal association, or a lack thereof, between biosolids exposure and adverse human health effects. They should include an assessment of the occurrence of disease and an assessment or measurement of potential exposures. . An example of a longitudinal epidemiological study would be an evaluation of health effects in a cohort of biosolids appliers; these workers should be characterized by duration and level of exposure, with appropriate follow-up.

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4

Advances in Risk Assessment Since the Establishment of the Part 503 Rule

The committee's review of the risk assessment used to support the Part 503 rule was carried out in the context of current and emerging practice in risk assessment. The committee determined that its review of the risk assessment should communicate the committee's interpretation of how the risk-assessment process has evolved from the time the Part 503 rule was issued until present. Of particular interest to the committee were documents from EPA and the National Research Council that propose and encourage methods that differ substantially from the methods used in the 503 risk assessment. This chapter provides a foundation and context for the following chapters.

This chapter first describes new approaches and considerations in risk assessment since the Part 503 rule (Standards for Use or Disposal of Sewage Sludge) was established in 1993 (40 CFR Part 503). It focuses on the changing priorities of cancer versus noncancer end points, acute versus chronic end points, probabilistic risk-assessment approaches, and the need to address aggregate exposures and cumulative risk. A brief description is then given of the changes in risk-assessment approaches of EPA over this period.

THE RISK-ASSESSMENT PROCESS

Risk assessment is a process for identifying potential adverse consequences along with their severity and likelihood. In contrast to other tools used for environmental evaluation and policy, the principal objective of the risk assessment and risk management approach is not to eliminate all risk but to quantify the risk and provide risk managers with tools to balance the level of risk against the cost of risk reduction, against competing risks, or against risks that are generally accepted as trivial or acceptable. Controlling the exposure of human populations to environmental contaminants in biosolids using a risk-based approach requires a definition of both an appropriate metric for assessing the impacts of contaminants on human health and a defensible process for assigning value to the predicted impacts. The end product of a risk-based approach to environmental management is either to identify an acceptable level of exposure or prescribe the technical controls or political process needed to attain acceptable risk. Intervention can be achieved through technical or political controls.

Components of the Risk-Analysis Process

The National Research Council (NRC 1982, 1994) has divided and continues to divide the practice of risk analysis into two substantially different processes—risk assessment and risk management. Along with these processes are concurrent efforts to communicate and evaluate

risk (NRC 1989, 1996). This section explores the evolution of the risk-assessment process over the last decade by considering the component steps in the process.

Risk assessment is the process of selecting and quantifying the adverse consequences that result from an action such as application of biosolids to soils, or from inaction. A risk assessment begins with efforts to identify the potential hazards associated with a chemical or microbial agent and its use or occurrence. Hazard identification addresses the potential for harm but not the likelihood of harm. Risk characterization establishes the significance of an identified hazard by quantifying the likelihood and severity of exposure scenarios linked to that hazard. As applied to toxic agents, risk characterization has five principal elements—(1) quantification of sources and environmental concentrations in exposure media; (2) quantification of exposure to the target population and distribution of the dose among the population; (3) characterization of a dose-response function for all potential toxic agents that have been identified; (4) estimates of the number of people affected and severity of consequences expected within the population at risk; and (5) an assessment of the magnitude and sources of uncertainty that limit the precision of the estimate of consequences.

Risk management is the process of weighing policy alternatives and selecting the appropriate societal or institutional response. Risk management is used to integrate the results of a risk characterization with social, economic, and political valuation to reach a decision. The goal of the risk-management process is to establish the significance of the estimated risk, compare the costs of reducing this risk with the benefits gained, compare the estimated risks with the societal benefits derived from incurring the risk, and carry out the political and institutional process of reducing risk.

Linking the risk-assessment and risk-management processes are the concurrent efforts to evaluate and communicate risk. Risk evaluation is the process by which the risk characterization and risk-management processes are reconciled with individual and societal valuations of risk (NRC 1996). A key step in this link is effective risk communication. According to the NRC (1989), risk communication has become more difficult in recent decades and common misconceptions often hamper communication efforts. In considering these issues, the NRC (1989) emphasizes that solving the problems of risk communication is as much about improving procedures as improving the content of risk messages.

Figure 4-1 provides a view of how the risk-analysis process might proceed for assessing the health impacts of pollutants in biosolids. Each of the major steps in this process involves one or more actions that are listed to the right of each major step.

Confronting Uncertainty and Variability

An important and often ignored final step in the risk characterization process is the characterization of uncertainties. Important sources of uncertainty and variability in risk assessments involve the data and models used. With incomplete data and models used to characterize contaminant transport representing heterogeneous geographic and climate regions, the variability and uncertainty associated with the resulting risk estimates are large.

In evaluations of uncertainty in risk assessment, Morgan et al. (1990) and Finkel (1990) distinguish among parameter uncertainty, model uncertainty, decision-rule uncertainty, and natural variability in any of the parameters and call for separate treatment of the different types of

Figure 4-1

uncertainty. Probabilistic methods such as Monte Carlo analysis are available to evaluate uncertainty in parameters. According to Finkel (1990), model uncertainty derives from a number

of actions, including the use of simplifications that might exclude relevant variables from the analysis; the use of surrogate variables that might not be appropriate for the variable of interest; the appearance of abnormal conditions that might occur in nature but that might not be appropriate in the model; and the use of incorrect model forms. Morgan et al. (1990) noted that relatively little research has been done on uncertainty or disagreement about what form of model to use. Decision-rule uncertainty applies to risk management and arises whenever ambiguity or controversy exists about quantifying or comparing social objectives. According to Finkel (1990, p. 16), "to take any actions using the outputs of a risk assessment, including the decision not to take action, one must be prepared to make a series of potentially controversial value judgments."

An important source of uncertainty in risk characterization is the development and application of dose-response models. Among the many issues that complicate the process of establishing a dose-response function is the variation in human susceptibility. In large heterogeneous populations, there are large variations in susceptibility to toxic effects. Those variations are due in part to variations in genetic predisposition to certain disease states, variations in age, and large variations in physical stresses and other chemical or non-chemical exposures that might be extant in the system of interest.

NEW APPROACHES AND CONSIDERATIONS IN RISK ASSESSMENT

This section reviews new approaches to risk assessment that were developed since the Part 503 rule was issued. A summary of key documents from the NRC, the Presidential/Congressional Commission on Risk Assessment and Risk Management, and EPA are provided. Then, consideration is given to how those documents have altered the standard practice in each of the key steps of the risk-assessment process.

Recent Reports Define New Directions in Risk Assessment

Among the reports that have had particular impact are two reports issued by the NRC. The first report titled *Science and Judgment in Risk Assessment* provided an update on the process of risk assessment and management (NRC 1994). This report made seventy-five specific recommendations, but among its overarching recommendations are those to address explicitly uncertainty and variability in risk assessment, address multimedia exposures and cumulative intake through multiple exposure pathways, and foster more interaction among risk assessors and risk managers. The second report titled *Understanding Risk, Informing Decisions in a Democratic Society* (NRC 1996) used several case studies to evaluate the emerging trends in risk assessment methodology.

The Presidential/Congressional Commission on Risk Assessment and Risk Management was created through the 1990 Clean Air Act amendments to make recommendations for improving the risk-assessment and risk-management process. In 1997, the Commission issued *Framework for Environmental Health Risk Management*. The report emphasizes how to present a risk assessment and how to work with community concerns in an iterative fashion. It identifies a clear need to modify the traditional approaches used to assess and reduce risks. Traditional approaches rely on a chemical-by-chemical, medium-by-medium, risk-by-risk strategy. The report states the need to focus less attention on refining assumption-laden mathematical

estimates of the small risks associated with exposures to specific chemicals and the need to focus instead on the overall goal of reducing risk and improving health status. There is strong emphasis on stakeholder participation. Stakeholders are groups who are potentially affected by the risk, groups who will manage the risk, and groups who will be affected by efforts to manage the source of the risk. Involving stakeholders throughout the risk-assessment process provides opportunities to gather information and to bridge gaps in understanding, language, values, and perspectives.

Over the last decade, EPA issued a number of reports that are having an impact on the framework and process of regulatory risk assessment. Of particular note are the 1992 Habicht memo, which provided guidance to EPA managers on risk characterization (Habicht 1992); a journal report on benchmark dose (Barnes et al. 1995), which provides guidance for a more harmonized approach for addressing cancer and noncancer health end points; and the proposed guidelines for carcinogen risk assessment (EPA 1996a). The Habicht memo emphasized the need to avoid point estimates of risk and to provide instead details on the scientific basis of decisions, including clear statement of assumptions and uncertainties. Barnes et al. (1995) recommend the use of the benchmark-dose approach as an alternative to using the no-observed-adverse-effect level. EPA's proposed guidelines for carcinogen risk assessment put more emphasis on "margin of exposure" (relative to a benchmark dose), weight of evidence, and the use of uncertainty factors in the risk characterization process. Also of note is EPA's (1997a) *Exposure Factors Handbook*, which provides a large compendium of information on human activities that relate to exposure—including time-activity data, exposure duration, consumption of homegrown food, and water ingestion.

In addition, there is an ongoing effort to address aggregate exposures to the same substances from multiple sources and pathways and cumulative exposures and risk from mixtures. The 1996 Food Quality Protection Act (FQPA) explicitly calls for addressing aggregate exposure and cumulative risk in setting standards for pesticide residues in food.

From a risk assessment perspective, this report will clearly establish that biosolids are a complex mixture of chemical and biological agents, the exact composition of which can change from time to time and place to place. Moreover, it will never be possible to account for all the components of the mixture, although its stable components are well characterized. As discussed in detail in various sections of this report, considerable effort has been devoted to an enumeration of the hazardous constituents of biosolids. During the course of its study, the committee found that it remains necessary to conduct risk assessments on biosolids based on their component parts.

Figure 4-2 provides a time line showing when a number of significant risk-guidance documents have been issued relative to the year when the Part 503 rule was issued.

Figure 4-2

Advances in Hazard Identification

Since EPA issued cancer and mutagenicity risk-assessment guidelines in 1986 (EPA 1986a,c), the types and reliability of methods used to identify potential hazard have advanced. In the 1986 guidelines, the stated goal of a hazard assessment was to provide a review of the relevant biological and chemical information on an agent that might pose cancer or other health hazards. At that time, the recommended elements of the hazard identification included (1) a summary of an agent's physical-chemical properties and routes and patterns of exposure; and (2) a review of toxic effects, structure-activity indicators of toxicity, metabolic and pharmacokinetic properties, short-term animal and cell tests, long-term animal tests, and human studies. These elements have remained the core components of hazard identification, but the arsenal of methods, the reliability of techniques, and the relative emphasis on the various hazard identification elements have changed over the past decade. In particular, risk assessors can now make use of better markers of genetic damage (toxicogenomics) for rapid assessment, improved structure-activity relationships (SAR), and improved quantitative structure-activity relationships (QSAR). However, to date, these emerging methods have seen only limited use in regulatory risk assessment. Health-effects research has focused more on early indicators of outcome, making it possible to shorten the time between exposure and observation of an effect. Use of measures of exposure as hazard indicators (e.g., Hertwich et al. 2001) has increased, and more-sophisticated measures of hazard such as the human toxicity potential have been developed. Human toxicity potential includes emissions, exposure potential, and toxic hazard indicators in a single measure of potential harm. It has been used as a cumulative-exposure screening tool for multiple chemical agents.

Public-health and environmental concerns about biosolids foster a need for hazard assessments that can address multiple and complex issues. Among these issues are health hazards from chemical mixtures and pathogens, as well as concerns about specific categories of chemical hazard, such as metals, persistent organic pollutants (POPs), and high-production-volume chemicals (HPVs). Recent advances in hazard assessment provide EPA with better tools for those issues. Community issues are not adequately addressed in the current risk-assessment paradigm (e.g., property intrusions, odor, and truck traffic). Other issues have been addressed in EPA programs but have not been explicitly addressed in the risk-management goals of the biosolids program. Those include potential health effects from added diesel exhaust and potential environmental effects from added nitrogen burdens, runoff, damage to endangered species habitat, and conversion of inorganic mercury to organic mercury in situ and in water bodies following runoff.

Advances in the Dose-Response Characterization Process

A number of important changes have been proposed and, in some cases, applied to dose-response characterization over the last decade. In 1993, the NRC considered the scientific basis, inference assumptions, regulatory uses, and research needs in risk assessment and focused on two dose-response issues—the use of maximum tolerated dose in animal bioassays and the use of two-stage models of carcinogenesis (NRC 1993). The report presented options for revising those default procedures. Recent EPA documents (EPA 1996a, 2001a) proposed that dose-response characterization be handled differently from that proposed in the 1986 risk-assessment guidelines (EPA 1986a). According to the 1986 guidelines, risk for carcinogens is modeled

using potency—the increase of risk per unit increase of dose or exposure. Risk for noncarcinogens is addressed using a hazard index—the ratio of the predicted dose to the reference dose. More recently, efforts have been made to harmonize those two approaches by using a margin of exposure (MOE) to characterize risk for both carcinogens and noncarcinogens. MOE is the ratio of a dose derived from a tumor bioassay, epidemiologic study, or biologic marker study to an actual or projected human exposure.

Changes in Dose-Response Methods

Several proposals within and outside EPA have been made to modify the standard approach for building dose-response models on the basis of animal or human data. The most important and comprehensive proposal is EPA's 1996 proposed revisions to its carcinogen risk-assessment guidelines (EPA 1996a). These guidelines, which are still undergoing review and revision within EPA, propose a different weight-of-evidence classification and the option of using an MOE in place of potency to estimate risk. Risk-assessment literature has provided proposals for the use of time-to-tumor models (Krewski et al. 1983), Bayesian methods for constructing and revising dose-response models (Taylor et al. 1993; Evans et al. 1994; Wilson 2001), and meta-analysis.

EPA's Proposed 1996 Carcinogen Risk-Assessment Guidelines

In 1996, EPA issued its proposed *Guidelines for Carcinogen Risk Assessment* (EPA 1996a) for a 120-day public review and comment period. EPA issued the guidelines as a replacement for the 1986 *Guidelines for Carcinogen Risk Assessment* (EPA 1986a). The revised guidelines were issued in part to address changes in the understanding of the variety of ways in which carcinogens can operate. For example, because many laboratories now use test protocols aimed at mode of action, the 1996 proposed guidelines provide a framework that allows for incorporation of all relevant biological information and flexibility to consider future scientific advances.

In contrast to the single default dose-response relationship (the linearized multistage model for extrapolating risk from upper-bound confidence intervals) used in the 1986 cancer guidelines, the 1996 guidelines provide several options for constructing the dose-response relationship. Biologically based extrapolation, that is extrapolation from animals to humans based on a similar underlying mechanism of action, is the preferred approach for quantifying risk. However, because data for the parameters used in such models are not likely to be available for most chemicals, the 1996 guidelines allow for alternative quantitative methods, including several default approaches. In the default approaches, dose-response assessment is a two-step process. In the first step, response data are modeled in the range of observation; in the second step, a determination is made of the point of departure (benchmark) or the range of extrapolation below the range of observation. In addition to modeling tumor data, the new guidelines call for the use and modeling of other kinds of responses if they are considered measures of carcinogenic risk. Three default approaches—linear, nonlinear, or both—are provided. Curve fitting in the observed range provides the effective dose corresponding to the lower 95% limit on a dose associated with a 10% response (LED_{10}). The LED_{10} is then used as a

point of departure for extrapolation to the origin as the linear default or for an MOE as the nonlinear default. The LED_{10} is the standard point of departure, but other departure points can be used when the data justify it.

Other modifications of interest in the 1996 guidelines include the following:

- Emphasis is placed on all biological information rather than only tumor findings in the hazard-assessment phase of risk assessment.
- Mode of action is emphasized to reduce the uncertainty in describing the likelihood of harm and in determining the dose-response approaches.
- A weight-of-evidence narrative replaces the current alphanumeric classification categories (A, B1, B2, C, D, E) from the 1986 cancer guidelines. The narrative summarizes the key evidence, describes the agent's mode of action, characterizes the conditions of hazard expression, and recommends appropriate dose-response approaches. The overall conclusion on the likelihood of human carcinogenicity is given by route of exposure. Only three descriptors for classifying human carcinogenic potential are now available—known/likely, cannot be determined, and not likely.
- In contrast to the 1986 guidelines that provide very little guidance for risk characterization, the 1996 guidelines provide direction on how the overall conclusion and the confidence of risk are presented for the risk manager and call for assumptions and uncertainties to be clearly explained.

Time-to-Tumor Models

Because dose-response functions for many chemical substances are derived from lifetime animal-feeding studies, results apply to lifetime risk of cancer. The most common dose-response model derived from such toxicological experiments describes the lifetime change in cancer incidence with dose. However, the stage theory of cancer and other diseases emphasizes that many harmful exposures can be more accurately characterized as reducing the time to tumor induction rather than increasing the lifetime risk of tumor (Armitage and Doll 1954). In a time-to-tumor dose-response model, important information is disclosed by the time it takes for a fraction of the test subjects to get tumors (Krewski et al. 1983). Some animal bioassay data indicate when individual bioassay animals died before scheduled terminal sacrifice and whether they died with or without tumors. In some human populations, time to tumor or other disease is also available. Use of time-to-tumor data in the analysis of the tumor dose-response relationship provides a credible estimate of the potency of the carcinogen by incorporating considerable information. These models are not common but have much potential when data are substantial.

Use of Subjective Statistics: Bayesian Methods

Bayesian analysis is an important tool now widely used in many domains, including some parts of risk analysis (Taylor et al. 1993; Evans et al. 1994). It provides the foundation for the technical field of decision analysis. Bayesian approaches have begun to be applied to assessments of exposure for human health and environmental risks. In 2000, Resources for the Future (RFF) in conjunction with EPA and other organizations held a workshop to discuss ways in which Bayesian approaches could be useful in improving techniques for estimating exposure-response functions. Participants in the workshop agreed that wider use of Bayesian approaches can improve human health risk-assessment practices (Wilson 2001). The areas judged to have the most significant opportunities include estimating exposure-response functions; inferring causality, especially when interpreting results of epidemiological studies; and performing complex exposure assessments.

Use of Meta-Analysis in Place of Single-Species Data Sets

In the evaluation of chemical compounds for carcinogenic risk, regulatory agencies have traditionally fit a low-dose linear dose-response model to data from rodent bioassays. Recently, there is much interest in incorporating additional scientific information on the properties of the chemical under investigation into the risk-assessment process, including biological mechanisms of cancer induction. However, few attempts have been made to investigate the overall relationship between the shape of dose-response curves and mutagenicity.

Assessment of Mixtures

In 1986, EPA issued risk-assessment guidelines for chemical mixtures (EPA 1986b). This framework described three approaches to conduct a quantitative risk assessment for the potential health effects associated with exposure to chemical mixtures. First, when data are available on the health impacts of the mixture of concern or similar mixtures, these data should be used in formulating the risk models. When data are not available on the actual mixture or similar mixture of concern, data from risk assessments of individual components are then used to estimate the risk of the mixture of concern by applying a dose-additivity model (second approach) for systemic toxicants and a response-additivity model (third approach) for carcinogens. Both of these models assume that no interaction occurs among chemicals. The two most accepted dose-additivity models are the hazard-index (HI) model and the toxicity-equivalency-factor (TEF) model. The response-additivity model is used primarily in cancer risk assessment of chemical mixtures; it is assumed that the components in the mixture act independently on the same target site but by different mechanisms of action, thus the toxicological responses to each component in the mixture are summed.

A significant advance in chemical-mixture risk assessment was the newly developed interaction-based method in which Mumtaz and Durkin (1992) used binary interaction data to modify the dose-additive HI. Recently, EPA (2000a) issued a revised guidance document for chemical mixtures as a supplement to the original guidelines of 1986. The document *Supplementary Guidance for Conducting Health Risk Assessments for Chemical Mixtures*

provides details on the nature of mixtures and the procedures to use for data analyses. It also describes recent scientific advances in the area of chemical-mixture risk assessment, including methods for using whole-mixture data on a toxicologically similar mixture, methods for incorporating information on toxicological interactions into an HI (modified from the original method developed by Mumtaz and Durkin 1992), procedures for including carcinogen interactions in mixture risk characterization, and generalized procedures for assessing mixtures of similar chemicals.

The incompleteness of the classic risk-assessment process as applied to biosolids can be illustrated by reference to the EPA guidance document (EPA 2000a), which details EPA's current thinking on the mixture issue. A complex mixture is defined as "a mixture containing so many components that any estimation of its toxicity based on its components' toxicities contains too much uncertainty and error to be useful. The chemical composition may vary over time or with different conditions under which the mixture is produced. Complex mixture components may be generated simultaneously as by-products from a single source or process, intentionally produced as a commercial product, or may coexist because of disposal practices. Risk assessments of complex mixtures are preferably based on toxicity and exposure data on the complex mixture" (EPA 2000a). In Chapter 3, it shows that health risk data on the complete mixture is insufficient in the case of biosolids to provide the basis for a risk assessment. Hence, assessors are dependent on a component-based assessment strategy that, while not containing "too much uncertainty and error to be useful," will be incomplete as a basis for defining a strictly prospective strategy for risk management (EPA 2000a).

Advances in the Exposure Characterization Process

There have been a number of important changes in the exposure characterization process over the past decade. Among the changes of note are increasing focus on indoor and residential environments; methods for monitoring biological agents in exposure media (air, water, and soil); a movement away from simple bounding estimates to probabilistic assessments that include explicit treatment of uncertainty and variability; and the use multimedia and multiple-pathway exposure assessments. In the sections below, the committee highlights the changes in exposure assessment methods that have particular relevance to biosolids risk assessments. A review and evaluation of specific exposure pathways in the Part 503 rule risk assessment are provided in Chapter 5.

Ten years ago it was common to conduct an exposure assessment using simple models that define a maximum exposed individual (MEI). The MEI was one who obtained all of his or her air, water, and/or food from an area contaminated by the pollutant of interest over a lifetime. The implicit and unquantified overestimate of exposure in the MEI as well as the failure of the MEI to capture all exposure pathways, led to a search for alternative schemes. At first, there was an effort to define a highly exposed individual (HEI) as someone who had a plausibly high exposure but less exposure than the MEI. However, the HEI was found to have many of the same limitations as the MEI. Current practice is to use a reasonable maximum exposure (RME) receptor. EPA (1989) specifies that calculation of the RME requires a combination of average and upper-bound values for various exposure parameters, so that the final exposure estimate will represent an upper bound exposure that could reasonably be expected to occur. This is commonly interpreted to be a 90^{th} to 95^{th} percentile of exposures for each pathway. Due to its

inconsistent combination of upper percentile and mean values, the RME approach can be arbitrary and fail to fully account for population exposure variability. Nevertheless, the use of RME in place of HEI has fostered the increasing use of probabilistic methods in exposure assessments (EPA 2001b). In its recent assessment of exposures to dioxins in biosolids, EPA partially makes use of a probabilistic risk-assessment approach (EPA 2001c).

Increased Focus on Indoor and Residential Environments

One theme that is clear in the literature on exposure assessment is the importance of the indoor environment and residential factors in understanding human exposure to many agents. Indoor and residential scenarios received little attention in the Part 503 rule risk assessment, but those issues have received much greater attention in risk-assessment practice over the last decade.

Assessments of the human health impact of airborne pollutants revealed the importance of cumulative exposure to microenvironments, such as indoor air, and of household sources, such as consumer products, combustion, appliances, and tracked-in soil. Efforts to better understand urban air pollutants, such as particulate matter, revealed the importance of increased indoor concentrations of certain pollutants (Melia et al. 1978; Dockery and Spengler 1981; Spengler et al. 1983). Subsequent studies, most notably EPA's Total Exposure Assessment Methodology (TEAM) studies, demonstrated that for a variety of contaminants, residential indoor air is often a more significant source of exposure than outdoor air (Pellizzari et al. 1986; Thomas et al. 1993; Wallace 1993).

Methods for Monitoring Biological Agents in Exposure Media

Although the issue of exposure to and risk from pathogens is addressed in Chapter 6, it is of note here that methods available for monitoring exposure to pathogens have improved greatly in the last decade. Traditional detection of microorganisms is performed using microscopy, culture, biochemistry, or immunoassay. Microscopy is used to detect total microbial populations in a given sample without regard to the physiological state of the organism; both viable and nonviable organisms can be detected. Culture-based assay is limited to detection of those organisms that will proliferate under the growth conditions of the analysis design. Biochemical and immunological-based analyses have improved the identification and enumeration of specific microbial contaminants in environmental samples. Improved detection and identification of microorganisms have been achieved using advanced biotechnology-based methodologies, including polymerase chain reaction (PCR) amplification, microchips, molecular beacons, electrochemiluminescence, biosensors, mass spectrometry, and flow cytometry.

Explicit Treatment of Uncertainty and Variability

Estimating potential human exposures and source-to-dose relationships for harmful substances in biosolids involves the use of models and large amounts of data. Because these data and models must be used to predict individual behaviors, engineered system performance, contaminant transport, human contact and uptake, and dose among large and often heterogeneous populations, variability and uncertainty associated with these predictions are large.

Over the last decade, explicit assessment of sensitivity and uncertainty has become common practice in many risk assessments. This practice has been driven in large part by the ready availability of software for uncertainty and sensitivity analysis, improvements in computers that make it possible to run large numbers of repeated simulations, and the availability of Monte Carlo guidance from EPA (1997b). Also supporting this process is the wider availability of summary statistics for exposure factors, available in references such as the EPA (1997a) *Exposure Factors Handbook*.

One of the key issues in uncertainty analysis that has been addressed over the last decade is how to distinguish between the relative contribution of true uncertainty and that of interindividual variability (heterogeneity) to characterize the predicted population risk (Bogen and Spear 1987; NRC 1994). Uncertainty or model-specification error (e.g., statistical estimation error) can be modeled using a random variable, but the characteristics of this variable are often subjective. In contrast, variability refers to quantities that are distributed empirically within a defined population. Such factors as food ingestion rates, exposure duration, and expected lifetime are considered as variable but not uncertain. The recognition of the difference between uncertainty and variability has resulted in efforts to carry out assessments in which both uncertainty and variability are characterized in the final results.

The Habicht memo (1992) seems to have encouraged the growth in efforts to address uncertainty. The recent Exposure Factors Handbook (EPA 1997a), the Monte Carlo guidance document (EPA 1997b), and the recent report on policy for use of probabilistic risk assessment (EPA 1997c) reveal that EPA has and will continue to support and encourage more explicit treatment of uncertainty and variability. In its 1997 Monte Carlo guidelines and its Superfund guidance for conducting probabilistic risk assessment, EPA identified a tiered scheme for updating and calibrating a model as more data become available (EPA 1997b, 2001b). As a first step in this scheme, the variance of all input values should be clearly stated, and the impact of these variances on the final estimates of risk should be assessed using sensitivity analysis. Here, it helps to provide a clear summary and justification of the assumptions used for each aspect of a model. In addition, it should be stated whether these assumptions are likely to result in representative values or conservative (upper bound) estimates. The next step in this scheme is the use of variance propagation methods (including but not necessarily limited to Monte Carlo methods) to map how the overall precision of risk estimates is tied to the variability and uncertainty associated with model choice, inputs, and scenarios.

The risk assessment for the Part 503 rule does not provide a clear analysis of uncertainties and their potential impacts on the assessment of risks. A quantitative analysis would allow identification of critical parameters that have a strong influence on the outcome of the calculations of risk. However, the limits of time and resources at EPA mean that choices must be made when planning whether and how to update risk assessments and collect site-specific data in support of the risk assessment calculations. In making revisions to the biosolids

risk assessment, EPA must strike a balance between expending resources to carry out site-specific data collection and expending resources to model and assess risk using existing information.

Multimedia and Multiple-Pathway Exposure Assessments

Efforts to assess human exposure to contaminants from multiple environmental media have been evolving over the past several decades. Knowledge of potential environmental pathways is an important component of a health risk assessment for biosolids. The need to assess human exposure to global fallout in the 1950s resulted in the development of a framework that included transport of contaminants through air, soil, surface water, vegetation, and food chains. More recently, reported concentrations of semivolatile organic compounds and mercury species in water, vegetation, soil, and food products have increased interest in more accurate characterizations of chemical transport on a local, regional, and global scale. In response to the need for better characterization, a number of multimedia transport and transformation models for organic chemicals and metal species have appeared. Multimedia models are also being developed for pathogens. Over the past decade or so, relatively detailed single-domain transport and transformation models have been developed to model aspects of chemical transport and transformation within a single medium or domain (e.g., groundwater models, vadose zone models, surface-water mixing models, and air-dispersion and transformation models).

Multimedia, multipathway assessments have fostered increasing interest about indirect exposure pathways. But only limited efforts have been made to develop source-to-dose relationships using multimedia models. Moreover, these complex source-to-dose models are difficult to validate. The increasing sophistication of mass-transfer models has as yet had almost no impact on human exposure models. None of the exposure models available to date provides an integrated simulation of major transport processes and indoor and outdoor relationships for toxic substances in air, water, food, and soil.

The FQPA of 1996 draws attention to the need for methods to assess aggregate intake of agents with similar target organs.

Biological Markers

Outside of occupational settings or specific research studies, most current exposure-sampling strategies do not rely on biological markers. Although there are reasonable biomarker methods for several metals (e.g., mercury, arsenic, cadmium, chromium) and some organic compounds, the lack of reliable and non-intrusive biomarkers continues to limit their widespread use in exposure tracking studies. For example, the Centers for Disease Control and Prevention (CDC) is exploring biomarkers for classes of organophosphate (OP) pesticides. In some occupational settings, biological markers (e.g., for lead) are part of the surveillance process. It is feasible that a set of biomarkers could be created using less invasive methods (e.g., urine, saliva, and hair sampling). Urinary biomarkers have worked well for some metals, tobacco smoke, and some other pollutants. As new biomarkers are developed and existing ones improved, emerging sampling strategies will rely more on them. It is conceivable that in the future EPA will be able to evaluate more DNA adducts, possibly even after exposure of embedded personal DNA worn

by individuals as a monitor. For many contaminants of concern in biosolids, biomarker approaches may be both feasible and informative. However, for the near future, it is not likely that biomarkers will be of great value for monitoring exposures near biosolids-application sites.

Challenges to the Risk-Characterization Process for Biosolids

The emphasis here is on how the process of risk characterization is changing and how those changes impact the Part 503 rule. Particular challenges to the risk-characterization process are to better link risk assessment to risk management, consider risk perception and risk valuation more explicitly, and provide better risk communication between risk assessors and affected populations.

To examine the Part 503 rule risk assessment in the context of the evolving risk-assessment paradigm, EPA must consider the objectives of the 503 rule risk assessment: Was it to convince the community that it is safe? Was it to justify what is being done or what has been decided? Was it to organize information on exposures and health effects to communicate what is known and what the information gaps and key uncertainties are?

One key risk characterization and management issue that emerged during the committee discussions was whether quality-of-life issues that have the potential to affect health, such as odors, should be considered a factor in setting standards for land application of biosolids**.** In particular, could minimizing odors be an effective way to manage some potential risks?

Acceptance of a risk assessment by regulators and community groups often requires surveillance and monitoring to ensure that the assumptions used in the risk assessment are in place. Many of the chemical substances in municipal waste streams are also in biosolids. The chemicals in municipal solid-waste landfills are monitored. Should the same chemicals be monitored following biosolids application? Answers to these questions help to put the risk assessment in both a scientific and political context. That is, once the objectives of the risk assessment are established, what and whose decisions are being informed by the assessment and the level of scientific confidence needed can be identified.

Characterizing Exposures to Children as a Subpopulation

Organizations such as EPA and the National Institutes for Health are giving special consideration to children's risks from exposure to environmental contaminants. In 1996, EPA's Office of the Administrator issued *Environmental Health Threats to Children* (EPA 1996c) and set an agenda that called for consideration of children's risks in all EPA actions. The report also emphasized the need for more research to support children's risk assessments. Children are considered a special subpopulation because their health risks can differ from those of adults because of their immature physiology, metabolism, and differing levels of exposure due to factors such as greater food consumption per unit of body weight and outdoor play activities.

Differing levels of exposure for children are typically considered in risk assessments, but the underlying toxicity database often does not specifically address effects on children. Such limitations in toxicity data are typically addressed by application of uncertainty factors to protect susceptible populations, such as children. Additional research would allow an assessment of the adequacy of such uncertainty factors.

Participation of the Affected Populations

Local opposition to land application of biosolids appears to be growing, in part because regulators, such as EPA, have failed to systematically address concerns and experiences of residents near land-application sites. Because no process is in place to register complaints, EPA might be unaware of complaints lodged with a local or state agency. Public meetings held by the committee have identified residents near land-application sites and biosolids appliers who believe that they have suffered health impacts and believe that they have been excluded from having input in the risk-assessment process. Health complaints include irritation of the eyes, nose, and throat; headaches; nausea; cough; chest tightness; congestion; shortness of breath; drowsiness; skin lesions; and mood disorders (Schiffman et al. 2000; Lewis and Gattie in press; Shields[1]). The committee was not charged with the task of evaluating the legitimacy of the complaints, nor of determining whether application of sewage biosolids is related to the complaints. However, it notes that the primary concerns of neighbors to land-application sites and the alleged health impacts associated with land application of biosolids have not been addressed in the risk assessments upon which the Part 503 rule is based.

A critical aspect of the risk-assessment process is ensuring that those assessing risks are asking the right questions. Potentially affected people often have knowledge to contribute to the accurate characterization of exposures and to the assessment of risks. When such knowledge is not tapped, the outcome of the process can be flawed, rejected by stakeholders, or both. Tapping local knowledge is necessary but not sufficient to characterize risks. Some risks, such as secondary exposures or effects with long periods of latency, might not be apparent to those exposed.

The risk assessment in support of the Part 503 rule was the product of agency and academic experts, including individuals with long-term associations with land applications and were likely aware of community concerns. As required under federal law, EPA took public comment on the proposed regulations. Nevertheless, there was no evidence of efforts to engage people living adjacent to sites where biosolids are being or could be applied at the level recommended by the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997). EPA guidance, such as the supplement to *Risk Assessment Guidance for Superfund, Part A* (EPA 1999a), provides information to improve community involvement in the Superfund risk-assessment process. Specifically, this document identifies where community input can augment and improve EPA's estimates of exposure and risk and illustrates why community involvement is valuable during the human health risk-assessment process.

[1] H. Shields, Citizens for a Future New Hampshire and the New Hampshire Sierra Club, Sludge Victims, May 2001 Update. Materials provided to the committee on June 4, 2001.

Link Between Risk Assessment and Management of Land-Application Sites

Risk assessments are conducted with the assumption that specific management practices are in place and remain in force. If these practices are not followed, the estimated risks can differ from those estimated under the assumed management practices. The risk assessment for the Part 503 rule was conducted with the assumption that specific management practices are followed. For example, complete incorporation of biosolids into the soil is assumed in assessing runoff impacts. For many sites, however, surface application to pastures is normal practice and is allowed under the 503 rule. Surface application provides the potential for erosion and off-site movement of biosolids and their constituents in a form much different from that assumed in the risk assessment.

The risk assessment for the Part 503 rule included the assumption that specific management practices are followed. However, because the rule does not explicitly require some of these practices, it is difficult to confirm the extent to which site operators employ these management practices. Some are measures that may be useful in minimizing risks; however, most are not requirements under the 503 rule.

It should be recognized that even in cases in which specific management practices are clearly delineated and required under regulations, there can be cases in which management practices are not followed through oversight, negligence, or willful noncompliance. Efforts to make risk assessment more realistic are challenged by the issue of dealing with the likelihood of noncompliance. For example, risks of home-use pesticides are assessed assuming that label directions are followed; yet experience shows that a significant number of users disregard such directions. In the case of land application of biosolids, concerns have been raised about the ability of EPA to enforce the 503 rule (EPA 2000b). When there are such alleged violations as applying biosolids within buffer zones and grazing of livestock on land where Class B biosolids were applied in less than 30 days, any risk assessment that ignores the likelihood of those violations will not be applicable where those conditions exist. No information is available on the frequency and severity of violations of management requirements. Moreover, the committee is not aware of any risk assessment that was carried out under the assumption that one or more violations had occurred. An assessment of the risks both with and without the specified management practices would indicate the significance of noncompliance. This would provide information to be used in risk-management decision-making. Without a system that provides for registration, investigation, enforcement, and documentation of complaints concerning management practices, EPA will not be able to compile relevant data on the level of compliance with biosolids management requirements in the 503 rule.

Odors present a challenge to risk assessors and managers. Until recently, odors were assumed to be an aesthetic issue. Odor control, however, is an important focus of recommendations for good practice (NBP 2001), and Schiffman et al. (2000) have suggested that odors can affect health. Odors and disease vectors as health issues are clearly within the scope of EPA. Less clear is whether EPA may address quality-of-life issues as enjoyment of property where odors or flies might be objectionable but not an unacceptable health risk.

CHANGES IN RISK-ASSESSMENT APPROACHES IN EPA OFFICES

A number of EPA offices and programs are involved in developing risk-assessment protocols for chemical releases to ambient air, indoor air, surface water, soil, and groundwater. The methods developed in these programs and the evolution of risk-assessment methods within these offices and programs over the past 10 years provide benchmarks against which the relevance and reliability of the 503 rule risk assessments can be evaluated. The committee recognizes that other government agencies, such as the CDC, the U.S. Department of Agriculture, and the National Institute of Environmental Health Sciences, have also been involved in research of risk-assessment methods and in developing risk-assessment protocols. In some cases, those agencies have had a direct interest in biosolids risk. Nevertheless, the committee believes that it is beyond the scope of this report to explore the evolution of the risk-assessment process in all U.S. government agencies. Moreover, because EPA has lead responsibility for biosolids risk and works closely with other agencies on issues of risk assessment, the committee decided to focus on the offices of EPA in its review of risk-assessment methods in the U.S. government.

Office of Research and Development (ORD)

EPA's ORD is the principal scientific and research arm of EPA. It conducts research and fosters the use of science and technology in fulfilling EPA's mission. ORD's two major programs involved in developing guidance on risk assessment are the National Center for Environmental Assessment and the National Exposure Research Laboratory. A brief description of some of the major risk-assessment developments in each of these programs is provided below.

National Center for Environmental Assessment (NCEA)

NCEA serves as the national resource center for the overall process of human health and ecological risk assessments. It develops methods that reduce uncertainties in risk assessments (e.g., dose-response models and exposure models), conducts assessment of contaminants and sites of national significance, and provides guidance and support to risk assessors. Two major program areas with important developments since the risk assessments were conducted for the Part 503 rule are exposure assessment and cancer assessment.

Exposure Assessment

In 1992, EPA promulgated a new set of exposure-assessment guidelines to replace the 1986 version (EPA 1992a). The new guidelines explicitly consider the need to estimate the distribution of exposures among individuals and populations and discuss the need to incorporate uncertainty and variability analysis into exposure assessments. The guidelines discuss the roles of both analytic measurement and mathematical modeling in estimating concentrations and durations of exposure. They do not recommend specific models but suggest that models match the objectives of the particular exposure assessment being conducted and that they have the

accuracy needed to achieve those objectives. They also call for detailed explication of the choices and assumptions that often must be made when faced with incomplete data and insufficient resources.

In 1997, NCEA published a support document to the guidelines called the *Exposure Factors Handbook* (EPA 1997a). It contains a summary of human behaviors and characteristics that affect exposure to environmental contaminants and recommends values to use for these factors. A new exposure factors handbook dealing specifically with children is in development. EPA gives special consideration to children, because they can be more heavily exposed to environmental contaminants than adults. EPA released an external review draft of the handbook in June 2000 (EPA 2000c).

NCEA has also developed a guidance document on how to conduct dermal exposure assessments (EPA 1992b). The dermal route of exposure is not understood as well as the other major routes of exposure (ingestion and inhalation). NCEA's guidelines discuss the principles of dermal absorption from exposures to water, soil, and vapor media and presents methods for applying those principles to human exposure assessment. The guidelines were developed primarily for evaluations of waste-disposal sites or contaminated soils but are applicable to land-applied biosolids. The Office of Solid Waste and Emergency Response has also developed guidance for dermal risk assessment (EPA 2001a).

Guidance is also being developed for approaches to modeling health risks from indirect exposures to environmental contaminants. For example, *Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions* (EPA 1998b) presents procedures for estimating exposures resulting from atmospheric pollutants emitted from stationary combustors, transferred through the atmosphere, and deposited on environmental media and biota. It discusses ways to estimate indirect exposures that could result from uptake and transfer from atmospheric agents through the terrestrial or aquatic food chains. This example also illustrates the need for conducting multimedia and multiple-pathway exposure assessments.

Cancer Risk Assessment

In 1996, NCEA proposed a revision to the 1986 EPA *Guidelines for Carcinogen Risk Assessment* to reflect new developments in understanding carcinogenesis (EPA 1996a). Revisions have been made since that proposal, and work on the guidelines is still in progress (EPA 1999b). The proposed revisions include placing greater emphasis on analyzing all the biological information on an agent rather than analyzing only the tumor data; understanding an agent's mode of action; taking a weight-of-evidence approach to drawing conclusions about hazard; and providing guidance on assessing risks to children. When finalized, the guidelines will provide an analytical framework that will allow the incorporation of all relevant biological information, recognize a variety of situations regarding cancer hazard, and be flexible enough to allow consideration of future scientific advances.

National Exposure Research Laboratory (NERL)

NERL is EPA's resource for guidance on exposure assessment for all environmental stressors (e.g., chemicals, biological agents, and radiation). NERL conducts research on stressor sources; pollutant transport, transformation, and exposure; and source-to-receptor predictive exposure models. NERL is also involved in the development of innovative exposure-assessment technologies.

National Exposure Surveys

One of NERL's major efforts is to address the need to reduce uncertainty and variability in exposure assessments and the need to develop realistic exposure scenarios and assumptions. A key determinant of exposure variability is human activity. Between October 1992 and September 1994, NERL conducted the National Human Activity Pattern Survey (NHAPS) to collect data on activity patterns of subjects over a 24-hour period. The survey was intended to provide comprehensive exposure information over broad geographical and temporal scales that can be used for detailed exposure studies targeted to specific populations in the United States. Detailed tables of the survey results have been compiled (EPA 1996d), and some of the data were incorporated into the *Exposure Factors Handbook* (EPA 1997a).

NHAPS provides a broad description of individual activities for distinct combinations of location and time (macroactivity, e.g., amount of time spent in an enclosed vehicle). For specific risk assessments, activity patterns can be analyzed in even greater detail using microactivity models, which can be used to describe specific contacts with exposure media (e.g., frequency of a child's hand contact with soil and mouth). Exposures from residential environments have been given greater attention in recent years.

Another survey that was undertaken is the National Human Exposure Assessment Survey (NHEXAS). This survey was designed to evaluate comprehensive human exposure to multiple chemicals on a community and regional scale. The first phase of the survey involved measuring concentrations of chemicals in various exposure media (e.g., air, food, drinking water, soil, and dust) and in biological samples (e.g., blood and urine), and administering questionnaires to identify possible sources of exposure to chemicals. The sample collection and laboratory analyses were completed in 1998, and statistical analyses of the data are being performed. As the database is developed, it will be possible to use the data as a baseline to determine whether specific populations are exposed to increased levels of environmental contaminants.

Pharmacokinetic Models and Biomarker Data

NERL's Exposure Methods and Monitoring Branch develops indicators of human exposure to environmental stressors. One set of indicators that provides a direct measure of exposure is biomarker data sets. Biomarkers are indicators, specific to a contaminant, of variation in cellular or biochemical components or processes, structure, or function that are measurable in biological systems or samples. When used with pharmacokinetic data and information on the interval between exposure and collection of the biomarker information, biomarker data can be used to reduce uncertainties about exposure.

The study of pharmacokinetics provides an understanding of a chemical's absorption, distribution, metabolism, and excretion that occurs between the time a chemical enters the body

and when it leaves. Pharmacokinetic models are a mathematical representation of those processes and can be used to describe the quantitative differences between an exposure dose, a delivered dose, and, when possible, a biologically active dose at the target organ. EPA's strategic plan for evaluating data from NHEXAS (EPA 2000d) discusses the need to consider pharmacokinetic models and parameters in evaluating the time course and associations between exposure and dose.

Office of Air and Radiation (OAR)

EPA's OAR is responsible for national programs, technical policies, and regulations for controlling air pollution and radiation exposure. Currently, there are OAR programs to address pollution prevention, indoor and outdoor air quality, industrial air pollution, pollution from vehicles and engines, radon, acid rain, stratospheric ozone depletion, and radiation protection. Of particular interest for considering applications of risk-assessment policy are the Radiation Protection Division, Indoor Air Quality Programs, and the Office of Air Quality Planning and Standards within OAR.

Radiation Protection Division

The Radiation Protection Programs within the Radiation Protection Division provide the methods and scientific basis for EPA's radiation exposure, dose, and risk assessments. These assessment, in turn support the development of EPA policy, guidance, and rule-makings concerning radiation protection and risk management. Among other functions, the Radiation Protection Program develops radionuclide fate and transport models, dose and risk models, and dose and risk coefficients.

Indoor Air-Quality Programs

Because of the importance of understanding the sources and pathways of exposure in indoor environments, EPA has established and promoted indoor air-quality programs over the past decade. These programs deal with indoor exposures to contaminants originating from both outdoor and indoor sources. Among the sources of indoor pollution addressed by EPA are combustion sources, such as oil, gas, kerosene, coal, and wood-combustion and tobacco products; building materials and furnishings, such as wet or damp carpet and cabinetry or furniture made of certain pressed-wood products; household cleaning and maintenance products; central heating and cooling systems and humidification devices; and outdoor sources, such as radon, pesticides, and outdoor air pollution. Of particular interest to the issue of biosolids risk assessment is the potential for indoor exposures to pathogens.

Office of Air Quality Planning and Standards (OAQPS)

EPA's OAQPS directs national efforts to meet air-quality goals, particularly for smog, air toxics, carbon monoxide, lead, particulate matter (soot and dust), sulfur dioxide, and nitrogen dioxide. OAQPS is responsible for implementing major provisions of the Clean Air Act,

including those related to visibility, permitting, and emissions standards for a wide variety of industrial facilities. Of particular interest in risk assessment is the OAQPS effort to develop methods to assess human exposure and health risks for particulate matter (PM) and multimedia pollutants released in urban air sheds. As part of that effort, OAQPS had formulated advanced and novel methods for addressing multimedia pollutants. Those methods are being incorporated into the OAQPS total risk integrated model (TRIM). TRIM provides a multimedia fate analysis and multipathway exposure assessment for toxic air pollutants and aerosols (PM).

OAQPS is also working on the National Air Toxics Assessment (NATA), a program to assess the cumulative exposures of the U.S. population to toxic air pollutants through a combination of monitoring and models.

The OAQPS effort to assess PM exposure has particular relevance to biosolids risk. PM exposure from biosolids application is raised as a concern of local communities and some public-health officials. From biosolids-application sites, PM is produced by numerous sources, including diesel emissions, traffic, and dust suspensions. A related issue is rafting—pathogens catching a ride on dust particles. Whether and how allergen proteins are transported from site to receptor is still poorly understood.

Office of Solid Waste and Emergency Response (OSWER)

OSWER provides policy, guidance, and direction for EPA's solid-waste and emergency-response programs. Within OSWER, the Office of Solid Waste (OSW) develops guidelines for the land disposal of municipal and hazardous waste and the Office of Underground Storage Tanks (OUST) develops guidance for limiting the risks from leaks of underground storage tanks. OSWER provides technical assistance to all levels of government to establish safe practices in waste management. OSWER is also home to the Superfund program, which addresses health concerns of communities with abandoned and active hazardous waste sites and accidental oil and chemical releases. Superfund also encourages innovative technologies to address contaminated soil and groundwater.

Office of Solid Waste (OSW)

OSW is responsible for setting limits on the concentrations of chemicals that can be placed in municipal landfills. Limits are set through a risk-assessment process that identifies and evaluates multiple exposure pathways. OSW has identified a number of potential exposure pathways linked to landfills and uses multimedia risk assessments to link human exposure and health risk to chemicals in the landfill waste. The assessment is a forward-calculating analysis that evaluates the risks of multiple exposure pathways to human and ecological receptors. One of the pathways that the OSW landfill risk assessments addresses is the advection of chemicals out of the landfill due to forced convection that results from methane and carbon dioxide generation in the waste pile.

Office of Underground Storage Tanks (OUST)

OUST was created in 1985 to carry out a congressional mandate to develop and implement a regulatory program for underground storage tank (UST) systems. OUST works with EPA regional offices and state and local UST programs to promote the use of risk-based decision-making. In OUST, risk-based decision-making (RBDM) is a process by which decisions are made about contaminated sites using a site-specific assessment of the risk each site poses to human health and the environment. In cooperation with the American Society for Testing and Materials (ASTM), OUST is evaluating whether its RBDM programs are achieving their stated agency management goals.

Office of Emergency and Remedial Response (OERR)

The EPA Superfund program is administered by the OERR. After a hazardous waste site is listed on the National Priorities List, risk assessment has an important role in the characterization and cleanup of Superfund sites. OERR provides general tools and specific tools to assist in the major steps of the risk-assessment process. In 1989*, Risk Assessment Guidance for Superfund* (RAGS), Part A, was issued (EPA 1989). This document provides recommended algorithms and data for calculating potential exposures to chemical contaminants found at Superfund sites. In contrast to the OUST risk methods, RAGS are more generic in providing uniform national risk-assessment defaults. Additional RAGS documents were issued in 1991 in Part B (EPA 1991b, which provides guidance on using EPA toxicity values and exposure information to derive risk-based preliminary remediation goals, and Part C (EPA 1991c), which provides guidance on the human health risk evaluations of remedial alternatives. In 1998, OERR issued Part D (EPA 1998c), and in 1999, it issued a supplement to Part A (EPA 1999a). This document is of interest to biosolids risk assessors, because the supplement provides information to improve community involvement in the Superfund risk-assessment process. Specifically, the supplement suggests ways for Superfund staff and community members to work together during the early stages of Superfund cleanup; identifies where community input can augment and improve EPA's estimates of exposure and risk; recommends questions that the site team should ask the community; and illustrates why community involvement is valuable during the human health risk assessment at Superfund sites. A review draft of Part E provides dermal risk assessment guidance (EPA 2001a). OERR has also developed probabilistic risk assessment guidance for Superfund (EPA 2001b).

Office of Water (OW)

EPA's OW is responsible for all national water-quality activities, including the regulation of surface water and groundwater supplies to protect human health and the environment. OW is responsible for implementing the Clean Water Act, Safe Drinking Water Act, and portions of other environmental laws and treaties that apply to water quality. Several organizations make up the OW, including the Office of Wetlands, Oceans, and Watersheds; the Office of Science and Technology; the Office of Wastewater Management (which oversees EPA's biosolids program); and the Office of Ground Water and Drinking Water.

A major task of OW is to set drinking-water standards. Risk assessment provides a key input to this process. Since 1986, OW has more than tripled the number of contaminants for

which it has published drinking-water standards, bringing the total to 94. A current challenge for OW in its effort to minimize health risks from water supplies is to find the appropriate balance between the risks from naturally occurring microbial pathogens and the chemical by-products of disinfection processes used to remove the pathogens. It is important to provide protection from these microbial pathogens while ensuring decreasing health risks to the population from disinfection by-products.

As part of its effort to protect watersheds, OW has established the total maximum daily load (TMDL) program. A TMDL is a calculation of the maximum amount of a pollutant that a body of water can receive and still meet state water-quality requirements. TMDLs are determined in part by considering multiple sources of pollutants (from point, nonpoint, and background sources, including atmospheric deposition), seasonal variations, and margins of safety. The calculations of these programs provide benchmarks for the continuing evaluation of biosolids standards.

Office of Prevention, Pesticides and Toxic Substances (OPPTS)

EPA's OPPTS develops national strategies for toxic substance control and promotes pollution prevention and the public's right to know about chemical risks. OPPTS has an important role in protecting public health and the environment from potential risk from toxic chemicals and pesticides. OPPTS is dealing with issues such as endocrine disruptors and lead poisoning prevention.

Within OPPTS, the Office of Pesticide Programs (OPP) regulates the use of all pesticides in the United States and establishes maximum concentrations for pesticide residues in food. As part of this effort, OPP is expanding access to information on risk-assessment and risk-management actions to help to increase transparency of decision-making and facilitate consultation with the public and affected stakeholders. OPP has a mandate under the FQPA of 1996 to address aggregate exposure and cumulative risk from multiple sources of pesticide exposure. To address that issue, OPP developed a framework for conducting cumulative risk assessments for organophosphates and other pesticides that have a common mechanism of toxicity (that act in the same way in the body). Through its cumulative risk-assessment framework, OPP will be able to consider whether the risks posed by a group of pesticides that act the same way in the body meet the FQPA safety standard of "reasonable certainty of no harm." As part of that framework, OPP is developing new methods to assess cumulative risk, to assess residential exposure, and to aggregate exposures from all nonoccupational sources.

FINDINGS AND RECOMMENDATIONS

The Part 503 rule risk assessments were carried out more than a decade ago. In this chapter, the committee considered the likely impact of changes in risk-assessment practice in general and in various EPA offices in particular on the risk-assessment process for biosolids. The committee found that the development of methods in the broader academic community and the evolution of risk-assessment methods within various EPA offices and programs provide important benchmarks for the committee's assessment of the relevance and reliability of the 503 rule risk assessments. Of particular note are updates to the risk-assessment framework

recommended by the NRC, the Presidential/Congressional Commission on Risk Assessment, and various EPA offices.

The risk-assessment methods and policies practiced and advocated at EPA have changed significantly, although not at the pace recommended by the NRC and the risk commission. As a result, the Part 503 rule, which has not been modified to account for any new methods and policies, is now inconsistent with current NRC recommendations and EPA policies within various offices. Particularly relevant examples of the inconsistency are the absence of stakeholder participation and the lack of explicit treatment of uncertainty and variability.

Recommendation: *Because of the significant changes in risk-assessment methods and policies over the last decade, EPA should revise and update the Part 503 rule risk assessments. Important developments include recognition of the need to include stakeholders throughout the risk-assessment process, improvements in measuring and predicting adverse health effects, advances in measuring and predicting exposure, explicit treatment of uncertainty and variability, and improvements in describing and communicating risk. EPA should consider how the updated risk assessments would change the risk-management process. A similar approach can be taken with the issue of biological agent risks.*

In recent years, health-effects research has made use of large-scale studies of human health end points at multiple sites. Health-effects research has also focused on early indicators of outcome, making it possible to shorten the time between the exposure and the observation of an effect. In addition, more use has been made of meta-analysis, better modeling of dose-response relationships, and more sophisticated regression models. These improvements make possible more site-specific assessments of the impacts of biosolids land-application practices.

Managing exposure of human populations to environmental contaminants using a risk-based approach requires an accurate metric for the impacts of contaminants on human health and a reliable process for monitoring and recording the exposures within populations assumed to be at risk. Over the past decade, the practitioners of exposure assessment have made important improvements in methods to measure and model source-to-dose relationships. These improvements have been made through greater use of time-activity surveys, personal monitors, and biomarkers of exposure, and they have made it possible to confirm some of the exposures predicted in risk assessments.

Recommendation: *Many of the measures of risk used in developing the Part 503 rule guidelines cannot be monitored. Because of that inability to monitor, the committee acknowledges that EPA must perform theoretical risk assessments. Nevertheless, there is a continuing need to provide some measures of performance that can be monitored (e.g., concentrations of selected chemicals in exposure media, such as indoor air, house dust, or tap water of residences near land-application sites; and exposure biomarkers in the blood or urine of nearby residents). Recent improvements in health surveillance and exposure monitoring provide new opportunities for EPA to develop more explicit and measurable metrics of performance for biosolids land-application practices.*

Advancements in monitoring health outcomes and exposure have resulted in improvements in the description and communication of risk. In particular, improved exposure assessments have led to better exposure classification in health-effects studies. Better

descriptions of risk are available, using benchmark dose and margin of exposure to communicate hazard and risk in place of risk of death, hazard quotients, or exposure-potency product relationships. There have also been improved methods for prioritizing compounds using measures of risk.

Recommendation: *In making revisions to the Part 503 rule risk assessment, EPA must strike a balance between expending resources to carry out site-specific data collection and expending resources to model and assess risk using existing information. In light of improvements in exposure and health monitoring, the committee encourages EPA to consider options carefully for collecting new data in support of risk-assessment assumptions before resorting to another risk assessment that relies only on existing data, models, and default assumptions. Among the data that would be of value are data on proximity of receptors to land-application sites; surveys of activities that could increase direct and indirect exposures; and samples of biosolids, air, vegetation, runoff, groundwater, and soil in environments surrounding land-application sites. In addition, EPA should conduct site-specific surveys of performance (e.g., monitor the extent to which rates and depth of application are consistent with risk-assessment assumptions) and scientifically relevant studies of health complaints.*

Risk assessments make use of a number of assumptions to define chemical loading in biosolids that pose no undue risk to surrounding populations. Implicit in this process is the premise that these assumptions and the associated demographic and operational conditions will persist. However, there are no guidelines to ensure that these conditions persist.

Recommendation: *Because there are no guidelines to ensure that conditions assumed in the risk assessment actually transpire, the committee recommends that the Part 503 rule provide guidance for periodic reassessments that will be used to ensure that the demographic and operational conditions of biosolids land application are consistent with the assumptions of the applicable risk assessment.*

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5

Evaluation of EPA's Approach to Setting Chemical Standards

The U.S. Environmental Protection Agency used risk-assessment methods to set biosolids chemical standards (termed "pollutant limits" under the Part 503 rule) to be protective of human health and the environment. Risk-based standards are generally maximum levels that should not be exceeded. Risks experienced by a typical receptor population are likely to be lower, and in most cases, much lower than target risk levels used to derive risk-based standards. However, the protectiveness of the risk-based standards is dependent on the data and methods used to establish the standards, as well as on compliance with specified conditions of use.

The risk-assessment methods for establishing the Part 503 rule were developed in the mid-1980s. Since that time, EPA has refined risk-assessment methods and approaches and has issued a number of guidance documents to support standardized approaches to risk assessment (see Chapter 4). In this chapter, the methods used for the Part 503 rule risk assessments are reevaluated in light of the current practice of risk assessment. Specific assumptions made in the risk assessments are also reevaluated on the basis of available scientific information.

Risk assessments typically include four steps: hazard identification, exposure assessment, toxicity (dose-response) assessment, and risk characterization (NRC 1994). Elements of all four steps are considered in the following sections. The first section considers the hazard-identification approach used to select chemicals for inclusion in the risk assessment (EPA 1985, 1992a,b). Subsequent sections address general issues for exposure assessment and risk characterization. These sections are followed by a discussion of issues relevant to specific inorganic and organic chemicals, including toxicity assessment.

HAZARD ASSESSMENT AND CHEMICAL SELECTION

To date, EPA has conducted two rounds of assessments to identify chemicals to regulate in the Part 503 rule. Round 1 was conducted to identify an initial set of chemical pollutants to regulate, and Round 2 was conducted to identify additional pollutants for regulation. Standards for the Round 2 pollutants have not been established, but EPA is considering regulation of dioxins (a category of compounds that has 29 specific congeners of polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans, and coplanar polychlorinated biphenyls) for land application. Therefore, although evaluation of EPA's dioxin risk assessments for biosolids is outside the scope of the committee's charge, it believes that evaluating the selection of dioxins for regulation is within the charge.

Round 1 Pollutant Selection

EPA used a two-stage process to select its initial set of contaminants to regulate under the Part 503 rule. First, a list of chemicals was subjected to a hazard screening. Second, chemicals found to represent a potentially significant risk were subject to formal risk assessment.

In 1984, using available data on effects in humans, plants, domestic animals, wildlife, and aquatic organisms and frequency of chemical occurrence in biosolids, EPA identified 200 potential chemicals of concern in biosolids. A panel of scientific experts selected 50 chemicals of potential concern for evaluation by EPA. A screening process was then used to select 22 pollutants for potential regulation (Table 5-1). The process involved developing environmental profiles for each pollutant for which data were readily available on toxicity, occurrence, fate, and pathway-specific hazards. When relevant, aggregate cancer risks from exposure via several pathways were assessed. Risks posed by some of the pathways subsequently analyzed in the risk assessment were not used in the screening process (pathways 11-14, see Table 5-4 in summary of exposure pathways).

TABLE 5-1 Pollutants Selected for Potential Regulation

Inorganic Chemicals	Organic Chemicals
Arsenic	Aldrin and dieldrin
Cadmium	Benzo[*a*]pyrene
Chromium	Chlordane
Copper	DDT, DDD, DDE
Lead	Heptachlor
Mercury	Hexachlorobenzene
Molybdenum	Hexachlorobutadiene
Nickel	Lindane
Selenium	*N*-Nitrosodimethylamine
Zinc	Polychlorinated biphenyls
	Toxaphene
	Trichloroethylene

DDT, 1,1,1-trichloro-2,2-bis(*p*-chlorophenyl)ethane;
DDE, 1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene;
DDD, 1,1-dichloro-2,2-bis(p-chloropheyl)ethane.
Source: EPA 1992a.

To determine whether a full risk assessment was warranted for a particular chemical via a specific exposure pathway, a hazard index was calculated for each contaminant and pathway that had sufficient data (EPA 1985). This index is the ratio of the estimated concentration of the pollutant in the environment (soil, plant or animal tissue, water, or air) to the established human health or other regulatory criteria (e.g., acceptable daily intake for noncarcinogens or a cancer risk-specific intake). The calculated soil concentrations were based on "typical" and "worst" concentrations of the contaminant found in biosolids and were evaluated at application rates of 5 and 50 metric tons per hectare (mt/ha) and a cumulative application of 500 mt/ha based on the assumption of 5 mt/ha per year for 100 years. Data on concentrations of pollutants in sewage sludge were obtained primarily from survey data collected in a 40-city study (EPA 1982). Median values were used to represent typical concentrations, and the 95th percentile was used to represent the worst-case concentrations. It is not clear how calculations on typical

concentrations and low application rates were used in the screening process, because the hazard index was reportedly derived using worst-case conditions.

After the screening process, pollutants with a hazard index equal to or greater than 1 were evaluated further. The hazard index for each of these pollutants was adjusted so that it reflected the hazard attributable only to biosolids for the specific pathway of exposure being evaluated. This adjustment was done by excluding background exposure to the pollutant from sources other than biosolids. When adjusted values exceeded 1, the pollutant was evaluated for that particular pathway in a detailed risk assessment. Thus, background exposure was eliminated, and only pollutants for which the hazard index was greater than 1 for the increment contributed by biosolids were subjected to further analysis through risk assessment. This analysis assessed exposure via each pathway to each chemical. For human-health-related pathways, this procedure resulted in the elimination of fluoride and lindane from consideration in several pathways.

After the proposed 503 rule was issued in 1989, EPA completed a National Sewage Sludge Survey (NSSS) (EPA 1990). The NSSS collected data on more than 400 pollutants from approximately 180 sewage treatment plants throughout the country to produce national estimates of concentrations of pollutants in sewage sludge. Using the NSSS data and information from the risk assessments, EPA conducted a further screening analysis to eliminate from regulation any pollutant that was not present at concentrations deemed to pose a significant public health or environmental risk. On the basis of this screening analysis, the 12 organic chemicals were exempted, leaving only inorganic chemicals for regulation by the Part 503 rule. The following criteria for exempting organic pollutants were used:

1. The pollutant has been banned from use, has restricted use, or is no longer manufactured for use in the United States.
2. The pollutant has a low frequency of detection in sewage sludge (less than 5%) based on data from the NSSS.
3. The concentration of the pollutant in sewage sludge is already low enough that the estimated annual loading to cropland soil would result in an annual pollutant-loading rate within allowable risk-based levels.

Aldrin and dieldrin; chlordane; 1,1,1-trichloro-2,2-bis(*p*-chlorophenyl)ethane, 1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene, 1,1-dichloro-2,2-bis(p-chlorophenyl)ethane (DDT, DDE, DDD); heptachlor; lindane; *N*-nitrosodimethylamine; polychlorinated biphenyls (PCBs); and toxaphene were eliminated on the basis of criterion 1. All the organics except aldrin and dieldrin, bis(2-ethylhexyl)phthalate, and PCBs met criterion 2. On the basis of agricultural application assumptions, all the organics except benzo[*a*]pyrene, hexachlorobenzene, *N*-nitrosodimethylamine, and PCBs met criterion 3. Under different application scenarios, some of these same organics might not meet criterion 3. For example, EPA (1992b) noted that under scenarios for applications to forests and public contact sites, toxaphene and the organics eliminated under the agricultural scenario do not meet criterion 3.

Round 2 Pollutant Selection

Subsequent to the promulgation of biosolids regulations in 1993, another evaluation was conducted to develop a list of Round 2 pollutants to consider for regulation (EPA 1996a). As

with the Round 1 pollutants, EPA conducted a preliminary hazard identification followed by a risk assessment for those contaminants and pathways identified as potential hazards. In this evaluation, degradation products of organic contaminants were assumed to be nontoxic.

The list of 411 pollutants analyzed in the NSSS (EPA 1990) was the starting point of the Round 2 assessments. Pollutants were eliminated from consideration if they were not detected (254 pollutants) or were detected in less than 10% of sewage sludge (69 pollutants). Pollutants present in more than 10% of sewage sludge but with insufficient toxicity data were also eliminated from Round 2 consideration (see Table 5-2). Some of these chemicals lack toxicity values due to a relative lack of toxicity. Several pollutants were grouped into classes of congeners (e.g., PCBs, chlorinated dioxins, and furans).

TABLE 5-2 Chemicals Eliminated from Consideration in the Round 2 Assessments Because of Lack of Toxicity Data

Pollutant
Calcium
Decane, *n*-
Dodecane, *n*-
Eicosane, *n*-
Hexacosane, *n*-
Hexadecane, *n*-
Hexanoic acid
Iron
Magnesium
Octacosane, *n*-
Sodium
Tetracosane, *n*-
Tetradecane, *n*-
Triacontane, *n*-
Yttrium

Source: EPA 1996a.

The screening process identified 30 pollutants that had a frequency of detection of 10% or greater in the NSSS and that had data on human health and/or ecological toxicity (Table 5-3). Asbestos, which was not analyzed in the NSSS, was added as another potential candidate for regulation because it is toxic, persistent, and can be in biosolids. These 31 pollutants were subject to further analysis in a comprehensive hazard identification study. The study used a mix of conservative and average value assumptions similar to those used in the Round 1 risk assessments. The aggregate exposure through more than one pathway was not assessed. Analysis of a particular pathway of exposure for certain candidate chemicals was not conducted when EPA determined that chemical-specific data were insufficient for that pathway. The result of the evaluation was that only dioxins, furans, and coplanar PCBs (considered as a group) were subject to further risk assessment (EPA 1996a). That risk assessment led to a proposed standard in December 1999 (EPA 1999a). EPA sponsored a peer review of that risk assessment and proposed standard (Versar 2000). On the basis of review comments and the agency's reassessment of dioxin risks, EPA decided to revise the risk assessment. A peer-review draft was released November 30, 2001 (EPA 2001a), and a notice of data availability was subsequently issued for public comment on June 12, 2002 (EPA 2002c).

TABLE 5-3 Candidate Pollutants for Round 2 Regulations[a]

Pollutant
Acetic acid (2,4-dichlorophenoxy)
Aluminum[b]
Antimony
Asbestos[c]
Barium
Beryllium
Bis(2-ethylhexyl)phthalate
Boron
Butanone, 2-
Carbon disulfide
Cresol, *p*-
Cyanides (soluble salts and complexes)
Dioxins and dibenzofurans
Endosulfan-II
Fluoride
Manganese
Methylene chloride
Nitrate
Nitrite
Pentachloronitrobenzene
Phenol
Polychlorinated biphenyls-coplanar
Propanone, 2-
Propionic acid, 2-(2,4,5-trichlorophenoxy)
Silver
Thallium
Tin
Titanium
Toluene
Trichlorophenoxyacetic acid, 2,4,5-
Vanadium

[a]Pollutants detected at a frequency of at least 10% with human health and/or ecological toxicity data available.
[b]Aluminum does not have human health or ecological toxicity data available but is included because of its potential for phytotoxicity. [c]Asbestos was not tested in the NSSS but is toxic, persistent, and can be in sewage sludge.
Source: EPA 1996a.

Limitations of the Assessment and Selection Process

Survey Data

Accurate data on pollutant concentrations in biosolids are crucial to the selection of chemicals to regulate under the Part 503 rule. Many of the decisions made in the chemical selection process were based on concentration data from the NSSS (EPA 1990). The NSSS was an ambitious undertaking and provides the most comprehensive data on the content of sewage sludge in the United States to date. However, the survey was conducted over a decade ago, and

there is a need to conduct a new survey to characterize the concentrations and distribution of chemicals now present in biosolids. For example, state survey data presented in Chapter 2 show that concentrations of some of the regulated inorganic elements have generally decreased over the past decade. Furthermore, the accuracy of the NSSS data was called into question by an earlier NRC committee that was asked to evaluate the use of biosolids on croplands (NRC 1996). That committee found inconsistencies in the survey's sampling analyses and data-reporting methods that undermined the reliability of the data. Therefore, it recommended that another comprehensive survey be conducted to rectify the NSSS's sampling and analytical limitations. To date, no such survey has been done.

TABLE 5-4 Exposure Assessment Pathways Use in Risk Assessment for Land Application of Biosolids

Pathway Number	Receptor	Pathway
1	Human	Biosolids-soil-plant-human
2	Human	Biosolids-soil-plant-home gardener
3	Human	Biosolids-soil-child
4	Human	Biosolids-soil-plant-animal-human
5	Human	Biosolids-soil-animal-human
6	Ecological and agricultural	Biosolids-soil-plant-animal
7	Ecological and agricultural	Biosolids-soil-animal
8	Ecological and agricultural	Biosolids-soil-plant
9	Ecological	Biosolids-soil-soil biota
10	Ecological	Biosolids-soil-soil biota-predator of soil biota
11	Human	Biosolids-soil-airborne dust-human
12	Human	Biosolids-soil-surface water-fish-human
13	Human	Biosolids-soil-air-human
14	Human	Biosolids-soil-groundwater-human

Source: EPA 1995.

Some chemicals that were undetected because of analytical problems or detection limits that exceeded risk-based concentrations were likely eliminated mistakenly. Each of the chemicals in the NSSS was assigned a "detection limit," which was equivalent to the minimum concentration of pollutant that could be quantitated (EPA 1990). The detection limits are difficult to discern from the NSSS data, and actual detection limits for a given chemical varied over a wide range of concentrations among samples (Figures 5-1 through 5-4). Data presented in the technical support document for the Round 2 assessment (EPA 1996a) indicated that some detection limits exceeded several hundred parts per million for some of the organic chemicals. At the request of the committee, detection limits of NSSS samples for eight chemicals, four of which were not detected in the NSSS (ideno[1,2,3-cd]pyrene, *n*-nitrosodimethylamine, pentachlorophenol, and toxaphene), were provided by EPA (Charles White, EPA, personal communication, February 2001). Before conducting a risk assessment, the adequacy of the available chemical concentration data to support the risk assessment is typically evaluated (EPA 1991). It is current risk assessment practice to evaluate the adequacy of analytical detection limits by comparing them with conservative risk-based screening concentrations (RBCs). For example, EPA (2001b) has developed soil screening levels (SSLs), which are based either on incidental ingestion of and dermal contact with soil or on inhalation of vapors or resuspended soil particulates. Figures 5-1 through 5-4 show chemical concentrations and detection limits for

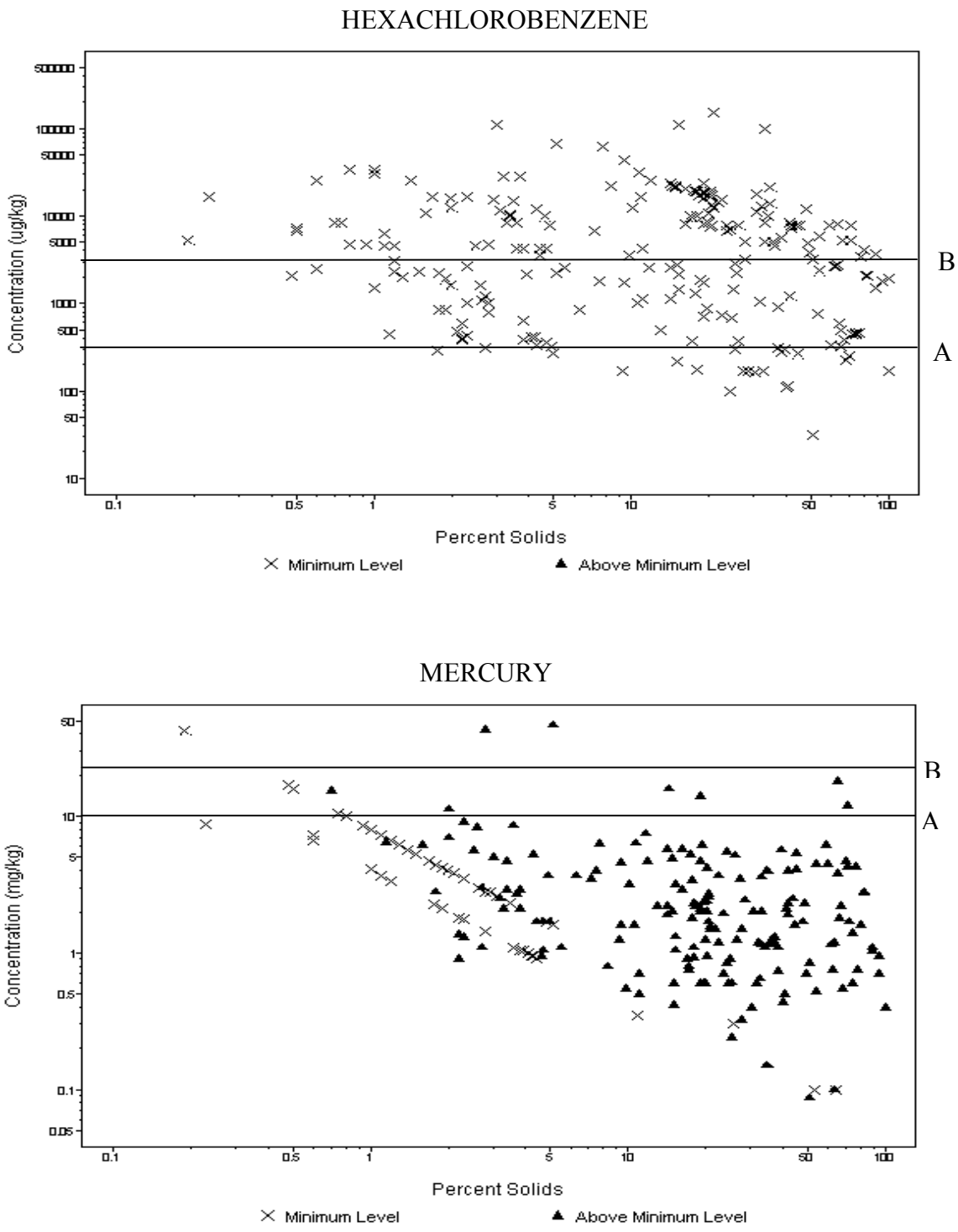
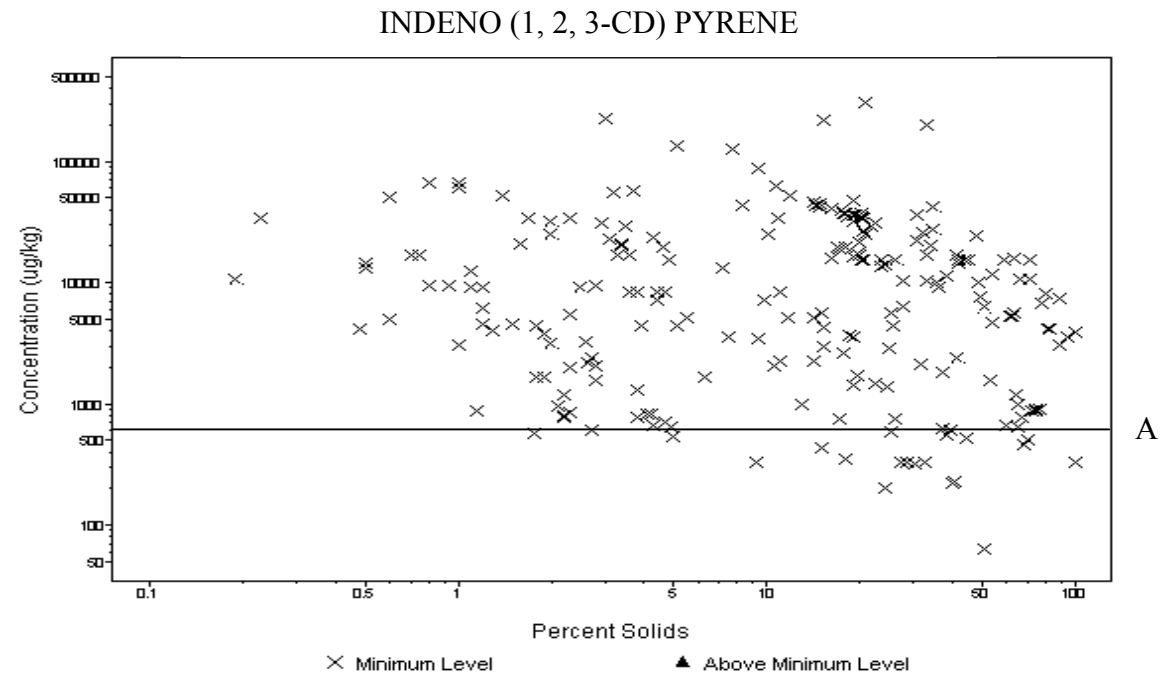


FIGURE 5-1 NSSS data. Detected concentrations (▲) and detection limits (×) for nondetects (as a function of solids content of sewage sludge) compared with soil screening levels (A, ingestion and dermal; B, inhalation) for hexachlorobenzene and mercury.



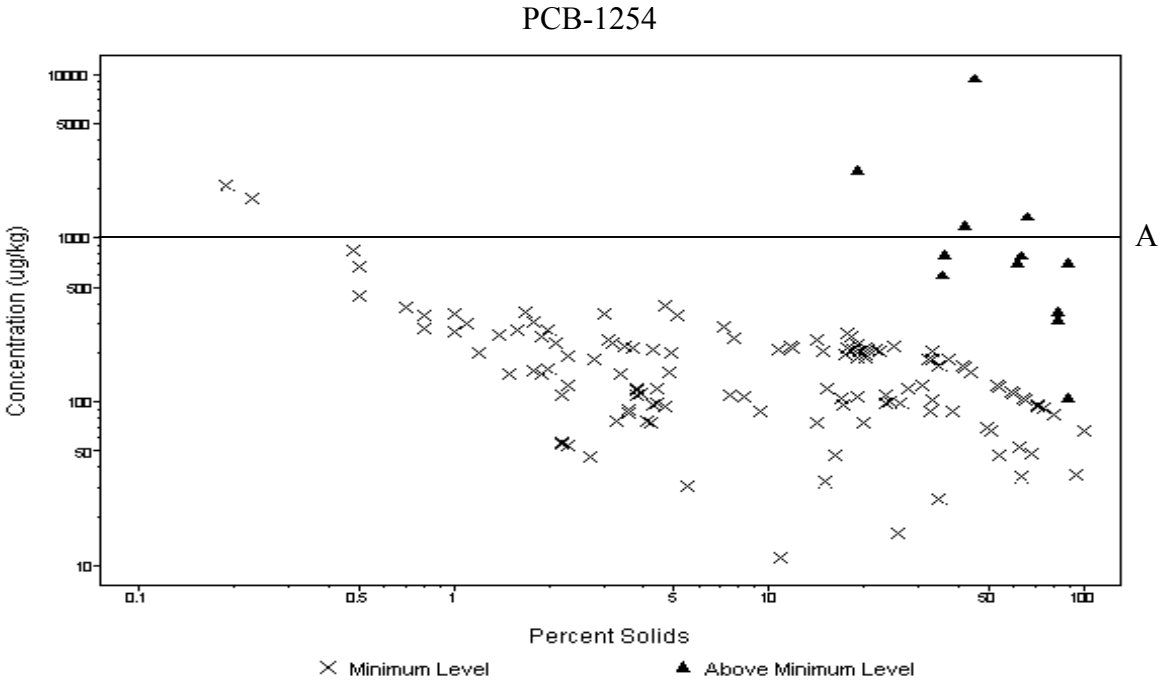
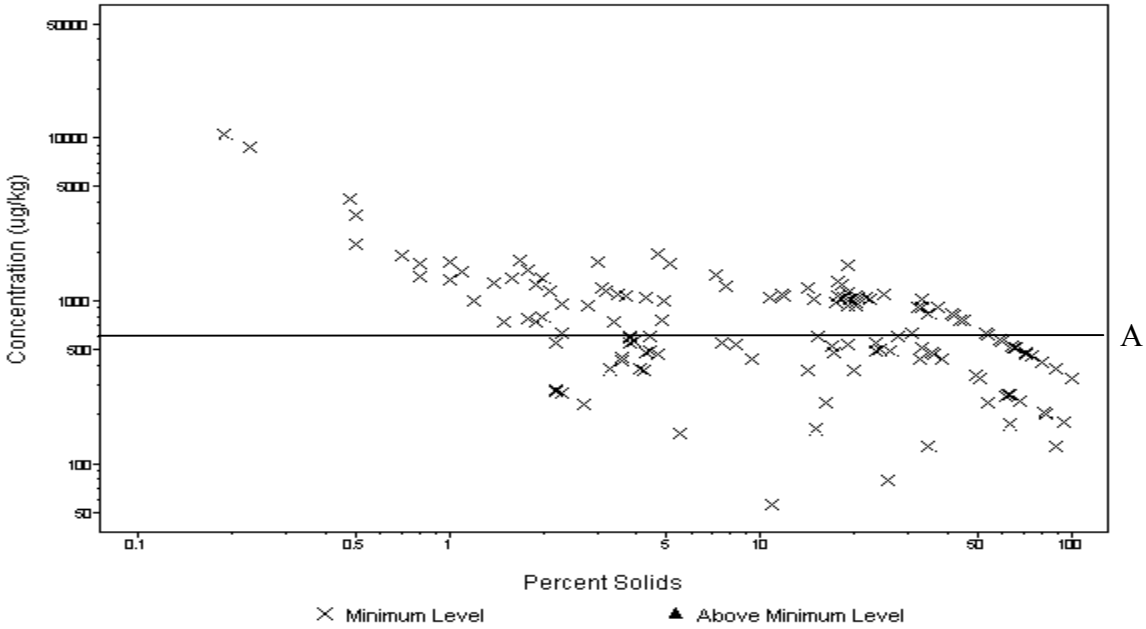


FIGURE 5-2 NSSS data. Detected concentrations (▲) and detection limits (×) for nondetects (as a function of solids content of sewage sludge) compared with soil screening levels (A, ingestion and dermal) for ideno(1,2,3-cd)pyrene and PCB-1254.

TOXAPHENE



PENTACHLOROPHENOL

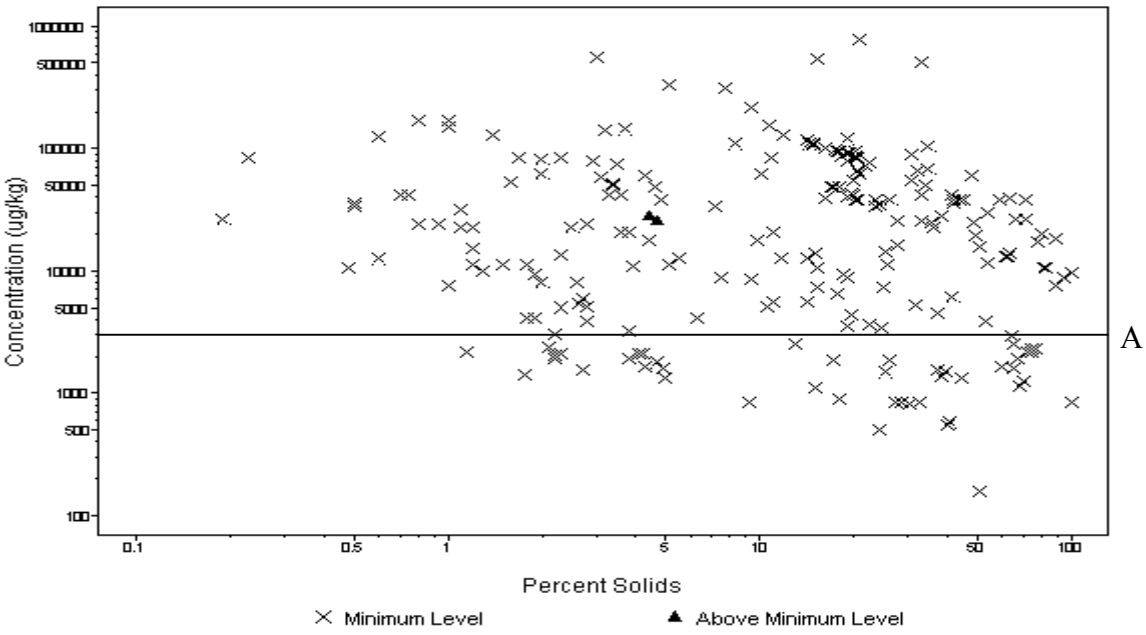


FIGURE 5-3 NSSS data. Detected concentrations (▲) and detection limits (×) for nondetects (as a function of solids content of sewage sludge) compared with soil screening levels (A, ingestion and dermal) for toxaphene and pentachlorophenol.

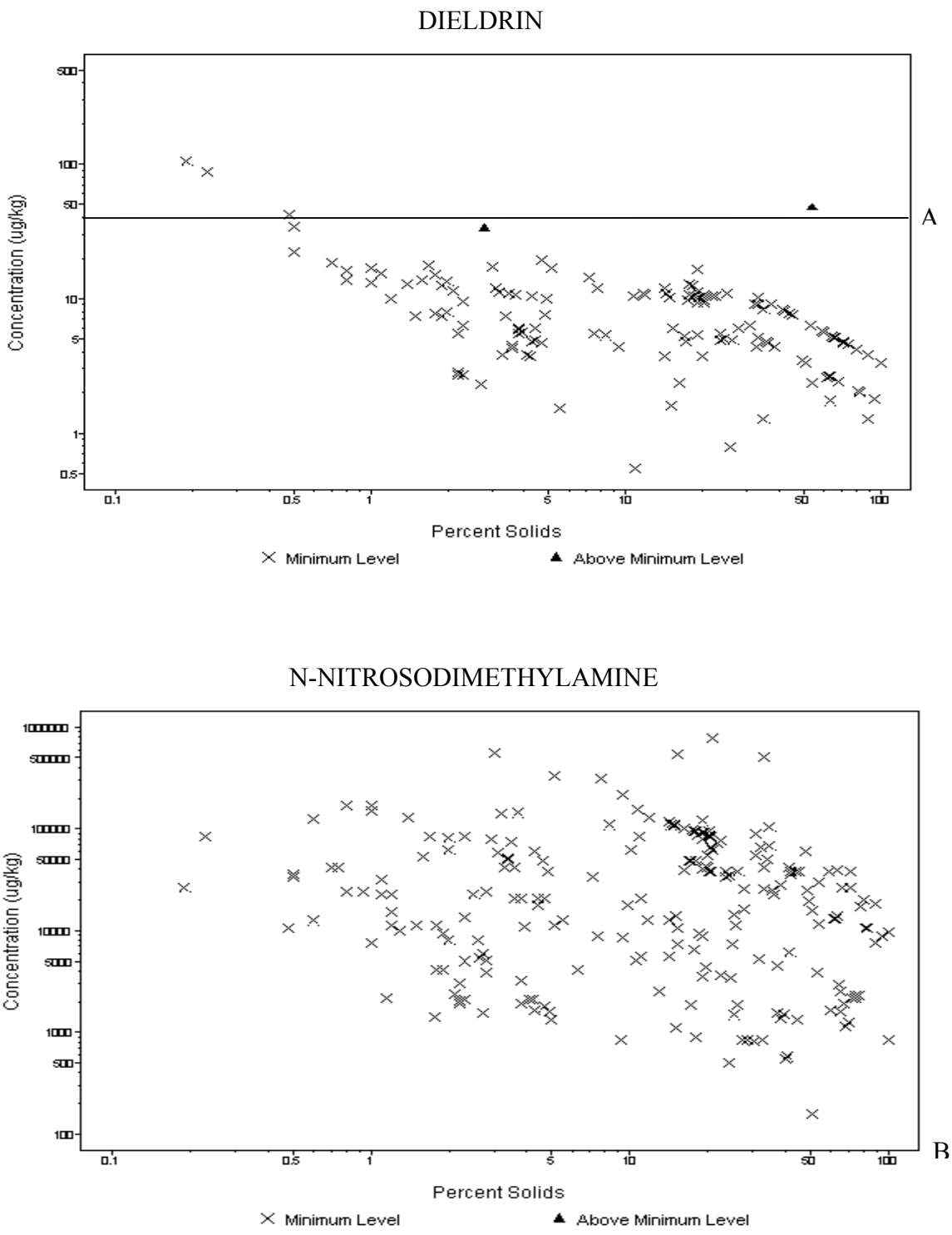


FIGURE 5-4 NSSS data. Detected concentrations (▲) and detection limits (×) for nondetects (as a function of solids content of sewage sludge) compared with the soil screening level for dieldrin and the EPA Region 9 preliminary remediation goal (A, ingestion and dermal) for *n*-nitrosodimethylamine (B, ingestion) (EPA 2002c). Note: the PRG for *n*-nitrosodimethylamine is approximately 1 µg/kg, and could not be shown graphically in the figure.

selected chemicals in sewage sludge as a function of the percent solids in the sample (elevated detection limits were sometimes associated with low percent solids). These values compared with the SSLs[1] show that for some of those chemicals, most sample detection limits exceed the lowest SSL. Thus, the NSSS failed to achieve sufficient detection for four of the eight chemicals, selected as examples, to determine whether they were present at concentrations requiring further evaluation in a risk assessment.

Data regarding detection frequency were used to make critical decisions in Rounds 1 and 2. For example, chemicals were eliminated from consideration in Round 1 if they were detected at a frequency of less than 5% in the NSSS (EPA 1992a) and in Round 2 if detected at a frequency of less than 10% (EPA 1996a). On a national scale a 10% elimination criterion might seem reasonable; however, because of the local use of most biosolids, that criterion could overlook potentially significant site-specific risk.

NSSS data were also used in calculating the hazard screening indexes that determined whether a chemical would be evaluated in a risk assessment. For example, some organic chemicals were excluded from regulation because their concentrations in biosolids were already low enough, and their estimated annual loading to cropland soil would result in an annual pollutant loading rate within allowable risk-based levels. EPA compared the annual pollutant loading rate (APLR) of a specific chemical, based on its 99th percentile concentration in the NSSS, with the annual pollutant loading concentrations calculated by the Part 503 exposure assessment. If the 99th percentile concentration of a pollutant resulted in an APLR less than the loading rate calculated through the risk-based exposure assessment, EPA did not regulate the pollutant. However, as noted by the 1996 NRC committee, the 99th percentile concentrations of four pollutants (PCBs, benzo[*a*]pyrene, hexachlorobenzene, and *N*-nitrosodimethylamine) resulted in calculated APLRs higher than those calculated by the exposure assessment (NRC 1996). The four compounds were eliminated from regulation because they were either no longer manufactured (PCBs and *N*-nitrosodimethylamine) or had a low frequency of detection in the NSSS (benzo[*a*]pyrene and hexachlorobenzene). If these pollutants are present in biosolids at concentrations approaching the 99th percentile, they can pose more of a risk than would be considered acceptable in the exposure assessment.

Additional Chemicals of Potential Concern

A number of contaminants not included in the NSSS have since been identified as biosolids pollutants. Some of these chemicals enter wastewater from industrial releases, but analyses for them are not routinely conducted, whereas other chemicals entering wastewater primarily from domestic releases are not typically included in environmental analyses, which usually focus on industrial chemicals found at hazardous waste sites.

Some categories of chemicals, such as pharmaceuticals, personal-care products, and chemicals added to condition and dewater sewage sludge, that are especially likely to be present in domestic sewage, remain unstudied in biosolids. Only a few studies have been conducted on the wide variety of odorants present in sewage sludge. New data described below and other considerations demonstrate the need for a new hazard assessment of biosolids to expand the suite of chemicals evaluated. Some categories of pollutants in addition to those mentioned above that

[1] When an SSL was unavailable, the EPA Region 9 preliminary remediation goal was used.

should be considered in future assessment are discussed later in this chapter in the section Organic Chemicals.

The Toxics Release Inventory, which tracks the release of over 600 pollutants that are discharged by businesses meeting certain thresholds, documents that pollutants continue to be released to sewer systems from industrial and commercial sources. Although data on a core set of chemicals tracked consistently between 1988 and 1999 show that transfers to publicly owned treatment works (POTWs) substantially decreased (for example, transfer of metals decreased by 65%), trend data between 1995 and 1999 indicate a transfer increase for all tracked chemicals of about 7.6% to POTWs, with greater increases for tracked metals[2] (EPA 2001c). Over the same period, wastewater flows into sewage treatment plants and sewage sludge volumes increased approximately 8.5% (calculated based on data in Appendix A of EPA [1999b]). This suggests that overall industrial discharges to POTWs are increasing at a similar rate as sewage sludge volumes.

Under the Clean Water Act, EPA is required to review the regulations in Part 503 at least every 2 years to identify additional toxic pollutants and promulgate regulations for such pollutants (33 USC Section 1345(d)(2)(C)). A new hazard assessment should include review of new studies from the United States, Canada, Europe, and elsewhere to identify additional pollutants to be evaluated. In addition to evaluating more industrially used chemicals, consideration must be given to identifying and characterizing nonindustrial chemicals that are released into sewer systems (e.g., pharmaceuticals and personal-care products) or added to wastewaters during treatment processes (e.g., dewatering agents).

Data Gaps

Some pollutants and exposure pathways were eliminated in the screening processes and risk assessments when chemical-specific data were insufficient to perform pathway-specific calculations or when toxicity data were insufficient for a given pollutant. For example, a plant uptake factor for lindane was not available, so no assessments were conducted for any pathway that relied on that factor. Thus, the potential risks from lindane via those particular pathways were not assessed. The technical support documents for EPA's Round 1 and Round 2 assessments do not provide a list of data gaps, nor do they specify the chemicals and pathways that were eliminated from consideration because of data gaps. The lack of that information makes it impossible to identify the implications of the data gaps. Lack of information does not equate to lack of risk. Therefore, data gaps should not be used as a criterion for eliminating chemicals from consideration but should be used to identify important areas for future research.

In conclusion, new studies of the contaminant concentrations in biosolids should include evaluation of pollutants, such as surfactants, flame retardants, and pharmaceuticals, not included in previous surveys. Biosolids should be monitored periodically as new pollutants are identified and analytical methods improved. As analytical methods are identified, risk-based screening concentrations should be used to ensure that detection limits are adequate to support risk assessment. Use of a lower frequency of detection to eliminate contaminants from regulation should be considered. Data gaps that result in the inability to assess risks need to be identified so that research can be conducted to fill those gaps.

[2]Transfers of tracked TRI metals increased 31% during this four-year period. It should be noted that the tracked metals are not the same as the inorganic chemicals regulated under the Part 503 rule.

EXPOSURE ASSESSMENT

As described in Chapter 4, exposure assessment is the identification and quantification of potential exposures. For exposure to chemicals to occur, a complete exposure pathway must exist. A complete pathway requires the following elements (EPA 1989):

- A source and mechanism for release of chemicals.
- A transport or retention medium.
- A point of potential human contact (exposure point) with the affected medium.
- An exposure route at the exposure point.

These elements are typically identified in a conceptual site model. If any one of these elements is missing, the pathway is not considered complete. For example, if human activity patterns and the location of human populations relative to the location of an affected medium prevent human contact, then that exposure pathway is not complete. One of the primary differences between the Part 503 rule risk assessment and current risk-assessment practice is that the Part 503 rule risk assessment derived separate risk-based levels for each individual exposure pathway evaluated, whereas current practice is to perform aggregate risk assessments, in which risk-based standards are derived after aggregation of exposures by all pathways to which a single individual is likely to be exposed.

EPA has used a conceptual site model in a new analysis of risks associated with dioxins in biosolids (EPA 2001a). The conceptual site model used by EPA for agricultural application is shown in Figure 5-5. A number of important assumptions that may be questioned are embedded in such a model (e.g., the notion of the buffer zone). However, this figure provides an example of how a conceptual site model illustrates the mechanisms by which contaminants in biosolids are transported from the site of application to a point of contact with a human receptor. For each category of receptor identified, exposures from all identified pathways are summed to provide an estimate of total exposures.

This section reviews the approach used by EPA to select exposure pathways for the Round 1 Part 503 rule risk assessment, describes current EPA exposure-assessment procedures (focusing on multipathway risk assessment), and then attempts to assess the implications of the differences in current versus historical approaches. The final section reviews and compares the historical and current exposure assumptions for pathway-specific parameters and examines methodological issues for derivation of some chemical-specific parameters.

Summary of Approach Used to Select Exposure Pathways

The Part 503 risk assessment evaluated 14 exposure pathways, 9 of which included human pathways (Table 5-4). The human exposure pathways consider direct ingestion of biosolids by a child, ingestion of produce grown on biosolids-amended soil by either a home gardener or consumers buying the produce in stores, ingestion of animal products derived from livestock exposed via food or soil ingestion, inhalation by a farmer of dust or inhalation of vapors containing chemicals released from biosolids-amended soils, and ingestion of fish and water affected by release of chemicals from amended soils. Although these pathways may include the primary exposure pathways for a resident near biosolids-amended fields, EPA did not

FIGURE 5-5 Agricultural application conceptual site model. Source: EPA 2001a.

identify a single common receptor and calculate exposures in such a way that exposure via multiple pathways could be added. The conservatism in the exposure assumptions varies widely in the 503 rule risk assessment. The variability in the conservatism of the assumptions for the various pathways results in the highest risks being associated with the pathway with the most conservative assumptions—that is, the child ingesting undiluted biosolids—rather than the pathways most likely to contribute to exposures. A more robust assessment of potential exposures to contaminants in biosolids would be provided by an aggregate assessment of total exposures from all pathways that a single receptor is likely to encounter. While it is likely that one or two pathways will be the dominant contributors to exposure for any one chemical, the dominant pathways may vary with chemicals and are not always correctly predicted before conducting the risk assessment.

Description of Conceptual Model and Exposure Scenario Approach

For each biosolids-application scenario being evaluated, a conceptual model should be developed to describe the scenarios under which exposures could occur. Agricultural, forestry, and land-reclamation applications may all result in somewhat different conceptual models. A conceptual site model should identify the biosolids source (e.g., biosolids tilled into soil or applied to the surface for agricultural soils), the pathways by which biosolids constituents may be released and transported, and the nature of human contacts with the constituents. The limitations of the assessment should be clearly articulated (e.g., whether exposures are evaluated only after land application), and any exclusion of exposures associated with processing and transporting biosolids should be reported.

The conceptual site model developed for the risk assessment for dioxins in biosolids (EPA 2001a) provides an illustration of this approach for the agricultural application scenario. Although some of the assumptions of the site model are open to question, the model is clearly laid out. The dioxin risk assessment examines exposures of two primary kinds of human receptors: a farm family living adjacent to and downhill from the land-application site (in an area termed a buffer) and a recreational fisher catching fish from a stream downhill from the land-application site. For the farm family, aggregate exposures by the following pathways are assessed:

- Incidental ingestion of soil in the buffer.
- Ingestion of above- and below-ground produce grown on cropland.
- Ingestion of beef and dairy products from a pasture.
- Ingestion of home-produced poultry and eggs from the buffer.
- Inhalation of ambient air (particulates and vapor).
- Ingestion of mother's milk by an infant.

Only chronic exposures to dioxins are evaluated, and one pathway (groundwater ingestion) considered in setting the Part 503 standards is excluded. The inclusion of some pathways and exclusion of others in this focused risk assessment reflects both assumptions about the exposure, such as the absence of a farm pond used for fishing, and the expected behavior of the chemicals being evaluated. Dioxins, dibenzofurans, and coplanar PCBs are persistent lipophilic chemicals that are expected to partition into meat, eggs, and milk but are not expected

to leach to groundwater. Similarly, the focus on chronic exposures is appropriate for persistent chemicals present in biosolids in low concentrations.

In developing a conceptual site model that could form the foundation for a multipathway risk assessment for a great variety of chemicals, it is necessary to think more broadly about the exposure pathways and exposure durations to be evaluated. Consequently, groundwater ingestion and short-term exposures to volatile chemicals should be included in a biosolids risk assessment. Similarly, different application practices, such as forestry, land reclamation, or direct application of biosolids to home gardens by consumers, would require separate conceptual site models.

Evaluation of Exposure Models and Parameters

Estimation of potential exposures to chemicals for the purpose of deriving risk-based concentrations requires theoretical calculations based on understanding how people come into contact with chemicals in environmental media and how chemicals move among various environmental media. These calculations include assumptions for many parameters, beginning with fate and transport models for predicting chemical concentrations in the exposure media. Some of the assumptions for each of the pathways evaluated in the Part 503 rule risk assessment are presented in Table 5-5. Working backward from land application of biosolids, it is necessary to predict chemical concentrations in soil, in plants grown in the soil, in livestock grazed in the fields or fed forage from the fields, and in other media identified in the various exposure pathways. Once chemical concentrations in the exposure media are estimated, assumptions must be made about the values of other parameters that control the degree of exposure to the media. Some of these parameters are specific to the exposure pathway being evaluated. For example, to evaluate incidental ingestion of chemicals in soil, an assumption must be made about the amount of soil a person will ingest. Other parameters are chemical specific, such as the relative bioavailability of a chemical in soil.

In addition, several management requirements in the Part 503 rule could affect predicted chemical concentrations in exposure media. The risk assessments assume compliance with those requirements. Management requirements and compliance with them are discussed in more detail in Chapter 2. The committee found that EPA does not have an adequate program for ensuring compliance with those requirements. Some of the critical management practices and assumptions are discussed in Box 5-1.

As discussed in Chapter 4, there have been several important advances in risk assessment since the Part 503 rule was promulgated. One of the most significant advances in exposure assessment has been the development of probabilistic risk assessment methods that provide a quantitative description of variability and uncertainties in exposure estimates (EPA 2001d). EPA's most recent risk assessment for dioxins in biosolids (EPA 2001a) includes both deterministic and probabilistic risk assessments. In the following sections, the methods and assumptions used to identify exposure parameters in the Part 503 rule risk assessment are reviewed in light of those advances. The assumptions make use of scientific data and knowledge, but policy decisions are inherent in making choices about what estimates to use. While general issues related to exposure parameters are addressed, specific values are not recommended because such values must be identified in the context of the risk assessment being

TABLE 5-5 Exposure Assumptions for the Human Exposure Pathways

Pathway	Assumptions in the Part 503 Rule Risk Assessment
1. Biosolids → Soil → Plant → Human (except home gardener) lifetime ingestion of plants grown on biosolids-amended soil	♦ 2% of vegetables biosolids-amended ♦ Average U.S. diet circa 1980 ♦ Plant uptake coefficient was geometric mean
2. Biosolids → Soil → Plant → Human (home gardener) lifetime ingestion of plants grown in biosolids-amended soil	♦ 59% of most vegetables biosolids-amended ♦ Average nonmetropolitan diet circa 1980 ♦ Biosolids mixed into 15 cm of soil ♦ Plant uptake coefficient was geometric mean ♦ 70 kg of body weight
3. Biosolids → Human (child) ingesting biosolids	♦ Child ingests 200 mg/d for 5 yr ♦ Soil ingested is undiluted biosolids ♦ Contaminants are 100% bioavailable
4. Biosolids → Soil → Plant → Animal → Human lifetime ingestion of animal products (animals raised on forage grown on biosolids-amended soil)	♦ Average nonmetropolitan diet circa 1980 ♦ Biosolids mixed into 15 cm of soil ♦ Average nonmetropolitan percent of animals raised at home and thus exposed to biosolids ♦ Uptake coefficient into animals is geometric mean of data ♦ 100% of forage grown on biosolids-amended soil ♦ 70 kg of body weight
5. Biosolids → Soil → Animal → Human lifetime ingestion of animals products (animals ingest biosolids directly)	♦ 1.5% animal diet is soil ♦ Soil is undiluted biosolids ♦ Uptake coefficient into animals is geometric mean ♦ Animal exposed 1 yr out of 3 ♦ 70 kg of body weight
11. Biosolids → Soil → Airborne Dust → Human lifetime inhalation of particles (dust) (e.g., tractor driver tilling a field)	♦ Tractor operator (did not assess mine reclamation land applicators or residents) ♦ Dust level representing NIOSH occupational standard is acceptable ♦ Dust is biosolids diluted with soil ♦ Receptor will not be exposed to >10 mg/m^3 (the OSHA standard at which it is assumed farmer will be in an enclosed cab)
12. Biosolids → Soil → Surface Water → Human lifetime drinking surface water and ingesting fish containing pollutants in biosolids	♦ Person drinking 2 L/d ♦ Person eating 40 g/d of fish ♦ 0.24% of watershed is biosolids-amended soil ♦ Average erosion rates ♦ Eroded materials are diluted with soil ♦ Contaminant concentrations in eroded materials are reduced through leaching and volatilization ♦ 70 kg of body weight
13. Biosolids → Soil → Air → Human lifetime inhalation of pollutants in biosolids that volatilized to air	♦ Receptor lives 1.6 km downwind ♦ 20 m^3/d inhalation rate ♦ Biosolids diluted with soil ♦ 4.5 m/s wind speed ♦ 15°C temp
14. Biosolids → Soil → Groundwater → Human lifetime drinking well water containing pollutants from biosolids that leached from soil to groundwater	♦ Well immediately down gradient ♦ High dilution and attenuation (chemical-specific values) ♦ 1 m depth to groundwater ♦ Partition coefficients from lab experiment with sandy loam, pH 8, aerobically digested biosolids ♦ 0.5 m/yr recharge ♦ 70 yr of exposure ♦ 70 kg of body weight

Abbreviations: NIOSH, National Institute for Occupational Safety and Health; OSHA, Occupational Safety and Health Administration. Source: EPA 1992a.

BOX 5-1 Management Practices and Assumptions

Management Practices

- Biosolids shall not be applied to land if it is likely to adversely affect a threatened or endangered species or its designated critical habitat.
- Biosolids cannot be applied to flooded, frozen, or snow-covered land in such a way that bulk biosolids enter a wetland or other waters of the United States unless allowed in a permit. The implementation of this requirement is unclear.
- A 10-meter setback from watercourses is required for biosolids not meeting Class A and vector attraction reduction requirements and pollutant-concentration limits.
- Regulations require that bulk biosolids be applied to agricultural fields, forests, and public contact sites at a rate equal to or less than the nitrogen-based agronomic rate. This requirement also applies to reclamation sites unless otherwise approved by the permit authority. It is not applicable to bagged products or bulk application of Class A biosolids meeting pollutant-concentration limits.

Management Assumptions

- EPA (1992a) states that surface application is normally limited to slopes of 6% or less to reduce surface runoff. That is not a requirement, and how or whether that slope limitation was used in the biosolids risk assessments is unclear.
- Field storage of biosolids at the site of land application is a common practice that is allowed under the 503 rules. Recognizing the potential for stockpiling and field storage to cause problems, including odors, EPA developed nonregulatory guidance (EPA 2000). The Part 503 risk assessments and rules do not address stockpiling.
- Tile drains (drainage pipes installed at shallow depths in agricultural fields) are common in some portions of the United States. Designed to dry out soils, these drains provide conduits for the rapid movement of contaminants from land-applied biosolids into surface waters. The Part 503 risk assessments and rules did not consider the potential for this type of exposure.
- Different methods of biosolids application are not addressed and may have different implications for risks, particularly those associated with airborne emissions.

conducted. Similarly, no recommendation is made regarding using deterministic or probabilistic approaches because the relative utility of these approaches varies (EPA 2001d).

HEI Receptor Versus RME Receptor

One of the most critical policy decisions in conducting the biosolids risk assessments was the decision to use the highly exposed individual (HEI) as the receptor of concern (EPA 1992a). The HEI is an individual who remains for an extended period at or adjacent to the site where maximum exposure occurs. Current practice is to use a reasonable maximum exposure (RME) receptor. EPA (1989) specifies that calculation of the RME in a deterministic risk assessment requires a combination of average and upper-bound values for various exposure parameters so that the final exposure estimate will be an upper-bound exposure with a reasonable expectation of occurrence. This calculation is commonly interpreted to be a 90th to 95th percentile of exposures for each pathway. For some exposure pathways, the use of more than one or two upper-bound exposure parameters might result in exposure estimates with no reasonable expectation of occurrence. Thus, the impact of multiple conservative assumptions must be evaluated carefully. For probabilistic risk assessment, risks corresponding to the 90th to 99.9th percentiles of the risk distribution are considered plausible high-end risks for selection of the

RME (EPA 2001d). However, EPA notes that very high percentiles may be numerically unstable, and should only be used if reproducible.

The goal of the Part 503 rule is to establish pollutant limits that are protective of reasonably anticipated adverse effects. But this standard should be applied to all settings, to all biosolids, and to all land-application practices that are reasonably anticipated to occur. That goal necessitates assessing risks under the most sensitive exposure setting that is likely to occur. For example, a farm family living near a land-application site may produce much of their own food and have exposures via multiple pathways. In addition, parameters that are linked should be identified, and those links should be maintained throughout the risk assessment. For example, in the revised risk assessment for dioxins in biosolids (EPA 2001a), dioxin and PCB congener data were linked within samples, and those links were maintained throughout the probabilistic risk assessment.

Determination of Chemical Concentrations in Exposure Media

Most of the exposure pathways evaluated by EPA require that chemical concentrations be estimated in one or more exposure media. The exposure media for which concentrations were estimated in the Part 503 rule risk assessment are soil, plants, livestock, airborne dust, vapors, surface water, fish, and groundwater. Estimates of chemical concentrations in those media are based on a number of assumptions, such as assumptions about chemical fate and transport. This section reviews one of the more important assumptions about chemical fate (mass balance and distribution of contaminants) and evaluates EPA's approach to estimating concentrations in environmental media. Special emphasis is given to the determination of soil and plant concentrations. This section is followed by a brief assessment of assumptions about human intake parameters.

Mass Balance and Distribution of Contaminants

For pathways involving exposure via surface water, air, or groundwater (Pathways 12-14), losses of pollutant mass from soil due to partitioning to other media are assumed by EPA. For example, pollutant mass losses from soil are assumed to occur to surface water through erosion, to air through volatilization, and to groundwater through leaching. For organic chemicals, it is assumed that degradation occurs and that degradation products are nontoxic, an assumption that is not universally true. In assessing risk via these pathways, the assumption is made that pollutant mass is conserved. Thus, for example, the amount of a pollutant in sediment eroded from a site is adjusted to account for the amount that is predicted to be removed because of leaching, degradation, and volatilization. Many of these estimates are based on models that make a number of assumptions on scant data, resulting in a high degree of uncertainty. For example, data on partition coefficients for specific chemicals were based on a single study of only one type of biosolids (see discussion below).

Soil Concentrations

Most of EPA's exposure pathways begin with estimated soil concentrations resulting from the mixing of biosolids into soil, the exceptions being Pathway 3 (inadvertent direct ingestion of biosolids) and Pathway 5 (biosolids applied to pastures and not mixed with soil). Consequently, the accuracy of the exposure assessment is highly dependent on the accuracy of the predicted soil concentrations. These predictions are based on assumptions regarding the incorporation of biosolids into soil and the depth of the incorporation; chemical retention in soils; and the frequency, duration, and loading rates of application.

Incorporation. In exposure scenarios in which biosolids are incorporated into soil, EPA's risk assessment assumed a tillage depth of 15 centimeters (cm). The revised dioxin risk assessment assumes 20 cm (EPA 2001a). However, 10 cm has been proposed as a more realistic figure when biosolids are incorporated by disking rather than plowing (Versar, Inc. 2000), and for home gardens, hand tillage could be shallower than 15 cm. Surface application without incorporation is typical in some scenarios, such as pasture-land application or conservation tillage.

Retention. Inorganic chemicals in biosolids were assumed to stay in soil for all pathways except Pathways 12-14, where a mass-balance approach was used to predict soil concentrations. Retention or release of metals and organic contaminants in soils is highly dependent on the characteristics of the contaminants; the mineralogical composition of the biosolids and the soil to which it is applied; and the pH, wetting and drying, and ionic strength of the soil solution.

Soils that are sandy and that contain low amounts of clay and organic matter (e.g., those in the Atlantic Coastal Plain Region) will have less capacity to retain metals and organic chemicals than those that have high amounts of clay and organic matter. The latter soils are often accompanied by metal oxide coatings electrostatically bound to the clay minerals and organic matter, enhancing the soil's ability to retain contaminants. In higher clay and organic-matter soils, metals and organic chemicals can be strongly bound and resistant to release into groundwaters. Organic matter is especially important in the retention of organic contaminants.

In many instances, an "aging" effect is observed with metals, oxyanions, and organic chemicals in soils—that is, the longer the time of contact between the contaminant and the soil, the more sequestered the contaminant. It is well documented that with many organic chemicals, the release of the chemical and its bioavailability is greatly diminished as time in soil increases (Alexander 2000; Pignatello 1999**;** Young et al. 2001). The aging effect with organic chemicals has been largely ascribed to interparticle diffusion into the organic matter of the soil. The aging effect has also been observed with such metals as cadmium, zinc, cobalt, and nickel (Barrow 1998; McLaren et al. 1998; Scheckel et al. 2000). This effect has been attributed to diffusion into the inorganic components of the soils, inner-sphere complex interactions, and surface precipitation. It should not be assumed that the aging effect precludes release of chemicals from soil. For example, certain metals, including cadmium, molybdenum, and zinc, show continued availability for plant uptake from biosolids-amended sites despite aging (McBride et al. 1997; McGrath et al. 2000; Broos et al. 2001).

The aging effect must be considered when predicting the fate of contaminants in biosolids in soils and waters. Traditionally, partition coefficients (Kps) are based on a 24-h reaction time; however, if the rates of retention and release are slow and a residence time effect is pronounced, the Kp values can be greatly underestimated when a 24-h reaction time is

assumed in the calculation. Consequently, the mobility of the contaminant would be overpredicted.

Application Rates and Duration. The Part 503 rule addresses several application scenarios, including agricultural use, silvicultural use, and land reclamation. Different biosolids-application techniques are used in these scenarios and can affect the resulting contaminant concentrations in soils. For example, the rate of application at reclamation sites is usually much higher than that at agricultural sites, although reclamation applications typically involve one-time or limited-time applications rather than repeated applications. Estimates of application rates were based on data from the NSSS (EPA 1990) and are presented in Table 5-6. The number of applications before regulatory cumulative pollutant loading rates are reached at these application rates is approximately 13, 32, 55, and 100 years for reclamation, public contact, forest, and agricultural uses, respectively (EPA 1992a). EPA based its chemical standards on biosolids application to agricultural land for 100 years, which was considered applicable to the other types of land applications that would not occur as routinely or for as long a duration.

TABLE 5-6 Estimated Biosolids Application Rates for Different Scenarios

Scenario	Number of Observations	Mean Application Rate, metric tons/ha/y, DW	Standard Deviation	75th Percentile, metric tons /ha/y, DW
Agricultural	87	6.8	105	16
Forest	2	26	26	34
Public contact	11	19	122	125
Reclamation	7	74	148	101

Abbreviation: DW, dry weight. Source: EPA 1992b.

Plant Concentrations

Plant uptake of metals from biosolids-amended soils is another important factor in several of the exposure pathways. To determine plant uptake, EPA (1992a) derived plant uptake coefficients (UCs) for each pollutant. A UC is the uptake-response slope of a pollutant in plant tissue for each food group and is estimated by the increase in pollutant in plant tissue for each kilogram of pollutant added to the soil from biosolids. Five main steps were used to estimate UCs: (1) the primary literature was reviewed and evaluated; (2) the relevant data were compiled in a database; (3) the uptake slope for each study was calculated by linear regression of the concentration of the pollutant in plant tissue against the application rate of the pollutant; (4) the plants were placed in categories (e.g., leafy vegetables and garden fruits); and (5) the uptake slope of each plant group was calculated for each pollutant by using the geometric mean of the uptake slopes from relevant studies.

The likely concentrations of the pollutant in food groups were then calculated for the risk assessment by using information on the amount of soil contamination and the UC. Data for those calculations were derived from three categories of studies: (1) field studies of biosolids, (2) non-field studies of biosolids (greenhouse or potted) or field studies with biosolids spiked with additional metals, and (3) studies of metal salts, metal-contaminated soils, or mine tailings. Obviously, the first category of studies was the most relevant to the risk assessments. Studies have unequivocally demonstrated that greenhouse or potted plants and added inorganic metal

salts do not mimic the characteristics of metals within biosolids. Such studies are irrelevant to real land application of biosolids. For the metals regulated on the basis of human health, the UCs were based on field studies for cadmium, field and nonfield studies for selenium and mercury, and primarily studies of metal salts, metal-contaminated soils, or mine tailings for arsenic.

Factors affecting the estimates of UCs and limitations in the UCs selected due to the variation in bioavailability of metals to plants in different situations are discussed below.

Plant Response to Metals. Some field-plot experiments with biosolids show that plant concentrations of some metals do not increase with high rates of biosolids application (Corey et al. 1987; Mahler et al. 1987; Chaney and Ryan 1994). EPA (1992a, 1995) attributes that observation to the binding of metals by biosolids and uses it to support the concept of a plateau response in plant uptake. (The rate of pollutant uptake by plants in the biosolids-soil mixture decreases with increasing biosolids loadings, because adsorptive materials in the biosolids become as important as or more important than the adsorptive materials initially in the soil.) One of the main limitations of the available database is that the data are insufficient to separately characterize the changes in uptake with the metal concentration at a constant biosolids loading rate as compared with the changes in uptake with increasing biosolids loading. Accurate prediction of plant concentrations requires both characterizations.

EPA used a linear-response, rather than a plateau-response, assumption for the low biosolids loading linear portion of the uptake curve in its risk assessments, because it was a conservative approach and assumed that the linear response would overestimate pollutant uptake by plants. EPA's assertion that metals bind to biosolids and are thus less available for plant uptake should be validated using the latest direct molecular scale techniques. That assumption does not consider the extent to which the proposed binding is reversible (Bell et al. 1991). If soil conditions and land use change, such as the soil acidifying when organic matter decays, uptake could increase (Heckman et al. 1987; Mulchi et al. 1987a,b; Bell et al. 1988; Adamu et al. 1989; Chaney 1990), although this was not the case for cadmium uptake by lettuce after 13-15 years in one experiment (Brown et al. 1998). Other researchers believe that the plateau effect could be due to plant physiological factors rather than attenuation due to biosolids chemistry (Hamon et al. 1999). If that is the case, the conservatism of the linear assumption will depend on the metal concentration at the plateau as compared with the concentration used in the biosolids standards. For example, Sloan et al. (1997) show some evidence of curve linearity in uptake of cadmium by lettuce above about 8 mg/kg of cadmium in soil.

EPA pointed out that the linear approach underestimates the UC at low concentrations. As the metal concentrations in biosolids have been reduced and result in low-end concentrations in soil, EPA's approach may underestimate uptake. Thus, any further risk assessment should focus on plant uptake over the likely loading rates and range of soil concentrations resulting from biosolids applications in practice. In addition, other explanations for a plateau effect should be investigated. For example, higher rates of biosolids application might have other effects, such as increasing soil pH or enhancing plant growth, which results in the "growth dilution" effect on metal concentrations.

Many studies on plant uptake of metals have been published since the risk assessments were conducted for the Part 503 rule. Some of the most relevant studies to review are those of Sauerbeck and Lübben (1991), McGrath et al. (2000), Chang et al. (1997), Logan et al. (1997), Sloan et al. (1997), Brown et al. (1996, 1998), and Chaudri et al. (2001).

Older data on trace elements in soils and plants must be carefully evaluated, as most of those data were derived using analytical methods that had higher detection limits than those that are characteristic of methods used today. Error in crop analyses of low-concentration cadmium, mercury, and lead is well documented (Tahvonen 1996). Those errors may be associated with the high values observed in crops grown on some control plots used for UC calculations in the EPA database. Erroneously high values for controls have the effect of decreasing the slope of the UC. Real UCs may be higher if accurate measurements on control plots are used (McBride 1998).

Finally, the observed concentration in plant materials used as food, including both above- and below-ground produce, is assumed in the above studies to be derived from actual uptake into the tissues. However, dust and soil particles can be deposited on plant surfaces by wind, harvesting, and soil "splash" after rain. In the case of metals, especially those that are relatively insoluble in soil, these particles may become included in the plant tissue (Preer et al. 1984). This "entrapment" can be a substantial proportion of the concentration of leafy or root vegetables (e.g., up to 5% of dry weight of leafy greens may be soil particles) (Cary et al. 1994). Although these particles may not be strictly taken up into the tissues, they strongly adhere and are not efficiently washed off during food preparation. Consequently, the metals in soil embedded in plant tissue will be included in estimated plant metal concentrations.

Exposure to Plants. In the database used by EPA (1992a,b) to derive UCs, some experiments have concentrations measured in the topsoil of each experimental rate, whereas others were not measured and recorded only the loading of metal added to the soil. EPA used metal loading rates to calculate plant uptake of metals for all studies, necessitating conversion to loadings for those with concentrations given by multiplying the concentration by the weight of topsoil. The studies that gave loading rates rather than soil concentrations have several problems associated with their use. First, loading assumes that all the metals remain on the plot for the duration of the experiment. That assumption ignores two factors: leaching losses (McBride et al. 1997, 1999; Barbarick et al 1998; Richards et al. 1998) and physical movement of soil laterally due to cultivation. Both factors have the effect of decreasing the actual concentrations of metals that plants are exposed to and make the plant uptake slopes less steep. Only those studies in the database for which actual soil concentrations were recorded avoid this underestimation. Second, in the mainly short-term experiments that constitute the majority of the evidence, plant roots respond to the concentration of metals in their environment and not to loading rates. That factor is important for assessing exposure. For example, in the short-term studies typical of the experiments used for the risk assessment, if biosolids were surface applied and not incorporated into the soil, the roots might not have been exposed to the full metal concentration. Alternatively, if the biosolids were ploughed deeper than the assumed 15 cm, crop roots would be exposed to a smaller concentration than anticipated.

Soil concentrations of metals are therefore better estimates of exposure to plants than loading rates. However, several additional factors must be taken into consideration when using soil concentrations or loadings. The rate at which metal concentrations in experimental field plots decrease due to cultivation and dispersion is proportional to the plot size, the repetition of application, the number of cultivations, and the amount of control soil surrounding each plot and the difference in concentration (Sibbesen and Andersen 1985; Sibbesen et al. 1985; Sibbesen 1986; McGrath and Lane 1989; Berti and Jacobs 1998; Sloan et al. 1998). If a metal is added once or only on a few occasions, the concentration within the original treated area declines particularly rapidly with increasing number of cultivations on small experimental plots (McGrath

and Lane 1989; Berti and Jacobs 1998). Decreasing metal concentrations in soil has the effect of making the dose-response curve for plant uptake steeper, as illustrated in Figure 5-6. The data in Table 5-7 show that 50:50 mixing of a biosolids-treated soil results in a plant uptake slope that is twice that when cultivation effects are ignored.

Another effect of mixing due to cultivation is the increase in metal concentrations in nearby control plots. That effect might be another explanation for the unusually high concentrations of metals in plants from some of the control treatments in the database. Lack of proper controls may have made some of the reported UC curves shallower and underestimated the real UC values (McBride 1998). This may not be as important in the few experiments that used large treatment plots (e.g., 30 × 73 meter plots used by Sloan et al. [1998]).

Calculations. Two basic methods were used for calculating plant uptake slopes:

1. For studies in which one metal application rate and one plant tissue concentration were given, the following algorithm was used:

$$UC = \frac{\text{Tissue Concentration (microgram of pollutant/gram of plant tissue, dry weight)}}{\text{Metal Application Rate (kilogram of pollutant/hectare of land, dry weight)}}$$

2. For studies in which multiple application rates and tissue concentrations were given, the slope was determined by least-squares linear regression.

The first method is not an accurate method of measuring an uptake slope, as a full response curve is not used. The second method also has problems. For example, using data on cadmium in spinach, EPA fitted a linear function for five data points. The "best-fit" line for those data points resulted in an intercept for cadmium at nearly 10 mg/kg in spinach. The control (no biosolids added) was in fact only 5 mg/kg. The effect of that difference is to make the UC slope 0.40 (less steep than if the four data points had been treated separately in the same way as the single-point UC calculations), resulting in UCs of 1.75, 1.75, 0.75, and 0.45.

EPA grouped crop species into seven categories and used the geometric mean of all available UC data on metals from field experiments for each of those crop groups. There are a number of reasons why the geometric mean may not be the appropriate statistic to use to represent these data. In many cases, an arithmetic mean will best approximate exposure for use in risk assessment. EPA should reexamine the statistic used to represent the UC after considering the risk assessment goals (i.e., identifying a reasonable maximum exposure [RME]) and the causes of variation in the data set. The number of data points used by EPA to determine the geometric mean UC value varies significantly for each pollutant, with only four points available for arsenic and 167 available for cadmium. Data included a range of study conditions, including varied pH. Obviously, if the data set is very small, the causes of variation will be difficult to elucidate. However, for the large data sets, such as the one for cadmium, a more sophisticated evaluation of the causes of variation should be possible, and should be used to derive the most appropriate statistic for the risk assessment.

Within a category, such as leafy vegetables, results were not weighted according to the fraction of diet. Thus, for example, cadmium uptake into leafy vegetables constitutes a major component of the potential dietary dose of cadmium. Data on crucifers compose a high proportion of the available data, yet most diets contain a lower fraction of crucifers than lettuce.

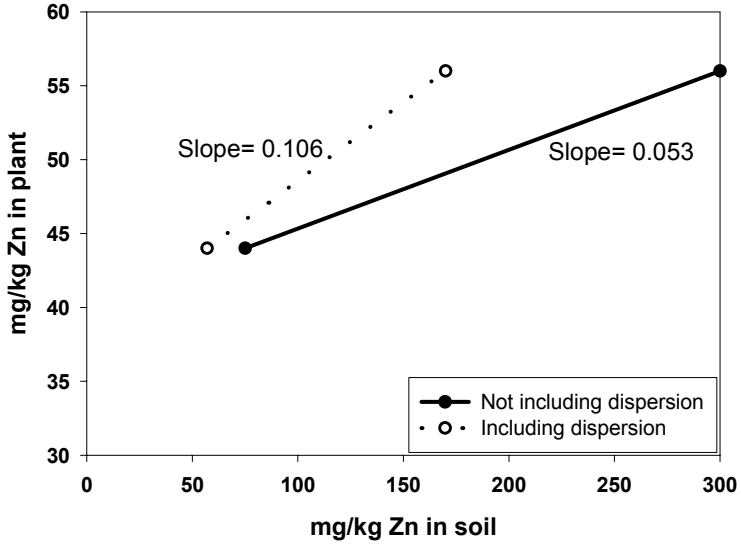


FIGURE 5-6 Effect of dilution of soil zince concentration by cultivation (data from Table 5-7).

TABLE 5-7 Effect of Soil Mixing on Actual Soil Concentrations Due to Cultivation of Field Experimental Plots

	Biosolids rate 1	Biosolids rate 2
Metal in plant (mg/kg of dry weight)	44	56
Soil (mg/kg), calculated from the loading[a]	75	300
Soil (mg/kg) actual[b]	57.5	170

[a]Loadings 150 and 600 kg/ha, both divided by 2 to account for mixing to 15 cm in soil of 1.33 density (EPA 1992a). UC = 12/(300 - 75) = 0.05.

[b]Loadings assumed to be 50:50 mixed with surrounding control soil with 40 mg/kg background concentration, so actual concentrations (75 + 40)/2 = 57.5 and (300 + 40)/2 = 170. UC = 12/(170 - 57.5) = 0.11.

The UC for cadmium into crucifers is generally much lower than the UC for lettuce. Thus, taking the geometric mean of available data gives greater weight to the lower-UC crucifers than lettuce. Weighting the UCs by the fraction of diet would give a more representative UC for dietary exposures.

Environmental and Crop Considerations. A variety of environmental factors affect contaminant bioavailability, including soil organic matter, buffering capacity, oxide content, pH, temperature, and rainfall. In addition, different crops and even different cultivars of the same crop type vary greatly in their tendency to take up pollutants from the soil. That variation highlights the importance of considering regional variations in environmental conditions and crop types when assessing plant uptake assumptions for national applications.

EPA recognized that soil pH has a significant influence, the uptake of metal cations generally being higher at lower pH and the uptake of such anions as arsenate and molybdate being higher at higher pH. EPA also indicated that the data set considered included studies with pH as low as 4.5. However, pH differences between untreated controls and biosolids-treated plots might also be another contributory reason for the apparent plateau effect in the relationship between loading and crop uptake. Compared with control soil pH, biosolids soil pH frequently increases after initial application of biosolids, especially when lime is part of the treatment process. However, that effect does not persist, and pH can fall by 1-1.5 units because of leaching of cations and the mineralization of the added organic matter (Chaney et al. 1977). In the database, the duration of many of the experiments is restricted to a few years after biosolids are applied, and that might also underestimate the UC slopes for many metals.

EPA stated that agricultural biosolids-applied soils rarely have a pH below 5.5. That is true, but taking the median calculated UC from the data collected tends to have the effect of biasing the effective UC to the near-neutral pH range (Stern 1993). Because the risk assessment does not take into account pH and instead sets allowable loading for all soils, this approach relies on the practice of maintaining pH at near neutral values for crop production reasons.

Cadmium, zinc, and chloride in soil have important effects on crop uptake and consequences for human or animal nutrition (Chaney et al. 1998; Reeves and Chaney 2001). Zinc in soil has a competitive effect on cadmium uptake by crops, thus reducing cadmium uptake, whereas chloride ions (present in saline soils or derived from irrigation water) preferentially increase cadmium mobility and crop uptake compared to zinc (McLaughlin et al. 1994; Chaney et al. 1998). In earlier experiments that were used in the original risk assessment database, zinc was, of course, present when cadmium uptake was studied.

Livestock Concentrations

EPA used assumptions about transfer of pollutants from biosolids to livestock and resulting human exposures to contaminants in meat, organ meat, poultry, dairy products, and eggs in its screening process for identifying pollutants to regulate and in its risk assessments for Pathways 4 and 5 (human consumption of animal products affected by chemicals taken up into forage from biosolids or by direct ingestion of biosolids). It is not clear why these two pathways were not combined to estimate chemical concentrations in livestock because of both soil ingestion and plant ingestion. A much more appropriate integrated approach was used by EPA in the revised risk assessment for dioxins in biosolids (EPA 2001a) and in the dioxin reassessment (EPA 2000a). This approach, developed by Fries and Paustenbach (1990),

involves the prediction of chemical concentrations in livestock based on the proportions of soil, grass, and feed in dry-matter intake.

In the initial screening process to select contaminants for detailed risk assessment, biosolids intake by livestock was assumed to be 5% of diet (presumably dry matter), even though intake could be 10% from a combination of adherence to forage crops and direct ingestion of treated soil (EPA 1985). In the pathway-specific risk assessments used to develop the Part 503 rule, EPA (1992a) assumed that 1.5% of a grazing animal's diet is biosolids. That value was based on the assumption that biosolids are applied to pasture once every 3 years and that biosolids intake is 2.5% of diet in the year of application and 1% in the other 2 years.

Assumptions about pollutant intake due to biosolids should be based on estimated pollutant concentrations in soil, pollutant uptake into crops, soil intake by livestock, and the relative bioavailability of the pollutant in soil relative to the bioavailability in forage. The proportion of biosolids in ingested soil is variable, depending on the type and form of biosolids application, climate, grazing habits, percent of time spent in pasture, percent of diet obtained from pasture, season, and management conditions. Soil ingestion by cattle feeding on pasture can range from 1% to 18% of the diet, depending on the growing season and climate (Fries 1995), and sheep might ingest as much as 30%, depending on the seasonal supply of grass and grazing management (Thornton and Abrahams 1983). On average, soil is estimated to comprise about 6% of the total dry matter intake of most grazing stock (Fries 1995; Wild et al. 1994). In risk-assessment documents, EPA (1998, 2000a, 2001a) assumed that soil ingested by cattle averages 4% of diet dry matter, and soil ingested by dairy cattle averages 2-3% of diet, because dairy cows spend less time in pasture. For uptake of pollutants from soil into animal tissue, a relative bioavailability factor is needed to adjust for differences in the relative bioavailability of a chemical in soil as compared with that in forage. In 1998, EPA suggested using a default assumption of 1 (no difference in bioavailability) in the absence of more specific supporting data. In risk assessments for dioxins (EPA 2000a, 2001a), default values of less than 1 were used (e.g., 0.65 for the relative bioavailability of dioxins in soil to cattle). In the Part 503 rule risk assessment, bioavailability was calculated as the geometric mean of values obtained from research literature. The appropriate statistic to use should be selected in the context of characterizing RME exposures.

In addition to direct ingestion of biosolids applied to soil, biosolids sprayed onto forage adhere to plant surfaces. It is important that pollutants in biosolids sprayed onto and adhering to crops be included in the forage chemical concentrations.

Air Concentrations

Exposure to biosolids pollutants in air is considered in Pathway 11 (airborne dusts) and Pathway 13 (volatilization from soil). Critical parameters that influence air concentrations of pollutants, such as wind velocity and temperature, should be reconsidered. EPA (1992a) used a "typical" wind speed of 4.5 m/s in its risk assessments, but data from the National Oceanic and Atmospheric Administration (NOAA 2000a) show that at 115 of 275 locations in the United States for which long-term data are collected, average annual wind speeds exceed 4.5 m/s. For air temperature, EPA used a national annual average of 15ºC, but average daily temperatures are higher than that for approximately one-third of the United States (NOAA 2000b). The revised risk assessment for dioxins in biosolids (EPA 2001a) addressed regional differences by relying

on a database that divides the country into 41 distinct regions on the basis of climate and other factors. Meteorological data from each region were used in the risk assessment to predict a distribution of annual average air concentrations. Whether average values are appropriate in assessing risks is subject to question; however, the use of regional data as part of a probabilistic assessment is a useful approach.

Biosolids are generally spread during the growing season and not under winter conditions. Therefore, warmer temperatures and higher rates of volatilization would be expected at the time biosolids are applied. This issue will be particularly important in the valuation of short-term exposures. For these exposures, risks posed under high-wind and high-temperature conditions should be assessed.

Surface-Water Concentrations

Calculations of the concentration of contaminants in surface water rest on several assumptions, including watershed ratio, contaminant load from sediments, and dilution. EPA's risk assessment for Pathway 12 (human drinking water and ingesting fish from surface water contaminated by biosolids) assumed that the biosolids-amended area is 1,074 ha, which is based on data from the NSSS (90th percentile for the size of agricultural areas used by publicly owned treatment works). The water body for which risks were assessed was assumed to have a watershed of 440,300 ha (mean watershed size for the United States), an area greater than the size of Rhode Island and representing a fifth- to sixth-order stream. Only 0.24% of the watershed is thus assumed to receive biosolids. EPA (1998) protocol suggested that the impacts on farm ponds be assessed, because the farm family might be exposed through fishing and swimming. In the EPA (2001a) reassessment of risks for dioxins in biosolids, a much smaller, third-order stream was assumed, and chemicals were assumed to enter the stream via wet and dry deposition from air and via runoff and erosion from the local (farm with agricultural fields and a buffer zone) and regional watersheds. It is not clear, however, what proportion of the watershed was assumed to receive biosolids.

In the original assessment of exposures from surface water, EPA assumed that the entire watershed is agricultural and that soil loss is the same throughout the watershed. It is also assumed that all pollutants in the receiving stream are from biosolids and that no other pollutants enter the stream. For a watershed as large as that postulated, significant portions are likely to be forested areas that have lower erosion rates than agricultural areas, and other areas will be paved, increasing storm runoff and erosion. Thus, a higher proportion of the sediment in receiving water would be from agricultural areas, including those amended with biosolids. For a large watershed, other sources of pollutants would be expected.

The Part 503 rule risk assessment used an average soil loss estimated from agricultural lands of 8.5 metric tons (mt)/ha-y. This rate appears to be low, as the average annual soil loss has been measured to be 3.57 ± 5.64 kg/square meters, and loss of 8.5 mt/ha-year was below the 50th percentile for measured rates (Risse et al. 1993). Sand was used as a worst-case soil type in the 503 risk assessment. Although sand would be a worst case for leaching, it would not necessarily be that for erosion (Brady and Weil 1999). Also, no consideration was given to heavy rainfall events. Many of these issues could be appropriately addressed by using a probabilistic surface-water model.

In estimating the amount of pollutant available via surface water, the total concentration in biosolids is reduced by estimating the fractions lost through leaching, volatilization, and degradation (see earlier discussion of mass balance). The eroded material, thus adjusted, is assumed to be biosolids diluted with soil because of tilling into the top 15 cm of soil. For surface application, such as that on pastures or in conservation tillage scenarios, that assumption would not be valid. In the draft reevaluation of dioxins in biosolids, EPA (2001a) assumed that over time biosolids are mixed with the top 2 cm of soil in pastures; however, it is not clear whether or how this assumption was incorporated into the runoff and erosion model.

Groundwater Concentrations

Prediction of groundwater concentrations that might result from biosolids application requires modeling and making assumptions about critical parameters, such as the partition coefficient, leaching, and dilution and attenuation. Partition coefficients are used in the Part 503 rule risk assessment to estimate the proportion of a contaminant that dissolves and is thus leachable. Partition coefficient values for the regulated contaminants were taken from the work of Gerritse et al. (1982), who studied only one type of biosolids and several soil types. Recent studies suggest that processing methods for biosolids have an influence on metal mobilities (Richards et al. 1997, 2000), as does pH and soil type. A single partition coefficient based on a single type of aerobically digested biosolids and on a sandy loam soil of pH 8 was used for each contaminant in the risk assessment. Some contaminants, such as cadmium, show much greater movement at lower pH and in sands. Thus, the partition coefficients used by EPA are not necessarily representative of the range of conditions that exist in the United States.

Leaching calculations are based on a model of contaminant movement through soil. However, there are several limitations of the model used, including failure to account for rapid transport through preferential flow paths and for facilitated transport of contaminants in association with organic constituents (McCarthy and Zachara 1989). For a number of inorganic and organic contaminants, evidence indicates that leaching might be greatest immediately after application (Beck et al. 1996; Richards et al. 2000). More accurate modeling is needed to estimate rates of leaching. Soil-screening guidance (EPA 1996b) pertaining to groundwater impacts from leaching suggests a dilution and attenuation factor of 1 or 20 in initial screening evaluations. EPA noted that those values can be used at sites with shallow water tables, fractured media, or karst topography. However, in the Part 503 rule risk assessment, much higher dilution factors appear to have been used. In the example given by EPA, a DAF of 152 was used in evaluating arsenic in groundwater.

Groundwater conditions vary greatly throughout the United States. For the Part 503 rule to be applicable nationwide, reasonable worst-case scenarios, such as areas with karst or gravel conditions, need to be evaluated. Groundwater was not evaluated in the reassessment of dioxins in biosolids (EPA 2001a), because dioxins are unlikely to leach to groundwater to an appreciable degree; however, the regional climate and soils database developed for that risk assessment could be adapted to support a more robust groundwater model.

Human Intake Parameters

Assumptions regarding the intake behavior and characteristics of the human receptor should be updated using the most recent EPA (1997) guidance on exposure factors (see Chapter 4 for more details), as well as newly published studies. One broad issue for both deterministic and probabilistic risk assessment applies to many of the intake parameters. This issue is the reliability of identified distributions and upper percentile values for many intake parameters estimated from short-term studies with observations occurring over a period of days (EPA 1997). Upper percentiles identified in such studies are values for short-term intakes only. It is not appropriate to apply these values to represent variability in chronic intakes without assessing the potential for bias due to short survey periods (Wallace et al. 1994; Buck et al. 1997). A number of factors contribute to overestimation bias in the upper percentiles of such distributions (Chaisson et al. 1999). The various approaches proposed to correct these biases (Wallace et al. 1994; Buck et al. 1997; Chaisson et al. 1999) should be considered prior to using biased distributions or upper percentile values in risk assessments. If the biases cannot be corrected, use of extreme upper percentile values should be avoided, and the impact of the biases should be examined in an uncertainty assessment. This issue is an important consideration in assessing intakes of soil, food, and water. The potential impacts are described in greater detail below for soil ingestion. The uncertainty and variability associated with many of these parameters might be characterized by using probabilistic risk-assessment approaches (Stern 1993).

Some important parameters and special considerations that should be given to biosolids exposures are duration of exposure, bioavailability, soil ingestion, dietary intake of vegetables and animal products, water consumption, inhalation rate, and body weight.

Duration of Exposure. Default assumptions about length of residence are based on data on the amount of time people reside in one home. Data on length of residence in one location vary among different populations. Farm residents have an average residence time nearly four times that of other households (Israeli and Nelson 1992). In performing a risk assessment pertaining to land application of biosolids, the human receptor for many of the exposure pathways is a farm family member. Residence times also vary regionally, the northeastern region having residence times nearly twice those in the western United States (Israeli and Nelson 1992).

Bioavailability. The relative bioavailability of individual chemicals to human receptors can vary with exposure medium and should be accounted for in risk assessments if sufficient supporting data are available (EPA 1989). Soil-ingested chemicals typically are less bioavailable than soluble forms of drinking-water-ingested chemicals (NEPI 2000a,b). Even for a given exposure medium such as soil, many factors can affect relative bioavailability, including the characteristics of the biosolids matrix and the form of the contaminant (e.g., metal salt and organic complex). The contaminant's form and relative bioavailability can change over time and with environmental conditions. The Part 503 rule risk assessment did not make adjustments to reflect differences in the relative bioavailability of chemicals in different exposure media. There is no EPA guidance regarding relative bioavailability, but the default assumption is typically 1.0. The reassessment of dioxins in biosolids (EPA 2001a) is silent on this issue.

Soil Ingestion. Incidental soil ingestion by children and adults is assumed to occur primarily from adherence of fine soil particles to hands or objects that are subsequently placed in the mouth (EPA 1997). In the Part 503 rule risk assessment, soil ingestion was considered only for children, who were assumed to ingest 200 mg/day of pure biosolids for 5 years. It was

calculated as the most limiting pathway for four of the regulated contaminants. This pathway should be revised to use estimated soil concentrations rather than biosolids concentrations and should use the same exposure duration as other exposure pathways. Estimates of soil intakes should include intakes by teenagers and adults and particularly for home gardeners and farm family members, whose ingestion of soil might be relatively high.

The assumption that children ingest 200 mg of soil per day is consistent with current EPA guidance that describes this value as a conservative estimate of the mean (EPA 1997). More recent studies suggest that this value might exceed a 95th percentile for long-term average daily exposure (Stanek and Calabrese 2000; Stanek et al. 2001). Reported upper percentiles in soil-ingestion studies typically represent the upper percentiles among the observations reported for all subjects during a short study period (e.g., among 64 children observed for 7 days). Estimates of true average 95th percentile soil ingestion over longer periods might be much lower (Table 5-8). It is critical that new, more reliable information on the distributions of soil ingestion be considered in new risk assessments.

TABLE 5-8 Estimates of True Average 95th Percentile Soil Ingestion for Children Over Various Time Periods

	95th Percentile Soil Ingestion Per Day (mg)	
Time (days)	Anaconda[a]	Amherst[b]
1	141	210
7	133	177
30	112	135
90	108	127
365	106	124

[a]Study of 64 children aged 1-4 years residing in Anaconda, MT, mean soil ingestion = 31 mg/day.
[b]Study of 64 children aged 1-4 years residing in Amherst, MA, mean soil ingestion = 57 mg/day.
Source: Data from Stanek and Calabrese 2000.

Pica behavior for soil was considered in the screening process to select chemicals for regulation, but the child with pica was not used as a receptor in the risk assessments. There is no evidence that geophagia occurs routinely in children over long periods; however, many children might occasionally ingest 1-10 g or more of soil (EPA 1997). This finding suggests that consideration of pica behavior is most important when assessing acute exposures (EPA 1997).

The average amount of soil ingested by adults was estimated to be 10 mg/day (Stanek et al. 1997). EPA recommended that 50 mg/day be used as a "reasonable central estimate of adult soil ingestion" (EPA 1997); however, the estimate was based on an earlier study by Calabrese et al. (1990) and did not include this group's more recent analysis (Stanek et al. 1997). Given the high degree of uncertainty in soil-ingestion data, EPA should make further research on soil ingestion among children and adults a high priority. Probabilistic assessments might also be useful for characterizing uncertainty and variability of this parameter.

Dietary Intake of Vegetables. The risk assessment of vegetable intake evaluated risks based on an average nonmetropolitan diet around 1980 (USDA 1982). A limitation of the 3-day food-consumption survey in this study is that 3 days is insufficient to ascertain typical dietary intake (Anderson 1986) and is likely to overestimate long-term average upper-percentile intake. Vegetable consumption varies greatly, and surveys suggest that vegetable intake has been increasing in the general population (EPA 1997). Biosolids exposure of the vegetarian home gardener would be a reasonable maximum exposure. Data used by EPA in its risk assessment for developing the biosolids standards show that farm households on average consume 2.5 times more vegetables than the nonmetropolitan population (EPA 1997). Consumption also varies

within a particular population. Unfortunately, no data could be found that address vegetarians who would be expected to have high rates of intake. Consideration should also be given to regional differences in production and assessment of the fraction of homegrown and nonhomegrown crops that are grown on biosolids-amended soils for the RME receptor.

Dietary Intake of Animal Products. The risk assessment of animal-product intake (not including poultry or eggs) is based on an average nonmetropolitan diet around 1980 (USDA 1982) and is limited by its short-term surveys that do not adequately predict long-term average upper-percentile intake. Consumption of animal products varies greatly. An RME receptor would be represented by a livestock farm family consuming home-raised products (meat, poultry, and dairy). Data show that those households consume far more animal products than the average nonmetropolitan consumer. Farm resident mean meat intake is approximately four times that of nonmetropolitan residents, and mean dairy intake is approximately nine times greater for farm residents (EPA 1997). Consideration should be given to the assumptions made for the RME receptor about the fraction of the animal products coming from animals exposed to biosolids.

Water Consumption. Water-consumption rates should reflect more recent studies and account for variations in expected activity and climate. The study that forms the basis for EPA's default water-ingestion rates was conducted over 20 years ago. Consequently, the distribution of tap-water-ingestion rates used in the model does not reflect expected reductions in tap-water ingestion because of increases in consumption of soft drinks and bottled water. An analysis based on a 1994-1996 food consumption survey suggested as much as a 30% drop in mean tap-water consumption during the last two decades (EPA 2000b). Additionally, the tap-water-intake data reported by Ershow and Cantor (1989) were collected for only a 3-day period; therefore, the extrapolation to chronic intake is uncertain, particularly for the upper percentiles (EPA 1997).

Inhalation Rate. Assumptions about inhalation rates should be based on the specific RME receptor and likely activities by the receptor during exposure. Assessment of acute exposures should reflect the higher inhalation rates that may be sustained for shorter periods, whereas assessment of chronic exposures should reflect the variation in average population breathing rates over longer periods. Age-related variations in inhalation rate should also be part of the evaluation.

DERIVATION OF RISK-BASED STANDARDS

The risk assessment conducted to support the Part 503 rule was designed to support the development of risk-based standards—that is, to identify concentrations of specific chemicals in biosolids that could be applied to land in the manner specified by the rule without posing unacceptable risks. Four types of standards were developed: (1) cumulative pollutant loading rates, (2) annual pollutant loading rates, (3) pollutant concentration limits, and (4) ceiling pollutant concentration limits. A deterministic approach was used to calculate the various standards (see Table 5-9) for the nine regulated metals. EPA identified an allowable dose for each chemical as a starting point and then used pathway-specific algorithms that incorporate a number of exposure parameters (discussed previously in this chapter) to calculate the biosolids standards. The exposure pathway with the lowest pollutant limit was considered the “limiting” pathway, and this lowest value was used to establish the cumulative pollutant loading rates, annual pollutant loading rates, and pollutant concentration limits. The ceiling concentration

TABLE 5-9 Pollutant Concentration Limits and Loading Rates for Land Application in the United States, Dry Weight Basis

Contaminant	Ceiling Concentration Limit (mg/kg)	Cumulative Pollutant Loading Rate Limit (kg/ha)	Pollutant Concentration Limit (mg/kg)	Annual Pollutant Loading Rate (kg/ha-yr)
Arsenic	75	41	41	2.0
Cadmium	85	39	39	1.9
Copper	4,300	1,500	1,500	75
Lead	840	300	300	15
Mercury	57	17	17	0.85
Molybdenum[a]	75	—	—	—
Nickel	420	420	420	21
Selenium	100	100	100	5.0
Zinc	7,500	2,800	2,800	140

[a]Standards for molybdenum were dropped from the original regulation. Currently, only a ceiling concentration limit is available for molybdenum, and a decision about establishing new pollutant limits for this metal has not been made. Source: 40 CFR Part 503.

limits were set at either the 99th percentile level found in the NSSS or the risk-based number, whichever was greater. The major aspects of the process are discussed below.

Toxicity Assessment

The starting point of EPA's calculations was to identify a chemical dose that is not expected to cause unacceptable adverse effects in humans. For most of the chemicals, the starting point was an EPA-established measure of either toxicity (reference dose [RfD] or reference concentration [RfC]) or carcinogenicity (cancer potency value [q_1*]). For two chemicals, copper and zinc, a recommended daily allowance (RDA) was the starting point. This was done for copper, because EPA has not established toxicity or carcinogenicity values for it. An RfD is available for zinc, but that value was considered insufficient to meet daily nutritional requirements, so the higher RDA value was used (EPA 1992a). None of the regulated contaminants were assessed as carcinogens.

All the starting points are based on chronic exposure scenarios. EPA risk assessments typically focus on chronic exposures, because long-term exposure is generally a more sensitive end point than acute or short-term exposures. (The use of chronic toxicity data will yield a lower or more protective standard.) EPA periodically reviews the literature and updates the dose-response assessments for individual chemicals. Thus, any reassessment of risks associated with land application of biosolids should include verification that the most recent toxicity values are used. Consideration should also be given to evaluating risks from short-term episodic exposures, which may be important for volatile chemicals.

Calculations

In deriving the risk-based standards, a number of calculations and algorithms were used to determine the concentration of a specific chemical that can be present in biosolids and not result in exceedance of the acceptable dose. Because EPA's acceptable doses include consideration of chemical exposures to the evaluated inorganic contaminants from all sources, the first step was to determine the dose of the chemical from biosolids alone by subtracting total background intake (TBI) of a chemical from the EPA-established acceptable dose. The adjusted health parameter was then used in algorithms specific to each exposure pathway. The algorithms incorporated pathway-specific information and assumptions regarding chemical intake, such as plant uptake of the pollutant, to derive a pollutant limit. In most cases, calculation of the pollutant limit involved two or more algorithms.

Target Risks

Selection of target risks is a policy decision made by EPA. For carcinogens in biosolids, EPA used a target incremental cancer risk of 1 in 10,000 (1×10^{-4}), the high end of the 1×10^{-6} to 1×10^{-4} risk used by EPA in establishing various regulations. For noncancer health effects, a hazard index of 1 (the ratio of the predicted exposure either to the threshold dose for toxicity or to the predicted cancer risk) was used. It was beyond the committee's charge to assess the adequacy of target risks used to derive risk-based standards; however, actual risks might be substantially less than the target risks, because in many cases the concentrations of the regulated contaminants in biosolids are generally less than the regulatory limits.

In developing the 503 rule, EPA sought to develop one standard for each chemical that would be protective in all circumstances that could be reasonably anticipated to occur. Thus, a standard derived for use nationwide must provide adequate protection for all reasonably anticipated environmental conditions, biosolids types, and application practices anywhere that biosolids application might occur. This goal necessitates assessing risks for exposure conditions that might occur anywhere in the United States.

The Part 503 rule standards were derived to be protective for land application in accordance with the regulations. Exposures that might occur due to failure to comply with the regulations were not considered during the development of the biosolids standards. An assessment of risks associated with noncompliance is an enforcement issue and is not related to a determination of the adequacy of the methods used to derive risk-based standards. Noncompliance associated with risk assessment is thus beyond the scope of this report.

INORGANIC CHEMICALS

In light of the advances made in risk-assessment methods discussed in Chapter 4 and the need to update many of the exposure parameters used in the risk assessment process, the existing biosolids standards for inorganic chemicals clearly need to be reevaluated. As noted in Chapter 2, average concentrations of some regulated inorganics in biosolids decreased substantially throughout the 1980s and early 1990s, and have stabilized since that time (see Tables 2-23 and 2-24). Recent survey data from Pennsylvania that includes 95th percentile values, as well as

TABLE 5-10 Median and 95th Percentile Trace Element Concentrations in Pennsylvania Sewage Sludge Produced in 1996 and 1997 Compared to Limits Contained in the Part 503 Rule

	Concentration in Sewage Sludge, mg/kg		Pollutant Concentration
Trace Element	Median	95th Percentile	Limit, mg/kg
Arsenic	3.60	18.7	41[a]
Cadmium	2.26	7.39	39[a]
Chromium	35.1	314	1,200[b, c]
Copper	511	1,382	1,500[c]
Mercury	1.54	6.01	17[a]
Molybdenum	8.18	36.0	18[b, d]
Nickel	22.6	84.5	420[c]
Lead	64.9	202	300[a]
Selenium	4.28	8.47	100[a]
Zinc	705	1,985	2,800[c]

[a]Based on risks for child eating biosolids.
[b]The current Part 503 rule does not include chromium, and there is no cumulative pollutant loading limit or pollutant concentration limit for molybdenum. The values given in this table were included in the original Part 503 rule.
[c]Based on plant phytotoxicity.
[d]Based on animal eating feed.
Source: Adapted from Stehouwer et al. 2000.

median values, suggest that in Pennsylvania, and perhaps in other states, pollutant limits will only rarely be exceeded for most inorganics (Table 5-10).

In order to assess the potential impacts of reevaluating the standards, it is instructive to compare the pollutant limits for biosolids with current risk-based soil screening levels (SSLs) for residential scenarios. Such a comparison is predicated on the assumption that inorganic chemical concentrations in soil to which biosolids are added will never exceed the pollutant limits. EPA (1995) has projected that at such time as the cumulative loading rate (kg/ha) has been achieved, the risk based limit of acceptable soil concentration (mg/kg) will also have been reached and would be 50% of the cumulative loading rate, plus the initial background concentration of the pollutant. As can be seen from Table 5-11, most of the pollutant limits are lower (i.e., more conservative) than the EPA residential SSLs based only on dermal and direct ingestion pathways. A limitation of such a comparison is that the residential SSLs are based on exposures via a limited number of exposure pathways, including soil ingestion, dermal contact with soil, and inhalation of resuspended particulates. The SSLs may not be adequately protective for chemicals for which other exposure pathways may be especially important. This limitation is of particular concern for cadmium, due to potential uptake into plants, and for mercury, due to the potential for mercury entering surface water via runoff from soil to be converted to methylmercury and bioaccumulated in aquatic organisms. For this reason, Table 5-11 also shows risk-based screening levels developed by the British (UK Environment Agency 2002) that include consideration of home garden exposure. The importance of differing assumptions in assessing risk is pointed out by comparing the UK and EPA values (columns 2 and 3), which for some elements are significantly different. The potential impact of including the plant uptake pathway on risk-based soil concentrations for some pollutants (e.g., cadmium) is demonstrated by comparing the values in columns 3 and 4 of Table 5-11.

In addition to SSLs based on exposure pathways involving direct contact with chemicals, EPA has also devised soil SSLs for the protection of groundwater (EPA 2001b). A comparison

TABLE 5-11 Pollutant Concentration Limits in Sewage Sludge Compared to Risk-Based Soil Concentrations

Trace Element	Part 503 Pollutant Concentration Limit,[a] mg/kg DW	EPA Residential SSLs (ingestion and dermal), mg/kg DW	UK Residential SGVs (ingestion), without plant uptake,[b] mg/kg DW	UK Residential SGVs (ingestion), with plant uptake,[c] mg/kg DW
Arsenic	41	0.4 (40)[d]	20	20
Cadmium	39	70	30	1 (pH 6) 2 (pH 7) 8 (pH 8)
Chromium	NA[e]	230/120,000[f]	200[g]	130[g]
Lead	300	400	450	450
Mercury	17	23/10[h]	15	8
Nickel	420	1,600	75	50
Selenium	100	390	260	35

[a]Pollutant concentration limits for biosolids based on human health risks, except for nickel (plant phytotoxicity).
[b]House or apartment with no private garden area.
[c]House with a garden with the possibility of ingestion of home-grown vegetables.
[d]Arsenic SSL is 0.4 mg/kg based on a 1 in 1,000,000 cancer risk. Value of 40 in parentheses reflects the cancer risk of 1 in 10,000 used for the Part 503 rule.
[e]Chromium was deleted from the Part 503 rule because of a court suit.
[f]Chromium SSL assumes that all chromium is Cr(VI). Value for Cr (III) is 120,000.
[g]The UK SGV for chromium assumes that all chromium is CR (VI).
[h]Mercury SSL is based on the reference dose for mercuric chloride. SSL for inhalation is 10 mg/kg.
Abbreviations: DW, dry weight; NA, not applicable; SGV, soil guideline value; SSL, soil screening level; UK, United Kingdom
Sources: 40 CFR Part 503; EPA 2001b; UK Environment Agency 2002.

of selected pollutant concentration limits in biosolids with U.S. background soil concentrations and soil screening levels for groundwater are presented in Table 5-12.

A comparison of the biosolids pollutant limits with risk-based SSLs suggests that the pollutant standards are adequately protective for some exposure pathways (i.e., soil/biosolids ingestion), but may need to be reevaluated for others (i.e., ingestion of homegrown produce grown on biosolids-amended soil). In this section, two factors that are important for assessing human exposure to inorganic compounds and their toxicity—bioavailability to human receptors and metal speciation—are discussed. Other factors—plant uptake of metals and bioavailability of metals to plants—were addressed earlier in the section on exposure parameters. The general discussion is followed by a description of issues specific to several of the regulated metals.

Bioavailability to Humans

The term "bioavailability" may have different meanings in different contexts. In the context of human exposures to chemicals in environmental media, bioavailability is the degree to which a chemical present in an environmental medium is capable of being absorbed into the systemic circulation. Bioavailability depends on the release of the chemical from the medium and the absorption efficiency of the released chemical. Oral toxicity assessments of metals are often based on studies in which a metal salt is dissolved in water or mixed with food. If the toxicity factors (reference doses and cancer slope factors) used in risk assessments in soil or

TABLE 5-12 Pollutant Concentration Limits in Biosolids Compared with Background Concentrations and Soil Screening Levels for Groundwater

	Part 503 Pollutant Concentration Limit, mg/kg DW[a]	Background Concentrations[b]				SSL for Groundwater[c]	
Trace Element		Arithmetic mean, mg/kg	Geometric mean, mg/kg	Geometric standard deviation, mg/kg	Range, mg/kg	DAF = 20, mg/kg	DAF = 1, mg/kg
Arsenic	41	7.2	5.2	2.23	<0.1-97	29	1
Cadmium	39	0.02-1.67[d]	0.175	2.70	ND-11[d]	8	0.4
Chromium	NA[e]	54	37	2.37	1-2,000	38[f]	2[f]
Lead	300	19	16	1.86	<10-700	-[g]	-[g]
Mercury	17	0.09	0.058	2.52	<0.01-4.6	2	0.1
Nickel	420	19	13	2.31	<5-700	130	7
Selenium	100	0.39	0.26	2.46	<0.1-4.3	5	0.3

[a]CFR 40 Part 503. Pollutant concentration limits for biosolids based on human health risks, except for nickel (plant phytotoxicity).
[b]Data for U.S. soils, Shacklette et al. (1984)
[c]EPA (2001b)
[d]Range of means reported in Dragun and Chaisson (1991) for various states and soil types. Single U.S. mean not reported.
[e]Chromium was deleted from the Part 503 rule because of a court suit.
[f]SSL for total Cr and Cr(VI). This pathway is not of concern for Cr(III).
[g]A screening level of 400 mg/kg has been set for lead.
Abbreviations: DAF, dilution attenuation factor; NA, not applicable; ND, not detected; SSL, soil screening level

other heterogeneous exposure media are based on studies using soluble forms of the metals, the impacts of soil exposures could be overestimated.

Reduced absorption of metals from biosolids-amended soils ingested by human receptors might be due to sorption and precipitation reactions of the metals with soil components, such as metal oxides and humic substances, and due to the presence of metals in compounds with limited water solubility (Ruby et al. 1999). For example, it is well established that metals, such as cobalt, manganese, nickel, and zinc, can form metal hydroxide surface precipitates on metal oxides, clay minerals, and soils. The formation of these surface precipitates significantly reduces the release of the metal, even when strong acids and complexing organic ligands are used as dissolution agents (Scheidegger et al. 1997, 1998; Ford et al. 1999; Scheckel et al. 2000). Arsenic, lead, mercury, and nickel also occur in soils in compounds exhibiting a wide range of water solubility. Thus, metal dissolution from ingested soil could be limited during movement through the gastrointestinal tract. Accordingly, absorption will be reduced, as the major mode of absorption of many metals is passage of dissolved metal species across the small intestine epithelium (Whitehead et al. 1996).

Risk-assessment guidance from EPA (1989) acknowledges the need to make adjustments in exposure assessments to account for differences in relative bioavailability between the exposure medium in toxicity studies and the exposure medium in risk assessments. These adjustments for reduced bioavailability of chemicals from such media as soil are typically termed relative absorption factors (RAF). RAFs typically take the form of a fractional adjustment in the exposure algorithms used to estimate intake or dose.

In the Part 503 risk assessment, EPA considered making such adjustments for relative bioavailability (using the term "relative effectiveness") but concluded that available data were inadequate to support default adjustments for the metals being evaluated. During the past decade, substantial research better characterizing the occurrence of reduced metal bioavailability in soils has been published (NEPI 2000a). Reduced metal bioavailability in biosolids-amended soils is very likely, and several laboratories have active research programs on the use of biosolids amendments as a method of reducing metal bioavailability in contaminated soils (Basta and Sloan 1999; Henry and Brown 1997).

Metal Speciation and Availability

The lack of direct information on the speciation of metals and metalloids in biosolids and soil-biosolids mixtures complicates attempts to assess both toxicity and bioavailability of these chemicals. Although a great deal of information on metal contents of biosolids and soils exists, the total content is not indicative of the forms or species of the metals. For several of the regulated metals, toxicity varies with different forms of the metal, and it is important to distinguish differences in the nature of toxicity from differences in solubility and bioavailability of different metal forms.

Mercury may be present in three forms with varying toxicity (i.e., elemental mercury, inorganic mercury compounds, and methylmercury). The exposure routes of concern are different for the different mercury forms. Inhalation is the primary route of exposure to elemental mercury released from soil, and ingestion is the exposure route of concern for inorganic and methylmercury. Consequently, for evaluation in risk assessment, the forms of mercury in soil and other exposure media must be known or assumptions must be made

regarding the forms present. Arsenic compounds also exhibit marked variation in toxicity. The organic forms are practically nontoxic, and inorganic forms are quite toxic. Typically, only inorganic arsenic compounds are assumed to be present in soil, but for the reasons described below, that assumption might not apply to biosolids. In contrast, the toxicity of inorganic cadmium and lead compounds expected to be present in biosolids does not vary, although solubility and bioavailability can be highly variable.

Most bioavailability studies of metals in soil have relied on animal species that have anatomical and physiological characteristics different from humans. Only a few studies have assessed metal absorption from ingested soil by humans. The relative bioavailability of metals in soil is dependent on speciation of the metal, size distribution of soil particles, and composition of the soil.

Chemical extractions (e.g., sequential extractions) can provide some information on the extraction ease, such as readily exchangeable or occluded from various phases, but the order of extractions and extractants that are used can create artifacts. Such extractions also do not mimic dissolution rates likely to occur in the human gastrointestinal tract. Sequential extractions do not provide direct speciation analyses. For example, many metals can exist as inorganic and organic species and in multiple oxidation states and can be associated with multiple solid phases (e.g., metal oxides, phyllosilicates, and humic substances). Metals primarily form strong inner-sphere chemical bonds with metal oxides, clay minerals, and humic substances that substantially restrict their mobility in natural environments. Moreover, with time, metals can undergo transformations with soils that often render them less prone to leaching. In laboratory experiments, such metals as nickel and zinc can form surface precipitates on soils, aluminum oxides, and clay minerals that transform over time to more stable mixed metal hydroxide phyllosilicate phases. Some fraction of the metals is sequestered even with treatment with acids and organic ligands, such as ethylenediaminetetraacetate (Scheidegger et al. 1997, 1998; Ford et al. 1999; Roberts et al. 1999; Scheckel et al. 2000; Scheckel and Sparks 2001). Furthermore, metal speciation, and thus bioavailability, is not static in the natural environment. Changes may result from weathering reactions and microbiological activity in soils (Hooda and Alloway 1994; Sadovnikova et al. 1996; Basta and Sloan 1999; Kamaludeen et al. 2001).

The speciation of metals and metalloids in biosolids and biosolid-amended soils is critical in determining the mobility and bioavailability of the toxic metals (Ruby et al. 1999). In the last decade, important advances have occurred in the use of in situ molecular-scale techniques that can provide direct information on chemical speciation of metals and metalloids in model systems, such as metal oxides and clay minerals, and in soils. One major innovation has been the use of synchrotron-based spectroscopies, such as x-ray absorption fine-structure spectroscopy (XAFS), to determine oxidative states and local chemical environment of metals and metalloids at natural particle interfaces. Thus, metal species in heterogeneous materials can be determined in the presence of water without having to dry the sample and subject it to desiccation. Numerous studies have appeared in the scientific literature on the application of XAFS and other in situ spectroscopic techniques to speciate metals in natural systems. Recent changes have been the use of micro-focused XAFS and micro-x-ray fluorescence spectroscopy to speciate and map metal distributions in soils (Manceau et al. 2000; Roberts 2001). With these techniques, an area of square microns can be chemically mapped and the chemical associations of various metals can be determined, certain spots can be zoomed in on, and via XAFS data analyses, the species of the metals at different locations can be determined. Additionally, the quantitative associations of the metals with various components of the solid can be determined (e.g., metal oxides, clays, and

humic substances). Scientists have applied micro-XAFS and micro-x-ray absorption near-edge structure (XANES) to phosphorus and arsenic speciation in poultry-litter and poultry-litter amended soils (Arai and Sparks 2001; Peak et al. 2001), both extremely heterogeneous materials. Biosolids-applied soils will also be heterogeneous in regard to the distribution of biosolids-borne metals. Application of such techniques to biosolids would allow for direct speciation of the metals and metalloids and a better understanding of the mechanisms affecting bioavailability.

Regulated Metals and Metalloids

The inorganic chemicals regulated on the basis of human health (specifically risks to children from direct ingestion of biosolids) are arsenic, cadmium, lead, mercury, and selenium. Specific issues to consider in updating the risk assessments for the first four of these metals are described below.

Arsenic

The primary issue related to arsenic is EPA's treatment of arsenic in soil as noncarcinogenic in the Part 503 rule risk assessment. However, ingestion of inorganic arsenic in drinking water is an established cause of skin cancer, and recent studies strengthen the evidence that arsenic can also cause cancers of the lung and urinary bladder (NRC 1999, 2001). In the 503 rule risk assessment, EPA justified using the arsenic reference dose on the grounds that there was no evidence that soil arsenic is carcinogenic. Although that assertion is true, there is no evidence that arsenic absorbed into the body from ingested soil and arsenic absorbed from drinking water behave any differently. Consequently, current EPA risk-assessment practice is to treat inorganic arsenic in all media as potentially carcinogenic.

However, if arsenic is treated as a carcinogen, it will be necessary to confirm that it is present in biosolids as inorganic arsenic rather than organic forms that are much less toxic and noncarcinogenic. As with many toxic metals and metalloids, the speciation of arsenic in biosolids is not well characterized. Although organic arsenicals are generally not present in soils in measurable quantities, the extent of their presence in biosolids is not known. Thus, the forms of arsenic present in biosolids should be assessed, and only the fraction that is inorganic should be regulated.

Total arsenic in soils has been reported to range from 0.1 to 97 ppm with an arithmetic mean concentration of 7.2 ppm and a geometic mean of 5.2 ppm for surface soils in the United States (Shacklette and Boerngen 1984). Gustavsson et al. (2001) reported that U.S. soils have a mean arsenic concentration of 5.57 ppm, and 25th and 75th percentile concentrations of 4.21 ppm and 7.06 ppm, respectively. Arsenic occurs in two major oxidative states, arsenous acid (As^{III}) and arsenic acid (As^{V}). As^{III} is primarily present in anoxic environments, and As^{V} is found in oxic soils. Both arsenic species occur primarily as oxyanions in the natural environment and strongly complex with metal oxides, such as aluminum and iron oxides, as inner-sphere products. These oxides, and particularly manganese oxides, can affect oxidation of As^{III} to As^{V}, which reduces the toxicity of arsenic. Arsenic can also occur as sulfide minerals, such as arsenopyrite (FeAsS) and enargite (Cu_3AsS_4), at mining sites.

There is reason to suspect that some of the arsenic in biosolids is in organic forms; however, no studies testing this hypothesis were found. Ingested inorganic arsenic is methylated and excreted primarily as monomethylarsonic acid (MMA) and dimethylarsinic acid (DMA) (NRC 2001). Farmer and Johnson (1990) examined the speciation of arsenic in urine excreted by workers exposed to inorganic arsenic compounds, and found 1-6% As^{V}, 11-14% As^{III}, 14-18% MMA, and 63-70% DMA. Most dietary arsenic is organic arsenic, and many of these organic forms are excreted unchanged in the urine. Thus, most arsenic from domestic sources in wastewater may be organic. Under certain environmental conditions, however, organic arsenic has the potential to mineralize. The possibility that biosolids-borne arsenic can be transformed from organic to inorganic forms should be evaluated. The greater water solubility of organic arsenic compounds makes it unlikely that these compounds will preferentially segregate to biosolids and makes it difficult to predict the predominant speciation of arsenic in biosolids.

Studies of the relative bioavailability of soil arsenic have been limited primarily to soils from mining and smelting sites and from arsenic pesticide manufacturing or application (NEPI 2000a; Kelley et al. 2002). Those studies yielded relative bioavailability estimates of soil arsenic of 10% to 50% as compared with bioavailability of soluble arsenic forms. It might not be practical to determine the relative bioavailability of arsenic in biosolids in animal experiments because of the low arsenic concentrations typically present in biosolids. However, in vitro approaches are available that may be used to estimate relative bioavailability of arsenic in biosolids. Ruby et al. (1999) noted that the particle-size distribution and the chemical composition of the arsenic species greatly affect bioavailability. Dissolution rates (and bioavailability) increase as particle size decreases. In vivo and in vitro studies show that for a constant particle size, soil-arsenic phases, such as arsenic sulfides and arsenic found in slag, have a lower bioavailability than iron, manganese, and lead-arsenic oxides (Ruby et al. 1999). Bioavailability data also suggest that bioavailable arsenic from soil occurs primarily from dissolution of surface-bound arsenic fractions or the exterior part of individual arsenic-containing grains rather than from complete dissolution of discrete arsenic mineral phases (Ruby et al. 1999).

Cadmium

The most limiting exposure pathway for cadmium in the Part 503 rule risk assessment was exposure to a child from direct ingestion of biosolids. To derive concentration limits for cadmium in biosolids, EPA used the oral RfD and considered only a childhood exposure rate. However, the oral RfD is based on a lifetime accumulation of cadmium in the kidney to the point where the toxicity threshold, which is associated with toxicity to the kidney cortex, is reached. Consequently, it is more appropriate to average child and adult exposure rates over the course of a lifetime. Children are expected to ingest greater quantities of soil per unit of body weight than adults but do so over a shorter period. Thus, a safe average daily dose will typically be an average of the child daily dose for 6 years and an adult dose for 24 years or more.

Conducting a multiple pathway risk assessment that aggregates exposures from all pathways is particularly important for cadmium. Because plants take up cadmium more efficiently than most other metals, dietary cadmium is likely to be an important exposure pathway in a revised risk assessment.

A number of dietary factors are known to affect cadmium toxicity, most notably dietary deficiencies in iron, calcium, and zinc may be associated with increased cadmium body burden and toxicity (ATSDR 1999). There have also been studies demonstrating a protective effect of zinc at overtly toxic doses of cadmium (ATSDR 1999). More recent studies suggest that even when dietary cadmium intakes are only slightly increased, increased zinc intake may limit increases in cadmium body burden (Vahter et al. 1996; Reeves and Chaney 2001). Thus, it may be useful to consider predicted dietary zinc intake when evaluating predicted dietary intake of cadmium.

Lead

The bioavailability of lead in biosolids-amended soils is an important factor is assessing lead exposures. Absorption of lead in the gastrointestinal tract varies with age, diet, nutritional status, and the chemical species and particle size of lead that is ingested (Ruby et al. 1999). Adults absorb 7-15% of lead ingested by dietary means, and dietary absorption by infants and children ranges from 40% to 53% (Ziegler et al. 1978). In the Part 503 rule risk assessment, EPA used a version of the integrated exposure uptake biokinetic (IEUBK) model to assess lead exposures of children. EPA revised that model in 1994. The Part 503 rule limit for lead was also set more restrictively than the IEUBK-based value for policy reasons.

The revised model includes a default assumption that children absorb 30% of lead from soil as compared with 50% of lead from diet and drinking water. Recent reviews have summarized studies of soil lead from many kinds of sites and show that soil lead bioavailability ranges from near zero to somewhat higher than the EPA default value of 30% (NEPI 2000a; Ruby et al. 1999). The great variability in soil lead bioavailability reflects the great variation in solubility of different lead compounds. For example, soil lead from mine sites with sulfidic ores exhibits low bioavailability, and that from mine sites with carbonate ores exhibits much more bioavailability.

Dissolution rate-controlling processes are important in determining oral lead bioavailability, because lead must dissolve in the gastrointestinal tract to become bioaccessible (Ruby et al. 1992). Less-soluble lead minerals, such as lead in calcium phosphates, dissolve by surface-reaction controlled kinetics. The bioavailability of metals that dissolve via a transport-controlled mechanism is dependent on the mixing that occurs in the gastrointestinal tract, and dissolution via surface-controlled phenomena is sensitive to transit times (Ruby et al. 1999).

A number of studies have been conducted on the bioavailability of lead in biosolids to livestock. A study at the University of Maryland (1980) used 0%, 3.3%, and 10% sewage-sludge compost in diet that had lead at 215 μg/g of dry weight for 180 days. No significant change occurred in the indicator tissue lead concentrations despite the finding that fecal analyses show that the animals ingested greatly increased amounts of lead. In similar studies, Keinholz et al. (1979) found that tissue lead was significantly increased by ingesting 12% sewage sludge containing lead at 780 μg/g. These studies are suggestive of low bioavailability but do not provide quantitative information that can be used in a risk assessment.

Mercury

The speciation of mercury in land-applied biosolids is a critical factor in assessing its fate and transport. EPA assumed that mercury in soil from land application of biosolids was similar in toxicity and bioavailability to mercuric chloride, a highly water-soluble form of inorganic mercury. However, methylmercury has been shown to be present in biosolids-amended soils (Cappon 1981, 1984; Carpi et al. 1997).

The formation of methylmercury is much greater in aquatic systems owing to biomagnification in aquatic food chains. For this reason, the potential transport from application sites to surface water is of greater concern for mercury than for other metals. Several studies have also reported emission of mercury vapors from biosolids. Sunlight and heat can cause reduction of Hg^{II} to elemental mercury (Hg^0) and volatilization from surface soils (Carpi and Lindberg 1997, 1998; Carpi et al. 1997). That was observed when biosolids were applied to a soil in which the vegetative cover had been removed, and the biosolids were incorporated in the soils to a small depth (Carpi and Lindberg 1997; Carpi et al. 1997). Methylmercury was also shown to be emitted to the atmosphere (Carpi et al. 1997).

Other Regulated Inorganic Chemicals

Copper, molybdenum, nickel, selenium, and zinc are also regulated under the Part 503 rule. These metals are much less toxic when ingested as compared with the four metals described above, suggesting that it is appropriate that they are regulated on the basis of ecological or plant effects. Standards for copper, nickel, and zinc were based on effects on plants, the standard for selenium is based on human health, and the standard for molybdenum is a non-risk-based ceiling limit. Nickel is the most toxic to humans when inhaled, so it is important that inhalation of resuspended particulates be considered in any risk assessment for this metal.

ORGANIC CHEMICALS

Biosolids are likely to include many categories of chemicals that differ from the categories of chemicals of concern in industrial discharges. Although it is impossible to identify all of these pollutants, it is important that EPA continually think about the types of chemicals released into wastewaters and added during wastewater and sewage-sludge treatment processes as part of its process for updating the Part 503 rule. Because some organic chemicals, such as organochlorines, are persistent in the environment, consideration should be given to their tendency for trophic transfer and biomagnification, which is a longstanding public-health concern (Svensson et al. 1991). Particular attention should also be paid to chemicals that are lipophilic or that have lipophilic metabolites or degradation products, because these chemicals are more likely to partition to sewage sludge. Consideration should also be given to toxic end points that might not have been evaluated adequately in the earlier assessment (e.g., potential interactions of chemicals with the endocrine system) (Colburn et al. 1993; Safe 2000).

As discussed previously in the section Hazard Assessment and Chemical Selection, all organic chemicals considered by EPA were originally exempted from regulation. In 1999, EPA proposed to add dioxins (a category of compounds that includes 29 specific congeners of

polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans, and coplanar polychlorinated biphenyls [PCBs]) to the regulation in response to its Round 2 assessment of additional chemicals to regulate under the Part 503 rule. No standard for dioxins has yet been finalized. This section reviews some of the important considerations that should be given to dioxins and other organic chemicals and provides examples of some of the types of chemical categories EPA should be assessing in the future.

Environmental Fate and Transport

A variety of factors jointly determine which organic pollutants will partition from wastewater to sewage sludge and how human receptors might come into contact with these chemicals in biosolids. These factors include treatment processes for wastewaters and sewage sludge, the concentration of the pollutant in the wastewater and biosolids, the method of biosolids application, the physicochemical properties of the chemical, and environmental conditions. Some factors that are particularly important for organic pollutants are their persistence in the environment, their potential for transport from soil to other environmental media, and their potential for uptake into plant and animal foods.

Degradation rates vary among chemicals, their half-lives ranging from days to years. For individual chemicals, degradation rates may also vary with environmental conditions, and measures of persistence may be substantially affected by the experimental design and analytical capabilities (Beck et al. 1996). It is also noteworthy that degradation of parent compound may not lead to loss of toxic potential if persistent, toxic breakdown products are formed. The breakdown of DDT (1,1,1-trichloro-2,2-bis(*p*-chlorophenyl)ethane) to DDE (1,1-dichloro-2,2-bis(p-chlorophenyl)ethylene) and DDD (1,1-dichloro-2,2-bis(p-chlorophenyl)ethane) is an example of this phenomenon.

Decreases in organic contaminant concentrations in biosolids-amended soils is usually not a linear function of time (Beck et al. 1996). Chlorobenzene concentrations initially decline rapidly from biosolids-amended soil, but about 10% of the residues become recalcitrant and remain in soil up to 30 years after application (Wang et al. 1995). Reports of persistence of polyaromatic hydrocarbons (PAHs) in biosolids-amended soil vary widely. In a review of the available literature, Beck et al. (1996) found one study reporting a decline in total soil PAHs of 80-100% 20 years after biosolids application and another reporting 60% of benzo[*a*]pyrene (a persistent PAH) remaining 30 years after 25 biosolids applications to a sandy loam soil. In a study of biosolids-associated di-(2-ethylhexyl)phthalate in a laboratory microcosm, approximately half remained after 1 year (Madsen et al. 1999). A study of flocculent polymers used as dewatering agents in wastewater treatment processes reported that the polymer is partially degradable under both aerobic and anaerobic conditions (Chang et al. 2001); however, no data were available on the persistence of these compounds in environmental media.

Half-lives for organic contaminants are also influenced by sewage sludge-treatment processes. For example, the half-life of linear alkylbenzene sulfonates can be over a year under anaerobic conditions, but they degrade with half-lives of 7-30 days under aerobic conditions (Cavalli and Valtorta 1999; Scott and Jones 2000). Climatic conditions, especially temperature and rainfall, also influence degradation, volatilization, and leaching rates for organic chemicals in mixtures of biosolids and soil.

Contaminants in biosolids are typically most available to plants and potentially to animals immediately after application and before degradation may have reduced concentrations. For both organic and inorganic contaminants in biosolids, the greatest potential for leaching, which may also be related to bioavailability, appears to occur immediately after application (Marcomini et al. 1988; Beck et al. 1996). Sorption of organic contaminants from biosolids to soil particles is another important determinant of mobility and availability. Soil composition and moisture interact to influence sorption capacity for organic contaminants (Chiou and Shoup 1985). In moist soils, organic matter is the dominant constituent to which sorption occurs. In dry soils, where water occupies little of clay particle surfaces, clay can absorb large amounts of organic contaminants. However, the ability of a soil to sorb organic contaminants generally increases with organic matter content. Sorbed organic contaminants may degrade by chemical, biochemical, or photochemical reactions. Desorption may occur from solid-to-solid, solid-to-liquid, or solid-to-gas phases.

Mobilization into air may be an important route for transport of organic contaminants to plants. The rate of degradation and bioavailability of organic contaminants in soils decreases with time (Alexander 2000). Sequestration into the solid phase or nanopores of soil may explain this phenomenon. This sequestration should be considered when evaluating data on total chemical concentration in soil and may be addressed by studies of relative bioavailability.

The relative importance of specific routes of exposure will vary with the organic contaminant of concern, climate, and soil type. For example, volatile chemicals will be released from soil to air, and hydrophobic, persistent organics are more likely to be retained in soil.

Dioxin and Dioxinlike Chemicals

The dioxins category includes seven chlorinated dibenzo-*p*-dioxins (CDDs), 10 chlorinated dibenzofurans (CDFs) and 12 coplanar PCB congeners. These compounds share common modes of toxic action and are considered a group for risk assessment (Van den Berg et al. 1998). Although the toxicity of these chemicals varies up to 5 orders of magnitude, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD) is the most potent. All the dioxins bind and activate the aryl hydrocarbon receptor (AhR). The AhR is a ligand-activated transcription factor that participates in regulating a battery of genes (Gu et al. 2000). A change in expression of AhR-regulated genes is the current explanation for much of the toxicity of TCDD and dioxinlike compounds. The CDDs, CDFs, and PCBs that activate the AhR are approximate stereoisomers of TCDD. Because the stereoisomers of TCDD are all less potent than TCDD, each is assigned a potency relative to TCDD for AhR activation (Van den Berg et al. 1998). The assigned potency is referred to as a toxic equivalency factor (TEF). By definition, the TEF for TCDD is 1. Multiplying the concentrations of each CDD, CDF, or dioxinlike PCB in biosolids by their TEFs and summing the products yields the toxic equivalents (TEQs) in that material.

EPA (1999a) has proposed application of TEQs in biosolids for setting regulatory standards. The validity of this approach is supported by reviews of recent literature that consider tissue concentrations (Van den Berg et al. 1998; Gu et al. 2000). There is at least one major limitation to application of the TEQ concept to estimating risks of dioxins in biosolids-amended soil. Bioavailability of all CDDs, CDFs, and PCBs that contribute to TEQs is not equivalent (Jones and Sewart 1997). A particular chlorination pattern distinguishes each of over 400 potential CDD (75), CDF (135) and PCB (209) congeners. Extent and pattern of chlorination

markedly influences hydrophobicity and hence the tendency for sorption to and desorption from organic matter in a biosolids-amended soil. Biodegradation rates, water solubility (an inverse function of hydrophobicity), and volatility generally decrease with an increase in chlorination for aromatic hydrocarbons. Theoretically, each CDD, CDF, and PCB congener processes a specific half-life and bioavailability in a biosolids-amended soil. Complete characterization requires data on each congener. Because of the impracticality of that requirement, environmental chemistry data for the most toxic congener (TCCD) typically provide the basis for risk assessment.

EPA (1999a) has proposed a TEQ limit of 300 parts per trillion (ppt) in biosolids applied to land, which is well above the means of 32 or 48 ppt detected in recent biosolids surveys (Alvarado et al. 2001; EPA 2002c). In the Alvarado survey, 14 of 201 biosolids samples contained dioxin TEQs greater than 60 ppt. Thirteen of those samples were in the range of 62-256 ppt, and one sample contained dioxins at 3,590 ppt. The one unusually high dioxin level has been verified by two laboratories, the source of the dioxin has been identified, the sewage sludge is being land filled, and investigation into the high dioxin level continues (Robert Dominak, AMSA Co-chair Biosolids Management Committee, personal communication with Greg Kester, Wisconsin Department of Natural Resources, May 24, 2002).

Eljarrat et al. (1997) reported that soil concentrations of CDDs, CDFs, and dioxinlike PCBs in biosolids-amended soil were 1.2 to 11.6 times greater than those in control soils one year after application of biosolids containing 56-260 ppt TEQs. Biosolids were applied in four consecutive years at rates that exceeded the nitrogen-based Spanish annual application recommendations for agriculture (5-10 ton/ha) by 4- to 15-fold. In soils with low initial TEQs (0.3 ppt), concentrations remained suitable for agriculture. In soil with high initial TEQs (3.1 ppt), concentrations increased to levels (8.6 picograms (pg)/g TEQ) that would trigger German crop restrictions. Molina et al. (2000) concluded that CDD and CDF concentrations in biosolids-amended soils are directly related to loading 1 year after application.

Both atmospheric transport and biosolids application contribute to total TEQ loading in agricultural soils (Jones and Sewart 1997). Atmospheric loading was more significant in urban sites than in rural sites. The half-life of CDDs and CDFs in soils is generally accepted to be about 10 years (Jones and Sewart 1997). Therefore, the history of contamination and atmospheric loading in addition to biosolids application are worthy of consideration in site evaluation. For example, assuming (1) biosolids with dioxins at 300 ppt, (2) a biosolids application rate of 10,000 kg/ha, (3) biosolids incorporation into 15 cm of soil, (4) soil mass of 1,200 kg/m^3, and (5) a dioxin half-life of 10 years with exponential decay, rough estimates of dioxin concentrations are 1.65 ppt in agricultural soil after a single application and 12.57 ppt after annual applications for 10 consecutive years. For biosolids containing dioxins at 50 ppt, the corresponding concentrations are 0.28 and 2.10 ppt.

EPA (2001a) released a peer-review draft of a revised risk assessment for dioxins in biosolids that reflects responses to comments on the earlier risk assessment supporting the proposed TEQ limit of 300 ppt. The revised risk assessment uses data from a recent biosolids survey and both deterministic and probabilistic approaches to estimate dioxin concentrations in soil and other exposure media near land-application sites. Risks were evaluated for a farm family residing in an area receiving runoff from cropland and for a recreational fisher. For the farm family, risk results were presented for specific pathways (soil ingestion; air inhalation; produce ingestion; ingestion of poultry, eggs, beef, and milk; and breast-milk ingestion for an infant) and for total multiple pathway risks. Beef and milk ingestion were the primary contributors to risks for both adults and children. The risk results did not change when survey

samples exceeding 300 ppt TEQ (the proposed standard) were excluded from the database because of low frequency of occurrence of increased concentrations. A notice of data availability on EPA's revised risk assessment was released for public comment on June 12, 2002 (EPA 2002c).

Other Organic Chemicals

Data regarding the occurrence of organic chemicals in biosolids is needed for additional chemical categories, and they should be given consideration in future risk assessments. Among these are flame retardants (e.g., brominated diphenyl ethers), surfactants, chlorinated paraffins, nitro- and polycyclic musks, pharmaceuticals, odorants, and chemicals used to treat sewage sludge (e.g., dewatering agents). Evaluation of these types of chemicals in risk assessment will depend on the characteristics of the compound, their occurrence in biosolids, and the availability of toxicity data. In this section, brominated diphenyl ethers are used as an example to illustrate a specific class of chemicals identified as a potential hazard in biosolids. Other categories of compounds are reviewed briefly; special consideration is given to pharmaceuticals and odorants.

Brominated Diphenyl Ethers

Brominated diphenyl ethers (BDEs) are flame retardants used in the furniture, electrical and computer component, and housing industries. Only penta-, octa-, and deca-BDEs are of commercial interest (WHO 1994). The composition and production estimates in 1994 for these BDEs are presented in Table 5-13. Environmental concerns about BDEs have arisen because they have been detected in various environmental media, are highly persistent in the environment, and bioaccumulate in aquatic food webs (de Boer et al. 1998; Hale et al. 2001).

BDE formulations differ in their toxicological properties (WHO 1994). The acute toxicity of the deca-, octa-, and penta-BDEs is low. There are no apparent adverse effects in rats fed deca-BDE at 50 g/kg for 13 weeks. That response is largely explained by very low

TABLE 5-13 Composition and Approximate Annual Use of Brominated Diphenyl Ester Formulations

Preparation	Composition	Annual Worldwide Production (ton)
Deca-BDE	97-98% deca-BDE 0.3-3% nona-BDE	30,000
Octa-BDE	43-44% hepta-BDE 31-35% octa-BDE 10-12% hexa-BDE 9-11% nona-BDE 0-1% deca-BDE	6,000
Penta-BDE	50-62% penta-BDE 24-38% tetra-BDE 4-8% hexa-BDE 0-1% tri-BDE	4,000

Source: Data from WHO 1994.

absorption of deca-BDE across the gastrointestinal tract (about 0.3%). There is evidence of toxic effects from exposure to the less highly brominated BDE formulations. For example, rats fed a diet containing octa-BDE at 1 or 10 g/kg for 13 weeks had reduced body weight at both doses and decreased red-blood-cell count at the high dose. An increase in liver weight and no changes in body weight or blood-cell counts were found in rats fed a diet containing octa-BDE at 0.1 g/kg for 13 weeks. Rats fed penta-BDE at 0.1 or 1 g/kg for 4 weeks had increased liver weight without a change in body weight. Histopathology analyses indicate higher doses of octa- and penta-BDE alter liver and thyroid tissue.

More recent work focused on actions of BDEs on liver enzymes and thyroid hormones in rats. Octa- and penta-BDE formulations increased the activities of hepatic enzymes that metabolize thyroid hormone, whereas deca-BDE did not (Zhou et al. 2001). These increased enzyme activities were associated with reduced serum concentrations of thyroxin. Because thyroid-stimulating hormone was not altered by BDEs, increased elimination by the liver rather than decreased secretion by the thyroid appeared to explain the reduced serum thyroxin. The potential for BDE metabolites to interact with transthyretin (a protein that carries thyroxin in blood) was demonstrated by Meerts et al. (2001). Three hydroxylated BDEs effectively displaced thyroxin from this protein. Eriksson et al. (2001) reported neurotoxic actions of a tetra-BDE and a penta-BDE congener in mice. Neonatal exposure to both congeners altered spontaneous behavior, and the penta-BDE reduced memory.

Despite the evidence of the toxic potential of BDEs, a review of the above studies and other toxicological studies estimated that current human dietary intakes of BDEs were a million times lower than the lowest-observed-adverse-effect levels in animal studies (Darnerud et al. 2001). Concentrations of BDEs in human breast milk and fish have increased over time. BDE concentrations in breast milk from Swedish women have been reported to increase exponentially over the past 25 years as commercial use of these chemicals has increased (Hooper and McDonald 2000). Preliminary data indicated that concentrations in milk from North American women were 10- to 40-fold higher than those from Swedish women (Betts 2001). Norén and Meironyté (2000) reported that BDEs in the breast milk of Swedish women ranged from 0.07 to 0.48 ng/g of lipid between 1972 and 1980 and from 0.72 to 4.01 ng/g of lipid between 1984 and 1997.

Few data are available on concentrations of BDEs in biosolids. One study reported that the sum of penta- and deca-brominated BDEs in biosolids ranged from 1 to 7 ppm in the United States (Hale et al. 2001). The extent to which BDEs in biosolids are related to current human body burdens is unclear.

Surfactants

Surfactants used in laundry detergents and other cleaning products enter wastewater in large quantities from domestic and commercial wastewater sources. Linear alkylbenzene sulfonates (LAS), alkyl phenol ethoxylates (APE), and alcohol ethoxylates (AE) are high-production surfactants that have respective U.S. annual consumptions of 415, 322, and 208 million kg in 1990 (McAvoy et al. 1998). Standards for LAS and APE established in some European countries are largely based on ecotoxicological impacts and not human health (Cavalli and Valtorta 1999). Use of nonylphenol-based surfactants is banned in Switzerland.

Studies of LAS dominate the literature on degradation of surfactants. The type of sewage-sludge treatment will have a strong impact on the presence of surfactants. LAS, for example, is readily degraded in an aerobic environment but not in an anaerobic environment (Scott and Jones 2000). The half-life of LAS in aerobic soils is 7-30 days (Cavalli and Valtorta 1999; Scott and Jones 2000) and over a year under anaerobic conditions (Cavalli and Valtorta 1999). Soil concentrations of LAS immediately after biosolids applications range from 0.5 to 66.4 ppm (Scott and Jones 2000). Differences in amounts of aerobic and anaerobic treatment before application might at least partially explain this wide range. A 2-year feeding and reproduction study in rats with a LAS preparation (hydrocarbon-chain-length distribution of 10 to 14 carbons) revealed little or no toxicity (Buehler et al. 1971). Rats fed LAS at a concentration of 5 g/kg gained body weight and consumed food at the same rate as controls. Hematology and visceral organ histology were normal. Oral LAS dosing of rhesus monkeys also indicated very low toxicity (Heywood et al. 1978). Some studies reported that these anionic surfactants are rapidly degraded in soils, and risk assessments suggested that they pose little threat to the food chain (de Wolf and Feijtel 1998; Jensen 1999).

Talmage (1994) reviewed the biodegradation and toxicology of the nonionic surfactant AEs and APEs. Most AEs are mixtures of 8 to 18 carbon linear primary alcohols, but linear secondary and branched AEs are also used. About 90% of AEs undergoing activated sewage sludge treatment degrade, indicating rapid aerobic metabolism. Feeding rats a medium-chain-length AE for 2 years at 10 g/kg reduced food consumption and body-weight gain, but these effects were not seen at 1 g/kg. A dose-dependent increase in myocarditis was the only effect observed. Direct attachment of a branched alkyl chain (usually 9 carbons) and ester linkage of a polyethoxy chain (4-40 carbons) to phenol yields APEs. Although activated sewage sludge treatment removes up to 97% of APEs, substantial adsorption to sewage sludge occurs. APE concentrations of tens to hundreds parts per million occur in sewage sludge. The concentrations of potentially toxic metabolites, especially nonylphenol, range from an approximate equivalent to the parent compound to several times higher. Survival and growth of rats fed a long polyethoxy chain (40 carbons) APE at 14 g/kg for 2 years were the same as those of controls. No pathological lesions were associated with treatment. Reduced body weight and enlarged livers occurred in rats fed a short polyethoxy chain (4 carbons) APE at 1 g/kg/day. At lower doses (30 and 140 mg/kg/day), no growth reduction or evidence of histopathological changes were found after 2 years of feeding. APEs degrade to nonylphenols and octylphenols in aerobic environments, and that increases toxicity of the material up to 10-fold (Scott and Jones 2000). For example, the mono- and di-ethoxylates degrade to 4-nonylphenol. Studies from the United States (LaGuardia et al. 2001) and Switzerland (Giger et al. 1984) detected nonylphenol polyethoxylates in sewage sludge. A nonylphenol concentration of 4.7 ppm was reported in soil soon after biosolids application (Scott and Jones 2000). Concentrations of nonylphenols in anaerobically digested sewage sludge may be as high as 4,000 mg/kg (Bennie 1999). They may be rapidly degraded in soil, limiting the potential transfer into the food chain, but there are few field-based data. Although recent evidence suggests that nonylphenols spiked into uncontaminated biosolids are degraded over several months, a significant portion of the nonylphenols in aged biosolids is recalcitrant to biological transformation (Topp and Starratt 2000). In addition to persistence in the soil, the sorption of nonylphenol onto organic matter may give rise to the facilitated transport of these compounds into groundwater (Nelson et al. 1998). Nonylphenol and other alkylphenolics activity as endocrine disruptors is of some concern. The

risk from environmental exposure is most clear for fish in surface waters receiving waste-water treatment plant (WWTP) effluents (Jobling et al. 1996).

Chlorinated Paraffins

Chlorinated paraffins or polychlorinated *n*-alkanes (PCAs) are used as additives in lubricants, plastics, flame retardants, paints, sealants, and cutting and lubricating oils. These chemicals are actively produced in large tonnages and have numerous uses and sources. When dissolved in a polymer, they probably leak slowly into the environment, and almost half of the oils used in manufacturing might enter wastewater streams (Alcock et al. 1999). Therefore, industrial effluents are much more likely sources of chlorinated paraffins in biosolids than in domestic wastewater.

High doses of chlorinated paraffins (100-1,000 mg/kg/day for 14 days) increased liver size and peroxisomal enzyme activity in rats and mice (Wyatt et al. 1993). They also reduced plasma thyroid hormone concentrations in rats at the highest dose in that study. Chlorinated paraffins induced liver and thyroid tumors in rats and mice and are probable human carcinogens (NTP 1986). These materials deserve attention in future analytical work on biosolids.

Nitro and Polycyclic Musks

Nitro and polycyclic musks are fragrances in a variety of personal-care products, including shampoos, soaps, detergents, perfumes, and skin lotions. Feeding mice musk xylol at 1.5 g/kg for 80 weeks increased liver tumor incidence (Maekawa et al. 1990). Although sewage treatment markedly reduces nitro musk concentrations in wastewater, amino metabolites that are more toxic than parent compounds occurred in effluents at 1-250 ppt (Daughton and Ternes 1999). Herren and Berset (2000) reported concentrations of nitro musks, their amino metabolites, and polycyclic musks in sewage sludge from 12 Swiss WWTPs. Nitro-musk concentrations in sewage sludge ranged from less than 0.1 to 7 ppb dry weight. Amino metabolites ranged from less than 0.1 to 49 ppb dry weight. Much higher concentrations of polycyclic musks in sewage sludge occurred at up to 12 ppm dry weight for galaxolide and 4 ppm dry weight for tonalide. Those concentrations can be explained by the phase out of nitro musks and the increased production of polycyclic musks (reviewed in Daughton and Ternes 1999) and slow rates of degradation. One estimate of half-life for polycyclic musks in soils is 180 days (Balk and Ford 1999). Future risk assessment on biosolids should consider polycyclic musks.

Pharmaceuticals

Since the early 1980s, there have been increasingly frequent reports of pharmaceuticals detected in wastewater treatment effluent or surface water in trace concentrations (typically in nanograms per liter) (Daughton and Ternes 1999; Ayscough et al. 2000). These reports have become more frequent as analytical techniques have improved to enable identification of very low concentrations of these chemicals in complex mixtures. Many of these chemicals are

produced in very high volumes, and they or their metabolites are added directly to wastewater after use. Most of the concern regarding the potential effects of these chemicals, particularly the potential endocrine-disrupting effects of hormones, has been for the impact on aquatic receptors. The majority of drugs are water soluble, and metabolism after ingestion generally increases the solubility further. Consequently, most drugs and their metabolites are unlikely to be present in significant quantities in biosolids. Nevertheless, more lipophilic compounds will have a greater tendency to partition to biosolids.

Since 1969, the National Environmental Policy Act has required the assessment of risk to the environment from use of drugs. Environmental assessments are part of the registration procedure for new human pharmaceuticals (FDA 1985; Eirkson 1987). The procedure in place since 1995 calls for estimation of an expected introductory concentration (EIC) based on dividing the expected annual production volume by the number of liters of wastewater entering publicly owned treatment works per year (U.S. Center for Drug Evaluation and Research 1995). When the predicted EIC in wastewater effluent is less than 1 μg/liter, a detailed environmental assessment is not needed.

Active pharmaceutical compounds and a wide variety of metabolites enter wastewater after personal use at home and work (Ayscough et al. 2000). A somewhat different spectrum of chemicals will enter wastewater after use in hospitals and medical centers. The parent compounds may also be disposed of directly to wastewater. These chemicals may be further degraded or biodegraded in wastewater and during treatment at wastewater treatment plants. Analytical methods to characterize the resulting complex mixtures of chemicals are useful for research but are not currently adequate for routine screening (Daughton and Ternes 1999). Standard reference materials are often not readily available, and many of these substances are not included in environmentally oriented mass spectral libraries.

The efficiency of removal of drugs in wastewater treatment plants has mainly been determined by measuring influent and effluent concentrations. Removal efficiency varies greatly among different pharmaceuticals and varies over time at any single treatment plant (Daughton and Ternes 1999). Removal of a drug could reflect either degradation and biodegradation or sequestration in biosolids; no data on drug concentrations in sewage sludge or biosolids were identified for this review. Partition coefficients between organic matter and water vary up to 500-fold for different drugs (Tolls 2001). Since thousands of drugs are approved for use, any attempt to determine whether drugs are routinely present in biosolids would require a carefully focused approach, perhaps looking for the highest volume drugs that have lipophilic properties and are not predominantly metabolized to water-soluble forms.

Toxicity studies have been conducted for most drugs, but the results of such studies are often not reported in the peer-reviewed literature. If drugs are detected in biosolids, approaches for evaluating potential adverse health effects will need to be considered. Typically, effects of toxicity would be limited to doses exceeding the therapeutic doses. However, therapeutic dose effects in a non-target population might be considered adverse effects. Therefore, health-based screening could rely on toxicity values that are a specific fraction of therapeutic dose levels.

In summary, pharmaceuticals and personal care products are produced in high volumes, and they and their metabolites are excreted directly to wastewater, where they have been detected in very low (generally, nanograms per liter) concentrations. The potential for most of these chemicals to partition to biosolids is limited by their generally high water solubility; however, some drugs may be sufficiently lipophilic to partition preferentially to biosolids. At present, there is not adequate evidence that pharmaceuticals are likely to occur in biosolids at

concentrations sufficient to warrant their inclusion in a biosolids risk assessment; however, EPA should continue to monitor research in this area.

Volatile Emissions and Odorants

The chemical selection process used for the Part 503 rule risk assessment included consideration of volatile organic chemicals (VOCs) that are priority pollutants. These VOCs are generally limited to chlorinated and aromatic volatiles, which might be present in biosolids as a result of industrial or other discharges to sewer systems. Because the majority of these VOCs will be released to the air during wastewater processing, VOCs were ruled out as chemicals of concern for land application of biosolids.

Sewage sludge also emits many VOCs not included in the EPA priority pollutant list. These VOCs include sulfur and nitrogen-containing chemicals that are strong odorants, as well as acids, aldehydes, and ketones that are also odorants. A review by Gostelow et al. (2001) provides an overview of odorant generation during wastewater treatment and describes measurement methods. Many of these chemicals are generated during the biodegradation of wastewater and sewage-sludge components, and the protein breakdown contributes to the generation of sulfur and nitrogen-containing compounds (Gostelow et al. 2001). Sufonates from detergents are additional sources of sulfur, and urine and amino acids contribute to formation of nitrogen-containing compounds. Carbohydrate fermentation during anaerobic sewage sludge treatment contributes to the formation of volatile fatty acids, aldehydes, alcohols, and ketones.

The mixture of odorants in biosolids will differ from that in sewage sludge, and the relative concentrations will differ between the two mixtures for odorants present in both. Table 5-14 lists odorants associated with wastewater treatment, their characteristic odors, and their odor thresholds. As noted in the table, many of these odorants have been detected in biosolids. Although hydrogen disulfide is the predominant odorant associated with wastewater treatment, it is less of a factor in the odors of biosolids (Striebig 1999). In an unpublished laboratory study, the predominant odorants varied, depending on treatment methods used to reduce pathogens in the biosolids. Overall odor increased with lime treatment and increasing temperature (Striebig 1999). Additional studies are needed to provide a more robust database of odorants released from biosolids. Potential risks associated with odorants cannot be properly assessed until such a database is developed.

Noxious odors are one of the primary causes of complaints from the public about land application of biosolids. Odor perception consists of two steps: physiological reception and psychological interpretation (Gostelow et al. 2001). Although odorants may cause toxic effects, perception of an odor as noxious is not directly linked to toxicity. Perception of sewage odors as unpleasant might be due to an association with decaying material that needs to be avoided. As noted by Schiffman et al. (2000), foul environmental odors frequently engender concerns for safety. Odor perception has been shown to affect mood, including levels of tension, depression, anger, fatigue, and confusion (Schiffman et al. 1995). Mood impairments and stress can potentially lead to physiological and biochemical changes with subsequent health consequences (Shusterman et al. 1991; Cohen and Herbert 1986). In addition, conditioned responses (behavioral and physiological) can be developed to odors perceived to be associated with health symptoms (Bolla-Wilson et al. 1988; Shusterman et al. 1988).

TABLE 5-14 Odorants Generated during Sewage Treatment

Class[a]	Compound[a]	Formula[a]	Character[a]	Detected in Biosolids[b]	Odor Threshold (ppm)
Sulfurous	Hydrogen sulfide	H_2S	Rotten eggs	X	0.0081[c]
	Dimethyl sulfide	$(CH_3)_2S$	Decayed vegetables, garlic	X	0.001[d]
	Diethyl sulfide	$(C_2H_5)_2S$	Nauseating, ether		0.005[d]
	Diphenyl sulfide	$(C_6H_5)_2S$	Unpleasant, burnt rubber	X	0.0001[e]
	Diallyl sulfide	$(CH_2CHCH_2)_2S$	Garlic		0.0001[d]
	Carbon disulfide	CS_2	Decayed vegetables	X	0.0078[d]
	Dimethyl disulfide	$(CH_3)_2S_2$	Putrification	X	0.000026[d]
	Methyl mercaptan	CH_3SH	Decayed cabbage, garlic	X	0.0016[c]
	Ethyl mercaptan	C_2H_5SH	Decayed cabbage	X	0.0003[e]
	Propyl mercaptan	C_3H_7SH	Unpleasant	X	0.0005[e]
	Butyl mercaptan	C_4H_9SH	Unpleasant		0.00043[d]
	t-Butyl mercaptan	$(CH_3)_3CSH$	Unpleasant		
	Allyl mercaptan	CH_2CHCH_2SH	Garlic	X	0.0001[d]
	Crotyl mercaptan	$CH_3CHCHCH_2SH$	Skunk, rancid		
	Benzyl mercaptan	$C_6H_5CH_2SH$	Unpleasant	X	0.0002[e]
	Thiocresol	$CH_3C_6H_4SH$	Skunk, rancid	X	0.0001[e]
	Thiophenol	C_6H_5SH	Putrid, nauseating, decay		
	Sulfur dioxide	SO_2	Sharp, pungent, irritating		1.1[c]
Nitrogenous	Ammonia	NH_3	Sharp, pungent	X	5.2[c]
	Methylamine	CH_3NH_2	Fishy	X	3.2[c]
	Dimethylamine	$(CH_3)_2NH$	Fishy	X	0.34[c]
	Trimethylamine	$(CH_3)_3N$	Fishy, ammoniacal	X	0.00044[c]
	Ethylamine	$C_2H_5NH_2$	Ammoniacal	X	0.95[c]
	Diethylamine	$(C_2H_5)_2NH_2$			0.13[c]
	Triethylamine	$(C_2H_5)_3N$		X	0.48[c]
	Diamines (cadaverine)	$NH_2(CH_2)_5NH_2$	Decomposing meat		
	Pyridine	C_6H_5N	Disagreeable, irritating	X	0.66[e]
	Indole	C_8H_6NH	Fecal, nauseating	X	0.0001[e]
	Scatole or skatole	C_9H_8NH	Fecal, nauseating	X	0.001[e]
Acids	Acetic (ethanoic)	CH_3COOH	Vinegar	X	1.02[d]
	Butyric (butanoic)	C_3H_7COOH	Rancid, sweaty	X	0.0003[d]
	Valeric (pentanoic)	C_4H_9COOH	Sweaty		0.0006[d]
Aldehydes and ketones	Formaldehyde	HCHO	Acrid, suffocating		0.83[c]
	Acetaldehyde	CH_3CHO	Fruit, apple	X	0.067[e]
	Butyraldehyde	C_3H_7CHO	Rancid, sweaty		0.0046[d]
	Isobutyraldehyde	$(CH_3)_2CHCHO$	Fruit		
	Isovaleraldehyde	$(CH_3)_2CHCH_2CHO$	Fruit, apple		
	Acetone	CH_3COCH_3	Fruit, sweet		13[c]
	Butanone	$C_2H_5COCH_3$	Green apple		

[a]Gostelow et al. 2001; [b]Unpublished data from Striebig 1999; [c]Amoore and Hautala 1983; [d]Ruth 1986; [e]WEF/ASCE 1995.

Odors associated with biosolids are due to complex mixtures of odorous chemicals that vary greatly in toxicity and in odor thresholds. The olfactory system processes stimuli from the chemicals in these mixtures, perceiving one overall odor. There are two primary approaches to measuring odors: analytical measurements of individual odorants in a mixture and sensory studies in which human subjects provide subjective evaluations of odors (reviewed in Gostelow et al. 2001). Fully characterizing an odor requires the use of both approaches. Although analytical measurements allow for identification of the chemicals present, sensory studies may provide assessments of the intensity, character, and hedonic tone (pleasantness or unpleasantness) of an odor. Analytical measurements are crucial for an assessment of the potential toxicity of odorous chemicals, because toxicity thresholds often do not correlate with odor thresholds.

In assessing odorants, it is important to distinguish between symptoms or health complaints due to odor perception and irritant effects and other forms of toxicity. Participants at a workshop held at Duke University in 1998 defined a set of odor levels to clarify the intensities associated with potential health impacts (Schiffman et al. 2000) (see Table 5-15). These levels begin with odor detection and progress through odor intolerance (defined as physical symptoms occurring at a nonirritant concentration, irritant effects, and chronic and acute toxicity. Identification of these levels does not imply that consistent increases in concentrations trigger each level of response. For example, some odorants might have minimal irritant effects but produce chronic or acute toxicity. Strong odorants might be detected at concentrations far less than those that cause toxicity, whereas weak odorants might cause toxicity at concentrations close to odor detection thresholds. Table 5-16 provides a comparison of odor thresholds and thresholds for toxicity of odorants detected in biosolids. Toxicity threshold values for airborne chemicals are derived by a variety of organizations. EPA and the Agency for Toxic Substances and Disease Registry are the primary sources of toxicity values for evaluating effects of chronic exposure. EPA is also overseeing the development of acute exposure guideline levels (AEGL) to evaluate acute exposures of the general public, and the National Institute for Occupational Safety Health, the American Conference of Governmental Industrial Hygienists, and the Occupational Safety and Health Administration derive acute exposure guidelines for occupational exposures. The divergence of odor threshold and toxicity is illustrated by comparing values for hydrogen sulfide and carbon disulfide. The odor thresholds for the two chemicals are similar, but the reference concentrations suggest that the chronic toxicity of hydrogen sulfide is more than 100 times greater than that of carbon disulfide

As can be seen in Table 5-16, toxicity values are available for only a small number of odorants found in biosolids. Evaluation of risks of exposure to odorants will depend on the availability of appropriate toxicity values for these chemicals. Appropriate toxicity values will need to be based on the likely exposure duration (short-term vs. chronic). Consequently, initial efforts to evaluate the potential hazards of odorants identified in biosolids should focus on dose-response assessment for exposure durations likely to occur in the exposed populations. Because many of these chemicals are structurally similar, quantitative structure activity analysis (QSAR) might be a useful tool to augment the limited toxicity database. In conclusion, a wide variety of odorants are present in wastewater effluents, and the chemical compositions and concentrations of odorants in biosolids vary with the treatment processes as well as the origin of the effluents. Inhalation is the only exposure pathway of concern for VOCs, and both acute and chronic exposures should be considered. Additional studies are needed to identify odorants typically released from biosolids and to determine the range of likely air concentrations near biosolids-

TABLE 5-15 Perception of Odors and Health Complaints

Level	Description
1. Odor detection	The level of odor that can first be differentiated from ambient air.
2. Odor recognition	The level of odor at which the odor quality can be characterized, e.g., the level at which a person can detect that an odor is apple or manure.
3. Odor annoyance	The level at which a person is annoyed by an odor but does not show or perceive a physical reaction. Note: Health symptoms are not expected at these first three levels unless the odor occurs with a co-pollutant such as dust as in Paradigm 3 or the level of annoyance is intense or prolonged.
4. Odor intolerance (causing somatic symptoms)	The level at which an individual may show or perceive physical (somatic) symptoms to an odor. Note: This level corresponds to Paradigm 2 in which the odor induces symptoms even thought the odorant concentration is lower than that known to cause irritation.
5. Perceived irritant	The level at which a person reports irritation or physical symptoms as a result of stimulation of nerve endings in the respiratory tract.
6. Somatic irritant	The level at which an odorant (not an odor) results in a negative physical reaction regardless of an individual's predisposition. This can occur when an odorous compound (e.g., chlorine) damages tissue. Note: Perceived and somatic irritation correspond to Paradigm 1.
7. Chronic toxicity	The level at which an odorant can result in long-term health impact.
8. Acute toxicity	The level at which an immediate toxic impact is experienced, e.g., a single event may evoke an acute health impact. Note: In the case of chronic or acute toxicity, the compound should not be considered an odorant but rather a compound with toxic effects that happens to have an odor.

Source: Schiffman et al. 2000. Reprinted with permission from Journal of Agromedicine, copyright 2000, Haworth Press, Inc.

application sites. Acute and chronic toxicity values (air concentrations determined to be safe for specified kinds of exposures) should be developed for the predominant odorants, and a hazard analysis should be conducted to determine whether air concentrations generated near application sites are high enough to warrant more detailed risk assessment for this category of chemicals. Research is also needed on the impacts of odors. Particular attention should be paid to the degree to which effective biosolids treatment reduces odorant concentrations and impacts.

TABLE 5-16 Comparison of Odor Thresholds and Thresholds for Toxicity

Class	Compound	Odor Threshold (ppm)[a]	Threshold Limit Values (ppm)[b]	Acute Exposure Guideline Levels (ppm)[c]	Reference Concentrations (ppm)[d]
Sulfurous	Hydrogen sulfide	0.0081	10	0.11	0.0007
	Carbon disulfide	0.0078	10		0.22
	Methyl mercaptan	0.0016	0.5	0.5	
	Ethyl mercaptan	0.0003	0.5		
Nitrogenous	Ammonia	5.2	25	25	0.14
	Methylamine	3.2	5		
	Dimethylamine	0.34	5		
	Trimethylamine	0.00044	5		0.0017
	Ethylamine	0.95	5		
	Triethylamine	0.48	1		
	Pyridine	0.66	5		
Acids	Acetic (ethanoic)	1.02	10		

[a] Value taken from Table 5-11.
[b] Eight-hour time-weighted averages for workers (ACGIH 2001a,b,c)
[c] AEGL-1 values for 8-hr exposures (nondisabling); protection of general public from irritation (Paul Tobin, EPA, personal communication, October 2001)
[d] Reference concentrations expected to pose no risk of adverse effects in public populations with chronic exposures (EPA 2002b, IRIS database).

FINDINGS AND RECOMMENDATIONS

In responding to the committee's charge to evaluate the technical basis of the biosolids chemical standards, it is important to distinguish between the appropriate risk-assessment methods at the time the standards were developed versus the most appropriate methods now. The committee did not attempt to determine whether the methods used at that time were appropriate, and the committee's findings and recommendations should not be construed as either criticism or approval of the standards when issued. Instead, the findings and recommendations focus on how current risk-assessment practices and current knowledge regarding chemicals in biosolids can be used to update and strengthen the scientific credibility of EPA's chemical standards.

In light of the advances made in risk-assessment methods and the need to update many of the exposure parameters used in the risk assessment process, the existing biosolids standards for inorganic pollutants clearly need to be reevaluated. A comparison of the pollutant limits with risk-based soil screening levels suggests that the pollutant standards are adequately protective for some exposure pathways (i.e., soil/biosolids ingestion), but may need to be reevaluated for others (i.e., ingestion of homegrown produce grown on biosolids-amended soil, groundwater). Reevaluating the standards is not the same as saying that the standards should be lower. In fact, some standards might increase after a reevaluation. A lower standard for a particular pollutant also would not necessarily indicate the presence of a health risk. The risk would depend on the actual concentrations of the pollutant in biosolids to which people were exposed. Nonetheless, the current limits cannot with confidence be stated to be adequately protective for all of the regulated pollutants. Additionally, limitations in the chemical selection process apply to inorganic, as well as organic, pollutants.

Recommendation: *A revised multipathway risk assessment should be performed for the currently regulated pollutants, with particular attention paid to arsenic and to indirect exposure pathways for cadmium and mercury. Additionally, new survey data should be used to identify any additional inorganic or organic pollutants that might need to be included in a risk assessment.*

The science and body of knowledge underlying the practice of risk assessment have evolved substantially since the risk assessment supporting the Part 503 rule was conducted. Consequently, different approaches and supporting data would be used if the Part 503 rule risk assessment were conducted again today or in the future. One important development has been the recognition of the importance of engaging stakeholders in the risk-assessment process to help characterize potential exposures. Stakeholders are groups potentially affected by the risk, risk managers, and groups affected by efforts to manage the source of the risk. Involving stakeholders throughout the risk-assessment process provides opportunities to bridge gaps in understanding, language, values, and perspectives and to address concerns of affected communities.

Recommendation*: Risk-based standards for land application of biosolids should be reevaluated on a regular basis to take into account new information regarding the identity and properties of chemicals present in these mixtures and current approaches to evaluating the risks of exposure to such mixtures. Stakeholders should be included in the process, particularly in the development of the exposure assessments.*

The chemical selection process used to identify chemicals of concern for the risk assessment is now outdated. Data from the NSSS that was used in the selection process are over a decade old, and there is a need to characterize the concentrations and distribution of chemicals now present in biosolids. Additional chemicals not included in the NSSS analyses have now been identified as new concerns. Analytical methods have improved since the NSSS was conducted.

Recommendation*: The committee endorses the recommendation of the previous NRC committee (NRC 1996) that a new national survey of chemicals in biosolids be conducted. It recognizes that more recent survey data are available through many state programs and recommends that EPA consider those databases in the course of designing a new national survey. Other elements that should be included in a new survey are the following: evaluation of the adequacy of analytical methods and detection limits to support risk assessment; consideration of categories of chemicals of current concern that were not previously evaluated (e.g., odorants, surfactants, and pharmaceuticals); and assessment of the possible presence of multiple species of mercury, arsenic, and other metals that have different toxic end points.*

EPA's decision to eliminate all chemicals detected at less than 5% or 10% frequency in the NSSS is unjustified. Data gaps may now be filled for toxicity and fate and transport characteristics that were previously used to eliminate chemicals from the risk assessment. In addition, uncertainties associated with the chemical selection process have not been adequately evaluated.

***Recommendation**: Selected persistent, bioaccumulative, and highly toxic chemicals should be retained in the risk assessment even if they are detected relatively infrequently or if some chemical-specific fate and transport parameters are missing. An uncertainty assessment should be performed to evaluate the significance of eliminating chemicals from the risk assessment because of lack of toxicity data or other parameters.*

The Part 503 rule risk assessment focused on agricultural land-application scenarios. Conceptual site models documenting the exposure pathways judged to be major and minor are not available for the scenarios evaluated. Consequently, it is difficult to determine whether all relevant pathways were identified. Although the pathways evaluated are likely to be the major exposure pathways for chronic exposures in agricultural scenarios, there might be differences in the significance of pathways for short-term exposures and for different scenarios.

***Recommendation**: A new risk assessment should include separate exposure scenarios that represent substantial differences in exposure potential (e.g., land reclamation and forestry applications). For each scenario, a conceptual site model approach should be used to identify major and minor exposure pathways and routes of exposure. Risks from short-term episodic exposures should also be evaluated for volatile chemicals, such as odorants.*

The degree of realism varies by exposure pathway. The pathways were not evaluated in a consistent manner (i.e., it is not apparent that exposure estimates were comparably conservative for all pathways). Exposures also were not added for multiple pathways affecting a single receptor. For the indirect pathways, the use of multiple, highly conservative assumptions could result in unrealistic overestimates of risk. However, because of the diversity of exposed populations, environmental conditions, and agricultural practices in the United States, exposure analyses based on a nationwide range of exposures might not be adequately protective for all cases.

***Recommendation**: A comparable reasonable maximum exposure (RME) should be evaluated for each exposure pathway in each exposure scenario, and where the same receptor is likely to be exposed to more than one pathway, exposures should be added across pathways. Such considerations are applicable for both deterministic and probabilistic exposure assessment approaches. Multiple highly conservative assumptions should be avoided; however, care should be taken to ensure that the risks are assessed for the high-end population and that the most sensitive conditions for biosolids application are considered. For example, for the groundwater infiltration pathway, if biosolids application is likely to occur in areas of sandy soil or karst topography with shallow groundwater, those conditions should be used in the risk assessment.*

As described above and in Chapter 4, new scientific data are now available that could be used to support alternative assumptions for many of the exposure parameters used in the risk assessment. Comprehensive reviews and updated recommendations for many parameters have been compiled in several EPA guidance documents. Fate and transport models used to estimate exposure point concentrations for many pathways have also been updated.

***Recommendation**: The most recent EPA reviews and new studies reported in the literature should be used to identify updated assumptions for exposure parameters for use in risk assessment. Updated fate and transport models should be used to estimate exposure point concentrations. For each exposure pathway, fate and transport models and exposure parameter assumptions should be selected so that pathway exposures reflect the RME.*

Biosolids are likely to include many categories of chemicals that differ from the categories of chemicals of concern in industrial discharges. Although it is impossible to identify all of these pollutants, it is important that EPA continually think about the types of chemicals released into wastewaters and added during wastewater and sewage-sludge treatment processes as part of its process for updating the Part 503 rule. EPA eliminated certain chemicals of concern from further assessment when there was an absence of data on fate, transport, and toxicity. New data on some of these chemicals might now be available for determining whether risk assessments for those chemicals are needed. Because some organic chemicals, such as organochlorines, are persistent in the environment, consideration should be given to their tendency for trophic transfer and biomagnification. EPA has already undertaken such an evaluation for dioxins. Consideration should also be given to toxic end points that might not have been evaluated adequately in the earlier assessment (e.g., potential interactions of chemicals with the endocrine system). Two categories of chemicals deserving special attention are pharmaceuticals and odorants. Considering the amounts discharged to sewage systems, the presence of pharmaceuticals in biosolids has not been adequately investigated. For odorants, the need for further evaluation is driven by the high level of public concern, as well as very limited characterization of the odorants present in biosolids and their toxicity.

***Recommendation:** In addition to the recommendation above for a new biosolids survey and chemical selection process, it is recommended that a research program be developed for pharmaceuticals and other chemicals likely to be present in biosolids that are not currently included in routine monitoring programs. This included chemicals eliminated from Round 1 and Round 2 evaluations because of data gaps. The research program should have the goal of identifying additional chemicals that should be included in routine biosolids surveys, and in future risk assessments. For odorants, research in needed to identify the odorants present in various kinds of biosolids. For odorants commonly present in biosolids, EPA should move aggressively to develop acute toxicity values for use in assessing the risks posed by these chemicals and should support research on the interaction between these chemicals and pathogens in causing human disease.*

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6

Evaluation of EPA's Approach To Setting Pathogen Standards

Treatment of domestic sewage sludge is required to minimize the risk of adverse health effects from pathogens in biosolids applied to land. In 1993, EPA published regulations establishing the processes and conditions it deemed necessary to minimize these risks. Unlike the chemical standards, the pathogen regulations are not risk-based standards but are operational standards intended to reduce the presence of pathogens to concentrations that are not expected to cause adverse health effects. The standards include treatment requirements, site restrictions, and monitoring requirements.

This chapter reviews the pathogen standards for land-applied biosolids in light of current knowledge of the potential pathogens in biosolids, how humans might be exposed to those pathogens, and factors that affect exposure (environmental fate, regional variations, and host factors). It also reviews approaches for conducting microbial risk assessments and discusses how those approaches might be used to improve EPA's pathogen standards for biosolids. This chapter does not review health effects studies (see Chapter 3).

PATHOGEN STANDARDS

EPA established two categories of biosolids: Class A biosolids, which have no detectable concentrations of pathogens, and Class B biosolids, which have detectable concentrations of pathogens. With the goal of providing equivalent levels of public-health protection from pathogen exposure, EPA applied different use restrictions to each biosolids category.

Class B Requirements

A combination of treatment and site restrictions for Class B biosolids are intended to result in a reduction of pathogenic and indicator microorganisms (certain species of organisms believed to indicate the presence of a larger set of pathogens) to undetectable concentrations prior to public contact (Southworth 2001). Bulk biosolids applied to land must meet both treatment and use requirements (40 CFR 503.15[a]). EPA (1993) recognizes that those requirements do not necessarily consider risks to workers applying the biosolids at a site.

Treatment Requirements

Class B biosolids must be treated to meet one of three criteria: a fecal coliform count of less than 2×10^6/gram (g) of dry solids at the time of disposal, treatment by a process to significantly reduce pathogens (PSRP), or treatment by a process that is equivalent to a PSRP. In the 1993 regulations, five processes were listed as PSRPs (and thus sufficient to meet the Class B treatment requirements):

1. Aerobic digestion at defined time and temperature combinations.
2. Air drying for 3 months, with at least 2 months at average ambient daily temperatures above freezing.
3. Anaerobic digestion under defined time and temperature conditions.
4. Composting under defined time and temperature conditions.
5. Lime stabilization so that the pH is greater than 12 after 2 h of contact.

These PSRPs were selected because they result in fecal-coliform concentrations of less than 2×10^6/g of dry solids, and they reduce *Salmonella* and enteric virus concentrations by a factor of 10 (EPA 1999).

The third treatment criterion requires that the permit authority approve the processes being used as equivalent to a PSRP. In practice, permit authorities have relied on the recommendations of the EPA Pathogen Equivalency Committee (PEC) (Cook and Hanlon 1993) when determining whether a particular treatment system should be designated PSRP. As of October 1999, PEC had recommended that two additional processes be designated PSRPs.

Site Restrictions

The site restrictions for Class B biosolids (listed in Box 6-1) were developed on the basis of the time attenuation required to reduce the levels of pathogens (bacteria, viruses, and helminths) to below detectable concentrations at the time of public exposure (equivalent to those achieved by Class A biosolids) (Southworth 2001). The use restrictions correspond to important exposure pathways (Table 6-1).

Several potential exposure routes do not appear to have been considered when those use restrictions were developed. For example, inhalation of dust was presumed to occur only on-site, and controlling access to the site was intended to prevent such inhalation. The potential for off-site exposure to wind-blown dust and aerosols does not appear to have been considered. Nor was the potential transport of pathogens in runoff from the site to neighboring properties considered.

In addition, regulations require that public access to the site be restricted for either 30 days or 1 year, depending on the probability of public exposure. This restriction is vague, however, and has been interpreted by some state agencies as a requirement for posting warnings but not necessarily providing access barriers. In other contexts, such as municipal solid-waste landfills, EPA has been more specific about access controls, "Owners or operators [of landfills] must control public access … by using artificial barriers, natural barriers or both, as appropriate to protect human health and the environment" (40 CFR 258.25). Furthermore, there is no

requirement that on-site measurements be taken to confirm that the treatment and site restrictions for Class B biosolids result in pathogens concentrations below detection.

BOX 6-1 Site Restrictions for Class B Biosolids

- Food crops with harvested parts that touch the biosolids/soil mixture and are totally above the land surface shall not be harvested for 14 months after application of biosolids.
- Food crops with harvested parts below the surface of the land shall not be harvested for 20 months after application of biosolids when the biosolids remain on the land surface for four months or longer prior to incorporation into the soil.
- Food crops with harvested parts below the surface of the land shall not be harvested for 38 months after application of biosolids when the biosolids remain on the land surface for less than four months prior to incorporation into the soil.
- Food crops, feed crops, and fiber crops shall not be harvested for 30 days after application of biosolids.
- Animals shall not be grazed on the land for 30 days after application of biosolids.
- Turf grown on land where biosolids is applied shall not be harvested for one year after application of the biosolids when the harvested turf is placed on either land with a high potential for public exposure or a lawn, unless otherwise specified by the permitting authority.
- Public access to land with a high potential for public exposure shall be restricted for one year after application of biosolids.
- Public access to land with a low potential for public exposure shall be restricted for 30 days after application of biosolids.

Source: Adapted from 40 CFR 503.32(b)(5).

Class A Requirements

For biosolids to be categorized as Class A with respect to pathogens, they must meet one of six criteria:

1. Time and temperature requirements based on percentage of solids in the material.
2. pH adjustment accompanied by high temperature and solids drying.
3. Monitoring of enteric viruses and helminths after a treatment process to ensure below-

detection concentrations.

4. Monitoring of enteric viruses and helminths in the biosolids at the time they are distributed or applied to land.
5. Treatment by a process for the further reduction of pathogens (PFRP).
6. Treatment in a process deemed equivalent to a PFRP. There are seven processes that are designated PFRPs for Class A biosolids: (a) composting with minimum time and temperature conditions, (b) heat drying with specified temperature and moisture conditions, (c) high-temperature heat treatment (no moisture content condition), (d) thermophillic aerobic digestion at specified time and temperature, (e) beta irradiation at specified dosage, (f) gamma irradiation at specified dosage, and (g) pasteurization. As with Class B biosolids, PEC has the authority to recommend to permit authorities that additional processes be designated PFRP. As of October 1999, nine additional processes were granted PFRP status by PEC (EPA 1999).

The goal of the treatment processes to achieve Class A biosolids is to reduce pathogen densities to below the following detection limits for these organisms: less than 3 most probable number (MPN) per 4 g of total solids for *Salmonella* sp.; <1 plaque-forming unit (PFU) per 4 g of total solids for enteric viruses; and <1 viable ova per 4 g of total solids for helminths. When the Part 503 regulations were developed, Class A certification was generally based on the

TABLE 6-1 Pathways of Exposure and Applicable Use Restrictions (Class B Biosolids Only)

Pathways	Part 503 Required Use Restriction
Handling soil from fields where biosolids have been applied	No public access[a] to application until at least 1 year after Class B biosolids application
Handling soil or food from home gardens where biosolids have been applied	Class B biosolids may not be applied on home gardens
Inhaling dust[b]	No public access to application sites until at least 1 year after Class B biosolids application
Walking through fields where biosolids have been applied[b]	No public access to fields until at least 1 year after Class B biosolids application
Consuming crops from fields on which biosolids have been applied	Site restrictions that prevent the harvesting of crops until environmental attenuation has taken place.
Consuming milk or animal products from animals grazing on fields where biosolids have been applied	No animal grazing for 30 days after Class B biosolids have been applied
Ingesting surface water contaminated by runoff from fields where biosolids have been applied	Class B biosolids may not be applied within 10 meters of any waters to prevent runoff from biosolids-amended land
Ingesting inadequately cooked fish from water contaminated by runoff from fields where biosolids have been applied, affecting the surface water	Class B biosolids may not be applied with 10 meters of any waters prevent runoff from biosolids-amended land
Contact with vectors that have been in contact with biosolids	All land-applied biosolids must meet one of the vector-attraction-reduction options

[a]Public-access restrictions do not apply to farm workers. If there is low probability of public exposure to an application site, the public-access restrictions apply for only 30 days. However, application sites that are likely to be accessed by the public, such as ballfields, are subject to 1-year public-access restrictions. [b]Agricultural land is private property and not considered to have a high potential for public access. Nonetheless, public-access restrictions are applied.
Source: Adapted from EPA 1999.

presence of either *Salmonella* or fecal coliforms (indicator bacteria) (Southworth 2001), because only a few laboratories were capable of conducting virus and helminth analyses and more time was required for these analyses (2-4 weeks). Since then, the number of laboratories capable of such analyses has increased dramatically, and analysis time has decreased.

Class A pathogen requirements must be met before or at the same time that vector-attraction reduction requirements are met. For any criteria, the microbial agents are measured when the biosolids are used, disposed of, or prepared for distribution. At that time, Class A biosolids must meet one of two requirements: either the density of fecal coliforms is less than

1,000 MPN per gram of total solids or the density of *Salmonella* sp. is less than 3 MPN per 4 g of total solids.

EPA's Approach to Assessing Microbial Risks

The Part 503 standards for pathogens were not developed using a risk-based framework, nor were they intended to be. In 1989, the Cooperative State Research Service Technical Committee W-170 (1989) reviewed the proposed Part 503 standards and stated, "There is some concern regarding EPA's treatment of pathogens. While it was stated that the state of the art was such that a risk assessment for pathogens was not possible, we feel that this point was glossed over rather quickly and needs greater justification." The W-170 committee also noted that EPA was developing risk-based criteria for exposure to viruses in drinking water at the time of the proposed Part 503 standards.

A few years before the Part 503 rule was proposed, EPA stated the following (Venosa 1985) on the use of PSRPs for the operative Part 257 sewage sludge regulations:

> For a sludge treatment process to qualify as a 'process to significantly reduce pathogens' (PSRP), it must produce a pathogen reduction equivalent to that obtained by a good anaerobic digestion. The logic of the definition rests on the observation that agricultural use of anaerobically digested sludge as a fertilizer has been practiced for many years with no evidence that the practice has caused human illness, provided that the digestion is adequate. Since these farming operations were on land with limited access and clearly defined use, this same restriction was applied to the use of PSRP sludge. Unfortunately, this definition is not based on sound scientific information related to the survival and transport of pathogens in sludge amended soils. Further, the paucity of documented health problems associated with the land application of sludge may reflect the lack of sufficiently sensitive epidemiological tools to detect small scale incidents of disease.

The committee notes, however, that the lack of such studies does not suggest that there is a risk from pathogens.

The lack of a risk-assessment approach means that there is no explicit delineation of acceptable risk concentrations for Class A or Class B biosolids in the Part 503 rule. Before promulgation of the regulations, EPA funded development of preliminary risk assessments for exposure to parasites (EPA 1991a), bacteria (EPA 1991b), and viruses (EPA 1992) in biosolids. However, it is not clear to what extent these preliminary assessments were used in the development or revision of the Part 503 rule. The exposure assessments would be useful for more substantial risk-assessment development.

Although a risk-based approach might have been problematic when the Part 503 rule was proposed, it is clearly an appropriate approach to use at present. A risk-based approach to assessing pathogens in biosolids offers several distinct advantages over the present framework. First, a risk-based approach would help to address the lack of sufficient epidemiological study of

microbial risk from biosolids exposure. See Chapter 3 for discussion of the need for more epidemiological investigation.

Second, as noted by Venosa (1985), the fundamental basis of biosolids regulations with respect to protection against pathogens rests on the assertion that, historically, agricultural use of anaerobically digested biosolids on fields (with protection from public access) results in no discernable human health effects. In promulgating the Part 503 rule for pathogens, EPA made a judgment that the treatment and disposal practices for Class A and Class B biosolids provided public-health protection equal to that of the traditional use of anaerobically digested biosolids. That judgment was in effect an implicit risk assessment. If EPA performed an explicit risk assessment, the levels of public-health protection for Class A and Class B biosolids could be more consistently compared.

Third, EPA explicitly excluded risk to on-site workers from its consideration of appropriate levels of treatment. This exclusion might be particularly important for Class B biosolids, which have less stringent treatment before land application. In addition, EPA did not consider the potential for airborne and waterborne release and dispersal of microorganisms for off-site exposure (although it did consider the potential for on-site exposure to microorganisms). The use of a risk-assessment approach can allow a systematic consideration of these pathways.

Fourth, the basis for the EPA definitions of Class A biosolids relies on a numeric fecal coliform or *Salmonella* standard and a below-detection standard for viruses and helminths in a defined amount of biosolids (criteria 3 and 4). EPA reasoned that the combination of Class B treatment requirements and site-management restrictions resulted in an acceptable level of public-health protection. The use of below-detection criteria in some defined amount of biosolids originates from the use of a particular sample size in analysis (for logistical reasons). The absence of microorganisms in a small amount of material does not ensure that microorganisms are absent in a larger sample from the same source. Additionally, as has been suggested in the case of re-use of wastewater for agricultural purposes, a below-detection standard might be unnecessarily stringent (Blumenthal et al. 2000). A risk-assessment approach can establish numerical limits to achieve a defined level of human health risk.

Evaluation of Operational Standards

Techniques for Reducing Pathogens

As discussed above and in Chapter 2, techniques that combine physical, chemical, and biological processes are used to optimize pathogen reduction in biosolids. Two of the physical factors for reduction are heating and cavitation. It is difficult to examine the impact of only one physical factor, such as temperature, on reduction. Some studies have isolated temperature effects on *Ascaris* egg inactivation. Table 6-2 gives predicted detention times for complete (100%) inactivation of *Ascaris* eggs at different temperatures (Mbela 1988). At 52°C, complete inactivation of the eggs requires approximately 20 days. Inactivation with thermophilic alkaline processes and composting of biosolids requires approximately 3 to 5 days. Inactivation will also be affected by other factors such as ammonia, organic constituents, dissolved solids, and hydroxide anions (Evans and Puskas 1986; Reimers et al. 1986a).

Cavitation processes are also used to inactivate resistant microorganisms. Cavitation is a term for processes that impart high mechanical energy to a fluid, resulting in local transient

microzones of high temperature and pressure. Full-scale installation of such systems has not been done. However, cavitation processes, such as ultrasound or pulse power, have inactivated protozoan oocysts and assisted in enhancing anaerobic digestion processes (Reimers et al. 1985; Arrowood 1995; Patel 1996).

TABLE 6-2 Detention Times for Complete Inactivation of *Ascaris* Eggs in Aerobic and Anaerobic Digestion Processes

	Detention Time	
Temperature (°C)	Aerobic Digestion	Anaerobic Digestion
25	130 d	74 d
35	90 d	53 d
45	50 d	30 d
55	10 d	9 d
57	2 d	4 d
58	<1 h	3 d
59	<1 h	12 h
60	<1 h	<1 h
70	<1 h	<1 h

Source: Mbela 1988. Reprinted with permission from the author.

Chemical disinfection of biosolids has been used for over 50 years. The chemicals are classified on the basis of the mode of disinfection and stabilization (see Table 6-3). At present, only alkaline stabilization is used on a large-scale basis. Alkaline stabilization agents include lime, cement kiln dust, Portland cement, and alkaline fly ash (C-fly ash). Alkaline stabilization processes produce Class B biosolids. To yield Class A biosolids, increased temperatures or ammonia are necessary to inactivate highly resistant viruses, protozoan spores, and helminth eggs. Alkaline processes coupled with increased temperature yield a stable Class A product within 3 days. By increasing the temperature to 50°C, the effectiveness of ammonia and noncharged ammonia is increased by 5-fold and 10-fold, respectively (Bujoczek 2001). Yang (1996) confirmed this interrelationship (Table 6-4). As the solids content of the biosolids increases, the effectiveness of the alkaline disinfection increases (Yang 1996). Acid trimming enhances the exothermic reaction, because the acids generally release 10 times more heat than pulverized quicklime.

TABLE 6-3 Chemicals Used for Disinfecting Biosolids

Alkaline Agents	Acid Trimming Agents	ORP Controlling Agents	Noncharged Disinfectants
Lime	Sulfuric acid	Ozone	Ammonia (alkaline treatment)
Cement kiln dust	Nitric acid	Peroxide	Amines (alkaline treatment and composting)
Portland cement alkaline	Phosphoric acid sulfamic acid		Organic acids, aldehydes, and ketones (anaerobic digestion and composting)
Fly ash			Nitrous acid (acidic treatment)
Silicates			
Spent bauxite hydroxide anions			

Abbreviation: ORP, oxidation reduction potential
Source: Reimers et. al. 1999. Reprinted with permission from the author.

TABLE 6-4 Relationship Between Ammonia Concentration and Temperature in *Ascaris* Inactivation

	Ammonia Dosage for *Ascaris* Inactivation, days		
Temperature	0.1%	1.0%	4.0%
25°C	180	10	<1
35°C	10	3	<1
52°C	<1	<1	<1

Source: Data from Yang 1996.

Biological processing has been effective in the digesting, composting, and storage of biosolids. In these processes, there is mechanical or autothermal heating. Biocidal inactivation has been observed in lagoon storage. Anaerobic biosolids required 40% less inactivation time than aerobic biosolids, although above 50-55°C, thermal inactivation is predominant. Furthermore, as the solids content of anaerobic biosolids increases, the inactivation rates increase. An increase in solids from 4% to 24% resulted in a 5-fold increase in parasite and bacteria die-off and a 25-fold increase in virus die-off. Soils tend to reduce the rate of die-off of parasites and viruses by 3 to 5 times in nontreated or lagoon-stored biosolids (Reimers et al. 2001). The impacts of pathogen inactivation factors on biosolids processing are shown in Table 6-5.

TABLE 6-5 Parameters for Pathogen Inactivation in Biosolids

Biosolids Disinfection Process	Irradiation	Temperature	Solids Content	NH_3	Organic By-Products	Desiccants
Composting	-	+	-	±	+	-
Anaerobic digestion	-	+	+	-	+	-
Aerobic digestion	-	+	+	-	-	-
Lagoon storage	-	+	+	-	+	-
Air drying	+	+	+	-	-	+
Alkaline stabilization	-	+	+	+	-	+
Irradiation	+	-	-	-	-	-

+, the effect of the parameters in the column heads is to increase the rate or extent of inactivation in the process in column 1; –, the effect of these parameters do not influence the inactivation process.
Source: Reimers et al. 1986a, 1999; Yang 1996; Rohwer 1984.

Reliability of Processes

In assessing the risk associated with biosolids management, the reliability of the treatment processes is important to consider, because adverse effects might result from a single exposure to an infectious agent. Reliability may be defined as the frequency (or probability) at which a certain concentration or lower of a pathogen is attained in the effluent of a process. To assess the risk distribution from pathogen disinfection processes, data collection is required.

As an example, Figure 6-1 presents the probability distribution for virus and helminth counts in raw sewage sludge at the Metropolitan Water Reclamation District of Greater Chicago (Lue-Hing et al. 1998). The treatment sequence included anaerobic digestion, dewatering, and long-term lagoon storage. All treated virus samples were below detection. The data are plotted using a Kaplan-Meir approach to impute values for the below-detection samples. For example, in the finished solids, 95% of the time the helminth concentrations were below 0.05 organisms per 4 g of solids.

In setting standards, both the typical (e.g., mean) performance and the proportion of time that a specific numerical level is exceeded are appropriate metrics to be considered. For example, EPA-recommended water-quality criteria for micoorganisms in recreational waters be

specified according to geometric mean levels (over 7 d) and not-to-exceed levels. No such metrics have been established for pathogens in biosolids.

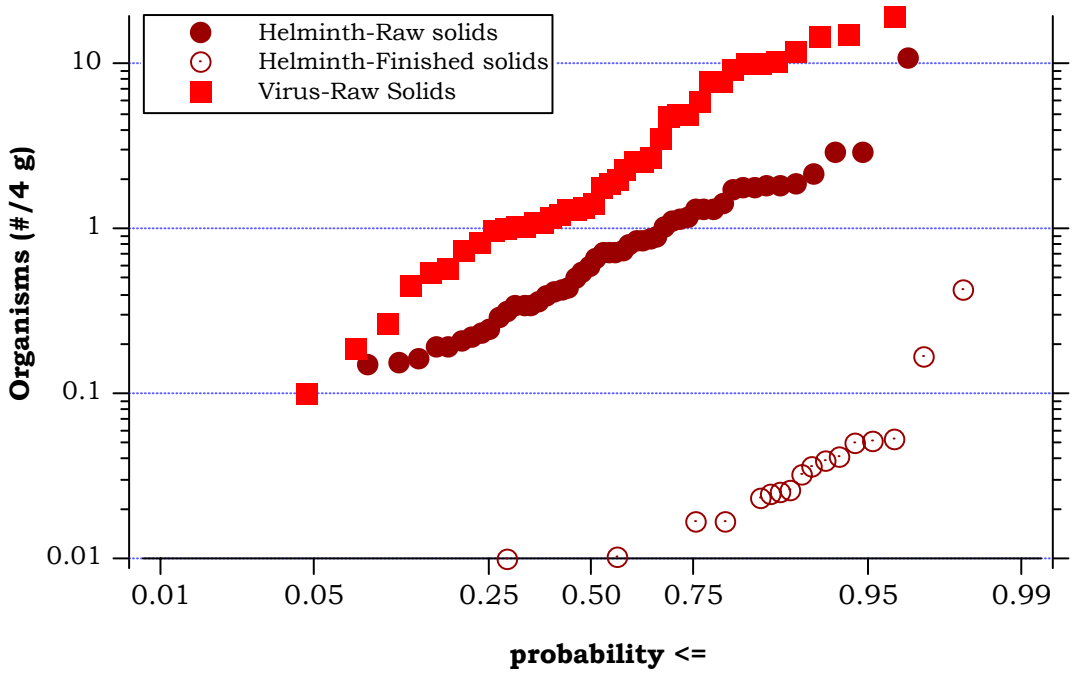

FIGURE 6-1 Virus and helminthes in raw and treated sludge at the Metropolitan Water Reclamation District of Greater Chicago. Source: Lue-Hing et al. 1998.

Reliability of Use Controls

For Class B biosolids, use requirements (described earlier in Box 6-1) are relied on as impediments to exposure, at least for the general public. The resulting risk reductions can be assessed if the pathogen die-off rates are known and if the degree to which the use controls prevent exposure are known. Unfortunately, the reliability of these controls has not been studied on a systematic basis.

PATHOGENS IN BIOSOLIDS

Four major types of human pathogens can be found in biosolids: bacteria, viruses, protozoa, and helminths. EPA reviewed a broad spectrum of these agents in establishing its biosolids standards. Some of the principal pathogens considered by EPA are listed in Box 6-2. Since the development of the Part 503 rule, many new pathogens have been recognized, and the importance of others has increased. A selection of these pathogens are discussed below. It must be noted that despite the ability to isolate pathogens from raw sewage sludge and partially and

fully treated biosolids, the mere isolation of pathogens does not in and of itself indicate that a risk exists. There are no scientifically documented outbreaks or excess illnesses that have

BOX 6-2 Principal Pathogens of Concern in Domestic Sewage and Sewage Sludge Considered in Establishing the Part 503 Rule

BACTERIA	**PROTOZOA**
Salmonella sp.	*Cryptosporidium*
Shigella sp.	*Entamoeba histolytica*
Yersinia sp.*Vibrio cholerae*	*Giardia lamblia*
Campylobacter jejuni	*Balantidium coli*
Escherichia coli	*Toxoplasma gondii*
ENTERIC VIRUSES	**HELMINTH WORMS**
Hepatitis A virus	*Ascaris lumbricoides*
Adenovirus	*Ascaris suum*
Norwalk virus	*Trichuris trichirua*
Caliciviruses	*Toxocara canis*
Rotaviruses	*Taenia saginata*
Enteroviruses	*Taenia solium*
-Polioviruses	*Necator americanus*
-Coxsackieviruses	*Hymenolepis nana*
-Echoviruses	
Reoviruses	
Astroviruses	

Source: Adapted from EPA 1999.

occurred from microorganisms in treated biosolids. As will be discussed in detail later, risk is a function of the level of exposure, not simply the occurrence of an organism per se.

Viral Pathogens

More than 140 enteric viruses can be transmitted by biosolids. The caliciviruses, adenoviruses, hepatitis A and E viruses, astroviruses, and rotaviruses are of particular concern. These viruses are discussed below, but it must be emphasized that there are other viruses of potential health concern in biosolids.

Caliciviruses

Caliciviruses infect both humans and animals, but no evidence suggests that they infect across species. Human caliciviruses have been divided into two genera—the Norwalk viruses and the Sapporo viruses (Green et al. 2000). These viruses are believed to be a major cause of viral gastroenteritis (Deneen et al. 2000; Monroe et al. 2000) and are common causes of foodborne and waterborne disease. Little is known about the occurrence and environmental fate of these viruses because they cannot be grown in cell culture. Methods using polymerase chain reaction (PCR) are available for their detection in environmental samples, but a viability assay is

not available (Huang et al. 2000). Feline caliciviruses (FCV) and a primate calicivirus (PAN-1) can be grown in cell culture and have been used as models for human calicivirus survival and removal by water-treatment processes (Dawson et al. 1993).

Adenoviruses

Adenoviruses are one of the most common and persistent viruses detected in wastewater (Enriquez et al. 1995). They are heat resistant. Enteric adenoviruses have been detected in Class B biosolids (Sabalos 1998), and adenovirus type 40 has been detected in anaerobically digested biosolids. Some adenoviruses cause primarily respiratory diseases, and others appear to be only enteric pathogens. They are a common cause of diarrhea and respiratory infections in children. In immunosuppressed cancer patients, enteric adenoviruses cause serious infections, resulting in case fatalities of up to 50% (Gerba et al. 1996). Adenoviruses have been transmitted by recreational and drinking waters (Kukkula et al. 1997; Papapetropoulou and Vantarakis 1998).

Hepatitis A and E Viruses

These viruses are now classified as two distinct groups of picornaviruses. Hepatitis E has caused major waterborne-disease outbreaks in developing countries but is not believed to be a serious problem in the United States. It has been reported to grow in cell culture (Wei et al. 2000). Hepatitis A has long been known to be transmitted by food and water, but no work has been done on its occurrence in biosolids. Cell-culture methods are available for its growth in the laboratory and detection in the environment. It is very stable at high temperatures (Croci et al. 1999) and has prolonged survival in the environment (Enriquez et al. 1995).

Astroviruses and Rotaviruses

Astroviruses are a cause of gastroenteritis primarily in children and have been associated with foodborne and waterborne outbreaks. They have been detected in water, wastewater, and more recently, in biosolids (Chapron et al. 2000). Rotaviruses are a leading cause of gastroenteritis in children and a major cause of hospitalization of children in the United States (Gerba et al. 1996). Rotaviruses are responsible for waterborne and foodborne outbreaks in the United States. They have been detected in wastewater, but few data are available on their occurrence in biosolids. Rotaviruses are the only double-stranded RNA viruses transmitted through water to humans. Both astroviruses and rotaviruses can be grown in cell culture.

Bacterial Pathogens

***Escherichia coli* 0157:H7**

Several types of *E. coli* are pathogenic to human. Enterohaemorrhagic *E. coli* of the serotype 0157:H7 has been of the greatest concern in the United States. Exposure to contaminated drinking water, recreational water, and food has resulted in numerous outbreaks of diarrhea and, in some cases, mortality in young children because of hemolytic uremic syndrome.

Exposure to both human and animal wastes have been associated with outbreaks (Rice 1999). Many of the outbreaks have resulted in some mortality. *E. coli* 0157:H7 occurs in domestic wastewater and has been detected in biosolids (Lytle et al. 1999). Because *E. coli* is common in biosolids and has the potential for regrowth (Pepper et al. 1993), it is important to assess its survival in biosolids. A quantitative risk-assessment model is available to assess the risk of infection from exposure to this pathogen (Haas et al. 2000).

Listeria montocytogenes

L. montocytogenes is primarily a foodborne pathogen that causes an invasive disease in immunocompromised people. It has a predilection for pregnant women and has potentially lethal consequences for the fetus and the newborn. Animals are also infected by the organism. Transmission of the organism has been linked to the use of biosolids on agricultural land, potentially contaminating crops and domestic animals. *L. montocytogenes* has been detected frequently in sewage sludge and in inactivated and anaerobically digested biosolids (Watkins and Sleath 1981; De Luca et al. 1998). For that reason, De Luca et al. (1998) suggested that biosolids not be applied to vegetable crops. Crop contamination was observed in Iraq where sewage-sludge cake was applied (Al-Ghazali and Al-Azawi 1990). A risk-assessment model is available to evaluate the health risks associated with *L. montocytogenes* in contaminated food (Lindqvist and Westoo 2000).

Helicobacter pylori

H. pylori is a major cause of stomach ulcers in humans and is associated with an increased risk of stomach cancer. Epidemiological evidence indicates that contaminated water and uncooked foods, particularly vegetables irrigated with untreated wastewater, are associated with increased risk of infection (Brown 2000). No culture methods are available for its detection in the environment. Molecular methods are available to determine its occurrence but not its viability (Hegarty et al. 1999).

Legionella spp.

Legionella spp. are associated with a potentially life-threatening respiratory illness in older people. *Legionella* is also associated with a milder fever and flulike illness called Pontiac fever. Outbreaks usually occur following the growth of the organism in cooling towers of buildings or thermally heated water. However, outbreaks also have been associated with composted potting mixes (Okazaki et al. 1998). Recently, an outbreak of Pontiac fever was reported among sewage treatment plant workers repairing a decanter for sewage sludge concentration (Gregersen et al. 1999). Positive antibody titers to *L. pneumophilia* were found in all the ill workers, and high concentrations were isolated from biosolids. *Legionella* has been detected in aerosols at sewage treatment plants (Stampi et al. 2000). *Legionella* spp. will grow at temperatures of 40°C, and survival at higher temperatures is possible. Methods are available for its detection in environmental samples.

Staphylococcus aureus

Speculation has arisen about the possibility of *S. aureus* illness from land-applied biosolids. Although not always considered normal human microflora, *S. aureus* is nonetheless found on the skin of a large number of people (Voss 1975; Welbourn et al. 1976; McGinley el al. 1988; Noble 1998). Some skin conditions associated with this bacteria include atopic dermatitis, a superficial inflammation of the skin (Nishijima et al. 1995). It is uncertain whether *S. aureus* has a specific pathogenic role in atopic dermatitis or whether its presence represents an opportunistic colonization at a site rendered more susceptible by an underlying condition, thus complicating the clinical management of this condition (Lever 1996). Eczema is another inflammatory skin condition that may have a bacterial link. Eczema is characterized by redness, itching, and oozing lesions that can become scaly, crusted, or hardened. Increased severity and spreading of the condition has been associated with a cytotoxic effect of antibacterial antibody and complement reacting with bacterial antigens on skin cells (Welbourn et al. 1976).

It is possible that *Staphylococcus* is present in raw wastewater as a result of washing and personal hygiene. Indeed, Casanova et al. (2001) found *S. aureus* in graywaters from households, and Ashbolt et al. (1993) isolated *S. aureus* from primary wastewater, although chlorinated tertiary wastewater had only sporadic occurrences of these organisms. However, there are no publications documenting *S. aureus* in biosolids. Recent work at the University of Arizona optimized culture media for *S. aureus*, which was then used to evaluate the presence of the organism in biosolids. Biosolids from Tucson, Arizona, were negative for *S. aureus* (C. Gerba, University of Arizona, personal communication, June 2002).

Protozoan Pathogens

Cryptosporidium and *Giardia* are the protozoan parasites most often associated with biosolids. They are parasites of the small intestine that cause diarrhea. *Cryptosporidium* oocysts and *Giardia* cysts have been detected in products of wastewater treatment and anaerobic sewage sludge digestion (Chauret et al. 1999) and in biosolids (Bean and Brabants 2001b). These pathogens have been observed to die within days of Class B biosolids treatment (Bowman et al. 2000). However, there is little research on the survival of these organisms in biosolids-amended soil.

Microsporidia are obligate intracellular parasites (e.g., *Encephalitozoon* spp.) that have been associated with gastrointestinal illness in patients with acquired immunodeficiency syndrome (AIDS) and in some healthy individuals. One waterborne outbreak has been described (Cotte et al. 1999). Of over 1,200 species described, only 14 have been associated with human infections. At least three of the species that infect humans will grow in animal cell culture (Wolk et al. 2000). No method is available to assess infectivity in environmental samples. The spores of the microsporidia are not unusually resistant to heat (Koudela et al. 1999).

Helminths

EPA considered the human pathogens *Ascaris lumbricoides, Trichuris trichiura, Taenia saginata, Taenia solium, Necator americanus*, and *Hymenolepsis nana* in establishing the pathogen standards of the Part 503 rule. Also included were two animal pathogens *Ascaris suum* (of pigs) and *Toxocara canis* (of dogs). Human infections with *A. lumbricoides, T. trichiura,* and *H. nana* are obtained through direct consumption of embryonated eggs. *T. saginata* infections in people are typically acquired from the ingestion of beef. The eggs of this organism have been detected in some biosolids (Barbier et al. 1990). The eggs of *Taenia solium* are infectious to pigs, but also are capable of producing larvae that infect people and can cause central nervous system disease (Bale 2000). People are infected with *N. americanus* by the larvae penetrating the skin. People who ingest the eggs of *A. suum* of pigs can develop pneumonic, asthma-like signs and can develop a few single adult worms. People who eat the eggs of *T. canis* can develop visceral or ocular larva migrans, syndromes that occur mainly in children who eat contaminated dirt (Overgaauw 1997; Taylor 2001).

Recently, concerns have been raised about roundworm *Baylisascaris procyonis*. The egg of this worm is similar to that of the related *Ascaris* spp., and the ingestion of the eggs of this parasite can cause severe neurological and ocular disease in humans and has been linked to some fatalities (Sorvillo et al. 2002). However, eggs of *B. procyonis* have not as yet been identified in biosolids samples.

Prions

Concern about prions has arisen with the advent of prion animal diseases such as bovine spongiform encephalopathy (BSE) in the United Kingdom and other parts of Europe. The BSE prions concentrate in an animal's brain and spinal cord, but they have been detected only in sheep blood at low concentrations. Animal manure would have no or low concentrations of BSE prions except possibly for wastes from slaughterhouses (Ward et al. 1984); however, the presence of prions in such wastes is uncertain (EPA 2001). Prions are generally transmitted from animal to animal (cow to cow, sheep to sheep). The risk of prion transmission to biosolids from animals is low but can increase with the presence of small amounts of neural tissues or placenta coming from slaughter houses. At present, there has been little evidence of prion-contaminated manures in the United States.

Prions are very difficult to inactivate and require rigorous treatment (Godfree 2001). The higher the solids content of the waste, the more rigorous the treatment required (EPA 2001). Table 6-6 presents inactivation data for scrapie prions under a variety of disinfection treatments.

Prions are resistant to high temperatures; scrapie prions are inactivated at temperatures of 100^{o}C or above. At 121°C, 0.01% of the prions were resistant to thermal inactivation (Rohwer 1984). Prions have been reported to survive boiling and autoclaving (D.M. Taylor et al. 1999; EPA 2001). Prion survival at increased temperatures coupled with chemical or biological treatment associated with biosolids processing has not been studied, nor are data available to directly assess prion survival through sewage-sludge treatment processes.

In addition to chemical treatment (shown in Table 6-6), gamma radiation is also used to inactivate prions. The required irradiation dose is related to pathogen size. As the size decreases, the gamma dose increases, because it is harder for the gamma irradiation to hit the

specific sensitive targets in the smaller infectious agents. The inactivation dose for helminth eggs, viruses, and prions was found to be 200 kilorad (unit of absorbed dose) (McDonell 1985), 1 megarad (Ward et al. 1984), and 5 megarad (Rohwer 1984), respectively.

TABLE 6-6 Inactivation of Scrapie Prions

Disinfectant	15 Min (log reduction)	60 Min (log reduction)
Hypochlorite (5,250 mg/L)	3	4
Sodium metaperiodate (0.01M)	1.5	3
Iodine I_2 (20,000 mg/L) NaI (24,000 mg/L)	1.0	2
Phenol (5,000 mg/L)	0.3	1
Hydrogen peroxide (30,000 mg/L)	2.5	4
Potassium permanganate (1,000 mg/L)	0.3	1
Formaldehyde (200,000 mg/L)	0	1
Lime treatment	-	1

Source: Rohwer 1984; EPA 2001

Rationale for Selecting Emerging Organisms

In the current regulations, the only pathogens considered are enteric viruses, helminths, and *Salmonella* (or coliforms). In this section, the committee outlines criteria that should be used to identify other pathogens that EPA should review and for which information on occurrence, persistence, and risk should be obtained. Once that information is obtained, a decision can be made on whether biosolids regulations need to be modified to control the risk from these agents or whether the existing regulations suffice to control these agents at an acceptably low level of risk.

The selection of microorganisms for analysis in biosolids or wastewater should based on the following criteria (C. Gerba, University of Arizona, personal communication, September 2001):

- **Reliable viability assay.** Availability of a reliable and relatively consistent assay is critical for the study of a pathogen.
- **Water-related disease-causing agents.** All selected pathogens must be found in wastewater and should be capable of transmission via exposure (airborne, waterborne, or contact) to biosolids.
- **Extent of existing data on probability of surviving biosolids treatments.** The pathogens that have the greatest probability of surviving biosolids treatment processes are increasingly of concern for land application. The pathogens that can survive at high pH (above 11–12) and are heat resistant are of most concern.

- **Extent of survival in the environment.** The longer a pathogen survives in the environment, the greater the chance of its transmission to a susceptible host.

Table 6-7 shows the criteria and a list of the pathogens that can be considered for analysis.On the basis of these criteria, adenovirus 40, astrovirus, hepatitis A virus, rotavirus, and *E. coli* 0157:H7 are potential target organisms for analysis. In addition, caliciviruses, including Norwalk viruses, are important, but methods of analyzing viability are not currently available. The protozoan parasites were not selected, because they are unlikely to survive the heat treatment, and viability methods are not available for their detection. Although the bacterial pathogens *Legionella* spp. probably deserve further study, they were not included, because the current detection methods have low efficiency, are difficult to use, and are costly.

TABLE 6-7 Emerging Pathogens Likely to be Present in Biosolids

Organism	Reliable Viability Assay	Waterborne Outbreaks	Probability of Surviving Biosolid Treatment	Survival in the Environment
Adenovirus	Yes	Yes	High–heat Low–pH	Months
Norwalk virus	No	Yes	Unknown	Unknown
Astrovirus	Yes	Yes	Moderate	Weeks
Hepatitis A	Yes	Yes	High–Heat Moderate–pH	Months
Rotavirus	Yes	Yes	Moderate	Months
Hepatitis E	No	Yes	Unknown	Unknown
Mycobacterium	Yes	Yes	High	Days
E. coli 0157:H7	Yes	Yes	High	Months, regrowth possible
Legionella	Yes	Yes	Unknown	Yes
Listeria	No	No	High	Weeks
Microsporidia	Yes ?	Yes	Low	Unknown

Role of Indicator Organisms

The routine examination of biosolids for the presence of human pathogens is often tedious, difficult, and time consuming. Therefore, considerable effort has been made to identify indicator microorganisms whose presence would suggest that human pathogens might also be present. A benefit of using indicator organisms is that tests for them should be simpler and more routine.

In the Part 503 regulation, fecal coliforms are used as indicator organisms in two ways. First, as an indicator of health hazards, fecal coliform density can be used to classify Class A biosolids. Second, as an indicator of wastewater-treatment efficiency, fecal coliform density is used to evaluate whether *Salmonella* sp. has repopulated when Class A biosolids are stored before land application. Fecal coliforms are an appropriate indicator of treatment efficiency, but because they have the potential for regrowth (Pepper et al. 1993), their use as an indicator for public-health hazards is less justified. In addition, some pathogens are more hardy than fecal coliforms, highlighting the potential for underestimating a specific health hazard.

Clostridium perfringens has been suggested as another possible indicator organism to assess the efficiency of biosolids disinfection processes. *C. perfringens*, a spore-forming bacteria, is a good monitoring organism for processes using noncharged biocides (molecules that do not carry a net electrical charge, such as NO_2 and NH_3) or temperatures greater than 120°C (Blanker et al. 1992). It has been suggested as a tracer for less hardy indicators and for the absence of protozoan parasites or viruses during wastewater treatment (Payment and Franco 1993). Because *C. perfringens* is typically found at densities of 10^6 colony-forming units (CFUs) per gram of solids in raw or untreated biosolids, its spores might be an excellent surrogate for the eggs of *Ascaris suum* (Reimers et al. 1991; Sobsey et al. 1991) in the following systems: oxyozone, thermophilic alkaline treatment, two-stage anaerobic digestion, composting, anaerobic digestion, and lagoon storage. *C. perfringens* spores were selected for monitoring *Ascaris* egg survival in chemically processed municipal sewage sludge, because both organisms appear to exhibit similar resistance to physical and chemical agents (heat, alkaline pH, hydroxide concentration, and nitrous acid content). The external structures of both microorganisms may account for some similarities in resistance and inactivation; however, the *Ascaris* egg is more sensitive to high temperatures (>45°C) (Blanker et al. 1992), whereas *C. perfringens* spores, unlike other indicator microbes, are not inactivated in thermophilic processed sewage sludge. Furthermore, *C. perfringens* is susceptible to hydroxide, whereas *Ascaris* eggs are resistant to high concentrations. *Ascaris* is very sensitive to high concentrations of ammonia (0.05% to 2%), depending on temperature (Blanker et al. 1992). Detection of airborne clostridia is dependent on a method for analyzing biosolid-generated bioaerosols (Pillai et al. 1996; Dowd et al. 1997). Unlike most microbial bioaerosols, spore-forming bacteria are resistant to desiccation.

Other anaerobic bacteria, such as *Bifidobacterium* and *Bacteroides*, have also been suggested as potential indicators. However, better standard methods for detecting anaerobic bacteria are needed before they can be routinely monitored.

Bacteriophages have also been suggested as indicators of fecal matter and viruses, because they are consistently found in sewage. Somatic coliphage infects *E. coli* strains and can be detected by simple and inexpensive techniques within 18 h.

A concern with the parasite criteria in the Part 503 regulations is the lack of a timely method to monitor indirectly for the inactivation of *Ascaris* eggs. *Ascaris* inactivation is used to determine whether a disinfection process produces Class A biosolids. The direct method of studying *Ascaris* egg inactivation requires recovering the eggs from biosolids and placing them in culture for 3 to 4 weeks and then examining the culture microscopically. This method is costly, and few laboratories accurately perform the assay. A reliable indirect method requiring only a few days would be beneficial, as would inexpensive, simple, and viable techniques to monitor helminth eggs by surrogate microbes. *C. perfringens* could possibly be a good indicator organism for *Ascaris* inactivation where noncharged chemical species are utilized as disinfection agents (e.g., ammonia). However, when temperature is the controlling inactivating factor, a different type of indicator organism or monitoring of temperature and time directly would be needed.

EXPOSURE TO PATHOGENS

The major routes of potential human exposure to pathogens in biosolids are air, soil, water, and vectors. Factors that affect exposure by each of these routes is discussed below.

Air

Land application of biosolids may result in the formation of infectious bioaerosols. Bioaerosols are defined as aerosolized biological particles, ranging in diameter from 0.02 to 100 micrometers (μm) (Dowd and Maier 2000). The composition, size, and concentration of the microbial bioaerosols vary with the source, dispersal mechanisms, and, most important, the environmental conditions at a particular site. Bioaerosols generated from water sources during splashing and wave action often consist of aggregates of several microorganisms (Wickman 1994) and usually have a thin layer of moisture surrounding them. Bioaerosols released into the air from soil surfaces, such as those surrounding biosolids and composting facilities, are often single organisms or are associated with particles. In many instances, these particles serve as "rafts" for microorganisms (Lighthart and Stetzenbach 1994).

The dispersal and settling of bioaerosols are affected by their physical properties and the environment in which they are airborne. The most important physical characteristics are the size, density, and shape of the droplets or particles, and the most important environmental characteristics are air currents, relative humidity, and temperature (Lighthart and Mohr 1987; Pedgley 1991). Nonspecific open-air factors have also been reported to play a role (Cox 1987).

Aerosols can originate from point (e.g., a biosolids pile) or area (e.g., an agricultural field spread with biosolids) sources (Dowd et al. 2000). Point sources can be further categorized into instantaneous (e.g., sneezes) or continuous sources (e.g., release of bioaerosols from a biosolids pile). The launch patterns of bioaerosols from point sources have a conical dispersion pattern, whereas bioaerosols from area sources have a particulate-wave type of dispersion. Bioaerosol transport can be defined in terms of distance and time, submicroscale transport being less than 10 min and distance less than 100 meters (m), as is common in indoor environments. Microscale transport ranges from 10 min to 1 h and from 100 m to 1 kilometer (km). Mesoscale and macroscale transport are greater than 1 h (Hugh-Jones and Wright 1970). Atmospheric turbulence influences the diffusion and thus the concentration of bioaerosols. Bioaerosol stability varies among bacteria, viruses, and other microorganisms.

Although there are reports on pathogen occurrence and survival on agricultural lands and waterways exposed to biosolids, there is surprisingly little information on airborne pathogen occurrence during land application of biosolids. Most aerosol studies have been conducted near water treatment plants, at effluent spray irrigation sites, within waste-handling facilities, and at composting facilities (Lembke et al.1981; Brenner et al. 1988; Millner et al.. 1994). Different bioaerosol-sampling methods can lead to recoveries of different organisms. Sorber et al. (1984) used a large volume electrostatic precipitator air sampler to study bioaerosols from the land application of biosolids. They showed that bioaerosols are generated during the application of biosolids by tanker trucks and at spray irrigation sites. However, enteric viruses were not detected in the bioaerosol samples that were analyzed. In studies conducted at a large land-application site in Texas, Pillai et al. (1996) used an AGI-30 impingement-based sampler to detect bioaerosolized microbial populations, including bacteriophages. Under low-wind conditions, none of the samples contained any presumptive *Salmonella* spp., although some of the samples were positive for hydrogen sulfide-producing organisms and pathogenic clostridia. In subsequent monitoring during high-wind conditions, fecally associated male-specific coliphages, thermotolerant clostridia, and presumptive *Salmonella* spp. were also detected

(Dowd et al.1997). Bioaerosol concentrations were higher at sites where biosolids material was physically agitated as compared with sites where "manure applicators" were used. These studies were used to generate microbial release rates from biosolids to model bioaerosol transport (Dowd et al. 2000) and, in conjunction with assumed dose-response relationships, to compute an estimated risk.

Exposed people might develop allergic and toxic reactions to high concentrations of noninfectious microorganisms. The health effects from exposure to such agents have been well documented in sewage treatment plants, animal housing facilities, and biowaste collection sites. Studies using culture-based and nonculture-based methods have indicated that workers at the sites can be exposed to concentrations of microorganisms as high as 10^2-10^9 CFU/m^3 and 10^4-10^{10} microorganisms per cubic meter, respectively. Such exposures are substantially higher than those generally found indoors (Eduard and Heederik 1998).

Several studies have documented that microbial bioaerosols are strongly linked to waste-application practices, biosolids handling, wind patterns, and micrometeorological fluctuations (Brenner et al. 1988; Lighthart and Schaffer 1995; Pillai et al. 1996; Dowd et al. 1997). Studies conducted on land-applied Class B biosolids have shown that physical agitation of biosolids material releases *Salmonella* and fecal indicator viruses (Dowd et al. 1997). Bioaerosols averaging 300 most probable number of presumptive *Salmonella* spp. per cubic meter were detected at biosolids loading and application sites at an arid location in the United States. The detection of microbial pathogens at distances from the point source is indicative of how wind gusts and wind patterns can transport bioaerosols over distances.

Mathematical models have been designed to predict the transport of microorganism-associated bioaerosols. Pasquill (1962) described a classic model of particulate airborne transport of aerosols launched from a continual point source. Lighthart and Frisch (1976) modified Pasquill's equation to include a microbial inactivation constant to account for ultraviolet radiation inactivation and desiccation during transport. Bioaerosol sampling used in conjunction with aerosol transport models can be used to estimate inhalation exposure. These estimates in turn can be used in microorganism-specific dose-response models to determine the risks of infection (Haas et al. 1999a). On the basis of field-sampling data, Dowd et al. (2000) modeled microorganism concentrations based on point and area sources at a biosolids application site in the arid western United States at distances ranging from 100 to 10,000 m and wind speeds ranging from 1 to 20 m/s (4.5 m/s is the average U.S. wind speed). As expected, the projected risk of infection from exposure to a single organism was greater at higher wind speeds and closer to the source and was correlated with duration of exposure. The risk of infection at 1,000 m was predicted to be low; however, at 100 m, the potential risks of bacterial and viral infections ranged between 1% and 29% (between 1/100 and 29/100). It is important to note that this is a worst-case situation based on the method of application, which tossed biosolids into the air. Application was done in this manner because there were no towns or human populations in close proximity to the land-application site.

Soil

Pathogen survival in and transport through soil are considered together in this section. Environmental factors that affect survival of pathogens are summarized in Table 6-8.

Human pathogens that are routinely found in domestic sewage sludge include viruses, bacteria, protozoan parasites, and helminths. Of those pathogens, viruses are the smallest and least complex, generally have a short survival in soil, and have the greatest potential for transport in soil. Using a plaque-forming-unit method, Straub et al. (1993a) evaluated the survival of three viruses in a biosolids-amended desert soil: poliovirus type 1 and two bacteriophages (MS2 and PRD-1). Survival was temperature-dependent and decreased as temperature increased. Soil type

TABLE 6–8 Environmental Factors Affecting the Survival of Pathogenic Microbes

	Survival Time		
Parameter	Virus	Bacteria	Protozoa
Temperature increasing	–	–	–
Soil moisture decreasing	–	–	–
Rate of desiccation increasing	–	–	–
Clay content increasing	+	+	Not known
pH range of 6-8	+	+	+

–, decreasing survival time; +, increasing survival time.
Source: Gerba et al. 1975; Straub et al. 1993a, 1993b, 1995; Jenkins et al. 1999.

affected virus survival, longer survival occurring on clay loam biosolids-amended soils compared with sandy loam biosolids-amended soils (Straub et al. 1993b). Rapid loss of soil moisture also limited virus survival. When conventional plaque-forming methods were used, virus survival ranged from 3 days to greater than 10 days, depending on soil type, temperature, and moisture (Straub et al. 1992, 1993a). When molecular polymerase chain reaction (PCR)-based methods were used, enteroviruses were detected in soil 3 months after land application (Straub et al. 1995). However, PCR by itself only detects viral nucleic acid, and does not indicate that viable viruses were actually present.

Like virus survival, bacteria survival in soil is affected by temperature, pH, and moisture (Gerba et al. 1975). Soil nutrient availability also plays a role in bacteria survival. Lower temperatures usually increase survival, as do a neutral soil pH and soil at field capacity (Straub et al. 1993b). Of the pathogenic bacteria, *Salmonella* and *E. coli* (Newby et al. 2000b) can survive for a long time in biosolids-amended soil—up to 16 months for *Salmonella* (Hess and Breer 1975). In contrast, *Shigella* has a shorter survival time than either *Salmonella* or *E. coli* (Feachem et al. 1983). Studies on indicator organisms have shown that total and fecal coliforms as well as fecal streptococci can all survive for weeks to several months, depending on soil moisture and temperature conditions (Pepper et al. 1993).

Regrowth is also important when evaluating the survival of pathogenic and indicator bacteria in soil and biosolids compost. *Salmonella*, *E. coli,* and fecal coliforms are all capable of regrowth. Following land application of biosolids or composting of biosolids with soil, pathogen concentrations decrease below the detection limit but subsequently increase after rainfall (Pepper et al. 1993; Soares et al. 1995; Gibbs et al. 1997).

The protozoan parasites often associated with biosolids include *Giardia* and *Cryptosporidium* spp. However, little research has been conducted on the survival of these parasites in biosolids-amended soil. One report documented increased inactivation of *Cryptosporidium parvum* as temperature increased from 35°C to 50°C and water potential decreased (Jenkins et al. 1999). Little is known about the viability of these parasites following land application of biosolids, and research in this area should be encouraged. Helminths are

perhaps the most persistent of enteric pathogens. *Ascaris* eggs survive several years in soils, although very dry or very wet soils decrease survival (Straub et al. 1993b).

The transport of microorganisms through soils or vadose zone materials is affected by a complex array of abiotic and biotic factors, including adhesion processes, filtration effects, physiological state of the cells, soil characteristics, water flow rates, predation, and intrinsic mobility of the cells (Newby et al. 2000a), as well as the presence of biosolids. For viruses, the potential for transport is large, although viruses can adsorb to soil colloidal particles and to the biosolids themselves, thus limiting transport (Schijven and Rietveld 1996). Virus sorption is controlled by the soil pH. Most viruses are negatively charged (isoelectric point 3-6) so that at a neutral soil pH, soil sorption is reduced, whereas at more acidic soil pH values, the viruses are positively charged, increasing sorption. Dowd et al. (1998) confirmed that the isoelectric point was the predominant factor controlling viral transport through soil; however, for virus particles greater than 60 nanometers (nm) in diameter, size began to limit transport. The sorption of bacteriophages and viruses to nine soil types was examined by Goyal and Gerba (1979), who confirmed that sorption is greatest at soil pH values of less than 5.

There are few field studies on the transport of viruses from biosolids through soil. Most studies on virus transport have been conducted in laboratory columns, using pure virus cultures. Straub et al. (1995) evaluated transport of enteroviruses from land-applied, anaerobically digested biosolids. Viruses were detected at soil depths of 200 centimeters (cm), indicating greater transport than that reported in previous studies (Damgaard-Larsen et al. 1977; Bitton et al. 1984). In the Straub study, a more modern PCR-based detection method was used, rather than the conventional cell-culture methods used in earlier studies. However, PCR alone does not indicate viability of the viruses.

The larger size of bacteria means that soil acts as a filter, limiting bacterial transport. Soil would also limit the transport of the even larger protozoa and helminths (Newby et al. 2000a). However, microorganisms may be transported through soil cracks and macrochannels via preferential flow. Transport of indicator organisms from land-applied, anaerobically digested biosolids was evaluated by Pepper et al. (1993), who found occasional fecal coliforms at soil depths of 300 cm, presumably due to preferential flow.

Pathogen survival and transport in soil should be evaluated from a public-health perspective. Pathogens are routinely present in Class B biosolids and are capable of surviving for days, weeks, or even months, depending on the organism and environment. Therefore, site restrictions with durations based on subsequent land use are necessary following land application. For many soils, contamination of underground aquifers due to vertical migration of pathogens from land-applied biosolids is unlikely because of the sorption of viruses and the soil filtration potential for larger pathogens. However, in coarse textured, sandy soil or high permeability karst topography, groundwater contamination events are possible. For example, surface-water contamination can occur from land-applied biosolids because of soil runoff. In the U.S., groundwater sources unrelated to biosolids have been associated with 58% of total waterborne-disease outbreaks, compared with 33% from surface-water sources (Schijven 2001). The committee notes that there is a dearth of contemporary information on pathogen transport through and on soil from land-applied biosolids in field situations. The transport of pathogens through biosolids-amended soil is different than from soil alone because of sorption and binding to the biosolids.

Water

In principle, pathogens present in biosolids can contaminate surface or groundwaters if runoff and leachate are not controlled. When municipal solid waste is landfilled, microbial contamination of groundwater from leachate is possible, albeit at low levels (Sobsey et al., 1975; Sobsey, 1978; Pahren, 1987). Ritter et al. (1992) found that lime-treated septage applied to land did not deteriorate groundwater quality in regard to pathogens. The committee did not identify any studies of microbial contamination of surface or groundwater near land where either Class A or Class B biosolids had been applied.

Vectors

There are no published reports that specifically implicate vectors in the transmission of infectious organisms from land-applied biosolids to humans. However, there have been reports of fly proliferation and mosquitos in standing water bodies, such as sewage effluent and septic tanks (Carlson and Knight 1987; D.S. Taylor et al. 1999; Learner 2000). A number of studies indicate that vectors such as flies, rodents, and birds harbor infectious agents commonly associated with animal and poultry wastes. Butterfield et al. (1983) reported that herring gulls carry *Salmonella*, and Juris et al. (1995) reported that flies disseminate helminth eggs from sewage treatment plants. Although data (Grubel et al. 1997) suggest that houseflies harbor *Helicobacter pylori*, direct transmission of the organism from flies to humans has not been demonstrated. Although flying insects are usually attracted to odors (Morris et al. 1997), there are no published data on whether land application of biosolids results in an increase in flies, mosquitoes, or birds. If biosolids application is not managed properly, heavy rainfall in conjunction with biosolids application could result in pools of biosolids-contaminated runoff that could attract vectors. Land-application practices as specified in the Part 503 rule are designed to reduce vector attraction, but it is unclear whether these practices discourage vectors. Although flies and other vectors have been detected on biosolids-applied lands, the extent to which these vectors are involved in the transmission of infectious organisms to humans or the food chain is unknown.

Regional Differences

The extent and routes of human exposure to biosolids varies greatly across the United States, depending on the overall "experience with biosolids use." Four exposure factors that vary by region are methods of biosolids application, climate, soils, and land availability for biosolids application versus population density.

- **Methods of Biosolids Application.** Biosolids-application methods vary depending on region, type of biosolids, and individual site. For example, in the southwestern desert, liquid anaerobic-digested biosolids are generally injected into soil subsurface. On pastures, biosolids are generally applied to the soil surface. In other areas, biosolids "cakes" are added and disked into soil. The application method directly affects the potential for bioaerosol generation,

chemical odors, and ultraviolet inactivation of pathogens. It is important to note that incorporation of biosolids is more difficult with pastureland than cropland.

- **Climate.** Regional differences in climate affect the fate and transport of pathogens in biosolids-amended soil. In general, moist, cool soils, such as those in the northeastern region of the United States, favor survival, whereas hot, dry soils, such as those in the southwestern region, adversely affect pathogens. Differences in rainfall are not as important as temperature, because application of biosolids on desert agricultural lands is often followed by irrigation.
- **Soils.** Although climate affects regional soil types, texturally, all soil types can be found throughout the United States. Of all soil characteristics, soil pH differences are perhaps the most important. Typically, more acidic pH ranges and more organic matter are in soils east of the Mississippi than in the more arid western states.
- **Land Availability and Population Density.** Land availability and population density

are the most important factors for acceptability of the "experience with biosolids use." In the desert Southwest, agricultural areas are often located far from urban centers, so that there are fewer surrounding residents who may be affected by biosolids applications. In the Northeast, the potential impact of land application is much greater because of the magnitude of land application and the proximity of that land to people. For example, in areas such as Rhode Island, almost all land would need to receive biosolids to accommodate use and disposal. In high-density urban centers, there is an increased potential for nuisance odors and for increased exposure to pathogens. Thus, the regional differences in land availability for biosolids application relative to the proximity of urban centers mean that "experience with biosolids use" is not uniform nationwide.

HOST FACTORS

Assessing potential risks from exposure to pathogens is complicated by the need to consider a variety of factors that affect an individual's susceptibility to pathogens. Three of these factors, concomitant exposures, genetic factors, and acquired immunity, are discussed below.

Concomitant Exposures

Studies have shown that concomitant exposures to infectious organisms, noninfectious organisms, cellular components, irritants, and odors can cause synergistic effects, especially in humans in highly contaminated environments (Schiffman et al. 2000). For example, the adverse health effects from exposure to a combination of ammonia and particles were greater than the additive effect of ammonia and particles by a factor of 1.5 to 2.0 (Bottcher 1998, as cited in Schiffman et al. 2000).

Particles, allergenic constituents, and microbial metabolites, such as endotoxins (lipopolysaccharides [LPS]), glucans, and aflatoxins, can have a role in the development of various respiratory diseases and systemic effects (Eduard and Heederick 1998). Chromogenic end point and kinetic endotoxin assays are used to estimate the relative biological activity of LPS rather than measure the exact amount of LPS present. However, there are accuracy and

reproducibility concerns with these assays (Hollander et al. 1993). Carbohydrate components of molds, such as glucans and mannans, are known to act as inflammatory agents and can function as biomarkers for exposure to molds (Murphy 1990).

Because endotoxins and glucans are cellular components of microorganisms, anaerobic digestion would not be expected to totally destroy or inactivate those compounds. The detection of viable cells in land-applied biosolids implies that endotoxins should also be present. However, local climatic and biosolids-management practices dictate the extent of endotoxin aerosolization.

Van Tongeren et al. (1997) reported considerable variation in endotoxin concentrations in municipal wastes at a compost plant with concentrations ranging from 0.2 ng/m^3 at a compost plant to 353.6 ng/m^3 at a waste-resource recovery operation. Nielsen et al. (2000) found seasonal variations in endotoxin concentrations around operations involving containers of biosolids; concentrations ranged from 0.3 ng/m^3 in spring to a maximum of 100 ng/m^3 in autumn. Ivens et al. (1999) reported a direct relationship between bioaerosol concentrations of endotoxins and nausea and diarrhea among waste collectors. Endotoxin concentrations ranged from 0.36 enzyme unit (EU)/m^3 to 9.2 EU/m^3 (0.03 ng/m^3 to 0.77 ng/m^3, assuming 1 EU = 12 ng/m^3). Melbostad et al. (1994) reported that municipal sewage workers in Norway were exposed to endotoxin concentrations of 0-370 ng/m^3 over 8 h (median level, 30 ng/m^3); however, no relationship was seen between endotoxin concentrations and such symptoms as nausea, tiredness, and headaches.

People with atopic asthma have increased sensitivity to respirable endotoxins, resulting in a variety of immune responses, including increased eosinophils in the airways (Peden et al. 1999). Studies suggest that asthmatic individuals exposed to allergens will have greater nasal inflammations if exposed to endotoxins (Gavett and Koren 2001; Liu and Redmon 2001; Reed and Milton 2001).

Genetic Factors

Data suggest that host genetic factors (e.g., predisposition to asthma attacks) have a key role in the manifestation of a health effect from infectious organisms, particles, odors, endotoxins, or allergens (Lacey and Crook 1988; Michel et al. 1991, 1992, 1996; George et al. 2001**)**. These studies have been conducted on biowaste collectors, compost workers, sewage treatment plant workers, and animal house workers, who are constantly exposed to high concentrations of these agents. There are no data on the roles of genetic factors in health effects due to bioaerosols from land-applied biosolids. Furthermore, although particles, allergens, and microorganisms can cause health effects in occupationally exposed workers, data are lacking on whether the concentrations observed at land-application sites are sufficient to cause health effects in surrounding populations.

Acquired Immunity

A potential factor modulating the risk from exposure to infectious agents is acquired immunity, which can reduce the extent of illness in a population exposed to microbial contamination or alter the dynamics of disease occurrence. For most agents of concern, the existence, extent, and duration of any acquired immunity is not well understood. For a number

of infections, immunity may be highly short-lived (Anderson and May 1991; Bailey 1975). In the case of *Salmonella*, only partial immunity appears to occur, resulting in reduced severity (McCullough and Eisele 1951). In the case of *Cryptosporidium*, there is also some reduction in susceptibility following an infection, although in some cases the severity of the infection in individuals rechallenged may be more severe (Chappel et al. 1999).

If information on the extent and duration of immunity is found, it can be incorporated into population models of infectious disease, as described in Chapter 7.

EXPOSURE TO WORKERS

Sewage sludge and biosolids are used in a number of ways, including application to agricultural fields, recreational fields, lawns, and home gardens and reclamation of mines and other disturbed lands. The process of preparing and applying biosolids involves workers who are potentially at risk of exposure to infectious pathogens in the sewage sludge during preparation in the treatment plant, transportation of the biosolids to places of application, application to land, and following application in the fields. The worker populations were not considered in setting EPA's standard for pathogens in biosolids. As reported in Chapter 3, there are few studies of worker exposure to biosolids. However, there are a few studies of exposure and effects observed in workers at wastewater and sewage treatment plants. Although these studies are not substitutes for studies of biosolids exposure, they are useful for identifying potential health concerns and pathogens that might be relevant to biosolids.

The presence of human pathogens in raw sewage sludge has been well documented. Ayres et al. (1993) reported on the accumulation and viability of human nematode eggs (primarily *Ascaris lumbricoides*) in the sewage sludge of a waste-stabilization pond. *Cryptosporidium* oocysts and *Giardia* cysts were recovered from products of wastewater treatment and anaerobic sewage sludge digestion (Chauret et al. 1999). Specific infectious agents have been recovered from biosolids applied to land, including eggs of the helminth *Taenia saginata* eggs (Barbier et al. 1990). Thermotolerant clostridia were detected in aerosols from a large commercial application site (Dowd et al. 1997). In a multiyear study, 21 *Salmonella* serotypes were isolated from sewage sludge from four treatment plants in different geographic areas of Ohio (Ottolenghi and Hamparian 1987). In the same study, family members residing on farms showed antibodies to salmonellae, but the investigators were unable to determine whether there was a significant difference between exposed and control subjects.

Immunoglobulin G antibodies to molds and actinomycetes were found in biowaste collectors and compost workers exposed to bioaerosols (Bünger et al. 2000). Higher exposures to rod-shaped and total bacteria were found in sewage workers with airway symptoms, headache, tiredness, and nausea than in workers not reporting these symptoms (Melbostad et al. 1994). Hepatitis A was reported in workers from a wastewater treatment plant during a small community outbreak (De Serres and Laliberté 1997).

ANTIBIOTIC RESISTANCE

There is constant acquisition and loss of genetic sequences among bacteria (Ochman et al. 2000). Bacteria can acquire antibiotic resistance through point mutations, plasmid transfer events, transposons, and integrons. Mobile DNA sequences make up a substantial portion of the transferred sequences in *E. coli* (Lawrence and Ochman 1998). There are reports that antibiotic-

resistant organisms can be isolated from biosolids (Pillai et al. 1996, 1997), and antibiotic resistance transfer events have been documented under laboratory conditions in sewage effluent (Arana et al. 2001). A recent study found tetracycline-resistance genes in waste lagoons and groundwater at two swine production facilities (Chee-Sanford et al. 2001). This study also suggested that the resistance genes can be mobilized into soil inhabitants. However, there are no data to suggest that land application of biosolids will preferentially promote such transfer events. Assuming that biosolids contain a number of potential donors and recipients of antibiotic resistance genes, it is important to keep in mind that multiple processes should occur for the stable incorporation and expression of new traits in the recipient cells. The donor DNA must be delivered to the recipient cells, the transferred genes should be incorporated into the recipient's genome or plasmid, and finally, the incorporated genes should be expressed in a manner that benefits the recipient cells (Ochman et al. 2000). A German study suggests that there is minimal likelihood of functional antibiotic compounds persisting in biosolids (Hirsch et al. 1999); therefore, it is doubtful whether the incorporation and maintenance of antibiotic resistance genes in recipient cells would provide them with any selective advantage. Antibiotics are, however, present in raw sewage sludge and sewage treatment plant effluent. Resistant bacteria can therefore be present in biosolids without a selective advantage in that medium and without specific gene transfer in that medium. Pillai et al. (1997) reported no significant differences in the antibiotic resistance index of *E. coli* isolates obtained from undigested and digested municipal sewage from rural and urban environments when 13 antibiotics were screened. The ability of biosolids-related organisms to transfer their resistance markers to indigenous soil bacteria would depend on the survival of the introduced strains in addition to the factors mentioned above. On the basis of this information, the committee does not believe that land-applied biosolids have any substantial potential to alter the prevalence of antibiotic resistance among pathogenic microorganisms.

PATHOGEN RISK ASSESSMENT

Risk assessment has been used in several environmental and public-health applications to determine (or reduce) exposure to pathogenic microorganisms. In this section, available approaches to conducting microbial risk assessment are briefly reviewed and their applicability to biosolids is assessed. The committee was aware that methodology for assessing risks to human health from pathogens via exposure to biosolids is being developed by researchers at the University of California at Berkeley. The methodology has an exposure-assessment component for quantifying pathogen levels, and a health-risk component that accounts for special infectious disease considerations (secondary transmission and immunity) (J. Eisenberg, University of California, Berkeley, personal communication, May 24, 2002). However, the methodology was not finalized in time for the committee to evaluate it and include it in this report.

Drinking Water

Historically, the acceptable levels of microorganisms in drinking water, contact recreational waters, and shellfish harvesting waters have been set using indicator organisms, most often either total or fecal coliforms. With the advent of better methods for direct

measurement of pathogens in water (Leong 1983; Ongerth 1989; Gerba and Rose 1990; Gregory 1994; Rose 1990; Rose et al. 1991a) and the development of risk-assessment paradigms for setting environmental standards (NRC 1983, 1989; Silbergeld 1993), these methods can now be applied to the development of microbial standards for acceptable water quality to supplement or replace traditional indicator measurements.

The quantitative microbiological risk assessment (QMRA) approach that has been used in the development of the Surface Water Treatment Rule (SWTR) and the Enhanced SWTR follows the framework proposed for chemical risk assessment by the National Research Council (NRC 1983). The framework has the same steps as those for chemical risk assessment: hazard assessment, exposure assessment, dose-response analysis, risk characterization, and risk management.

Alternative protocols specific to microbial risk assessment have been proposed by such groups as the International Life Sciences Institute (ILSI) Pathogen Risk Assessment Working Group (1996). A schematic of the ILSI protocol is shown in Figure 6-2. This protocol emphasizes the interrelationships between the technical and policy-making components surrounding the risk-assessment process, particularly at the problem-formulation stage.

A quantitative microbial risk-assessment approach has, in part, been used by EPA. Using data from human volunteer studies, Regli et al. (1991) developed a dose-response relationship for infection from the ingestion of *Giardia lamblia*. The result was compared with infection rates observed from waterborne outbreaks to assess the likelihood that an infected person would become ill (Regli et al. 1991; Rose et al. 1991b). Using a target risk of one infection per 10,000 persons per year, which was regarded as acceptable by EPA in the SWTR and a daily average water consumption of 2 liters (L) per person per day, EPA estimated that an acceptable finished water concentration would be 6.75×10^{-6} organism per L (one organism in 148,000 L). Verification of such low microbial occurrence represents a technological impossibility; therefore, it is necessary to use an estimated finished water concentration based on the microbial quality of source water and the reduction of microorganisms achieved by a particular set of treatment processes.

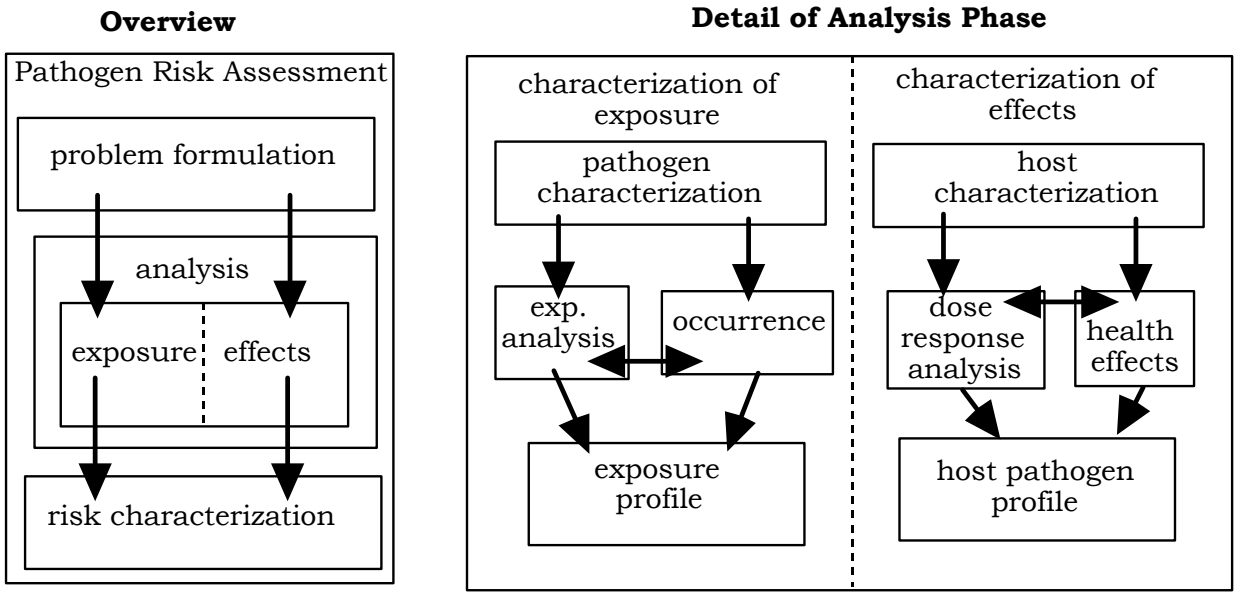

FIGURE 6-2 Schematic of ILSI microbial risk analysis protocol. Source: Adapted from ILSI Risk Science Institute Pathogen Risk Assessment Working Group 1996.

In the proposed SWTR, a tiered treatment requirement incorporated this approach; however, the final promulgated regulation required a single fixed-value reduction (in logs), which was based on an estimated upper value of source-water microbial concentrations across the United States.

Under the Long-Term Enhanced Surface Water Treatment Rule (LT2ESWTR), surface-water treatment plants will be required to use control strategies based on the concentrations of *Cryptosporidium* oocysts found in their source water. Although not explicitly founded on risk assessment, the relationship between the oocyst concentrations in source water and the required degree of control is predicated on achieving a minimal degree of public-health protection, regardless of source-water quality.

Food and Air

The methods for assessing risks from exposure to pathogens in food and air are still in their infancy. Several modeling approaches have been used, but modeling pathogens pose specific challenges, such as how to model dose-response relationships (Coleman and Marks 1998) and pathogen reduction or multiplication in food. There are also the issues of susceptibility, particularly for sensitive subpopulations, such as children, the elderly, pregnant women, and immunocompromised individuals (Balbus et al. 2000), and the potential for secondary transmission of disease.

A general framework for microbial food-safety risk assessment has been proposed by McNab (1998), but this framework requires refinement of appropriate distributions and mathematical relationships before it can be applied to a specific pathogen. In the past 10 years, the U.S. Department of Agriculture has developed risk-assessment models for pathogens in foods of animal origin, focusing on *Salmonella* in eggs (FSIS 1998a) and *E. coli* in beef (FSIS 1998b). Another study (Marks et al. 1998) used *E. coli* 0157:H7 to demonstrate dynamic-flow tree modeling. In an assessment of bioaerosol transport and biosolids placement and the risk of bacterial and viral pathogens, both point- and area-source risk-assessment modeling approaches were used (Dowd et al. 2000).

Applicability of Available Approaches to Biosolids Standards

Methods for conducting microbial risk assessment have advanced substantially since the promulgation of the Part 503 rule. Although these methods have not progressed as far as those for chemical risk assessment, the committee believes that they can be used by EPA as a basis to develop criteria for biosolids to maintain acceptable levels of risk from microbial exposure.

The committee envisions an approach conceptually similar to that used in developing the SWTR and LT2ESWTR. From stipulation by EPA of an acceptable risk level for a particular pathogen, the concentrations in biosolids, either at the time of disposal (where there is immediate potential for exposure) or after a required holding period, can be computed by application of QMRA methods. EPA can then develop experimentally based relationships between process conditions (e.g., time, temperature, pH, chemical doses, and holding times) and indicator organism concentrations (either density or reduction through treatment) that can ensure

consistent attainment of the target maximum acceptable pathogen concentrations. A regulation can then be crafted to mandate achievement of particular process conditions and indicator densities or reductions to produce acceptable biosolids for the designated use.

The committee does not recommend that QMRA methods be required by regulation to monitor potential risks at any particular site. Such monitoring should be conducted by using indicator organisms and controlling operational parameters and practices, such as temperature, time, buffer zones, and pH, so that tolerable risk levels are not exceeded.

To conduct microbial risk assessments, a variety of information is needed, including concentrations of the pathogen in biosolids, its fate and transport in environmental media, and its infectivity (dose-response relationship). The extent of the available data on specific pathogens varies, and there are a number of difficulties with obtaining the needed information and conducting the risk assessments. Some of the obstacles include limitations with available sampling and detection methods, lack of dose-response data, inadequate information on infectivity from inhalation and dermal routes of exposure, and difficulties with population-level modeling. These obstacles are discussed in more detail below.

Potential Limitations in Sampling and Detection Methods

Bacteria

Better sampling and detection methods are needed for pathogens in bioaerosols. Impaction, impingement, filtration, and electrostatic precipitation are some of the methods routinely used to concentrate microorganisms from bioaerosols. There are important differences in the equipment and collection efficiencies of these methods. The ASTM (2001) standard (E-884-82) for assessing occupational exposures to bioaerosols in indoor facilities uses an impinger (AGI-30) to sample a total volume of 240 L of air in 20 min. Currently, there is no standard for assessing occupational exposures from bioaerosols in outdoor environments, such as biosolids-application sites. Although specific microbial pathogens and fecal indicator organisms from biosolids-application sites have been detected using the AGI-30 sampler, there are studies showing that the AGI-30 is relatively inefficient at concentrating bacterial cells from bioaerosols. Samplers with improved airflow rates (up to 400 L/min), concentration efficiency, and portability have been developed to detect bioaerosols, primarily for biological weapons research, and are commercially available. Although many of these samplers have been reportedly field tested for their efficacy in detecting biological weapons, peer-reviewed published data on their efficacy are not available. The limitations of commercially available bioaerosol samplers include considerable variation in sampling efficacy (Juozaitis et al. 1994), ability to culture some microbial samples, and ability to characterize the microbial populations beyond plate counts. During transport, deposition, and sampling, bacteria can be inactivated or desiccated. The "injured" cells might be incapable of being cultured on routine microbiological media, thus underestimating the actual number of viable cells within a bioaerosol. For example, the Anderson sampler, which relies on an impaction-based sampling approach, has provided a large amount of data on indoor bioaerosols. Because the Anderson sampler is based on impaction and the microbial population estimates are based on direct plate counts, the impaction-based sampling approach can lead to an underestimation of the actual bioaerosol load for the following

reasons. First, bioaerosolized organisms may be in a viable but non-culturable state, thereby not forming colonies on the plates. Second, the larger cut-off size of the sixth stage of the Anderson sampler may make it inefficient at collecting very small bioaerosolized particles (Terzieva et al. 1996).A key limitation in bioaerosol sampling is the portability of the samplers for use in remote field sites. Many of the samplers, such as the AGI-30, that rely on external vacuum and power sources cannot be easily used at remote sites. The hand-held, highly portable SAS surface impaction-based sampler has been used for monitoring; however, the samples are impacted on a solid surface, which can be extremely detrimental to their survival and culture.

Some molecular-biology-based assays, such as gene-probe hybridization and gene amplifications, have promise for detecting and characterizing specific microbial groups within bioaerosols. However, those methods have some technical shortcomings, such as inhibitory sample effects, sample processing deficiencies, laborious protocols, and possible laboratory-based contamination (Alvarez et al. 1995, Pena et al. 1999). Droffner and Brinton (1995) have detected *Salmonella*-specific nucleic acids within thermophilic compost piles, suggesting that microbial nucleic acids can be resistant to degradation, even at the raised temperatures found in compost piles. However, the detection of stable nucleic acid sequences does not imply the presence of viable organisms; therefore, molecular analyses, such as gene probe hybridizations and gene amplifications, should be interpreted with caution. Furthermore, because noninfectious microorganisms and microbial components (e.g., cells, spores, endotoxins, glucans, chemical markers, antigens, and allergens) might cause allergic and toxic reactions independent of cell viability, nonviability-based assays are also necessary (Eduard 1996).

Another concern in assessing the potential impacts of pathogen-laden bioaerosols from biosolids-application sites is the sampling scheme. Land-application programs may involve tens of acres with highly variable micrometeorological conditions within the same general site. The fluctuations can be due to topography, vegetation, and mechanical agitation. Wind direction and speed also can fluctuate, even within a 20-min sampling time. Because no standards exist for bioaerosol sampling in outdoor environments, the exact number of replicate samples needed to get a fair representation is unclear. The choice of an appropriate statistical analysis to give environmentally significant conclusions is also important. Spicer and Gangloff (2000) reported on the limitations of using data on nonparametric statistical treatments of bioaerosols. A further concern is that the definition of upwind and downwind sampling locations at sites may be too broad for bioaerosol samplers with sampling orifices of only a few centimeters in diameter.

Thus, there are challenges to developing and implementing an effective bioaerosol-monitoring program, including the need for a rigorous sampling scheme, integrated sampling to account for micrometeorological fluctuations (which may be the most important challenge from a public-health standpoint), and the lack of efficient and portable bioaerosol samplers. Other than the ASTM standard sampling protocol for evaluating the microbiological quality of municipal solid wastes (ASTM 2001) there are no standardized sampling schemes for determining the bacteriological and viral quality for biosolids land-application programs. Standards are needed for bioaerosol sampling that account for outdoor site characteristics, especially variations in site size.

The environmental conditions under which microbial pathogens are aerosolized from biosolids piles at field sites and from biosolids applied to agricultural land need to be accurately determined. The precise composition of biosolids material and bioaerosols from those sites also need to be studied using conventional and contemporary molecular tools, such as qualitative and quantitative PCR assays, and the bacterial isolates archived. Archived isolates permit the use of

DNA fingerprinting methods to determine whether the isolates originate from land-applied biosolids (Dowd and Pillai 1999).

Viruses

Sewage sludge and biosolids, particularly Class B biosolids, contain a variety of human pathogenic viruses (Straub et al. 1993b). Sufficient viruses are normally present, so that sampling and detection are relatively simple. The choice of detection method is critical, however, when documenting the elimination of viruses. Standard-cell culture methods for viruses in environmental samples are expensive and time consuming, requiring up to a month for confirmed positive results (Reynolds et al. 1997). Cell-culture assays are further complicated by the presence of toxic organic and inorganic materials found in sewage sludge. An alternative detection method is PCR, which, using specific oligonucleotide primers, relies on in vitro enzymatic amplification of target nucleic acids (Saiki et al. 1988). PCR analyses are quicker, less costly, and more sensitive than other cell-culture methods. Direct reverse transcriptase PCR (RT-PCR) can potentially detect intact nucleic acid sequences in viral protein coats, even when the viral particles have been inactivated. In that case, inactive viruses can be detected and the potential risk from their presence overstated. PCR is positive for virus detection long after cell-culture results are negative.

The issue of virus viability versus virus detection with PCR has led to a debate on the efficacy of the PCR method. However, development of the integrated-cell-culture-PCR (ICC-PCR) has defused the debate (Reynolds et al. 1996). ICC-PCR combines biological amplification of viruses in cell culture and enzymatic amplification of viral RNA via PCR. There are many advantages to this method, particularly the prerequisite that the virus grow in cell culture for positive PCR amplification, thus detecting only viable viruses. A comparison of all three virus detection methods (Table 6-9) shows that for viral risk assessment analysis, ICC-PCR is the method of choice. Cell culture could potentially underestimate exposure, while RT-PCR could easily overestimate exposure.

TABLE 6-9 Comparisons of Methods for Detection of Virus

	Method of Detection		
Issue	Cell Culture	RT-PCR	ICC-PCR
Reduced time of detection	No	Yes	Yes
Infectious virus detected	Yes	Yes/No	Yes
Increased sensitivity	Yes	No	Yes
Affected by PCR inhibitory substances	No	Yes	No
Reduced costs	No	Yes	Yes
Detects only viable organisms	Yes	No	Yes
Detects viable but nonculturable virus	No	Yes	Yes

Source: Marlowe et al. 2000. Reprinted with permission from Environmental Microbiology, copyright 2000, Elsevier Science.

Protozoa and Helminths

Over the past 20 years, various assays for helminth eggs in biosolids have been developed, but no assay has been universally accepted, primarily because there are few

published quality-assurance and quality-control (QA-QC) data for the various protocols that have been used. Die-off studies with *Ascaris* eggs collected at different seasons showed that a consistent protocol for egg collection, storage, and use in spiking biosolids must be addressed. When such a protocol is developed, consistent QA-QC data can be obtained for helminth eggs spike studies (Reimers et al. 1981, 1986b, 1990). When detecting helminths, sample preservation and pretreatment is often overlooked. For *Ascaris* eggs, a neutralization and cooling process is necessary to assess the alkaline and acidic disinfection and stabilization of biosolids (Meehan et al. 1986). Several methods can be used to detect *Ascaris* eggs, including those of Bean and Brabants (2001a), Huyard et al. (2000), EPA (1999), and Yanko (1987). Each of those methods has a different percent recovery of eggs, and QA-QC data are available for only the Tulane assay. The Tulane assay is accurate for anoxic and acidic biosolids at 75-80% with a precision of approximately 10-15%. A summary of the Tulane *Ascaris* assay is presented in Table 6-10.

TABLE 6-10 Summary of Tulane *Ascaris* Assay for Viability and Determination in Percent Recovery or Percent Variation from the Mean Density

Biosolids Matrix	% Recovery (Accuracy)	% Variation (Precision)	Reference
Acid treated	80.5-79.0	10.2-3.8	Reimers et al.1991
Anaerobic digested and lagoon stored	75.5	14.8	Reimers et al.1990
Soil blends	75.5	32.5	Leftwich et al.1987
Alkaline treatment	58.5	34.4	Meehan et al.1986
EPA White House document	<50.0	-	Bean and Brabants 2001a
In-vivo assay	<10.0	-	Burnham 1988

This Ascaris assay gives no indication of QA-QC data relative to other helminth eggs or protozoa, and helminth eggs other than *Ascaris* are liable to require assay modifications. The process should work well for the eggs of the canine and feline ascarids *Toxocara canis, Toxocara cati,* and *Toxascaris leonina* which can enter wastestreams through toilets or storm runoff, because these eggs are slightly larger than the eggs of *Ascaris* and have similar densities. This method may not be as effective for eggs of the human whipworm *Trichuris trichiura* and the different human taeniid tapeworms. The technique is inappropriate for protozoa, because those of primary concern, *Giardia* and *Cryptosporidium*, will pass through the final sieve. Thus, for those pathogens, another form of final sample processing is required. At this time, the process described for *Ascaris* is good for verifying inactivation of pathogens in various spiked samples, but further work is required to verify recovery methods for routine samples when other pathogens are of equal or greater concern.

There is substantial concern over the reliability and accuracy of viability assays. Currently, the helminth egg assay for *Ascaris* is much more accurate, precise, and efficient than the *Cryptosporidium* oocyst assay, possibly because *Cryptosporidium parvum* is much more sensitive to temperature, cavitation, and noncharged biocidal constituents than *Ascaris* (Reimers et al. 1999). In general, *Cryptosporidium* can be inactivated with properly operated Class B

disinfection, even though *Cryptosporidium* have been reported to survive Class B disinfection with lime stabilization (Bean and Brabants 2001b). In alkaline stabilization, the ammonia content generally controls the inactivation of helminth eggs and protozoan oocysts. *Ascaris* eggs require 1-3% ammonia for inactivation instead of the 0.1% required for *Cryptosporidium*. Cavitation is effective in inactivation of *Cryptosporidium* but is not as effective for *Ascaris* eggs, and the inactivation of *Cryptosporidium* occurs at 15 ^{o}C less than that of *Ascaris* (Reimers et al. 1999; Bowman et al. 2000).

The preservation and pretreatment techniques for protozoan oocysts have not been developed to the level of those for helminth eggs. The viability and infectivity assays typically use one of the following techniques (Jakubowski et al. 1996): vital dye staining, animal infectivity, cell culture, or polymerase chain reactions (B-tubulin messenger RNA or RT-PCR). The animal viability assay would be useful for *Cryptosporidium* of human origin. Cell culture and mRNA testing also appear to have merit. *Cryptosporidium* recoveries from biosolids appear to be far less efficient than those from helminths, having a recovery efficiency of about 10% for the sedimentation technique and less than 3% for the flotation technique (Bean and Brabants 2001b). Recoveries of *Cryptosporidium* oocysts and *Giardia* cysts from biosolids varied from 3.2 to 16.3% and 2.4 to 41.7%, respectively. These data illustrate the need to optimize the techniques for protozoan preservation, pretreatment, and analysis, because recovery efficiencies vary, depending on the sampling matrix.

Potential Limitations in Dose-Response Information

One intrinsic feature of risk assessment is that the data used to define a dose-response relationship for both chemicals and microbial agents are most often obtained at relatively high doses. A mathematical relationship is then used to extrapolate the risk at lower exposure levels. It has long been known, however, that dose-response relationships may yield quite different low-dose risk levels (e.g., see Van Ryzin 1980). Thus, it is important to develop the appropriate specifications for plausible dose-response models for infectious microorganisms. Initial attempts at expressing such characteristics have been made (Holcomb et al. 1999). The two most successful models are the exponential and the beta-Poisson models, both of which express the risk at low doses as a linear function of dose. This linear function has been demonstrated with outbreak data on *Shigella* and *Giardia* and risks extrapolated from human volunteer trials (Crockett et al. 1996; Rose et al. 1991b).

A second important aspect of dose-response assessment is the relationship between the ingested dose and the severity and duration of effects. For some pathogens, the severity of the outcome depends on the initial ingested dose (Teunis et al. 1999). There may also be species and subspecies differences in infectivity (and in the severity of illness). Ideally, a dose-response relationship for the particular subspecies (or "strain") should be obtained; however, that might not be possible in practice.

The differences in infectivity of different species of *Salmonella* and *Shigella* have been demonstrated (Crockett et al. 1996; Fazil 1996). *Cryptosporidium parvum* and different subspecies of *E. coli* manifest different dose-response relationships (Haas et al. 1999b; Okhuysen et al. 1999). Infectivity differences likely result from differences in pathogenicity. The degree to which biochemical markers may be used to predict infectivity quantitatively is an important research area.

A number of human dose-response relationships have been developed for bacteria, viruses, and protozoa (Regli et al. 1991; Rose et al. 1991b; Haas et al. 1993, 1996, 1999a; Crockett et al. 1996; Fazil 1996; Medema et al. 1996; Teunis et al. 1999). However, human or animal dose-response relationships for infection or illness from sewage sludge helminths (e.g., *Ascaria*, *Tanenia*) do not appear to have been identified.

Although it would be best to use human dose-response data, it is not possible for many organisms, and extrapolations must be made from animal studies. Studies on *Listeria monocytogenes,* a foodborne pathogen, and *E. coli* O157:H7 have used animal dose-response data to develop human dose-response information (Haas et al. 1999a, 2000). Exposures estimated from human infection rates during outbreaks were comparable to the estimated infection rate based on animal dose-response data, thus validating the use of animal data as a quantitative predictor of human response. However, such validation needs to be conducted in the case of each particular pathogen when an inference from animal dose-response information is to be made.

Protection of sensitive or susceptible subpopulations is frequently desired, although the definition of these subpopulations has not been rigorously defined. In a recent expert working group (Balbus, et al. 2000), one definition was crafted: "Susceptibility is a capacity characterizable by a set of intrinsic and extrinsic factors that modify the impacts of a specific exposure upon risks/severity of outcomes in an individual or population." Under that definition, susceptible subpopulations could include the immunocompromised (including HIV-infected persons and persons taking immunosuppressive drugs), pregnant women, the elderly, and children (Gerba et al. 1996). In addition, susceptible subpopulations could include persons with less access to health care or with concomitant factors, such as diet or use of illicit drugs, which might enhance risk or infectivity. As yet, there is no validated way to incorporate altered susceptibility for infectious microorganisms into a risk assessment. Such incorporation will probably require animal models to assess dose-response alterations associated with differing susceptibility.

Exposure Routes Other Than Ingestion

Microbial risk assessment is usually based on ingestion of contaminated food or water; however, biosolids exposure might occur by inhalation or direct dermal contact. Outbreak reports suggest that microorganisms found in biosolids might be transmitted by inhalation (Giubileo et al. 1998; Gregersen et al. 1999; Marks et al. 2000). Dose-response relationships and exposure models for these microorganisms are needed. In some cases, for example, for pathogenic fungi, there are no ingestion analogs on which to base infectivity via inhalation. Some animal models have been developed for inhalation exposure to biotoxins (including bacterial endotoxins and other microbial inflammatory agents) (Thorne 2000). A research program is needed to develop methods for the risk assessment of these agents.

Population Level Modeling

Two considerations of pathogen risk assessment that have no analog in chemical risk assessment is the need to address the potential for secondary transmission and acquired

immunity. Secondary cases of infection may arise by a variety of mechanisms, such as transmission among close family members. Household secondary cases can arise by direct or indirect (e.g., surface contamination) contact, particularly when the primary case or one household secondary case is a child (Heun et al.1987; Griffin and Tauxe 1991; Mac Kenzie et al.1995). Presumably, secondary cases may also arise from close contact with an asymptomatic individual (in the "carrier" state). This is well-known for highly acute and now uncommon illnesses, such as typhoid. Excretion of Norwalk virus following recovery and resulting in additional cases has been documented to occur for as long as 48 h after recovery (White et al. 1986).

There is evidence that transmission of organisms, at least for some illnesses, may occur before as well as after symptoms appear. In studying day-care rotavirus infections, Pickering et al. (1988) noted that more than 10% of the children excreted rotavirus up to 5 days before the onset of symptomatic illness. This pre-symptom excretion of rotavirus represents one route of transmission.

The impact of secondary infections may be considered in at least two ways. A first approximation may be made by multiplying the estimated number of primary cases by a secondary-case ratio. A second estimate may be made by using population-based models, as discussed in Chapter 7. These models have been documented in a number of reports (e.g., Eisenberg et al. 1996, 1998; Haas et al. 1999b). However, the models are still at the research stage, as certain parameters (e.g., incubation time, duration and intensity of immunity, and effectiveness of person-to-person contact) are poorly characterized for waterborne diseases. Furthermore, there might be an underlying endemic baseline of illness on which an outbreak can be superimposed (Morris et al. 1998). As additional data become available, it might be possible for population-based risk assessments to assess the impact of control options for infectious organisms.

FINDINGS AND RECOMMENDATIONS

The pathogen standards of the Part 503 rule are technologically based requirements intended to reduce the presence of pathogens. The standards consist of treatment, use, and monitoring requirements. Classification of Class A and Class B biosolids are based largely on fecal coliforms as indicator organisms. Class A biosolids do not have detectable concentrations of pathogens (determined by indicator organisms) and, therefore, risks from them are expected to be lower than those from Class B. Pathogens are normally present in Class B biosolids, but the risk they pose is unknown, because no risk assessment has been performed.

In determining the pathogen standards for biosolids, EPA considered a variety of potential bacteria, viruses, protozoa, and helminths that might be present in biosolids, their fate and transport in the environment, and the potential for human contact. The committee found that EPA considered an appropriate spectrum of pathogens and indicator organisms in setting its standards, but new information on those and other pathogens not considered are now available for conducting a national sewage sludge survey of pathogens and updating hazard identification. Because of the variety of pathogens that have the potential to be in biosolids, the committee supports EPA's use of pathogen-reduction requirements, use restrictions, and monitoring of indicator organisms, rather than pathogen-specific concentration limits, in its regulations.

Recommendations:

- *EPA should conduct a national survey of pathogen occurrence in raw and treated sewage sludges. Important elements in conducting the survey include use of consistent sampling methods, analysis of a broad spectrum of pathogens that could be in sewage sludge, and use of the best available (preferably validated) pathogen measurement techniques.*
- *Additional indicator organisms, such as* Clostridium perfringens*, should be considered for potential use in regulation of land-applied biosolids. Such indicators and other operational parameters (e.g., time, temperature, pH, and chemical dose) may be suitable for assessing day-to-day compliance with the regulations.*

As with the chemical standards, EPA based its pathogen standards on selected pathogens and exposure conditions that were expected to be representative and conservative enough to be applicable to all areas of the United States and for all types of land applications. However, pathogen survival in soils may range from hours to years, depending on the specific pathogens, biosolids-application methods and rates, initial pathogen concentrations, soil composition, and meteorological and geological conditions. In addition, very few data are available to estimate the occurrence, transport, and decay rates of pathogens and endotoxins in bioaerosols.

Recommendation: *Site restrictions, buffer zones, and holding periods for land-applied Class B biosolids, should consider geographic and site-specific conditions that affect pathogen fate and transport.*

Regulations for Class B biosolids include use restrictions. These restrictions are intended to limit animal and human contact with land-applied biosolids until environmental factors reduce pathogens to concentrations that are not expected to cause adverse effects. Because there are no requirements for on-site monitoring of pathogens, there is little information available to evaluate the reliability of use restrictions in achieving their intended minimum exposure levels or to verify that those desired levels are maintained over an extended time.

In addition, the committee found that some potential exposure pathways were not sufficiently considered when the use restrictions were developed. For example, potential off-site inhalation of dust and aerosols does not appear to have been considered. The potential for groundwater contamination by pathogens was not sufficiently addressed. This is a concern in geologically sensitive areas, where there is the potential for leachate from application sites to contaminate subsurface-water resources. In addition, the potential for runoff to contaminate surface waters was not adequately addressed.

Recommendations:

- *Studies should be conducted to determine whether the site restrictions specified for Class B biosolids in the Part 503 rule actually achieve their intended effect with regard to pathogen levels.*
- *As recommended in Chapter 5 for chemicals, EPA should develop a conceptual site model to identify the major and minor exposure pathways (including secondary transmission) by which humans might come into contact with pathogens in biosolids.*

Substantial advances in detection and quantification of pathogens in the environment have been made since the promulgation of the 503 rule. For example, new molecular techniques for detecting pathogens, such as PCR, are now available. In addition, new approaches to environmental sample collection and processing are available. However, no consensus standards have been developed for pathogen measurements in biosolids and bioaerosols.

Recommendation: *EPA should foster development of standardized methods for measurement of pathogens in biosolids and bioaerosols. EPA should include round-robin laboratory testing to establish method accuracies and precisions at the various pathogen concentrations expected in raw sewage sludge and partially and fully treated biosolids. These new detection methods should be used to verify that EPA's prescribed pathogen reduction techniques are reliable in achieving their intended goals. Mechanisms should be developed for incorporating new methodologies into the verification process as they become available.*

Microbial risk-assessment methods similar to those used in chemical risk assessments have been developed for pathogens in drinking water and food. These methods are not as well-established as those for chemicals, and there are important differences between the two. For example, a microbial risk assessment must include the possibility of secondary infections, either through person-to-person contact or from transmission of the pathogen to others through air, food, or water. The importance of secondary transmission depends in part on the level of acquired immunity to the pathogen in the community, a phenomenon that has no analog in chemical risk assessment.

The committee believes quantitative microbial risk assessment (QMRA) is a feasible approach to setting standards for pathogens in biosolids. The committee does not recommend that QMRA be used to establish pathogen-specific regulatory concentration limits but recommends that it be used as a tool for developing treatment, use, and monitoring requirements (or for validating current requirements) to meet acceptable risk levels. However, there are still substantial data gaps, such as characterization of dose-response relationships and transport and fate of pathogens and endotoxins in biosolids and bioaerosols. Monitoring of compliance with the regulations should continue to be conducted using indicator organisms and operational parameters and practices (e.g., temperature, buffer zones, and pH) to ensure that tolerable risk levels are not exceeded.

Recommendation: *QMRAs should be developed and used to establish (or validate) regulatory criteria (treatment processes, use restrictions, and monitoring) for pathogens in biosolids. They can also be used for sensitivity analyses and identifying critical information that is needed to reduce uncertainty about the risks from pathogens in biosolids. To conduct these risk assessments, consideration must be given to assessing risks from all potential routes of exposure (e.g., bioaerosols, groundwater), dose-response relationships, pathogen survival, and secondary transmission of disease. In some cases, research will be needed to fill gaps in knowledge of those inputs. As additional information is gathered on exposure, dose-response relationship, and pathogen survival, the risk assessments should be reviewed and updated as necessary.*

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7

Integration of Chemical and Pathogen Risk Assessment

The final element of the charge to the committee is to explore whether approaches for conducting pathogen risk assessment can be integrated with those for chemical risk assessment. This inquiry leads to a summary and synthesis of many of the previous chapters' findings and recommendations that resulted directly or indirectly from the committee's need to address the inherent uncertainty of the complex composition of biosolids. This uncertainty precludes the possibility of completely separating the risk-assessment and risk-management processes. Risk assessment for such mixtures is an ongoing process that requires quality control of treatment processes and some form of surveillance for adverse effects from exposure to biosolids. In this chapter, the question of whether pathogen risk assessment can be integrated with chemical risk assessment will be explored first in the agent-by-agent context of the original risk assessment used for the Part 503 rule and then in the broader and more recent context of risk assessment for complex mixtures.

AGENT-BY-AGENT RISK ASSESSMENT

The pathogen and chemical regulations of the Part 503 rule were developed differently. EPA conducted risk assessments for chemicals to establish concentration limits and loading rates but deemed microbial risk assessment to be too immature for developing risk-based limits for pathogens. Instead, EPA established treatment and site restrictions to reduce the concentrations of pathogens in biosolids. Advances in microbial risk assessment have occurred since then, but there remains a difference in the maturity of risk-assessment procedures for chemicals and those for pathogens. The question posed is whether this difference is simply an artifact of the different stages of development of these two branches of risk assessment or whether generic differences are attributable to the nature of the agents themselves. In addressing this question, it is useful to consider the four components of the traditional risk-assessment process (hazard identification, dose-response characterization, exposure assessment, and risk characterization) and ask which, if any, of those components has inherent differences in the way pathogens and chemicals are assessed.

Hazard identification is the process of reviewing relevant biological and chemical information on an agent that might pose a health hazard. Although there are obvious differences in the types of information available on chemicals and pathogens, there appears to be little fundamental difference in the process of identifying their hazards. This is supported by a recent NRC report *Classifying Drinking Water Contaminants for Regulatory Consideration* (NRC 2001), in which no distinction between chemical and biological contaminants is made. In general, however, pathogens usually are grouped into generic classes with less of an agent-specific focus than is common in chemical risk assessment.

The process for characterizing dose-response relationships is not as straightforward for pathogens as it is for chemicals. The process is complicated by the possibility that exposure to a pathogen may engender an immune response that might persist and alter an individual's

subsequent susceptibility to infection or clinical disease. Acquired immunity has no relevant analog for chemical exposures in the risk-assessment context, although there are chemicals for which sustained exposure can result in tolerance for some toxic end points. Also, the converse can be true when an individual becomes sensitized to a chemical and develops serious and persistent hypersensitivity. For infectious agents, however, acquired immunity can be a major modifier of population risk. An exposed population is likely to be an unknown mixture of those with acquired immunity and those without. Moreover, the population can change over time as susceptible individuals become infected and move from one subgroup to the other. Acquired immunity might simply be addressed by developing two dose-response functions in the risk-assessment process, one for the susceptible population without immunity and a second for the population with acquired immunity. The conservative approach would be to conduct an assessment of a totally susceptible population, and while the results could be very conservative, this option would be consistent with EPA's practice of protecting sensitive subpopulations.

Perhaps the greatest methodological difference in the risk-assessment process for chemicals and pathogens occurs in the exposure assessment process. The difference is because of the possibility of secondary transmission of infectious agents (discussed in-depth below). The challenge posed by secondary transmission is that an individual is at risk not only from direct exposure to pathogens in biosolids but also from population-level interactions that can result in exposure to and infection from individuals already infected. In addition, there are environmental pathways (e.g., contamination of surface waters used for drinking or recreation) by which an individual infected with an enteric pathogen, for example, can alter the risk for populations not primarily exposed to the pathogen in biosolids. Whatever the pathway, secondary transmission can expand the population at risk beyond those involved in the original exposure scenario. Hence, the likelihood of secondary transmission is an issue that must be addressed generally in pathogen risk assessments, as contrasted with those for chemical exposures.

The risk-characterization process for a single pathogen versus a single chemical will differ in the need to account for the implications of acquired immunity and secondary transmission. In the case of biosolids, however, that distinction is somewhat academic, because both chemicals and pathogens are part of a complex mixture, the exact composition of which can change from time to time and place to place. As noted above and in Chapters 4 and 6, methods for conducting chemical and microbial risk assessments have advanced since the promulgation of the Part 503 rule, including methods for assessing risks of chemical mixtures. These advances are clearly relevant to updating the biosolids standards. However, the additional complexity of dealing with chemical and pathogen mixtures has the potential of being counter to the recommendations of the Presidential/Congressional Commission on Risk Assessment and Risk Management (1997). In particular, the commission advised a diminished reliance on assumption-laden procedures for arriving at agent-by-agent and medium-by-medium mathematical estimates of risk. Instead, it advises assessments focused at particular exposures and health end points, clarified with stakeholder input, with the objective of achieving and sustaining practical reductions in risk. Issues about mixtures are discussed further below, and the committee outlines data needs and the nature of studies that would inform more focused assessments in Chapters 2 and 3.

SECONDARY TRANSMISSION

Most quantitative risk assessments for pathogens have focused on ingestion of waterborne pathogens (Fuhs 1975; Haas 1983; Regli et al. 1991; Anderson et al. 1998). In these studies, static models were used to calculate the probability of individual infection or disease as a result of a single exposure event. This approach is based on an early chemical model for risk assessment (NRC 1983). In chemical risk assessment, there is generally a straightforward relation between risk to an individual and risk to a population of similarly exposed people. For example, if a particular exposure scenario results in an estimate of an individual risk of chemically induced disease of 1×10^{-4}, then the expected number of cases in an exposed population of 100,000 is 10. This result is valid under the assumption that any person's probability of disease is independent of whether anyone else gets the disease. Both estimates of individual and population risk are determined by the dose-response function and the exposure assumptions, and both of those are unmodified by the disease status of others in the population. As noted above, that straightforward relation is not the case for all infectious diseases. For example, for an individual, the probability of infection from a particular pathogen in biosolids, $P_{I,}$ is the sum of two terms:

$$P_I = P_{(\text{direct exposure to pathogen in biosolids})} + P_{(\text{exposure to pathogen shed by infected person})}$$

The possibility of exposure to a pathogen shed by an infected person is peculiar to pathogens in being an important and sometimes dominant pathway of exposure. The pathway by which the shed pathogen gets from the infected to the susceptible person can be from direct contact or by circuitous routes through the environment.

The limitations of treating infectious disease transmission as a static disease process, with no interaction between those infected or diseased and those at risk, has been illustrated in studies of *Giardia* (Eisenberg et al. 1996), dengue (Koopman and Longini 1994), and sexually transmitted diseases (Koopman et al. 1991). However, risk-assessment approaches for environmentally mediated pathogen exposures involving secondary transmission are only now being developed (Colford et al. 2001). These approaches allow exploration of the importance of the secondary infection process. However, the need for data for execution of calculations based on these approaches is also greater than that for static risk assessments. When secondary infection is possible, risk is by definition manifested at a population level and risk calculations are dynamic in nature. (The overall risk calculation is based not only on current exposures to contaminated media but also on all subsequent secondary infections.) In addition, the existence and development of acquired immunity in the population must be accounted for in the analysis.

The dynamic systems approach was used to study the conditions under which environmentally mediated secondary transmission could be important in the transmission of *Giardia* (Eisenberg et al. 1996). An exposure scenario was studied in which swimmers were exposed to *Giardia* from a recreational swimming impoundment filled with water reclaimed from community sewage. The important finding in this study was that the rate of infected swimmers shedding pathogens into the impoundment was a crucial factor in determining (1) the degree to which a contribution of the incidence of giardiasis came from transmission via swimming; and (2) the most effective control strategy.

Clearly, the methods of risk assessment for chemicals and pathogens have inherent differences in some elements of the risk-assessment process. Thus, the committee concludes that

in conducting single-agent risk assessments, there are inherent differences between chemical and pathogenic agents that must be considered. In particular, infection of an individual from exposure to pathogens in biosolids may lead to secondary infections in others from person-to-person contact or from transmission of the pathogen to others through air, food, or water.

The importance of secondary transmission depends in part on the level of acquired immunity to the pathogen in the community. In assessing the likelihood of secondary transmission, it is clear that the use of the dynamic modeling approach to fully assess the risks of the pathogen component of biosolids for all pathogens and all exposure scenarios would be a complex undertaking. Generally, site-specific data (e.g., population size) are required, and the models are themselves analytically complex. The use of default parameter values and appropriately structured analysis may be able to provide a practical procedure for using the modeling approach to explore the importance of immunity and secondary transmission in preliminary analyses. At present, however, it may be more practical to use less comprehensive methods as a form of preliminary analysis to address the importance of these effects. The objective of such a preliminary analysis would be to determine whether a particular pathogen possesses characteristics that result in secondary transmission and, if so, determine the possible pathways through which this transmission can occur.

For pathogens that can be transmitted via infected individuals, the preliminary analysis can proceed following the standard format of chemical risk assessment with the focus on the susceptible individual. A new feature of this process is the need to determine the existence of exposure pathways connecting a susceptible individual to others in the community assumed to be infected already. If plausible pathways do not exist, then no further analysis is needed. Alternatively, if such pathways are identified, it will be necessary to explore their importance. If their importance is low with respect to direct exposure, no further action is needed, whereas a significant risk with respect to background incidence of disease suggests the need for a comprehensive assessment.

From another perspective, the issue here is to gain some insight into what is termed the "force of infection" by infectious disease epidemiologists (Anderson and May 1991). The force of infection represents the probability that a given susceptible host becomes infected per unit time only because of the presence of other infected individuals in the population. A complicating feature of the concept is that the force of infection is generally assumed to be linearly proportional to the number of infected individuals in the population. This proportion in turn depends on the level of population immunity. Those factors again underscore that if pathways of secondary infection exist, it is only possible in an approximate way to carry out the preliminary analyses on an individual basis rather than at the population level. A feasible approach might be to conduct a two-tiered evaluation, the first dealing with the potential for secondary transmission of a set of candidate pathogens and the second analyzing the exposure pathways for those pathogens with a secondary transmission potential.

COMPLEX MIXTURES

It is a challenge to integrate the outcomes of each agent-specific risk assessment into a comprehensive whole, even for simple mixtures. One reason for the difficulty is the lack of information usually available on the biological interactions between components of the mixture. The second reason is the challenge to characterize in a useful way the range of risks that might

occur. For biosolids, the possible adverse outcomes of exposure will include acute and chronic effects from chemical exposures and principally acute effects from exposures to pathogens. Further, these effects will range from short-term non-life-threatening outcomes like irritation and diarrhea to chronic life-threatening outcomes like cancer. Although the exposure-assessment component of the risk-assessment process will characterize the extent of various chronic versus acute hazards for specific population groups, an integrated assessment will sometimes be needed to balance the risk of outcomes of modest severity with those of great severity.

This same challenge exists for mixtures of chemical agents alone, as discussed in EPA's "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures" (EPA 2000). This document offers valuable guidance on the assessment of risks arising from the chemical mixtures found in biosolids. The strategic guidance from that document that can be extrapolated to biosolids is that it is preferable to base risk assessments on studies of exposure to the whole mixture, for example, epidemiological studies of biosolids workers. However, as noted in Chapter 3, that type of data is not available for biosolids in either sufficient amount or quality, consequently making it necessary to use a component-based approach to assess risks from pathogens and chemicals in biosolids.

Although the chemical mixtures document discusses in some detail the various options available for risk characterization, including guidance on the formulation of hazard indexes, there is no equivalent guidance, either from EPA or in the scientific literature, for mixtures of pathogens, let alone the chemical-pathogen mixture that biosolids comprise. Introducing risks from pathogens to the process of integrating diverse outcomes in the risk characterization step would seem to present no new challenges beyond the implications of acquired immunity and secondary infection discussed previously. However, despite progress in integrating risks for mixed chemical exposures, the possibility of pathogen-pathogen or chemical-pathogen interactions between the components in either inhibiting or enhancing the adverse effects expected from individual exposures presents an array of unexplored issues in the context of risk assessment. That pathogen-pathogen and chemical-pathogen interactions occur is illustrated by examples, including the increased likelihood of tuberculosis infection among workers exposed to silica dusts (Hnizdo and Murray 1998; Ding et al. 2002). Of greater relevance to biosolids is the experimental demonstration that short-term inhalation exposures to nitrogen dioxide increase the susceptibility of rodents to pneumonia (Coffin et al. 1977; Gardner et al. 1977). The committee concludes that the knowledge base for generating summary indexes of risk for finite mixtures of chemicals and pathogens is incomplete. However, research is clearly needed to synthesize existing information on potential interaction of chemicals and pathogens that might be associated with biosolids exposures and lead to an increased susceptibility to infection, particularly by inhalation.

It is important to note that, even if a summary index of the risk of an adverse response to mixtures was available, it would not necessarily reflect the total hazard of exposure to biosolids because of the inability to identify all of its hazardous constituents and their potential for interaction in vivo. Moreover, the composition of biosolids is susceptible to unanticipated changes from time to time and place to place. Thus, it is not possible to conduct a risk assessment for biosolids at this time (or perhaps ever) that will lead to risk-management strategies that will provide adequate health protection without some form of ongoing monitoring and surveillance. There is a degree of uncertainty that, when exceeded in the risk-assessment process, requires some form of active health and environmental tracking in the risk-management strategy to ensure against unanticipated outcomes. This situation led the committee to conclude

that although the Part 503 agent-specific risk-assessment process can be improved with new risk assessment methodology, the remaining uncertainty for complex mixtures of chemicals and biological agents is sufficient to preclude the development of risk-management procedures based on these agent-specific analyses that can reliably result in acceptable levels of risk. Some form of process quality assurance and ongoing surveillance must be done to ensure that effects not anticipated by the chemical- and pathogen-specific risk assessments do not occur. Strategies for the management of risks arising from biosolids exposure should include audits of process performance and management practices, periodic hazard surveillance, and studies of health outcomes, including epidemiological studies and studies in response to episodic events.

As recounted in this report, the various steps in the treatment, transport, application, and use of biosolids present multiple opportunities for both human exposure and monitoring and surveillance of the process to ensure minimization of risks. Figure 7-1, adapted for biosolids (Halperin 1996), attempts to summarize the process, the opportunities for hazard surveillance, and the opportunities for study of exposed human populations. Also shown are the points in the process amenable to quality control and compliance audits to ensure that the management practices assumed in the risk assessment process or required by the Part 503 rule are, in fact, carried out appropriately.

In Figure 7-1, each of the center boxes is a process to which biosolids are subjected, beginning with the original treatment process (top) that converts the raw sewage sludge into Classes A or B biosolids, which are then packaged or otherwise prepared for transport and delivery to the application site. Biosolids are then applied to land where they are subject to weathering, and some of the constituents may be transported off-site. The right side of the figure shows a second set of boxes that represent human exposures to biosolids at any point between initial processing and final decay or inactivation of off-site contaminants. Exposed populations can be monitored or studied at particular times and locations to assess the relation between any abnormal health conditions and the biosolids exposure experienced. Any information gained from studying health outcomes is collected and fed back into the risk assessment to support or improve the risk-management process, as indicated by the vertical line on the far right of the figure.

The left side of the figure shows the stages in the process amenable to quality-assurance activities or hazard surveillance. At any point in the process, it is possible to obtain bulk samples of biosolids (or biosolids-soil mixtures) to determine whether its hazardous constituents are present in expected or unexpected concentrations. It is also possible to monitor the media of exposure to chemicals or pathogens originating in biosolids (e.g., personal air monitoring of workers engaged in land application).

With respect to quality assurance, as indicated in Chapter 2, a need exists to verify the efficacy of treatment technologies used for pathogen control. Because the regulations for pathogen control are technologically based rather than risk based, it is important to verify that the technology is achieving the intended results. Such verification includes a review of the management practices required for Class B land application, because they are predicated on the assumption that further pathogen reduction is achieved through the implementation of such practices.

The right side of the figure shows the points in the process where human exposures can occur and, by implication, the different populations and circumstances that might be involved.

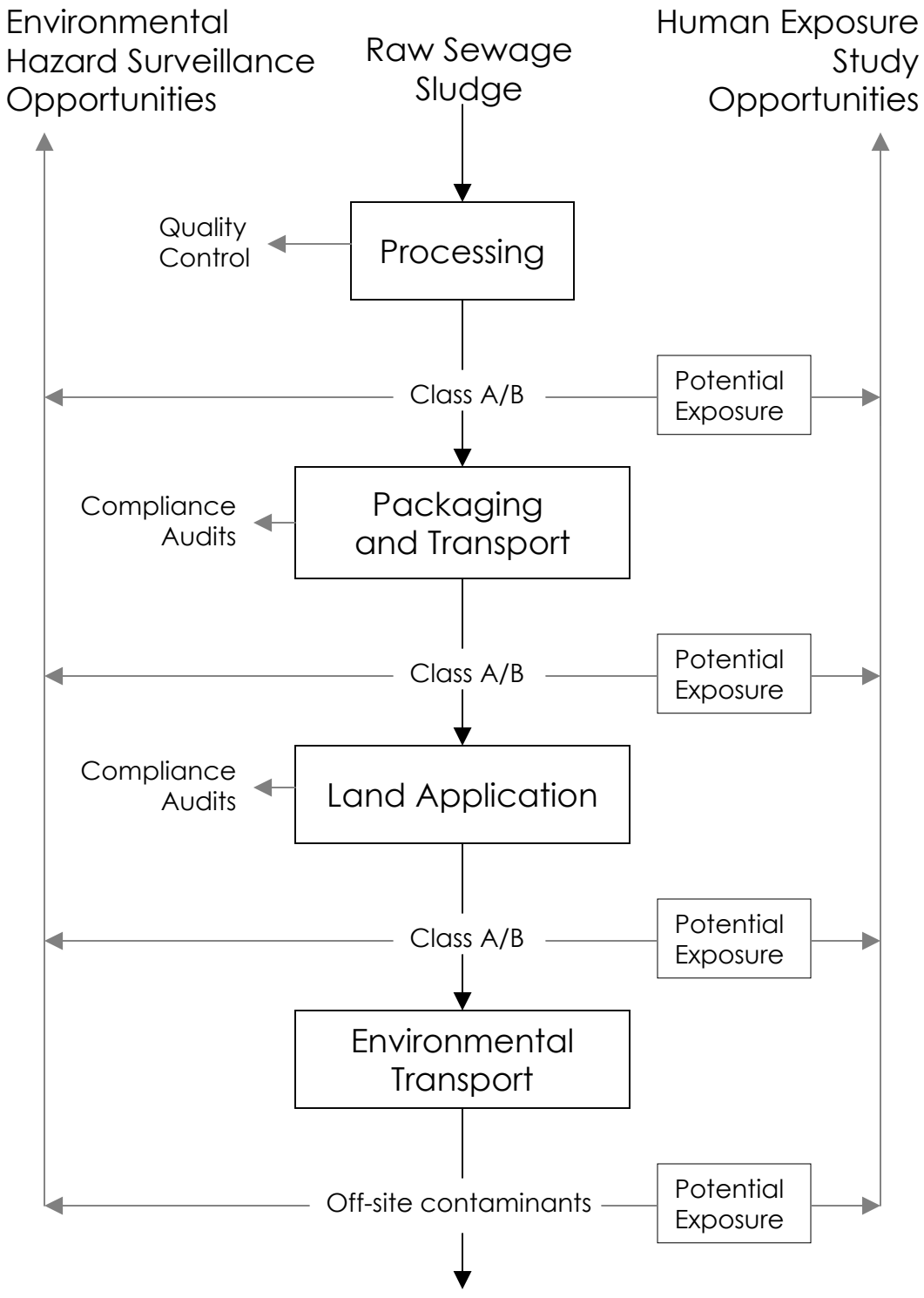

FIGURE 7-1 Processing, transport, and land application of biosolids with options for hazard surveillance and studies of human exposures.

Although routine human health surveillance is unnecessary and impractical because of the wide variety of possible outcomes, the committee believes that specific circumstances might afford opportunities for health effects studies, such as epidemiological studies of occupational groups or investigations arising from reports of disease outbreaks plausibly connected to biosolids exposure.

FINDINGS AND RECOMMENDATIONS

Ideally, risk assessment of biosolids should be based on complex-mixture data to include risks from chemicals and pathogens. However, that type of data is not available in either sufficient quantity or quality (see Chapter 3), and methods have not been developed for integrating and characterizing the range of risks that might occur from exposure to mixtures of chemicals and pathogens. Thus, it remains necessary to use a component-based approach to assess risks from pathogens and chemicals in biosolids. The committee found that although the chemical-specific risk assessments conducted to establish the Part 503 regulations can be improved by using new risk-assessment methodology, the remaining uncertainty for complex mixtures of chemical and biological agents is sufficient to preclude the development of risk-management procedures that can reliably result in acceptable levels of risk. Some form of treatment-process quality assurance and ongoing surveillance must be done to ensure that effects not anticipated by the agent-specific risk assessments do not occur.

Recommendations:

- *Figure 7-1 should be used by EPA as a framework for managing the risks from exposure to biosolids. The framework includes audits of treatment-process performance and management practices, periodic hazard surveillance, and studies of health outcomes, including preplanned studies and studies in response to episodic events. For example, as recommended in Chapters 2 and 6, surveys should be conducted to verify that Class A and Class B treatment processes perform as assumed by engineering principles, and determinations of pathogen density and destruction across the treatment process and in the soil over time should be completed. Recommendations contained in Chapter 5 also address the need for process-performance measures that can be monitored and used in site-specific surveys of performance. In Chapter 3, the nature and objectives of hazard surveillance studies and studies of health outcomes of exposed populations are described more fully. All the recommendations reflect the committee's concern that the complex risk-assessment task posed by biosolids cannot serve as a useful and reliable guide without an ongoing effort to ensure that the assumptions underlying the assessment are valid and that the risk-management procedures put in place in response to the assessment are being routinely implemented. Broad-scale and site-specific feedback, graphically depicted in Figure 7-1, is needed.*
- *Research should be conducted to synthesize existing information on potential interaction of chemicals and pathogens that might be associated with biosolids exposures and lead to an increased susceptibility to infection, particularly by inhalation.*

Methods for conducting chemical and microbial risk assessment have advanced since the promulgation of the Part 503 rule in 1993. In reviewing these methods, the committee found that there are inherent differences between chemical and pathogenic agents that must be considered

in single-agent risk assessments. In particular, infection of an individual from exposure to pathogens in biosolids might result in secondary infections in others. The secondary infections might be caused by person-to-person contact or transmission of the pathogen to others through air, food, or water. The importance of secondary transmission depends in part on the level of acquired immunity to the pathogen in the community. Another development of importance is the recommendation of the Presidential/Congressional Commission on Risk Assessment and Risk Management to diminish reliance on assumption-laden procedures for arriving at agent-by-agent and medium-by-medium mathematical estimates of risk in favor of stronger interaction with stakeholders in achieving and sustaining practical reductions in risk.

Recommendation: *As outlined in Chapters 5 and 6, future risk assessments of biosolids components should be conducted using the most current methods and data. For pathogens, it is important that risk assessments include an evaluation of the potential for secondary transmission of disease. Representatives from all stakeholders should be included in future risk assessments. Stakeholders can provide information and insights into the use of biosolids in practice and the potential health problems, which are particularly important in the development of exposure assessment. Involving stakeholders throughout the risk-assessment process provides opportunities to bridge gaps in understanding, language, values, and perspectives.*

The committee is aware that this report poses a challenge to EPA in that much of the discussion in this chapter, as well as in Chapters 3 and 4, recommend very different emphases in updating the Part 503 rule than is reflected in the charge to the committee. In many ways, the contents of Chapters 2, 5, and 6 are a more direct response to the charge, which is grounded in the original approach and methodology, while acknowledging that this review would be carried out in the context of new developments. However, the committee believes that the differences in point of view and approach underlying its response to the various elements of the charge accurately reflect the countervailing currents in the broader risk-assessment community and the differences in perspective among those directly involved in the management of biosolids risks. The overall objective of the process, which this report is a part of, is to better assess and manage the risks associated with the land application of biosolids in the United States.

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Appendix A

Biographical Information on the Committee on Toxicants and Pathogens in Biosolids Applied to Land

Thomas A. Burke (*Chair*) is professor in the Department of Health Policy and Management at the Johns Hopkins University School of Hygiene and Public Health, with joint appointments in the Department of Environmental Health Sciences and the School of Medicine's Department of Oncology. He is also founding codirector of the university's Risk Sciences and Public Policy Institute. Before joining the university, Dr. Burke was deputy commissioner of health for the State of New Jersey and director of science and research for the New Jersey Department of Environmental Protection. In New Jersey, he directed pioneering initiatives that influenced the development of national programs, such as Superfund, the Safe Drinking Water Act, and the Toxics Release Inventory. His research interests include environmental epidemiology, the evaluation of community exposures to environmental pollutants, the assessment and communication of environmental risks, and the application of epidemiology and health risk assessment to public policy. Dr. Burke is chair of the advisory board to the directors of the Centers for Disease Control and Prevention, National Center for Environmental Health, and is a member of the National Research Council (NRC) Board on Environmental Studies and Toxicology. He received his Ph.D. in epidemiology from the University of Pennsylvania and his M.P.H. from the University of Texas.

Lawrence R. Curtis is professor and head of the Department of Environmental and Molecular Toxicology at Oregon State University. His research interests are focused on understanding the cellular level processes that determine bioaccumulation of persistent chlorinated hydrocarbons and polycyclic aromatic hydrocarbons and the trophic transfer and ecotoxicology of persistent organic contaminants. Dr. Curtis is on the editorial board of the *Journal of Toxicology and Environmental Health: Critical Reviews* and has served as chair of the Membership Committee of the Society of Toxicology. He received his M.Sc. from the University of South Alabama and his Ph.D. in pharmacology and toxicology from the University of Mississippi Medical Center.

Charles N. Haas is the L.D. Betz Chair Professor of Environmental Engineering at Drexel University. He is widely recognized for his research in the areas of microbial and chemical risk assessment, hazardous waste processing, industrial wastewater treatment, waste recovery, and water and wastewater disinfection processes. Dr. Haas is a fellow of the American Academy of Microbiology and is the founding editor in chief of *Quantitative Microbiology*. He is also a member of the Council of the Society for Risk Analysis. He received his M.S. in environmental engineering from the Illinois Institute of Technology and his Ph.D. from the University of Illinois.

William E. Halperin is professor and chairman of the Department of Preventive Medicine and Community Health at the New Jersey Medical School. Before joining the faculty of the medical school, Dr. Halperin was a senior scientist with the National Institute for Occupational Safety and Health and also held the position of deputy director. His research interests are in occupational medicine, occupational epidemiology, and public-health surveillance. Dr. Halperin was a member of the NRC Committee on Risk Assessment Methodology and currently serves on the NRC Committee on Toxicology and its Subcommittee on Spacecraft Water Exposure Guidelines. He received his M.D., M.P.H., and Dr.P.H. from Harvard University and is certified by the American Board of Preventive Medicine and the American Board of Occupational Medicine.

Ellen Z. Harrison is director of the Cornell Waste Management Institute, a program of the Cornell Center for the Environment that develops solutions for waste-management problems and addresses broader issues of waste generation and composition, waste reduction, risk management, environmental quality, and public decision-making. Ms. Harrison has been involved for many years in the assessment of health and environmental risks from land application of sewage sludges. She has served as cochair of the Northeast Regional Research Project on Land Application of Sewage Biosolids since 1997 and is the coauthor of *The Case for Caution: Recommendations for Land Application of Sewage Sludges An Appraisal of the U.S. EPA's Part 503 Sludge Rules*. She also served on the council for the town of Ithaca, New York, from 1993 to 1999. Ms. Harrison received her M.S. in geological sciences from Cornell University.

John B. Kaneene is professor of epidemiology and director of the Population Medicine Center at Michigan State University. He also holds professorships in the Department of Large Animal Clinical Sciences, the Department of Epidemiology, and the Animal Health Diagnostic Laboratory. His research is focused on the application of epidemiological methods to understand disease dynamics in populations and the use of these methods in designing, implementing, and evaluating prevention and control strategies. Some specific areas of research include the epidemiology of food-borne pathogens (*Campylobacter, Salmonella,* and *Escherichia coli*) and their relationships to the development of antimicrobial resistance in animal and human populations, the epidemiology of drug and chemical residues in foods of animal origin and their potential human health risks, and the epidemiology of tuberculosis. Dr. Kaneene was a member of the NRC Committee on Drug Use in Food Animals and currently serves as a member of the NRC Board on Agriculture and Natural Resources, Subcommittee on Food and Health. Dr. Kaneene received his D.V.M. from the University of Khartoum and his M.P.H. and Ph.D. in epidemiology and statistics from the University of Minnesota.

Greg Kester is a civil and environmental engineer at the Wisconsin Department of Natural Resources, where he serves as the state residuals coordinator overseeing all aspects of Wisconsin's biosolids program. In that position, he has incorporated all necessary provisions of federal biosolids regulations, set policy for the Wisconsin biosolids program implemented by field engineers, and made determinations on the adequacy of solids-handling design. He developed and maintains a communication network for all state biosolids coordinators. The network provides a forum for the exchange of questions and dialogue on implementation, technical standards, and enforcement strategies. Mr. Kester has also been involved with a

Wisconsin workgroup to develop risk-based soil criteria for PCBs. Before Mr. Kester became an environmental engineer, he worked for 10 years as an operator and biosolids-reuse program worker for the Madison Metropolitan Sewerage District. He received his B.S. in civil and environmental engineering from the University of Wisconsin at Madison.

Stephen P. McGrath is a program leader in the Agriculture and Environment Division of the Institute of Arable Crops Research-Rothamsted in the United Kingdom and special professor at the School of Life and Environmental Sciences at the University of Nottingham. His research is focused on understanding the source, behavior, fate, and impact of pollutants (particularly heavy metals) in soil and the food chain, biological impacts of waste disposal, phytoremediation, and soil remediation. His research on ecotoxicology of metals and waste disposal led to new national rules in the United Kingdom for sewage-sludge disposal. He is also involved in international projects with the International Atomic Energy Agency and the United Nations Food and Agriculture Organisation on the use of stable isotopes to determine the optimal utilization of wastes. Dr. McGrath received his Ph.D. in physiological ecology from Sheffield University.

Thomas E. McKone is a senior scientist at the Ernest Orlando Lawrence Berkeley National Laboratory and is an adjunct professor in the School of Public Health at the University of California at Berkeley. His research interests include the chemical transport and accumulation of toxic chemicals in multiple environmental media (air, water, and soil), the development of multimedia compartment models that can be used in quantitative risk assessments, and human exposure and health risk assessment. He is responsible for the development of CalTOX, a model used by the California Department of Toxic Substances Control to conduct health-risk assessments that address contaminated soils and the contamination of adjacent air, surface water, sediments, and groundwater. Dr. McKone is a past-president of the International Society of Exposure Analysis, and has served on several NRC committees. He received his M.S. and Ph.D. in engineering from the University of California at Los Angeles.

Ian L. Pepper is professor and research scientist in the Departments of Soil, Water and Environmental Science, and Microbiology and Immunology at the University of Arizona. He also serves as director of the university's National Science Foundation Water Quality Center. His research interests are in molecular ecology of soil and biosolids, particularly with respect to the risk from pathogens and metals from land-applied biosolids. Dr. Pepper received his M.S. in soil biochemistry and his Ph.D. in soil microbiology from Ohio State University.

Suresh D. Pillai is associate professor of food safety and environmental microbiology in the Poultry Science Department of Texas A&M University. He also serves as associate director of the university's Institute of Food Science and Engineering. Dr. Pillai's research interests include the occurrence, fate, transport, and activity of microbial pathogens in natural and developed ecosystems, such as groundwater, surface water, wastewater, bioaerosols, and food processing. He is also involved in the development and testing of rapid diagnostic molecular assays for microbial pathogens and the evaluation of public-health risks from microbial pathogens. He received his M.Sc. in industrial microbiology from the University of Madras, India, and his Ph.D. in microbiology and immunology from the University of Arizona.

Frederick G. Pohland is professor and Edward R. Weidelein Chair of Environmental

Engineering at the University of Pittsburgh. His research interests include environmental engineering operations and processes; industrial, solid, and hazardous waste management; and environmental impact assessment. He has studied an array of innovative technologies for environmental monitoring and remediation, with special emphasis on groundwater, soils, and surface waters. Dr. Pohland is past president of the American Academy of Environmental Engineers and was elected to the National Academy of Engineering in 1993. He received his M.S. in sanitary engineering and his Ph.D. in environmental engineering from Purdue University.

Robert S. Reimers is professor in the Department of Environmental Health Sciences at Tulane University. He also holds an adjunct appointment in the university's Department of Civil and Environmental Engineering. He is an environmental engineer and applied chemist specializing in natural resource management, including the management of residuals and toxic waste. His research interests include biosolids treatment, disinfection, stabilization, and reuse; industrial residual product development; and innovative process development. Dr. Reimers has studied the translocation of chemical pollutants, such as PCBs, in soils and has been involved in studying the prevalence, survival, and control of parasites (e.g., Ascaris eggs) in municipal wastewater biosolids. Dr. Reimers received his M.A. in chemistry from the University of Texas and his Ph.D. in engineering (environmental and water resources) from Vanderbilt University.

Rosalind A. Schoof is a principal at Gradient Corporation, which is a environmental consulting practice. She conducts evaluations of chemical toxicity, health risk assessment for cancer and noncancer end points, and multimedia assessment of exposure to environmental chemicals. Dr. Schoof is particularly interested in the bioavailability of metals (e.g., arsenic, cadmium, and lead) found in soils and has been involved in evaluating exposures at mining, smelting, and pesticide manufacturing sites. She received her Ph.D. in toxicology from the University of Cincinnati and is a diplomate of the American Board of Toxicology.

Donald L. Sparks is S. Hallock duPont Chair of Environmental Soil Chemistry and Francis Alison professor, and at the University of Delaware at Newark. He also holds joint faculty appointments in the Departments of Civil and Environmental Engineering and Chemistry and Biochemistry and in the College of Marine Studies. Dr. Sparks is internationally recognized for his research in the areas of kinetics of soil chemical processes, surface chemistry of soils and soil components using in situ spectroscopic and microscopic techniques, and the physical chemistry of soil potassium. He is the recipient of many awards and honors, including being named a fellow of the American Society of Agronomy, the Soil Science Society of America, and the American Association for the Advancement of Science. He is a past-president of the Soil Science Society of America and is currently president-elect of the International Union of Soil Science. Dr. Sparks received his M.S. in soil science from the University of Kentucky and his Ph.D. from the Virginia Polytechnic Institute and State University.

Robert C. Spear is professor of environmental health sciences in the School of Public Health at the University of California at Berkeley. He is also the founding director of the university's Center for Occupational and Environmental Health. His research interests include the mathematical modeling of toxicological and infectious disease processes and statistical issues in exposure assessment. Dr. Spear has an extensive publication record in this field, spanning farm

workers' exposures to pesticides to strategies for the characterization and control of the exposure of rural populations to parasites in the developing world. He has also served on a number of scientific advisory committees, including the Board of Scientific Councilors of the National Institute for Occupational Safety and Health. Dr. Spear received his B.S. and M.S. in mechanical engineering from the University of California at Berkeley, and his Ph.D. in control engineering from Cambridge University.

Appendix B

Participants at Public Sessions

March 14, 2001 — Washington, DC
Alan Hais, Office of Water, U.S. Environmental Protection Agency
Robert Bastian, Office of Wastewater Management, U.S. Environmental Protection Agency
Albert Page, University of California, Riverside
Nancy Burton, National Institute for Occupational Safety and Health
Frank Hearl, National Institute for Occupational Safety and Health
Bill Kelly, Center for Regulatory Effectiveness
Cecil Lue-Hing, representing Association of Metropolitan Sewerage Agencies
Sandy Smith, PEN Green Sludge Busters
Henry Staudinger, citizen
Rufus Chaney, U.S. Department of Agriculture
Rich Anderson, consultant
Albert Gray, Water Environment Federation
Susan Boutros, Environmental Associated Ltd.

June 3, 2001 — Irvine, CA
Richard Stehouwer, Pennsylvania State University
James Ryan, Office of Research and Development, U.S. Environmental Protection Agency
Robert Southworth, U.S. Environmental Protection Agency (retired)
Robert O'Dette, Synagro

June 4, 2001 — Irvine, CA
Mark Gray, Synagro
Lauren Fondahl, U.S. EPA
Gary Feldman, Riverside County Health Services Agency
Jane Williams, California Communities Against Toxics
Penny Newman, Center for Commuity Action and Environmental Justice
Larry Charpied, organic farmer
Donna Charpied, citizen
Lyle Talbot, Desert Citizens Against Pollution
Athena Geges, resident
Janine Matelke, resident
Marc Miller, resident
Margie Newman, citizen
Ms. Schembri, citizen
Jerry Cody, citizen
Steve Stockton, Responsible Biosolids Management, Inc.
Robert O'Dette, Synagro
Lorrie Loder, Synagro

Glossary

Aggregate exposure Exposure to a single chemical by multiple pathways and routes of exposure.

Benchmark dose An exposure level that corresponds to a statistical lower bound on a standard probability of an effect, such as 10% of people affected.

Bioaerosols Aerosolized biological particles that range is diameter from 0.02 to 100 micrometers.

Biomarker Changes in the characteristics of a biologic sample, such as changes in enzyme levels, that reflect a particular environmental exposure, a particular human or animal disease process, or evidence of increased or decreased susceptibility to adverse effects from such exposures.

Biosolids Defined by EPA as the primarily organic solid product yielded by municipal wastewater treatment processes that can be beneficially recycled (whether or not they are currently being recycled). *The term is defined in this report as sewage sludge that has been treated to meet the land-application standards in the Part 503 rule or any other equivalent land-application standards.*

Cumulative exposure Combined exposures to multiple pollutants by multiple pathways and routes of exposure.

Default assumption An assumption about a receptor population characteristic that is made when actual information about that characteristic is unavailable.

Domestic sewage Waste and wastewater from humans or household operations that is discharged to or otherwise enters a treatment works.

Endotoxin A complex bacterial toxin composed of protein, lipid, and polysaccharide, which is released upon lysis of the cell.

Exposure Contact of an individual with a chemical or physical agent. Exposure is quantified as the amount of the agent available at the exchange boundaries of the individual (e.g., skin, lungs, gut) and available for absorption.

Exposure assessment The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure pathway The course a chemical or physical agent takes from a source to an exposed individual. An exposure pathway describes a mechanism by which an individual or population is exposed to chemical or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the

exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermediate transfer) also is included.

Highly exposed individual (HEI) An individual who remains for an extended period at or adjacent to the site where maximum exposure occurs.

Indicator organism A microorganism that is used for monitoring whether a certain set of pathogens might be present.

Indirect exposure Exposure involving multimedia transport of chemicals from source to exposed individual. For example, consumption of produce grown on biosolids-amended soil.

Loading rate The maximum loading limit of a chemical per unit of time, permissible on a given site.

Margin of exposure A ratio defined by EPA as a dose derived from a tumor bioassay, epidemiological study, or biologic marker study, such as the dose associated with a 10% response rate, divided by an actual or projected human exposure.

Mutipathway exposure Exposure to an agent (chemical, physical, or biological) by various routes, such as inhalation, ingestion, and dermal absorption.

No-observed-adverse-effect level The highest dose of a chemical that was administered to animals in a toxicity study without producing an observed adverse effect.

Probabilistic approaches Evaluating a range of possible risk estimates and their likelihood, tied to various mathematical models of the likely distribution of potential values, instead of relying on single numbers or point estimates.

Reasonable Maximum Exposure (RME) A semiquantitative term referring to the lower portion of the high end of the exposure distribution. It typically determined using a combination of average and upper-bound values for various exposure parameters so that the final exposure estimate will be an upper-bound exposure with a reasonable expectation of occurrence, usually considered the 95^{th} percentile.

Receptor population The groups of people that may be exposed to the contaminated media.

Secondary transmission The spread of disease by indirect transmission of the infectious agent. Transmission can be from person-to-person contact, whereby an infected individual infects another, from exposure to contaminated objects, or via environmental pathways, such as contamination of soil or surface water.

Sewage sludge The solid, semi-solid, or liquid residue generated during the treatment of domestic sewage in a treatment works.

Stakeholders Stakeholders are groups who are potentially affected by the risk, risk managers, and groups that will be affected by efforts to manage the source of the risk. They could include federal regulators, state regulators, biosolids managers, local businesses, industries, public health officials, clinicians, and citizens.

Susceptible subpopulation Populations which may exhibit a greater effect in response to particular exposures.

Uncertainty analysis Analysis of information about risks that is only partly known or unknowable. Mathematical uncertainty analyses can be used to generate probabilistic distributions of risk estimates that reflect the extent to which the information used to assess risk is uncertain.

Variability A population's natural heterogeneity or diversity, particularly that which contributes to differences in exposure levels or in susceptibility to the effects of chemical exposures.

Vector An organism capable of transmitting an infectious agent to another organism.