

In Summary...

Biosolids Applied to Land: Advancing Standards and Practices Board on Environmental Studies and Toxicology

For several decades the wastewater treatment industry has recycled sewage sludge by applying a treated form of it (often referred to as biosolids) to agricultural or other lands in order to improve the properties of the soil. The practice offers an alternative to disposal options such as landfilling or incineration, and its use has increased since disposal of sewage sludge in oceans was prohibited in 1992. Today, roughly 60% of the 5.6 million dry tons of sewage sludge disposed of annually is used for land application in the United States.



Biosolids are complex mixtures that can contain pollutants from household, commercial and industrial wastewaters with organic contaminants (such as pharmaceuticals), inorganic contaminants (metals and trace elements) and pathogens (bacteria, viruses and parasites). Depending on the extent of treatment, biosolids may be applied on areas with limited public exposure such as farms, or with more treatment on public sites such as parks, golf courses, lawns and home gardens.

In 1993, EPA established a regulation governing land application of sewage sludge under the Clean Water Act with the intent to protect public health and the environment from reasonably anticipated adverse effects. The regulation (Code of Federal Regulations Title 40, Part 503, commonly referred to as the Part 503 rule) sets chemical pollutant limits, operational standards designed to reduce pathogens and the attraction of disease vectors (such as insects), and management practices.

Public health concerns regarding the use of biosolids are growing, especially from citizens living near application sites. The EPA asked the National Academies to convene a committee 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. The committee was not asked to determine whether EPA should continue to promote land application of biosolids or to judge the adequacy of the individual standards in protecting human health, but rather to reassess the scientific basis of the Part 503 rule.

Overarching Recommendations

There is uncertainty about the potential for adverse human health effects from exposure to biosolids. To assure the public and to protect public health, there is a need to update the scientific basis of the Part 503 rule. The committee identified several data gaps and issues

in management practices that should be addressed including:

- *A lack of exposure and health information on exposed populations.* The committee recommends implementing human health studies, 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.
- *Reliance on outdated risk-assessment methods.* Since 1993 when the rule was established, risk-assessment methods have advanced significantly. The committee recommends that new risk assessments be used to update the scientific basis of the chemical limits and the regulatory criteria for pathogens.
- *Reliance on outdated characterization of sewage sludges.* Changes in treatment processes and chemical uses over the last decade have changed the composition of sewage sludges. The committee recommends a new national survey of chemicals and pathogens in sewage sludges and a review of management practices to ensure that risk assessment principles are put into practice.
- *Inadequate programs to ensure compliance with biosolids regulation.* EPA should expand its oversight activities to include procedures to 1) assess the reliability of biosolids treatment processes and effectiveness of management practices, 2) monitor compliance with chemical and pathogen standards, 3) conduct environmental hazard surveillance, and 4) study human exposures and health.
- *Lack of resources devoted to EPA's biosolids program.* More funding and staff resources are needed to implement the recommendations in this report. The committee also recommends that EPA delegate authority to more states to administer the federal biosolids regulation.

Health Effects Recommendations

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. The Committee recommends that the EPA promote and support studies of exposed populations in order to document whether any health effects can be linked to biosolids exposure through the following types of studies:

- Studies in response to unusual exposures and unusual occurrences of disease.

- Preplanned assessment studies to characterize exposures of workers and the general public who come into contact with biosolids.
- Complete epidemiological studies, for example, evaluating health effects in a group of biosolids appliers.

Chemical Standards Recommendations

In developing the 1993 Part 503 rule, the EPA relied heavily on its 1988-1989 National Sewage Sludge Survey to identify chemicals to regulate, selecting 9 inorganic chemicals (arsenic, cadmium, copper, lead, mercury, molybdenum, nickel, selenium, and zinc). Risk assessments were conducted on each chemical to establish acceptable concentration limits.

Since 1993, new chemicals of concern have been identified, such as organic compounds used as flame retardants (i.e., brominated diphenyl ethers), pharmaceuticals and odorants. Chemicals eliminated in earlier selection processes because of data gaps might now be reevaluated in light of new data.

To set the 1993 limits for the regulated chemicals, the EPA considered 14 major exposure pathways, nine of which involve exposure to humans. EPA elected to estimate human exposure based on a theoretical, highly exposed individual (HEI), and gave no consideration to aggregate exposure, but rather evaluated each exposure pathway independently.

The Committee made the following recommendations regarding chemical standards:

- A new national survey of chemicals in sewage sludge should be conducted. Data from the survey should be used to determine whether additional chemicals should be considered for regulation.
- Using current risk-assessment practices, EPA should reassess standards for regulated chemicals. Because of the diversity of exposed populations and environmental conditions in the United States, it is important that nationwide chemical regulations be based on the full range of exposure conditions that might occur.
- Conceptual site models should be used to identify major and minor exposure pathways.

- A hypothetical individual with reasonable maximum exposure (RME, such as a farm family living adjacent to an application site), rather than an HEI, should be evaluated for each exposure pathway. If there is likely more than one pathway, exposures should be added across pathways.
- Representatives of stakeholders should be included in the risk-assessment process.

Pathogen Standards Recommendations

EPA considered a spectrum of bacteria, viruses, and parasites in setting its 1993 pathogen standards. No risk assessments were conducted to establish these standards. Instead, EPA established requirements to reduce pathogens by treatment or a combination of treatment and use restrictions. Given the variety of pathogens that have the potential to be present in biosolids, the committee supports this approach. However, the reliability of EPA's treatment techniques should be better documented using current pathogen detection technology, and more research is needed to verify that current management controls are adequate to maintain minimal exposure concentrations over an extended period of time.

The Committee recommends the following:

- EPA should conduct a national survey of pathogen occurrence in raw and treated sewage sludges.
- Quantitative microbial risk assessments (QMRA) should be developed and used to establish regulatory criteria for pathogens in biosolids. QMRA should include evaluation of all potential exposure pathways (e.g., transport of bioaerosols, runoff), and the possibility of secondary transmission of disease such as through person-to-person contact.
- 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.

Committee on Toxicants and Pathogens in Biosolids Applied to Land: **Thomas Burke** (*Chair*), Johns Hopkins University, **Lawrence R. Curtis**, Oregon State University, **Charles N. Haas**, Drexel University, **Ellen Z. Harrison**, Cornell University, **William E. Halperin**, New Jersey Medical School, **John B. Kaneene** Michigan State University, **Greg Kester**, Wisconsin Department of Natural Resources, **Stephen P. McGrath**, Institute for Arable Crops Research, **Thomas E. McKone**, University of California, **Ian L. Pepper** University of Arizona, **Suresh D. Pillai**, Texas A&M University, **Frederick G. Pohland**, University of Pittsburgh, **Robert S. Reimers**, Tulane University, **Rosalind A. Schoof**, Gradient Corporation, **Donald L. Sparks**, University of Delaware, **Robert C. Spear**, University of California at Berkeley, **Susan Martel** (Study Director), the National Academies' Board on Environmental Studies and Toxicology.

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