HEALTH EFFECTS OF BIOSOLIDS APPLIED TO LAND: AVAILABLE SCIENTIFIC EVIDENCE

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INTRODUCTION

Sewage sludge is the solid, semisolid or liquid residue generated during treatment of domestic sewage (1). The term "biosolids" was introduced by the wastewater treatment industry in the early 1990's and is now also used by the United States Environmental Protection Agency (EPA) (1,2,3,4), the agency responsible for federal regulations governing the application of sewage sludge to land. The term is meant to distinguish sludge that has been sufficiently processed to permit it to be land-applied from raw sewage or that containing large amounts of pollutants (1,2,3,4). Some organizations, however, prefer to continue to use the term sewage sludge, whether it is for land application or not. Throughout this paper both terms are used and reflect the usage in the reference document from which the related information was obtained. The term biosolids does not refer to ash remaining after incineration of sewage sludge, and it is distinct from industrial sewage sludge, although there may be industrial waste in some domestic sewage (2,6).

There are two classes of biosolids. Class A biosolids are sold directly to the public for lawn and garden use and are not intended to have any detectable concentrations of pathogens (5). Class B biosolids are utilized on agriculture and forest lands and usually applied by commercial applicators. Although Class B biosolids may have pathogens, a combination of treatment and restrictions at the application site are intended to remove detectable pathogens for public contact (5), but do not address risks to applicators (1).

Land application is defined by EPA as "the spreading, spraying, injection, or incorporation of sewage sludge, including a material derived from sewage sludge (e.g., compost and pelletized sewage sludge), onto or below the surface of the land to take advantage of the soil enhancing qualities of the sewage sludge (7)."

In the U.S. there are an estimated 16,583 wastewater treatment facilities (8). More than 92% of the total quantity of wastewater solids is generated by about a fifth of the facilities (8). Of the 7,189,000 dry U.S. tons of biosolids produced in 2004, an estimated 55% were applied to soils for agronomic, silvicultural (forests), and/or land restoration purposes, or were stored for such uses (8). The remaining 45% were disposed of in municipal solid waste landfills, surface disposal units, and/or incineration facilities (see Table 1 for percentages) (8). Of the total applied to soils, 74% was used on farmlands for agricultural purposes (Class B), 22% was treated and tested to meet the standards for public use (Class A), and small percentages were used for land restoration and in silviculture (8). In European countries an average of 37% of biosolids are land-applied on agriculture soils (9).

There is no easily accessible central database for obtaining complete data on the sources and distribution of biosolids in Virginia so the data from a national survey conducted in 2004 is incomplete (8). Approximately 160,000 dry metric tons of biosolids were produced in Virginia in 2004 (8). The estimate for land-applied biosolids in Virginia that year was 223,739 dry metric tons (8). The difference between the amount applied and the amount produced reflects the contributions from outside Virginia (8). The Washington, D.C. Water and Sewer Authority Blue Plains treatment facility contributes approximately 27% of the total amount of biosolids distributed in Virginia (10). Blue Plains receives sewage from Washington, D.C. (43%), Maryland (40%), and Virginia (17%) (10). Of the biosolids reported to originate from Virginia in 2004, 31% was land-applied, 40% was incinerated, 20% was landfilled, and 9% was in long term storage (8). There are multiple incinerators for biosolids in the Hampton Roads Sanitation District and one each in Blacksburg, Hopewell, and the counties of Fairfax and Prince William (CM Sawyer, pers.comm.).

The chemical and biological makeup of biosolids can vary greatly depending on the source of the sewage and the treatment processes it undergoes. Sources include wastewaters of households, commercial establishments, industries, medical facilities, and in some cases street run off. EPA has pre-treatment standards that set industry-specific effluent limits (11). Treatment plants must have approved ordinances that establish quality standards, and monitoring and enforcement penalties before they can accept industrial wastewater contributions (11).

Treatment processes include thickening (low force separation of water and solids by gravity, flotation, or centrifugation), digestion (anaerobic and aerobic, i.e. biologic stabilization through conversion of organic matter to carbon dioxide, water, and methane), alkaline stabilization (e.g., adding lime or kiln dust), conditioning (causes biosolids to coagulate to aid in separation of water), dewatering (high force separation of water and solids using vacuum filters, centrifuges, filter and belt presses, etc.), composting (aerobic, thermophilic, biological stabilization in a windrow, aerated static pile or vessel), and heat drying (to kill pathogens and eliminate most water content) (4). Each wastewater treatment facility makes its own decision on how its sewage sludge is treated (8).

Pollutants that are found in sewage sludge can generally be divided into the following categories: 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) (1). Although they are not presently regulated, radioactive contaminants may be present in biosolids. For that reason a section on radioactive contaminants is included in this paper.

To allow and regulate the land application of sewage sludge, EPA promulgated Standards for the Use or Disposal of Sewage Sludge in the Code of Federal Regulations, Title 40, Part 503 (commonly referred to as the 503 rule) of the Clean Water Act in 1993 (12). Prior to the release of the final regulations of the 503 rule, EPA completed a National Sewage Sludge Survey (NSSS) (13). EPA used the data collected on more than 400 pollutants from 180 sewage treatment plants throughout the country to produce national estimates of concentrations of pollutants in sewage sludge.

Most states, including Virginia, have additional regulatory programs (either pollutant limits or management practices for land application) that are more stringent than the 503 rule (4,8). Virginia regulations define biosolids as "a sewage sludge that has received an established treatment for a required level of pathogen control and has been treated or managed to reduce vector attraction to a specified level and contains acceptable levels of pollutants in accordance with an issued permit (14)." See Attachment 1 for an outline of the areas covered by the current Virginia regulations. These regulations incorporate the 503 rule into Virginia law and establish more restrictive conditions in terms of permitting, buffering, slope restriction, time of year for application, and nutrient management plans. There are also specific requirements for features unique to Virginia such as coastal plains (6).

The Clean Water Act requires EPA to periodically reassess the scientific basis of the 503 rule and to address public health concerns (1,15). EPA asked the National Research Council (NRC) of the National Academies to conduct an independent evaluation of the technical methods and approaches used to establish the standards for biosolids. The NRC convened the Committee on Toxicants and Pathogens in Biosolids Applied to Land (NRC Committee), which prepared the report, *Biosolids Applied to Land: Advancing Standards and Practices* that was published in 2002 (1). EPA published a final action plan to address the NRC Committee's recommendations in December 2003 (15). The plan included 14 projects, which have been distributed to numerous offices in EPA. Also in response to the NRC report, the Water Environment Research Foundation (WERF) organized the Biosolids Research Summit in July 2003 (16). WERF is a non-profit organization of state and regional water environment associations. It provides science and technology research to enhance management of water resources. Municipal agencies, academia, government laboratories, and industrial and consulting firms carry out the research. Thirty-one priority research project concepts were identified at the summit. Many have been or are being presently addressed.

Although research is ongoing to answer many of the questions and fill a number of data gaps regarding health effects from biosolids applied to land, the projects and results are not collected in one easily accessible central location. The list of references on sewage sludge and biosolids is daunting. As of October 2007, PubMed listed 19,100 references on sewage sludge and 428 on biosolids. On the EPA website there were 8,328 hits for sewage sludge and 3,025 for biosolids. New references appear with great regularity. Research on biosolids is being conducted by academic centers, the sewage treatment industry, and other organizations. For example, at a recent web seminar, Alan Hais of WERF reported that 40 projects had been completed, 20 were currently under study, and there were 2 new projects in 2007 (17). Study results are presented at meetings and, with some delay, in peer-reviewed journals. The rapid evolution of this research field is probably due to the need to respond to the NRC report and pressure on the sewage treatment industry to ensure that there are acceptable ways to dispose of the ever-increasing burden of sewage sludge.

This paper focuses on land application of Class A and Class B biosolids and does not consider risks from the sewage treatment processes (including composting), storage, transportation, disposal practices of landfilling, surface disposal or incineration, except where such information may shed light on human health risk. Because most of the information for this paper was drawn from the NRC publication, the reader should assume attribution to that document unless otherwise noted. Other references include EPA documents, some of the more recently published journal articles, and government and industry websites. For those who want a more detailed and comprehensive understanding, each of the references provided has many more supporting references.

MANAGEMENT OF LAND-APPLIED BIOSOLIDS

EPA and the wastewater treatment industry have been encouraging the recycling of sewage sludge since the early 1970s. After the United States Congress banned the dumping of municipal waste in the ocean in 1988, the need to recycle biosolids escalated. Biosolids are recognized as a useful soil amendment and source of nitrogen, phosphorus, organic matter, and other nutrients, which can enhance soil physical properties as well as plant yield (9). Because of these soil improvement qualities and the need to dispose of a continuous supply of biosolids, wastewater treatment plants produce different forms of biosolids products for agricultural, landscape, and home use (9). In addition to the use of biosolids on farm and forest soil, they are also used commonly in large-scale landscaping, home landscaping and gardens, remediation of abandoned mining sites, and soil-surface revegetation (9), and at least one Class A product has been touted as a deer repellant in the popular press.

The 503 rule is intended to protect public health and the environment, and contains: numerical limits for metals; pathogen reduction standards; site restrictions; crop harvesting restrictions and monitoring; and record keeping and reporting requirements for land-applied biosolids, as well as similar requirements for biosolids that are surface disposed or incinerated (1,5). EPA used risk-based standards to establish the chemical regulations, but for pathogens it used operational standards intended to reduce the presence of pathogens to concentrations that are not expected to cause adverse health effects.

There are two different classes of biosolids, each with its own application rules. Class A biosolids, which contain no detectible concentrations of pathogens can be sold directly to the public. Class B biosolids have detectable concentrations of pathogens, but a combination of treatment and site restrictions is intended to result in a reduction of pathogenic and indicator microorganisms to undetectable concentrations prior to public contact. For virtually all forms of Class B biosolids, there are buffer requirements, and public access and crop harvesting restrictions (1,5). In general, Class A biosolids (sometimes referred to as exceptional quality biosolids) used in small quantities by the general public have no buffer requirements or crop type, crop harvesting, or site access restrictions. When used in bulk, Class A biosolids are subject to buffer requirements, but not to crop harvesting restrictions.

Federal, state and local regulations, ordinances or guidelines place limits on land application of biosolids based on topography; soil permeability, infiltration and drainage patterns; depth to groundwater; and proximity to surface water (4). In addition to the state and local permit requirements, farmers have the right to negotiate with the biosolids applicator on how operations are to be conducted on the property (4). To determine whether biosolids can be applied to a particular farm site, the land applier generally performs an evaluation of the site's suitability (5). Nutrient management planning ensures that the appropriate quantity and quality of biosolids are land-applied to improve the farmland soils (5). The biosolids application is specifically calculated to match the nutrient uptake requirements of the particular crop (5).

RISK ASSESSMENT AND RISK MANAGEMENT

When considering human health effects from biosolids, risk assessment and risk management are key to providing appropriate protection to the public. The NRC Committee raised a number of concerns about the adequacy of the risk assessments used by EPA to support the 503 rule. Since the NRC Committee completed its review, further advances and changes have probably been made in this field, but this section outlines the findings of the NRC Committee.

Risk assessment is a process for identifying potential adverse consequences along with their severity and likelihood, whereas risk management is a decision-making process that accounts for political, social, economic, and engineering implications together with risk-related information in order to develop, analyze and compare management options and select the appropriate managerial response to a potential health hazard. The principal objective of the risk assessment and risk management approach is not to eliminate all risk, but quantify it and provide the risk manager with tools to balance the level of risk against the cost of risk reduction, against competing risks, or against risk generally accepted as trivial or acceptable. The end product of a risk-based approach either identifies an acceptable level of exposure or prescribes technical controls or political processes needed to attain acceptable risk.

A number of significant risk guidance documents that were issued after publication of the 503 rule are discussed in Chapter 4 of the NRC book. These include EPA and NRC documents as well as a report from the Presidential/Congressional Risk Commission (18).

New approaches and advances that were made in risk assessment since the establishment of the 503 rule include: hazard identification, dose-response, cancer risk assessment guidelines, time-to-tumor models, subjective statistics (Bayesian), meta-analysis in place of single-species data sets, assessment of mixtures, exposure characterization process, increased focus on indoor and residential environments, monitoring biological agents in exposure media, explicit treatment of uncertainty and variability, multimedia and multiple-pathway exposure assessments, and biological markers. In addition, some EPA offices have changed their risk assessment approaches making them different from those used for the 503 rule. Lastly, there was an absence of stakeholder participation, which is necessary to establish public confidence in the process.

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 the specified conditions of use. Because the risk assessments used for the 503 rule are now outdated and are inconsistent with policies of other EPA offices, they contribute to a lack of public confidence and may be either over or under protective of public health.

CHEMICALS

INTRODUCTION

The following inorganic chemicals are currently regulated under the 503 rule: arsenic, cadmium, copper, lead, mercury, molybdenum, nickel, selenium, and zinc (1,2). There are no organic chemicals regulated at this time. EPA calculated the concentration limits and loading rates for eight of the inorganic chemicals using risk assessment methods; the standard for molybdenum is a non-risk based ceiling limit. The EPA standards are termed “pollutant limits” in the 503 rule. Arsenic, cadmium, lead, mercury and selenium are regulated based on their risks to children from direct ingestion. EPA based the standards for copper, nickel and zinc on their effects on plants. A summary of the steps taken by EPA to arrive at this list of chemicals is in Attachment 2.

REGULATED CHEMICALS

Most information on human chemical toxicity comes from evaluations of occupationally or accidentally exposed individuals. Following are brief summaries of exposures, health effects and some issues for consideration in the regulation of biosolids related to the chemicals presently included in the 503 rule.

Arsenic is considered non-toxic in the organic form, but the inorganic form is highly toxic. Ingestion of inorganic arsenic in drinking water is an established cause of skin cancer. Epidemiologic studies on populations with occupational exposure show an increase in the incidence of squamous cell carcinoma of the lung (19) and some other studies give evidence of arsenic causing cancers of the urinary bladder (1). Unfortunately, the speciation of arsenic in soils is not well characterized. Most arsenic from domestic sources is probably organic, but there is a possibility that it can be transformed to the inorganic form in biosolids. The bioavailability of soil arsenic has only been studied in mining and smelting operations, and pesticide manufacturing or application.

Cadmium: The most frequent long-term effect of chronic exposure from either ingestion or aerosols of cadmium is proteinuria associated with damage to the proximal tubule of the kidney; renal failure is an infrequent consequence (19). EPA based the 503 rule standards on children ingesting biolsolids, but because plants take up cadmium more efficiently than most other metals, dietary cadmium is likely to be an important exposure pathway from biosolids. Dietary factors such as iron, calcium and zinc deficiencies affect cadmium toxicity; zinc may have a protective effect.

Copper was included by EPA due to its affect on plants, a decision with which the NRC Committee agreed. Copper toxicity is usually reported in conjunction with dialysis (19) and should not represent a risk to humans from biosolids.

Lead absorption by the gastrointestinal tract varies with age, diet, nutritional status, and the chemical species and particle size. The major toxic affects are on the blood, gastrointestinal, and nervous systems (19). Lead interferes with red blood cell enzyme systems and in severe acute poisoning causes anemia (19). CNS symptoms begin as vague and are not usually considered serious, but as damage progresses the symptoms become more severe and can lead to encephalopathy (19). Peripheral nerve involvement is seen more commonly in adults than children (19). Since the 1980s there has been increasing evidence of subtler brain damage without encephalopathy (19). The information on the bioavailability of lead in soils to which biosolids have been applied is not sufficient to adequately assess risk.

Mercury can be found in several different forms and the form can dictate the exposure route, as well as the biologic effects, tissue distribution, and toxicity (19). The greatest exposure to metallic (elemental) mercury is in industry where chronic aerosol exposures can result in a wide range of symptoms, including respiratory, gastrointestinal, skin, CNS, and renal (19). Ingestion of large amounts of metallic mercury usually produces no clinical disturbance (19). **Inorganic mercury** exposure is most often the result of ingestion in industrial settings. The major manifestations are gastrointestinal and renal, but hepatic dysfunction, CNS disease, and rhabdomyolysis may also occur. **Methyl mercury** is a serious teratogen found in fungicides and is readily absorbed from the intestinal tract and widely distributed throughout the body (19). Major epidemics have occurred as a result of industrial contamination of water with elemental and inorganic mercury, which then was biotransformed into methyl mercury (19). Humans were affected by eating fish from such waters (19). Other epidemics have occurred as a result of eating grains contaminated with pesticides (19). Methyl mercury has been shown to be present in biosolids and several studies have reported emission of elemental and methyl mercury vapors from biosolids. In order to adequately evaluate the risk to humans from mercury in biosolids that are applied to land, the forms of mercury that are present in biosolids will first have to be identified and then their fate and transport will need to be studied.

Molybdenum causes diarrhea, anemia, alopecia, diminished growth, and bone and joint abnormalities in animals (19). No clearly defined human toxicity has been reported (19). Molybdenum is less toxic than arsenic, cadmium, lead or mercury when ingested and it is probably appropriate to regulate it based on plant and ecological effects.

Nickel is also less toxic when ingested (1), but industrial aerosol exposure to nickel carbonyl can cause serious illness leading to death (19). Nickel is also a potent contact allergen (19). Although the dermatitis may be persistent and severe, systemic reactions among allergic persons have only been reported from such things as nickel containing dental prostheses, jewelry, or intravenous needles (19). The inhalation of resuspended particles should be considered in any risk assessment of this metal due to its toxicity when inhaled. There is no mention of concern about allergic dermatitis from suspended particles and the NRC Committee listed it as appropriate to regulate it based on its plant and ecological effects.

Selenium is well absorbed from the gastrointestinal tract and lungs (19), but is much less toxic when ingested than arsenic, cadmium, lead or mercury (1). Acute selenium toxicity has been reported with inordinate exposure to fumes in occupational settings and symptoms usually disappear when the source is removed (19). Chronic poisoning is related to ingestion (19). Although EPA based the standard for this chemical on human health, the NRC Committee thought it appropriate to regulate it on the basis of plant or ecological effects.

Zinc is also one of the less toxic chemicals when ingested (1) and is not considered a reproductive risk or a carcinogen (19). The most common toxic effect is to welders, smelter workers and solderers who are exposed to aerosolized zinc and may experience “fume fever” (19). Usually all manifestations disappear when the exposure is eliminated (19). The NRC Committee supported EPA’s decision to regulate this chemical based on plant or ecological effects.

ORGANIC CHEMICALS

EPA chose not to regulate organic pollutants because all the priority organic chemicals that were considered fell into at least one of the three exemption categories: 1) the pollutant was banned in the US and was no longer manufactured, 2) the pollutant was detected by EPA in less than 5 percent of the sludge from wastewater treatment plants sampled in the NSSS, or 3) the concentration of the pollutant was low enough that it would not exceed the risk-based loading rates. This justification does not, however, adequately address the potential for adverse health effects from organic chemicals.

Biosolids present a difficult matrix from which to separate individual chemicals for analysis. For that reason research on the presence and fate of organic chemicals in biosolids is somewhat behind that of research regarding their presence and fate in receiving waters (9, 20, 21). In addition, aquatic systems are monitored more frequently because of their potential use as drinking water sources (21). When biosolids are applied to land, the duration of time for decomposition and assimilation is much longer than in aquatic systems (21). Because land-based systems have a greater capacity to buffer the potential toxic effects of waste-associated organic contaminants and to contribute to their assimilation into the soil system, the majority of studies conclude that they pose little or no risk to the environment when applied appropriately (21).

A paper published in 2006 reported on the examination of peer-reviewed literature and government documents for information on sludge concentrations of organic chemicals (22). Of the tens of thousands of organic chemicals currently in use, sludge concentration data were only found for 516. There were groups of chemicals for which the sludge concentration data were relatively abundant (such as PCBs, pesticides and polycyclic aromatic hydrocarbons), and there are others for which few data had been collected (such as nitrosamines). Certain classes of chemicals in sludge were shown to have a high percentage of concentrations that exceeded the guideline levels for determining whether industrially contaminated sites needed remediation (22).

A study published in 2006 reported on the testing of 9 different kinds of biosolid products from 7 states for 87 different organic wastewater chemicals to determine the range of compositions and concentrations of organic wastewater chemicals in biosolids (9). Fifty-five of the 87 chemicals were detected with a range of 30 to 45 chemicals in any one biosolids product. The chemicals represented a diverse cross section of emerging organic contaminants from medicinal, industrial and household sources. The results suggested that organic wastewater chemicals are present in substantial concentrations in biosolids and can constitute a ubiquitous nonpoint source of such chemicals to the environment when land-applied. The fate of some of these chemicals depends on their susceptibility to biodegradation or absorption to solids. Previous studies suggest that the brominated flame retardants, some synthetic fragrances, and pharmaceuticals can be persistent once introduced into the soil. Additional research is needed to see if the results reported from the 2006 paper are representative of most biolsolids and to determine the transport and behavior of these chemicals. Although it is not clear what kind of human risk these results represent, concern has been expressed that exposure could result in adverse physiological effects, increased rates of cancer, and reproductive impairment in humans and other animals, as well as antibiotic resistance among pathogenic bacteria (9).

More specific information on some of the organic chemical contaminants of concern follows.

Polybrominated Diphenyl Ethers (PBDEs) are flame retardants that have been detected in a variety of environmental sources, are highly persistent in the environment and bioaccumulate in aquatic food webs. Concentrations of PBDEs in humans have increased over time. Different formulations have different toxicological properties. Few data are available on the concentrations of PBDEs in biosolids and it is unclear if human body burdens are related to biosolid concentrations or other sources.

Surfactants used in laundry detergent and other cleaning products enter wastewater in large quantities from domestic and commercial wastewater. Some of these compounds are persistent in soil and may be transported into groundwater by sorption onto organic matter. There is concern about the ability of some of these compounds to act as endocrine disruptors. The clearest risk is to fish in surface waters receiving wastewater treatment plant effluents.

Chlorinated Paraffins or polychlorinated *n*-alkanes have numerous uses such as additives to lubricants, plastics, flame retardants, paints and sealants. Industrial effluents are much more likely sources than domestic wastewater. Rat studies indicate they are probably human carcinogens.

Nitro and Polycyclic Musks are fragrances found in a variety of personal care products. Sewage treatment reduces concentrations in wastewater, but amino metabolites that are more toxic than the parent compounds are occurring in increasing concentrations in sewage sludge. One study that fed musk xylol to mice showed an increase in liver tumors.

Pharmaceuticals are produced in high volumes and they and their metabolites are excreted directly to wastewater where they have been detected in very low concentrations. Because they are highly water soluble, most are unlikely to occur in biosolids, however drugs that are sufficiently lipophilic will partition preferentially to biosolids. The NRC Committee did not believe that there was adequate evidence that pharmaceuticals were likely to occur in biosolids at concentrations sufficient to warrant their inclusion in a biosolids risk assessment, however they urged continued monitoring of research in that area. Pharmaceuticals and personal care products (PPCPs) are often grouped under one heading. In the 2006 paper discussed above, 19 different pharmaceuticals were detected (9). The portion of PPCPs in the environment originating from disposal versus excretion is not known (23). In addition, there is little information available on the health impacts of chronic exposure to subtherapeutic concentrations of pharmaceuticals (9). A North East Biosolids and Residuals Association (NEBRA) news article asserts that biosolids seem to be a relatively minor source of PPCPs in the environment when compared to animal manure management activities, individual septic systems, and wastewater treatment facility discharges of treated effluent (24). NEBRA is a non-profit organization in the Northeastern U.S. and eastern Canada dedicated to understanding and facilitating the recycling of biosolids and other residuals. Its membership includes wastewater treatment facility staff, farmers, environmentalists, compost operators, and biosolids recyclers.

Volatile Emissions and Odorants. Concern about odors is one of the primary public complaints associated with the land application of biosolids. The chemical compositions and concentration of odorants in biosolids vary with the treatment processes as well as the origin of the effluents. Toxicity and odor thresholds also have great variability. The mixture of odorants in biosolids is different from that found in sewage sludge, e.g., hydrogen disulfide (this was probably a misprint in the NRC book and should be carbon disulfide or hydrogen sulfide [K. Wasti, pers. comm.]) is less of a factor in biosolids. Inhalation is the only exposure pathway of concern. Odor perception includes both physiologic reception and psychological interpretation. Odorants may cause toxic effects, but there is no link between these effects and perception. Odors have been shown to affect mood, which can lead to physiologic and biochemical changes and subsequent health effects, as well as to conditional responses. Health complaints from odors must be assessed separately from irritants and other forms of toxicity. Non-toxicological explanations for odor-related symptoms should be considered when potent odorants alone are involved in the exposure or when the toxicology of co-pollutants is insufficient to explain observed symptoms (25). Toxicity values are only available for a small number of odorants found in the US. Without data on the common odorants released from biosolids, including concentrations near application sites, and acute and chronic toxicity values, it is difficult to assess human health risk.

A new National Sewage Sludge Survey is being conducted by EPA and should help fill some of the data gaps. At least 75 randomly selected publicly owned treatment works have been visited and 83 samples have been collected (26). The samples are being tested for metals, polycyclic aromatic hydrocarbons, polybrominated diphenyl ethers, semivolatiles, and inorganic ions (26). Recently PPCPs were added to the list of contaminants being studied (26). In addition, EPA is developing improved methods for measuring the toxicity of PPCPs (26).

SUMMARY

Biosolids can contain a wide array of both organic and inorganic chemicals depending on the source of sewage and the treatment processes. Once applied to land more chemical changes can occur resulting in a different chemical profile than found in the original product. In order to be able to state with confidence that there is adequate protection of the public from chemicals in land-applied biosolids, the current regulations need to be updated. At issue are the: outdated risk assessment methods used; questions about the adequacy of analytical methods and detection limits; exclusion of highly toxic chemicals because of infrequent detection or missing fate and transport information; and new information on chemicals and new chemicals that need to be considered. It is possible that some limits on chemicals could be lowered if analyses were done using more current data.

The 503 rule addresses only inorganic chemicals. The basis for calculating the risk to humans from these chemicals needs to be revisited. For example, the standards for arsenic, cadmium, lead, mercury and selenium were based on direct ingestion by children, but plants take up cadmium so dietary uptake should be considered. Selenium does not appear to be a human toxin so the standards should probably be based on plant and ecological effects. Most human health effect data on metals is from occupational exposures, which may over or under estimate the exposure from biosolids. To appropriately assess human risk from inorganic chemicals found in biosolids, the form of the chemicals, and their fate, transport and bioavailability needs to be known, e.g., arsenic, lead, mercury.

Organic chemicals should be considered for regulation. They are found in biosolids and are the chemicals of emerging environmental concern. Organic chemicals in aquatic systems have been studied more than in biosolids and soil. Land application may provide more capacity to buffer the toxic effects of some inorganic chemicals, but some chemicals may be persistent in soil. Although some of the emerging inorganic chemicals can be found in humans, the relative contribution of biosolids versus wastewater effluent, individual septic systems and animal manure has not been determined. The effect of chronic, low level exposure to these chemicals has not been studied.

As the primary cause of public complaints, odors from biosolids need further study to determine the contents that cause odors and the best way to reduce or eliminate them. Because odors can be associated with real and perceived health effects, complaints about them must take into consideration the potential for physical irritation, true toxicity, and psychological interpretation. Without data on the type and concentrations of odorants released from biosolids and the acute and chronic toxicity values, it is difficult to assess the human health risk.

PATHOGENS

INTRODUCTION

Unlike the risk-based chemical standards, EPA's pathogen regulations are operational standards intended to reduce the presence of pathogens to concentrations that are not expected to lead to adverse health effects. These standards include requirements for treatment and monitoring, and application site restrictions. The fundamental basis of the regulations 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.

Although pathogens can be isolated from raw sewage sludge, as well as partially and fully treated biosolids, this does not necessarily indicate that a risk exists. Risk is a function of the level of exposure and susceptibility of the exposed person. The infectious dose that is necessary to cause disease varies with the pathogen. For example the infectious dose for *Cryptosporidium parvum* is 1 to 10^3 oocysts, but for *Vibrio cholerae or Escherichia coli,* 10^8 organisms are needed to cause infection (27). There are no scientifically documented outbreaks or excess illnesses that have occurred from microorganisms in treated biosolids.

Class A biosolids are not intended to have detectable concentrations of pathogens. This is determined by using fecal coliforms as indicator organisms. Fecal coliform density is also used as an indicator of wastewater treatment efficiency to evaluate whether *Salmonella* sp. has repopulated when Class A biosolids are stored before land application. Details of treatment goals and acceptable processes for Class A biosolids can be found in Attachment 3. Pathogens are normally present in Class B biosolids, but a combination of treatment and site restrictions is intended to result in a reduction of pathogenic and indicator microorganisms to undetectable concentrations prior to public contact. See Attachment 4 for details of criteria and processes for Class B biosolids.

PATHOGENS OF CONCERN

Four major types of human pathogens can be found in biosolids: bacteria, viruses, protozoa, and helminths. Some references also include fungi (28,29). Potential transmission pathways of human pathogens from biosolids include air, soil, and water. In addition, it is possible that vectors, such as flies, could transmit pathogens from biosolids. The principal pathogens considered by EPA in establishing the Part 503 rule are listed in Table 5. Brief explanations about pathogens considered by EPA and new or newly important ones identified by the NRC committee follow.

Bacteria

Several types of ***Escherichia coli*** are pathogenic to humans. Enterohaemorrhagic *E. coli* of the serotype O157:H7 has been of the greatest concern in the US. Numerous outbreaks of diarrhea and, in some cases, mortality in young children from hemolytic uremic syndrome, have resulted from contaminated drinking water, recreational water, food and exposure to human and animal wastes. *E. coli* O157:H7 occurs in domestic wastewater and is common in biosolids. Its survival in biosolids has not been assessed.

Listeria monocytogenes is primarily a foodborne pathogen that causes invasive disease in immunocompromised persons and has potentially lethal consequences for the fetus and newborn if the mother is infected during pregnancy. Animals can become infected. Transmission has been linked to the use of biosolids on agricultural land, possibly via contaminated crops and domestic animals. *L. monocytogenes* has been detected frequently in sewage sludge and in inactivated and anaerobically digested biosolids. Crop contamination was observed in Iraq where sewage-sludge cake was applied.

Some publications have implicated ***Staphylococcus aureus*** from land-applied biosolids as the cause of skin infections (1,30). It is possible that *S. aureus* is present in raw wastewater as a result of washing and personal hygiene. It has been found in gray waters from households and isolated from primary wastewater, however chlorinated tertiary wastewater had only sporadic occurrences of these organisms. There are no publications documenting *S. aureus* in biosolids, including work done by the University of Arizona using optimized culture media for *S. aureus*. With estimates of 20-30 percent of the general population colonized by these organisms, one third of cases due to autoinfection, and airborne transmission considered rare (31), it does not look likely that *S.* aureus represents a serious health threat from biosolids.

Helicobacter pylori is a major cause of stomach ulcers in humans and is associated with an increased risk of stomach cancer. Epidemiologic evidence has incriminated contaminated water and uncooked foods, particularly vegetables irrigated with untreated wastewater, with an increased risk of infection. No culture methods are available for environmental detection; molecular methods can be used to determine presence, but not viability.

***Legionella* spp**. are associated with potentially life-threatening respiratory illness in older persons and with a milder fever and flu-like illness called Pontiac fever. Outbreaks usually occur following the growth of the organism in cooling towers of buildings or thermally heated water, but have also been associated with composted potting mixes and been reported among sewage treatment plant workers. Legionella has been detected in aerosols at sewage treatment plants. The organism will grow at temperatures of 40^0 C and survive at higher temperatures. Although methods are available for its detection in environmental samples, they have low efficiency, are difficult to use, and are costly.

Protozoa

Cryptosporidium* and *Giardia are the protozoan parasites most often associated with biosolids. As parasites of the small intestine they cause diarrhea. Cysts of the organisms have been detected in products of wastewater treatment and anaerobic sewage sludge digestion and in biosolids. They have been observed to die within days of Class B biosolids treatment, but there is little research on survival 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. There are over 1200 species, but only 14 have been associated with human infections. At least three of the species that infect humans will grow in animal cell culture. No method is available to assess infectivity in environmental samples. Spores are unlikely to survive heat treatments.

Viruses

Little is known about the occurrence and environmental fate of human **caliciviruses** (Noroviruses and Sapporo viruses) because they cannot be grown in cell culture. Although they can be detected by polymerase chain reaction (PCR), a viability assay is not available. Feline and non-human primate caliciviruses that can be grown in cell culture are used as models for human calicivirus survival and removal by water-treatment processes.

Adenoviruses are one of the most common and persistent viruses detected in wastewater and have been detected in Class B biosolids. They are heat resistant. In addition to causing enteric disease, some adenoviruses primarily cause respiratory diseases. They are a common cause of diarrhea and respiratory disease in children and cause serious infections in immunosuppressed cancer patients with case fatality rates of up to 50%. They have been transmitted by recreational and drinking waters.

Although **Hepatitis E virus** has caused major waterborne-disease outbreaks in developing countries, it is not believed to be a serious problem in the US. **Hepatitis A virus** 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 detection in the environment. It is very stable at high temperatures and has prolonged survival in the environment.

Astroviruses and rotaviruses cause gastroenteritis primarily in children with the latter being a major cause of hospitalization of children in the US. Rotaviruses have caused waterborne and foodborne outbreaks in the US and have been detected in wastewater, but few data are available on their occurrence in biosolids. Both can be grown in cell culture.

Helminth Worms (round, tape, hook and whip worms)

Human infections from ***Ascaris lumbricoides, Trichuris trichiura*** **and** ***Hymenolepsis nana*** are acquired by direct consumption of the embryonated eggs in the soil or on contaminated vegetables (31). ***Taenia saginata*** infections come from the ingestion of raw or undercooked beef containing the larval form. The eggs of this organism have been detected in some biosolids. ***Taenia solium*** eggs cause intestinal infections in humans who ingest them in contaminated food or water. The ingestion of raw or undercooked pork containing larvae can result in tissue infections with the larvae and can lead to death (31). ***Necator americanus*** larvae penetrate the skin and eventually mature in the intestinal tract (31). If humans ingest the eggs of ***Ascaris suum***, they can develop pulmonary symptoms due to larval migration, but worms rarely mature in humans (31). Humans who ingest the eggs of ***Toxocara canis*** can develop visceral or ocular larva migrans, syndromes that occur mainly in children who eat dog feces-contaminated dirt. A timely method to monitor indirectly for the inactivation of *Ascaris* eggs does not exist; the system takes 3-4 weeks and is costly.

Although there are concerns about the raccoon roundworm ***Baylisascaris procyonis***, especially because of the severe neurologic and ocular disease it can cause, including fatalities, its eggs have not been identified in biosolids samples.

OTHER INFECTIOUS DISEASE CONCERNS

The authors of an article published in 2004 raised concerns about the transmission of **Hepatitis B virus, Human immunodeficiency virus, and** ***Mycobacterium tuberculosis*** from biosolids (29), however they did not offer evidence of the presence of these pathogens in biosolids or the biological plausibility for transmission.

Prions are very difficult to inactivate and require rigorous treatment, however the risk of prion transmission from animals to biosolids is low. Prions are generally transmitted from animal to animal. Waste from slaughterhouses would have the highest likelihood of containing prions, especially if placenta or neural tissues were present. There has been little evidence of prion-contaminated manures in the US.

Bioaerosols (aerosolized biological particles ranging from 0.02 to 100 micrometers) can result from the land application of biosolids (1). The 503 rule has site restrictions for on-site dust exposure during and after the land application of biosolids, but does not include any guidelines regarding offsite exposure (32). There is little information on airborne pathogens, but high concentrations of noninfectious microorganisms such as non-viable agents, fungal spores, bacteria, endotoxins, and mites may cause allergic and toxic reactions. Such health effects have been well documented in sewage treatment plants, animal housing facilities, and biowaste collection sites. Concentration varies with the source, distance from source, dispersal mechanisms and, most importantly, environmental conditions at a particular site. Most aerosol studies have been conducted near water treatment plants, at effluent spray irrigation sites, within waste-handling facilities, and at composting facilities. These studies show that different sampling methods can lead to recoveries of different organisms. A recent study used DNA microbial source tracking methods to show a correlation between wind speed and direction with downwind biosolid concentrations (33). A study that evaluated the risk of infection from bioaerosols to residents living near biosolids land application sites sampled air from downwind sites for numerous bacteria and viruses. The authors concluded that the greatest annual risks of infection occurred among the workers during loading operations from inhalation of coxsackievirus A21, and that little community risk existed (34).

Vectors are not specifically implicated in the transmission of infectious organisms from land-applied biosolids to humans in any published reports. Although a number of reports implicate sewage effluent and animal and poultry waste with increases in flies, rodents and birds, there are no published data on whether land application of biosolids results in an increase in such vectors. The 503 rule designates land application practices to reduce vector attraction, however it is unclear whether these practices are really effective. Flies and other vectors have been detected on lands where biosolids were applied, but the extent to which these vectors are involved in the transmission of infectious organisms to humans or the food chain is unknown.

New and emerging pathogens need to be included in assessing health risks from biosolids. Since EPA's review of pathogenic agents that led to the current regulation of enteric viruses, helminths, and *Salmonella* (or coliforms), many new pathogens have been recognized and the importance of others has increased. Because of the variety of pathogens that have the potential to be in biosolids, pathogen-specific concentration limits are probably not suitable; instead, the present use of pathogen reduction requirements, use restrictions, and monitoring of indicator organisms makes more sense. However, biosolids regulations may need to be modified if information on occurrence, persistence, and risk of other pathogens show an increased risk to human health. The criteria for identifying microorganisms that need further study are: the availability of a reliable, viable assay; the agent is found in wastewater and is capable of transmission via airborne, waterborne or direct contact routes; adequate data on the probability of agents surviving biosolids treatments, especially high pH and heat resistance; and sufficient knowledge on the extent of survival in the environment. Based on these criteria, the NRC Committee recommended that EPA obtain information on the occurrence, persistence, and risk of to human health for the following pathogens: adenovirus 40, astrovirus, hepatitis A virus, rotavirus and *E. coli* O157:H7.

Pathogen survival and transport through soil must be factored into any risk assessment for pathogens in biosolids. Environmental factors that affect virus survival in soil include temperature, pH, moisture, and soil type. Of the human pathogens routinely found in domestic sewage sludge (viruses, bacteria, protozoan parasites, and helminths), viruses are the smallest and least complex, generally have the shortest survival time in soil, and the greatest potential for transport through soil. The survival of bacteria is also affected by temperature, pH and moisture. In addition, soil nutrient availability plays a role. Depending on the environmental factors and the species of bacteria, survival times can range from weeks to months. Although some bacteria can regrow under certain circumstances such as rainfall, very few species of human pathogenic bacteria can do so. Helminths are the most persistent pathogens with Ascaris eggs surviving for years in soil. Indicator bacteria may be at such a low level that they cannot be detected or may enter into a viable, but non-culturable state (35,36) and then under appropriate conditions can reactivate or increase to a culturable level (35, 37). In principle, pathogens present in biosolids can contaminate surface or groundwaters if runoff and leachate are not controlled. The NRC 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.

Host factors are important to consider in assessing potential risks from exposure to pathogens. The factors that affect an individual's susceptibility to pathogens, such as concomitant exposures, genetic factors, and acquired immunity can complicate any risk assessment. Synergistic effects may occur when concomitant exposures to noninfectious organisms, cellular components, irritants and odors occur. Data suggest that host genetic factors have a key role in the manifestation of a health effect from infectious organisms, particles, odors, endotoxins or allergens. 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 on health effects due to bioaerosols from land-applied biosolids. 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. A potential factor modulating the risk from exposure to infectious agents is acquired immunity. For most agents of concern, the existence, extent, and duration of any acquired immunity is not well understood. If such information is found, it can be incorporated into population models of infectious disease.

Exposure to workers was not considered in setting EPA's standards for pathogens in biosolids. 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. Although there are not many studies of worker exposure to biosolids, there are a few studies of exposure and effects observed in workers at wastewater and sewage treatment plants. These studies are not substitutes for studies of biosolids exposure, but they are useful for identifying potential health concerns and pathogens that might be relevant to biosolids. See the Epidemiology Section below for more detail on occupational exposure studies.

Antibiotic resistant organisms are seen as emerging contaminants by some (9, 38). Although antibiotic resistance is generally on the rise and antibiotic resistant organisms can be isolated from biosolids, the NRC Committee did not see that a selective advantage or specific gene transfer occurred in biosolids and stated that land-applied biosolids probably did not have any substantial potential to alter the prevalence of antibiotic resistance among pathogenic microorganisms. Others think that once established, resistance to a given antibiotic can be maintained, even in the absence of continued exposure to low concentrations of the antibiotic in the environment (9). In aquatic environments, low levels of antibiotics originating from wastewater treatment plants have been directly linked to an increased presence of antibiotic resistance among bacteria.

SUMMARY

Although there is no scientifically documented evidence of the public having health problems from pathogens in biosolids, knowledge gaps and outdated operational criteria allow for doubts and concerns about the risk to the public from such organisms. To increase public and scientific confidence in the ability of the pathogen standards to protect public health it will be necessary to use a risk-based approach that incorporates knowledge about new and emerging organisms, exposure routes other than ingestion, and data on the fate and transport of pathogens. In addition, the reliability of operational controls should be systematically studied (e.g., use standards similar to those for the water quality of recreational waters by considering both geometric mean levels and not-to-exceed limits) and the suitability of fecal coliforms as good indicators for public-health hazards should be evaluated because some pathogens may be more hardy than fecal coliforms or they may regrow later under different environmental conditions. Finally, well-documented epidemiologic studies of health complaints should be undertaken.

RADIOACTIVE CONTAMINANTS

INTRODUCTION

There have been no identified situations in the U.S. where radioactive materials in sewage sludge have posed a significant threat to the health and safety of workers in publicly owned treatment works (POTW) or to the general public. However, elevated levels of radioactive materials have been detected at a small number of treatment works (39,40). Three references were used for this section: two federal documents (39, 41) and one journal article (40).

Radionuclides are found naturally throughout the U.S. in soil and water in varying concentrations. Naturally occurring radioactive materials (NORM) can enter sewage treatment facilities from industrial process and drinking water treatment residuals (e.g., filter backwash, ion exchange fluids). Other sources of radioactivity include the authorized release of man-made radioactive materials into the sewer system by the US National Regulatory Commission and Agreement State licensees. A major source is radioactive materials used for medical diagnosis and treatment. Patient excreta containing medical isotopes may contribute a significant fraction of the radioactive materials releases to certain sewer systems, depending on the location of the medical facilities and the population served by the collection system. Reconcentration of radioactive materials can occur due to the concentration of contaminants into residual solids and the reduction of organic solids volume.

SURVEY

In order to collect information on radioactivity in sewage sludge and ash (from the incineration of sludge), the Interagency Steering Committee on Radiation Standards (ISCORS), the National Regulatory Commission and EPA conducted a joint survey of publicly owned sewage treatment plants from 1998 to 2000 (39,40). There were two parts to the voluntary survey: a questionnaire that asked about wastewater sources, wastewater and sludge treatment processes, and sewage sludge disposal practices. The second part was a sampling/analyzing program. Of the 631 surveys distributed, 420 were returned; 313 plants were sampled. Sampling focused on plants most likely to have higher levels of radioactive materials. Approximately half the samples were analyzed by the US Department of Energy's Oak Ridge Institute for Science and Education and the remainder by the EPA's National Air and Radiation Environmental Laboratory.

Samples primarily contained NORM, such as radium. Most other materials were at or near the limit of detection. Based on these results, ISCORS reported that the levels are generally comparable to what is found in other media such as soil and fertilizer.

DOSE MODELING

ISCORS undertook a dose modeling exercise that took into account typical sludge management practices in order to provide a perspective on the levels of radionuclides detected in the survey (41). They used seven generic scenarios that encompassed multiple environmental transport and exposure pathways that were designed to represent situations in which POTW workers or members of the public are most likely to be exposed, but were not intended to represent 'worst case' scenarios.

The basic conclusions from this study were:

1. None of the non-POTW scenarios showed a significant current widespread threat to public health.
2. If agricultural land application is carried out for a long time (50-100 years), the potential exists for future radiation exposure primarily due to Radon.
3. In specific case of very high levels of radioactive materials (e.g., above 95%), there is the potential for localized radiation exposure.
4. Within the POTW, the only potential for significant exposure (primarily to Radon) could occur when workers are in the same room with large quantities of sludge. The degree of exposure is dependent on room size, ventilation, and other plant physical factors.

The authors sited several factors that might account for higher doses in their computations that might not reflect typical exposures:

1. Exposure scenarios were somewhat conservative and doses were upper end percentiles.
2. Few farms have so far used sludge for even 20 years.
3. High doses are generally attributable to the indoor radon pathway. Radon exposures can be decreased radically through the use of readily available radon testing and mitigation technologies.

SUMMARY

The overall conclusions of the nearly ten-year ISCORS effort to address the management of radioactive materials in sewage sludge and ash are:

1. The levels of radioactive materials found in sewage sludge and ash samples from most POTWs are generally low and the associated radiation exposure to workers and the general public is very low, and not likely to be of concern.
2. The estimated radiation doses to potentially exposed individuals are generally well below levels requiring radiation protection actions. For unique POTW worker and on-site resident scenarios, doses exceeding protective standards could occur, primarily due to indoor radon generated as a decay product of NORM. Such exposures can be significantly reduced through use of readily available radon testing and mitigation technologies.

EPIDEMIOLOGY OF HUMAN HEALTH RISK

INTRODUCTION

The most recent authoritative publication on health effects associated with biosolids production and application appears in Chapter 3 of the NRC book (1). Although the NRC committee was aware of various human health allegations associated with biosolids exposure from news articles, written submission from the public, and citizens who attended its public meetings, the committee limited its review to studies published in the peer-reviewed literature and reports from government agencies. This included studies that investigated health effects or provided biomonitoring data and excluded studies limited to human exposure without evidence of biological absorption or human health effects. Information on worker exposures was included because occupational exposure is often higher than that of residents exposed to the general environment and such data can be used as a basis for extrapolating risk assessment. There were no epidemiological studies available on risks from odors and disease vectors.

STUDIES

The Committee evaluated the 23 studies described below:

1. Biosolids users (farmers and gardeners)

   This cross sectional study was conducted prior to the current regulatory requirements and evaluated PCB exposure. For biosolids users, PCB serum concentrations were associated positively with the percentage of garden care and negatively with wearing gloves while gardening. No overt symptoms of PCB toxicity were observed, and there were no correlations with hematological, hepatic or renal function tests. However, plasma triglyceride concentrations increased with serum PCB concentrations.
2. Populations near agricultural application sites

   The results of this 3-year health survey of farm residents and domestic animals at farm application sites were compared with residents of farms that did not apply biosolids. No significant differences were found for respiratory illness, gastrointestinal illness, general symptoms, disease in domestic animals, serological conversions to 23 viruses and the frequency of associated illness.

3. Workers involved in biosolids production and application

    This cross sectional study was based on interviews with 5 employees and environmental monitoring, including breathing-zone air samples for bacteria, endotoxins, volatile organic compounds and trace metals. There was a history of gastrointestinal illness among workers and enteric bacteria were detected in the air and bulk samples. Endotoxins, VOCs and trace metals were low. After the study was issued, it was reported that the biosolids to which the workers were exposed did not meet Class B requirements

4. Populations near sewage treatment plants

    The two retrospective and two prospective studies gave mixed results.

    In one retrospective study a greater than expected occurrence of respiratory and gastrointestinal illnesses was found in those living within 600 meters of a plant compared with those in more distant concentric rings, but the authors listed limitations of confounding due to the heterogeneous low socioeconomic population, lack of exposure and meteorological data, and relatively low volume of the exposure source.

    The second retrospective study monitored microorganisms in the air upwind and downwind and compared school absenteeism rates before and after the plant opened. Absenteeism decreased for two years after the plant began operation compared with 7 years prior.

    One prospective study was a health survey of a community before and after an activated sewage sludge treatment plant was operational. A subset of the community had serological tests and pathogen isolation from clinical specimens performed on them. There were statistically significant increases in self-reported incidence of skin disease, of a gastrointestinal syndrome (diarrhea, nausea, vomiting, and general weakness), and pain in chest on deep breathing in the population living within 2 kilometers of the plant (1,42). These increases occurred predominantly in the downwind quadrants and were not observed in more distant households (42). Other similar studies have shown an association between sewage treatment aerosols from sewage treatment plants and gastrointestinal symptoms and skin disease among nearby residents (42). Alternative hypotheses offered by the authors included odor induced bias in reporting, a sporadic outbreak from some other cause, or false positive statistical patterns (42). There were no increases in the isolation of *Pseudomonas, Salmonella* or parasites; a significant decrease in *Proteus* isolations was observed. Increases in isolates of other microorganisms after the plant opened were found not to be related to the plant opening. Antibody tests for enteric viruses and aerosol monitoring also showed no effects from the plant opening.

    The other prospective study was an eight-month survey that included analyses of blood, throat and fecal specimens for a subset of the population. Microbial aerosol monitoring and meteorological data were also collected. Regression analyses were all negative.

5. Workers in sewage treatment plants

    The 12 cross sectional, 1 prospective and 1 retrospective studies were sufficient to suggest transmission of specific infectious diseases to sewage plant workers (e.g., Pontiac Fever), but no firm conclusions could be made.

    Two cross sectional studies reported increases in hepatitis A infection associated with exposure to raw sewage and one of the studies showed additional risk factors related to years in industry, lack of face protection, and skin contact. A cross sectional study that compared the results of saliva tests for antibodies to hepatitis A among those working in wastewater plants and those not showed no increased risk for wastewater workers.

Another cross sectional study reported increased complaints of nasal irritation, tiredness and diarrhea, which were considered compatible with endotoxin exposure.

Other cross sectional studies reported evidence of pesticide absorption, increased rates of protozoan infections, and increased reports of skin disorders, diarrhea and gastrointestinal symptoms.

There was a confirmed outbreak of Pontiac Fever among sewage treatment workers who were repairing a decanter for sewage sludge concentration.

The retrospective study was a historical cohort of wastewater treatment workers (n=242) compared with college maintenance workers (n=54) followed for 12 months. A significantly higher prevalence of gastroenteritis and gastrointestinal symptoms and headaches was reported. However, there was not a higher prevalence of respiratory symptoms and there was no difference between high and low exposure categories.

The 12-month prospective study of wastewater exposed and nonexposed workers (n=336) in three different cities reported no differences in illness rates, or isolation of viruses or bacteria.

6. Compost workers

Two studies were suggestive that compost workers become colonized with fungi.

One was a cross sectional study in Germany that reported significant increases in diseases of the airways and skin and evidence of increased exposure to fungi and actinomycetes.

The other was a prospective study in multiple US cities that reported significant increases in eye and skin irritation and fungal colonization but no serological evidence of infection.

OBSERVED HEALTH OUTCOMES

The observed health outcomes of the 23 studies included toxic exposures, viral, bacterial and protozoan infections, and irritation and allergic reactions. Two studies demonstrated that workers and community residents could be exposed to chemical hazards that enter into the municipal waste stream.

The potential for viral infection of wastewater workers was documented in two studies and not in two others. One study documented the absence of serological evidence of viral infection among populations near application sites. There were no studies of viral infection among workers at production or application sites. There was no epidemiologic evidence for or against the potential for biosolids to serve as a vehicle for viral infection.

Three studies documented complaints of gastrointestinal illness related to sewage sludge and one did not. Two studies detected enteric bacteria in air and bulk samples and one did not. One study found evidence of protozoan infection among sewer workers. Without evidence of viable organisms in biosolids to add biological plausibility of a causal association or demonstration of the potential for exposure during specific aspects of production and application, there is not enough evidence to settle the issue of whether or not exposure to biosolids has potentially detrimental health effects.

Allergy or irritation was reported in one study of sewer workers and two studies of compost workers. The role of endotoxins was strengthened by demonstrated endotoxin content of biosolids but weakened by lack of association between level of exposure and effect.

ASSESSMENT OF CAUSALITY

In order to conclude that an association is causal there needs to be consistency of findings in independent studies, strength of association, temporal sequence, and biological plausibility (demonstration of dose-response relationships). The body of epidemiologic literature on the potential adverse health effects of biosolids is small.

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 chemical contamination prevention and monitoring systems are sufficient to ensure protection from chemical exposures.

Although there is evidence of sewage workers becoming infected with certain pathogens, it is unclear whether the infection of workers or community residents from viruses, bacteria, or protozoans in biosolids is plausible. The evidence documenting lack of infection is stronger than that documenting infection, and a similar statement can be made regarding a causal relationship for irritation and allergy and exposure to endotoxins.

If there is lack of evidence of a health hazard from occupational exposure, this cannot be extrapolated to mean that the risk from biosolids is negligible because the knowledge base regarding wastewater treatment workers is thin and contradictory, the exposure characteristics will be quite different between the wastewater industry compared with biosolids land application (e.g., wet sewage sludge vs. dried biosolids), routes of exposure may be different, and populations that are exposed to biosolids may not be equivalent to the occupational population (farm families and community residents will include children and individuals with respiratory disease).

It is virtually impossible to prove the absence of a health effect. Requiring such proof before proceeding to manage the risks associated with biosolids is probably not practical. On the other hand, regulators and stakeholders need to be careful not to over-interpret available studies that fail to show a health hazard. Even if there were a substantial number of robust epidemiological studies that had evaluated the health risk to populations living near biosolids application sites, it is important to remember when interpreting such studies that *the absence of evidence of a health effect is NOT the same as evidence for the absence of a health effect*.

OTHER VIEWPOINTS/STUDIES

There are papers (even in peer-reviewed journals) and documents on websites suggesting increased illness among residents living near biosolids land application sites. A paper published in 2002 reports on the investigation of 39 “incidents” of illness reported by neighbors of biosolids application sites (43). Although an association with land application of biosolids was never scientifically confirmed in these incidents, the authors report that there was no substantial investigation of the alleged health incidents by federal, state or local officials. A common set of symptoms was described including respiratory and gastrointestinal, skin disorders and headaches. Other frequent symptoms were nosebleeds; burning eyes, throat or nose; flu-like symptoms; and fatigue. The persons reported with these symptoms referred to them as "sludge syndrome." The authors suggest that the symptoms might be caused by exposure to irritating chemicals such as ammonia and organic amines, endotoxins, and pathogens, however there was no mention that this complex of vague symptoms could also be due to a multitude of unrelated etiologies. Two other papers suggest that chemical irritation from land-applied biosolids causes an elevated risk for infection (29, 30). These papers do not fulfill the need for well-designed epidemiologic studies conducted by epidemiologists with objective medical assessments of the study participants.

Several papers from the 1980s that were not included in the NRC review indicated limited risks of infection from exposure to sewers and wastewater spray irrigation. One study compared sewer maintenance workers with highway maintenance workers and found a slightly higher percentage of enteric parasite infections among the highway workers (5.4% vs. 14.5%) (44). A study that followed workers through a season of applying partially treated wastewater via low-pressure irrigation equipment reported no clinical illness, although enteroviruses were recovered from the wastewater (but not from the air during spraying) and workers who cleaned the spray nozzles had higher antibody levels to coxsackievirus B5 (45). A prospective study comparing two collective agricultural settlements (one with high wastewater aerosol exposure and one with no exposure) reported no difference in enteric disease rates between the two populations (46).

SUMMARY

The NRC Committee recommended that EPA conduct studies to examine exposure and potential health risks to worker and community populations to fill the gaps in epidemiologic evidence and to reduce uncertainty about the possible health consequences of exposure to biosolids. They suggested that studies on wastewater treatment workers not be used as substitutes for studies of actual biosolids exposure and that stakeholders be involved in the review of the design, conduct, and interpretation of studies.

One study that was at the top of both priority lists is a national system for the timely investigation of potential health incidents associated with biosolids applied to land. EPA and WERF have funded the University of North Carolina School of Public Health to develop such a system. The protocol development is complete and is awaiting implementation. The final product will include an investigation guide, outreach strategy, and recommendations on data collection and management (17). Even without a national system, it is important to collect information on reported symptoms and the time, location, and distance from the distribution site so that patterns may be detected and public health workers may evaluate and be responsive to indicators of health effects.

CONCLUSIONS

The chemical and biological makeup of biosolids is complex and can vary greatly depending on the source of the sewage and the treatment processes it undergoes. The fate of chemicals and pathogens in biosolids applied to land will vary with the soil type, weather, and application methods. The exact composition of contaminants in biosolids can change from time to time and place to place. Given present knowledge and analytical techniques, it is impossible to determine the full extent of chemical content or biological makeup of a particular biosolids mixture or the soil to which biosolids have been applied.

Research is constantly contributing information to provide the missing data and help formulate standards to reduce risk, but it must be remembered that as long as sewage is produced, it is not possible to have a totally risk-free environment. Every method of sewage disposal contains health and environmental risks. The goal is to reduce the risks as much as possible, be able to quantify those risks, and then balance the level of risk against the cost of risk reduction, against competing risks, and/or against risk generally accepted as trivial or acceptable. The end product of a risk-based approach either identifies an acceptable level of exposure or prescribes technical controls or political processes needed to attain acceptable risk. Despite all the data gaps and concerns about the basis for developing the 503 rule, the NRC Committee did not recommend eliminating the application of biosolids to land.

Although much still needs to be learned about the content, bioavailability and fate of chemicals and pathogens in biosolids and their health effects, there does not seem to be strong evidence of serious health risks when biosolids are managed and monitored appropriately. Human health allegations associated with biosolids usually lack evidence of biological absorption, medically determined human health effects, and/or do not meet the biological plausibility test. On the other hand, no concerted effort has been made to collect and analyze data on reported health effects resulting from biosolids applied to land.

To protect the public and ensure public confidence in the system, it is incumbent upon regulatory bodies to ensure that all standards are based on the best available science and that recommendations are assiduously applied. This includes updating the risk assessment methods used for chemical contaminants and incorporating risk assessment methodology in the evaluation of health risks from pathogens. In addition, biosolids-related health complaints should be investigated and documented so that trends or other indications of adverse health effects can be recognized and investigated in a timely manner by trained epidemiologists.

APPENDIX - TABLES

TABLE 1
DISTRIBUTION OF BIOSOLIDS IN THE US

Applied to Soils 55%		**Disposed 45%**	
Percent	**Application**	**Percent**	**Destination**
74	Farmland	63	Municipal Solid Waste Landfills
22	Public Use (Class A)	33	Incineration Facilities
4	Land Restoration and Silviculture	4	Surface Disposal Units

TABLE 2: POLLUTANTS SELECTED FOR POTENTIAL REGULATION IN ROUND 1, STAGE 1 OF EPA CHEMICAL SELECTION PROCESS

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

Abbreviations: 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*-chlorophenyl)-ethane.

TABLE 3: CHEMICALS PRESENT IN MORE THAN 10% OF SLUDGE, BUT ELIMINATED FROM CONSIDERATION IN THE ROUND 2 ASSESSMENTS BECAUSE OF A LACK OF TOXICITY DATA

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

TABLE 4: CHEMICALS WITH FREQUENCY DETECTION OF >10% IN NSS AND WITH HUMAN HEALTH AND/OR ECOLOGICAL TOXICITY DATA AVAILABLE

Acetic acid (2,3-dichlorophenoxy)	Methylene chloride
Aluminum[a]	Nitrate
Antimony	Nitrite
Asbestos[b]	Pentachloronitrobenzene
Barium	Phenol
Beryllium	Polychlorinated biphenyls-coplanar
Bis (2-ethylhexyl) phthalate	Propanone, 2-
Boron	Propionic acid, 2-(2,4,5-trichlorophenoxy)
Butanone, 2-	Silver
Carbon disulfide	Thallium
Cresol, *p*-	Tin
Cyanides (soluble salts and complexes)	Titanium
Dioxins and dibenzofurans	Toluene
Endosulfan-II	Trichlorophenoxyacetic acid, 2,4,5-
Fluoride	Vanadium
Manganese	

[a] Aluminum does not have human health or ecological toxicity data available but is included because of its potential for phytotoxicity.
[b]Asbestos was not tested in the NSSS but is toxic, persistent, and can be in sewage sludge

TABLE 5: PRINCIPAL PATHOGENS CONSIDERED BY EPA IN ESTABLISHING THE PART 503 RULE

Bacteria	Protozoa	Enteric Viruses	Helminth Worms
Salmonella sp	*Cryptosporidium*	Hepatitis A virus	*Ascaris lumbricoides* (humans)
Shigella sp.	*Entamoeba histolytica*	Adenovirus	*Ascaris suum* (pigs)
Yersinia sp.	*Giardia lamblia*	Norwalk virus	*Trichuris trichirua* (humans)
Campylobacter jejuni	*Balantidium coli*	Caliciviruses	*Toxocara canis* (dogs)
Escherichia coli	*Toxoplasma gondii*	Rotaviruses	*Taenia saginata* (humans)
		Enteroviruses Polioviruses Coxsackieviruses Echoviruses	*Taenia solium* (humans)

APPENDIX - ATTACHMENTS

ATTACHMENT 1

TOPICS COVERED BY VIRGINIA BIOSOLIDS REGULATIONS (12 VAC 5-585)

1. Requirements and procedures for issuance of permits to land appliers.
2. Procedures for amending permits to include additional sites and sludge types.
3. Standards for the treatment or stabilization of sewage sludge prior to land application.
4. Standards for determining the suitability of land application sites and storage facilities.
5. Required procedures for land application.
6. Requirements for sampling, analysis, record keeping, and reporting.
7. Provisions for the notification of local governing bodies to ensure compliance. with the notice and public hearing requirements.
8. Conditions under which nutrient management plans may be required.

These regulations incorporate the 503 rule into Virginia law and establish more restrictive conditions in terms of permitting, buffering, slope restriction, time of year for application, and nutrient management plans. There are also specific requirements for features unique to Virginia such as coastal plains.

ATTACHMENT 2

DEVELOPMENT OF EPA CHEMICAL STANDARDS

The chemical concentration limits and loading rates used in the 503 rule were calculated using risk assessment methods. When Congress passed the Clean Water Act (CWA), it included a section (405 (d)) that called for two rounds of sewage sludge regulations. The first round was to establish numerical limits and management practices for those toxic pollutants that, based on “available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations that may adversely affect public health or the environment.” The second round was to address toxic pollutants not regulated in the first.

In Round 1, a two-stage process was used to select the chemical pollutants. The first stage involved hazard screening of a list of 200 chemicals that had been identified from available data on effects in humans, plants, domestic animals, wildlife, and aquatic organisms, as well as the frequency of occurrence in biosolids. A panel of scientific experts selected 50 chemicals of concern in biosolids. Using a screening process, 22 pollutants were selected for potential regulation (see Table 2 for list of chemicals).

In the second stage of the first round, chemicals found to represent a potentially significant risk were subjected to a formal risk assessment. EPA chose not to regulate organic pollutants because all the priority organic pollutants that were considered fell into at least one of the three exemption categories: 1) the pollutant was banned in the US and was no longer manufactured, 2) the pollutant was detected by EPA in less than 5 percent of the sludge from wastewater treatment plants sampled in the National Sewage Sludge Survey, or 3) the concentration of the pollutant was low enough that it would not exceed the risk-based loading rates. The first rule was promulgated on February 9, 1993 (40 CFR part 503, 58 FR 9248) and included the following 10 inorganic chemicals for regulation: arsenic, cadmium, chromium, copper, lead, mercury, molybdenum, nickel, selenium, and zinc.

The Part 503 rule was amended several times in response to petitions that were filed challenging various aspects of the rule. As a result some changes were made in the standards for molybdenum and selenium, and chromium was eliminated from the list, leaving nine inorganic chemicals currently under regulation.

For Round 2, pollutants were first selected by preliminary hazard identification. This was 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 starting point was a list of 411 pollutants that were identified in the National Sewage Sludge Survey. 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 consideration (see Table 3 for list of these chemicals). Several pollutants were grouped into classes of congeners.

The screening process identified 30 pollutants that had a frequency of detection of 10% or greater in the NSSS and for which data on human health and/or ecological toxicity existed (see Table 4 for a list of these chemicals). Although asbestos was not analyzed in the NSSS, it was added as a potential candidate for regulation because it is toxic, persistent, and can be found in biosolids.

A comprehensive hazard identification study was then done on the 31 pollutants resulting in only two pollutant groups being identified for the second round of rulemaking in 1995: polychlorinated dibenzo-p-dioxins/dibenzofurans and dioxin–like coplanar polychlorinated biphenyls.

In December 1999, EPA proposed adding dioxins (a category of compounds that includes 29 specific congeners of polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and co-planar polychlorinated biphenyls [PCBs]). Following that, EPA sponsored a peer review of the risk assessment and the proposed standard. On the basis of that review and EPA's own reassessment of dioxin risks, the risk assessment was revised. In October 2003, EPA announced its decision to not regulate dioxins in land-applied sewage sludge.

ATTACHMENT 3

TREATMENT GOAL AND PROCESSES FOR CLASS A BIOSOLIDS

GOAL

Reduce pathogen densities to below the following detection limits:

1. Less than 3 most probable number per 4 gram (g) of total solids for *Salmonella* sp.;
2. Less than 1 plaque-forming unit per 4 g of total solids for enteric viruses; and
3. Less than 1 viable ova per 4 g of total solids for helminths.

PROCESSES

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.

   a. Composting with minimum time and temperature conditions
   b. Heat drying with specified temperature and moisture conditions
   c. High-temperature heat treatment
   d. Thermophilic aerobic digestion at specified time and temperature
   e. Beta irradiation at specified dosage
   f. Gamma irradiation at specified dosage
   g. Pasteurization
6. Treatment by a process deemed equivalent to #5*.

*Permit authorities have relied on the EPA Pathogen Equivalency Committee when determining whether a particular treatment system should be allowed (1).

ATTACHMENT 4
CLASS B BIOSOLIDS CRITERIA AND PROCESSES

CRITERIA
1. Fecal coliform count of less than $2x10^6$/g of dry solids at the time of disposal;
2. Treatment by a process to significantly reduce pathogens (PSRP); or
3. Treatment by a process that is equivalent to #2*.

The processes were selected because they result in fecal-coliform concentrations of less than 2×10^6/gram of dry solids, and they reduce *Salmonella* and enteric virus concentrations by a factor of 10 (1, 2).

The site restrictions for Class B biosolids were developed on the basis of the time and attenuation required to reduce the levels of pathogens to below detectable concentrations at the time of public exposure (equivalent to those achieved by Class A biosolids). The use restrictions correspond to important exposure pathways.

*As for Class A biosolids, the EPA Pathogen Equivalency Committee has the authority to recommend to permit authorities additional processes that qualify for #3.

PROCESSES TO MEET CRITERIA OF SIGNIFICANTLY REDUCING PATHOGENS (PSRPs)
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 hours of contact.

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