

Report of findings on environmental, public health and safety concerns related to land application of biosolids especially with respect to re-vegetation of mine lands in Schuylkill and surrounding counties in Pennsylvania.

Summary

Land applications of biosolids to enhance re-vegetation of mine lands in Schuylkill County and neighboring communities has become a locally contentious issue. In order to better understand and contribute to resolution of the conflict the Schuylkill Headwaters Association engaged Dr. Bryce Payne to review, analyze, and report on relevant technical literature and other information. Primary objectives of the work were to address the following priority concerns:

- Biosolids quality and quality assurance issues
- Health related issues
 - > Deaths allegedly because of land applications of biosolids (2 PA, 1 NH)
 - > Health hazards to waste water treatment workers
 - > Health hazards to neighbors and local community
 - > Health hazards to domesticated animals and wildlife
- Emissions and air quality impacts
- Water quality impacts
- History and effectiveness of previous land applications of biosolids in PA
- Current condition of local environmental resources (Is there actually a need for biosolids applications in PA independent of its usefulness as a waste management practice?)

As the work progressed it became apparent that the last listed concern, current condition of local environmental resources, is distinctly different from the other concerns. In order to more effectively utilize the limited resources for the project, Dr. Payne elected to apply no specific effort to address this issue. Nevertheless, it remains an issue of relevance to establishing in the public perception the value of biosolids for use in reclamation of mine and other severely disturbed lands.

It also became apparent during the work that virtually all the other issues had been addressed by the USEPA or PADEP in efforts to develop and improve the primary governing regulations in Pennsylvania, 40 CFR Part 503 and 25 PA Code Chapter 271. Some of the literature and data supporting the scientific bases of those regulations were reviewed during this project, but consideration of the full volume of such scientific materials was beyond the scope of this review effort. Further, with regard to potential pathogen and disease risks associated with land applications of biosolids, those regulations are based primarily on empirical observation. Thousands of sites have been receiving biosolids applications every year for more than ten years since promulgation of the 503 rules (and for decades before). Over that time there must have been tens, more likely hundreds, of thousands of human exposures to biosolids and bioaerosols

from them. Even with all those exposures, there have been no verifiable cases of injury or harm due to land applications of biosolids.

One may consider this empirical basis of the reliability of the 503 rules from a classical scientific perspective. From that perspective, the empirical basis of the pathogen and disease protective aspects of the 503 rules can be regarded as a hypothesis to be tested. Using this approach all that is necessary to establish that the hypothesis is unreliable is to find a single exceptional outcome, i.e., a single verifiable case of injury or harm due to land applications of biosolids. The opponents of biosolids applications have attempted to find such cases and present them in evidence against biosolids utilization.

Review of the documents and declarations of the opponents of biosolids applications revealed numerous claims of potential and actual harm. Those claims were, however, recurring claims of potential harm and of health related incidents associated with land applications of biosolids. Upon further review it became apparent that essentially all the claims derived from, or were included in, reports from two sources, the Waste Management Institute at Cornell University (WMI) and Dr. David L. Lewis (variously of the USEPA, University of Georgia, National Whistleblower Center, and other organizations). Two papers, one from each of these two sources, were identified as containing the fundamental aspects of all such claims. Those two papers were critically analyzed and found to contain logical and factual inconsistencies and to extrapolate without justification from selected observations to predetermined conclusions. Both papers were found to lack scientific and common sense credibility. In the end, the two papers provided no convincing evidence of their conclusions or propositions with regard to harm or potential for harm from land applications of biosolids. The data and information presented in those papers are, at best, uninformative with respect to verifiable cases of harm resulting from applications of biosolids. Information provided by and opinions of the authors of these papers were foundational to recent court cases. The courts have also found them to lack credibility. The rational basis and empirical approach of the USEPA and others, therefore continue to stand as valid (or more correctly, still have not been shown to be invalid) despite the considerable efforts of biosolids opponents to identify a verifiable case of harm due to land applications of biosolids.

The review revealed some of the complex issues that underlie biosolids utilization. Biosolids are the end product of the processing of human excrement, which evokes emotionally fundamental, negative reactions in many. As a consequence of increased efforts to reduce water pollution, biosolids production has increased, and biosolids utilization has become both more necessary and more prominent. Biosolids are by common perception and law both product and waste, depending on circumstances. Biosolids vary in quality among sources and over time. Biosolids have become the commodity upon which substantial businesses have been built, usually waste management businesses. Waste management and disposal businesses in the Schuylkill County area have been locally notorious. That history is related to long standing animosities deriving from the area's coal mining history. The presently

contentious biosolids applications projects appear to derive most of their contentiousness not as much from concern about biosolids, though that is important, as from the underlying widely felt distrust of the involved local business interests. Interestingly, and though at times it would not appear so, the fact that the biosolids at issue are coming from the Philadelphia Water Department (PWD) seems to be of less concern than who is handling it in the local area. The DEP apparently has a policy position that as enforcer of regulations they should not be involved within conflicts deriving from projects which they regulate. The USEPA has interest in and follows local conflicts around biosolids applications, but has no funding to provide support to local biosolids applications projects.

Given the preceding findings, several recommendations follow. The PWD appears to be well, indeed uniquely, positioned to take a lead role in educating the public and building public confidence in the reliability of PWD biosolids and land applications of them. To that end, a public outreach campaign would seem appropriate. The campaign would probably be most effectively based on open communication, preferably regular public forum reporting, of:

- Frequent quality assurance actions, e.g., fecal coliform determinations more frequently than required by 503 rules or current PWD practice. Frequency could be determined through discussions with community leaders and other local interested parties. This could begin immediately with presentation of historical and detailed data from last few years and continued until public confidence improves.
- Operational successes or failures, that is, what is being done to correct failures and assure repeated successes. This could begin immediately with press release discussing project efforts to date, successes, problems, and currently planned efforts, especially with respect to subjects of complaints; e.g., odors.
- Local biosolids applications contractors' support for, and involvement in, self monitoring and public reporting efforts with the objective of building public confidence in contractor's intent to perform responsibly and transparently. My impression is that local contractor representatives have done some harm to public relations with respect to their efforts and intentions and have dragged PWD along as a passive associate. The public impression should be that the contractor works for PWD and not that PWD effectively acts solely to assist the contractor to dispose of biosolids as quickly as possible. Disposal will be faster and cheaper once public confidence has been earned.
- Prompt but tactful (if possible) responses to future claims and challenges by vocal opponents of biosolids. This may require ongoing consulting support to local agencies and organizations who are continuously present and have a better awareness of appropriate times and places for and types of needed responses. It should be understood that responses are responses. The regular reporting and communication efforts mentioned above would serve as preemptive or countering educational efforts with regards to ongoing claims and misrepresentations by opponents to biosolids applications.)

- Preparation and publication (newspapers?) of retrospective responses to locally voiced fears and unjustified claims made since controversy began. Much of needed information is available in literature and information developed for this review. It would probably be appropriate to debunk lead opponents; e.g., WMI and Dr. D.L. Lewis.

In closing, a proactive, transparent, and forthright effort to thoroughly present the current biosolids projects, their multiple purposes, intentions, benefits, and difficulties is needed, and it appears that PWD is the only entity currently in position to take the lead. On future projects it would appear advisable to publicly deliver and promote distribution of background introductory information regarding PWD biosolids, quality assurance measures, and contractors' reliability and willingness to run biosolids applications projects transparently.

Introduction -- Historical Context

Federal Water Pollution Control Efforts: Cleaner Water = More Sludge

In the U.S. federal efforts to address water quality issues began in 1899 and increased incrementally through passage of the Water Pollution Control Act of 1948 (WPCA). Even though those efforts involved construction of Publicly Owned Treatment Works and consequent production of sewage sludges, they were aimed primarily at controlling spread of water borne diseases and were highly effective in that regard. In the 1970's concerns about a broader range of pollutants in U.S. waters led to multiple amendments of the WPCA until the law was completely rewritten and passed in 1972 being eventually amended until formally identified as the Clean Water Act (CWA) in 1977. U.S. waters were contaminated with excessive amounts of nutrient elements (e.g., nitrogen, phosphorus), toxic metals (e.g., cadmium, lead), organic chemicals (e.g., pesticides, industrial chemicals), and, often as a result, overgrown with micro-organisms that are more active in contaminated waters. Follow on legislation to the CWA encouraged beneficial uses of biosolids, including land applications. With the CWA and related funding programs, Congress initiated a water pollution reduction effort that continues today, though the attention of Congress has shifted to other subjects in recent years. (NRC 1996, 2002; Draeger, et al., 1999; R.K. Bastian, EPA, personal communications)

It was recognized relatively quickly that if our waters were to become clean(er), two objectives would have to be achieved. First, release of toxic pollutants into our waters would have to be reduced. For the most part, this has meant industry reducing its use of toxic materials and pre-treating its waste waters prior to release into host communities' waste water systems. This done, it still left community waste water streams contaminated with human, household, and other typically low risk wastes. Though not directly toxic, if left untreated to accumulate in our waters, water quality would still be seriously impacted. Hence, the second objective, waste water streams would have to be treated to achieve an acceptable quality level before those waters could be released into our waterways. As treatment systems improved; i.e., as more contaminants were removed from waste water streams, the amount of sewage sludge produced would necessarily increase.

As the volume of sewage sludge was increasing, the means of managing it were also changing. For simple cost reasons large cities on the coasts barged sewage sludge to ocean "dumps" and then simply released it into the sea. The excessive nutrient and pollutant loads and related environmental impacts of ocean dumping of sewage sludge led to federal prohibition of that disposal practice in the 1980's. That left some of the largest generators of sewage sludge with the need for an alternative, economical disposal practice at the same time the volume of sewage sludge was increasing.

Land application of sewage sludge had a history of success both in disposing of sewage sludge and in soil improvement. It was a practice which could make productive use of the nutrients and organic materials in treated sewage sludge. Though more expensive than ocean dumping, land application was still an economically viable alternative. Fortunately, as water quality improved so did the quality of the sewage sludge produced from treatment of waste water. Nevertheless, there were concerns about potential occupational and public health risks that might arise from land application of inadequately treated sewage sludge. Due to those concerns Congress directed the USEPA to develop and promulgate regulations that would assure that environmental and public health would not be negatively impacted by land application of treated sewage sludge. The EPA began work on those regulations in 1984.

In 1993 those regulations were promulgated as 40 Code of Federal Regulations Part 503 (commonly referred to as the 503 rules or just the 503's), and became the overarching regulations governing land application and utilization of treated sewage sludge. States remain free to establish more restrictive regulations as they may deem necessary within their respective jurisdictions. Interestingly, the mere existence of the 503's seems to have awakened fears among some individuals about the safety of land application of sewage sludge. This practically simultaneous awakening of fears and initiation of efforts to develop more sound and effective federal regulations may be little more than historical coincidence, both

arising from the fact that more biosolids were being produced and disposed of in more conspicuous ways and with more public discussion than ever before. This, however, is not an entirely satisfying explanation as utilization of residential sewage as a fertilizer and soil amendment is a practice that dates back thousands of years.

Land Application of Sewage Sludge: An Ancient Beneficial Practice

In the modern western world efforts to collect solids from municipal sewage and apply them to farm land date from the mid 1800's in the United Kingdom and the end of the 1800's in the U.S. Land applications of treated sewage sludge have been used to improve effectiveness of mine land re-vegetation in Pennsylvania for at least twenty-five years and to fertilize farm lands for even longer. I have been unable to discover any records of any cases of health or environmental damage that could be verified to have been due to land applications of appropriately processed sewage sludge. In fact, the common historical indication is that in some areas of the world, especially China, production of adequate food supplies and control of many diseases was probably due largely if not entirely to land application of "night soil." By modern U.S. standards most "night soils" would have to be regarded as effectively equivalent to inadequately treated sewage sludge. Though modern data suggest that the public health implications of returning untreated sewage sludge to the land are not so clearly good or bad, it is undeniable that this practice is ancient, and on balance more beneficial than harmful. Though modern waste water carries contaminants not present in ancient times, so also modern waste water and methods for monitoring and treating it are far better understood than in ancient times (NEBRA online; NRC 1996, 2002; Draeger, et al., 1999; F.H. King, 1911).

The 503 Rules: A Respectable and Important Contribution

It also appears reasonable to conclude that ultimately, recycling the nutrients and organic matter in appropriately processed sewage sludges will be environmentally essential if an ever increasing human population is to be supported on a fixed and finite amount of land. Hence, the application of sewage sludge to the land is a practice the benefits of which are beyond question, but the risks of which are not entirely clear and not easily elucidated. Hence, the nine years of effort needed by the EPA to produce the 503's. Further, the EPA made clear that it did not consider the original 503's a completed work. As risk based regulations, the 503's will require amendments and improvements as new and better information becomes available on health and environmental consequences of utilization of sewage sludge and risk assessment methods in general improve.

It was recognized that in order to be effective the 503's had to address a wide array of concerns and specific technical issues dealing with the chemical and microbiological composition of sewage sludges, determining which and at what levels components of sewage sludges could present a risk of harm to the environment or human health, and which treatment and utilization practices would reduce the implied risks to acceptable levels (and by implication what levels of risk were to be considered acceptable). Numerous documents (EPA 1992, 1993, 1995a,b, 2000a; Payne 1994, 1996; R.K. Bastian, EPA, personal communications) support that the EPA made a serious, sincere, and thorough effort to develop the 503's as a regulatory framework that would help assure that land applications of treated sewage sludges would be safe in both the short and long terms.

This current effort is the second time I have been engaged to perform work that involved professional scientific review of aspects of the 503's (Payne, 1994). Both times I have been satisfied that the 503's are as good a set of practical rules to protect human and environmental health as could be produced at the current state of knowledge. Since 1993 there has been a substantial increase in the amount of available information which could and should be considered with respect to possible amendments to the 503's. Indeed, as early as 1994 I myself suggested certain technical modifications would improve the enforceability of and public confidence in the 503's (Payne, 1996). Nevertheless, I remain convinced that

when effectively enforced the 503's assure that land application of appropriately treated sewage sludges is a safe and beneficial practice.

Biosolids: Contrived Name or a Useful New Term

In conjunction with the development of the 503's various interests involved in utilizing and obtaining public acceptance of utilization of treated sewage sludges developed the term "biosolids." "Officially" appearing on the scene in 1992 the term was developed through a "contest" for proposal of a new term to be used as a name for sewage sludge that had been treated adequately to be safely utilized. In retrospect one can easily conclude the new term for treated sewage sludge was actually being sought as a "sanitized," less "loaded" term which could be used to facilitate public acceptance of treated sewage sludge. The term was effectively and immediately adopted by almost all parties involved in the production, utilization, or disposal of sewage sludges or regulation of such activities. In retrospect it appears questionable that there was a serious functional need for a term to be used instead of "treated sewage sludge." Indeed, the original intent could be misinterpreted and produces occasional "back fires" actually increasing suspicions about those involved in promoting utilization of treated sewage sludges.

Nevertheless, in practice it is convenient to have a one-word name available. This is primarily because it reduces the burden of taking continuous precautions to ascertain whether or not the word "treated" precedes or should have preceded the term "sewage sludge" in any particular statement. Attaching inappropriately or failing to attach the word "treated" can produce ambiguities that cannot be resolved without considerable additional efforts to communicate or understand intended meanings. When such communications for clarification are not practical, forgetting or mistakenly including the term "treated" can result in complete, but unrecognized, miscommunication. Hence, regardless of the doubts that will linger about the motivation of some of the parties involved in development and adoption of the term "biosolids," it is valuable in communications on the production, processing, and utilization of sewage sludges. However, two cautions are appropriate here.

First, any word that finds itself rapidly adopted because of both promotion and effectiveness in use will also find itself rapidly misused, in the sense of being used to represent ideas other than the original, restricted meaning. So it is with "biosolids." I have on many occasions in discussions with employees of USEPA and industries involved with or interested in soil improvement heard "biosolids" used to refer to animal manures and other agricultural or biological wastes. The common sense appeal of this usage is easily understood, but it dilutes the value of "biosolids" as originally developed.

Second, to my mind, the originally intended use of the term "biosolids" is, in fact, ambiguous. It seems fitting to call the solid components of biological digestion or composting of sewage sludge "biosolids." These products are, in fact, the products of microbiological decomposition of the waste materials in sewage sludge. On the other hand, under the 503's, biosolids are also the result of treatment of sewage sludge with heat and(or) alkali to reduce or eliminate pathogens. Such treatments are included in the 503's because they have been demonstrated to achieve the target pathogen reduction objectives (EPA, 1992). However, the heat/alkali processes probably do not alter substantially the chemical/biochemical properties of the materials in sewage sludge. That is, the readily decomposable materials that would be converted into more stable materials in biological treatments are not rendered more stable by the heat/alkali treatment methods. Hence, though it is obvious why sewage sludge that is biologically treated can be reasonably called "biosolids," it is not so clear to me why nonbiologically treated sewage sludges should be regarded as fundamentally equivalent. Among the major resulting differences between biologically and nonbiologically treated sewage sludge is susceptibility to regrowth of fecal coliforms and, presumably, pathogens [regrowth is discussed more thoroughly near the end of this memo]. Despite this inherent ambiguity, in this memo, "biosolids" is used to mean sewage sludge solids that have been processed or are the final product of processes that render sewage solids safe for use in accordance with the 503's. Where needed for clarity, additional descriptive terms are used along with "biosolids."

Analyzing the Conflicts over Land Applications of Biosolids

Economic Progress versus the Public Good

In the 1960's-1970's there was a broad awakening of environmental concerns, water pollution being only one of them. Both scientific and popular writings of the day revealed the mutual dependence of the various natural resource systems upon which our individual and economic health depends, and how severely those systems had been damaged. There was a public need to blame someone for the damage and the direct line to industrial practices was easily followed. Many blamed industry outright for the newly recognized pollution and resource depletion. Industry moved quickly to defend itself by declaring it had followed all legal requirements and conventional practices. If there had been damage, industry could not be blamed. The response from the other side was that industry should have seen these problems developing and taken responsibility and measures to prevent further damage. Clearly if industry had not done so, then it was because industry had no interest in the general well-being of humanity, but was interested only in maximizing return on capital. And so it went.

The "environmentalists" believed themselves the bearers of the newly revealed truths about human dependence on the environment. They took the position that all technologically based utilization of resources was inherently dangerous with respect to environmental and therefore human health. Clearly industry always had and always would put profits before human or environmental health. The general human welfare had to be protected by preventing the spread of new technologies and practices until they were shown to be safe for the environment and thereby for humanity. Ultimately, this basic concept became known as the Precautionary Principle (SIRC Editorial, online no date).

The opposing school viewed the situation as one for which industry bore no responsibility. Technology had progressed, always improving standards of living. Each technological step had always led to another, each improving humanity's lot along the way. There were costs along the way, but the benefits had always outweighed the costs. This school of thought held that it was inappropriate for the government to intervene to inhibit the development of private property. Humanity only progressed as it developed and adopted new technologies. Interference in private property rights, cumbersome environmental regulations, and related interventions would hobble human progress by inhibiting the development and adoption of new technologies.

These two schools of thought, the new environmentalism and the traditional industrialism, effectively became ideologies. As with all ideologies, adherents cannot effectively grasp information or ideas that are beyond the scope of their creed of fixed ideas. The ideals and interests of the environmentalists and industrialists are diametrically opposed to each other. Consequently, effective communication and resolution of differences have been, and generally remain, out of reach. In the anthracite coal region of Pennsylvania, this conflict has roots that reach back considerably farther than the environmental awakening of the 60's and 70's. Hence, the current biosolids conflict found fertile ground in the region. Given the local mining history and related local conflicts it is surprising that it took so long for the conflict to coalesce around biosolids applications to mine lands owned by large local industrial interests. Now it has; and the parties to the conflict, the relationships among them, their interests, so far as they can be surmised, and their presentation or misrepresentation of the available information need to be considered.

Three groups of parties with interests in the current biosolids applications conflict can be readily identified: those in favor, those opposed, and the undecided. The parties who favor can be readily divided into four, more specific, groups: generators and applicators, land owners, regulators, and resource conservation groups; those who oppose into resource conservation, environmental and related special interest groups and individuals; and the undecided are primarily comprised of the general public and resource conservation and other groups for whom land application of biosolids was not previously recognized as a matter of local relevance or interest. With the exception of the resource conservation groups, each of the favoring and opposing groups and their interests will be discussed briefly below. The resource conservation groups will be discussed separately as representative of the undecided.

The Generators and Applicators

The generators of sewage sludge and biosolids were clearly historically the first to have interests in biosolids utilization. They produce sludges and biosolids and are obligated, both legally and functionally, to manage and dispose of them. Consequently they have been developing practical disposal methods and beneficial uses for biosolids since well before development of the 503's. In the present Schuylkill County area case, the only generator currently involved is the Philadelphia Water Department (PWD, City of Philadelphia). The primary interests of the PWD include:

- Disposal of the City's waste water treatment residues (sludges, biosolids, composted biosolids) at the lowest practical cost;
- Compliance with all applicable rules and regulations;
- Avoidance of harm to any party that might result from use, misuse, or improper disposal of PWD biosolids and related products; and
- Building a good neighbor relationship between the City of Philadelphia and other communities, especially those who host biosolids utilization projects.

The first listed interest of the PWD conflicts with the other three: the cheapest methods of sludge disposal (e.g., ocean dumping) are no longer available due to the other three interests of the PWD. It is precisely this conflict that compels the PWD [and other biosolids producers] to work diligently to achieve and maintain a successful balance among its interests. The PWD must work constantly to protect the interests and serve the needs of the City of Philadelphia. In order to so serve and protect, the PWD must support development of, and promptly adopt, new best practices with respect to production, disposal and utilization of sludges and biosolids. Failure to do so would subject the City to sanctions and penalties that would erase any marginal cost savings that might be had by sacrificing the safety of communities that host utilization of biosolids or other potentially affected parties. Ultimately the PWD bears the additional burden of assuring contractors who apply Philadelphia biosolids to the land do so responsibly, in compliance with current regulations, and with respect for the needs and concerns of the host communities. Failure on the part of the contractor could result in termination, threaten future contract opportunities, and impact upon the reputation and effectiveness of the PWD.

The Land Owners

As soon as there was a need for land to which sludge could be applied, land owners became involved as an interested party. Literature indicates that large cities in the U.K. and Europe and at least some in the U.S. purchased and operated their own farms in order to have lands on which their sludge could be applied. As cities grew larger, the farm land areas needed increased. Ocean dumping and land filling were found to be less expensive. City-owned "sludge farms" fell out of favor. As previously mentioned, the prohibition of ocean dumping, the increasing amounts of sludge being produced in the 1970s, and the expressed intent of Congress stimulated renewed interest in land applications. This time, however, it was not practical for municipalities to acquire and operate their own farms, although some still did (NEBRA online; Granato, 2001). Instead, land owners willing to accept application of biosolids were sought. Most of these land owners were farmers until the 1980's or so.

Then in Pennsylvania various generators and regulatory agencies, especially the USEPA, and the Pennsylvania DEP and Bureau of Mines, took an interest in the potential advantages of applying biosolids to more effectively revegetate mine lands undergoing reclamation. Experimental applications to mine lands were dramatic successes. Mine land owners became interested parties with respect to the land application of biosolids. In one regard the position of mine land owners was functionally the same as that of farmers with respect to biosolids: the generators and applicators were obligated to assure that the biosolids and practices were safe. Farmer concerns were that biosolids could be used in lieu of conventional fertilizers, would additionally supplement the soil with valuable organic matter, reduce the farmers' work load, and do so at lower cost or even provide some additional compensation without polluting the land. Under the 503's and PA rules, biosolids applications to ag lands cannot exceed the

rate at which biosolids are expected to provide sufficient nitrogen to meet the foreseeable nutritional needs of the planned crop. This generally amounts to not more than a few dry tons of biosolids per acre.

Mine land owners have additional considerations, and interests. The 503 rules allow for biosolids application rates on mine lands that are much higher than on agricultural lands. This was due to the generally far greater need for nutrient and organic matter supplementation on these degraded lands. Additionally there was the practical need to apply biosolids sufficient to meet these higher needs in a single application, or at least during the term of only one on-site project. The limited experimental data indicated that at application rates that were sufficient to achieve vegetation establishment on reclamation lands, leaching of pollutants was not a problem. Further, the long term damage to water quality caused by unvegetated mine lands far exceeded the risk of short term pollutant release (nitrogen, phosphorus) that might be associated with a heavy application of biosolids. Because of the higher application rates, eligible mine lands have greater value to biosolids generators in terms of amounts that could be disposed of, lower transportation and management costs per unit, and visually obvious and impressive success of the re-vegetation effects. Consequently owners of mine lands undergoing reclamation expect to benefit from the cost savings to be had by the generator (or applicator) from applications of biosolids for reclamation instead of agricultural purposes.

The actual application rates on PA mine lands are limited as a matter of Commonwealth policy. Annual nitrogen loading rates are used to determine application rates on ag lands. Under the 503's, on reclamation sites cumulative pollutant loading rates (CPLR) for listed pollutants are used to determine maximum application rates. Many generators now produce biosolids that are sufficiently clean that the CPLR for no pollutant is reached until hundreds of tons (dry) per acre are applied. Needless to say, such application rates would likely pose considerable risk of high nitrogen (and phosphorus) loading of surface and ground waters affected by runoff or infiltrating waters from the reclamation site. Experience in PA has been that 60 dry tons biosolids per acre is sufficient to meet reclamation needs for vegetation establishment while minimizing risk of excessive movements of nutrients (i.e., nitrogen and phosphorus). Consequently, even though it is not stipulated in the 503's or PA regs, there is relatively long standing policy in PA that reclamation applications of biosolids will not exceed a total cumulative maximum of 60 tons per acre, and it is anticipated that this application will occur as a one-time event. This PA policy maximum is total maximum application, even if no cumulative pollutant loading rate is reached by applying 60 dry tons of biosolids per acre on a reclamation site (at the time of release of this report, DEP was researching documentation of the origin of this limit).

In the current Schuylkill County case, the interests of the land owner have become even broader. The land owner (Reading Anthracite) accepted PWD biosolids for application to its mine lands, and a sister company bid for and won the PWD contract for application of those biosolids to that land. Though the land owner is technically distinct from the applicator (Waste Managers and Processors, Inc.), the owner and applicator companies have common owners, including members of the Rich family of Schuylkill County. Further, Gilberton Power, another company large portions of which are directly or indirectly owned by the Rich family, is supplying cogen plant ash for use in odor control trials in the biosolids applications. Such intertwining of business interests and activities of technically separate companies held by a small group of common owners is a common business practice. Nevertheless such relationships, and the profits they are set up to produce, are often viewed with skepticism by the public.

In Schuylkill County this skepticism is intensified by local history which is apparently fraught with conflicts between the Rich family's business interests and those of local labor and perhaps other local businesses. Additionally that history has generated abiding resentments among the same groups relating to environmental scars that remain as the heritage of past exploitation of natural resources, especially coal, and private property rights. When the current projects to use biosolids for mine land reclamation became publicly known, the picture was overlain on the underlying local historical conflicts, within the broader context of the conflict between environmentalists and industry, and government efforts to mediate and manage those conflicts by developing and applying effective regulations. It is apparent that the local biosolids conflict is a tangled web indeed with strands on both sides that reach well beyond the Schuylkill County region. Further, the adversarial parties are deeply vested in the various levels and aspects of the conflict and, not surprisingly, have demonstrated little interest in rationally resolving any of the involved

issues. Much of the information being provided is or appears to be rhetorical instead of informative. This report represents a serious attempt by the SHA and allied parties to thresh the information and facts out of the rhetoric. The objective of this attempt is to provide technical and scientific support to the SHA to reach its own conclusions on the advisability of land applications of biosolids for mine land reclamation in their service area and to share that support with other interested parties.

Regulatory Agencies

I was unable to determine the earliest regulatory agency in the US involved in matters relating to oversight of the management or disposal of sewage sludges and biosolids. Federal law on water pollution began in 1899, and the federal regulations (Part 257) that were predecessor to the 503's apparently developed out of the WPCA or CWA between 1948 and 1977. Between then and now, the regulatory agencies with jurisdiction in Pennsylvania have been the USEPA and the PADEP. The roles of these agencies seem to be misunderstood by many. The USEPA was charged by Congress with establishing a risk-based set of rules that would assure that utilization and disposal of sewage sludges in the U.S. would be safe for humans and the environment. The PADEP is responsible for adapting the 503's to the more specific needs and conditions of Pennsylvania, applying a more cautious and skeptical eye on the issues laid out by the 503's should the DEP determine that more caution is necessary. Once adapted (see especially Title 25 Pennsylvania Code Chapter 271 as amended and announced in the Pennsylvania Bulletin, Volume 27, Number 4, 25 January 1997; and referred to hereinafter as PA271) the DEP is responsible for enforcement and may contract with County Conservation Districts to assist in oversight and enforcement of land applications of adequately treated sewage sludges (biosolids).

The EPA has enforcement authority with respect to the 503's and related federal regulations, but its enforcement activities with respect to biosolids are limited. The limited enforcement activity on the part of the EPA is apparently because of lack of funding from Congress. The limited funding forces EPA to focus available funds into areas of greater concern. Biosolids is regarded by EPA as an area in which the current rules are working. There have been various allegations by opponents of beneficial use of biosolids that illnesses and deaths have been caused by land applications of biosolids. Despite lengthy investigations by EPA and others, and court proceedings, none of the allegations has ever been substantiated. Pragmatically it is also a fact that the number of individuals potentially impacted by beneficial uses of biosolids are much lower than the number currently actually being impacted by other environmental concerns such as drinking water quality and hazardous waste management problems.

It is important to realize that the interest of the EPA and DEP with respect to beneficial use of biosolids is actually to try to discern and serve the relevant interests of all parties when those interests can be established as legitimate. These agencies must help biosolids generators identify and utilize legitimate beneficial uses for their products and at the same time address all legitimate concerns about those uses. It has been my experience, and the information reviewed for this report supports, that these agencies do make reasonable, serious efforts to determine whether or not a concern or claim of injury is legitimate, and, if so, determine what measures must be taken to minimize future risk. This, of course, will lead to disappointment for those who believe they have suffered harm from biosolids applications. Similarly the agencies will, and have, identified cases where negative impacts have occurred because of failure of treatment plants or systems to adequately treat solids released for beneficial use (Burton and Trout, 1999; NIOSH 2000, 2002; Lodor, 2001; Kuchenrither, et al., 2003). In other words, the EPA and DEP must hold a difficult line upon which claims and counter claims are resolved into probable causes and effects, and then take actions in the collective interest of the citizens and residents of the U.S. and the Commonwealth of Pennsylvania, respectively. Bearing in mind all the parties to which these agencies respond, their performance as indicated by development of the 503 rules and PA271, and subsequent related actions as revealed by the information developed for this report (EPA, 2003; R.K. Bastian and EPA internal communications), I am convinced of the integrity of these agencies and their efforts.

Groups Opposing Land Applications of Biosolids

There are numerous individuals and groups who have declared their opposition to land applications of biosolids. The following is an incomplete list:

Pennsylvania Environmental Network (PEN)
Dr. David L. Lewis and the National Whistleblower Center
Cornell Waste Management Institute at Cornell University (WMI)
Center for Food Safety
Community Environmental Legal Defense Fund, Inc.
Coalition of Citizens Organized for Political Self-Expression (CROPS)
Sludge Busters
Mahanoy Creek Watershed Association
Army for a Clean Environment, Inc. (ACE)
Environmental Science Research Associates (ESRA)
Berks Citizens Against Toxic Sludge (BCATS)
The Lancaster County Green Party

While gathering information for this report I made efforts to establish direct contact by phone and email with staff at the PEN and WMI. I received no responses. It is my impression that many of the opponent organizations function largely through volunteer work. Consequently, a direct response may have been an unreasonable expectation. I concluded I should seek the most direct documentary communications of their positions that I could find. I consulted documents published by these organizations from their web sites and publications and through third parties. Though expressed in different ways by the different opponents, it appears to me that fundamentally their opposition is based on a belief that the EPA risk evaluations underlying the 503's are not correct, that the risks are either much higher or unknown, and if unknown should be presumed to be high (recall the Precautionary Principle discussed earlier). It follows logically, and was my conclusion from my review, that the fundamental interest of the biosolids opponents is to end outright any beneficial uses of biosolids, especially land applications. Indeed, the opponents state this is their objective through their own publications and in court documents (Center for Food Safety, et al., 2003; Harrison and Oakes, 2002; Lewis, et al., 2002; PEN, 1996).

Resource Conservation and Related Groups

The resource conservation groups are prominent among the interested parties to the present conflict over biosolids use in the Schuylkill County region. Despite their presumably closely related missions, there are strong differences of opinion among local resource conservation groups. Among the conservation groups who have voiced interest in land application of biosolids in the Schuylkill County region are the Mahanoy Creek Watershed Association (MCWA), the Schuylkill Conservation District (SCD), and the Schuylkill Headwaters Association (SHA). These three groups provide an effective cross section of opponents, proponents, and undecideds. The Mahanoy Creek Watershed Association and some of its members have been very outspoken in their opposition. From the information I have been able to compile, it appears that the current conflict is in large part because of the consistent efforts of members of the MCWA. The SCD supports land application of biosolids to reclamation sites almost as a default as the SCD has for years been involved in oversight and assistance to farmers who accept biosolids applications on their lands. The experience has generally been good and the results favorable (C. Morgan, personal communications). Additionally, the SCD, as other conservation districts, was contracted under PA271 to assist DEP in local administration of biosolids applications and related permitting functions. The SHA was impressed with reports of the effectiveness of biosolids use on reclamation sites and initially presuming the practice should be safe or it would have been prohibited, took a position favoring biosolids applications. As the conflict developed, the opponents to biosolids applications cited numerous documents and events as evidence that land applications of biosolids were not just risky but dangerous and potentially lethal to neighbors of the application sites. It is my impression from the information gathered that the proponents of biosolids either failed to respond or offered

unsatisfying responses to the opponents' claims. Faced with this situation the SHA concluded that they should seek their own independent source of scientific advice regarding the information available on the safety and effectiveness of the application of biosolids on mine lands undergoing reclamation. The SHA sought and obtained the support of the City of Philadelphia to commission this review in an effort to develop a more independent and well informed position on the use of biosolids for reclamation of mine lands.

Findings

The preceding introduction is lengthy but I felt it necessary to set the stage and establish the complexity of the conflict before moving on to findings regarding the relevant scientific information. The amount of relevant scientific information now available is substantial. With few exceptions all the scientific publications, operational data, and general information I obtained support the safety and effectiveness of the application of biosolids when carried out in compliance with the 503's and PA 271. Or, stated more correctly, among all those research results, data sets and information, there is no scientific evidence that land applications of biosolids in compliance with the 503's have or, hence, are likely to cause harm to humans or the environment.

Because some find a negative statement about undesirable outcomes unsatisfying, I am concerned that I try to clarify something about science and scientific information and conclusions. Science is actually the method humans use to try to understand the universe in which we live. Ultimately understanding something means to be able to predict what that thing will do. If I toss a coin up, will it come down? If I put my hand into a flame, will it hurt? If I take an acorn from an oak tree and plant it, will it grow? If it grows, will it grow up to be an oak? Scientifically each of these questions can be answered with a different likelihood of being correct and different levels of concern about the consequences of being wrong. It is easy to establish with a high level of confidence and little concern about the consequences, that things thrown up come back down, that some but not all acorns will sprout and grow up to be oaks but not pines. It is similarly easy to establish with a high level of confidence but a higher level of concern that most of the time flames will burn you.

Scientific conclusions are, in fact, conclusions about the probability that something that you expect to happen will happen. And, the only way to develop such conclusions is to test what happens, over and over, and wait for other scientists to test it again. Then when enough data have been collected, there is a scientific conclusion that if anyone does the same thing again, the same result will happen. Sounds simple enough, but it actually places scientists in the position of not being able to state that something that has never happened will never happen. Science allows us to draw reliable conclusions and make reliable predictions about things that do exist or occur and have been scientifically observed. Science cannot, however, make predictions about the likelihood of events that have never occurred or been observed or observed too infrequently to be scientifically studied. Consequently, even though many find it unsatisfying, the statement that there is no scientific evidence that biosolids applications in compliance with the 503's have ever caused human illness is the only scientifically valid statement that can be made regarding the safety of biosolids use in the future.

Restating, the only scientific conclusion that can be drawn is no one has been hurt yet. Again, this sounds like a denial of danger, not a declaration of safety. It is, in fact, however, a declaration of safety in the scientific sense, though quantitative data are difficult to come by. Though not so formally scientific as many would like, the rational, and scientific, reasoning supporting this conclusion of safety goes like this. Though no hard data are readily available, it is known that there are about 16,000 permitted wastewater treatment plants in the U.S. About 50% of the sludge produced is land applied biosolids. It seems reasonable to assume that about 50% of the sludge is produced by about 50%, or about 8,000 of the treatment plants. Further, it also seems reasonable to assume, conservatively, that each of these plants has at least one application site. It then follows that sites receiving land applications of biosolids must number in the thousands, probably several thousand, each year (R. Bastian, USEPA, personal communication). If one allows, conservatively, that only ten persons are exposed as biosolids workers and site neighbors at each site, then it follows that there must be several tens of thousands of relatively prolonged human exposures to biosolids that are land applied in the U.S. each year. This has been the situation since promulgation of the 503's in 1993 (and probably for twenty years or considerably more before that). That is, since 1993 the number of persons with relatively prolonged exposures to biosolids through land applications in the U.S. must be in the hundreds of thousands. If there were a substantial, or even a relatively minor risk, of serious illness due to land applications related exposures to biosolids, then it should have become confirmably apparent, at least once, since 1993. Not a single confirmed case

has been discovered. Therefore, it can be reasonably concluded that exposure to biosolids due to land applications does not increase risk of illness or increases it so little that the resulting occurrences of illness cannot be observed or, therefore, scientifically confirmed (California State Water Resources Control Board, 1999).

I would like to introduce the remainder of this report by pointing out the fundamental differences between the positions of the proponents and opponents of land applications of biosolids. This is most easily accomplished by considering, again, what fundamentally the 503's and PA271 are. The 503's and PA 271 are based on risk assessments that fundamentally rely on considerable experience with application of treated sewage sludges. Appropriate land applications of treated sewage sludges of appropriate quality have never been (scientifically) shown to cause human or environmental harm. That experience also reveals that inappropriate applications or utilization of inadequately treated sewage sludges do threaten human and environmental health. The purpose of the 503's is, at its essence, to assure that sewage sludges in the U.S. are adequately treated and appropriately utilized or disposed of. That is, the 503's are a set of guidelines that the federal government recognizes as minimally adequate to assure with a high level of confidence that land utilization or disposal of biosolids is safe for humans and the environment. Pennsylvania has chosen to add additional constraints in PA271 further raising the confidence level. Again, addressing the volume of scientific evidence supporting that land applications of biosolids in accord with the 503's and PA271 are safe is beyond the scope of this work.

The position of the opponents of land applications of biosolids is not quite so clear. Are the opponents opposed to utilization of biosolids regardless of how safe? Or, are they contending that the confidence level of safety provided by the 503's and PA271 is too low? Outright opposition is an utterly impractical and unreasonable position for at least two reasons. First, the existence of humans implies the production of human excrement. Therefore, sewage solids in some form are part of human existence, and sooner or later, somehow, must be managed by humans. Second, there can be no set of rules or management practices for sewage sludges which will provide a 100% assurance of human and environmental safety. That is, the outright opposition position simply ignores physical reality. Consequently, if the opponents' position is outright opposition, then it ignores physical reality upon which scientific knowledge is based. Hence, there is no point in presenting scientific data or rationale to dissuade its adherents. Many of the reported comments of the opponents have been highly emotionally charged. Consequently, even though many have declared that they want an outright ban on utilization of biosolids, I have not been able to draw a serious conclusion about how many of the opponents actually believe that would be a practical or reasonable position.

If outright opposition is not the position of the opponents, then they must accept that biosolids utilization is at some level inherently acceptable. They must be contending, then, that the confidence level of safety provided by the 503's and PA271 is too low (Harrison, et al., 1997).¹ This is a position that can be addressed with a scientific approach, but has a distinct advantage over the position of those who contend the 503's and PA271 do provide adequate protection. In practice the proponents of the 503's are making risk assessments and, again, are obligated effectively to predict the unlikelihood of the unknown from the known. The opponents, in contrast, are in the traditional position of the scientist as skeptic. Effectively the 503's and PA271 stand as equivalent to a classical scientific theory. All the opponents have to do is present a single, scientifically documentable case where utilization of biosolids in accord with the 503's and PA271 has failed to protect human health or the environment. If the contention that the 503's and PA271 are not adequately protective is correct, then it follows that finding a documentable case should be relatively easy.² This situation is also advantageous for me as a scientific reviewer because all I have to

¹ [*The opponents declare this as their position in some documents, but other documents or other parts of the same documents suggest that the confidence level they would find satisfactory is so high as to be in practice equivalent to an outright ban (Harrison and Oakes, 2002; Lewis and Gattie, 2002; Lewis, et al., 2002).*]

² [*This is the converse of the situation of the proponents who can only forecast the likelihood of safe outcomes, but cannot predict anything about any negative outcomes. It should perhaps be considered*

determine is whether or not the opponents have presented a single scientifically convincing case where the 503's and PA271 have failed to adequately protect human or environmental health. Examination of publications by or about the opponents revealed only a small number of contentions or cases that are repeated at different times and in different venues (Center for Food Safety, et al., 2003; Harrison and Oakes, 2002; Latshaw, 1997; Lewis and Gattie, 2002; Lewis, et al., 2002; PEN, September 1996; PEN online; Rockefeller, 1996; Tackett, 1994, 1997; see also attached list of local news articles). Those claims can be summarized as follows, and are addressed in detail below:

Claims:

1. The National Institute of Occupational Health and Safety has classified (Class B) biosolids as hazardous.
2. Waste water treatment plant workers suffer more illnesses (than other unexposed groups).
3. There have been numerous documented cases of illness due to land applications of Class B biosolids, including three deaths due to exposure at Class B biosolids application sites. Class B biosolids carry and cause humans to be infected and killed by *Staphylococcus aureus*. The odorous compounds from biosolids applications irritate human tissues causing them to suffer from injurious *Staphylococcus aureus* (and other?) opportunistic pathogenic infections.
4. Land applications of biosolids will contaminate soil, water, air, plants, and animals to dangerous levels.
5. Enforcement measures are inadequate.

Response:

1. The National Institute of Occupational Health and Safety (NIOSH) has classified Class B biosolids as hazardous. The opponents have cited a report by the NIOSH that Class B biosolids contained dangerous levels of pathogenic organisms, had been found to cause disease in biosolids workers, and that biosolids workers should wear personal protective equipment appropriate to handling hazardous materials (Burton and Trout, 1999; NIOSH, 2000; Lewis, et al., 2002; numerous public claims by Mahanoy Creek Watershed Association members and others). At first glance, this would certainly appear to be a damning indictment of the adequacy of the safety margin provided by the 503's. The NIOSH investigation, however, did not occur until several months after the actual event. During the investigation, the NIOSH investigators failed to verify that the biosolids in question were, in fact, Class B biosolids, that is, that the biosolids had actually met treatment requirements of the 503's. In fact, after the sludge had been land applied, the single treatment plant producing the sludge in question (Lesourdsville, Ohio) reported that the sludge had not met the pathogen reduction requirements of the 503's. Hence, after further investigation, the NIOSH released a 2002 report that superseded its 2000 report. In the 2002 report the NIOSH recommended biosolids workers should wear long sleeved shirts and long pants, change shoes when leaving work areas to avoid of tracking biosolids out of work areas, and practice good work place hygiene including such actions as washing hands before eating, etc. Hardly measures appropriate for protection from materials known to contain dangerous levels of pathogens. Though the opponents of biosolids cannot be criticized for a slow rush to erroneous judgment by a federal office, the NIOSH report they cite cannot be accepted as even common sense, let alone scientific, evidence of the inadequacy of the 503's.
2. Illness is prevalent among waste water treatment plant workers. The opponents cite reports of increased incidence of disease among waste water treatment plant workers. Citing these reports as evidence of the presence of pathogens is not scientifically valid for several reasons.

that if negative outcomes were even marginally acceptable, it would be helpful to allow them to occur so that the actual lowest cost, effective management level could be identified more quickly. I presume there is no need to explain why this is not the approach that the U.S. Congress, EPA, and other proponents of biosolids utilization have taken.]

First, sewage treatment plant workers are exposed to sewage and sewage solids at all stages of treatment from raw to fully treated. To extrapolate that disease among workers resulting from such exposures are evidence that biosolids treated to Class A or B per the 503's will similarly cause disease is to argue that sewage treatment processes must provide effectively no pathogen reduction effects at all. This contradicts available scientific data and historical human experience which have shown that disease from exposure to raw sewage, or even waters receiving raw sewage, does cause disease while, so far, there is no scientific evidence of disease because of exposure to adequately treated biosolids.

Second, citing illness among treatment plant workers as evidence that exposure to biosolids will similarly cause illness assumes that pathways of exposure are the same. The sewage stream to which treatment plant workers are exposed includes work place exposure to raw sewage streams and sewage liquids and solids at various stages of treatment. Assuming workers are using good work place hygiene practices (not necessarily a good assumption), the largest source of exposures is likely to be points in the process where droplets of sewage become suspended in the air. Those droplets could then be inhaled and subsequently swallowed, or settle on surfaces that might be regarded as "clean" because they have no direct contact with the sewage stream. In contrast, Class A or B biosolids are most commonly handled as biosolids "cake" which is the viscous semisolid to solid residue left after the biosolids water content is reduced by filtration, centrifugation, or other dewatering process. Consequently, to assume that workers handling biosolids would have the same type, intensity, or frequency of exposures to the same concentrations of potentially pathogenic organisms is to, again, ignore common sense.

Third, the contention that workers in modern U.S. sewage treatment plants suffer more illness than workers in other occupations appears to have no basis in fact. One study compiled and reviewed the medical records of workers in Chicago sewage treatment plants and control groups of other Chicago workers. Statistical analyses of the data found no significant differences in death rates due to disease (Kuchenrither, et al., 2003). Occurrences of various relevant diseases in California counties where biosolids were land applied were compared to occurrence of those same diseases in counties where no biosolids had ever been applied. No significant differences in rates of illness were found (California State Water Resources Control Board, 1999). Where illnesses have occurred, investigations have determined that the most probable cause has been poor work place hygiene practices; e.g., failure to wash hands before eating (NIOSH, 2000, 2002; R. K. Bastian personal communications).

Fourth, the reports cited by the opponents predate the 503's or are from outside the U.S. Consequently there is no reason to assume that treated sewage sludges from the plants subject of those reports met Class B biosolids pathogen reduction requirements. It is implausible that the general sewage stream itself would meet those requirements.

3. There have been numerous documented cases of illness due to land applications of Class B biosolids, including three deaths due to exposure at Class B biosolids application sites. Class B biosolids carry and cause humans to be infected and killed by *Staphylococcus aureus*. The odorous compounds from biosolids applications irritate human tissues causing them to suffer from injurious *Staphylococcus aureus* and other opportunistic infections.

This is the quintessential set of claims of those who oppose land applications of biosolids. Based on my review of the gathered information, it appears to me that effectively all the opponents' other claims derive from this core set. Hence, I spent disproportionate time considering it and reporting on it now.

The opponents' position on this set of related claims is thoroughly presented in a Harrison and Oakes (2002) paper. The language and structure of the paper are sophisticated, seductively so. When reading the paper, one can find oneself overlooking points which require more deliberate consideration. Harrison and Oakes claim to report on 39 sites where health complaints have been made by neighbors of sites where biosolids were applied. However, Harrison and Oakes could not confirm land application of biosolids actually occurred at sixteen of the selected sites. They offer no justification as to why they considered the health complaints at these sixteen sites as supplying any information on health incidents associated with land application of biosolids.

Harrison and Oakes (2002) used as "data" the personal recollections of complainants collected at unspecified times after the occurrence of the reported symptoms and associated biosolids applications. My primary concern is not that individuals' descriptions of their own symptoms and illness are necessarily not scientific or not scientifically useful, but that such recollections of personal experiences months or years later must be treated with an appropriate allowance for the blurring effects of time on human memory. Alternatively the descriptions would be considerably more reliable if they had been recorded or documented at, or shortly after, the time of occurrence. Additionally, there should be sampling controls; indeed, multiple controls for comparison to the individuals with health complaints. Harrison and Oakes could have attempted to invoke some semblance of controls for their selected sample population by including noncomplaining individuals who also were neighbors to the application sites. Harrison and Oakes do not mention noncomplaining neighbors. The lack of information forces the reader to infer that either everyone near the application sites reported on were symptomatic, or noncomplaining neighbors were selectively excluded. The former seems implausible while the latter suggests questionable motives or methods.

The Harrison and Oakes paper contends that there is no effective monitoring or recording system in place for complaints associated with biosolids applications. Harrison and Oakes did establish in a manner that could be reasonably construed as "scientific" that there was at the time of their investigation no effective system for recording, monitoring, and evaluating health complaints and incidents associated with biosolids applications. If they had constrained themselves to that objective, their report would have been solid and a potentially substantial contribution to concerns about the safety of biosolids applications. They did not, however, so restrain themselves. Their intention was to demonstrate that there is scientific evidence that land applications of biosolids is inherently dangerous. Consider in this regard the abstract of the paper which reads:

"The majority of U.S sewage sludges are disposed of by application to land for use [as] a soil amendment. Class B sludges, containing a complex mix of chemical and biological contaminants, comprise the majority. Residents near land application sites report illness. Symptoms of more than 328 people involved in 39 incidents in 15 states are described. ... Analysis of the limited data suggests that surface-applied Class B sludges present the greatest risk and should be eliminated. However, even under less risky application scenarios, the potential for off-site movement of chemicals, pathogens, and biological agents suggests that their use should be eliminated."

The authors felt compelled to use the incomplete government records they could locate, and the anecdotal reports of complainants as the "data" for their investigation into health incidents and the implied risks of land applications of biosolids. In fact, this approach amounts to little more than a survey of a self selected population of individuals who complained, or later thought they complained or should have complained, about health incidents. The WMI article lists a total of 50 references and citations. Among those 50:

- <> Two refer to www.sludgevictims.net which is cited as the primary source of anecdotal reports
- <> Four refer to one Lewis, et al. paper which is discussed below
- <> Five refer to compliance opinion letters or other related documents
- <> Nine refer to dictionaries, other reference volumes or nonspecific sources, and WMI authors' procedural notes
- <> 23 refer to policy or review documents by the EPA or NRC without substantive specific data on biosolids or in which, when such data were presented, the original authors of the cited document clearly disagreed with WMI authors' conclusions regarding the risk of land application of biosolids
- <> Only seven refer to technical articles presenting actual scientific data, but four of the seven predate the 503's and the other three cannot be reasonably construed to support Harrison and Oakes' conclusions regarding the risk of biosolids applications.

In the end, with the single exception of the Lewis, et al. paper, none of the literature cited or the data provided by Harrison and Oakes can be reasonably regarded as scientific evidence that supports any of their conclusions regarding health risks posed by land applications of biosolids.

The authors repeatedly refer to a 2002 publication by D.L. Lewis, et al. entitled, "Interactions of Pathogens and Irritant Chemicals in Land-Applied Sewage Sludges (Biosolids)" released through the Internet publication BMC Public Health (2:11) which can be found at <http://www.biomedcentral.com/1471-2458/2/11>". Harrison and Oakes cite that publication as, "The single published investigation of health incidents related to land application of sludges..." and the only "scientific investigation of the numerous anecdotal reports of illness associated with land application sites..." The Lewis, et al. paper is more sophisticated than the Harrison and Oakes paper in its approach to collecting and interpreting anecdotal reports as data. The need for an unexposed control group of residents is mentioned, but dismissed as unnecessary to the limited purposes of the investigation which were to "describe and document self-reported illnesses," and provide "guidance on which exposure routes (e.g., contaminated drinking water, dermal contact, or inhalation of aerosols) should be the focus of the research." As with the Harrison and Oakes paper, if Lewis, et al. had restrained themselves to conclusions that were directly supported by the data they collected, the paper would have to be regarded as a substantive initial contribution to development of a better understanding of health complaints and presumably the risks associated with land applications of biosolids. However, like Harrison and Oakes, Lewis, et al. did not so restrain themselves.

As in the Harrison and Oakes paper, difficulties arise early in the abstract. The "Abstract, Background" is a reasonably concise and accurate statement of introduction and purpose. Under "Abstract, Methods," the data source is identified as individuals interviewed apparently well after the events occurred as to their exposures near biosolids and their symptoms. This is not necessarily problematic until Lewis, et al. point out that "Information was obtained on five additional cases where an outbreak of staphylococcal infections occurred near a land application site..." The other 48 cases did not require special introduction as to specific disease conditions in order to be considered.

The "Results" section of the abstract begins with a concise statement of conclusions that can be drawn directly from the primary data source, anecdotal recollections. The remainder of this section is an argument that the number of *Staphylococcus aureus* infections, including two deaths, is somehow due to nearby biosolids applications and related to the common occurrence of *S. aureus* infections as secondary to diaper rashes, i.e., irritated skin.

The abstract "Conclusions" then present none of the conclusions supported by the data, but only the speculation that even low levels of pathogens in biosolids are hazardous because of the irritating effects of volatile contaminants in biosolids compromising resistance to infection.

In the full "Background" section of the body of the report, Lewis, et al. cite the retracted NIOSH 2000 report as supporting information on infectious levels of pathogens in sludge. If the details surrounding that episode and report are considered, it becomes apparent that the redundant conclusion that untreated sewage sludge can cause illness is being revisited. The question is, why would Lewis, et al. revisit this tired subject again? There seem to me to be two possible answers. Either they do not perceive it to be the same subject, or they paint all sewage sludges, regardless of degree of treatment, with the same brush. If one holds as a premise that all sewage sludges, treated or untreated, are effectively the same, then one may, indeed should, make blanket calls for banning land application of sludges. Once again, the question is, are treated sludges safer than untreated or inadequately treated? Lewis, et al. clearly hold there is no effective difference between the health threats posed by untreated and treated sewage sludges despite evidence and experience to the contrary.

The next citation discussed is that of Dorn, et al. (1985) who "found no evidence of elevated risk of infection in the only epidemiological study done with residents exposed to sewage sludges." Lewis, et al. then point out that Dorn, et al. "did not determine whether any pathogens were present in the material." Lewis, et al. elsewhere in their paper repeatedly proclaim and ultimately conclude that sludges effectively always present serious risk of causing pathogenic infections, a substantial proportion of which may be fatal. It seems curious that Lewis, et al. are willing to propose that the multiple applications of sludges involved in the Dorn, et al. project might have somehow been seemingly miraculously all pathogen-free. I can only find one reasonable explanation for Lewis, et al.'s willingness to consider a possibility that is

totally contrary to their conclusions and position. It was the only way they could explain findings of a recognized and widely accepted scientific study with a clear conclusion that repeated exposure to adequately treated sewage sludges over several years does not present a serious risk of illness.

In the last paragraph under "Background," Lewis, et al. state, "Our retrospective investigation was designed to use a survey for describing adverse effects ..., and evaluate whether any infections associated with exposure to sewage sludges were prevalent within the group." A survey may be able to establish some reason to believe there is an association between an event and occurrence of symptoms among those in the vicinity, but it is not clear to me how a link between results of a survey and causes of specific types of infections can be reliably established. Again, the only infections that have been reliably associated with sewage sludges have been associated with untreated or inadequately treated sludges. Either Lewis, et al. are unwilling to recognize this, or do recognize it and pursue their course for purposes other than scientific inquiry.

In the "Methods, Surveying Residents" section, Lewis, et al. cannot resist the inclination to -- again -- lump together treated and untreated sewage sludges stating that their survey was "based on symptoms associated with exposure to sewage sludges." The reliability of the data generated by the survey is brought into question when the authors point out that their subjects were queried with respect to "their symptoms and how much time elapsed between exposures and onset." This paper was submitted for publication in April 2002. If one assumes that the report was written over, say, the preceding year, then data would have been collected in 2000. The dates of sludge applications at the ten sites were not specified except for the Robeson, PA site (applications annually 1988-1995) and the Greenland, NH site where the only application discussed occurred in "late October 1995." If those dates are representative of the other sites, then it seems reasonable to conclude that four years was a typical minimum time interval between the events which the survey covered and the actual administration of the survey. It seems unlikely that most individuals would be able to reliably recall any kind of precise details with respect to dates and times of applications of sludge, sensations of odor, or specifics about symptoms. Hence, depending on the resolution of the data sought by the survey, the data provided would have to be interpreted with concern for reliability of details.

Under "Methods, Assessing Environmental Conditions," Lewis, et al. state that "Sludges ... at all but one agricultural site ... were limed or applied to alkaline soils then exposed to weathering." At the one mine reclamation site the soil was reportedly limed after sludge application. The authors seem to have a distinct concern about whether or not biosolids applied were lime stabilized, soils were limed in conjunction with biosolids applications, or soils were alkaline. The authors state in their "Discussion" that lime is an irritant. This suggests that the authors do not appreciate the multiple uses of the term lime in environmental and agricultural chemistry. Lime may be used to mean calcium oxide or hydroxide which are both irritants and capable of causing chemical burns, but which are unstable when exposed to air or soils. In the environment these "limes" are relatively rapidly converted into calcium carbonate, also known as lime. Calcium carbonate is common, taken as a calcium dietary supplement and antacid, and, even in fine dust form, no more than a nuisance dust.

In the second paragraph the authors discuss the case of one surveyed family of four near a site where county records indicated dairy wastes rather than biosolids had been applied. Lewis, et al. cited "unconfirmed reports" that Class B biosolids were mixed with the dairy wastes prior to application. Lewis, et al. decided that the "data" for this site where biosolids may or may not have been applied should be included in their investigation since biosolids might have been applied. This decision is either a conscious error intentionally made to maximize the amount of data that could be construed to weigh against applications of biosolids, or an error that Lewis, et al. actually believed to be a legitimate scientific decision regarding data sources in which case they were simply wrong.

Another curiosity was the decision to exclude "Individuals who were previously questioned by environmental activists." The scientific need for this exclusion is not explained. After the passage of four years, no one willing to provide information would be likely to have their recollections tainted by previous interviews. Given the low number of survey participants, and the already questionable accuracy of

recollections generally, it would seem more scientifically appropriate to acquire as much data as possible, then determine if there is reason for exclusion.

In the balance of the Methods section, Lewis, et al. discuss the Greenland, NH site and their use of data from this site to assess relationships between environmental conditions, biosolids applications, and occurrence of symptoms. This is the only site for which they make such an attempt presumably because this is the only site for which any kind of written record of symptoms was available. It still appears likely that the reliability of the detailed information for this site, even though written, should be questioned. The written record was begun "approximately two weeks after sludges were applied and continued for approximately two years (1995-96)." It seems suspicious that the only written record available to the Lewis, et al. investigation apparently could not be specifically dated. The specific date range October 31-November 23, 1995 is repeatedly referred to in discussions of the data period immediately following biosolids application and during which symptoms began to occur. Assuming this is the time period of actual relevance, then the written account would not have started until approximately 13 November 95, again raising doubts as to the reliability of recalled details as to date and times of exposure, initial and later symptoms, etc,

The 31 Oct-23 Nov 95 period is, also, the time interval for which computer simulations were run. This is important as the output of the simulations was the only source of quantitative data for the Lewis, et al. investigation. A computer program (WRPLOT v3.5) was used to develop predicted wind conditions at the application site using data from a reliable source 5 km from the site. Another program (Industrial Source Complex Dispersion Model ISC3) was used to predict concentrations of volatile contaminants that residents would likely experience relative to concentrations of those contaminants 2 m directly over the applied sludge given predicted wind conditions.

The treated field at the NH site is described as located at the end of a paved road on which there were eight residences. The distances (in meters) from the nearest edge of the field receiving biosolids applications to the seven participating residences are specified as two at 23, and one each at 77, 170, 130, 280, and 320 m. Presumably the residences were located progressively farther from the field along the paved road. One of the eight resident households apparently did not provide data to the investigation. No explanation was offered.

One other subject in the Methods section needs mention here. In presenting their computer simulation approach Lewis, et al. state that source emission rates are needed, but "Microbiological process rates, which largely control emission rates of airborne pollutants produced by sewage sludges, are highly unpredictable." They offer an alternative computer simulation which is reasonable. However, the just quoted statement suggests an error in those authors' understanding of the factors most likely governing emission rates from field applied biosolids. The authors were careful to point out that the biosolids applied were lime-stabilized, containing nearly 10% added lime and about 2.5 kg polymer per dry ton biosolids. If so, most microbiological processing would have been stopped by lime stabilization. Because of the high pH most of the free ammonia and amines would have been lost during lime treatment and any remaining would have been lost after application in the field. Little more would be produced and rates of loss would be governed primarily by the size and porosities of the particles (clumps) of biosolids on the soil surface in the field. Given that polymer was used to prepare the biosolids used in the NH case, those clumps would likely be relatively large and nonporous causing any emissions of volatiles to be slow and prolonged. Further, wind erosion of such clumps is slow at best. The slow breakdown of such clumps makes for reduced effectiveness of the plant nutrients in the biosolids, but also for minimal emissions of volatiles and wind erosion forces have to be severe to aerosolize infectious doses of pathogens, if there are even such numbers still present. New growth of soil microorganisms and regrowth of biosolids organisms could cause some emissions, but clumped lime-treated biosolids will not permit rapid growth. Consequently, Lewis, et al.'s presumption that microbiological process rates govern emission rates would be more reasonable for poorly treated or unconsolidated sludge, but not for biosolids, especially lime-stabilized biosolids with polymer.

Lewis, et al. divide the discussion of the results of their investigation into three sections: residents survey, environmental assessment, and prevalence of *Staphylococcus aureus* infections. In fact, the first two of

these are different approaches to analyzing the anecdotal data obtained from the residents survey. The third, along with parts of the first, is an unscientific extrapolation from medical records of some individuals among or related to the surveyed residents to conclude that there is a causal relationship between contact with biosolids or airborne components of biosolids and the occurrence of various infections, including especially *Staphylococcus aureus*.

The residents survey section of the paper presents an overall summary and analysis of the data obtained from the survey of the total of 48 residents at the ten locations in the study. Direct interpretation of the data did allow several seemingly legitimate conclusions to be drawn. All complaints were from individuals living "within approximately 1 km of the treated fields." The nature, prevalence, and time course of symptoms is summarized. Symptoms commonly reported after one hour of exposure seem consistent with airborne irritants or allergens. Within 24 hours of initial exposure more intense symptoms were reported. The onset of symptoms in one hour and worsening in less than 24 hours suggest irritants, toxins, or allergens as the likely cause rather than infectious organisms.

Up to this point the data, albeit anecdotal, are interesting, and the conclusions appear reasonable though there are some curiosities. The written record was not begun until two weeks after onset of symptoms, but time to onset of symptoms is specified to intervals of one hour. The NH data (written record) indicates initial symptoms did not occur until at least thirteen hours after exposure, while the general survey data indicated 25% of participants experienced symptoms within one hour of initial exposure. It seems unlikely to me that those who are providing information strictly from recollection would be so consistently able to recall such early onset when a written record indicates no such occurrence. Now, it could be argued that this delayed onset of conditions was because of wind conditions at the NH site delaying exposure after application of biosolids. The only predicted pollutant concentration data (considering wind, dilution effects) actually presented in the paper were presented in Figure 1. That figure indicates brief low level exposure around thirteen hours or so after application. However, the actual date of biosolids application[s] is not specified by Lewis, et al. Hence, the only legitimate conclusion is that a brief exposure occurred on 1 Nov 95. Thus, even if one accepts that the last major biosolids application occurred on 31 Oct 95, then exposures of likely (potential) symptomatic importance do not appear to occur until about 48 hours after application with prolonged exposures not until more than 120 hours after application. This weighs against the reliability of the general survey data and raises additional concerns as to how one should interpret the survey of NH participants' recollections of symptoms within 13-88 hours "after exposure."

There are other issues of concern with regard to Lewis, et al.'s interpretation of their NH data. Total data points (individuals) per household (mean) were 2 to 5. How was variability as presented in the report determined? Why were household means used instead of the 28 individual data points for which location information was available along with the added benefit of individual times to onset of symptoms? Why were there symptoms in the residences at 280 and 320 m distance after thirteen hours, but not until 21 to 88 hours in closer (23 to 170 m) residences? Why would the first symptoms have occurred in the residences farthest from the field?

Lewis, et al. then proceed to explore reports by 50% of the residents of "bacterial, viral or fungal infections within one month of exposure" [presumably exposure to airborne contaminants released from the applied biosolids]. The authors then proceed to present what they apparently regarded as scientific data regarding biosolids as the source and cause of staph (staphylococcal) infections.

Medical records indicated that *Staphylococcus aureus* (SA) infections were the most common, occurring in fourteen residents at three sites if the five PA site residents with SA infections are included. One should recall here that these five residents were included only because there was a SA "outbreak" near the PA site. The "outbreak" actually occurred in one house where eight of nine individuals residing in or frequenting the house 200 meters from the site developed SA infections over a period of five years while no infections were reported by residents in four other houses only 50 meters from the site. Lewis, et al. offer no reason or justification for assuming that eight SA infections over a period of five years in one house 200 m from the application site has anything to do with biosolids applications when no such infections occurred in four other houses only 50 m from the site. Lewis, et al.'s presumption would seem

to be even more unreasonable given that residents at the four other houses did recall respiratory symptoms associated with biosolids applications, but no infections. Finally, if there were respiratory symptoms among residents of the other four houses, why were not all five houses included in the general survey regarding health incidents associated with biosolids applications, especially since this was an agricultural site where repeated applications occurred and residents would likely have more reliable recollections of symptoms based on repeated experiences? Lewis, et al. cite the following as evidence, presumably "scientific," indicating widespread, presumably otherwise unexplainable SA infections in areas near the three relevant biosolids application sites.

<> "Affected residents in Greenland, NH recalled that respiratory infections experienced by individuals in several households treated by the same physician responded to erythromycin, an antibiotic primarily used for treating gram positive bacterial infections."

<> "In Menifee, CA two family members complaining of chemical irritation developed different staphylococcal infections. [One ... recurrent SA infections] of the nasal passages and oral cavity. The spouse was hospitalized for an invasive *S. epidermitis* infection that developed approximately two days after an undressed surgical incision became contaminated with sand blowing from an adjacent field treated with Class B biosolids."

<> In the same household, "Mild chronic maxillary sinusitis in one child ... deteriorated in recurrent bacterial infections" that did not respond to prolonged antibiotic and surgical therapies.

<> "Class B biosolids were applied to an adjacent field at the time the above mentioned illnesses developed. The pediatrician treating patients in the area (author C. Pumphrey) noted that children living near the application sites appeared to develop abnormally persistent sinusitis."

Lewis, et al. provide no reason to believe any of the cited infections were related to biosolids other than by coincidence. SA is one of the most common bacteria in the resident flora of the human skin; 15 to 30% of the U.S. population are carrying it at any given time. SA is the most common cause of skin infections, and toxins produced by SA are believed to be the most common cause of food poisoning (Wordnet.com, online; Merck Manual, 1997; J. Kipe-Nolt personal communications). Though a low level presence of SA can be reasonably anticipated in untreated sewage sludges, attempts to find SA in biosolids have failed (Rusin et al., 2003). Without providing definitive controls for background SA infection rates in the locales of the sites surveyed by Lewis, et al., and without eliminating other potential causes of the infections in the affected households, there can be no legitimate conclusion that biosolids applications were in any way related to the SA and other infection cases discussed. It is difficult to understand how citing such infections, which have numerous other equally or more credible explanations, can be legitimately suggested by Lewis, et al. as establishing a cause and effect relationship between biosolids application and human infections. It is also interesting to note that faculty colleagues of Lewis at the University of Georgia were concerned enough to publish a "clarification" article softening considerably the line of Lewis, et al. and that Lewis was the last listed co-author on that clarification article (Gaskin, et al., 2002).

4. Soil, water, air, plants and animals will be contaminated to dangerous levels. Biosolids have been used successfully on mine lands in PA for at least twenty years. The available records on water quality near these application sites indicate no contamination of water. Plants growing on soils treated with higher application rates than permitted on PA reclamation sites have shown only minor increases in some contaminant levels (Cox, 2002; Draeger, et al., 1999; Granato, et al., 2001). On the other hand, in some soils biosolids applications have actually been associated with reduced toxic contaminant levels in plants and soils (Shober, et al., 2002). Though there have been some experimental cases in which microbial or soil animal contaminant levels were increased by application of biosolids, the biosolids were exceptionally high in or intentionally spiked with soluble forms of the contaminants under study, or application rates were higher than allowed in actual use (Cela and Sumner, 2003; Chander, et al., 2001; Dahlin, et al., 1997; Diaz-Ravina, 1998; Fliessbach, 1994). My conclusion is the opponents have presented no evidence, and I have been unable to locate any, supporting this claim of biosolids application to mine lands causing pollution of natural resources.

5. Enforcement measures are inadequate. I find it somewhat disappointing, though true to form, that the opponents base their claims on work of others. The most direct, but least scientifically convincing, is that

of the Office of the Inspector General (OIG) of the EPA. The OIG concluded that the EPA did not have the means to enforce the 503's (EPA, 2002). The OIG based its determination that the EPA cannot be enforcing the 503's on an examination of the number of employees specifically assigned to biosolids enforcement in EPA headquarters and regional and state offices. This approach is inherently flawed for two reasons. All EPA biosolids enforcement work is administered out of EPA regional offices, not headquarters. Further, within the EPA and many state systems, biosolids enforcement is a function within the wastewater management office in each region and state. In most cases employees involved in biosolids enforcement activities will not have those activities explicitly denoted as distinct from their general wastewater management enforcement duties. Consequently, it has been contended that the OIG attempt at a head count of EPA employees dedicated to biosolids enforcement would necessarily not discover the amount of time employees actually spend on biosolids enforcement.

The National Research Council in its 2002 report concluded that there is no scientific evidence linking human illness to applications of biosolids, but pointed out several areas where additional work is needed to assure human and environmental health are protected by the 503's. To my mind, primary among their recommendations was the need for improved enforcement. The NRC reviewed information provided by the OIG and various other offices in the EPA and concurred with the OIG findings. Specifically, the NRC recognized the EPA management decision to allocate resources to highest priority needs first. Because of a good track record and apparently low risks associated with biosolids even assuming occasional violations of the 503's, biosolids are not a priority issue for the EPA. It is my impression that to a large extent EPA's priorities are set by or are in accord with the wishes of or directions from Congress, and are certainly circumscribed by the funding provided by Congress. The NRC reports, "Although more than 40% of the capital cost and the operation and maintenance expense of wastewater treatment is expended on biosolids treatment and management (much of which is federal dollars in the form of grants and low-interest loans), less than one-tenth of 1% of EPA's budget is devoted to the biosolids program. Of EPA's \$7.8 billion budget in FY 2001, only about \$4 million or 0.05% was devoted to biosolids staff and the program."

It appears to me that the discussed funding must not include wastewater management employees who, as previously mentioned, do biosolids enforcement and compliance work without being specifically marked as biosolids program employees. That seems likely to be the case, as \$4 million would only provide \$80,000 per state, enough to maintain, perhaps, one employee on staff per state. An average of one EPA employee per state responsible for oversight of all aspects of wastewater management, including biosolids, would seem an implausibly low budget. Regardless of how the head counts are made, the fundamental issue is whether there is widespread compliance with the 503's in actual land application projects. I have contacted EPA directly with regard to this question and was provided additional information.

There are apparently about 16,000 wastewater projects under the EPA's enforcement authority. There had been no attempt to keep a running account of the total number of complaint responses or enforcement actions taken by EPA's regional offices prior to the OIG audits and reports. EPA subsequently developed some retrospective estimates. From 1994-2000 there was a total of 558 enforcement actions taken by EPA. Many of those were regarded by EPA as minor violations of the 503's including, "failure to submit annual reports; use of inappropriate methods to analyze for pollutants; exceedances of Table 1 pollutant ceiling limits or Table 2 pollutant loading limits; discharge of sludge to a storm sewer; failure to demonstrate pathogen or vector attraction reduction requirements; improper sludge application." Presumably the exceedances mentioned were minimal as the EPA in cases of serious or egregious violations has continued its pursuit of cases to the point of criminal prosecution when warranted. In my efforts on this review project, EPA has been helpful and forthcoming whenever information has been requested.

It should also be pointed out that EPA depends largely on state agencies to handle permitting requirements and the bulk of biosolids enforcement. This appears appropriate in that state regs may be more restrictive than the 503's which were established as minimal requirements all producers of biosolids must meet, and, hence, no federal permit is required. Consequently, it seems reasonable that the entity whose regulations are likely to be most easily violated should be the more attentive to enforcement. Not

all states make strong efforts in this regard, however. Fortunately, Pennsylvania is one of the states with an active biosolids program, with twelve full time employees. Only four states have such a dedication of state personnel. In Pennsylvania, at least, it does not appear that biosolids enforcement is so lax as the OIG and NRC reports seem to suggest might be the case. Indeed, despite over ten years of experience of biosolids management under the 503's, the NRC report and this review still confirm that exposure to inadequately treated sewage sludge can cause disease, but no evidence has yet surfaced that supports exposure to biosolids causing disease. Given that over three million tons of biosolids are land applied each year and thousands are directly or indirectly exposed, it seems highly likely that either or both of two conditions must currently exist: first, the 503's are protective of human health and, second, unsafe violations of the 503's are not slipping through the current enforcement system. (There are a couple alternative explanations, one fairly unlikely and the other unreasonable. It is fairly unlikely that the 503's are excessively protective and unrecognized violations are occurring, but there are no noticeable impacts and, therefore, violations remain unnoticed. It is possible but unreasonable that the 503's are not protective or that violations are frequent, that impacts are substantial in number, but no one is noticing or reporting the resulting problems.)

Pathogen Reduction and Microbiological Quality Assurance Issues

Still, the enforcement issue is not so easily left. My 1994 review of the 503's pathogen reduction requirements and problems related to confirming compliance are still present in the system. This was confirmed by various findings and recommendations in the 2002 NRC report. Now, as in 1994, I am scientifically comfortable with the adequacy of the various requirements of the 503's with respect to assuring human and environmental health when biosolids are applied to land. I remain troubled, however, by the same two points as in 1994: there are weaknesses in the 503's pathogen reduction requirements and enforcement of those requirements is retrospective. It could and has been asked, given current apparent effectiveness of the 503's requirements and current enforcement efforts, what is to be gained from pursuing these two points? The response is, improved, more assured compliance with pathogen reduction requirements of the 503's and documentation of evidence of biosolids safety that can be publicly presented and understood.

The 503's provide that pathogen reduction requirements can be met for Class B biosolids by certification of treatment by a Process to Substantially Reduce Pathogens (PSRP) or by laboratory determination that fecal coliform (FC) levels are below 2 million colony-forming units (CFU) or most probable number (MPN) per dry gram of biosolids (geometric mean of seven samples). [CFU and MPN are the reported units for two different methods of determining fecal coliform levels. MPN is more sensitive and reliable for biosolids, but the 503's provide for acceptance of results obtained by either method.] PSRP certification is the sole responsibility of the biosolids generator. Certification is given for meeting sludge residence time and temperature requirements for a specified type of digester (EPA, 1992). Meter errors, material "short circuiting" through the digester, or operational errors that reduce residence time in the digester or cross contaminate treated with untreated materials can cause non-PSRP material to be certified PSRP. These types of problems have occurred. The PSRP certification requirements of the 503's would allow such violations to be identified, but only in retrospect and in most cases after the non-PSRP sludge has already been applied.

Alternatively the fecal coliform levels can be determined and material is Class B if levels are below 2 million CFU or MPN/g. The Class B by FC standard provides a means for assessing pathogen reduction for materials treated by methods other than PSRP. Measurement of FC is not required for material certified PSRP, but it is the only method by which proper function of a PSRP can be reasonably assured. [Most fecal coliforms are not pathogens, but the method is well established and most pathogenic bacteria are less robust than FC. Consequently, if FC levels have been reduced, it is reasonable to believe that pathogen levels have been reduced as much or more.] Interestingly, some large municipal generators have been running FC determinations on their PSRP Class B biosolids since at least the promulgation of the 503's. The Philadelphia Water Department (PWD) is one such generator.

I requested an opportunity to review the FC results for PWD Class B biosolids as part of the information gathering component of this project. I have reviewed the individual sample FC data for Mar 2003-Feb 2004 and monthly geometric means (seven samples) for 1994-1996. I found only two exceedances, one in 1994 and one in 1996. It was reported to me several operational improvements were made in 1996 and there have been no exceedances since. In fact, almost all were lower than the Class B limit by a factor of 10 or more. This supports two points. The PWD Class B biosolids are very consistent and of high quality. Properly functioning PSRP digesters typically provide biosolids with FC levels considerably lower than the 503 Class B limit. These facts suggest that biosolids from a routinely well-operated treatment facility will likely be even safer than the 503's actually require. On the other hand, it takes time (24-48 hours) to sample and determine FC in a batch of biosolids. Given the operational pace of most POTWs, a 24-48 hour hold on each volume of product biosolids to test FC levels could be a major operational obstacle. Hence, under the 503's FC measurements, like PSRP certification, actually function typically as retrospective verifications of compliance or noncompliance. This retrospective verification approach is the only obvious flaw I have observed in the safety assurances provided by the 503's (and PA271). In effect, the process and retrospective verification approach allows for sludges that have not been adequately treated to be applied to land and not detected until lab results are returned and reviewed. In practice the only likely consequence for the generator/applicator will be an inquiry by the EPA or state authority when required reports are filed. This does not strike me as an effective way to build public confidence in the monitoring and control effectiveness of the current 503's based regulatory system.

Biosolids generators have a reliable quality assurance tool in FC determinations and are missing the opportunity to use it. Routine and relatively frequent FC determinations would provide valuable insights into the operational consistency of a POTW's digesters. Additionally if the routine determinations could be applied in conjunction with a holding period of appropriate length (sampling and analysis time), the likelihood of inadequately treated sludges being applied would decrease substantially.

It is my opinion that routine FC determinations prior to application would be perceived by the public as a demonstration of good faith and confidence of the generator in its own product biosolids and an assurance that the biosolids being applied are not "loaded with pathogens" as opponents claim. I believe a substantive increase in public confidence would result if frequent FC monitoring were routine and openly reported. For municipalities that have their own water quality laboratory currently running routine FC determinations, such as Philadelphia, development of a frequent sampling and analysis schedule would presumably not present major additional costs. Whatever the costs, they would likely be more than compensated by the public confidence improvements and public relations benefits to be gained.

I have been surprised to find that some generators and staff of regulatory agencies are reluctant to determine FC levels on PSRP certified biosolids. This presents some difficulty as it suggests that the generators and regulators either have little confidence in the quality of Class B biosolids or believe the 503's standards unreliable or unreasonable with respect to actual function of PSRP digesters. With regard to public perception it matters little which of these is actually true. Similarly it is my opinion that it matters little that the public is not aware of generators' or regulators' doubts about the 503 FC levels requirements. The lack of confidence is perceivable without specific knowledge of the cause or basis of the lack of confidence.

It has been my impression that the hesitation of generators and regulators about FC results derives from the effective lack of broad-based empirical or experimental data to support the 503 FC standard. I have had occasion to review FC data for a dozen or so major POTWs (New York City and Philadelphia). All the data I have seen indicate that normally operating PSRP digesters will provide considerably better pathogen (actually FC) reduction than required by the 503's. It was my understanding in 1994 that no experimental FC data or compilation of FC results for operational digesters were available at that time. Apparently this is still the case and a generator or regulator speaking on this subject has little to support the position other than the information associated with the 503's. It is my understanding that there are some experimental PSRP units being developed that will provide FC data. I have been unable to discover any work, planned or in progress, to make use of the likely substantial data sets already

accumulated by larger POTW's. Such a data compilation and analysis should be undertaken and results published.

Potential for Growth/Regrowth of Fecal Coliforms and Pathogens

An additional concern has been expressed that pathogens might regrow if Class B biosolids are stored or spend time in prolonged transit. There is no microbiological reason to expect pathogen or FC regrowth in stored biosolids that have been adequately digested. During proper PSRP digestion of sewage sludge all decomposable materials in the sludge are microbially processed. Basically that process entails one set of microorganisms eating another, a version of a predator-prey relationship. The predators convert the prey cells into their own cells. Those predator organisms then become prey for another kind of predator and are consumed in turn. This continues until nearly all the food energy that can be extracted from the original material is gone. This process causes FC and pathogen cells to be replaced by cells and residues of other nonpathogenic decomposers. Once the level of decomposition that occurs under PSRP digestion is reached, there is little left for pathogenic organisms to eat. Hence, properly digested Class B biosolids should not be expected to support regrowth of pathogens.

There are exceptions to this reasoning. If the Class B biosolids are contaminated with raw organic or sewage materials or if the storage or shipping conditions are not reasonably similar to conditions inside the digester, then there will be opportunities for other organisms to use the remaining "food" supplies in Class B biosolids. Most digesters are mesophilic (20 to 35 degrees Centigrade) and anaerobic. Thorough aeration of biosolids will open biochemical pathways not open under anaerobic conditions. Hence, aeration of anaerobically digested biosolids would likely stimulate regrowth of organisms already present and capable of living in an aerobic environment. Preliminary data out of Indiana indicates that biosolids from thermophilic (35 to 55 degrees Centigrade) anaerobic digesters supported regrowth of fecal coliforms to very high population levels. This was reported in the last week of Feb 04. I do not yet have details, and it is reasonable to presume that regrowth occurred because of a shift to mesophilic or aerobic conditions. It should be kept in mind that regrowth by FC does not necessarily imply regrowth by pathogens. Regardless, in most cases biosolids are shipped in large volume containers that assure anaerobic conditions inside the bulk mass of biosolids until field handling begins. Subsequent to field handling environmental conditions (exposure to sunlight, drying conditions, competition from soil microflora, etc.) are not favorable to pathogens.

Biosolids Product Stability: Class A vs. Class B

Finally the issue of relative safety of Class A and Class B materials is worth considering. Class A biosolids are treated to effectively kill nearly all active microorganisms present in the treated sewage sludge. Class A biosolids meet stricter microbiological standards than Class B, but are not typically digested prior to being treated to Class A standards. Undigested sludge treated to Class A standards is effectively free from pathogens, but actually contains many more, and more readily utilizable, nutrients to support regrowth of FC and pathogens, if any remain or are reintroduced. This was recognized during development of the 503's and resulted in requirements that generators monitor Class A materials for regrowth until the latest practical time before application to land, release for use, or bagging (EPA, 1992). It is interesting to note that despite the EPA concern about regrowth, there is apparently a widely held misconception that Class A biosolids are necessarily safer than Class B.

If Class B biosolids are additionally treated to meet Class A standards, the result will be highly refined, safe, high quality material (PWD compost is so treated). On the other hand, sludge nonbiologically treated (by heat/alkali, or radiation) directly to Class A standards will be "hot," receptive to rapid infection, and capable of supporting rapid growth by almost any microorganisms that come into contact with it. Class B biosolids, especially those undergoing digestion to the FC levels that are consistently being achieved by the PWD, will be less receptive to and supportive of FC and pathogen regrowth than sludges nonbiologically treated directly to Class A standards. When the issues of preferability of Class A or Class

B for use on local lands are being considered, concerned parties should look into the costs of further treatment to Class A relative to the effective value of biosolids already produced by direct treatment to Class A or digestion to Class B. If choices of materials are available, and treatment methods are the same, that is, heat/alkali to Class A or Class B, then Class A is the more reliable material. If Class B is created by thorough digestion and Class A by heat/alkali treatment, Class B may be the better choice. If available, Class A by composting will generally be the best biosolids product for most soil amendment or land application uses.

Matters Left Unaddressed by This Review Project

Time and resources available to this review project did not allow consideration of all matters of potential interest with respect to conflicts and controversies over beneficial uses of biosolids. Two areas, however, bear mentioning as I close this report. One is that the science that appears to support the safety of land applications of biosolids is not always without fault. The other is that there may, in fact, be secondary health benefits from exposure to biosolids.

It was not my intention in the preceding criticism of the Harrison and Oakes (2002) and Lewis, et al. (2002) reports to leave an impression that science which has been done and reported as supporting the safety of land applications of biosolids is without fault. Errors in scientific work and reporting are, in fact, common. That is why science involves repetition of the same work by different scientists, to assure errors are discovered before conclusions are drawn. In fact, most of the scientific results indicating land applications of biosolids are safe are of high quality. Recently, there are indications that some scientists are becoming preoccupied with supporting the safety of biosolids rather than attempting to scientifically pursue reliable data and follow that data to logical conclusions, whatever they may be. Illustrative of this are the papers of Dowd, et al. (2000), Kuchenrither, et al. (2003), and Rusin, et al. (2003). The scientific work of Rusin et al. is of high quality, but the choice of wording in the title is clearly not scientifically valid. "Evidence for the Absence of *Staphylococcus aureus* in Land Applied Biosolids" suggests that a scientific effort was undertaken to prove that a condition did not exist. As discussed previously in this report, science cannot prove that something does not occur, only that it occurs too rarely to be measured, which, despite the title chosen by Rusin, et al., is what they accomplished.

Dowd, et al. (2000) reported results of their efforts to use computer modeling to estimate the chances of infection associated with land applications of biosolids. The results reported by Dowd, et al. (2000) indicated that the chance of infection approached 100% for an individual within 100 meters downwind of an application for eight hours, and that the probability of infection is not negligible even at distances as great as 10,000 meters from the application site. These results are obviously nonsensical. If they were correct, numerous serious illnesses would have been observed among biosolids workers and neighbors of virtually every biosolids application site, even miles from the site itself. When I made comments to this effect, the report was defended to me as a legitimate publication of scientific work. I was and remain unable to understand how this paper passed scientific peer reviews, assuming, of course, that it was reviewed before publication. Papers submitted for publication by widely recognized scientists are often subjected to less rigorous reviews than publications by lesser known scientists. This faith that widely recognized scientists always produce reliable results is suggested by the fact that Kuchenrither, et al. (2003) cite the Dowd, et al. paper as indicating that biosolids applications are safe. This is effectively an erroneous endorsement of obviously erroneous results presumably based on the notoriety and reputation of the scientists involved in the work as competent and consistently supporting biosolids utilization. While I was writing this report, I was informed that other negative comments had been received about the Dowd, et al. report. Pursuant to those comments, closer scrutiny by the Dowd, et al. authors had revealed an error in an equation had caused the initial estimates of chances of infection to be at least 1000 times higher than they should have been. Such an error during scientific work is not troubling. However, it is troubling that the science "system" failed to discern the results were unreasonable prior to publication and cited the erroneous results as reliable and meaningful, and that supporters of biosolids were willing to invoke results indicating biosolids applications are not safe as indicating that they are safe.

Again, the scientific information and data indicating that land applications of biosolids are safe are numerous and generally of consistently high quality. My concern in discussing the Dowd, et al., Kuchenrither, et al., and Rusin, et al. papers is to point out that as the conflicts over biosolids have become more intense, and the opponents more vocal, reputable scientists have begun to relax their scientific rigor in the interest of countering the opponents of biosolids applications. This is an unfortunate trend and one which will hopefully be recognized and reversed. If it continues, science will necessarily become less scientific and the value of scientific findings to resolution of conflicts over natural resource issues will be seriously diminished.

I have, also, made no attempt to address potentially positive health effects of exposure to biosolids, sludge composting operations, or bioaerosols from either. The Primary Hygiene Theory is gaining credibility among physicians. The theory holds that the human immune system needs to respond to nonlethal exposures and infections in order to function at full capacity and effectiveness against more serious diseases. It is not unreasonable to suggest that judicious use of biosolids, especially Class B, might provide an environmentally non-life-threatening exposure to common, infectious microorganisms of limited pathogenicity. There are, also, preliminary epidemiological results that recurring exposure to bioaerosols that carry endotoxins may prevent lung cancer (Lange, et al., 2003). Preliminary studies show that lung cancer occurs at much lower rates among workers in environments where bioaerosols carrying endotoxins are present. Even workers who smoke benefit from the exposure. There are hypothetical explanations for the effect which is suspected to be actually because of exposure of the lung tissues to low, intermittent doses of endotoxins. No definitive data have been developed yet. Though very interesting in the broad sense, I do not believe that these theoretical benefits of exposure to common infectious organisms and endotoxins should be part of an effort to raise public confidence in the value, reliability, and benefits of land applications of biosolids at this time.

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Compiled Literature and Information

Regarding newspaper and other popular or journalistic articles: In 2002 the Pottsville Republican and Evening Herald alone published at least 57 articles related to biosolids applications in Schuylkill County and surrounding areas. Additional articles have been published since 2002, undoubtedly some of which I have not reviewed. At the time of preparation of this report all of the reviewed articles could be accessed through www.republicanherald.com or using commonly available search engines for other sources. A tabulated list of the 57 Republican & Herald articles is attached to this memo.

Some of the literature in the following list was provided in digital form by email, intact without information on original or secondary sources. Readers who wish to consult such documents included below or referred to in the report can contact the author, Bryce Payne, or the Schuylkill Headwaters Association.

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