Demystifying the Great Biosolids Debate

Sound science removes emotion from decisions about biosolids recycling.

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The beneficial recycling of biosolids as regulated by the U.S. Environmental Protection Agency's (EPA) Title 40, Part 503 regulation, has been the focus of a contentious debate over the past several years. Wastewater treatment directors and other public officials responsible for regulating biosolids facilities have fielded complaints from a few vocal critics and some facility neighbors in California, New England, Pennsylvania, Virginia and other areas of the country. Allegations have focused on potential health effects of exposure around points of biosolids generation, composting facilities and land application sites.

On the federal, regional and local levels, these health concerns occasionally have dominated debates over siting, permitting and management of biosolids facilities. These concerns have been exacerbated by media reports on alleged health effects that are attributed to biosolids exposure by activists and other detractors. In the view of the biosolids industry, EPA, the Water Environment Federation (WEF) and the Association of Metropolitan Sewerage Agencies, much of this media coverage is fraught with scientific inaccuracy, conjecture and emotion.

While the debate continues, EPA maintains that when managed according to federal and state regulations, "the treated residuals from wastewater treatment, or biosolids, can be safely recycled." (See www.epa.gov/owm/bio.htm.) Both EPA and WEF also make a compelling case for biosolids recycling, and in the most recent Office of Inspector General Status Report on the land application of biosolids issued March 28, 2002, EPA reiterated its strong support. (See (www.epa.gov/oigearth/ereading_room/BIOSOLIDS_FINAL_REPORT.pdf.)

While helping local governments meet the challenge of managing wastewater treatment residuals, biosolids provide a nutrient-rich, organic fertilizer that reduces use of chemical fertilizers. Other benefits include cost savings to communities; reduced fertilizer costs and increased crop yields for farmers; strip mine reclamation uses; and less erosion and leaching of treated soils,

helping to protect groundwater and surface water quality. Biosolids recycling also saves landfill space and reduces energy consumption.

This article will introduce the best tools for evaluating allegations of public health effects from exposure to biosolids. Three case studies drawn from recent claims of exposure to biosolids also will illustrate real-life application of the principles of causation science. The first involves an allegation of biosolids-associated mortality. The second and third involve claims of health effects associated with ammonia emissions from biosolids. The results of these case studies show that exposure to biosolids, a natural byproduct of the wastewater treatment process, did not cause the health effects that were claimed.

Causation science and risk assessment

Critics have claimed biosolids facilities and operations are responsible for a litany of health effects ranging from headaches and nose bleeds to even death. Detractors who would derail biosolids programs have leveled claims that implicate pathogens and gases as potential causative agents of disease. These allegations have never been scientifically validated or proven, and when examined under the standard scientific protocols for causation analysis they are revealed as meritless.

For more than 100 years, scientists have been applying causation criteria to claims that materials in the environment cause illness. This article will introduce the Bradford Hill criteria, Koch's postulates and risk assessment concepts and discuss their application to actual land application scenarios.

Epidemiologic causation—In 1965, Sir Bradford Hill developed the first general criteria for evaluating causation in epidemiologic studies. The Bradford Hill criteria today are viewed as the cornerstone of sound science for demonstrating a causal connection between an environmental agent and health effect. When evaluating claims associated with alleged exposure to biosolids, analysts first determine whether the exposure caused the disease. Causation may be thought of as a chain of events that links an injury to toxic substance or pathogen exposure and which must not be broken for causation to be demonstrated.

Exposure analysis is based on measuring chemical and biological concentrations in humans and the environment, mathematical modeling and gathering reliable evidence both from individuals who may have been exposed and a non-exposed control group. Once exposure has been determined, a toxicology/microbiology/epidemiology review is conducted to determine if a health hazard exists. The health hazard is then linked to the exposure through risk assessment concepts such as dose-response quantification. Finally, potential alternative causes of the illness are considered. If proven exposure to a disease agent at levels sufficient to elicit an adverse health effect not explainable by other causes is identified, it can be causally linked to the disease.

In addition to individual criteria, epidemiological criteria for causation include the numerical strength of association between exposure and health effect, consistency of human associations among populations, and agreement with experimental evidence (from animal studies). Another criterion common to both individual and epidemiologic causation is that of scientific coherence. In essence, coherence means that the results of the study are in agreement with accepted views and established scientific method.

Microbiological causation—Infectious diseases are a significant cause of morbidity and mortality in the United States. While millions of infectious disease cases are reported annually to the Centers for Disease Control and Prevention, most mild cases such as common colds, mild influenza and mild gastroenteritis go unreported. Moreover, many claims regarding potential illness associated with alleged exposure to biosolids may be attributed to common infectious diseases that are caused by numerous sources of household, public and environmental exposure.

A case in point comes from the National Institute of Occupational Safety and Health (NIOSH). The NIOSH Hazard ID (HID-10) report, issued July 28, 2000, addressed complaints of gastroenteritis by five wastewater treatment plant workers in LeSourdesville, Ohio. The workers' symptoms were similar to those associated with infections caused by common bacteria such as Shigella, Salmonella and enteropathogenic E. Coli species. Given the common nature of most of the diseases and the ubiquitous presence of microorganisms in the environment, the question of causation between a microbial pathogen in biosolids and an illness is a critical one. In the end, NIOSH acknowledged it was unable to attribute the workers' symptoms to biosolids exposure. HID-10 is now being re-evaluated and many observers anticipate that it will be withdrawn.

The subject of microbial causation of disease was first addressed by Robert Koch in 1884. There are several keys to the application of Koch's Postulates, as they are known today, to claims of illness. First, the illness must have an infectious etiology. Claims of cancer, cardiovascular disease and reproductive effects are not likely to be of microbiological origin whereas claims of gastroenteritis and upper respiratory illness may well have an infectious source.

Second, an actual microorganism species must be identified using standard protocols. Normally this involves obtaining a sample from the patient, which is cultured and tested. At a minimum, testing should involve morphological and biochemical testing. To avoid ambiguity, most contemporary forensic investigators rely on DNA identification of microorganisms. Once an exact microorganism has been identified in both the potentially infected individual and possible source, the information may be used in the context of a quantitative microbiological risk

assessment. Without scientific identification of a specific pathogen in the infected individual, allegations that an illness is linked to a microorganism that can be found in some biosolids are baseless.

Risk assessment—This process combines scientific information to determine the probability that exposure to an agent will result in an adverse effect. Many scientific concepts of risk assessment are linked to the concepts of scientific causation noted above.

Independent scientists and regulatory agencies have used health risk assessments since the mid-1970s to assess and regulate chemicals in the environment. EPA's 503 regulations governing the management of biosolids are based on a multiple-chemical, multiple-pathway risk assessment. Probably the most fundamental concept of contemporary risk assessment is the dose-response relationship. Simply put, the probability or severity of an adverse effect is related to the amount of exposure to the agent causing the effect. For most effects and most chemicals, a toxicological threshold exists. Exposure to levels below this threshold will result in no adverse effect. Exposure above the threshold indicates a progressively higher probability of an adverse effect.

Instances involving alleged mortality

The media has reported three deaths of individuals following alleged exposure to land-applied biosolids. Application of the basic scientific principles discussed above demonstrates that these deaths cannot be linked to land application of biosolids.

In New Hampshire, a lawsuit known as the Marshall case involved an individual who died in 1995 approximately one month after Class B biosolids were applied to a field near his home. The plaintiffs' key expert, an EPA microbiologist and longtime biosolids opponent on whose theories the case was developed, was unable to establish a scientific link between biosolids and the fatality. Plaintiffs alleged that the individual's death was linked with airborne exposure to an unidentified pathogen following sensitization with ammonia. In the end, the plaintiffs acknowledged the lack of scientific support and in January 2002 agreed to settle.

In the Marshall case, the New Hampshire acting chief medical examiner, after conducting an autopsy, found no cause of death. In the context of causation, this basically breaks the first link in the chain. Without a cause of death, there is no identifiable disease or injury and thus, there can be no causation. Mere proximity to a land application site does not meet criteria for exposure assessment. Significantly, the New Hampshire Medical Examiner's Office also ruled out biosolids as a factor in the fatality. A differential diagnosis performed by two pathologists showed that the individual's death probably was associated with a sudden cardiac event.

The second instance involved an individual who died in 1994 several weeks after allegedly traveling near a surface mine reclamation site in Rush Township, Penn., where biosolids had been applied. The same plaintiffs' expert who was used in the Marshall case theorized that exposure to lime and ammonia in the biosolids opened a pathway for an infection that resulted in the fatality.

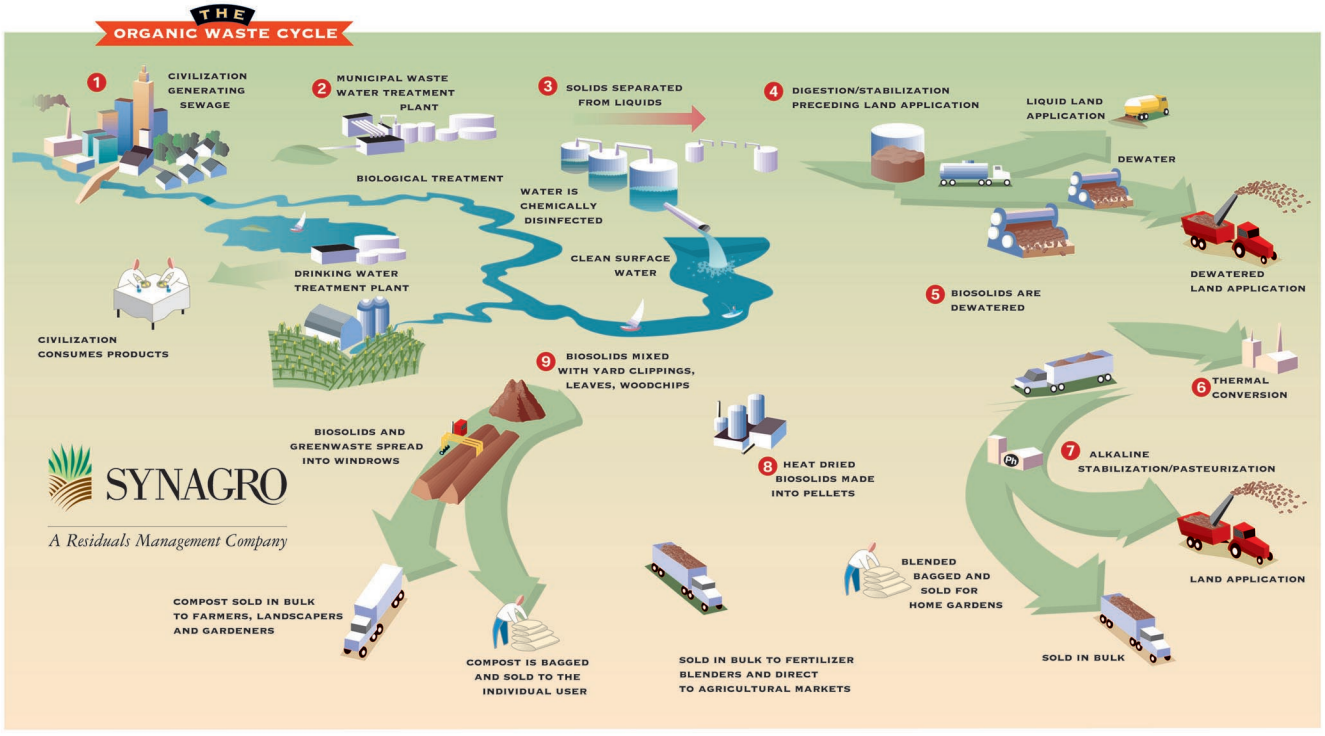
The Pennsylvania Departments of Environmental Protection and Health extensively investigated the individual's death. The results confirmed that he died of an infection caused by a pathogen common in the everyday environment but not known to survive in biosolids. Environmental and health officials concluded in May 2000 that there was "no medical or scientific evidence that [the] death was linked to any contact with the biosolids." Additionally, the biosolids in question were anaerobically digested, not lime-stabilized. This directly refutes claims by the expert.

The third alleged mortality linked to biosolids involved an individual who lived near a land application site in Heidelberg, Penn., but whose cause of death in 1995 could not be causally linked to biosolids exposure. These cases and other allegations of illness from biosolids often rely on an assumption of exposure to bioaerosols from land application sites. However, the literature also fails to support the hypothesis of airborne transmission of pathogens from land-applied biosolids. For example, in the LeSourdesville study, the total heterotrophic plate counts at the land application site reported by NIOSH at the land application site were typical of background levels in untreated fields. Salmonella, indicator organisms and coliphages were not found in the air downwind from a land application site. Thus, the hypothesis that the individual's death was associated with airborne pathogens lacks scientific coherence.

Instances involving exposure to ammonia

In the Marshall case, the plaintiffs alleged that exposure to toxic gases, primarily ammonia and dimethyldisulfide, was a precipitating factor in the illness and death. The plaintiffs stated that the deceased was exposed to 260 ppm of ammonia and between 24 ppm and 110 ppm of dimethyldisulfide emitted from lime-stabilized Class B biosolids over the period of a month. When this research was analyzed, it was found to be based on an unsubstantiated assumption of a steady-state, month-long concentration of 1000 ppm ammonia in the air over the land-applied biosolids. It was also based on inaccurate air dispersion modeling and inappropriate assumptions regarding exposure.

Such a claim fails to meet the scientific criterion of coherence. Clinical or epidemiological studies in which exposure to gases from land-applied biosolids resulted in an illness or fatality are not found in the literature. In addition, the theory that exposure to a reactive gas such as ammonia can predispose an individual to infectious disease has been reported only in cases where there is trauma to tissues and a corresponding reduction in defenses



against infection. No trauma associated with massive ammonia exposure, such occurs in farm fertilizer accidents, was observed during the autopsy in the Marshall case.

Finally, this claim lacks plausibility. Concentrations of ammonia this high have never been reported at land application sites, and simple mass balance calculations demonstrate that there was insufficient nitrogen in the biosolids to result in the emissions of ammonia as claimed. The author of the publication relied on by the expert rejected this interpretation and calculated that a maximum ammonia concentration over the land application in question would not exceed 3 ppm based on a mass balance.

This type of problem is amenable to classical risk assessment techniques. The chemicals of concern in the Marshall case already had been identified by the plaintiffs to be ammonia and dimethyldisulfide. For purposes of this analysis, we will limit discussion to ammonia, as the plaintiffs' key expert claimed it was present at much greater levels than dimethyldisulfide, and the expert has emphasized ammonia as a risk from biosolids. The risk assessment consisted of an analysis of the source and emissions of ammonia, an exposure assessment and a comparison to toxicological thresholds.

Emissions of ammonia from the land-applied biosolids were calculated using a mass balance approach. Information from the literature indicated that application method, pH and temperature were significant factors in determining volatilization; as such, they were used in the mass balance modeling. In addition, other research shows that emissions of ammonia from land-applied biosolids follow an exponentially declining emissions curve.

Based on a mass balance and the methods reported in the literature, a maximum emission rate for ammonia from the biosolids in question was calculated to be 18.7 µg/m2/sec for the first 12 hours following application. As anticipated based on literature reports, this rate declined exponentially. By the fifth day, for example, the emission rate was 4.2 µg/m2/sec and after a month it had dropped to 0.4 µg/m2/sec.

The exposure assessment used the mass balance emission rates as an input to EPA's Industrial Source Complex–Short Term air dispersion model. Site-specific meteorological data were used to yield the most reliable estimates of exposure. Concentrations of ammonia at the individual's residence were modeled for a month preceding his death. The maximum modeled air concentrations of ammonia at the individual's residence were 0.012 ppm for a 24-hour value and 0.080 ppm for the one-hour maximum value. For the entire exposure period, the concentrations for the one- and 24-hour concentrations were four-to 17-fold lower than the maxima.

Toxicological dose-response data for ammonia exposure have been developed by a number of regulatory and public health agencies. The American Industrial Hygiene Association (AIHA) developed threshold concentrations for short-term exposure. In this context, AIHA reports that any individual, including an especially sensitive individual, can be exposed to 25 ppm of ammonia without experiencing other than mild health effects or a transitory odor. All of these dose-response concentrations are orders of magnitude higher than even the maximum predicted

ammonia concentrations at the individual's residence.

Based on this analysis, which was conducted using currently accepted risk assessment techniques, it can be concluded that the individual's exposure to ammonia was well below a toxicological threshold. In the context of causation, ammonia could not have caused the claimed health effects alleged by the Marshall case's key expert.

Scientific conclusions

Widely accepted and applied scientific criteria and methods exist for evaluating the alleged links between exposure to a chemical or microbiological agent and putative adverse health effects. When these rigorous methods are applied to allegations regarding land-applied biosolids, it is found that the claims fail to demonstrate causation.

Scientific methods must be understood and employed to assess causation in the potential health effects of biosolids exposure if the often-sensationalized debate is to be redirected toward solutions that are productive and reflective of the information available on public health and safety. The biosolids industry, EPA, WEF and other respected organizations are obligated to provide the best information on these scientific methods.

Stakeholders also must be better informed about the regulatory review process establishing federal and state rules. Several modifications and revisions have taken place to the1993 40 CFR Part 503 regulation governing biosolids management. Development of these risk-based rules included a precedent-setting review of extensive university and field data by scientists independent of EPA. At EPA's request, the National Academy of Science (NAS) is reviewing biosolids management practices to determine any need to revisit the regulations. An earlier NAS-National Research Council evaluation in 1996 found that the use of biosolids on food crops posed "negligible risk" to human health.

EPA also supports development by the National Biosolids Partnership (NBP) of a national information network for local governments to learn about responsible biosolids management practices and materials. The NBP recently developed an environmental management system (EMS), a set of voluntary procedures for demonstrating to local governments environmental performance and management practices. (For more on the EMS, visit the NBP's Web site at http://www.biosolids.org.)

Despite the often emotional debate over biosolids, the availability of sound scientific information and progressive practices such as the EMS, coupled with the recent positive legal and regulatory rulings, appear to be successfully conveying the facts about human health, safety and environmental benefit. Today, thousands of municipalities are safely land applying biosolids or otherwise recycling their wastewater treatment residuals using innovative technologies and responsible management practices. **PE**

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