

California at Berkeley, and Eisenberg, Olevieri and Associates. The document describing this research also presents a methodology for assessing exposure and risks to human health from pathogens in biosolids. The present methodology provides initial screening for a given scenario, identifies broad conditions for high and low risk situations, and estimates where more data are needed. Future work (beyond 2004) may focus on applying this methodology to more refined scenarios. Such validation activities will assist EPA in developing microbial risk assessment guidelines, subject to available resources.

Potential future pathogens activities will include analytical methods development, exposure and risk assessment. The Agency is also considering continuing site-specific evaluations of current treatment and land application processes, studies of wastewater treatment sludge stabilization during biosolids production to reduce odors and vectors, and the use of pilot-scale treatment units to optimize sludge treatment techniques for pathogen and chemical control.

F. Human Health Studies

1. Summary of Human Health NRC Recommendations

The NRC recommended that the Agency conduct response incident investigations, targeted exposure surveillance, and well-designed epidemiological investigations of exposed populations. Data from these studies would be used to provide a means of documenting whether health effects exist that can be linked to biosolids exposure.

The NRC also recommended that preplanned exposure assessment studies characterize exposure of workers and the general public who come into contact with biosolids either directly or indirectly. Such studies could include the identification of microorganisms and chemicals, the selection of measurement methods for field samples, and the collection of adequate samples in appropriate scenarios.

Further, the NRC recommended that epidemiological studies of biosolids use be designed to provide evidence of a causal association, or lack thereof, between biosolids exposure and adverse human health effects. These studies could include an assessment of the occurrence of disease and an assessment of potential exposures. Because large scale and comprehensive epidemiological studies are expensive and require extensive data analysis,

priority could be given to studies that can help reduce uncertainty.

2. The Agency's Response to the Human Health Studies Category

How EPA Plans To Address NRC Human Health Studies Recommendations

At this time, the Agency does not plan to conduct an epidemiological study, as discussed in the NRC report. As noted by the NRC, comprehensive epidemiological studies are complex, time consuming, and require substantial additional funding. The Agency may assess the future need for epidemiological studies, but believes targeted human health studies (e.g., those of focused scope, such as exposure to pollutants via aerial transport and incident investigations) over the short-term might better address potential human health impact and persistent uncertainties surrounding exposed populations. These studies could help assess the potential airborne exposure to pollutants and could help determine whether incidents are occurring following biosolids exposure. Targeted exposure and human health studies could also help inform the design of any future epidemiological studies, should they prove necessary. Results from targeted studies would also allow the Agency to communicate with other public health-based federal agencies regarding human health exposure and epidemiological studies.

Planned Human Health Activities

Targeted Human Health Investigations: The Agency's primary objective is to characterize pollutants and microbial agents present in biosolids, as well as any associated human exposure pathways, that may have the greatest potential to adversely impact human health. Specifically, the NRC sees an immediate need for a systematic approach for investigating claims of disease or illness following biosolids exposure. Regulators, sewage sludge processors, and land appliers must be capable of responding rapidly to such reports. The Agency is investigating the possibility of developing a process for timely notification, recording, and tracking incident reports in collaboration with the Centers for Disease Control and Prevention (CDC). The Agency has initiated preliminary discussions with the CDC to discuss possible mechanisms for recording and tracking biosolids related disease incidents.

The University of Arizona's National Science Foundation, Water Quality Center, may also join cooperatively in

the USDA/EPA/State of PA study to evaluate risk from exposure to pathogens, particulates, endotoxins, and odors from farm fields and other agricultural and silvicultural settings upon which biosolids, animal manures, and other organic amendments have been applied. These cooperative studies will evaluate various application sites, terrain, climate, placements of receptor populations and downwind ambient air concentrations of pathogens and volatile organic chemicals near residents. The Agency plans to evaluate if the collected data can be used to develop models for estimating exposure of human populations downwind of these sites, which might then be used in predictive risk assessment applications.

G. Regulatory Activities

1. Summary of Regulatory NRC Recommendations

The NRC recommended that EPA revise or develop regulatory criteria for biosolids in a timely fashion and identify additional regulatory mechanisms to better protect human health and the environment from the exposure to land-applied biosolids. This recommendation includes the following components: a review of biosolids protocols used by other nations, adoption of national standard treatment design criteria, a refinement of stabilization controls correlated to outcomes using metabolic techniques, development of molybdenum standards, development of a quantitative microbial risk assessment (QMRA) to establish regulatory criteria for pathogens, studies to determine whether the management practices specified in the Part 503 rule achieve their intended effect, provisions for the distribution of Class A biosolids weighing less than 1 metric ton (*i.e.*, the NRC recommends that all biosolids sold should be exceptional quality (EQ)), and the elimination of exemptions for nutrient management and site restrictions for land-applied EQ biosolids.

The NRC also recommended that EPA consider additional risk-management practices when revising the part 503 rule. Considerations should include limitations on holding or storage practices, slope restrictions, soil permeability and depth to groundwater, and setbacks to residences or businesses, surface water, and drinking water supplies.