

establish sustainable vegetation cover on disturbed and highly contaminated sites, also included identification and determination of metals bioavailability in biosolids. The research was conducted to strengthen our understanding of the potential health impacts of metals, a particular focus during the development of the 1993 regulations. Results of this work showed that assumptions regarding metals availability used in earlier metals risk assessments were conservative. The Agency plans to reevaluate these findings in context with current practices and policies regarding exposure to metals in biosolids.

Exposure research: As part of a broader set of field studies, EPA recently initiated, in partnership with USDA and the State of Pennsylvania (PA), the planning of exposure-related research at five biosolids production and/or application sites. These studies are intended to gather site-specific information on current practices in biosolids production and application, and to identify and evaluate the fate of pollutants following biosolids application. Other objectives for this research, depending on the site, include (1) characterization of treated and untreated sludge (biological, physical, and chemical characterization), along with sampling and analysis during land application, (2) assessing the presence of pathogens, nitrogen, sulfur, volatile organic compounds and particulates in air, (3) determining how well the sewage sludge is disinfected as it moves through the different stages of processing, and (4) determining pathogen content in Class B sludge, once applied and following a period of natural attenuation. Other related work is being conducted by the University of Arizona's Water Quality Center.

Planned work is expected to begin in mid 2003. The plan is for facility operations for these sites to be documented, including the operation and performance of treatment process used to process sewage sludge and produce Class A and Class B biosolids. Pathogen and chemical occurrence data will also be collected at these sites. Proposed measurements over time for the production and land application processes may include total and volatile solids, pH, temperature, odor, appearance (e.g., color, paste, liquid, powder), fecal coliforms, *Salmonella* spp., *Staphylococcus aureus*, enteric viruses, and helminth ova.

Because of concern over bioaerosols, air samples will be taken prior to, during, and following land application at the point of application and the fence line, for up to thirty days. Air sampling

will be conducted in collaboration with USDA to address pathogens, chemicals, endotoxins, and particulates occurrence. Chemical and pathogen concentrations in air represent an initial step towards understanding the potential exposure of nearby communities. A description of the proposed studies can be found in the Pathogens category.

CAFO research: EPA is also conducting research on microorganisms and chemicals at animal manure land application sites, composting sites, and concentrated animal feeding operations (CAFOs). These include studies on the concentrations of airborne pathogens, toxic organic compounds, odorants, and particulates. The CAFO studies are important, because pathogen and chemical air transport and fate for animal manures resemble those for biosolids. The ongoing and proposed studies are described in the Methods Development category in this notice.

Planned Exposure Activities

EPA plans to continue its research partnership with USDA and the State of PA and to study an additional five field application sites.

The Agency is exploring a plan to conduct a molecular pathogen tracking exposure study as a follow-up to the PA/USDA/EPA study. This study would focus on individuals who have received medical attention and who suspect that they have been affected by biosolids application practices. This study would analyze human biological monitoring samples (e.g., feces, blood, or swabs from skin, ears, eyes, or throat) to isolate potential causative agents, and genetic characterization would be used to identify the potential source(s).

C. Risk Assessment

1. Summary of Risk Assessment NRC Recommendations

The NRC recommended that the Agency use improved risk assessment methods to better assess risks and establish standards for chemicals and pathogens under Part 503, since methods for conducting risk assessments have evolved substantially since the 1993 regulations were established. The recommendations also include reassessing standards for chemicals currently in the Part 503 regulation using the latest science. The NRC suggested that future risk assessments incorporate new information on exposure, dose-response relationships, pathogen survival, quantitative microbial risk assessment techniques, and consideration of site-specific factors that may affect risk management practices (e.g., odor).

Recommendations were also made to involve stakeholders in the risk assessment process and to examine biosolids management practices to ensure that the underlying risk assessment principles are effectively translated into practice.

2. The Agency's Response for the Risk Assessment Category

How EPA Plans To Address NRC Risk Assessment Recommendations Current and Planned Risk Assessment Activities

For this notice, risk assessment is defined as the process of identifying the potential adverse health effects associated with environmental exposures to pollutants in biosolids, their severity, and likelihood. Previously, EPA used a risk based approach for estimating risks to human health and developing management practices to reduce risks and set protective standards. When they were conducted, EPA's assessments were based on state-of-the-science methods, information and management practices. The NRC recommended areas where new or updated health and exposure information, models, and risk assessment methods may strengthen the Agency's assessments for land-applied biosolids.

Consistent with the recommendations of the NRC, EPA plans to address the potential health hazards and exposures associated with land application of biosolids using state-of-the-science risk approaches. Specifically, EPA plans to reassess methods and data used for previously evaluated pollutants, and apply these methods to new pollutants. For example, risks from pollutants not previously assessed due to a lack of toxicity, environmental fate, or exposure information, will be reevaluated if new information is available. This effort is expected to take place in FY03 and FY04. The Agency has assessed risks to children and sensitive populations, and will continue that approach in future assessments and reassessments.

The NRC also recommended that representative stakeholders could be included in the risk assessment process to help identify exposure pathways, local conditions that could influence exposure, and possible adverse health outcomes. The Agency's policy is to involve stakeholders at various stages of policy development. The Agency intends to consider how consultation with stakeholders should be included in developing future sewage sludge risk assessments.

EPA, in conjunction with States and other Federal agencies, has already been addressing local biosolids issues in a