

assess data and information related to multiple exposures, potential contaminant interactions, and potential effects on sensitive sub-populations, to the extent the state-of-the-science is available.

#### *D. Methods Development*

##### 1. Summary of Methods Development NRC Recommendations

The NRC recommended that the Agency develop and standardize methods for measuring pathogens and emerging chemicals in biosolids and bioaerosols. Standardized methods could be used to provide measures of performance and to verify that the Agency's management practices and standards are reliable.

Specifically, the NRC recommended developing, standardizing, and validating methods for pathogens in biosolids and bioaerosols (*e.g.*, airborne pathogens). In addition, research that uses improved pathogen detection technology, round-robin laboratory testing to establish method accuracies and precision for pathogen concentrations in raw and treated biosolids, mechanisms for incorporating new methodologies into the verification process, and measures of performance that can be monitored (*e.g.*, concentrations of selected chemicals in exposure media and human biological monitoring such as blood or urine of workers and residents) could be considered useful in conducting and interpreting future risk assessments and used to develop applicable risk-assessment technologies.

##### 2. The Agency's Response to Methods Development

###### How EPA Plans To Address NRC Methods Development Recommendations

For the methods development category, the Agency plans to focus its resources on pathogens and chemicals associated with biosolids. Validated analytical methods are necessary to support exposure assessments for toxic pollutants and pathogens. Methods are needed for determining the reliability of treatment processes, assaying pathogens and chemicals in raw and treated biosolids, incident follow-up, sampling environmental media, and human biological monitoring. Ongoing or planned methods development activities in the Agency that address the NRC recommendations follow.

###### Method Development Activities

Recently initiated EPA methods development work includes field studies at five biosolids production and

application sites. Currently available analytical methods are being identified or in some cases adapted for this study. A description of these field studies has been provided in the preceding Exposure subsection of this notice. Additionally, EPA is conducting field studies at animal manure land application sites, composting sites, and concentrated animal feeding operations (CAFOs). This research includes measurements of pathogens, toxic organic compounds, odorants and particulates in the air near CAFOs. Both the biosolids and CAFO studies include evaluation and adaptation of analytical methods for selected pathogens and chemicals. Results of these studies should assist the Agency in determining the need for additional methods development research.

Open-path Fourier Transform Infrared (FTIR) spectrometry will be used to measure volatile organic compounds from land application sites. EPA is validating analytical methods for microorganisms cited in 40 CFR Part 503. Fecal coliform methods have been validated, whereas *Salmonella* methods are being validated. Methods and validation studies for these two agents are expected to be published in 2004.

###### Planned Method Development Activities

As part of its field study programs, EPA plans to work with USDA to investigate methods for measuring bacteria and viruses in air upwind and downwind of biosolids land application sites. EPA is considering developing and validating analytical methods for enteric viruses and helminth ova, as well as chemical analytical methods for emerging chemicals of potential concern in biosolids (*e.g.* pharmaceuticals).

#### *E. Pathogens*

##### 1. Summary of Pathogen NRC Recommendations

The NRC recommended that the Agency review approaches for developing microbial analytical methods and conducting microbial risk assessments (Quantitative Microbial Risk Assessments) to analyze sensitivity and to ascertain what critical information is needed to reduce uncertainty about the risks from exposure to pathogens in biosolids. According to the NRC, research activities that might improve EPA's pathogen standards and reduce risk, from pathogens following exposure to biosolids include development, standardization and validation of detection and quantification methods

for pathogens and indicator organisms, conducting research on vectors carrying pathogens and bioaerosols, and conducting studies to determine whether site restrictions for Class B achieve intended effects for pathogen levels. The NRC also recommended that EPA not allow provisions for distributing Class A biosolids in bags or other containers (weighing less than one metric ton) when they do not meet pollutant concentration limits (*i.e.*, all biosolids sold or given away should be exceptional quality).

Other NRC recommendations include considering additional indicator organisms (*e.g.*, *Clostridium perfringens*) for use in regulations, as well as funding, supporting and officially sanctioning the Pathogen Equivalency Committee (PEC) as part of the Federal program. National field and laboratory surveys to verify that Class A and Class B treatment processes for pathogens perform as assumed by their engineering and design principles could also be conducted. Determinations could be made of pathogen density and elimination across the various accepted treatment processes and in the biosolids or environmental media over time, applying geographic and site-specific conditions that affect pathogen fate and transport to determine the effectiveness of site restrictions, buffer zones, and holding periods for Class B biosolids. EPA may also consider further refining, and directly correlating, stabilization controls to outcomes using metabolic techniques (*e.g.*, sour test, carbon dioxide metabolic release, methane metabolic release).

##### 2. The Agency's Response to the Pathogen Category

###### How EPA Plans To Address NRC Pathogen Recommendations

EPA currently uses a technology and management practices based approach to minimize pathogen exposure. The Agency is considering studies to better understand the measurement, control, and fate of pathogens during the production and land application of sewage sludge. Such studies include improved analytical methods, evaluation of treatment and application processes, site-specific pathogen occurrence studies, potential human health impacts, exposure assessment, and risk assessment.

Certain pathogen studies are discussed in the Methods Development subsection of this notice. Where other studies address several pathogen issues (*e.g.*, field studies, management, treatment, site restrictions), they are briefly described below.