

deciding on additional activities and next steps.

#### Project 7: Conduct Exposure Measurement Workshop

The purpose of this workshop is to identify exposure-related research priorities. This workshop is meant to complement the objectives of the WERF workshop (*see* Project 6) or be a related follow-up activity that is structured around issues and ideas identified in the WERF workshop. Workshop discussions will focus on exposure measurement tools that researchers or health agencies can use to investigate reports of adverse human health effects from land application of sewage sludge. The discussions and tools will focus on scientific uncertainties related to: (1) Which particular sewage sludge contaminants or combinations of contaminants may be potentially responsible for disease outbreaks; (2) how affected individuals are exposed to these contaminants; (3) how sewage sludge treatment and management practices can reduce potential risks; and (4) how good analytical methods and monitoring have to be to obtain satisfactory answers. The workshop will explore such topic areas for identifying research priorities as methods development, ambient measurements (including spatial and temporal monitoring requirements), fate and transport modeling, and exposure measurements, including identifying the specific exposure routes (*e.g.*, oral and inhalation), exposure pathways (*e.g.*, eating food, drinking water), and contaminants.

Workshop participants would include representatives from EPA; other Federal, State and local agencies; academia; wastewater utilities; environmental groups; industry; and citizen groups. Participants would identify and where possible prioritize what, when, and how they should be taken during rapid response investigations. EPA will develop a report to summarize discussions and identify the exposure research tools needed to investigate reported incidents of exposure. Pending the results from a similar effort being sponsored by WERF and in which EPA will participate (Project 6), we expect to hold this workshop in 2004.

#### Project 8: Assess the Quality and Utility of Data, Tools and Methodologies to Conduct Microbial Risk Assessments on Pathogens

The NRC recommended that EPA develop risk assessment methods to apply to pathogenic risks from land application of sewage sludge. While

numerical limits for chemical pollutants in sewage sludge are based on assessment of risk, EPA currently regulates pathogens in sewage sludge through technology-based operational standards. In issuing part 503 in 1993, the Agency acknowledged that it lacked essential tools and data to conduct microbial risk assessments on sewage sludge. As the NRC noted, while methods for assessing risks from pathogens have advanced since 1993, there are still obstacles with respect to available data, analytical methods, and exposure and risk assessment modeling.

EPA is working on a number of areas related to risk assessments of pathogens. There are two examples of projects that are ongoing and that will be assessed as part of this broader effort. One is a conceptual framework for assessing the risks of human disease following exposure to waterborne pathogens, as described in "Revised Framework for Microbial Risk Assessment" (International Life Sciences Institute, 2000). The second is a quantitative microbial risk assessment (QMRA), as described in "A Dynamic Model to Assess Microbial Health Risks Associated with Beneficial Uses of Biosolids" (WERF, 2003).

In the first example, the International Life Sciences Institute (ILSI), in cooperation with EPA, developed a framework that provides a useful and proven tool for conducting microbial risk assessments. The framework emphasizes the dynamic and iterative nature of the risk assessment process, and that future efforts need to be directed toward the examination of methods for estimating risk and ways to improve the estimates. Areas for further evaluating the assumptions in the framework model, described in the ILSI framework, include understanding the relationship between infection and subsequent illness, impact of critical susceptibility factors such as age and immune status, secondary transmission of diseases, and heterogeneous distributions of microorganisms and the potential changes in concentration of microorganisms in the environment.

In the second example, WERF and EPA are funding Quantitative Microbial Risk Assessment (QMRA) research. In addition to WERF and EPA, other organizations involved in this research include the University of 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 ultimately developing microbial risk assessment guidelines.

EPA will inventory and assess data, methods, and tools for risk assessment on pathogens in sewage sludge (such as the two examples discussed above as well as others) to better inform research activities in sewage sludge and microbial risk assessment. In conducting this assessment, EPA will review information gathered from others doing research on this issue, some of which was described in the April 2003 draft response (68 FR 17379). This project will start with a problem formulation step to identify the key elements in assessing pathogen risks in land-applied sewage sludge. During the second phase, EPA will develop a plan to identify the available and appropriate methods and data to perform the risk assessment defined in problem formulation. An expert panel will review the material and EPA will address panel comments in the final document. This project will serve as a vehicle to better define the deficiencies in microbial risk assessment and better identify research needs for microbial risk assessment in sewage sludge matrices. The final product in FY 2005 will be a peer-reviewed plan for future analysis.

#### Project 9: Support Pathogen Equivalency Committee

In its April 9, 2003, notice, EPA described the work of the Pathogen Equivalency Committee (PEC), which has been operating since 1985. Public comments mentioned the PEC Committee a number of times, and there was a generally favorable opinion of the Committee. Most commenters recommended that the PEC be fully recognized and authorized by EPA to approve new part 503 processes. Supporting comments by some agreed with both the Haas report (Haas, 2001) and the NRC conclusions that the PEC has an important mission. A few comments indicated that, if the PEC were further legitimized, it should be expanded to include industry and academic experts outside of the EPA.

EPA plans additional support for the PEC, including resources to help address the increasing number and complexity of requests for guidance regarding the regulatory requirements for reducing pathogens, as well as development of alternative treatment technologies. The NRC report affirmed