

few areas, and has used these opportunities to include stakeholders in the process to further evaluate and improve the assessment and management of biosolids. For example, stakeholders were involved in the scenario development and regulatory processes of a recent study in Pennsylvania. As part of this study, an informal information sharing group was formed that included concerned citizens, local officials, and contractors to assist the Agency in identifying stakeholder concerns and ensuring transparency in the field study process.

For the ongoing Round Two land application rulemaking, EPA conducted a revised risk assessment in response to public and peer review comments on the 1999 Round Two proposal. This revised assessment used a probabilistic approach instead of a deterministic approach to yield information on the sources of variability and uncertainty in the final risk estimates. The probabilistic approach used estimated values for certain input variables over the range of observed data to estimate the risks for the highly exposed population. This revised risk assessment also used new inputs, which included a redefined "highly exposed individual," new pathways and mechanisms of exposure, new exposure factors adopted from the latest EPA Exposure Factors Handbook, a sensitivity analysis to determine the relative importance of the input variables, and updated scientific information on the chemicals of concern, dioxins. EPA redefined the "highly exposed individual" as a member of a farm family that consumes 50 percent of his/her diet from home-produced crops and animal products grown on his/her own biosolids-amended land. EPA plans to use the Round Two risk assessment approach as a starting point for evaluating the NRC's recommendations, including the use of the reasonable maximum exposed (RME) individual for improving future risk assessments.

EPA is currently funding and conducting research related to risk assessment of biosolids. EPA is sponsoring research or has awarded grants to the Water Environment Research Foundation (WERF) and others to develop quantitative pathogen risk assessment methods and approaches. EPA plans to conduct a comprehensive evaluation and peer review of these results and, if deemed appropriate for use in assessing risk from pathogens found in biosolids, the Agency would incorporate these new risk assessment methods into any new or updated risk assessment and update the part 503 rule as necessary.

Other studies and related activities that EPA is conducting or sponsoring include the development of dose-response models for quantitative risk assessment of selected pathogens and the development of transmission models of pathogens and disease. These models are currently being developed for drinking water and, EPA plans to evaluate and, if appropriate, modify applicable models to be used in analyzing pathogens in biosolids. In addition, research is being conducted with USDA and various States on the extent of airborne concentrations of pathogens, toxic compounds, odorants, particulates and bioaerosols. EPA plans to evaluate the results of these studies for use in refining and improving future biosolids exposure and risk assessments. Further descriptions of these studies are provided in the pathogen section and the action plan.

To further the state of the knowledge surrounding all aspects of sewage sludge use and disposal, including improved risk assessments, EPA is supporting a workshop scheduled for January of 2004 on the "state of the science" on land application of municipal and industrial wastewater effluents, sewage sludge, and animal manures. This workshop is being coordinated by the University of Florida and will have numerous contributors from the Agricultural Research Service of USDA, and academia, among other groups. New and additional information on biosolids toxicities and environmental properties may emerge from this workshop; once evaluated, this information may be used in future risk assessment updates of the Part 503 Rule. The Web site <http://www.conference.ifas.ufl.edu/landapp/> contains information concerning the upcoming workshop, as well as other relevant information.

As discussed previously, EPA may use the risk assessment paradigm to provide both a focused reassessment of certain previously addressed pollutant risks, exposure pathways and risk assessment approaches, as well as assessing pollutants which have not been previously evaluated to effectively address the NRC risk assessment related recommendations and the review required by Section 405(d)(2)(C) of the CWA. These risk assessment activities will be initiated this year. This effort will be developed and outlined by an interdisciplinary workgroup within EPA and include external review of the analysis plan.

For this risk analysis, EPA is planning to focus on an evaluation of those key pollutants and pathways which are likely to be of greatest concern or where

the new scientific developments may have the greatest impacts. This may result in later updating the Round One risk assessment models and re-evaluating selected pollutants, pathways and endpoints and/or new pathways and endpoints not previously addressed.

EPA is planning a two-step process for addressing the NRC recommendations with respect to risk assessments for pollutants in sewage sludge. The first step would be to conduct a problem formulation which would re-evaluate or assess methods, approaches and pollutants considered in the Round One determinations, and any new qualitative information for future pollutants. This problem formulation step would include the development of exposure/risk assessment scenarios that would be used to identify critical/key stressors, routes of exposure, model application and data gaps. The primary focus of this effort will be on areas having the greatest potential risks and uncertainties (e.g. pathogens). The problem formulation will serve to eliminate those stressors, scenarios, routes of exposure, and endpoints that need not be evaluated further. It would retain those areas which are potentially significant or require more study. The problem formulation would also result in a research analysis plan that would not only identify risk assessment activities but also prioritize research to address exposure and risk management.

The second step would be to conduct quantitative risk assessments and risk characterizations for key pollutants identified and prioritized by the scenario/conceptual models, as appropriate. These assessments would initially be screening level risk assessments. More refined assessments would be conducted only on those pollutants and pathways for which the screening-level assessment indicate significant potential for risk. In conducting any risk assessments, screening or comprehensive, EPA will, as appropriate, apply the most up-to-date scientific information and risk assessment methodologies. In addition, EPA proposes to continue its efforts to evaluate and develop new methods for pathogen risk assessments and improved models for exposure assessments.

EPA's proposed activities are to continue to track development of methods for QMRAs and develop guidelines for assessing risk from pathogens. In addition, EPA also plans to continue work on the evaluation of data and models for improving exposure assessments. EPA may also evaluate and