

adequacy of the chemical and pathogen standards for protecting human health. To help address the human health concerns and the requirement for periodical reassessment of the Standards for Use or Disposal of Sewage Sludge, the Agency commissioned the NRC to independently review the technical basis of the chemical and pathogen regulations. The NRC study took place between January 2001 and June 2002. In July 2002, the NRC published a report entitled, "Biosolids Applied to Land: Advancing Standards and Practices" in response to EPA's request. For a copy of the full NRC report, visit our Web site at <http://www.epa.gov/ost/biosolids/nas/complete.pdf>. The NRC identified a need to update the scientific basis of Part 503 and provided approximately 60 recommendations.

In an agreement with the parties in *Gearhart v. Whitman*, EPA agreed to publish a notice in the **Federal Register** stating how it will respond to the NRC report recommendations and to seek public comments on its planned response. EPA also agreed to review publicly available information for the purpose of identifying additional toxic pollutants in biosolids and to publish a notice providing the results of the review and seek public comment. Today's notice fulfills this agreement.

IV. What Was EPA's Charge to the National Research Council?

EPA asked the NRC to conduct an independent evaluation of the regulations and standards for chemical pollutants and pathogens in biosolids that are land-applied. Specifically, the NRC was asked to focus on the adequacy and appropriateness of the risk assessment methods and data used by the Agency in setting regulatory requirements to protect human health. The NRC convened the Committee on Toxicants and Pathogens in Biosolids Applied to Land ("the committee"), which conducted and prepared a final report. The Statement of Tasks included the following:

1. Review the risk assessment methods and data used to establish concentration limits for chemical pollutants in biosolids to determine whether they are the most appropriate approaches. Consider the NRC's previous (1996) review and determine whether that report's recommendations have been appropriately addressed. Consider (a) how the relevant chemical pollutants were identified, (b) whether all relevant exposure pathways were identified, (c) whether exposure analyses, particularly from indirect exposures, are realistic, (d) whether the

default assumptions used in the risk assessments are appropriate, and (e) whether the calculations used to set pollutant limits are appropriate.

2. Review the current standards for pathogen reduction or elimination in biosolids and their adequacy for protecting public health. Consider (a) whether all appropriate pathogens were considered in establishing the standards, (b) whether enough information on infectious dose and environmental persistence exists to support current control approaches for pathogens, (c) risks from exposure to pathogens found in biosolids, and (d) new approaches for assessing risks to human health from pathogens in biosolids.

3. Explore whether approaches for conducting pathogen risk assessment can be integrated with those for chemical risk assessment. If appropriate, recommend approaches for integrating pathogen and chemical risk assessments.

The NRC report, "Biosolids Applied to Land: Advancing Standards and Practices," described the work of the committee, stating that "the committee searched for evidence on human health effects related to biosolids exposure" in its review of the risk assessments and technical data used by EPA to establish the chemical and pathogen standards and the management practices contained in part 503. The report noted that "the committee did not attempt to determine whether the approaches used by EPA to set the 1993 biosolids standards were appropriate at the time of their development, and the committee's findings and recommendations should not be construed as either criticism or approval of the standards issued at that time."

V. What Were the National Research Council's Major Findings and Recommendations Concerning Land Application of Biosolids?

The NRC committee concluded that "there is no documented scientific evidence to indicate that the part 503 rule has failed to protect human health," but additional scientific work is needed to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids. The committee recognized that land application of biosolids is a widely used, practical option for managing the large volume of biosolids generated at waste water treatment plants that otherwise would need to be disposed of at landfills or by incineration. The committee also identified a need to update the scientific basis of part 503 to (1) ensure that the

chemical and pathogen standards are supported by current scientific data and risk assessment methods, (2) demonstrate effective enforcement of part 503, and (3) validate the effectiveness of biosolids management practices. The NRC report focused on identifying how current risk assessment practices and knowledge regarding chemical pollutants and pathogens in biosolids can be used to update and strengthen the scientific basis and credibility of EPA's biosolids regulations.

The NRC report contains four overarching recommendations: (1) Use improved risk assessment methods to better establish standards for chemicals and pathogens, (2) conduct a new national survey of chemicals and pathogens in biosolids, (3) establish an approach to human health investigations, and (4) increase the resources devoted to EPA's biosolids program. These four overarching recommendations are discussed in detail and supplemented by 53 individual recommendations contained in Chapters 2–6 of the NRC report.

VI. What Process Did EPA Use To Address the NRC Recommendations?

Upon the release of the report, EPA established an Intra-Agency Committee (IAC) to respond to the recommendations in the NRC report and begin review of the existing Part 503 regulations to identify additional toxic pollutants that may warrant future regulation, pursuant to section 405(d)(2)(C). The IAC is comprised of EPA representatives from a cross-section of environmental program offices that are involved or interested in the biosolids program.

The IAC first developed an approach for responding to the NRC report and conducting the section 405(d)(2)(C) review of existing regulations. Activities for responding to the NRC report included developing a matrix to identify and track each recommendation, grouping the recommendations into eight categories based on subject area, evaluating the recommendations individually and establishing priorities, drafting initial responses by category, and developing a strategy to carry out the activities identified in response to the NRC recommendations. The approach for reviewing existing regulations to identify additional toxic pollutants that may warrant regulation, pursuant to section 405(d)(2)(C), is described in Section IX of this notice.

As stated above, the IAC first prepared a matrix (Compilation of National Research Council (NRC) Recommendations on Biosolids and