

overflows, and concentrated animal feeding operations. Both agriculture and urban runoff/storm sewers are listed in the top four sources of impaired river miles in the 2000 National Water Quality Inventory Report to Congress (section 305(b) report). Given the complexity and magnitude of addressing potential human exposures to pathogens and chemicals from untreated human and animal wastes from wet weather and the present scientific knowledge of the relative risks associated with biosolids, there is an appropriate level of resources allocated to biosolids compliance and enforcement activities.

Project 3: Methods Development, Optimization, and Validation for Microbial Pollutants in Sewage Sludge

EPA's sewage sludge regulations are designed to protect human health and the environment by requiring treatment of sewage sludge to reduce or eliminate pathogens (also referred to as microbial pollutants) when land-applied (40 CFR part 503, subpart D). The regulations require that land-applied sewage sludge meet either Class A or Class B requirements to treat sewage sludge using one of various treatment processes. There are six alternative methods, one of which must be met to be classified as Class A sewage sludge. In addition, in order to be classified as Class A sewage sludge, the pathogen reduction treatment must occur prior to or in conjunction with vector attraction reduction measures, except for vector attraction reduction by alkali addition or drying. To be classified as Class B sewage sludge, one of three alternative treatment methods must be met. Because these three Class B treatment methods do not reduce pathogens to the same extent as the Class A methods, Class B sewage sludge is also subject to site restrictions, such as restrictions on crop harvesting, animal grazing and public access.

EPA recently published a document entitled *Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge* (USEPA, 2003e). This document provides information concerning federal requirements under subpart D of part 503, a description of different treatment processes, vector attraction reduction issues, sampling and analysis protocols for pathogens, the process for applying for equivalency, and the kind of support EPA's Pathogen Equivalency Committee (PEC) can provide to permitting authorities. This publication not only serves to assist the user community and to link researchers with their clients, but also has been produced as part of the

Agency's strategic long-term research plan for preventing and reducing risks from pollution that threaten human health and the environment.

The NRC recommended that EPA undertake a new national sewage sludge survey to look for pathogens in sewage sludge. In addition, the NRC report identified standardization and validation of methods for detection and enumeration of indicator organisms and specific pathogens as essential for oversight and compliance testing. Raw sewage, anaerobically and aerobically digested sewage sludge, and wastewater are known to contain numerous residual microorganisms that can cause disease in humans and animals. These include viruses, bacteria, protozoans and helminth ova. As described in the April 9, 2003, notice, EPA agrees that pathogens deserve further attention, and the Agency had sponsored a workshop in 2001 and initiated a number of studies (see Project 11). Pathogen projects relate back to Category D, Methods Development, and Category E, Pathogens, in the April 9, 2003, FR notice. See 68 FR 17388.

Several commenters stated that there is an urgent need for EPA to develop and validate methods for detection and enumeration of bacteria and viruses in sewage sludge, soil, water and air. EPA agrees and recognizes that reliable analytical methods are critical to measuring pathogens in sewage sludge, whether "raw" or "finished." Therefore, one of the Agency's priority microbial agent research areas is the development or improvement of analytical methodology. The following sections describe the available methods for helminth ova, viruses, and bacteria, each of which are in need of improvement to increase analytical specificity, sensitivity, and accuracy.

It was also suggested that EPA propose a vigorous study program to determine whether or not Class B sludge site restrictions are protective against infectious diseases. The greatest number of pathogen-related comments were directed to the issue of EPA's response regarding risk assessment, treatment efficacy, and site-specific restrictions for both Class A and B Sewage sludge. Some recommended the sewage sludge industry be involved in study efforts because of their experience in the area, while others recommended against industry involvement because of their potential bias. EPA plans to improve the methods and procedures for determining the effectiveness of these pathogen reduction or elimination treatment processes.

In addition to developing and improving the microbial analytical

methods described below, WERF and EPA are funding research termed quantitative microbial risk assessment (QMRA), as described in "A Dynamic Model to Assess Microbial Health Risks Associated with Beneficial Uses of Biosolids" (WERF, 2003). See Project 8 later in this notice for a description of the QMRA project.

Project 3a: Optimization of the Method for Detecting, Enumerating, and Determining the Viability of *Ascaris* Ova in Sewage Sludge

The goal of this project is to optimize the helminth ova method for the detection in the various sewage sludge matrices in order to assess the effectiveness of treatment practices meant to inactivate ova. The helminth (*Ascaris*) ova assay described in *Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge* (USEPA, 2003e) has been used a number of times, it is time consuming, and it has never been fully optimized and validated for the various sewage sludge matrices.

The first stage will optimize the assay for various sewage sludge matrices. The next stage will be a single laboratory validation followed by multi-laboratory validation of the assay. We anticipate that this research will be conducted over the next three years. Products include publication of one or more scientific papers characterizing the *Ascaris* ova assay for the various sewage sludge matrices and a standard operating procedure (SOP) detailing the optimal method for laboratory validation studies by 2007.

Project 3b: Improved Methods for Detecting Viruses in Sewage Sludge

EPA will develop improved virus detection methods for evaluating treatment technology efficacy. Some members of EPA's PEC, an ongoing committee charged with making recommendations on the adequacy of new sewage sludge treatment processes, and the NRC have questioned the reliability of existing virus methods for analysis of sewage sludge matrices. The PEC has recommended research that would improve the reliability of available analytical methods.

40 CFR 503.8(b) specifies methods that must be used when analyzing for various pathogens. The publication *Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge* (USEPA, 2003e) lists the required pathogen methods, along with complete references for these methods. The appropriate method to test for enteric