

EXECUTIVE COMMITTEE
PRESIDENT

Marian A. Orfeo
Director of Planning
& Coordination
Massachusetts Water
Resources Authority
Boston, MA

VICE PRESIDENT

Kevin L. Shafer
Executive Director
Milwaukee Metropolitan
Sewerage District
Milwaukee, WI

TREASURER

Jeff Theerman
Executive Director
Metropolitan St. Louis
Sewer District
Saint Louis, MO

SECRETARY

David R. Williams
Director of Wastewater
East Bay Municipal
Utility District
Oakland, CA

PAST PRESIDENT

Christopher M. Westhoff
Assistant City Attorney
Public Works General Counsel
City of Los Angeles
Los Angeles, CA

EXECUTIVE DIRECTOR

Ken Kirk

October 31, 2008

Office of Environmental Information (OEI) Docket (Mail Code: 2822T)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460
Via Email: ORD.Docket@epa.gov

Dear Sir or Madam:

The National Association of Clean Water Agencies (NACWA) has reviewed the U.S. Environmental Protection Agency (EPA) document titled *Draft Problem Formulation for Human Health Risk Assessments of Pathogens in Land-Applied Biosolids*. This document represents an important element of EPA's 2004 action plan that sets new priorities for the agency in the area of biosolids management. The 2004 action plan was developed in response to issues raised in the 2002 National Research Council (NRC) Report *Biosolids Applied to Land: Advancing the Standards and Practice*. NACWA's nearly 300 public wastewater treatment agency members manage thousands of tons of biosolids on a daily basis and are committed to ensuring that their biosolids management practices continue to protect human health and the environment.

NACWA believes the document could be improved through the addition of an executive summary and conclusion sections. The new executive summary should highlight key summary statements captured in Appendix A of the report, including the statement that a causal association between exposure to pathogens in biosolids and adverse effects on human health has not been documented. In addition, the executive summary should clearly state that the use of indicator organisms to represent pathogens of concern has the potential to introduce large uncertainties into estimates of exposure and should identify data gaps and critical research to support the development of a pathogen risk assessment for biosolids.

NACWA also offers the following comments and observations based on its review of the document.

- The draft document appears to do a good job of citing relevant literature, although the literature review could be improved by providing additional detail for several of the major studies cited. The document describes a logical process for development of a model and risk assessment framework based on previously published reports.
- NACWA believes the document underscores the need for EPA to develop reliable analytical methods for evaluating pathogens, since accurately

determining pathogen levels in biosolids is an important part of the risk assessment process. While methodologies for commonly studied pathogens or indicators are available, methodologies for other pathogens have not undergone peer review and thus are appropriate for research purposes only. The lack of approved and reliable analytical methods is a major impediment to conducting meaningful exposure/risk assessments or moving forward with the development of risk-based regulations.

- The draft report contains a brief discussion of data quality objectives (DQO) for analytical methods, but the importance of establishing specific and meaningful DQOs cannot be overstated. The final report of the Federal Advisory Committee on Detection and Quantitation strongly recommended that EPA develop and publish analytical methods only after first establishing the DQOs for the programs that will use these methods.
- The report discusses the potential use of surrogates for treatment performance and post-treatment risk, and states that risk assessors would need to do substantial testing to quantify relationships between indicators and pathogens of potential concern. The uncertainty in the use of indicators, coupled with that of dose-response relationships specific to pathogens represented by these indicators could make it difficult to conduct meaningful and scientifically defensible risk assessments in many cases.

Remaining Data Gaps Currently Prevent Sound Risk-Based Approach

Based on its review of the document, NACWA believes that there are sufficient data gaps to prevent the development of a risk-based regulatory approach for pathogens in biosolids at this time. Appendix A of EPA's document identifies numerous data gaps associated with development of a pathogen risk assessment. For example, some standard exposure factors and effects levels for pathogens in biosolids are not currently available. Research being conducted by the Water Environment Research Foundation (WERF) and others will address several of the data gaps that may in the future allow such a risk-based approach.

NACWA encourages EPA to advance and support a research agenda that fills critical data gaps with respect to pathogens in biosolids, exposure factors, and effects levels. While a causal association between exposure to pathogens in biosolids and adverse effects on human health has not been documented, filling the data gaps will address important issues identified in the 2002 NRC report and will help ensure that biosolids continue to be managed in a manner that protects public health and environmental quality.

Thank you for the opportunity to comment on the draft problem formulation document. Attached for your review are additional suggestions and comments that should be considered when finalizing this document. Please contact me at 202/833-9106 or chornback@nacwa.org if you have any questions regarding these comments.

Sincerely,



Chris Hornback
Senior Director, Regulatory Affairs

Attachment

Specific Comments on *Draft Problem Formulation for Human Health Risk Assessments of Pathogens in Land-Applied Biosolids*.

- 1) On page 10, at the seventh line of Section 2.2, it should be added that not all pathogens can multiply and reproduce outside of the host under favorable environmental conditions. There are certain pathogens such as *Salmonella* spp and indicator bacteria (fecal coliform, *E. coli*) which have been shown to re-grow under favorable environmental conditions. The NRC report (2002) indicates that the pathogen re-growth is inhibited by competition with the existing microbial ecosystem.
- 2) The statement is made on page 14, at the end of the last paragraph, that the bacterium *Listeria monocytogenes* is widespread in the environment. The report should be more specific by reviewing the published literature on the measured concentration of this bacterium in Class B biosolids.
- 3) On page 21, at the end of the last paragraph in Section 2.2.3.3, there is no information on the levels of *Ascaris lumbricoides* in Class B biosolids. It should be pointed out that the studies conducted by Pepper and Gerba have shown that the eggs of *Ascaris* are not detected commonly in Class B biosolids.
- 4) Under development of conceptual models, endpoints and scenarios, it states that a causal association between exposures to biosolids and adverse effects on human health has not been documented. Since this strategy serves as the reference point in the general conceptual models discussed in the report, it is not clear if the model accounts for the background levels of pathogens, the existing health-risk from environmental sources (soil, air, and water), and the extent to which the incremental risk observed will be linked directly to the biosolids exposure.
- 5) Under the section 3.3, the review on fate and transport of pathogens is incomplete. The findings from the WERF Report (2006) titled, "Assessing the Fate of Emerging Pathogens in Biosolids," is not included in this report. This study provides a great deal of information regarding the susceptibility of specific microorganisms in biosolids to known mechanisms of inactivation. Full-scale evaluation of biosolids and fate and transport information provided in this manuscript provide significant insight regarding potential exposure to specific pathogens.
- 6) The discussion under the Section 5.3 refers to analysis plans for characterization of exposure related microbiological measurements of pathogens in the biosolids. It should be emphasized that precision, accuracy, representativeness, sensitivity, and reproducibility of pathogen measurement methods in biosolids need to be developed, standardized and evaluated.
- 7) In figures 1, 4 and 8, aerosolization of biosolids is directly connected to storage, transport and loading/unloading of biosolids and neither provide a direct connection between biosolids application/spraying and aerosolization.
- 8) On page 46, line 20, delete the word 'planting,' since Part 503 does not place temporal restrictions on the planting of crops.