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July 8, 2003

Water Docket – Docket ID No. OW-2003-0006
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Ariel Rios Building, MC 4101 T
Washington, DC 20460

RE: *Standards for the Use or Disposal of Sewage Sludge; Agency Response to the National Research Council Report on Biosolids Applied to Land and the Results of EPA's Review of Existing Sewage Sludge Regulations (April 9, 2003; 68 Fed. Reg. 17379)*

Dear Sir or Madam:

The Association of Metropolitan Sewerage Agencies (AMSA or the Association) is pleased to provide comments on the U.S. Environmental Protection Agency's (EPA) *Standards for the Use or Disposal of Sewage Sludge; Agency Response to the National Research Council Report on Biosolids Applied to Land and the Results of EPA's Review of Existing Sewage Sludge Regulations* (April 9, 2003; 68 Fed. Reg. 17379). Founded in 1970, AMSA represents the interests of nearly 300 of the nation's publicly owned treatment works (POTWs). AMSA members serve the majority of the sewered population in the United States and collectively treat and reclaim over 18 billion gallons of wastewater each day.

The *Agency Response* details EPA's preliminary review of the July 2002 National Research Council (NRC) report entitled, *Biosolids Applied to Land: Advancing Standards and Practices* (the *NRC Report*), as well as the strategy EPA plans to use for responding to the *NRC Report's* recommendations. The *Response* also provides the initial results of the Agency's ongoing review of existing biosolids regulations under the Clean Water Act (CWA).

AMSA strongly supports the Agency's continued position that the land application of biosolids is an appropriate and environmentally sound option for communities

when conducted in compliance with EPA regulations. While the NRC found that "there is no documented scientific evidence to indicate that the part 503 rule has failed to protect human health," AMSA supports EPA's efforts to reduce persistent uncertainty about the potential for adverse human health effects from exposure to biosolids. The Agency *Response* makes it clear that reducing this uncertainty will be a guiding principle for the Agency as it maps the future of the biosolids program. Acknowledging the limits of EPA's finite budget, and given the numerous recommendations made in the *NRC Report*, AMSA recommends that the Agency maximize its resources by targeting those areas that will directly address the public's persistent uncertainty and improve public confidence in the practice of land applying biosolids.

As it stated in its January 30, 2003 letter to Assistant Administrator G. Tracy Mehan, III, AMSA continues to maintain that EPA should focus its resources on improving its understanding of potential health effects, establishing procedures for tracking and responding to reported impacts, and most importantly, improving communication with the public.

General Comments

AMSA supports the Agency's initial strategy for responding to the NRC's recommendations. EPA has outlined three main objectives for attaining a better understanding of biosolids and reducing the potential for, and uncertainty related to, human health impacts: 1) Update the scientific basis of Part 503 by conducting research in priority areas; 2) strengthen the biosolids program by evaluating results of completed, ongoing, or planned studies both within and outside EPA; and 3) continue ongoing activities for enhancing communication with outside associations and with the public. These objectives largely mirror what AMSA has asserted must be the Agency's priorities for strengthening the biosolids program.

Additional Research Needed

The first two objectives above relate directly to the issue of additional research – both new studies designed to address priority areas in the Part 503 regulations and existing projects within and outside the Agency. AMSA believes that EPA's first priority for conducting research to update the scientific basis of Part 503 must be a series of exposure assessment studies to directly assess potential health impacts, especially those associated with pathogens, and to amass additional data on exposure. AMSA also encourages the Agency to support research on odor associated with biosolids management and ways to mitigate those odors during processing and land application.

Exposure-Assessment Studies to Compile Additional Human Health Data

Communities across the U.S. that are considering, or have established, bans or restrictions on the land application of biosolids consistently cite the lack of information on the human health effects of exposure to biosolids. This is where EPA can have the most impact on preserving land application as a long-term, sustainable management alternative for biosolids. The *NRC Report* makes a number of recommendations regarding this issue, foremost of which is the need to conduct exposure-assessment studies to characterize the exposures of workers and the general public who come into contact with biosolids either directly or indirectly. The studies "would require identification of microorganisms and chemicals to be measured, selection of measurement methods for field samples, and collection of adequate samples in appropriate

scenarios" (*NRC Report*, p. 6). These studies would determine the makeup of emissions (e.g., odors, bio-aerosols, volatiles) from biosolids land application sites, measure the exposure potential for workers, such as applicators and farmers, as well as nearby communities, and assess the potential nexus to human health impacts. Should the results of these exposure-assessment studies suggest a negative impact on human health, additional resources could be committed to conducting a complete epidemiological study of biosolids use to provide evidence of "a causal association, or lack thereof, between biosolids exposure and adverse human health effects" (*NRC Report*, p. 6).

AMSA is aware of a number of research efforts, either currently underway or being considered by organizations such as the Water Environment Research Foundation, which could provide critical information for such exposure assessment studies. In addition, as with previous EPA efforts, AMSA's public agency members would be willing to work with the Agency on its ongoing biosolids research efforts.

Enhanced Communication

EPA's third objective, to continue ongoing activities for enhancing communication with outside associations and the public, is by far the most critical for enhancing the broad understanding and acceptance of the biosolids program. EPA's continued support of the National Biosolids Partnership's Environmental Management System program is certainly a key component of this enhanced communication, but the Agency's efforts must go further to ensure the public has confidence in the Part 503 program and the practice of land application.

Response Team for Biosolids Health Reports

Alleged or unsubstantiated claims of adverse health effects are more damaging to local biosolids programs than any other issue and it is here that public relations and responsive investigation must meet. Without the proper response and investigation by a credible authority, citizens have no choice but to believe accounts, based more on fear than fact, that is presented to them regarding potential health effects from land-applied biosolids. The logistics of an incident response team capable of investigating past and future claims of health impacts are complicated. There must be a method for timely notification and a process for tracking and recording incidents. Federal involvement is key, as many of the questions regarding biosolids management are national in scope, but the process must also acknowledge that land-application decisions are local. EPA Headquarters and Regional offices, states, and local governments should all have a role in investigating such health claims.

AMSA encourages EPA to develop a process for timely notification, recording, and tracking incident reports in collaboration with other federal agencies. Given their expertise in such matters, AMSA believes that the Centers for Disease Control and Prevention (CDC) may need to play an integral role, if not the lead role, in any type of incident reporting process. Ultimately, a national tracking system to document the details of each investigation would be vital to ensure biosolids managers, local, state and federal regulators, and the public have the information they need to make educated decisions concerning the land application of biosolids.

Ensuring Public Awareness of EPA's Regulatory Program

It has grown increasingly clear to AMSA that the public, both at the local and national levels, as well as local elected and appointed officials, are not sufficiently aware of EPA's comprehensive regulations regarding the land-application of biosolids and, as such, are more susceptible to determining that biosolids are not beneficial. Local hearings around the country on whether to prohibit the land-application of biosolids have increased and it is critical that these local decision-makers hear from EPA that the Part 503 biosolids regulatory program ensures that land application is performed soundly and safely. AMSA recommends that EPA designate a specific staff position to voice EPA's perspective at such hearings and, more generally, to ensure that the Part 503 program's safeguards are broadly understood. This is a task that simply cannot be performed by other stakeholders and would go far toward guaranteeing that decisions regarding the land application of biosolids are made not on the basis of emotional and potentially misleading accounts, but on a full understanding of the safeguards currently in place. Should EPA not have the resources to hire someone new for such a position, the Agency should make every effort to use its current staff at both Headquarters and/or in the Regions to testify at these hearings and ensure that the Agency's perspective is voiced.

Specific Comments

The Association would like to offer the following more specific comments on two of the areas for which EPA sought input in the *Federal Register* notice.

1. *The Agency's preliminary strategy for responding to the NRC recommendations*

As mentioned previously, AMSA generally agrees with the Agency's proposed strategy for responding to the NRC's recommendations, and offers the following comments to address the eight categories EPA used to organize its Response.

Survey

AMSA strongly supports EPA's plan to conduct a "targeted survey" to help fill data gaps and inform decisions regarding further studies, rather than conducting a comprehensive national survey. In designing the survey, AMSA recommends that EPA actively seek input from all stakeholders, including academia, state and federal agencies and POTWs. AMSA also recommends that the Agency use to the fullest extent existing data sources, many of which were identified in the *Federal Register* notice, regarding pollutant occurrence and effects when designing the survey. AMSA agrees with EPA's proposed approach to examine some of the pollutants that were studied in the 1988-1989 National Sewage Sludge Survey, to the extent that resources allow. This would help maintain consistency in the survey data and analysis and provide a means of comparing results and observing trends. New chemicals of concern should be included to the extent that validated analytical procedures exist for the chemical, adequate risk criteria are available to conduct risk assessments, and Agency screening tools indicate a significant potential for risk.

Exposure

AMSA supports the Agency's plans to collect and review currently available exposure information from published literature, federal and state databases, the *NRC Report*, and other relevant sources to identify

data gaps and its plans to use a risk assessment framework to evaluate priorities for reassessing or updating underlying components including exposure assumptions of previously conducted risk assessments. AMSA supports, to the extent resources permit, reviewing exposure information used in the Round One and Round Two rules in light of new exposure information, and supports updating that exposure information if new data indicate that such changes are necessary to protect human health. AMSA cautions the Agency to employ a consistent approach in identifying and determining exposure pathways for ongoing and new studies.

Risk Assessments

AMSA supports EPA's plans to address the potential health hazards and exposures associated with land application of biosolids using state-of-the-science risk assessment approaches. AMSA strongly encourages the Agency to consider how representative stakeholders could be included in the risk assessment process to help identify exposure pathways, local conditions that could influence exposure, and possible adverse health outcomes.

AMSA understands that EPA plans to "use the Round Two risk assessment approach [a probabilistic approach] as a starting point for evaluating the NRC's recommendations, including the use of the reasonable maximum exposed (RME) individual" for improving risk assessments in future rulemakings. AMSA cautions the Agency to ensure that the probabilistic approach is consistent with Agency risk assessment policy and sufficiently validated to support future regulatory decisions. EPA should consider whether the probabilistic approach should be used only as a screening tool and whether it may need to be coupled with the more traditional deterministic approach in some applications.

AMSA further understands that the Agency's use of a risk assessment framework or paradigm to provide a focused reassessment of certain previously addressed pollutant risks, exposure pathways and risk assessment approaches, as well as an assessment of pollutants which have not been previously evaluated, may result in updates to the Round One risk assessment models and reevaluations of selected pollutants. AMSA would support any such reevaluations of, or updates to, the science associated with these earlier rulemakings to the extent that EPA's problem formulation process identifies them as priority areas.

AMSA suggests that EPA's efforts to understand the potential risks associated with biosolids focus primarily on those areas where there are perceived weaknesses in the current regulations, specifically pathogens in biosolids and bioaerosols.

Methods Development

In response to the *NRC Report's* recommendation to develop new and improved analytical test methods, EPA has outlined its ongoing and planned methods development activities. AMSA agrees with the NRC's recommendation and EPA's assessment that validated analytical methods are necessary, for example, to support exposure assessments, for determining the reliability of treatment processes, assaying pathogens and chemicals in raw and treated biosolids, and incident follow-up.

EPA describes recently initiated EPA methods development work including field studies at five biosolids production and application sites. EPA also describes ongoing field studies at animal manure land

application sites, composting sites, and concentrated animal feeding operations, which are measuring pathogens, toxic organic compounds, odorants and particulates. In addition to using these field studies on non-biosolids land application sites for methods development, AMSA encourages EPA to use the information collected from these studies to assess the relative risk posed by biosolids.

Pathogens

AMSA generally supports EPA's planned pathogen research areas: development of improved pathogen analytical techniques, assessment of exposure and risk for critical pathways, and evaluation of biosolids processing and land application methods and site restrictions.

The *NRC Report* recommended that the EPA consider funding, supporting, and officially sanctioning the Pathogen Equivalency Committee (PEC) as part of the federal biosolids program. While AMSA does not object to this recommendation, we do suggest that if EPA decides to officially recognize the committee, that it open membership on the PEC to include qualified scientists employed by wastewater treatment plants and private biosolids contractors. As currently structured, the PEC includes only employees from EPA and the CDC. Because of this limitation, the PEC has not benefited from the expertise that scientists from the regulated community could contribute, especially related to current application methods, site restrictions, and other local variables.

AMSA supports EPA's plans to continue funding relevant scientific research concerning the impact of biosolids on human health and the environment. As part of this effort, the Association recommends that EPA consider funding studies conducted by wastewater treatment agencies or private biosolids applicators. These entities may be able to develop data useful to EPA's long-term goals of understanding the benefits and potential consequences of biosolids land application and determining whether existing Part 503 site management restrictions are effective. In addition, both wastewater treatment agencies and private biosolids management companies may already have data from in-house studies that could be useful for EPA's activities. AMSA encourages the Agency to tap into this resource.

Human Health Studies

AMSA's comments on EPA's planned human health activities are outlined in the *General Comments* section above.

Regulatory Activities

AMSA agrees with EPA that revised standards for molybdenum should be considered. However, any proposed standards should be based on the most up-to-date scientific information and a newly conducted risk assessment.

AMSA understands that the NRC is recommending that all biosolids products sold or given away in bags or other containers should be exceptional quality (EQ). AMSA also understands that by eliminating the non-EQ Table 4 alternative, EPA would essentially prohibit selling or giving away biosolids products in bags or other containers weighing less than one metric ton unless those products met the EQ standard. Before making any final regulatory decision, AMSA encourages EPA to confirm whether there are any

biosolids products being sold that conform to the Table 4 alternative and to document their justification for removing the alternative.

Some AMSA members have expressed concern about the NRC's recommendation that the nutrient management exemption be eliminated. EPA never expressly addresses this recommendation in its response. Some AMSA members currently use this exemption and AMSA recommends that the Agency thoroughly research and document the need for any regulatory decision it might make on this issue.

AMSA agrees with EPA that states and local jurisdictions have a better understanding of local conditions and, therefore, are in the best position to establish additional management practices to enhance the protectiveness of the Part 503 standards as needed.

AMSA endorses the *NRC Report's* recommendation to study the correlation between pathogen destruction and indicator organism levels in biosolids from various treatment processes, such as anaerobic and aerobic digestion, and lime stabilization. Studies of this type will provide data that will either substantiate the protective nature of the Class A and Class B pathogen destruction criteria, or show there is a need to revise the m.

Biosolids Management

The *NRC Report* recommended that EPA devote additional human resources to management and oversight of the federal biosolids program. AMSA understands that EPA bases its allocation of resources to its biosolids compliance and enforcement program on its assessment of the risks to public health and the environment posed by biosolids and understands that, given the low assessed risk, the biosolids program has not been identified as a high priority area for Agency resources. Nevertheless, as mentioned above in the *General Comments* section, AMSA believes that some additional funding for staff at the national level is warranted to improve communication with the public on the Part 503 program and the safeguards it provides.

As EPA collects new information with regard to implementing the NRC's recommendations, the Agency should continue to evaluate whether the resources currently committed to the biosolids program are adequate. As stated in our January 30, 2003 letter, AMSA's members are top performers in the industry and would welcome any increase in resources, at the federal or state level, deemed necessary by the NRC or EPA to strengthen this critical program.

AMSA does not believe that the responsibility for making additional resource commitments rests solely with EPA. States also need to make commitments, especially in the areas of compliance assistance and enforcement. These types of investments will no doubt be challenging given the current economic condition of many state budgets, but such resource commitments will prove to be more than cost effective in the future. EPA should consider contributing additional funding to states to implement their own programs and take steps to remove roadblocks that hinder or prevent states from receiving approval authority to administer such programs. State run biosolids programs can improve biosolids management practices by providing more local technical support and reducing compliance activities associated with multiple permitting and regulatory requirements.

2. EPA requests comment on its review under section 405(d)(2)(C) of the CWA. EPA also requests information that may help to fill data gaps for those chemicals for which sufficient information is not yet available to conduct a risk-based screening analysis.

The process described by EPA for conducting its review under section 405(d)(2)(C) of the CWA appears to be both reasonable and appropriate as do the criteria for proceeding to a screening analysis. AMSA believes that EPA's efforts to review existing literature for information on pollutants that were not among the 411 originally listed is a critical component of the review effort given the recent focus placed on emerging pollutants such as polybrominated diphenyl ethers. AMSA believes that new chemicals of concern should be further evaluated to the extent that the Agency's criteria for proceeding to a screening analysis are met.

AMSA recommends that EPA provide a clear accounting of the status of the pollutants it is evaluating in its 405(d)(2)(C) review. Specifically, AMSA suggests that EPA make available a table detailing information such as frequency of detection, sufficiency of data for performing further evaluation, the literature source for the new information, and any human health information or benchmarks for the pollutant.

Conclusion

AMSA believes it would be impossible for the Agency to address every recommendation contained in the *NRC Report*, even over the next five to ten years, and believes the Agency must make an effort to identify those recommendations that will provide the most vital information on the land application of biosolids. AMSA is confident that those efforts related to human health effects, specifically the exposure-assessment studies, and those efforts geared toward improving communication with the public about the federal biosolids program will provide the most benefit for the nation's POTWs and the communities they serve, while further bolstering confidence in the Part 503 program.

AMSA appreciates the opportunity to comment on the Agency's draft strategy for addressing the recommendations in the *NRC Report*. If you have questions or wish to discuss our comments further, please contact Chris Hornback AMSA's Director of Regulatory Affairs at 202/833-9106.

Sincerely,



Adam Krantz

Managing Director, Government and Public Affairs

cc: Ray Kearney, City of Los Angeles

Bob Dominak, Northeast Ohio Regional Sewer District