



Association of
Metropolitan
Sewerage Agencies

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Executive Director
Ken Kirk

November 5, 2004

Attn: Docket ID No. ORD-2004-0004
ORD Docket
EPA Docket Center
U.S. Environmental Protection Agency
Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

*VIA ELECTRONIC MAIL: ORD.Docket@epa.gov;
Science_Advisor@epamail.epa.gov*

Dear Sir or Madam:

The Association of Metropolitan Sewerage Agencies (AMSA)¹ appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA or Agency) Notice of Availability of and Opportunity to Provide Comment on Issues in the Staff Paper: *An Examination of EPA Risk Assessment Principles and Practices* (69 Fed. Reg. 15326; March 25, 2004). AMSA understands that this staff paper reviews EPA's current methods for conducting risk assessments and is the first step in a multi-step process to engage interested stakeholders in dialogue regarding the Agency's risk assessment principles and methodologies. As EPA moves forward with this stakeholder process, AMSA would like to express its continued interest in working to improve the existing risk assessment methodologies. In this regard, AMSA offers the following thoughts and comments for consideration during the forthcoming dialogue.

As AMSA noted in its June 10, 2004, letter to the Docket requesting additional time to comment on this important effort, AMSA's members are

¹ Founded in 1970, AMSA represents the interests of nearly 300 of the nation's publicly owned wastewater treatment works (POTWs). AMSA members serve the majority of the sewer population in the United States and collectively treat and reclaim over 18 billion gallons of wastewater every day.

“end users” of the standards and criteria that are developed by EPA using various risk assessment methodologies and are, therefore, very interested in the assumptions, default values, and uncertainty factors that go into conducting such assessments. Over the last few months, AMSA member representatives have reviewed the staff paper and the comments submitted by other stakeholders in response to the Agency’s March 25, 2004 notice. AMSA shares many of the same concerns expressed in the comments and looks forward to discussing them in more detail with the Agency in the coming months.

In general, AMSA is concerned that the staff paper, which will be used to guide the stakeholder process, was developed without input from stakeholders. AMSA believes that EPA, at a minimum, should have invited experts from other agencies that rely on risk assessments, such as the Food and Drug Administration, to partner with EPA staff during preparation of the paper. Nevertheless, the staff paper does provide a good starting point for discussion with stakeholders.

Many of the Association’s specific concerns are long-standing issues that AMSA and its members have commented on in the past with respect to specific risk assessment applications and rulemakings. Most of these issues were raised by other stakeholders during the comment process, but AMSA would like to reemphasize them:

- EPA continues to intersperse policy issues within the risk assessment process. AMSA believes policy considerations should be reserved for the implementation stage or used as part of the risk management process, but should not enter into decisions made during the risk assessment phase.
- EPA relies too heavily on default values rather than specific data developed through toxicity studies by outside agencies. AMSA concurs with several commentators who state that EPA should use all valid studies and data when developing chemical risk assessment standards. EPA can improve the quality of those data by publishing clear guidelines as to what, in EPA’s opinion, constitutes credible and valid toxicity data sets for use in the risk assessment process.
- Stakeholders have repeatedly pointed out EPA’s tendency to multiply uncertainty factors together from various steps in the risk assessment process, which generally leads to overestimation of risk. Some analysis of the probability that all or several worst-case conditions will occur simultaneously should be included in all risk assessments. This is important because defaulting to a process of multiplying all the uncertainty factors together, when the probability of all the worst-case events happening simultaneously is very small, will always yield risk analyses that are significantly more restrictive than necessary.
- AMSA agrees with several commentators who state that the way EPA evaluates risk from multiple chemical exposure needs to be reevaluated because the effects of simultaneous

exposure to multiple chemicals may range from synergistic (additive) to antagonistic, or even neutral (no combined effect). It is not apparent that EPA has fully developed procedures to determine which effect is appropriate for the particular risk assessment being conducted.

- AMSA also agrees with stakeholder comments that EPA needs to maintain an ongoing and open dialogue with stakeholders on matters of risk assessment and risk management. Risk assessment and management should not be a closed-door process or policy at EPA because many stakeholders are affected by the final results.

Thank you for considering our comments. If you should have any questions or to discuss these issues further, please do not hesitate to contact Chris Hornback, AMSA's Director of Regulatory Affairs at 202/833-9106.

Sincerely,

A handwritten signature in black ink that reads "K Kirk". The "K" is large and stylized, followed by "Kirk" in a cursive script.

Ken Kirk

Executive Director