

Center for Regulatory Effectiveness

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June 28, 2002

Mrs. Theresa M. O'Malley Executive Officer Information Technology Center U.S. Department of Labor Room N-1301 200 Constitution Avenue, N.W. Washington, DC 20210

Re: <u>Draft OSHA/MSHA Risk Analysis Guidelines for Ensuring and Maximizing the Quality.</u>
<u>Objectivity, Utility, and Integrity of Information Disseminated by the U.S. Department of Labor</u>

Dear Mrs. O'Malley:

The Center for Regulatory Effectiveness (CRE) is pleased to provide you with our Comments on the risk analysis portion of the Department of Labor's proposed Data Quality guidelines. These comments supplement our comments of May 31st on DOL's draft guidelines.

DOL's Adaptation of SDWA Must be Consistent with OMB's Guidelines

DOL has not adhered to OMB's February 22nd government-wide guidelines requiring agencies to adopt or adapt the Data Quality principles set by Congress in the Safe Drinking Water Amendments of 1996. OMB allowed the option of adaptation instead of outright adoption in order to "provide agencies flexibility in applying these principles to various types of risk assessment."

Unfortunately, DOL's draft risk analysis guidelines stretch the concept of adaptation to the extent that they would effectively gut the risk analysis portions of the Department's Data Quality Guidelines. Specifically, the proposed guidelines would allow DOL to utilize risk analysis data and studies that do not comply, or come close to complying, with the SDWA standards.

As the DOL proposal and OMB both explain with regard to SDWA, "Under 42 U.S.C. 300g-1(b)(3)(A), an agency is directed, "to the degree that an Agency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." Furthermore, OMB goes on to state, "We also note that the OMB guidelines call for an additional level of quality "in those situations involving influential scientific or statistical information."

However, rather than applying the SDWA standards, either directly or through reasonable adaptation, DOL proposes to use a variety of data regardless of whether it meets the SDWA data quality standards including:

- Exposure data generated by enforcement activities, contained in published literature and submitted to the record;
- Testimony and comment from experts "familiar" with the underlying scientific information and other relevant information in the record;
- Incident or accident investigation provided by the public or private sectors; and
- Public comment and other information in the public record even if it does not meet SDWA standards.

Nothing in either the OSH Act or the Federal Mine Safety and Health Act precludes use of the SDWA standards. Instead, as DOL notes, "the OSH Act and Mine Act reflect the basic principle underlying the requirements of the Safe Drinking Water Act Amendments, and that is that agency actions be based on the best available scientific information." Thus, DOL's risk analysis guidelines need to ensure that risk-related information disseminated by the Department complies with the SDWA standards.

The Requirement to "Consider" Information in the Record Does Not Override Data Quality Standards

DOL's draft risks analysis guidelines state, "Because of the requirements of rulemaking procedures to consider all evidence and comment placed in the record by interested parties, the Department intends to adapt the principles set forth in the 1996 Safe Drinking Water Amendments to reflect that agencies must consider their statute and case law and data and evidence contained in the rulemaking docket, provided the agencies clearly state the reasons for relying on particular data and evidence."

Although DOL agencies certainly need to "consider" all data and evidence in the record, they must do so in accordance with the standards set by the Data Quality Act and OMB's guidelines, including the SDWA language. Thus, DOL agencies need to consider such information in accordance with the standards set by the Data Quality Act and SDWA and reject -- not rely on -- information in the docket that does not meet the required standards.

DOL Has Not Proposed Any Objective Minimum Quality Standard for Risk Analysis Information

DOL is not proposing to set objective minimum standards or criteria for acceptable quality risk-related information. For example, under DOL's proposal agencies may rely on unpublished "risk analyses conducted by rulemaking participants," public comments and other information. DOL is not proposing to set any minimum standard for relying on such data as long as it is in the record and they explain why they used such data and why they consider it "consistent with the statutory requirements to use the best available information." Under the Data Quality Act and OMB's guidelines, the information in the record could not be relied on in agency information disseminations unless it met at least certain minimum standards such as peer review.

Since DOL's draft risk analysis guidelines do not set certain objective minimum standards, they fall short of OMB's quality requirements. As discussed above, one of the fundamental precepts of the Data Quality Act is to set minimum standards for information disseminated by agencies, with higher standards applied to more important and influential data.

The Department's proposal, in reality, is not an adaptation of the SDWA standards but rather a statement that the agencies are free to use whatever information they consider to be best as long as they explain their decision. DOL's proposal is not only fundamentally odds with OMB's requirements, it could lead to arbitrary and capricious decisions.

OMB's June 10 Comments on Draft Agency Guidelines

OMB, in their June 10, 2002 memo, has provided agencies with comments and guidance on their draft guidelines. OMB urged that draft guidelines submitted to OMB by August 1 reflect consideration of the new guidance. In this new guidance, OMB states that, "agencies that are likely to use and/or disseminate influential information in their analysis of 'risks to human health, safety, and the environment' need to clearly state that they are adopting the SDWA standards or justify in what ways and for what kinds of information the agency is adapting the SDWA standards."

A duty to consider all information in the record or a frequent lack of quality data is not just cause to utilize virtually any information in the record that the agencies choose as long as they consider it, on whatever unspecified grounds, as the best available. DOL's proposal does not comply with OMB's June 10 memorandum.

Conclusion

• DOL's draft risk analysis guidelines do not comport with the requirements set by OMB.

Recommendation

• DOL should adopt the SDWA standards.

Sincerely,

Bruce Scott Levinson

Director, Federal Liaison Activities