



**U.S. Department of Labor**  
**Occupational Safety & Health Administration**

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## **ADAPTING THE PRINCIPLES UNDER THE 1996 SAFE DRINKING WATER ACT AMENDMENTS FOR SAFETY AND HEALTH RISK ANALYSES (DRAFT)**

### REQUEST FOR PUBLIC COMMENT:

The purpose of this draft guidance is to further expand the [Department of Labor's Draft Information Quality Guidelines](#) and adapt the principles under the 1996 Safe Drinking Water Act Amendments for Safety and Risk Analysis. This guidance is required by Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 and associated Office of Management and Budget (OMB) implementation guidance.

The Department welcomes comments on this draft document for a 30-day period.

Please submit comments by June 22, 2002 as follows:

#### Mail:

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

#### Fax:

202-693-4228

#### Email:

[Omalley-Theresa@dol.gov](mailto:Omalley-Theresa@dol.gov)

When disseminating influential information in the context of analyses of safety, health, or environmental risks, the final OMB guidelines instruct agencies to "...adopt or adapt the quality principles applied by Congress to risk information used and disseminated --pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C.300g-1(b)(3)(A) & (B))." According to the preamble to OMB's final guidelines (67 FR 375), these principles reflect a "...basic standard of quality for the use of science in agency decision making" and "...a basic quality standard for the dissemination of public information about risks of adverse health effects."

Specifically, 42 U.S.C. 300g-1(b)(3)(A) states that "to the degree that an agency action is based on science, the [EPA] Administrator shall 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)." Under 42 U.S.C. 300g-1(b)(3)(B), "the Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable." Finally, in documents made available to the public to support regulation, this section of the Safe Drinking Water Act Amendments requires such documents to specify the following, to the extent practicable:

- i. each population addressed by any estimate of public health effects;
- ii. the expected risk or central estimate of risk for the specific populations;
- iii. each appropriate upper-bound or lower-bound estimate of risk;
- iv. each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and
- v. peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile

inconsistencies in the scientific data.

Within the Department of Labor, analyses of safety and health risks are performed primarily by the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA). Such analyses have generally been done only in connection with promulgating safety and health rules; as such, risk analyses disseminated by these agencies are subject to statutory requirements governing the bases for regulatory decision making as well as the public rulemaking process.

The Department is adapting the principles of the Safe Drinking Water Act Amendments for both health and safety risk analyses. For health analyses, the principles will be adapted as follows:

1. In taking agency actions that are based on the use of science in the analysis of health risks, the agency shall use:
  - a. the best available peer-reviewed science, where available, and supporting studies conducted in accordance with sound and objective scientific practices;
  - b. 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);
  - c. exposure data such as that generated by enforcement activity, contained in published literature, and submitted to the rulemaking record; and
  - d. testimony and comment from experts familiar with the underlying scientific information related to the risk analysis and other relevant information in the rulemaking record.
2. In the dissemination of public information about risks, the agency shall ensure that the presentation of information about risk effects is comprehensive, informative, and understandable, within the context of its intended purpose.
3. In a document made available to the public in support of a regulation, the agency shall specify, to the extent practicable:
  - a. each population addressed by any estimate of public health effects;
  - b. the expected risk or central estimate of risk for the specific populations;
  - c. each appropriate upper-bound or lower-bound estimate of risk;
  - d. each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and
  - e. information, data, or studies, peer-reviewed where available, known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and a discussion that either reconciles inconsistencies in the data or information, or explains the rationale used by the agency to rely on the data or information used for the risk analysis.

For safety risk analyses, the principles will be adapted as follows:

1. In taking agency actions that are based on the use of science in the analysis of safety risks, the agency shall use
  - a. the best available statistical data from surveys of fatalities, injuries, and illnesses;
  - b. 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);
  - c. incident reports compiled from an agency's information collection or enforcement activities;
  - d. incident or accident investigation reports provided by the public or private sectors;
  - e. relevant analyses of such information or data, peer reviewed where available; and
  - f. testimony of experts familiar with the causal nature of fatalities, injuries, or illnesses being addressed in the safety risk analysis and other relevant information in the rulemaking record.
2. In the dissemination of public information about safety risks, the agency shall ensure that the presentation of information is comprehensive, informative, and understandable, within the context of its intended purpose.
3. In a document made available to the public in support of a safety regulation, the agency will specify, to the extent practicable:
  - a. the agency's best estimate of the size of the population at risk of such effects;
  - b. the agency's best estimates of the total number and or rate of fatalities, injuries, or illnesses that occur each year and that are relevant to the safety risks being addressed;

- c. the possible range in the agency's best estimate of the number or rate of fatalities, injuries, or illnesses, taking into account possible uncertainties in the data underlying the estimate; incident reports compiled from an agency's information collection or enforcement activities;
- d. data gaps identified in the process of the assessment of risk effects and the kind of data or information that would assist in reducing uncertainty; and incident or accident investigation reports provided by the public or private sectors;
- e. information, data, or studies, peer-reviewed if available, known to the agency that support, are directly relevant to, or fail to support any estimate of risk effects and a discussion that either reconciles inconsistencies in the data or information, or explains the rationale used by the agency to rely on the data or information used for the risk analysis.

With regard to statutory requirements, Section 6(b)(5) of the OSH Act of 1970 and Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 require the Secretary to set health standards, in part, "on the basis of the best available evidence," and require that development of standards be based upon "research, demonstrations, experiments, and such other information as may be appropriate." Section 6(b)(5) and Section 101(a)(6)(A) also state that "...[i]n addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field..." Furthermore, Section 6(f) of the OSH Act mandates that the Secretary's determinations be considered conclusive "if supported by substantial evidence in the [rulemaking] record considered as a whole."

Thus, 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. OSHA's and MSHA's risk assessments disseminated in past health rulemakings have relied on the kinds of scientific information described in the Amendments, i.e., "peer-reviewed science and supporting studies" as well as other data that the agency considers were collected by "accepted methods or the best available methods." The agencies recognize that peer review adds significant value to a scientific study. In OSHA's recent risk assessment, issued in support of the agency's Methylene Chloride rule, the Agency relied primarily on peer-reviewed animal data as well as both peer-reviewed and unpublished (non-peer-reviewed) data describing the pharmacology of methylene chloride in animals and humans. However, in developing risk assessments to support rulemakings, the agencies also consider all other information submitted to the record, including expert testimony, written comments from the scientific community on data and other information contained in the record, including risk analyses conducted by rulemaking participants and submitted to the record.

Part of what can be considered the risk analysis in the context of the Safe Drinking Water Act Amendments also appears in OSHA's and MSHA's Economic Analyses for proposed and final health rules. The Economic Analysis includes an analysis of worker exposures to the health hazard of interest, estimates of the sizes of the exposed worker populations in affected industry sectors, and an analysis of the numbers of exposure-related illnesses that occur in those populations and the numbers of illnesses potentially avoided by the new standard. In past rulemakings, OSHA and MSHA have found relatively few peer-reviewed studies available from which the agencies could reliably construct exposure profiles for all or most affected industry sectors. Information and data typically relied upon by the agencies to conduct these analyses include exposure data generated by enforcement activity, exposure data submitted to the record by industry or labor organizations, industry studies conducted by the National Institute for Occupational Safety and Health (NIOSH), and data obtained by the agencies or their contractors during the conduct of site visits to industrial facilities. In addition, OSHA has usually relied on statistics published by the Bureau of Labor Statistics (BLS) or the U.S. Bureau of the Census to develop estimates of the size of the population at risk.

Analyses of safety risks conducted by OSHA and MSHA to support safety standards are quite different from health risk analyses in terms of the kinds of data and information generally available to the agencies. The goal of a safety risk analysis is to describe the numbers, rates and causal nature of injuries related to the safety risks being addressed. OSHA and MSHA have historically relied on injury and illness statistics from BLS, combined with incident or accident reports from enforcement activities, incident or accident reports submitted to the record from the private or public sectors, testimony of experts who have experience dealing with the safety risks being addressed, and information and data supplied by organizations that develop consensus safety standards (such as the

American National Standards Institute or the ASTM International).

In disseminating its health and safety risk analyses for proposed and final rules, it has been OSHA's and MSHA's practice to state clearly its reasons for using the kinds of information and data described above; this is necessary to demonstrate that the agencies have relied on the "best available evidence" in making its conclusions. 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 Act 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 in the risk analysis. That is, in addition to "peer-reviewed science and supporting studies" and "data collected by accepted methods or best available methods," agencies may consider expert testimony, public comment, and other data and information contained in the rulemaking record, and may rely on such testimony and information in their risk analyses provided that the agencies clearly communicate their rationale for selecting such data and information and why it is consistent with statutory requirements to use the best available information.

The principles outlined by the Safe Drinking Water Act Amendments also contain a specification for reporting results of risk analyses, as described above. For health risk analyses, OSHA and MSHA have historically reported their "best estimate" of the risk to workers exposed to a health hazard; this has typically been an estimate that the agencies refer to as a "maximum likelihood" estimate derived from the statistical procedure of fitting a mathematical exposure-response curve to dose-response data. The agencies also typically have reported statistical upper limits of their estimates of risk. The industry and exposure profiles presented in the Economic Analysis provide estimates of the populations at risk, by affected industry sector. Finally, during the course of rulemaking, OSHA and MSHA must consider and address data, expert testimony, and public comment that deal with uncertainties in the risk assessment and with conflicting scientific evidence. As part of demonstrating that it has relied on the "best available evidence", the agency must also clearly present its reasons for accepting certain studies or data and rejecting others, and reconcile apparent discrepancies or conflicts in the available data to the extent possible. These practices are consistent with the reporting principles described by the Safe Drinking Water Act Amendments, as well as the obligations of the OSHAct and the Mine Act.

These general principles also apply to OSHA's and MSHA's reporting of results and conclusions from analyses of safety risks; that is, the agencies make every effort to reliably estimate the sizes of the populations at risk and the magnitude of the safety risk presented to workers, and to explain uncertainties and apparent discrepancies in the available data. However, as described above, the methods and underlying data relied on for safety risk analyses are often different from that for health risk analyses; thus, the Department has adapted the language of the Safe Drinking Water Act principles as applied to the dissemination of information on safety risks to reflect the kinds of results typically obtained from a safety risk analysis.

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