

DEPARTMENT OF LABOR

Office of the Assistant Secretary for Policy

RIN 1290-AA23

Requirements for DOL Agencies' Assessment of Occupational Health Risks

Action: Proposed Rulemaking

SUMMARY: The Department of Labor (“DOL or Department”) is proposing the following risk assessment requirements for its agencies to follow when developing health standards regulating occupational exposure to toxic substances and hazardous chemicals. This regulation is based on the Department’s historical experience promulgating rules under the Occupational Safety and Health Act of 1970 (“OSH Act”)¹ and the Federal Mine Safety and Health Act of 1977 (“Mine Act”)², and the Department’s technical expertise on the American workforce and occupational health.

DATES: Comments must be submitted on or before [insert date 30 days after publication in the Federal Register.]

ADDRESSES: You may submit comments, identified by RIN, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Office of the Assistant Secretary for Policy, 200 Constitution Avenue, NW, S-2312, Washington, DC 20210, Attention: Risk Assessment Policy.

Instructions: All submissions received must include the agency name and Regulatory Information Number (RIN) for this rulemaking. Comments received will be posted without

¹ 29 U.S.C. § 655 (2000).

² 30 U.S.C. § 811 (2000).

change to www.regulations.gov, and available for public inspection in the Office of the Assistant Secretary for Policy, 200 Constitution Avenue, NW, S-2312, Washington, DC 20210, including any personal information provided. Persons submitting comments electronically are encouraged not to submit paper copies.

FOR FURTHER INFORMATION CONTACT: Office of Regulatory and Programmatic Policy, Office of the Assistant Secretary for Policy, (OASP), U.S. Department of Labor, (202) 693-5959. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

Background

The Department's Mission under the Occupational Safety and Health Act and Federal Mine Safety and Health Act

The Secretary of the U.S. Department of Labor is charged with ensuring safe and healthful working conditions for every working man and woman in the Nation. To that end, the Secretary has broad authority to promulgate health standards. In Section 6(b)(5) of the OSH Act and Section 101(a) (6)(A) of the Mine Act, Congress required the Secretary to set health standards “on the basis of the best available evidence.”³ The Acts also state that, “in 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.”⁴ In sum, the OSH Act and Mine Act reflect a basic principle that agency actions should be based on the best scientific information available at the time of the agency action.

³ 29 U.S.C. § 655(b)(5) (2000), 30 U.S.C. § 811(a)(6) (2000).

⁴ Id.

Summary of the Department's Current Procedures for Risk Assessment

Within the Department, risk assessments related to the regulation of occupational exposure to toxic substances and hazardous chemicals are performed primarily by the Occupational Safety and Health Administration (“OSHA”) and the Mine Safety and Health Administration (“MSHA”). The agencies' risk assessments generally rely on peer-reviewed science and supporting studies, as well as other information submitted to the record, including expert testimony, written comments from the scientific community, and in some instances, independent risk analyses submitted to the record by rulemaking participants.

For the purposes of this NPRM, “risk assessment” is defined as the overall process of evaluating the risk associated with a health hazard from a toxic substance or hazardous chemical. A “hazard” is an intrinsic property of a substance or event, which has the potential to cause harm. “Risk” is the probability of the occurrence of harm given exposure to the hazard. The risk assessment paradigm incorporates the following steps:

1. *Hazard identification* – determining whether a toxic substance or hazardous chemical is a health hazard;
2. *Dose-response assessment* – determining a quantitative model (level of exposure, conditions, etc.) that accounts for the relationship between a hazard and an adverse health outcome;
3. *Exposure assessment* – estimating the exposure of a population to a hazard; and
4. *Risk characterization* – estimating the likely incidence of exposure-related morbidity and mortality in a given population, and the extent to which risk management measures will reduce the incidence.

OSHA and MSHA apply the risk assessment paradigm by evaluating the best available health data to determine whether employees will suffer a material impairment of health or functional capacity as a result of being regularly exposed to a particular health hazard over a working lifetime.

Once a risk assessment is complete, the agencies then turn to reduction of the risk through risk management. For the purposes of this rulemaking, “risk management” is defined as policy decision-making that applies the findings of risk assessment within statutory parameters to reduce, control or mitigate health hazards. The Supreme Court has interpreted the OSH Act to require that the Department find there is a “significant risk” that can be eliminated or lessened by a change in practices before promulgating any health standard.⁵ In addition, the Court has held that a cost-benefit analysis by OSHA is not required by the statute because a feasibility analysis is.⁶ The Court explained that, “Congress itself defined the basic relationship between costs and benefits, by placing the “benefit” of worker health above all other considerations save those making attainment of this “benefit” unachievable.”⁷

The Department’s agencies start the process of risk assessment by first reviewing a broad array of available scientific information to identify and characterize hazards to which employees are exposed in the workplace and that are likely to induce material impairments of health or functional capacity. This represents the *hazard identification* step of risk assessment and is published in the Health Effects preamble section of the Department’s proposed and final rules.

⁵ See *Industrial Union Dept. v. American Petroleum Inst.*, 448 U.S. 607, 614-15, 100 S.Ct. 2844, 2850 (1980).

⁶ *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490,509, 101 S.Ct. 2478, 2490-91 (1981).

⁷ *Id.*

The agencies then identify studies or other data that are useful in making quantitative estimates of the health risk among exposed employees over their working lives. While many studies may add to the overall weight of evidence, often only select data is suitable for making quantitative estimates of risk. The quantitative estimation of health risk often involves the use of dose-response mathematical models which allow the agencies to extrapolate scientifically observable data, in humans or animals, to a variety of exposure scenarios. This quantitative estimation of risk from the health effects data represents the *dose-response assessment* step and is published in the Risk Assessment preamble section of the Department's proposed and final rules.

The agencies are statutorily required to eliminate significant risk to the extent economically and technologically feasible.⁸ This feasibility analysis includes identification of all industry sectors potentially affected by the health standard, a detailed estimation of current exposures by industry and job title, and an assessment of technologically feasible methods of controlling those exposures. The detailed exposure profiles and their description represent the agency's *exposure assessment* and are provided in the Industry Profile chapter of the full Economic Analysis that accompanies the Department's proposed and final rules.

The range of risks posed to employees and how those risks pertain to the determination of significant risk and reduction in risk necessary to establish an occupational health standard are published in the Significance of Risk preamble section. This section represents one aspect of the agency's *risk characterization*. The occupational exposure profiles and the quantitative estimates of risk are used to predict the health impacts associated with current exposure conditions. Also addressed, are the benefits, in terms of health risk avoided, that are expected to arise from

⁸ 29 U.S.C. § 655(b)(5) (2000); 30 U.S.C. § 811(a)(6)(A) (2000).

compliance with the occupational standard. This is another aspect of *risk characterization* that is provided in the Benefits chapter of the full Economic Analysis that accompanies the Department's proposed and final rules.

Additionally, parts of the agencies' risk analyses generally appear in the Economic Analysis section of proposed and final 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, the number of exposure-related illnesses that occur in those populations, and the number 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 site visits to industrial facilities. In addition, to develop a profile of the population at risk, the Department usually relies on statistics published by the Bureau of Labor Statistics ("BLS") or the U.S. Bureau of the Census.

The Need for Consistency, Reliability and Transparency

The Secretary has determined that the Department's risk assessment and risk management practices should be consistent, reliable and transparent to affected workers, the

regulated community, and the public. The purpose of this rulemaking is to establish consistent policies and procedures for the Department's agencies to follow when conducting risk assessments and managing occupational health risks associated with workplace exposures to toxic substances and hazardous chemicals.

Federal risk assessment and management policies were studied by the 1997 Presidential/Congressional Commission on Risk Assessment and Risk Management ("the Commission on Risk"). The Commission on Risk was created by the 1990 Clean Air Act Amendments, "to make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances."⁹ The Commission on Risk made specific findings with respect to OSHA. In particular, it found that, "OSHA seems to have relied upon a case-by-case approach for performing risk assessment and risk characterization," and recommended that the agency publish guidelines laying out its scientific and policy defaults with regard to risk assessment and risk characterization in support of risk management.¹⁰

This NPRM addresses the Commission on Risk's recommendation by providing a policy and procedural framework for evaluating occupational risk. The Department's proposal is based on the Department's historical experience promulgating rules under the OSH Act and the Mine Act"), the Department's technical expertise on the American workforce and occupational health

⁹ 42 U.S.C. 7412 note, Pub. L. 101-549, § 303, Nov. 15, 1990.

¹⁰ Presidential/Congressional Commission on Risk Assessment and Risk Management, *Framework for Environmental Health Risk Management*, 2 Final Report 131-36 (1997) ("Commission on Risk Report").

and is consistent with the Office of Management and Budget's ("OMB") September 19, 2007, Memorandum to the Heads of Executive Departments and Agencies on Updated Principles for Risk Analysis.¹¹

The key objectives of this rulemaking are:

- **Transparency:** The reasoning, assumptions, calculations, methods and data on which risk assessment findings and risk management decisions are made should be presented in an open and readily accessible format to enable members of the public to review, critique, and replicate the process leading to the findings and decisions. Where results embody uncertainty, the degree of uncertainty should be clearly stated and quantified in probabilistic terms if adequate data is available and the analysis adds value to the risk management decision process.
- **Consistency:** Analytical methods, procedures and approaches should be uniformly applied across the range of hazards subject to risk assessment. The choice of methods, procedures and approaches should be based on objective criteria and adhere to basic principles that have achieved general scientific acceptance. While consistency is a key objective, risk analysis is an evolving scientific process and agencies must retain sufficient flexibility to incorporate methodological and analytical advances. In addition to the extent risk analyses must be tailored for particular projects, the Department's agencies should clearly articulate the reasons for selecting the methodologies used.
- **Reliability:** Analyses and calculations must be based on the best available scientific data and practices, informed by the most up-to-date scientific findings.

¹¹ U.S. Office of Management and Budget (OMB) and Office of Science and Technology Policy (OSTP), Memorandum for the Heads of Executive Departments and Agencies, *Updated Principles for Risk Analysis* (2007) M-07-24, available at <http://www.whitehouse.gov/omb/inforeg/regpol.html#opp>.

The Department is not required to seek public comment on its internal procedures under the Administrative Procedure Act (“APA”), but has chosen to do so in this case in order to gain valuable outside input and in the interests of full transparency and accountability to the public. Accordingly, the Regulatory Flexibility Act does not apply to this rulemaking.¹² In addition, because this rulemaking merely communicates to the public how the Department will regulate itself, and does not require the regulated community to provide conditions or adopt practices to provide safe or healthful employment, it does not constitute an “occupational safety and health standard” for the purposes of the public hearing requirements of the OSH Act¹³ and Mine Act.¹⁴

Data and Information Quality

Congress emphasized in the 1996 Amendments to the Safe Drinking Water Act (“SDWA Amendments”)¹⁵ that risk analyses under that Act should be based upon the best available scientific methodologies, information, data, and weight of the available scientific evidence. DOL has adopted that principle for both health and safety risk analyses conducted by OSHA and MSHA. Currently, through internal guidance, the Department mandates that:

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 and supporting studies conducted in accordance with sound and objective scientific practices; and

¹² See, 5 U.S.C. § 601 (2000).

¹³ See, 29 U.S.C. § 652(8) (2000) and § 655(b)(3) (2000).

¹⁴ See, 30 U.S.C. § 811(a)(3) (2000).

¹⁵ 42 U.S.C. § 300g-1(b)(3)(A) and (B) (2000).

b. data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justify use of the data), including:

i. exposure data such as that generated by enforcement activity, contained in published literature, and submitted to the rulemaking record; and

ii. 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 quantitative analysis of health risks made available to the public, 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 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 reconciles inconsistencies in the data or information, and explains the rationale used by the agency to rely on the data or information used for the risk analysis.

These principles and those contained in the OMB Guidelines have been incorporated in DOL's internal Information Quality Guidelines for occupational safety and health risk assessments performed by OSHA and MSHA.¹⁶

As described above, the SDWA Amendments also address the reporting of results of risk analyses. For occupational health risks from toxic substances and hazardous chemicals, OSHA and MSHA historically report their "best estimate" of the risk to workers exposed to a health hazard. This is typically 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 report statistical upper limits of their estimates of risk. The industry and exposure profiles presented in the Economic Analysis section of the preambles to the Department's proposed and final rules provide estimates of the populations at risk, by affected industry sector. Finally, during the course of rulemaking, OSHA and MSHA consider and address data, expert testimony, and public comments that deal with uncertainties in the risk assessment and with conflicting scientific evidence. The agencies present their 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 SDWA Amendments, as well as the Department's obligations under the OSH Act and the Mine Act.

In addition to ensuring the quality of the information relied upon, the Department further mandates that important scientific information shall be peer reviewed before dissemination or

¹⁶ U.S. Dept. of Labor, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor* (2002) (Appendix II) ("DOL Information Quality Guidelines"), available at <http://www.dol.gov/informationquality.htm>.

