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Good morning Madam Chair and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the Department of Labor's recent Notice of Proposal Rulemaking (NPRM) regarding our internal procedures for conducting rulemakings that involve the regulation of potential workplace exposure to toxins. The goals of this proposed rule are to increase the transparency, consistency and scientific reliability of the Department's health standard rulemakings that include risk assessments.

The Department's proposed rule codifies existing best practices into a single, easy to reference regulation, and includes two provisions to promote greater public input and awareness of Department rulemakings. Specifically, those provisions are the issuance of an Advanced Notice of Proposed Rulemaking (ANPRM) as part of the health standard rulemaking, and the electronic posting of all documents the Department relies upon when developing the health standard. It is important to note that this proposal does not affect the substance or methodology of risk assessments and does not impose additional standards or compliance obligations on the regulated community.

Commission on Risk

Currently, the Department does not have comprehensive regulations or guidance governing our procedures for conducting rulemakings that involve the regulation of workplace exposure to toxins. Federal risk assessment and management policies were thoroughly studied by the bipartisan Presidential/Congressional Commission on Risk Assessment and Risk Management (Commission on Risk), which 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."

In its 1997 final report, the bipartisan Commission on Risk made specific findings with respect to the Occupational Safety and Health Administration (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 and describe its scientific and policy defaults with regard to risk assessment and risk characterization in support of risk management.² This NPRM implements the Commission on Risk's recommendation by explaining the agency's existing best practices related to risk assessment in one easy-to-reference regulation, and by including two provisions to establish consistent procedures that promote greater public input into and awareness of the Department's health rulemakings.

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

² 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).

Principles Underlying this Proposal

This proposed regulation is a compilation of basic principles and practices related to risk assessment. As such, it ensures that DOL's scientists have the necessary latitude to exercise their professional discretion and to modify their assessments as science evolves, while assuring that the Department's process is fully accountable to the public.

The principles underlying this rulemaking are:

1. 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 Department's findings and decisions. Where results embody uncertainty, the degree of uncertainty should be clearly stated and quantified in probabilistic terms if adequate data are available, and the analysis adds value to the risk management decision process.

2. Consistency

The approaches used to assess risk should conform to accepted scientific practice and strive to be consistent with approaches used in previous occupational standards that address similar hazards and agents. A justification should be provided when alternate approaches are employed. 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.

3. Reliability

Analyses and calculations must be based on the best available scientific data and practices consistent with the Federal Government's directives on information quality and peer review.

Summary of the Proposal

DOL is proposing this rulemaking pursuant to the Secretary's authority at 5 U.S.C. Section 301 to prescribe regulations related to the performance of the agency's business and the conduct of its employees. Although the Department is not required to seek public comment on its internal procedures under the Administrative Procedure Act (APA), the agency has chosen to do so in order to gain public input and in the interests of full transparency and accountability. 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.

The Secretary of Labor is charged with ensuring safe and healthful working conditions for working men and women. To that end, the Secretary has broad authority to promulgate health standards. In Section 6(b) (5) of the Occupational Safety and Health Act of 1970 (OSH Act) and Section 101(a) (6) (A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) Congress required the Secretary to set health standards "on the basis of the best available evidence." 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." 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. The Government-wide Office of Management and Budget (OMB) Information Quality Guidelines, internal U.S. Department of Labor Information Quality Guidelines, and the OMB/ Office of Science and Technology Policy 2007 Memorandum on Updated Principles for Risk Analysis further reflect this principle. This proposal will help ensure that the best available evidence and latest scientific data in the field, including industry-specific information when available, is utilized in agency risk assessments.

The proposed regulation requests public comment on two matters. First, the rule seeks comment on the Department's issuance of an ANPRM before publishing an NPRM or other regulatory action in a health standard rulemaking. An ANPRM would permit the agency to cast a wide net for available information from the public, before proposing a health standard. Further, including an ANPRM in health rulemakings helps to ensure that the Department has the best information necessary to produce a thorough and accurate risk assessment; the ultimate purpose of which is to effectively protect workers. The Department has frequently utilized an ANPRM in its health standard rulemakings since the early 1970s when it began regulating exposure to workplace toxins. In fact, two of the last three health standard rulemakings began with an ANPRM and the third began with a Request for Information before the NPRM. The publication of the ANPRM, submission of public comments and agency review of comments will occur simultaneously with the ordinary development of a health standard. The proposal

suggests that the ANPRM could occur soon after the proposed standard is placed on the regulatory agenda, which is the period of time when the agency would typically be gathering information related to the proposed rulemaking, or concurrently with the Small Business Regulatory Fairness Act (SBREFA) process. The Department believes the risk assessment and rulemaking process will be strengthened by consistent opportunities for public input through an ANPRM.

Second, the Department requests comment on the electronic posting of all information associated with the development of regulations addressing occupational exposure to toxic substances and hazardous chemicals. This information would include for example, scientific studies relied upon in the rulemaking, risk assessment analyses underlying the NPRM and Final Rule, public hearing transcripts and briefs, SBREFA process documents, and public comments. The Department believes electronic posting of all documents related to a health standard rulemaking will promote greater public input, awareness, and transparency of the information underlying the Department's health rulemakings.

This proposed rule impacts only internal agency procedures for conducting health standard rulemakings. It does not affect the methodologies or substance of risk assessments and does not impose additional standards or compliance obligations on the regulated community. The proposal was published in the *Federal Register* on August 29, 2008 with a thirty (30) day public comment period.

Conclusion

The Department's proposal codifies the agency's existing best practices by compiling the Department's procedures for health standard rulemakings, into a single, easy to reference regulation. In addition, consistent with the agency's commitment to public participation in the rulemaking process, the proposal includes the issuance of an open call for relevant data through an Advance Notice of Proposed Rulemaking and provides the public with electronic access to all materials relied upon in those health rulemakings. Contrary to numerous erroneous reports and speculation, the Department's proposed rule is not a health rulemaking; it does not weaken any health standard; and it does not change the methodology for conducting risk assessments.

Thank you for the opportunity to testify today. I would be pleased to answer questions from the Subcommittee.