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.

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[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

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[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 Act[13] 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

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[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

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[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.

use by qualified, independent specialists or scientists who were not involved in producing the product. Peer review ensures that the quality of the Department's information meets the standards of the scientific and technical community, and the Department's practices are consistent with the requirements of OMB's Peer Review Bulletin. The Department posts on its website an agenda of peer review plans for all planned and ongoing influential scientific information and submits an annual report to OMB summarizing the peer reviews conducted by the agency during the previous fiscal year.

Hazard Identification

The foundation for every risk assessment is a thorough compilation of relevant studies and information. Risk assessors gather applicable information directly from NIOSH, the Environmental Protection Agency ("EPA"), academic researchers, stakeholders, petitioners, and other experts. Also, relevant studies are often provided to the Department's agencies as part of a petition for rulemaking. Supplementary searches may be performed using scientific literature databases to obtain a complete profile of the chemical of interest. The Department believes that risk communication should involve the open exchange of information among technical experts in relevant disciplines, policy makers, and the public. Therefore, the Department's agencies shall issue an Advance Notice of Proposed Rulemaking ("ANPRM") soliciting public input on relevant studies and scientific information, working life data for the affected industries and occupations, key default factors and assumptions, and other relevant information related to the development of a health standard regulating occupational exposure to a particular toxic substance or hazardous chemical prior to issuing a Notice of Proposed Rulemaking ("NPRM") or other regulatory action in that health rulemaking. The Department's agencies shall publish an

ANPRM except when issuing emergency temporary standards under Section 6(c) of the OSH Act, 29 U.S.C. § 655(c) and Section 101(b)(1) of the Mine Act, 30 U.S.C. § 811(b)(1).

An important component of hazard identification is the selection of health endpoints, which are the outcomes that result from exposure to a hazard. Endpoints can be selected for chemicals based on observational studies (epidemiologic studies), industrial hygiene assessments, medical assessments, experimental studies (toxicological studies), surveillance data, and toxicological screening batteries. The Department believes that the selection of health endpoints should be explicitly articulated in its future risk assessment documents. DOL further believes that the overall reliability of studies relied upon should be analyzed and discussed. Given that there are many different designs for studies, simple rules for their evaluation do not exist. However, key factors that affect the reliability of the epidemiological studies include: the power of the study to detect the endpoint, biases that may make the study data not representative of the whole population, and confounders (e.g., age, smoking, and alcohol or caffeine consumption, drug use). For animal studies, key considerations include quality of study design, number of dose groups, number of animals per dose group, range of dose levels employed, route of exposure, and human relevance of health outcomes found in the studies.

Hazard identification is typically presented in the Health Effects sections of preambles to the Department's proposed and final rules. This written analysis should include a summary of the database and an opinion as to the confidence with which conclusions can be drawn from this database, any alternative conclusions that are supported by the database, any significant data gaps, and any assumptions that will be made during the risk assessment process to address those gaps.

Dose-Response Assessment

The dose-response assessment examines the relationship between exposure to the agent in question and the health effects of concern. This assessment strives to quantitatively estimate health risk in the range of occupational exposures of interest (e.g. the current exposure limit and exposure levels being considered to set new or revised limits). The process generally involves: selection of suitable study data, exposure metrics, and health endpoints; application of appropriate risk models to the data; characterization of the uncertainties and limitations in the assessment; and a discussion of how the results compare to other published dose-response assessments for the same agent under similar exposure conditions.

Dose–response assessments should adhere to principles consistent with scientific objectivity and transparency. The criteria and rationale for the selection of studies and health endpoints used in the analysis should be fully explained. The assessment should explore a range of plausible risk models and exposure metrics consistent with scientific understanding about the agent and its mode of action. If physiologically based models are applied to the data, the chosen input parameters should be well supported and the model sufficiently validated. Risks descriptors should be presented as estimates of central tendency along with the appropriate upper and lower bounds. The assessment should strive to determine whether the quantitative estimates are consistent with other positive and negative studies. Any assumptions and other judgments used in the absence of data shall be stated and the rationale articulated.

The limitations and uncertainties in the data sets and models employed in the dose-response assessment should be characterized. To the extent possible, the assessment should discuss the impact of key assumptions, uncertainties, and factors that interact with the agent of concern. The assessment should address vulnerable and/or susceptible worker populations where

there is scientific evidence to support potential differences in risk. Quantitative variability in risk should be characterized when there is sufficient data and appropriate models. Quantitative uncertainty and sensitivity analyses should be considered if adequate information is available and its use would add value to the risk management decision.

Exposure Assessment

There should be adequate characterization of information in determining an association between health effects and exposure to an agent. Exposure parameters include the level, duration, route, and frequency of the exposure of individuals in one population as compared with another. A thorough risk analysis should summarize the scope of the assessment, including a description of: the agent, technology and/or activity that is the subject of the analysis; the hazard of concern; the affected entities (populations, subpopulations, individuals) that are the subject of the assessment; the exposure/event scenarios relevant to the objectives of the assessment; and the type of dose-response relationship for the hazard of concern. In the 2007 National Academy of Science ("NAS") Report on OMB's Proposed Risk Assessment Bulletin, the NAS reaffirmed that including full hazard information would improve the clarity of a risk analysis and is consistent with the recommendations of previous expert reports.[17] Where there are known differences in risk for different individuals or subpopulations, the Department's agencies should characterize this variability. Risk managers will be better informed when an understanding of variability and the key contributors to the cause of this variability are presented in the risk analysis.

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[17] National Research Council, National Academy of Sciences, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget* (2007) ("2007 NAS Report").

Risk Characterization

The risk characterization summarizes the hazard identification, dose-response assessment, and the exposure assessment steps. This step provides a bridge between the risk assessment and risk management processes. The risk characterization conveys to risk managers, decision makers, stakeholders, and the general public, the key findings and recommendations that risk assessors have derived about the nature and magnitude of the health risks. It also includes a discussion of the strengths and weaknesses of the risk assessment. With this knowledge, a risk manager is appropriately prepared to make policy decisions about how to best manage the particular risk.

A. Identification of Uncertainties and Assumptions

The elements that are included in the risk characterization depend on the purpose of the risk assessment and the information that is needed to characterize the risk assessment adequately. However, the risk characterization should always identify inherent uncertainties associated with estimates of risk. When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided. Quantitative uncertainty analysis, sensitivity analysis, and a discussion of model uncertainty should be utilized when possible.

In addition, the Department is usually faced with a range of choices on assumptions and inputs used in risk characterization models because risk assessments are typically conducted with limited amounts of data. Thus, some assumptions must be made to predict the effects of exposure to toxicants. The Supreme Court has confirmed that OSHA, "is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the

side of overprotection rather than underprotection."[18] While the agencies have wide discretion, the decision to adopt a particular assumption over another should always be transparent and explained. To assure that a consistent and scientifically defensible approach is used in risk assessment, the risk assessor should describe key assumptions that are made in the risk assessment. When such assumptions are adopted, their impacts on the outcome and proper interpretation of the risk assessment should be discussed. This rulemaking clarifies that DOL agencies shall identify the assumptions that may apply to a particular variable when presenting risk assessment data to DOL risk managers. The assumptions that apply shall also be identified in any public risk assessment document.

B. Tailoring "Working Life" to Reflect the Best Available Data and Evidence

Under Section 6(b)(5) of the OSH Act and Section 101(a)(6)(A) of the Mine Act, the Secretary is required to:

> ...set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.... 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, the feasibility of the standards, and experience gained under this and other health and safety laws.[19]

Historically, the Department has implemented this mandate by assuming a 45-year "working life" for the purpose of promulgating standards dealing with toxic materials or harmful physical agents. The Department has explained this assumption on the basis

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[18] Id. at 656, 2871.

[19] 29 U.S.C. § 655(b)(5) (2000) and 30 U.S.C. § 811(a)(6)(A) (2000).

"that it is reasonable to assume that a person begins work at age 20 and continues until the age of 65, a 45 year span of employment."[20]

The Department has also acknowledged, however, that use of the standard 45-year working life model may not always be appropriate. For example, in proposing to regulate occupational exposure to tuberculosis, the Department "solicit[ed] information regarding the . . . duration of employment in various occupational groups."[21] These acknowledgments reflect the Department's longstanding belief that the "working life" measure should reflect realistic estimates, based on the best available evidence, of the actual number of years that workers who spend their entire working life in a particular industry or occupation tend to work. In the Department's view, customizing the number of hours, days, weeks and years attributed to a "working life," on an industry-specific basis, most closely hews to Congress's intent in directing the Secretary to set standards based upon the "best available evidence" and upon consideration of the "latest available scientific data."

Thus, the Department believes that the hourly, daily, weekly and yearly components of the "working life" exposure assumption should, whenever the available data allows, be calculated on an industry-by-industry basis. In some cases, this may result in a yearly working life that is greater than 45 years, and in other cases it may result in a working life that is less than 45 years. If there is not reliable data upon which to accurately customize the hourly, daily, weekly and yearly components of "working life" for a particular occupation, the Department believes it is reasonable to rely upon the default 8 hours per day, 5 days per week, 50 weeks a year over 45 years working life that the courts have held is within the agency's discretion to use.

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[20] 54 Fed. Reg. 20672, 20681 (May 12, 1989) (Methylenedianiline (MDA) proposal).
[21] 62 Fed. Reg. 5460, 54193 (October 17, 1997).

Accordingly, in conducting future risk assessments for rulemaking related to health standards, the Department proposes to require its agencies to specifically request industry and occupation specific data on the hourly, daily, weekly and yearly components of working life in the initial ANPRM. The Department shall measure working life using the best available evidence to reflect general workforce data and any reliable data that exists for a particular industry or occupation.

In determining the working life specific to a given industry or occupation, the Department interprets Section 6(b)(5) of the OSH Act and Section 101(a)(6)(A) of the Mine Act as favoring the use of the average number of hours, days, weeks and years worked by a worker who spends his or her entire working life in that industry or occupation. The statute requires the Department to use a standard that ensures that "no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life," and the Department has always interpreted the statute as requiring that standards be based on the exposure that would be experienced by a hypothetical worker who is exposed to a substance for his or her entire working life. Although the statute uses the phrase "no employee," the Department has never interpreted this language as requiring it to use the longest actual or theoretical working life it can identify or imagine. Rather, the Department has used a default 45 year working life because it considered a 45-year estimate to most reasonably reflect the average working life of an American worker. To the extent the best available evidence allows, the Department proposes to continue to use the average number of years worked by a worker who spends his or her entire working life in an industry or occupation when making industry-specific working life calculations.

The Department notes that even where industry-specific working life calculations result in the use of a working life of less than 45 years, such standards will unquestionably remain extraordinarily protective of workers. In Tables 1-4, recent data from the biannual Employee Tenure supplement to BLS' monthly Current Population Survey ("CPS") show, that there is no industry or occupation in which more than 5% of workers remain with a single employer in the industry or occupation for a period of even 35 years. For most industries and occupations, the percentage of workers who remain with a single employer in the industry or occupation for 35 years is less than half that. Thus, the actual exposure of the overwhelming majority of workers will likely be substantially less than any industry-specific average working life estimate that is used by the Department. Similarly, average hourly, daily and weekly periods of work may vary significantly above or below the Department's 40 hours per week assumption based on the particular industry or occupation. CPS annual average data for 2007, shows that across all occupations, average weekly hours totaled 39.2 hours per week, and for some occupations, average hours actually worked were either significantly above or below the 40 hours per week assumption.[22]

[22] Bureau of Labor Statistics, 2007 Annual Social and Economic Supplement to the Current Population Survey. U.S. Dept. of Labor, *Current Population Survey*, March 2006.

Table 1. Percent distribution of employed wage and salary workers by tenure with current employer and industry, January 2004 and January 2006 average.

	10 years and under	10-20 years	20-30 years	30-40 years	40-45 years	45 years and over
Total	78.4	14.1	5.8	1.6	0.1	0.1
Agriculture, forestry, fishing, & hunting	78.1	13.0	6.1	2.4	(1)	0.3
Mining	71.5	14.4	10.8	3.0	(1)	0.3
Construction	84.2	11.1	3.8	0.8	(1)	0.1
Manufacturing	69.2	18.2	9.2	3.1	0.2	0.1
Wholesale & retail trade	85.1	10.4	3.3	0.9	0.1	0.1
Transportation & utilities	66.9	20.0	10.3	2.7	0.1	(1)
Information	76.9	13.7	6.8	2.3	0.2	(1)
Financial activities	81.4	13.2	4.2	1.0	(1)	0.1
Professional & business services	85.1	10.7	3.2	0.8	0.1	0.1
Educational & health services	75.7	15.8	6.6	1.8	0.1	(1)
Leisure & hospitality	92.0	6.2	1.7	0.1	0.1	(1)
Other services	83.4	12.5	2.9	1.0	0.2	0.1
Public administration	57.7	26.2	13.3	2.7	0.1	0.1

[1] Less than 0.05 percent.

Source: Assistant Secretary for Policy - OEPA tabulation of Current Population Survey micro data.

Table 2. Percent distribution of employed wage and salary workers by tenure with current employer and occupation, January 2004 and January 2006 average.

	10 years and under	10-20 years	20-30 years	30-40 years	40-45 years	45 years and over
Total	78.4	14.1	5.8	1.6	0.1	0.1
Management, business, & financial	70.4	18.5	8.8	2.0	0.2	0.1
Professional & related	74.4	16.0	7.4	2.1	0.1	0.1
Service	85.4	10.6	3.2	0.7	(1)	(1)
Sales & related	85.4	10.5	3.1	0.9	0.1	0.1
Office & administrative support	78.1	14.7	5.5	1.5	0.1	0.1
Farming, fishing, & forestry	82.5	11.1	4.3	1.6	0.2	0.3
Construction & extraction	84.2	11.0	4.0	0.8	(1)	0.1
Installation, maintenance, & repair	74.7	15.3	7.3	2.4	0.2	0.1
Production	73.6	16.3	7.4	2.5	0.2	0.1
Transportation & material moving	81.8	12.0	4.7	1.5	0.1	(1)

1 Less than 0.05 percent.

Source: Assistant Secretary for Policy - OEPA tabulation of Current Population Survey micro data.

Table 3. Share of wage and salary workers with only one employer since age 20 by age and industry, January 2004 and January 2006 average.

	20-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65 years and over
Total	45.4	7.3	4.1	3.6	1.7	0.8
Agriculture, forestry, fishing, & hunting	48.4	14.0	5.0	5.2	3.6	0.4
Mining	56.8	4.9	9.8	3.9	1.6	8.6
Construction	49.5	7.0	4.8	2.8	1.3	4.2
Manufacturing	41.7	10.6	5.6	7.6	4.6	1.6
Wholesale & retail trade	52.3	10.7	4.4	3.1	1.7	0.8
Transportation & utilities	45.7	8.7	6.9	6.0	3.3	0.9
Information	41.9	5.5	5.1	5.9	3.9	2.0
Financial activities	37.7	6.7	3.8	2.1	1.2	0.5
Professional & business services	35.0	3.6	2.2	1.2	0.5	0.9
Educational & health services	39.9	4.2	2.8	2.0	0.7	0.4
Leisure & hospitality	49.4	8.6	2.1	1.6	0.5	(1)
Other services	49.0	8.4	3.5	1.2	1.2	0.3
Public administration	42.1	7.4	5.3	5.8	0.8	(1)

[1] Less than 0.05 percent.

Source: Assistant Secretary for Policy - OEPA tabulation of Current Population Survey micro data.

Table 4. Share of wage and salary workers with only one employer since age 20 by age and occupation, January 2004 and January 2006 average.

	20-24 years	25-34 years	35-44 years	45-54 years	55-64 years	65 years and over
Total	34.0	6.8	4.7	4.1	2.1	0.5
Management, business, & financial	29.7	3.3	2.5	2.7	1.0	0.5
Professional & related	47.9	7.1	2.9	1.8	0.8	0.0
Service	50.6	9.3	3.5	2.7	1.3	0.6
Sales & related	48.3	8.9	5.4	4.0	1.4	1.1
Office & administrative support	42.8	19.9	2.3	4.2	4.8	(1)
Farming, fishing, & forestry	51.2	8.0	5.2	3.4	1.9	4.4
Construction & extraction	49.6	8.9	6.3	5.9	4.5	4.0
Installation, maintenance, & repair	49.4	12.9	5.9	7.3	3.9	2.5
Production	45.2	7.4	4.2	3.8	2.5	0.4
Transportation & material moving	45.4	7.3	4.1	3.6	1.7	0.8

[1] Less than 0.05 percent.

Source: Assistant Secretary for Policy - OEPA tabulation of Current Population Survey micro data.

Once a risk assessment is complete, the agencies then evaluate how to reduce the risk through risk management. Risk management integrates risk characterization results with Department policies and directives, statutory considerations, and other information to assess policy options and recommend regulatory action. The Commission on Risk stated that, "A good risk management decision is based on a careful analysis of the weight of scientific evidence that supports conclusions about a problem's potential risks to human health and the environment."[23] This may include consideration of both positive and negative studies, in light of each study's technical quality. The scientific community continues to develop techniques for weight of evidence evaluations, and DOL risk assessors and managers should make every effort to keep apprised of developments and recommended best practices.

Public Access to Rulemaking Information

Transparency and easy public access to all rulemaking information is a key objective of this rulemaking. Therefore, this proposal would require the Department to post together in an easily accessible format in the applicable docket on www.regulations.gov, all relevant documents related to any rulemaking addressing occupational exposure to toxic substances and hazardous chemicals no later than seven days after the conclusion of the relevant step in the rulemaking process. Those rulemaking steps shall include but are not limited to: publication of the ANPRM, conclusion of the Small Business Regulatory Fairness Act ("SBREFA") process, publication of the NPRM, conclusion of any public hearing under the OSH Act and Mine Act, and the publication of the Final Rule. The documents to be posted shall include but are not limited to: any underlying scientific studies relied upon in the document, to the extent possible given

[23] Risk Commission Report 1, p. 23, *supra* note 6.

copyright limitations, all risk assessment analyses underlying the NPRM and Final Rule, the ANPRM, SBREFA process documents, the NPRM, all public hearing transcripts and briefs, all public comments, the final docket of the rulemaking and the Final Rule.

Conclusion

The Department invites comment from the public on its proposed risk assessment procedures. We encourage you to participate by submitting your comments and other relevant information to the docket.

For the reasons outlined in the preamble, the Department of Labor proposes to amend [New 29 CFR §2.9 (Secretary's General Authority) or new 29 CFR. §1911.6 (OSHA) and new 30 CFR Part 2 in Subchapter A/ new Subchapter (MSHA)] as follows:

Regulatory Text

Assessment of Occupational Health Risks

These provisions apply to risk assessments prepared by DOL agencies and to risk assessments prepared by others, for use by DOL, in relation to the development of health standards. Risk assessments for the development of health standards addressing toxic substances and hazardous chemicals shall be prepared in the following manner.

(a) Authority. The Department's requirements related to the assessment of occupational health risks are issued under Section 6(b)(5) of the Occupational Safety and Health Act, 29 U.S.C. § 655(b)(5) (2000), and Section 101(a)(6) of the Federal Mine Safety and Health Act, 30 U.S.C. § 811(a)(6) (2000).

(b) Significant risk. The Department shall find, as a threshold matter, that there is a significant risk that can be eliminated or lessened by a change in practices before promulgating a health standard pursuant to the Occupational Safety and Health Act.

(c) Risk assessments generally.
    (1) Department agencies shall issue an Advance Notice of Proposed Rulemaking ("ANPRM") soliciting public input on relevant studies and scientific information,

working life data for the affected industries and occupations, key default factors and assumptions, and other relevant information related to the development of a health standard regulating occupational exposure to a particular toxic substance or hazardous chemical prior to issuing a Notice of Proposed Rulemaking ("NPRM") or other regulatory action in that health rulemaking, except when promulgating an emergency temporary standard under Section 6(c) of the OSH Act, 29 U.S.C. § 655(c) (2000) and Section 101(b)(1) of the Mine Act, 30 U.S.C. § 811(b)(1) (2000).

(2) In its risk assessments, the Department's agencies shall identify and discuss key issues not limited to the reliability of data, significant uncertainties, choice of assumptions and default factors, and address all related comments from the public and peer reviewers in its Notice of Proposed Rulemaking ("NPRM") and Final Rule.

(3) The hourly, daily, weekly and yearly components of the working life exposure assumption shall be calculated on an industry-by-industry basis utilizing the best available evidence, and the latest available scientific data in the field.

(4) Department risk assessments shall include and identify the following four components:

i. Hazard identification. The hazard identification step examines whether a toxic substance or hazardous chemical is a health hazard;

ii. Dose-response assessment. The dose-response step determines a quantitative model that accounts for the relationship between a hazard and an adverse health outcome;

iii. Exposure assessment. The exposure assessment step estimates the exposure of a population to a hazard;

iv. Risk characterization. The risk characterization estimates the likely incidence of exposure related morbidity and mortality in a particular population and examines how risk management will reduce the incidence.

(5) Information Quality and Peer Review. Risk assessments shall be performed in accordance with the Department's information quality and peer review guidelines.

(d) Public access to rulemaking information. The Department shall post together in an easily accessible format in the applicable docket on www.regulations.gov, all relevant documents related to any rulemaking addressing occupational exposure to toxic substances and hazardous chemicals no later than seven days after the conclusion of the relevant step in the rulemaking process, including but not limited to publication of the ANPRM, conclusion of the Small Business Regulatory Fairness Act ("SBREFA") process, publication of the NPRM, conclusion of any public hearing and the publication

of the Final Rule. The documents posted shall include but are not limited to any underlying scientific studies relied upon in the document, to the extent possible given copyright limitations, all risk assessment analyses underlying the NPRM and Final Rule, the ANPRM, SBREFA process documents, the NPRM, all public hearing transcripts and briefs, all public comments, the final docket of the rulemaking and the Final Rule.