

September 29, 2008

Leon R. Sequeira  
Assistant Secretary for Policy  
U.S. Department of Labor  
200 Constitution Avenue, NW, S-2312  
Washington, DC 20210

SUBJECT: Risk Assessment Policy  
RIN: 1290-AA23

Dear Assistant Secretary Sequeira:

I am writing in response to the notice of proposed rulemaking published on August 29, 2008 (73 *Federal Register* 50909-50915) on “Requirements for DOL Agencies' Assessment of Occupational Health Risks.” Your proposal would make significant changes to the rulemaking procedures employed by the Mine Safety and Health Administration (MSHA) and the Occupational Safety and Health Administration (OSHA) and would adversely affect the ability of these agencies to protect U.S. workers from on-the-job exposures to chemicals and other hazardous compounds.

I object to the legality, the procedures, and the content of DOL’s proposed rule on assessment of occupational health risks. I am therefore requesting a public hearing on this proposal as permitted by both Section 6(b)(3) of the Occupational Safety and Health Act of 1970 (29 USC §651) and Section 101(a)(3) of the Federal Mine Safety and Health Act of 1977 (30 USC §801, *et seq*).

The Secretary of Labor is bound by these statutory provisions, which state:

“any interested person may file with the Secretary written objections to the proposed rule [or proposed mandatory health or safety standard], stating the grounds therefore and requesting a public hearing on such objections.”

Your assertion at 73 *Federal Register* 50910 that the Department is offering a 30 day period for public comment “in the interest of full transparency and accountability” and in order “to gain valuable public input” is disingenuous. If the Department truly valued public input, it would allow more time for that process. At a minimum, the Department should extend the comment period for an additional 90 days to allow for robust public input, in particular from workers themselves who have the most at stake if this proposal were to take affect.

I find it extremely disturbing that Secretary Chao and her political appointees have been in office for nearly 8 years and not until August 29, 2008 did the Administration formally announce its desire to change OSHA’s and MSHA’s risk assessment practices. This idea was never suggested to the public in a single one of the 13 consecutive regulatory agendas published in the *Federal Register* by Secretary of Labor Elaine Chao. For at least the last 20 years, the regulatory agenda has served as the first initial notification to the public (and for historical records) of the

Department's regulatory initiatives. In the last regulatory agenda published by the Department only a few months ago (*73 Federal Register* 24720-24725, May 5, 2008) the Secretary wrote:

“This document sets forth the Department's semi-annual agenda of regulations that have been selected for **review or development during the coming year**. The Department's agencies have carefully assessed their available resources and what they can accomplish in the next 12 months...” (emphasis added)

That agenda includes no mention of this risk assessment proposal. The public deserves to know why this proposed rule on risk assessment was never included on a single regulatory agenda and how the Department could “have carefully assessed their available resources and what they can accomplish in the next 12 months” yet failed to provide even the slightest hint to the public that this regulatory initiative was underway.

As indicated above, I object to the legality, the procedures, and the content of DOL's proposal and therefore request a public hearing at which appropriate DOL officials are prepared to answer detailed questions about the proposed rule.

### Additional Comments

1. Pursuant to OMB's Final Information Quality Bulletin for Peer Review (2005), this proposal meets the definition of “influential scientific information” because it “will have or does have a clear and substantial impact on important public policies.” Therefore, this proposal should have been subject to peer review “prior to dissemination.” (*70 Federal Register* 2664-2677, January 14, 2005)(enclosed).

The Department is obligated to explain why the proposed rule's mandatory requirement for an advanced notice of proposed rulemaking (ANPRM) for all health standards will NOT “have a clear and substantial impact on important public policies.” Please provide empirical evidence to support your position.

2. On August 14, 2008, President G.W. Bush signed into law the “Consumer Product Safety Improvement Act of 2008” (Public Law 110-314). Under subtitle A (Administrative Improvements,) Congress and the President expressly agreed to strike the previous law's requirement that all regulatory initiatives for hazardous substances commence with an Advanced Notice of Proposed Rulemaking. The new law specifically allows the CPSC to decide whether an ANPRM or a notice of proposed rulemaking (NPRM) would better serve the public interest.

Given the comparable mandates of OSHA, MSHA and CPSC for public health protection, what is DOL's rationale for a mandatory ANPRM for worker health rules, when the White House recognizes the benefit of a notice of proposed rulemaking?

3. Pursuant to the Department's "Information Quality Guidelines" this proposed rule meets the definition of "influential" information.

a) Which "Quality Assurance Techniques and Methods" were applied to the proposed rule to comply with these guidelines?

b) In the interest of "full transparency and accountability," (73 *Federal Register* 50910, August 29, 2008) the documents related to the quality assurance techniques and methods applied to this proposed rule should be made part of the rulemaking record.

c) In the interest of "full transparency and accountability," (73 *Federal Register* 50910, August 29, 2008) the documents related to the quality assurance techniques and methods applied to this proposed rule should be available for public comment; the rulemaking record should be re-opened for 60 days to allow for public comment on these documents.

4. In several place in the preamble to the proposed rule, DOL indicates its rationale for this regulatory action is the 1997 Presidential/Congressional Commission on Risk Assessment and Risk Management report. The Department states:

"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."

What the Department fails to mention in its preamble is the complementary statement contained in the Presidential/Congressional Commission report which states:

"OSHA should publish, after appropriate public involvement and review, one or more sets of guidelines that lay out its scientific and policy defaults."

a) Please provide an explanation of why the Assistant Secretary for Policy is proposing these regulations, rather than OSHA, as recommended by the 1997 Presidential/Congressional Commission.

b) Please provide an explanation of why the Assistant Secretary for Policy is proposing these changes as a regulation, rather than "guidelines" as recommended by the 1997 Presidential/Congressional Commission.

c) The Department should explain to the public why the Assistant Secretary for Policy is proposing a mandatory advanced notice of proposed rulemaking (ANPRM) when the 1997 Presidential/Congressional Commission clearly states that agencies need flexibility in determining which kind of guidance documents are necessary. In the Commission's OSHA-specific recommendation, they acknowledge that OSHA may decide on "one or more sets of guidelines." Moreover, the Commission recognized that one-size-fits-all rules are not appropriate for risk assessment: The Commission wrote:

“the guidelines should help OSHA decide how extensive a risk assessment is needed in different situations”

d) In the interest of “full transparency and accountability,” (73 *Federal Register* 50910, August 29, 2008) the 1997 Presidential/Congressional Commission on Risk Assessment and Risk Management report should be made part of the rulemaking record.

e) In the interest of “full transparency and accountability,” (73 *Federal Register* 50910, August 29, 2008) the 1997 Presidential/Congressional Commission on Risk Assessment and Risk Management report should be available for public comment; the rulemaking record should be re-opened for 60 days to allow for public comment on this report.

5. OSHA has nearly 30 years of history developing risk assessments, and information from these rulemakings could have been evaluated methodically to identify scientific assumptions, controversies, and other issues in order to assemble “best practices.”

a) What effort was made by ASP to assemble the Department’s best practices for DOL’s risk assessment practices and where are the documents resulting from that effort?

b) What provisions of the regulatory text are specific outgrowths of the identified “best practices”?

6. There are a number of definitive statements and instructions in the preamble to the proposed rule which appear to be mandates directed at MSHA and OSHA, yet they are not incorporated into the regulatory text. Under the heading “Transparency,” for example, the preamble states:

“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.”

a) If it is the Department’s intent to enforce this provision, why is it not incorporated into the regulatory text?

b) If OSHA promulgated a final rule without complying with this language, what is the Solicitor of Labor’s opinion on whether failure to comply with the preamble language would it be subject to judicial review by an interested party?

7. Under the heading “Consistency,” for example, the preamble states:

“The choice of methods, procedures and approaches should be based on objective criteria and adhere to basic principles that have achieved general scientific acceptance.”

- a) What is the Department's definition of "general scientific acceptance"?
- b) If the Secretary of Labor chose to assess the risk of a deadly workplace hazard using a novel methodology, what is the Solicitor of Labor's opinion on whether failure to comply with the preamble language requiring an adherence to "basic principles that have achieved general scientific acceptance"?
- c) Would the Secretary's failure to comply with the preamble's "general scientific acceptance" requirement be subject to judicial review by an interested party?

8. The preamble to the proposed rule reads:

"Under the Department's existing current Information Quality Guidelines, OSHA and MSHA are required to use the best available scientific methodologies, information and health and exposure data when conducting the analyses for each of the four steps in the risk assessment paradigm." (emphasis added)

The phrase "best available scientific methodologies" does not appear anywhere in DOL's Information Quality guidelines. In contrast, the OSH Act and Mine Act require the agencies to "use the best available evidence." Under what authority is ASP amending the agencies' statutes?

- a) From what authoritative body does the term "best available scientific methodologies" come, in the context of risk assessment?
- b) What is ASP's definition, for risk assessment purposes, of "scientific methodologies."
- c) Please provide a specific example of a "scientific methodology" in the occupational health risk assessment context?

9. The preamble reads:

"If physiologically based models are applied to the data, the chosen input parameters should be well supported."

In terms of occupational health risk assessments issued by OSHA to support a determination of a significant risk to workers' health, what models have been used other than physiologically based models?

10. Please provide an example of an "input parameter" with respect to the preamble's discussion of "physiologically based models."

11. What would constitute “sufficient documentation and validation” of a model?

a) Please provide an assessment of OSHA’s final health risk assessments issued since 1985, characterizing whether, in ASP’s opinion, the assessment included or failed to include “sufficient documentation and validation of a model.”

12. Please provide the definition you are proposing that MSHA and OSHA to use for the following terms (which appear in the preamble to the proposed rule):

a) “Positive animal study”

b) “Negative animal study”

c) “Positive epidemiological study”

d) “Negative epidemiological study”

e) “Industry sector”

f) “empirical strengths and weaknesses” (i.e., in contrast to “strengths and weaknesses”)

13. The preamble to the proposed rule states:

“Thus, some assumptions must be made to predict the effects of exposure to toxins or hazardous chemicals.”

What is the basis for the Department’s use of the term “predict” rather than the term “estimate”?

14. The preamble to the rule indicates:

“The scientific community continues to develop techniques for weight of evidence evaluations...”

but fails to provide any references or specific examples from public health regulatory agencies to support this claim. Please provide examples being used in regulatory agencies of “techniques for weight of evidence evaluations.”

15. The document states:

“OSH Act's and Mine Act's mandates that the Secretary set health standards based on the best scientific information available at the time of the agency action...”

- a) Please provide the specific provisions in the two statutes which require health standards to be based on “the best scientific information available at the time of the agency action.”
- b) What is the Solicitor of Labor’s opinion on whether the phrases “best scientific information available at the time of the agency action” and “best available evidence” are equivalent based on existing case law.

16. The preamble to the proposed rule states:

“...it is particularly important that the Department seek out and receive all relevant data before proposing a health standard.”

- a) What legal authority do MSHA or OSHA have to compel employers or other interested parties to submit “all relevant data” before a health standard is proposed?
- b) What legal authority do MSHA or OSHA have to compel employers or other interested parties to submit “all relevant data” after a health standard is proposed?
- c) Would the Department support a legislative change to the OSH Act of 1970 and the Mine Act of 1977 which would provide the Secretary with subpoena power to compel employers to submit all relevant data related to an occupational health standard.

17. During OSHA’s rulemaking to protect workers from exposure to the carcinogen hexavalent chromium, the agency specifically asked employers and other members of the public in its notice of proposed rulemaking:

“Are there updated analyses available for [this cohort]?” and “Are there other cohorts available to look at low exposures?” (69 *Federal Register* 59307 (October 4, 2004)).

No such data was forthcoming during the three-month comment period. OSHA also conducted 11 days of public hearings, and again made requests from employers and other members of the public for data such as that described in ASP’s proposed rule (i.e., “data describing the frequency, intensity and duration of exposure of workers in the affected industries and occupations” at 73 *Federal Register* 50914.) Again, no such data was provided despite numerous requests from OSHA seeking such information. Yet, this exact kind of data had been generated and submitted to a journal for publication by epidemiologists working on behalf of the chromium industry at the same time that OSHA was formally requesting it. As my colleagues and I wrote in “Selected science: an industry campaign to undermine an OSHA hexavalent chromium standard,” (*Environmental Health: A Global Access Science Source* 2006; 5:5):

“parties submitting scientific analyses and reports to the record should be required to disclose the true sponsorship of the study, including the original source of the sponsor’s funding. Parties involved in the rulemaking process should also be required to certify

that they have submitted all relevant data to the public record, whether or not those data have undergone peer review.”

a) What is the Department’s position on a regulatory mandate to implement such certification requirements?

18. The preamble to the propose rule states:

“...the Department is proposing that when developing a health standard regulating occupational exposure to a toxic substance or hazardous chemical, its agencies shall issue an Advance Notice of Proposed Rulemaking (ANPRM) soliciting public input on studies, scientific information, data describing the frequency, intensity and duration of exposure of workers in the affected industries and occupations, key default factors and assumptions, and other relevant information, prior to issuing a Notice of Proposed Rulemaking (NPRM) or other regulatory action in that health rulemaking.”

a) What assessment of data in OSHA’s rulemaking dockets was conducted by ASP to provide evidence that the information submitted from the public in response to an ANPRM is of sufficient quality to contribute to health risk assessment?

19. As noted in the comments submitted September 26 by the United Steelworkers, “the real problem with OSHA and MSHA rulemaking is delay, not the quality of risk assessment or opportunities for stakeholders to participate.” The United Steelworkers noted, the National Advisory Committee on Occupational Safety and Health (appointed by the Secretary of Labor) thoroughly reviewed OSHA’s rulemaking process in 2000 and issued a report. I am enclosing copies of the transcripts of the Committee’s meetings and the report for inclusion in this record (Risk Assessment Policy, RIN: 1290-AA23) The transcripts from these meetings provide rich insight and examples from OSHA’s past rulemakings which could be identified as “best practices” in terms of risk assessment.

20. I am enclosing the U.S. Environmental Protection Agency’s guidance document for assessing health risks associated with mixed chemical exposures. (EPA/630/R-00/002) The document addresses the need for agencies, such as OSHA and MSHA, to move beyond single-chemical risk assessments and recognize that individuals in certain exposure scenarios are at potential health risks from multiple exposures including cumulative and synergistic health consequences. The document provides guidance on how to make health-protective regulatory decisions related to mixed exposures in a systematic way despite data gaps and uncertainties.

21. I am enclosing a copy of the U.S. Environmental Protection Agency’s “Guidelines for Carcinogen Risk Assessment” (EPA/630/P-03/001F) as an example of a comprehensive guidance document on one type of risk assessment. It was not developed by the EPA Administrator as a regulation, but as publicly transparent policy statement. Moreover, it was developed over several years of public comment, public hearings and internal and external deliberation. It provides useful default assumptions, such as:

“When cancer effects in exposed humans are attributed to exposure to an agent, the default option is that the resulting data are predictive of cancer in any other exposed human populations.”

“...positive effects in animal studies indicate that the agent under study can have carcinogenic potential in humans.”

ASP should assemble the relevant risk assessment guidance documents prepared by other federal and State agencies (e.g., California) to assess how its proposed regulatory text compares with risk assessment guidelines prepared by science-based agencies.

Finally, I am also enclosing comments from Stuart Shapiro, PhD, who served for five years at the Office of Management and Budget’s Office of Information and Regulatory Affairs (OIRA), where he was deeply involved in reviewing both MSHA and OSHA proposed and final rules. Professor Shapiro provides evidence that this proposed rule “will have profound social costs” and notes that ASP failed to assess such costs under the Unfunded Mandates Reform Act and under Executive Order 12866.

In conclusion, I strongly urge the Department to withdraw this proposed rule. It will impede, not improve, health protections for workers.

Sincerely

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Attached: See list of documents (next page)

## List of Documents Attached with this Letter for Submission to the Record

1. National Research Council. Scientific review of the proposed risk assessment bulletin from the Office of Management and Budget. Washington DC: The National Academies Press, 2007.
2. Office of Management and Budget. Final Information Quality Bulletin for Peer Review. 70 *Federal Register* 2664-2677. January 14, 2005.
3. U.S. Department of Labor, Occupational Safety and Health Administration. National Advisory Council [Committee] on Occupational Safety and Health (NACOSH). Transcript from April 12, 2000. (Pages 1-219)
4. U.S. Department of Labor, Occupational Safety and Health Administration. National Advisory Council [Committee] on Occupational Safety and Health (NACOSH). Transcript from April 13, 2000. (Pages 220-368)
5. Michaels D, Monforton C, Lurie P. Selected science : an industry campaign to undermine an OSHA hexavalent chromium standard. *Environmental Health: A Global Access Science Source*. 2006; 5:5.
6. U.S Environmental Protection Agency. Risk Assessment Forum. Supplementary Guidance for Conducting Health Risk Assessment for Chemical Mixtures. EPA/630/R-00/002, August 2000.
7. U.S Environmental Protection Agency. Risk Assessment Forum. Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F, March 2005.\
8. Stuart Shapiro, PhD. Rutgers University. Comments on RIN: 1290-AA23.
9. U.S. Department of Labor, Occupational Safety and Health Administration. National Advisory Committee on Occupational Safety and Health (NACOSH). Report and Recommendations related to OSHA's Standards Development Process, June 6, 2000.

