



Keith Smith

Director, Employment and Labor Policy

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Sent Electronically to:

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and Via Hand Delivery

Office of the Assistant Secretary for Policy
200 Constitution Ave., NW
S-2312
Washington, DC 20210

Re: RIN 1290-AA23/Comments of the National Association of Manufacturers

To whom it may concern:

Attached please find the National Association of Manufacturer's comments on
"Requirements for DOL Agencies' Assessment of Occupational Health Risks," RIN 1290-AA23.

Sincerely,

A handwritten signature in black ink, appearing to read "Keith Smith", written in a cursive style.

OF COUNSEL

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Enclosure

Manufacturing Makes America Strong

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**Requirements for DOL Agencies' Assessment of Occupational Health Risks
Comments of the National Association of Manufacturers**

I. Introduction

The National Association of Manufacturers (“NAM”) appreciates the opportunity to comment on the Department of Labor’s “Requirements for DOL Agencies’ Assessment of Occupational Health Risks” published in the *Federal Register* on August 29, 2008. 73 FR 50909.

The NAM is the nation’s largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. Headquartered in Washington, D.C., the NAM has 11 additional offices across the country. The NAM’s mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to U.S. economic growth, and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing to America’s economic future and living standards.

At the outset, the NAM would like to express concern with the process by which the Department of Labor (“DOL”) developed this proposal. Stakeholders in both the employer and employee communities were unaware of DOL’s intentions; therefore no advance input from these groups was provided. In the future, the NAM requests the agency to provide advance notice to the public of its intent to develop a proposed rule and that the agency seek input from key stakeholders early in the development process. Unfortunately, this opaque process has caused unnecessary controversy and charges that DOL is publishing a “secret rule” that will be detrimental to employee safety and health.

While the NAM has concerns with the process used by DOL in publishing the proposal, the NAM supports the core principles of transparency, consistency, and reliability in rulemaking that the proposed rule is designed to foster. The NAM also generally supports the two specific proposals put forward in the *Federal Register*: (1) that OSHA publish an Advance Notice of Proposed Rulemaking (ANPR) on risk assessment before issuing a Notice of Proposed Rulemaking (NPRM) or taking other regulatory action in a health rulemaking; and (2) that OSHA make available electronically in an easily accessible format all relevant documents related to the rulemaking.

The NAM elaborates on these points and offers other suggestions below.

II. Comments on the Proposed Rule

A. Core Principles of Transparency, Consistency, and Reliability

DOL identifies three core principles underlying the rulemaking: transparency; consistency; and reliability. 73 FR at 50910. The NAM supports these core principles. They are embodied in DOL's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor" (October 1, 2002) ("Information Quality Guidelines"). They are also the underlying principles in agency rulemaking generally. In particular, one of the core principles of rulemaking under the Occupational Safety and Health Act of 1970 ("OSH Act"), the Federal Mine Safety and Health Act of 1977 ("MSH Act"), and the Administrative Procedures Act ("APA") is a transparent process where stakeholders are fully informed of agency actions and are able to comment on them.

B. Specific Proposals for an ANPR and Electronic Posting

NAM generally supports the two basic proposals requiring DOL agencies in health rulemakings to issue an ANPR related to risk assessment and to electronically post rulemaking information.

1. ANPR

The proposal would require DOL agencies to issue an ANPR on various scientific issues before publishing an NPRM or proceeding with other regulatory action in health rulemakings. Proposed paragraph (c)(1). The NAM believes requiring an ANPR is good policy and will significantly improve the quality of agency risk assessments.

As the proposed rule indicates, requiring DOL agencies to issue an ANPR for health standards rulemakings will help ensure that agencies gather and analyze as much information on risk as possible at an early stage of the rulemaking process. 73 FR 50913. It is critical for agencies to have access to and consider all of the information available for risk assessment purposes before they start quantifying the risk faced by employees to toxic materials or harmful physical agents.¹ The NAM recognizes that agencies are constantly acquiring information on the hazards they intend to regulate; as might be expected, however, there are situations where agencies are not aware of certain studies that are useful in analyzing risk. Publishing an ANPR seeking comment from the public on these issues will help fill in any gaps in the agencies' own data collection efforts.

The proposed requirement also provides an opportunity for employers and employee groups to provide information on risk that is not otherwise publicly available. Employers and employee groups often have important information on risk, health effects, employee exposure to toxic materials or harmful physical agents, medical surveillance, and so on. For a number of reasons, however, this information is not made publicly available. DOL agencies thus would typically not have access to it. Providing employers and employee groups the opportunity to provide this information to DOL agencies *before* development of proposed rules will improve

¹ The NAM notes that the proposed rule uses the terms "toxic substances" and "hazardous chemicals" to describe the types of hazards covered. The NAM suggests using the terms "toxic materials" and "harmful physical agents" in any final rule, as that is the language used in Section 6(b)(5) of the OSH Act. 29 U.S.C. 655(b)(5).

agency risk assessments by increasing the overall amount of data available for the agencies to review and utilize before quantifying risk.

In addition, as the proposed rule is drafted, the ANPR would seek information useful to OSHA's and MSHA's technological and economic feasibility analyses, in addition to their risk analyses. The proposal specifically requires agencies to solicit public input on "data regarding the frequency, intensity, duration and other parameters of worker exposure in the affected industries, occupations and activities." Proposed paragraph (c)(1). Aside from assisting the agencies with analyzing risk, this information is useful to the agencies in analyzing technological and economic feasibility. Currently, OSHA relies on a hodge-podge of Integrated Management Information System (IMIS) data, site visit information, and National Institute for Occupational Safety and Health (NIOSH) reports to analyze the feasibility of rules. Because the ANPR would solicit input from the public on information used in analyzing feasibility, these analyses will also benefit from the proposed rule.

As the proposal points out, it has been common practice for DOL agencies, and in particular OSHA, to publish ANPRs after deciding to pursue rulemaking to regulate toxic materials or harmful physical agents. The proposal identifies some instances where OSHA has published ANPRs for health standards. 73 FR at 50914. The NAM also notes that OSHA has frequently published ANPRs for safety standards. These include ANPRs for Tree Care Operations (73 FR 54118 (September 18, 2008)), Power Presses (72 FR 30729 (June 4, 2007)), Standards Improvement Project, Phase III (71 FR 76623 (December 21, 2006)), Hazard Communication (71 FR 53617 (September 12, 2006)), and Safety Standards for Fall Protection (64 FR 38077 (July 14, 1999)). OSHA also published an ANPR for its controversial ergonomics standard. *See* Ergonomics Program, 65 FR 68262, 68264 (November 14, 2000).

Publishing an ANPR will also not further slow down the rulemaking process. An ANPR can and should be published simultaneously with the agencies performing other rulemaking tasks. Agencies can be preparing the proposal while they are publishing the ANPR and reviewing comments. During this time period, the agencies can have contractors performing feasibility analyses and compiling the industry profile. In the case of OSHA, it can be preparing its SBREFA package.

In fact, the NAM believes it will speed up the process and may be more cost effective for the agencies to issue ANPRs for each health standards rulemaking. When agencies decide to regulate toxic materials or harmful physical agents, one of the first things they do is spend months, if not years, gathering data to determine risk and feasibility. They engage in literature reviews, they meet with scientific experts in the field, they discuss the underlying science with NIOSH and other scientific bodies, they hire contractors to review the scientific literature, and for feasibility purposes, they hire contractors to conduct site visits. All of this is done with the purpose of gathering as much information as is possible about the underlying toxic material or harmful physical agent.

In certain instances, OSHA will hold stakeholder meetings to acquire information from employers and employee groups. OSHA has held numerous stakeholder meetings on a variety of rules, such as diacetyl, ionizing radiation, electric power generation, transmission, and

distribution/subpart V, crystalline silica, and ergonomics. These meetings take months to plan, involve significant resources, sometimes take days to complete, and often end in the agency spending hours drafting notes of the meetings to put on OSHA's website. Drafting and publishing an ANPR is a simple, convenient, and expeditious way to gather much of this same information, and may obviate the need for the agencies to engage in these other resource-intensive information gathering efforts.

Opponents of this proposed requirement will undoubtedly argue that even if issuing an ANPR is good policy, it should not be required in every health standards rulemaking. The opponents will argue that DOL agencies need discretion to issue an ANPR depending upon the circumstances of each individual rulemaking and the need for swift agency action. The NAM disagrees with this. First, the proposed rule itself provides an exception to the requirement for emergency temporary standards issued under the OSH Act and the MSH Act. Thus, in those instances where the agencies must act quickly, they will not be required to issue an ANPR.² Second, requiring agencies to issue ANPRs except in those rare emergency situations is the only way to effectively integrate the procedures into DOL's rulemaking process and ensure that it becomes a meaningful information-gathering step.³ The public needs to know that in every health standards rulemaking it will have an opportunity to provide important information and data to the agencies at the very beginning of the process. Agency officials also need to know that this will occur so they can effectively plan their rulemaking activities and best utilize the information received through the ANPR.

2. *Electronic Posting of Rulemaking Information*

The NAM also generally supports the proposal to require DOL agencies to post together in an easily accessible and well-organized format on www.regulations.gov and/or www.dol.gov all relevant documents related to health standards rulemakings. Proposed paragraph (d). OSHA and MSHA are already required to make available to the public the information they rely on in promulgating rules. The proposed requirement reinforces that preexisting obligation.

The NAM, however, does not believe the requirement to make the information available within 14 days of the completion of *all* relevant rulemaking steps is appropriate. For ANPRs and NPRMs, the documents being relied on by the agencies must be made available to the public electronically on the *same* day the documents are published in the *Federal Register*. This allows the public adequate time to review the information and submit comments on the ANPR or proposal. In instances where the agencies establish a short comment period (*e.g.*, 30 or 60 days), allowing the agencies fourteen days to make the information available electronically will diminish the ability of stakeholders to comment on the information.

²The NAM fully supports the exception to issuing an ANPR in those circumstances justifying an emergency temporary standard.

³The NAM also notes that the value of ANPRs in rulemaking has been expressly recognized by Congress. There are several statutes that require federal agencies to issue ANPRs before proceeding in rulemaking. *See, e.g.*, the Federal Trade Commission Improvements Act (15 U.S.C. § 57a(b)(2)(A)), the Consumer Product Safety Act (15 U.S.C. §2058(a)), and the Energy Policy and Conservation Act (42 U.S.C. § 6295(p)(1)).

With respect to information obtained during SBREFA panels for OSHA, public hearings, and post-hearing comment periods, the NAM does not object to a requirement that DOL agencies make the material available electronically within 14 days. The NAM also does not object to making all information available to support a final rule within 14 days.

C. Other Comments on the Proposed Rule

The NAM offers the following additional comments for DOL's consideration.

1. Application to Safety Standards

The NAM urges DOL to apply the proposed rule to occupational safety standards. While there is no doubt that health standards present difficult issues related to risk, safety standards also involve complicated issues that could benefit from advance public input.

When promulgating a safety standard, OSHA typically examines statistics from the Bureau of Labor Statistics Survey of Occupational Injuries and Illnesses and Census of Fatal Occupational Injuries. Based upon a general analysis of these databases, OSHA makes a determination as to whether there is a significant risk of injury or death from exposure to a particular safety hazard. After making such a determination, OSHA typically examines its own IMIS database to determine whether a proposed rule would substantially reduce the injuries and deaths that are occurring. *See, e.g.*, OSHA's Recent Proposed Rule on Electric Power Generation, Transmission, and Distribution; Electrical Protective Equipment, 70 FR 34822, 34900-01 (June 15, 2005).

OSHA uses this approach for virtually all safety standards. One of the greatest areas of uncertainty with this approach is in the determination of whether any proposed requirements would actually reduce the risk of injury and death. This is particularly the case because often IMIS data does not provide detailed descriptions of the causes of accidents. Thus, OSHA must essentially "guess" whether particular measures proposed would truly prevent injuries and fatalities from occurring.

In the NAM's view, there would be significant value in OSHA, in particular, seeking information early on in the rulemaking process on safety standard risks. Like with health rulemakings, OSHA must perform a significant risk analysis before issuing safety standards. Information from employers and employee groups on the incidence of injuries in the workplace due to hazards and effective measures to prevent injuries would be particularly useful. Having information provided at the outset by employers and employees in the field would improve the quality of OSHA's safety risk assessments and in particular, its analysis of what effectively prevents injuries and fatalities from occurring.

Another reason to apply the proposed requirements to safety standards is to avoid confusion by the public on what is expected by DOL agencies when they engage in rulemaking. For Washington D.C. "insiders," it may be clear that a particular OSHA or MSHA regulatory effort is a "health standard" and thus covered by the proposed rule. For others, however, it is not always clear. Even OSHA, for example, has struggled with how to classify certain rulemakings.

It classified its ergonomics program standard as a health standard when it proposed that rule, but a safety standard when it finalized it. *See* Ergonomics Program, 65 FR 68262, 68270-71 (November 14, 2000). How would OSHA or MSHA classify a safety and health program standard that would require employers to set up a process to address both safety and health hazards? This confusion can be avoided if DOL applies the proposal to all rules issued by OSHA and MSHA.

The proposed requirements are not so tailored to health standards that application to safety standards would be inappropriate. In fact, there is no reason not to apply the ANPR and electronic posting requirements to safety standards. DOL provides no reasons for excluding safety standards in the proposal. For manufacturers, safety standards are as important as health standards. They should not be ignored by DOL in a final rule.

2. *Definition of Significant Risk*

The proposed rule offers a definition of significant risk as follows:

(b) *Definition. 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.

Proposed paragraph (b). The NAM believes this definition is misleading and objects to its inclusion in the final rule, unless significant changes are made to the language.

The NAM understands that the key language in the definition is taken from the Supreme Court's decision *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980) (*Benzene*) related to significant risk. The definition in the proposed rule, however, omits other key parts of the discussion which the NAM believes are important. In particular, it does not discuss the Court's language that not *all* risks are significant and that some risks in the workplace are "plainly acceptable." *Id.* at 655. Further, it provides no guidance to DOL agencies on the factors they should consider in determining whether a risk is "significant."

To the extent that paragraph (b) is attempting to restate OSHA's statutory obligations for promulgating health standards under the OSH Act, the NAM urges DOL to revise the language to fully recite those obligations. For example, in addition to a threshold finding of significant risk, section 6(b)(5) states that "in promulgating standards dealing with toxic materials or harmful physical agents" OSHA "must set the standard that 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." 29 U.S.C. 655(b)(5). Section 6(b)(5) contains the important concepts of "material impairment" and "best available evidence" that should be added to any final rule that explicitly lays out OSHA's legal obligations to promulgate health standards.

3. *Consideration of Vulnerable Populations*

The preamble to the proposal states that when analyzing risk, “[t]he assessment should address vulnerable and/or susceptible worker [sic] populations where there is scientific evidence to support potential differences in risk.” 73 FR at 50912. The NAM is very concerned about this statement and asks DOL to remove it from any final rule.

The NAM appreciates the difficulties faced by agency risk assessors in analyzing data to make determinations about risk. Those difficulties are made more challenging by the varying characteristics of the workforce. DOL agencies have not in the past, however, attempted to “address” all the different characteristics of worker populations to support potential differences in risk.

The NAM is concerned that this language in the preamble to the proposed rule would lead OSHA and MSHA to begin performing separate risk assessments for disparate groups of individuals based on what the agencies view as vulnerable populations. This would be wholly unmanageable for OSHA and MSHA and employers attempting in good faith to comply. It would require employers to explore the “vulnerabilities” of their workforce and monitor exposures accordingly.

Without more information about what DOL intends with this guidance, the NAM asks the agency to remove it. The NAM would support a broader rulemaking by DOL on the extent to which agencies should examine vulnerable populations or other demographic characteristics when assessing risk. DOL has not focused adequate attention on the issue in this proposed rule, however, and the NAM requests that this guidance be removed.

4. Industry-by-Industry Evidence of Working Life Exposure

The NAM supports the requirement in the proposed rule that risk assessments use the “best available evidence, and the latest available scientific data in the field, including industry-by-industry evidence relating to working life exposures.” Proposed paragraph (c)(3). This requirement recognizes the changing nature of the United States workforce, along with the need for DOL agencies to base their decisions on the latest and best scientific evidence available.

Under the OSH Act, OSHA is required when promulgating a health standard to assure – to the extent feasible and based on 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.” 29 U.S.C. 655(b)(5). OSHA has historically assumed in its risk assessments that employees will be exposed to a toxic material or harmful physical agent over the course of a 45-year working lifetime and this assumption has been upheld by the courts. *See, e.g., Building & Constr. Trades Dep’t v. Brock*, 838 F.2d 1258, 1264-65 (D.C. Cir. 1988). OSHA is not required, however, to assume a 45-year working lifetime when analyzing risk and dose-response. The courts have only recognized that OSHA can permissibly make that assumption under the OSH Act and in accordance with its rulemaking obligations. *Id.*

The NAM believes that OSHA should in each rulemaking on a toxic material or harmful physical agent utilize data on working life exposure on an industry-by-industry basis. This will

provide OSHA the opportunity to make assumptions on exposure that are in-line with the evidence of what is actually happening in the industries affected. This does not mean that OSHA cannot continue to make conservative assumptions with respect to working life exposures. Nor does it mean that OSHA cannot assume a 45-year working life exposure. Finally, it does not mean that OSHA must set different PELs for different industries based on evidence of the different working life exposures. It only means that OSHA must utilize, consistent with its other statutory obligations, information on actual working life exposures in the industries affected in determining and assessing risk.

It is also useful to note that this requirement will not create an enormous new burden on OSHA. When compiling an industry profile during rulemakings, OSHA already analyzes the revenues and profits of industries, the number of employees, turnover rates, and baseline exposures to the toxic materials or harmful physical agents at issue. Folding an analysis of working life exposures into the existing comprehensive industry profile will not add tremendous burdens on the agency.

5. Compliance with Information Quality and Peer Review

The NAM supports the proposed requirement that DOL agencies conduct risk assessments in accordance with Office of Management and Budget (OMB) and DOL information quality and peer review guidelines. Proposed paragraph (c)(5). In particular, the NAM believes it is important to incorporate the DOL Information Quality Guidelines into any final rule.

Appendix II of the Information Quality Guidelines sets forth in detail important principles for OSHA and MSHA risk assessment. In the case of health standards, these principles include: (1) using the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, (2) collecting data by accepted methods or best available methods; and (3) presenting information about risk effects in a comprehensive, informative, and understandable fashion. More importantly, the Information Quality Guidelines state that in performing quantitative analyses of health risks, the agency shall specify, to the extent practicable:

- each population addressed by any estimate of public health effects;
- the expected risk or central estimate of risk for the specific populations;
- each appropriate upper-bound or lower-bound estimate of risk;
- each significant uncertainty identified in the assessment of public health effects and studies that would assist in resolving the uncertainty; and
- information, data, 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.

Information Quality Guidelines, p. 16.

These principles reflect Congress's views on risk assessment as set forth in the 1996 Safe Drinking Water Act Amendments, but tailored to the unique aspects of OSHA and MSHA rulemaking. They ensure a high level of quality in agency risk assessments, while not unnecessarily delaying agency promulgation of rules.

While the NAM supports the concept of requiring agency adherence to the various information quality and peer review guidelines, the NAM suggests that DOL revise the language of paragraph (c)(5) to make the requirement clearer. To that end, the NAM suggests citing the specific documents that OSHA and MSHA must follow. The NAM would suggest the following language:

(5) Information quality and peer review. Risk assessments shall be performed in accordance with Office of Management and Budget (OMB) "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" (February 22, 2002); "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Department of Labor" (October 1, 2002); and OMB "Final Information Quality Bulletin for Peer Review" (December 16, 2004).

III. Conclusion

While the NAM has some concern with the manner that the rule was developed, we support the core concepts of the proposed rule. Greater opportunity for public participation early in the agency's development of health standards is sound policy and will not further delay DOL rulemakings. The requirement for electronic posting of information is also welcome. The NAM also strongly encourages DOL to consider its other suggestions to improve the proposal such as the inclusion of safety standards in any final rule.

The NAM thanks DOL for the opportunity to comment on this important proposed rule.