Institute *for* Policy Integrity
New York University School of Law

September 29, 2008

Assistant Secretary Leon Sequeira
Office of the Assistant Secretary for Policy
U.S. Department of Labor
200 Constitution Avenue, N.W., S-2312
Washington, D.C. 20210
Attn: Risk Assessment Policy

cc: Susan Dudley, Administrator, Office of Information and Regulatory Affairs
James Nussle, Director, Office of Management and Budget

Re: **Requirements for DOL Agencies' Assessment of Occupational Health Risks (RIN 1290-AA23)**

Dear Assistant Secretary Sequeira:

As an organization dedicated to improving the quality of governmental decisionmaking, we are deeply troubled by the recent rule, "Requirements for DOL Agencies' Assessment of Occupational Health Risks," proposed by the Department of Labor ("the Department"). RIN 1290-AA23, 73 Fed. Reg. 50909 (Aug. 29, 2008) (to be codified at 29 C.F.R. pt. 2). We are especially alarmed by the Department's classification of this rule as not a significant regulation and therefore not subject to the requirement of a cost-benefit analysis. Accordingly, we wish to submit the following comments to that proposed rule.

The proposed regulation makes two important changes. First, it creates a requirement that agency risk assessments utilize industry-by-industry evidence on working life exposures. The model currently employed by OSHA and MSHA relies on risk estimates that consider workers' cumulative exposure to a contaminant up to 45 years of exposure. Second, the proposed rule will require Advance Notice of Proposed Rulemaking (ANPR) for all standards relating to workplace exposure to toxins or chemicals.

The Department has classified this regulation as not a "significant regulatory action" under Executive Order 12,866, and therefore has not performed a cost-benefit analysis. *Id.* at 50914. However, as this regulation is likely to result in an annual effect on the economy in the amount of $100 million, the Department should have classified this rule as a significant action and undertaken a formal analysis of the potential costs and benefits of the proposed regulation in economic terms. We request that these actions be taken promptly. We also request that, even if the Department chooses not to classify this rule as significant, the Department perform a voluntary cost-benefit analysis considering the potential large effects of this rule. Finally, we request that the Department withdraw this rule and instead utilize a guidance document to formalize its risk assessment procedures.

I. Legal Mandate to Perform Cost-Benefit Analysis

Executive Order 12,866, as amended by Executive Order 13,422, governs regulatory planning and review conducted by federal agencies. Exec. Order No. 12,866, 58 F.R. 51735 (Sept. 30, 1993) (amended by Exec. Order No. 13,422, 72 FR 2703 (Jan. 18, 2007)) (the "Order").

As a preliminary matter, before engaging in any rulemaking, the Order mandates that "each agency shall identify in writing the specific market failure . . . or other specific problem that it intends to address . . . that warrant new agency action, as well as the significance of that problem, to enable assessment of whether any new regulation is warranted." Order § 1(b)(1). The Office of Management and Budget ("OMB") issued a Circular that expands upon this mandate for agencies. OMB, "Regulatory Analysis," Circular A-4 (Sept. 17, 2003). That Circular states: "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem. Thus, you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy." *Id.* at 4. If, like the proposed rule at hand, the regulation is not designed to correct a market failure, the agency "should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values." *Id.*

The Order also provides that if a rulemaking is classified as a "significant regulatory action," an agency must provide "an assessment of the potential costs and benefits of the regulatory action" before issuing the rule. Order § 6(3)(B). The Order classifies a rule as a "significant regulatory action" if it is "likely to result in" any of a number of specified effects, including: "an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." *Id.* § 3(f)(1). When making this classification, agencies must ensure

consistency with the letter and spirit of the Order. This language is clearly expansive and designed to subject a broad array of regulatory actions to cost-benefit analysis and review by OMB. Although OMB does not formally review all non-significance decisions, it may choose to do so.

The Order lists specific analyses agencies must undergo when assessing the potential costs and benefits of a rule classified as a significant regulatory action under Section 3(f)(1). Agencies must provide:

- "[a]n assessment, including the underlying analysis, of the benefit anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;"

- "[a]n assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets . . ., health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs;" and

- "[a]n assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives."

Id. § 6(3)(C).

The Order further mandates that "costs and benefits" must by understood by agencies "to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantity, but nevertheless essential to consider." *Id.* § 1. Agencies "should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)" unless a statute requires another approach. *Id.*

Under the Administrative Procedures Act ("APA"), actions of federal agencies, including rulemakings, are generally subject to judicial review by federal courts. A court will hold an agency action unlawful if it is "arbitrary, capricious, an abuse of discretion, or

otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency action is considered "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1989) (construing 5 U.S.C. § 706(2)(A)).

II. A Cost-Benefit Analysis Should be Conducted

The Department has erroneously classified this regulation as not significant without offering a reasoned rational for doing so. As explained below, the rule is in fact likely to have an effect on the domestic economy in the amount of $100 million annually, and thus the Department is obligated to perform a cost-benefit analysis. We request the Department so classify this rule, and in conducting a cost-benefit analyses considered the costs and benefits listed below, among others.

A. Significant Regulatory Action

The Order defines a "significant regulatory action" as "any regulation action that is likely to result in a regulation that may . . [h]ave an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." Given the broad intent of the Executive Order, deregulatory measures that have adverse net effects of $100 million on social welfare (even though it might reduce compliance costs) are also subjected to review.

Safety standards promulgated by the Occupational Safety and Health Administration (OSHA) have an enormous impact on the economy. The impact of federal workplace safety standards on the economy has been estimated to be at least between $34.1 billion to $69.1 billion annually.[1] OSHA regulations govern exposure limits for a very large number of toxins, and since its inception in 1970, OSHA has issued health and safety standards governing essentially every sector of the American economy and applying to all employers. The process by which OSHA, or the Mine Safety and Health Administration (MSHA), decide to adopt, or not adopt, standards is integral to the agency's mission. Any change in

[1] *See* Harvey S. James, Jr., "Estimating OSHA Compliance Costs," *Policy Sciences* 31: 321-341 (1998) (estimating that the cost of OSHA rules in 1993 was between $23.1 billion and $46.7 billion annually). James's estimate converted into 2008 dollars would be approximately $34.1 billion to $69.1 billion. This estimate, however, only includes the *costs* of these regulations. It does not include the benefits (e.g. lives saved, lowered disease rates, improved worker health). Assuming all OSHA regulations are cost-benefit justified, and the benefits are at least as great as the costs, the effect on the economy of OSHA regulations would be at least twice as high as these projected numbers. Additionally, this number does not account for OSHA regulations issued between 1993 and 2008. Thus, the estimate of an $34.1 to $69.1 billion impact is extremely conservative.

that process, even a small change, can therefore be expected to generate a large economic impact. The proposed rule makes substantial changes in this process that will have an effect on which safety standards are proposed and finalized, and will in turn affect the economy.[2]

The proposed regulation governs how risk assessments will be performed for the evaluation of toxic substances and hazardous chemicals in the workplace. The first mandate requires that risk assessments utilize industry-by-industry evidence on working life exposures. The model currently employed by OSHA and MSHA relies on risk estimates that consider workers' cumulative exposure to a contaminant, even up to 45 years of exposure. *See* "Requirements for DOL Agencies' Assessment of Occupational Health Risks," RIN 1290-AA23, at 17-20 (Draft, submitted to OMB July 7, 2008). Agencies also set a single permissible limit for all workers exposed to a hazard regardless of industry. Under the new proposal, all Department risk assessments must utilize "the latest available scientific data in the field, including industry-by-industry evidence relating to working life exposure." This proposal would effectively do away with the exposure assumption currently employed by agencies. This change may also require agencies to set differing standards on an industry-by-industry basis. Regardless of whether the current exposure assumptions are accurate or inaccurate, the proposed rule substantially changes that assessment by deleting those assumptions. By altering the exposure scenarios for all toxins and chemicals, this variable, once inserted into the dose response curve, will undoubtedly alter the risk models, and all resulting health risk estimates will be affected.

Second, the proposed rule would introduce an additional step at the front-end of the rulemaking process. Specifically, the rule would require OSHA and MSHA to issue an Advanced Notice of Proposed Rulemaking (ANPRM) when regulating *all* standards relating to workplace exposure to toxins or chemicals. Before proposing any rule, agencies would be required to solicit public input on any data used in risk assessments before issuing any health standard regulating occupational exposure to any particular toxic substance or hazardous chemical (except in emergencies). This extra step would be in addition to currently required economic reviews, small business reviews, OMB reviews, and public comments and hearings, and would be required even for well-understood contaminants like coal mine dust

[2] We strongly disagree with the Department's contention that "the proposal does not affect the substance or methodology of risk assessments." *Secret Rule: Impact of the Department of Labor's Worker Health Risk Assessment Proposal: Hearing Before the Subcomm. on Workforce Protections of the H. Comm. on Education and Labor*, 110th Cong. (Sept. 17, 2008) (Statement of Leon R. Sequeira, Assistant Secretary for Policy, U.S. Department of Labor). The proposal does change the risk assessment procedure in three important ways. First, an ANPRM is not currently required for health standards; whereas the proposal would require ANPRMs for all rules. Second, even the Department itself admits agencies are currently using upward bound default assumptions of working life exposures; whereas the proposal would require working life exposure estimates to be based on industry-by-industry evidence not assumptions. *See* "Requirements for DOL Agencies' Assessment of Occupational Health Risks," RIN 1290-AA23, at 17-20 (Draft, submitted to OMB July 7, 2008). Third, agencies currently set single exposure limits to toxins on a country wide basis regardless of industry; whereas the proposal would require industry-by-industry evaluations and possibly industry-by-industry safety standards. *See id.* These are obvious, arguably significant, changes.

and silica. Although this extra step would not *necessarily* be harmful, there is the possibility of significant delays that has neither been characterized nor addressed by the Department.

Regulatory delay imposes costs and benefits. For example, reducing silica exposure to 50 $\mu g/m^3$ from the current threshold is likely to produce beneficial health effects and will create additional regulatory burdens on employers. If the new standard were to reduce mortality by 60 lives yearly, and impose a cost that is roughly half of the valuation of that benefit (using $6 million as a hypothetical value of statistical life), there would be $540 million in yearly costs and benefits. If the new ANPRM requirement were to add even one additional year to the rulemaking timeline, this would result nearly half a billion dollar effect on the economy, and will have substantial public health consequences.

Changes in exposure scenarios can also produce clear costs and benefits. Extending the silica example, if the working life exposure limit was changed from the default assumption to, for example, 20 years for a specific industry, this is likely to result in a higher exposure limit for any final rule adopted, thereby reducing compliance costs and increasing silica related deaths. Again, given the large numbers at stake, even small changes in the exposure scenario can lead to large economic effects.

Given that small change in the procedures governing one rule could have important economic effects, the overall consequences of the two important changes in risk assessment procedures contemplated in this draft regulation can be expected to have a very large overall impact on the economy. These changes will affect how *all* future workplace toxin regulation is evaluated. Since existing workplace toxin rules currently affect the economy by at least between $34.1 billion and $69.1 annually, a procedural change that has less than a 0.3% effect on OSHA's yearly economic impact would impact the economy by $100 million, thereby meeting the threshold.[3]

This rule clearly meets the threshold significance inquiry of whether it is "likely" to affect the economy by $100 million, and a cost-benefit analysis should be conducted in compliance with EO 12,866. Even if these changes in the procedures would lead to a decrease in regulation, the effect of the regulation is likely to be high given the current net economic impacts of safety regulations. The proposed rule is likely to lead to decreased compliance costs to employers, as well as increase health risks to workers (including mortality and morbidity risks) with associated secondary economic effects – including increased health care costs and lost productivity. Rules that reduce regulatory compliance costs – and that potentially lead to increases in exposure to health risks – can be as costly in economic terms as new regulatory measures, and should be fully evaluated in the same way as regulations that increase compliance. At the very least, if the Department does not believe a cost-benefit analysis is in order, we request that the Department describe its basis for the

[3] $100 million is .0029 of $30.2 billion. Further, as discussed in note 1, since this estimate does not take into consideration the beneficial impact of OSHA rules or the impact of OSHA rules promulgated between 1993 and 2008, the actual percentage impact necessary to reach the threshold would be much smaller.

conclusion that such a far-reaching change in current agency risk assessment requirements is not likely to lead to a significant economic impact.

B. Potential Costs and Benefits of the Rule

When considering any regulation, a responsible regulator must estimate all costs and benefits of that regulation in accordance with the mandates of EO 12,866. Even for regulations motivated by goals other than economic efficiency, costs and benefits are clearly a relevant consideration under the Order. While measuring and monetizing costs and benefits in this area can be difficult, OSHA regularly conducts cost-benefit analyses on a routine basis for regulations that involve effects on public health that are difficult to quantify and monetize. While developing these valuations may be difficult, it is essential to conducting meaningful cost-benefit analysis.

The Department has failed to actually evaluate whether any costs or benefits would likely result from the rule. The Department has merely conjectured that the rule would produce a number of benefits without any scientific or empirical basis. The Department has conducted no studies, cited no empirical evidence, and found no scientific support for any of these conjectured benefits. The Department has also completely ignored any potential costs of the rule. There are a number of potential costs and benefits of the proposed rule that the Department must scientifically and economically evaluate before promulgating such a far-reaching rule that would affect the way all risk assessments are conducted for all safety standards. These benefits and costs include, but are not limited to, the following:

Potential Benefits:

- Consistency: The rule codifies all risk assessment procedures into a single regulation that will make these requirements accessible to agencies. This may result in more efficient, consistent, and systematic risk assessments, and consequently more efficient, consistent, and systematic safety standards.
- Greater Public Input: The electronic posting requirement may promote greater public input, awareness, and transparency of the information underlying the Department's health rulemakings. This may result in better and more informed public comments, and therefore better rulemakings.
- Greater Agency Transparency: Both the electronic posting requirement and the ANPRM may increase the agencies' transparency by shedding more light on the agency's risk assessment procedures.
- Increase in Information to Agencies: The addition of the ANPRM may lead to greater public input and awareness of Department rulemakings, allowing Department agencies to have better information to produce more accurate and thorough risk assessments.
- More Accurate Working life Exposure Estimates: Requiring agencies to base working life exposure estimates on industry-by-industry evidence, as opposed

to an upward bound assumption, may be more scientific and accurate, thereby leading to more accurate limits for toxin exposure limits.

- More Accurate Safety Standards: Setting exposures to toxins on an industry-by-industry basis, based on evidence as opposed to an upward bound assumption, may lead to more accurate health standards.
- Decreased Regulatory Costs: Relying on industry-by-industry data, as opposed to an upward bound assumption, may lead to a decrease in regulation and perhaps avoidance of unnecessary regulation, and therefore decreased regulatory compliance costs to employers.
    - The ANPRM may also lead to a delay in adoption of safety standards, thereby reducing compliance costs on businesses

Potential Costs:

- Delay in Promulgating Safety Standards. The ANPRM is likely to result in a sufficient delay in the finalization of standards to protect workers' health. Each year that each safety standard is delayed will result in preventable deaths, diseases, and injuries.
- Undervaluation in Risk: The use of working life industry-by-industry exposure estimates may lower the risk valuation. Currently, agencies use an upward bound number of up to 45 years of working life exposure when conducting risk assessment for toxins. This upward bound assumption is employed for two reasons – because evidence of working life exposures is limited and because an upward bound assumption attempts to account for exposure to multiple toxins/contaminants in the work environment. The proposed rule does not inform agencies how to proceed when there is limited or no evidence of industry-by-industry working life exposures, or when workers are possibly exposed to multiple toxins during their working life. This may lead to a systematic under-calculation of risk, thereby leading to lower toxin exposure limits.
- Increased Burden on Agencies: Requiring agencies to gather and analyze industry-by-industry evidence on working life exposures (which agencies do not do now) will add significant time and cost to the rulemaking process and a significant burden on agencies.
    - Additionally, positing all documents related to an occupational health standard, including all underlying studies and analysis within 14 days will impose additional costs and burdens on agencies and may result in delay.
- Inaccurate Risk Assessments: The rule gives no instructions on how to perform risk assessments in the absence of all needed information, as is the case in all risk assessments. It is unclear whether industry-by-industry working life exposure for toxins and hazardous chemicals actually exists. It is also unclear whether agencies may continue using the upward bound working life assumption. The mandate to use scientific evidence thus may result in a

difficulty in promulgating safety standards, and may be such a high bar that no safety standard could ever meet that threshold. As all risk assessments include a substantial amount of assumptions during statistical analysis, the rule may be overlooking scientific reality and lead to inaccurate or undoable risk assessments. This will create confusion in agencies and impose burdens that the agencies will not be able to meet, thereby resulting in none or decreased safety standards.

- Confusion. One of the most glaring omissions in the rule is its failure to define "industry." It is completely unclear how analysts are to determine an industry-by-industry standard without knowing what is classified as an industry. Industries could be broken down into 5, 10, 15, 50, or 500 categories. Agencies are completely in the dark as to how many working life risk exposure estimates they would be required to conduct. This will create confusion and may lead to delays in promulgating of safety standards.
- Ineffective Safety Standards. It appears the rule would require agencies to issue safety standards on an industry-by-industry basis as opposed to the country-wide standards set now. However, it remains unclear whether an industry-by-industry basis is the best way to set safety standards—the Department cites no scientific or empirical evidence on this point.
- Difficulty in Promulgating Safety Standards: The increased burdens on and confusion in agencies and delays, will result in difficulty for agencies to promulgate safety standards. This would make it even more difficult for OSHA to carry out its mission in protecting American workers.
    - Additionally, as these risk assessment procedures would be codified, all future administrations will find it more difficult to propose workplace safety regulations.
- More Dangerous Workplace: The net effect of a delay and difficulty in promulgating safety standards and undervaluation of risk and ineffective standards will be a lowering of safety standards in the workplace, leading to a more dangerous workplace.
- Increase in Preventable Deaths and Diseases: Lowered or no safety standards that result in more dangerous workplace, will lead to an increase in exposure to health risks for American workers, including increased mortality, morbidity, and disease risks. This will also lead to associated secondary economic effects – including increased health care costs and lost productivity.

In accordance with EO 12,866, the Department must take into consideration these and other potential effects to when performing an accurate cost-benefit analysis. The Department must monetize these costs and benefits to the extent feasible. Although this is not an easy task, there are methodologies to monetize costs that are deployed on a regular basis by agencies, including OSHA and MSHA. The Department must then weigh the full costs against the full benefits in a complete analysis.

III. Deviations from Rational Rulemaking

The Department has deviated from rational rulemaking and violated the spirit and letter of EO 12,866 in a number ways. The Department has not shown the existence of a problem nor has the Department offered and assessed feasible alternatives to solve any problem that this regulation is meant to address. The Department has also failed to engage in a voluntary cost-benefit analysis, and should do so even if it does not believe the rule to be significant. Finally, the Department has deviated from the standard procedural timetables. Each of these is troubling on their own, and extremely disconcerting in terms of their additive effects, and we request that the Department correct these deviations.

A. Failure to Prove Existence of Problem

At the outset, the proposed rule fails to accurately identify or quantify the harm that it is intended to relieve. EO 12,866 mandates that each agency "identify in writing the specific market failure . . . or other specific problem that it intends to address . . . that warrant new agency action, as well as the significance of that problem, to enable assessment of whether any new regulation is warranted." Order § 1(b)(1).

The proposed rule offers a number of rationales and purposes. First, the proposed rule ostensibly implements the recommendations of the 1997 Report of the Presidential/Congressional Commission on Risk Assessment and Risk Management. *Inter alia*, the Report found that "OSHA seems to have relied upon a case-by-case basis for performing risk assessment and risk characterization, and recommended that DOL publish guidelines laying out its scientific and policy defaults with records to risk assessment and is characterization." *See* 73 Fed. Reg. at 50910 (quoting Presidential/Congressional Commission on Risk Assessment and Risk Management, Framework for environmental health risk management, 2 Final Report 131-36 (1997)). The Report, however, only advises that OSHA write guidelines laying out risk assessment defaults—it does not suggest or imply that OSHA change its current risk assessment practices in any way. The Report merely calls for consistency, not for changes to the current practice.

Second, the proposed rule states a need to "promote greater public input into and awareness of the Departments' health rulemakings." *Id.* at 50910. However, the rule provides no reasonable basis or evidence for a belief that the current procedures (including public notice and comment periods, and public hearings) do not provide for sufficient public input or awareness. Moreover, even if current public input and awareness were insufficient, the Department provides no evidence that an ANPRM is the best method by which to achieve this goal. The Department also attempts to justify the ANRPM by citing a need to "increase the open and vigorous exchange of information" and a need for the Department to "seek out and receive all relevant data" before proposing a rule. *Id.* at 50914. Again, however, the rule points to absolutely no evidence that the current risk assessment procedures do not allow for enough exchange or receipt of information.

Third, the Department has not presented any evidence that current working life exposure estimates are problematic or lag behind the state of science. In general, it is possible that more specific risk-exposure scenarios will result in more efficient levels of regulation. The current 45-year assumption is likely conservative because it reflects an upper-bound assumption. The proposed regulation, however, does not state that the problem it is intended to address is an overly conservative working life assumption, nor does it justify its choice of the industry-by-industry standard on that basis. There may be compelling reasons for a conservative assumption that the Department has not acknowledged. Industry-by-industry standards may not be the correct mechanism to deal with an overly conservative assumption. While it is possible that relaxing this assumption will lead to a socially beneficial weakening of standards, the Department has not show that this will be the case, nor has the Department has justified the rule on this basis.

The Department has offered no evidence of a compelling need to alter risk assessment procedures or working life exposure estimates. Nor has the Department evaluated the likelihood that the proposals would cure any of the identified purported problems. The Department, in violation of EO 12,866, has wholly failed to identify any specific problems in the current risk assessment procedures that warrant new agency action.

B. Failure to Assess Alternatives, including Guidance Document

The Department has not attempted to offer or assess other possible solutions to any alleged problems with the current risk assessment procedures. Under EO 12,866, when promulgating any rule, agencies are mandated to "select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)" unless a statute requires another approach. *Id.* at § 1. Further, when promulgating a significant rule, an agency is required to assess the "costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation identified by the agencies *or the public* . . ., and an explanation why the planned regulatory action is preferable to the identified potential alternatives." *Id.* § 6(3)(C).

First, there is no evidence presented to suggest that ANPRM is a best practice for risk assessment, or that it is the best method by which to increase public input into and awareness of safety standard or increase the exchange of information. No evidence has even been presented that the ANPRM would achieve these goals. There are a multitude of other options that could increase public input and the exchange of information to a greater degree than an ANPRM, such as increasing public notice and comment periods, holding more public hearings, or increasing the input of agency scientists. These options must be evaluated before the ANRPM can be chosen the most effective method.

Second, industry-by-industry working life exposures may not be the most efficient method to determine risk exposures. The Department has presented no evidence that this is a better alternative than the current standard. Even if the current risk assessment assumptions were faulty, the Department has not proven that an industry-by-industry method would be

more effective and accurate. The Department does not explain how it will account for the exposure to multiple toxins/contaminants in the work environment that is currently taken into consideration by the conservative worklife exposure assumptions. Nor does the proposed rule inform agencies how to proceed when there is limited or no evidence of industry-by-industry work life exposures. There are many other types of working life estimates that may be more accurate, such as, for example, a job category by job category evidence, factory by factory evidence, region by region evidence, or even a single standard that is to based on scientific evidence of working life when available. These options must be evaluated before the industry-by-industry estimate may be chosen as the most effective method.

Finally, the Department has offered no rationale to support the notion that a rule, rather than a guidance document, would better achieve the Report's recommended goal of "laying out scientific and policy defaults with regard to risk assessment." In fact, the Report itself suggests the agency to "publish *guidelines*" to achieve this goal. *Id.* at 50910. A guidance document would be a non-mandatory, flexible directive of general applicability that encapsulates the views, policies, and practices of the Department that could be changed if necessary. By proposing to codify these risk assessment practices into a formal rule, these underjustified and underevaluated requirements whose consequences have not been appropriately analyzed would be imposed on all future administrations. The Department must evaluate whether a rule is the best method by which to achieve its goals – especially given that this rule would start the Department down a path leading to decreased protections for American workers.

C. Failure to Perform Voluntary Cost-Benefit Analysis

Even if the Department does not believe this rule is "significant," as defined by the Order, such a far-reaching regulation should be subjected to cost benefit analysis. This rule would change and codify risk assessment procedures for all future administrations, and thereby affect all future proposed regulations of workplace exposure toxins or hazardous chemicals. This rule could also result in the significant costs, as explained above, without an appropriate compelling purpose or benefit. Further, there has been such a public outcry surrounding this rule that it has prompted Congress to hold a public hearing and introduce legislation to prevent the promulgation of the proposal. *See Prohibiting the Department of Labor's Secret Rule Act*, H.R. 6660, 110th Cong. (referred to House Comm. on Education and Labor, July 30, 2008); *Secret Rule: Impact of the Department of Labor's Worker Health Risk Assessment Proposal: Hearing Before the Subcomm. on Workforce Protections of the H. Comm. on Education and Labor*, 110th Cong. (Sept. 17, 2008). The Department has ignored the strong recommendation of EO 12,866 to undertake a more formal accounting of the impacts of the proposed regulation in economic terms. Given the potential grave consequences and the controversy generated by this rule, it would be imprudent of the Department not to undertake a voluntary cost-benefit analysis and we therefore request that the Department do so.

D. Temporal Irregularities

Finally, the Department has engaged in a variety of deviations from the traditional rulemaking process in proposing this rule.

First, the proposed regulation is in clear violation of a White House directive and the Administration's expressed commitment to principled regulation. On May 9, 2008, the White House directed the heads of executive departments and agencies to submit all proposed regulations they wish to finalize before the end of the Bush Administration by June 1, 2008, except in "extraordinary circumstances." Mem. from Joshua B. Bolten, White House Chief of Staff, to Heads of Executive Departments and Administrator of Office of Information and Regulatory Affairs, at 1 (May 9, 2008). This directive explicitly sought to "resist the historical tendency of administrations to increase regulatory activity in their final months." *Id.* Presumably, the purpose of the deadline was to ensure that agencies did not engage in ill-conceived rulemakings prior to a change of administration. This deadline represented sound policymaking procedure by creating a sufficient window for the vetting and review of new rules and discouraging "last-minute" policymaking. Unfortunately, in recent months, there have been a number of new rules proposed, including the rule at hand, in violation of the White House instruction. The Department must comply with that directive – either by explaining why these regulations are proposed under "extraordinary circumstances," or, if the Department cannot make this showing, by withdrawing the proposed rule.

Second, the Department has decided not to hold a public hearing on this rule and has also shortened the comment time to 30 days. *See* 73 Fed. Reg. at 50909. Under EO, 12,866, an "agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days." Order § 6(a)(1). We request that the Department increase its public comments period to at least 60 days, or perhaps longer, and hold a public hearing, given the considerable effects of this proposed rule.

IV. Conclusion

Agencies are mandated by EO 12,866 to select approaches to regulations that maximize net benefits, and the Department has not complied with this mandate. First, the proposed regulation clearly meets the threshold inquiry of EO 12,866, classifying it as significant and requiring the Department to systematically evaluate the costs and benefits of the proposed regulation – which it has not done. Second, the Department has still failed to the engage in the rational, purposed, and efficient rulemaking required by EO 12,866. The Department has ignored the Order's mandates to articulate an existent problem and demonstrate how the proposed regulatory solution is superior to alternatives. The Department has also chosen not to engage in a voluntary cost-benefit analysis that would ensure that the rule follow the letter and spirit of EO 12,866. By failing to accurately

quantify costs and failing to accurately account for and quantify benefits, the Department lacks information on whether this regulation maximizes net benefits.

Finally, the Department should consider whether its goals are better achievable through a guidance document, as opposed to a codified regulation. The Department has presented no compelling reason for deviating from the recommendations of the Risk Commission's Report and codifying agency risk assessment procedures as a rule.

Because of the failures in its decision making process, the proposed regulation may be considered "arbitrary and capricious" under Section 706(2)(A) of the Administrative Procedures Act.

We respectfully request that the Department promptly comply with the directives of EO 12,866 and engage in the reasoned rulemaking mandated.

Sincerely,

Michael A. Livermore	Inimai M. Chettiar
Executive Director	Legal Fellow