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From: Francois, Vennia <francois@khlaw.com>
Sent: Thursday, December 29, 2011 2:25 PM
To: NIOSH Docket Office (CDC)
Cc: Halprin, Lawrence P.
Subject: Docket Number NIOSH-240 Written Comment
Attachments: 12 29 2011 Final-Keller and Heckman Comments on NIOSH RFI on RELs and Cancer Policies.pdf

Dear Mr. Lentz,

On behalf of Mr. Halprin of Keller and Heckman LLP, attached is the firm's written comment regarding docket number NIOSH-240. If you have any questions, please feel free to contact us.

Best regards,

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December 28, 2011

Via Federal Express and Email

nioshdocket@cdc.gov

NIOSH Docket Office
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**RE: Docket Number NIOSH-240, Request for Information:
Announcement of Carcinogen and Recommended Exposure
Limit (REL) Policy Assessment**

Dear Sir/Madam:

Keller and Heckman LLP appreciates the opportunity to submit these comments to NIOSH in response to the referenced Request for Information (RFI) issued by NIOSH on August 23, 2011.¹ This firm represents numerous clients that are substantially affected by NIOSH's current policies for indentifying and classifying chemicals as carcinogens and developing recommended exposure limits (RELs), and would be substantially affected by a change in those policies.

This NIOSH initiative is inextricably intertwined with the OSHA rulemaking process and the broader objective of enhancing workplace safety and health through the measures described in Section 2 (Congressional Findings and Purpose) of the Occupational Safety and Health Act

¹ Request for Information: Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment, Docket Number NIOSH-240, 76 Fed. Reg. 52664 (August 23, 2011).

("OSH Act"). We believe it is essential to recognize that linkage and to review the NIOSH policies in the context of the role of NIOSH in the overall process of formulating OSHA standards. It is only in that context that the practical utility of NIOSH's current policies can be meaningfully evaluated and compared with alternative approaches.

After careful analysis, for the reasons set out below, we believe NIOSH's policy on RELs should remain consistent with OSHA's policy on PELs and provide OSHA with both a balanced risk assessment and practical research on what is technically and economically feasible to enable OSHA to formulate and adopt necessary and appropriate occupational safety and health standards in an efficient manner.

I. OSHA'S AUTHORITY TO ADOPT AN "OCCUPATIONAL SAFETY AND HEALTH STANDARD"

A. OSHA's Authority To Adopt An "Occupational Safety And Health Standard" Addressing Workplace Exposure To A Toxic Material Is Subject To OSHA Satisfying The Applicable Legal Criteria Established By Sections 3(8), 6(B)(5) And 6(F) Of The Osh Act

To prevail in a court challenge to an occupational safety and health standard, OSHA must satisfy the criteria established by Sections 3(8), 6(b)(5) and 6(f) Of The OSH Act. Section 3(8) of the Occupational Safety and Health Act (OSH Act) defines an occupational safety and health standard as:

A standard which requires conditions, or the adoption or use of one or more means, methods, operations, or processes, reasonably necessary or appropriate to provide safe and healthful employment and places of employment.

Section 6(b) of the OSH Act provides that:

The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall 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. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. 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 [emphasis added] of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

Section 6(f) of the OSH Act provides that:

The determinations of the Secretary shall be conclusive if supported by substantial evidence [emphasis added] in the record considered as a whole.

B. Court Decisions Have Given Practical Meaning To The Applicable Legal Criteria Established By Sections 3(8), 6(B)(5) And 6(F) Of The OSH Act

Generally, to prevail in a court challenge to an occupational safety and health standard, OSHA must demonstrate the following:

- a) Current workplace exposure levels to the identified hazards pose a significant risk of harm to the workers who would be covered by the standard;²
- b) The proposed requirements would significantly or materially reduce the workplace risk to workers exposed to those identified hazards;
- c) The proposed requirements are technically and economically feasible and within the bounds of what are reasonable for each industrial sector;
- d) The proposed requirements are the most cost-effective approach for achieving the reduction in risk by those identified hazards;
- e) For health standards dealing solely with harmful physical agents, the standard must, to the extent feasible and within reasonable bounds, reduce workplace exposures to a level below that which presents a significant risk of material impairment of health or functional capacity to employees.

II. NIOSH'S AUTHORITY TO DEVELOP A RECOMMENDED "OCCUPATIONAL SAFETY AND HEALTH STANDARD"

A. Section 20 of the OSH Act Directs NIOSH to Develop Criteria Enabling OSHA to Meet Its Responsibility for the Formulation Of Occupational Safety and Health Standards, and Section 22 Authorizes NIOSH to Develop and Establish Recommended Occupational Safety and Health Standards

Section 20(a) of the OSH Act directs the Secretary of Health and Human Services or NIOSH to perform the following research functions:

- (2) ... consult with [OSHA] ... to develop specific plans for such research, demonstrations, and experiments as are necessary to produce criteria, including criteria identifying toxic substances, enabling [OSHA] to meet [its] responsibility for the formulation of safety and health standards under this Act; and . . . on the basis of such

² *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 615 (1980) (Benzene) (vacating the benzene standard).

research, demonstrations, and experiments and any other information available . . . develop and publish at least annually such criteria as will effectuate the purposes of this Act.

(3) . . . on the basis of such research, demonstrations, and experiments, and any other information available . . . develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience.

Section 22 of the OSH Act authorizes NIOSH to perform the following functions:

(c)(1) develop and establish recommended occupational safety and health standards;

(d)(1) conduct such research and experimental programs as . . . are necessary for the development of criteria for new and improved occupational safety and health standards, and (2) after consideration of the results of such research and experimental programs make recommendations concerning new or improved occupational safety and health standards.

The commonly understood meaning of the term “research” is:

studious inquiry or examination; *especially* investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws; the collecting of information about a particular subject.

It is not limited to reviewing toxicological studies and performing risk assessments. It also includes researching whether recommended control measures are technically and economically feasible.

NIOSH recently described its responsibilities for developing occupational safety and health standards under the OSH Act as follows:³

³ *Qualitative Risk Characterization and Management of Occupational Hazards: Control Banding (CB) -- A Literature Review and Critical Analysis*, DHHS (NIOSH) Publication No. 2009-152 August 2009.

Through the Act, Congress charged NIOSH with [1] recommending occupational safety and health standards and [2] describing exposure levels that are safe for various periods of employment, including but not limited to the exposures at which no worker will suffer diminished health, functional capacity, or life expectancy as a result of his or her work experience.

III. NIOSH IS NOT FULFILLING ITS STATUTORY ROLE TO DEVELOP RECOMMENDED "OCCUPATIONAL SAFETY AND HEALTH STANDARDS"

A. Current NIOSH Practice Makes Ineffective Use of its Authority and Does not Provide OSHA with Criteria that Effectively Enable OSHA to Meet Its Responsibility for the Formulation Of Occupational Safety and Health Standards

As NIOSH acknowledged in the language quoted above, through the OSH Act, "Congress charged NIOSH with recommending occupational safety and health standards" [emphasis added]. That means Congress charged NIOSH with recommending "occupational safety and health standards" as that term is used in the OSH Act and interpreted by the decisions of the U.S. Supreme Court. The term cannot mean one thing for NIOSH and another for OSHA. For both NIOSH and OSHA, this term refers to mandatory control measures that are technically, analytically and economically feasible, whether the measure is a standalone PEL, or a PEL in a comprehensive substance-specific standard that includes a PEL, an action level and the traditional ancillary requirements.

The process of developing a health standard would be far more cost-effective if NIOSH did what it acknowledges was expected of it under the OSH Act -- if NIOSH recommendations were based on and supported by an integrated and well-documented technical and economic feasibility analysis rather than the more theoretical technical feasibility analysis found in its traditional criteria documents. For example, as recently as the pending criteria document on diacetyl, NIOSH stated that engineering controls, such as general ventilation or dust collection, are feasible, without considering EPA requirements or combustible dust issues.

In its initial criteria document for hexavalent chromium, NIOSH recommended an airborne exposure limit (1 ug/m³, 8-hour TWA) that OSHA found to be technically infeasible -- impossible for some sectors and requiring an unacceptably high use of respiratory protection for others (52% of affected employees). In its 2005 post-hearing comments in the OSHA chromium rulemaking (Item 9 on pp. 9-10), NIOSH did acknowledge the concern that a PEL of 1 ug/m³ would result in excessive use of respirators. However, that was very late in the process. Meanwhile, because NIOSH made a recommendation based on aspirations rather than a sound feasibility analysis, the business community lived with years of uncertainty that, as a practical matter, should have come to an end only in 2009 when the PEL of 5 ug/m³ and AL of 2.5 ug/m³

were upheld by the Third Circuit.⁴ However, in 2008, for reasons that remain unclear, NIOSH issued a draft updated criteria document for hexavalent chromium with a REL of 0.2 ug/m³ based on what we understand was the same risk assessment OSHA had relied on in setting a PEL of 5 ug/m³.⁵ We believe NIOSH needs to collect and analyze all of the data needed to ensure its recommendations have real world application and are not academic risk assessment exercises that create unrealistic expectations, and needlessly expose the business community and the jobs they create to these kinds of uncertainties.

Under the current division of labor leading to the adoption of a substance-specific occupational safety and health standard for a particular chemical, NIOSH typically identifies and classifies the hazards associated with that chemical, performs a risk assessment and a theoretical technical feasibility assessment, and then issues a criteria document containing that information. Prior to issuance, the draft criteria document is released for public comment, but not under the procedures applicable to a rulemaking. Informed by the criteria document, OSHA also performs a risk assessment, and attempts to develop an applied technical feasibility analysis and a relatively minimal economic feasibility analysis through a variety of generally inefficient and less than effective research techniques. This division of labor has greatly contributed to what most experts acknowledge is a dysfunctional OSHA rulemaking process.

B. Current NIOSH Practice with Respect to RELs Has Contributed to a Dysfunctional OSHA Rulemaking Process

Over time, the OSHA rulemaking process became less transparent and less effective at facilitating meaningful stakeholder participation. This is due to several factors. First, court decisions have established a principle of administrative law, known as deference, under which the courts defer to scientific and policy determinations that are entrusted to regulatory agencies by their enabling statutes and that the agency has supported with a reasonable explanation and substantial evidence.⁶ In response to this loosening of the reins, OSHA developed a tendency to use the rulemaking process to develop ambiguous and over-reaching standards that could later be interpreted or re-interpreted to address issues that either were not anticipated, were ambiguously addressed or were intentionally avoided during the rulemaking -- always subject to the overriding OSHA policy of adopting the "most protective" interpretation.

⁴ Public Citizen Health Research Group v. Dept. of Labor, 557 F.3d 165 (3d Cir. 2009).

⁵ <http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-144/0144-090108-ExternalReviewDraft.pdf>

⁶ *Martin v. OSHRC (CF&I Steel Corp.)*, 499 US 144, 157 (1991).

Second, Congress appropriately imposed significant legal requirements or constraints on OSHA in an effort to ensure OSHA used its delegated rulemaking authority in an appropriate manner. As noted by the U.S. Supreme Court in *Benzene*:⁷

Finally, with respect to the legislative history, it is important to note that Congress repeatedly expressed its concern about allowing the Secretary [of Labor, acting through OSHA] to have too much power over American industry.

Particularly in the absence of a much greater level of support from NIOSH, OSHA has frequently found those requirements inconvenient and attempted to ignore them. The clearest example of that behavior was the generic PELS update rulemaking that led to the issuance of the OSHA Air Contaminants Standard.⁸ OSHA provided the following explanation as justification for its use of a generic short-cut in an attempt to adopt or amend hundreds of PELs:

In response to both the court challenges [to previous rules] and the need to face difficult issues, OSHA has engaged in detailed and extensive analyses [in the preambles to final rules from prior rulemakings]. These have resulted in lengthier preamble discussions and in-depth analyses for all issues....

Now that OSHA has reviewed these issues in depth several times, has experience "gained under this ...law" (sec. 6(b)(5)) on these issues, and has had its analysis upheld in the Courts, somewhat less detailed chemical-by-chemical analyses should be appropriate. The accumulated judicial guidance and agency experience reduces the need for as extensive a discussion of some of the issues. [53 Fed. Reg. at 20964.]

The Air Contaminants Standard was the subject of numerous pre-enforcement court challenges and, on review, the Eleventh Circuit assessed OSHA's explanation of its approach to the underlying rulemaking as follows:⁹

This implies that OSHA need no longer perform detailed analysis and explanation when promulgating PELs because the agency's analysis for other substances has been upheld in prior rulemakings. Besides displaying more than a touch of hubris, this passage reveals a fundamental

⁷ *Industrial Union Dept., AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 651 (plurality opinion) (hereinafter "*Benzene*").

⁸ 54 Fed. Reg. 2332 (1989).

⁹ *AFL-CIO v. OSHA*, 965 F.2d 962, 979-980 (11th Cir. 1992).

misperception of the OSH Act and the case law interpreting that act.

For example, the language from section 6(b)(5) that is quoted in this passage refers to the types of things that should be taken into consideration by OSHA when determining what a standard should be: e.g., feasibility, the latest scientific data, etc. This language was clearly not intended to be used as a way to cut corners. Nor is it appropriate for those given such serious tasks to adopt an attitude of “trust us, we are working for the government.”

Third, the unfortunate reality is that the members of the regulated community and their trade associations have limited resources to allocate among the competing demands for participation in rulemakings conducted by EPA, DOT, FDA and numerous other federal and state agencies.

Dissatisfied with how OSHA had exercised its delegated rulemaking authority over the years, but believing OSHA should retain that power, Congress adopted the Congressional Review Act and proceeded to place additional constraints on OSHA in an effort to better ensure that the agency would exercise its delegated rulemaking authority in an appropriate manner. This led Congress to adopt the Regulatory Flexibility Act, the Paperwork Reduction Act and the Small Business Regulatory Enforcement Fairness Act (“SBREFA”) to further control the manner in which OSHA and other federal agencies exercised that authority. A series of Executive Orders, issued by presidents from both major parties, have also been employed in an attempt to rein in the excesses from OSHA and other federal regulatory agencies.

It appears that, with each new set of Congressional constraints, OSHA has sought to find a way to minimize or work around those constraints rather than addressing the concerns that led Congress to impose them. NIOSH’s failure to address technical and economic feasibility, and its practice of recommending more theoretical, aspirational measures rather than “occupational safety and health standards” significantly contributes to the problem. OSHA’s Injury and Illness Prevention Program rule initiative, apparently supported by NIOSH, is seen by many within the regulated community as an unprecedented effort to circumvent the constraints imposed by Congress on OSHA’s rulemaking power and has led some to conclude that the only effective constraint on OSHA rulemaking is embodied in the REINS Act under which a final rule would go into effect only if approved by Congress.

IV. CONGRESS CHARGED NIOSH WITH DEVELOPING RECOMMENDED “OCCUPATIONAL SAFETY AND HEALTH STANDARDS” AND THAT IS WHAT NIOSH SHOULD BE DOING

As NIOSH recently acknowledged, “Congress charged NIOSH with recommending occupational safety and health standards.” The term “occupational safety and health standard” has one meaning under the OSH Act, equally applicable to OSHA and NIOSH.

What is needed from NIOSH is an integrated technical and economic feasibility analysis based on the best available data. Under the current OSHA rulemaking process, OSHA, either directly or through a contractor, takes years to collect and analyze the minimum amount of data it believes is necessary to support a proposed rule. Industry then has only the relatively short time allowed by the rulemaking to organize and collect additional data. Agencies cannot expect industry to be continuously collecting and updating data from the time a NIOSH criteria document is issued. For example, the NIOSH criteria document on hexavalent chromium was issued in 1975 and the NPRM initiating the OSHA rulemaking was issued in October of 2004.

Rather than continuing the current inefficient division of labor, NIOSH could facilitate and manage the operation of stakeholder groups working to prepare pre-rulemaking documents more along the lines of how the California Division of Occupational Safety and Health supports the development of health standards by the California Standards Board. The pre-rulemaking process and documents generated from it would provide OSHA a head start in promulgating a standard by:

- Summarizing and incorporating stakeholder-provided data on hazards, exposures, risk assessment and the technical and economic feasibility of various compliance options (rather than theoretical control measures) into its recommendations;
- Summarizing relevant NIOSH-sponsored research or analysis, conducted to fill in data gaps on hazards and exposures, identify and characterize compliance options (rather than theoretical control measures), and/or evaluate their technical and economic feasibility;
- Identifying points of agreement among stakeholders; and
- Identify points of disagreement that will need to be resolved by OSHA during formal rulemaking

Pre-rulemaking documents could serve as a resource for employers during the time it takes OSHA to promulgate final rules.

In short, we believe, at a minimum, NIOSH must address technical feasibility in a meaningful way that advances the cooperative development of occupational safety and health standards rather than suggesting theoretical approaches that create false expectations as to what is feasible. We also believe it is critical for NIOSH, in cooperation with OSHA and all stakeholders, to effectively address economic feasibility. The examination of technical feasibility independent of economic feasibility tends to become an academic exercise that generates impractical if not misleading conclusions.

Assessing economic feasibility is often the most difficult and most contentious part of setting occupational safety and health standards. Affordability is both difficult to determine with precision and a matter of the highest importance as the viability of businesses and the jobs they provide are at stake. For these reasons, we encourage NIOSH to consider allocating more of its research budget in consideration of economic feasibility.

* * * *

Thank you for your consideration of our views. We would be pleased to respond to any questions you may have.

Respectfully submitted,

A handwritten signature in cursive script that reads "Lawrence P. Halprin". The signature is written in black ink and is centered on the page.

Lawrence P. Halprin