



Office of Advocacy

December 17, 2004

The Honorable John Henshaw
Assistant Secretary for Occupational Safety and Health
U. S. Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

**Re: Occupational Exposure to Hexavalent Chromium, Proposed Rule,
69 Federal Register 59306 (October 4, 2004).**

Dear Assistant Secretary Henshaw:

The Office of Advocacy (Advocacy) of the U.S. Small Business Administration is pleased to submit these comments in response to the Occupational Safety and Health Administration's (OSHA) Notice of Proposed Rulemaking (NPRM) on Occupational Exposure to Hexavalent Chromium. In the NPRM, OSHA solicits comments on proposed changes to 29 CFR Parts 1910, 1915, 1917, 1918 and 1926, including the permissible exposure limit (PEL) and several ancillary requirements.

The Office of Advocacy is proud to have participated in the Small Business Advocacy Review Panel (Panel) convened by OSHA prior to publication of the proposed rule, in accordance with the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). Advocacy is convinced that involving small entities early in the rule development process helps OSHA produce rules that better accomplish the agency's objectives of protecting worker safety and health while also establishing a regulatory scheme that allows small businesses to flourish, consistent with the goals of the RFA and Executive Order 13272. Advocacy is an independent office within the U.S. Small Business Administration (SBA), so the views expressed in this letter do not necessarily reflect the views of SBA or the Administration.

I. Advocacy Background

The Office of Advocacy monitors and reports on agencies' compliance with the RFA, as amended by SBREFA. The purpose of these laws is to bring the voice of small business into the regulatory development process. The requirements of small business impact analysis, small employer outreach and input, and consideration of less burdensome alternatives were enhanced by President Bush's Executive Order 13272. The Executive Order, signed on August 13, 2002, requires agencies to implement policies protecting small entities when writing new rules and regulations. (1) This Executive Order highlights the President's goal of giving "small business owners a voice in the complex and confusing federal regulatory process" (2) by directing agencies to work closely with the Office of Advocacy and properly consider the impact of their regulations on small entities. In addition, Executive Order 13272 authorizes Advocacy to provide comment on draft rules to the agency that has proposed the rule, as well as to the Office of Information and Regulatory Affairs of the Office of Management and Budget. (3) Executive Order 13272 also requires agencies to give every appropriate consideration to any comments provided by Advocacy. Under the Executive Order, the agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to any written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so. (4)

II. Contributions of the SBREFA Panel

Advocacy commends OSHA for making numerous changes prior to publication of the proposed rule in response to the recommendations in the Panel's final report.⁽⁵⁾ Table IX-15 in the NPRM summarizes the Panel's recommendations and OSHA's responses.⁽⁶⁾ The table illustrates how the proposed rule was improved in several ways by the participation of small entities in the SBREFA panel process. As OSHA points out, the Panel recommended against a PEL which would be applied in a rigid, one-size-fits-all scheme.⁽⁷⁾ OSHA has "preliminarily" proposed a less expensive approach for intermittent users of hexavalent chromium. In addition, OSHA has proposed special approaches for shipyards and construction, reducing the requirement for monitoring and eliminating restricted/regulated areas entirely.⁽⁸⁾

As OSHA is aware, Advocacy submitted a report, "Alternatives to OSHA's Draft Proposed Hexavalent Chromium Standards for General Industry, Maritime Operations, and Construction," prepared for Advocacy by its contractor, Jack Faucett Associates (JFA),⁽⁹⁾ to the Panel. The JFA report suggests several regulatory alternatives to the draft proposed rule reviewed by the Panel and small entity representatives. Many of those alternatives either were adopted by OSHA in the proposed rule or are still under consideration by OSHA. Advocacy reiterates its interest in the alternatives presented in the JFA report.

Advocacy concurs with the Panel's recommendation that OSHA not extend the scope of the rule to occupational exposures to wet cement. Although such exposures can lead to irritation and cement burns, and irritant dermatitis or contact dermatitis, at least three OSHA rules (personal protective equipment, hazard communication, and sanitation) currently provide requirements to protect employees from such exposures. In addition, industry-produced guidance and training programs addressing this hazard are widely used.

In response to issues raised by several small entity representatives (SERs) regarding the adequacy of OSHA's draft estimation of the rule's potential costs,⁽¹⁰⁾ the Panel recommended that OSHA revise its economic estimates as time allows. Both Advocacy and the SERs understood that OSHA was under strict court-imposed time constraints to produce the proposed rule. Due to the substantial size and broad scope of OSHA's economic analysis, Advocacy was not able to review the adjustments made by OSHA to assess their adequacy. Advocacy has urged representatives of small businesses in each of the affected industries to examine OSHA's estimation of costs and to comment to OSHA on the accuracy of OSHA's cost estimates. Advocacy urges OSHA to continue to adjust its estimates of the potential economic impact of the rule as more data is obtained.

III. Risk Assessment Issues

A. OSHA's Use of the Linear Relative Risk Model

To predict cancer risk from exposure to hexavalent chromium, OSHA utilized a linear relative risk model. In its explanation for use of this model, OSHA stated that this model is an accepted and extensively used approach for assessing carcinogen risk. Advocacy recognizes that the linear relative risk model is an accepted approach. However, Advocacy believes that there are concerns surrounding use of this model to determine cancer risk at the OSHA recommended PEL. This is because there is some evidence that suggests a linear risk model may overpredict lung cancer risk at low exposure levels and that it improperly discounts the potential existence of a threshold effect. Given these uncertainties, Advocacy questions whether OSHA has established that there is significant risk of lung cancer due to exposure to hexavalent chromium at or above the PEL OSHA proposes. OSHA should more fully address the concerns raised by commenters regarding the problems associated with use of the linear relative risk model.

B. Supporting Exposure Data Is Not Representative of Modern Exposure Levels

OSHA primarily uses data from the Luippold cohort study,⁽¹¹⁾ conducted in Painesville, Ohio and the Gibb cohort study conducted in Baltimore, MD.⁽¹²⁾ The Gibb cohort was based on workers employed between 1950 and 1974. The Luippold cohort was based on workers employed between 1940 and 1972. Advocacy appreciates the value of both studies. However, the studies are based on worker populations with much higher exposure levels than occur in industry today, using processes no longer used, and using forms of calcium chromate, a compound not widely encountered in today's facilities. The hexavalent chromium exposure levels differ

substantially. As a result, it is likely that the risk of cancer would be greater among the Gibb and Luippold populations than would be the case today. Advocacy is concerned that the predictive value of these studies is not as precise as OSHA presents, and encourages OSHA to explain the differences in exposure levels between the cohort population and present day.

C. Interaction between Smoking and Hexavalent Chromium

OSHA discusses the confounding effect of smoking as well as the combined effects of smoking and hexavalent chromium exposure on the two cohort populations. (13) OSHA indicates that the combination of smoking and hexavalent chromium exposure have a multiplicative relationship. Since there is a lack of data on the interactive effects of smoking and hexavalent chromium, Advocacy is concerned that the calculated cancer risk is improperly increased.

D. Differences in Risk Associated with Types of Hexavalent Chromium Exposure

OSHA discusses the differences between water soluble and water-insoluble hexavalent chromium compounds. Although the workers in the study cohorts were primarily exposed to the water-soluble hexavalent chromium compounds, considered less carcinogenic, OSHA extrapolates from that data an even greater risk for individuals exposed to the less water-soluble hexavalent chromium compounds. Advocacy has concerns about this extrapolation. Advocacy believes that this blanket assertion cannot be made about the cancer risk associated with exposure to water-insoluble hexavalent chromium compounds.

During the SBREFA Panel discussions, some small entity representatives addressed the differences between lead chromate and zinc chromate compounds. Several small entities affected by the rule use lead chromate compounds in their operations. While both lead and zinc chromate compounds are less-water soluble, it is not clear whether they present the same cancer risk. The small entity representatives assert that they do not present the same risk as other less-soluble or water insoluble hexavalent chromium compounds. The studies utilized by OSHA do not adequately address the differences in the two types of compounds. Advocacy encourages OSHA to consider the differences in actual carcinogenic effects of the various hexavalent chromium compounds when developing the final rule.

Advocacy believes that OSHA must account better for the uncertainties introduced by the translation of exposure data from the 1930s and 1940s to present circumstances, must make a better case for the use of a linear dose-response model, must make some attempt to determine the effect of cancers due to secondhand smoke, and must explain better why separate PELs for various hexavalent chromium compounds cannot be established.

IV. Economic and Regulatory Flexibility Analysis

Advocacy continues to be concerned that OSHA has underestimated the costs of controls and recordkeeping related to the proposed rule. In addition, although the Small Business Advisory Review Panel provided data, OSHA has not addressed the problem of business failures and businesses which will discontinue working with substances containing hexavalent chromium. OSHA acknowledges that some business will no longer do this work, but they give no indication if that work will be replaced or what the economic impact will be.

Small businesses have pointed out that OSHA has underestimated the costs of hygiene requirements that the rule proposes. For example, there is no estimation of costs associated with handling wastewater, either by commercial laundries which engage to launder hex chrome-contaminated clothing, or by facilities that construct their own hand washing and shower facilities.

There is no cost estimate associated with training of commercial laundry employees. Laundry employees unfamiliar with the health effects and proper handling of hexavalent chromium will need training, even if their exposure is limited. Laundries that decline to accept contaminated clothing are likely to lose business to laundries already equipped and trained to handle contaminated clothing.

OSHA's figures for the cost of construction and maintenance of change rooms and washing facilities are too

low. SBREFA Panel members discussed this, but OSHA has not adjusted its figures.(14) In addition, OSHA has under-estimated the time required for changing, hand washing and showering. The agency's estimates appear to be based on multiplying the number of affected employees by OSHA's estimates of the time required for each of those tasks. That assumes, however, that all employees can wash, change or shower simultaneously. More likely, there will be waiting time. Facilities could conceivably schedule break times and stagger the ends of shifts to avoid long waiting periods, but this may have an impact on productivity.

Advocacy is also concerned that OSHA has not limited its requirement for regulated areas to industries and processes in which regulated areas would likely reduce exposures. In some industries, as pointed out by SERs, the requirement of regulated areas will have the effect of requiring respirators or other controls for more employees than necessary.

Advocacy is concerned also that OSHA has failed to evaluate the impact of this rule on many additional industry operations that will be substantially affected by the proposed PEL. For example, zinc plating operations have a hexavalent chromate conversion bath process as a final step to provide additional corrosion protection. The amount of hexavalent chromium involved is very low and until now these operations have not been affected by OSHA's PEL for hexavalent chromium or the Environmental Protection Agency's Chrome Maximum Achievable Control Technology air emissions standard.(15) However, as proposed the PEL will cause small businesses with these operations to incur all costs associated with implementation of controls required by both standards. Advocacy is concerned that other industries and operations are similarly situated and OSHA has failed to evaluate the compliance costs and economic impact that the proposed PEL will have on these small businesses.

V. Recommendations

Advocacy urges OSHA to set a permissible exposure limit (PEL) of 23 micrograms per cubic meter, as stated in the JFA report to the Panel, while continuing to study the effect of hexavalent chromium exposures at lower levels. Advocacy continues to support the regulatory alternatives proposed in the JFA report, and urges OSHA to re-consider its estimates of costs and impacts on small businesses consistent with the comments it receives and new information as it becomes available.

Thank you for this opportunity to comment on the proposed rule. If you have any questions about this comment, please do not hesitate to contact Charles Maresca at (202) 205-6533.

Sincerely,

Thomas M. Sullivan
Chief Counsel for Advocacy

Carrol Barnes
Assistant Chief Counsel

Charles Maresca
Assistant Chief Counsel

Radwan Saade
Regulatory Economist

cc: Dr. John D. Graham, Administrator, Office of Information and Regulatory Affairs

ENDNOTES

1. Exec. Order. No. 13272 at § 1, 67 Fed. Reg. 53,461 (2002).
2. White House Home Page, President Bush's Small Business Agenda, (announced March 19, 2002) (last viewed December 17, 2004) <<http://www.whitehouse.gov/infocus/smallbusiness/regulatory.html>>.

3. E.O. 13272 at § 2(c).
4. Id. at § 3(c).
5. Report of the Small Business Advocacy Review Panel on the Draft OSHA Standards for hexavalent Chromium, hereinafter "Panel Report," OSHA Docket No. H054A, Exhibit No. 34, also available at http://archive.sba.gov/advo/laws/is_hexrpt04_0420.pdf.
6. 69 Fed. Reg. 59438.
7. 69 Fed. Reg. 59440 (Panel recommends separate PELs); 69 Fed. Reg. 59441 (Panel recommends PELs based on toxicity, and recommends longer phase-in period for certain businesses).
8. See Question 24, 69 Fed. Reg. 59309.
9. Alternatives to OSHA's Draft Proposed hexavalent Chromium Standards for General Industry, Maritime Operations, and Construction, Final Report (March 29, 2004) by Jack Faucett Associates for the Office of Advocacy under contract SBAHQ-00-D-006.
10. Panel Report, p. 29.
11. 69 Fed. Reg. 59319-25. Luippold, R. S., et al., "Lung Cancer Mortality Among Chromate Production Workers," *Occup. Environ. Med.* 2003; 60:451-457.
12. 69 Fed. Reg. 59319-23. Gibb, Herman. J., et al., "Lung Cancer Among Chromium Chemical Production," *Am. J. Ind. Med.*; 38: 115-126 (2000).
13. See, e.g., 69 Fed. Reg. 59321.
14. OSHA tables indicate that all affected industries are currently required to provide hand washing and, in some industries, showering facilities; OSHA tables in the Preliminary Economic Analysis indicate costs for compliance with these current requirements only.
15. 40 CFR Part 63.