

**U.S. Department of Labor**

Assistant Secretary for  
Occupational Safety and Health  
Washington, D.C. 20210



JAN - 6 2010

Mr. Robert E. Glenn  
Consulting Scientist  
Crowell and Moring, LLP  
1001 Pennsylvania Avenue, NW  
Washington, DC 20004

Dear Mr. Glenn:

Thank you for your letter of October 21, 2009, on behalf of the Brick Industry Association (BIA) regarding factors related to silica exposure in the brick industry and the Occupational Safety and Health Administration's (OSHA's) plans for conducting a peer review of the Health Effects Analysis and Quantitative Risk Assessment for crystalline silica. In your letter, you express the opinion that OSHA is conducting the peer review in a "closed-door manner" and you ask OSHA to take immediate action to make the preliminary health effects analysis and quantitative risk assessment public. You also ask OSHA to place your letter in the public docket and provide copies of it to the peer reviewers for the silica quantitative risk assessment. You also indicate that you do not believe that the approach OSHA plans to follow comports with the Office of Management and Budget's *Final Information Quality Bulletin for Peer Review* (OMB Bulletin) or with the administration's commitment to transparency, open government, and scientific integrity. In addition, you have provided OSHA with studies that you believe support your opinion that the current OSHA PEL for crystalline silica is amply protective of brick manufacturing workers.

As described in the Peer Review Agenda, peer reviewers will review OSHA's draft Health Effects Analysis and Preliminary Quantitative Risk Assessment, and will submit written letter reports that the Agency will consider prior to publication of a proposed rule. OSHA will revise the draft documents as appropriate in response to peer reviewer comments, and will make the revised documents available to the public as part of the Notice of Proposed Rulemaking that the Agency will publish in the *Federal Register*. OSHA will make the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' reports, and the Agency's response to the peer reviewers' reports publicly available with publication of a proposed rule. The public docket will also be opened at the time of publication of the proposed rule. At that time, the public may submit comments to the docket; comments on the health effects analysis and quantitative risk assessment will be made available to the peer reviewers prior to the public hearing. OSHA also plans to schedule time during the informal rulemaking hearing for participants to testify on the Health Effects Analysis and Preliminary Quantitative Risk Assessment in the presence of peer reviewers. Thus, the open comment period and informal hearing will provide BIA an opportunity to submit information to the record that it believes will benefit the peer review, and to testify in the presence of the reviewers. Peer reviewers will subsequently be asked to submit their final reports to the record, which will be considered by the

Agency prior to development of a final rule. OSHA will not place your letter in the public docket or provide copies of it to the peer reviewers at this time. The peer reviewers will have access to the comments of all interested parties that have been submitted to the docket. Therefore, it is not appropriate to provide the peer reviewers with only your comments now, before the docket is open. We encourage the Brick Industry Association to submit your letter and any additional comments to the docket when it opens upon publication of the proposed rule. This material will then be made available to the peer reviewers.

OSHA believes that the process established for peer review of the Health Effects Analysis and Preliminary Quantitative Risk Assessment for crystalline silica will enable the Agency to ensure a high level of scientific rigor in its risk assessment. Because the process provides a vehicle for the public to provide written and oral testimony to the peer reviewers, and because interested parties will have the opportunity to provide input prior to completion of the peer review, OSHA believes that its approach is consistent with the guidance contained in Section III.5 of the OMB *Bulletin*. OSHA also believes that its approach reflects the administration's commitment to transparency, open government, and scientific integrity expressed in the OMB *Bulletin*, the Presidential Memorandum on Transparency and Open Government (74 FR 4685, January 21, 2009), and the Presidential Memorandum on Scientific Integrity (74 FR 10671, March 9, 2009).

OSHA recognizes and appreciates the Brick Industry Association's experience and expertise in silica-related health issues. The Agency thanks you for the valuable information that you have submitted with your letter and for sharing your thoughts on the crystalline silica peer review process. I look forward to and welcome your participation in the rulemaking process.

Sincerely,

A handwritten signature in black ink, appearing to read 'David Michaels', with a stylized flourish at the end.

David Michaels, PhD., MPH

cc: Ms. Susan Miller