February 10, 2014

David Michaels, PhD, MPH Assistant Secretary of Labor for Occupational Safety and Health U.S. Department of Labor 200 Constitution Avenue NW Washington, DC 20210 **SUBMITTED VIA:** Regulations.gov

SUBJECT: Occupational Safety and Health Administration (OSHA)

Docket #: OSHA-2010-0034

Occupational Exposure to Respirable Silica

Dear Dr. Michaels.

The Center for Effective Government (CEG) is pleased to provide the following comments regarding OSHA's proposal to amend its standards regarding the permissible occupational exposure limit (PEL) for respirable silica (hereafter "the proposed rule"). The Center for Effective Government's mission is to build an open, accountable government that invests in the common good, protects people and the environment, and advances the national priorities defined by an active, informed citizenry.

Health Effects

Question 1. CEG believes that OSHA has conducted a thorough review and evaluation of the peer-reviewed literature on the health effects associated with exposure to respirable crystalline silica as of the conclusion of OSHA's literature review. Numerous articles regarding the health impacts of occupational silica exposure have been published in the peer-reviewed literature since the conclusion of OSHA's literature review. OSHA is referred to comments on the proposed rule submitted by the American Public Health Association (APHA), which include an appendix with articles published in the peer-reviewed literature subsequent to OSHA's literature review (Occupational Exposure to Respirable Crystalline Silica -- Review of Health Effects Literature and Preliminary Quantitative Risk Assessment), as well as the supplemental literature review of epidemiological studies (Supplemental Literature Review of Epidemiological Studies on Lung Cancer Associated with Exposure to Respirable Crystalline Silica), regarding the association of occupational silica exposure with increased risk of silicosis, chronic obstructive pulmonary disease, lung cancer, autoimmune disorders, and chronic kidney disease. With respect to additional health effects associated with occupational silica exposure not included in the OSHA literature review, we note the study by Chen et al. (2012)¹, also cited in the APHA comment

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¹ Chen W, Liu Y, Wang H, et al. Long-term exposure to silica dust and risk of total and cause-specific mortality in Chinese workers: a cohort study. PLoS Med. 2012; 9(4):e1001206.

appendix, which found significantly elevated standardized mortality ratios (1.65, 1.35 – 1.99) for ischemic heart disease in silica-exposed workers. The authors conclude that "Long-term silica dust exposure was associated with substantially increased mortality among Chinese workers. The increased risk was observed not only for deaths due to respiratory diseases and lung cancer, <u>but also for deaths due to cardiovascular disease</u>. (emphasis added)."

Risk Assessment

Questions 3 – 7. CEG supports OSHA's use of cumulative silica exposure as the basis for modeling the lifetime risk of death from lung cancer, silicosis, and non-malignant respiratory disease, as well as the lifetime risk of silicosis morbidity, in its quantitative risk assessment. The selection of the cumulative exposure model as opposed to a non-linear exposure dose rate model is appropriate given the lack of a consistent finding in the scientific literature regarding an attenuation of the exposure-response function for lung cancer risk at the highest levels of exposure, as well as the need for conservatism in selection of a PEL that reduces the risks to worker health. OSHA's preliminary quantitative risk assessment has relied on the best published scientific evidence available and appropriately has given greater weight to studies with the most robust methodological designs and statistical analyses.

PEL (§ 1926.1053(c)) and Action Level

Question 38 & 40. As documented in Table VII-2 of the published proposed rule and acknowledged in numerous references throughout the rule (see for example pages FR56281 and FR 56283), OSHA's risk assessment indicates that there is a "very high level of risk remaining at the PEL" for adverse health effects from diseases even at the proposed 50 $\mu g/m^3$ level. OSHA's risk assessment estimates a remaining lifetime excess risk of death associated with silica exposure of 6-26 lung cancer deaths per one thousand workers, 43 deaths from non-malignant respiratory disease (including silicosis) per one thousand workers, and 32 deaths from renal disease per one thousand workers. This substantial level of residual risk at the proposed PEL, well in excess of the benchmark of 1/1,000 excess risk over a working lifetime that OSHA has used for other health standards, strongly underscores the need for an action level (AL) set at a substantially lower exposure level to minimize the unavoided health impacts. CEG supports adoption of the proposed the 50 µg/m³ PEL, though we note that a threshold limit value equivalent to 25 µg/m³ (0.025 mg/m³, TWA) was set in 2006 by the American Conference of Government Industrial Hygienists and this exposure limit for silica has been adopted by several international countries (e.g., Japan, Italy, and the Canadian provinces of Alberta, Nova Scotia and Saskatchewan). We urge OSHA to evaluate the evidence that is submitted to the record of this rulemaking to determine if more recent experience and evidence support the feasibility of a lower limit, and, if so, to set a lower PEL in the final rule.

CEG also supports the proposal to set an AL of $25~\mu\text{g/m}^3$ that includes requiring medical surveillance every three years (with the clarification that workers are able to request to see a

clinician at an earlier interval if there is a concern about shortness of breath, excessive exposure levels, or ability to use respiratory protection) and exposure monitoring for silica exposures at or above the AL for the general industry categories. Since the rationale for OSHA's selection of 50 µg/m³ as the PEL for all affected industries is not based on a level that eliminates significant risk but rather on the feasibility of engineering controls and work practices, CEG recommends that OSHA require reporting of results from the exposure monitoring required when silica exposures are at or above an action level (AL) of 25 µg/m³ to inform the ability of controls to reduce exposures below the proposed PEL. With respect to the construction industry standard, Table 1 of the proposed rule should be reviewed within five years and, where necessary, revised with updated information on control technology that is technically and economically feasible to achieve lower exposure levels.

Methods of Compliance (§ 1926.1053(f)(2)

Question 63. CEG urge OSHA to prohibit the use of silica sand for abrasive blasting. In the 1974 criteria document supporting the recommended standard of 50 µg/m³ for occupational exposure to crystalline silica, National Institute for Occupational Safety and Health (NIOSH) noted that silica sand (or other substances containing more than 1% crystalline silica) should be prohibited as abrasive blasting material. The 1992 NIOSH Hazard Alert document 92-102 (http://www.cdc.gov/niosh/docs/92-102/) notes that the use of crystalline silica for blast cleaning operations was prohibited in Great Britain in 1950 and in other European countries in 1966. The NIOSH Alert recommends: "Prohibit silica sand (or other substances containing more than 1% crystalline silica) as an abrasive blasting material and substitute less hazardous materials." OSHA's website lists numerous alternatives to silica sand for abrasive blasting that are feasible and available.

Benefits Analysis

Question 24. CEG notes that per *The Cotton Dust* case² OSHA is not required to conduct a costbenefit analysis as OSHA's feasibility analysis includes an assessment of the economic feasibility of health standards, though Executive Orders 12866 and 13563 requires OSHA to prepare a regulatory impact analysis for major rules. With respect to the calculation of the economic benefits associated with the reduction in death and illness from implementation of the proposed PEL, CEG supports adjusting the estimates of the economic benefits of the proposed rule based on selection of a monetary value of a statistical life that increases over time resulting from an increase in real per capita income and the estimated income elasticity of the value of life. Given that the benefits analysis considers the potential for a long-term future societal benefit of avoided mortality and morbidity, CEG also suggests that OSHA place greater emphasis on the benefit economic valuations calculated using a three percent discount rate, as this approach

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² Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981)

appropriately reflects a social rate of time preference approach consistent with recommendations for benefits evaluation by the U.S. Environmental Protection Agency³.

General Comments

The current PEL for quartz silica of approximately 100 µg/m³ for general industry and approximately 250 µg/m³ and 50 µg/m³ for cristobalite and tridymite silica were developed in 1971 as a 'start-up' standard pursuant to the passage of the Occupational Safety and Health Act of 1971. As discussed in Section 3 of the proposed rule and noted above, NIOSH issued criteria in 1974 for a standard limiting occupational exposure for all forms of crystalline silica to a level of 50 µg/m³ based on a time-weighted average for a 10-hour workday, 40-hour workweek. The NIOSH recommendations were based on the epidemiological data then available as well as an assessment of the technical feasibility of attainment of the standard, including availability of engineering controls for selected industries where exposure to silica was deemed to be prevalent. Based on the NIOSH criteria, OSHA published an advanced notice of proposed rulemaking in December 1974 regarding a revised exposure limit for crystalline silica based on the NIOSH criteria. Almost forty years later, the process for developing a revised exposure limit and related components of a rule to reduce the health impacts of silica exposure on workers has yet to be completed. OSHA's action to adopt a more health protective PEL is long overdue, and should be completed on an accelerated schedule to ensure that workers are provided as soon as possible with the improved health protections afforded by the revised standards.

The Center for Effective Government appreciates the opportunity to provide comments on this important and long delayed regulation to improve worker health protections.

Sincerely,

Ronald H. White, M.S.T. Director of Regulatory Policy

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³ US EPA; Guidelines for Preparing Economic Analyses; December 17, 2010