

Background

- Crystalline silica is the second most abundant mineral in the Earth's crust (12%) and is virtually ubiquitous in rocks, sand, and soils.
- In the form of quartz, crystalline silica is perhaps the most common construction, manufacturing and agricultural material in the world – contained in sand, brick, concrete, and in the gravel, rocks and soil disturbed in farming or used in road building and construction.
- Silica is a critical material for foundries and steel, and is a key component of abrasives, paints, high tech equipment, glass, ceramics, and thousands of consumer products.

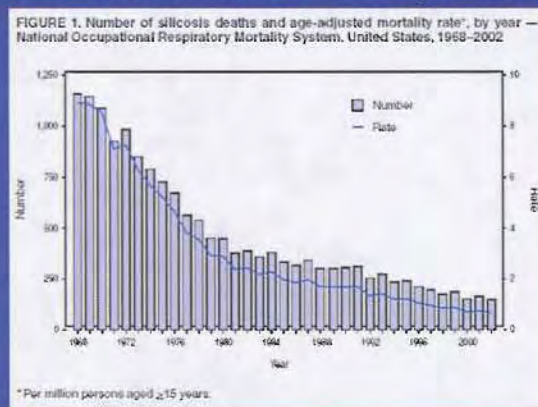
Background – continued

- Silicosis is an ancient occupational disease resulting from excessive inhalation of silica dust.
- There has never been any evidence of silica-related disease in non-occupational settings, and in the last 50 years, silica-related disease has largely come under control in occupational settings as well.
- According to the CDC, from 1968-2002, the silicosis mortality rate in the U.S. declined by 93% – falling from 1,157 cases in 1968 to 148 in 2002 – about the same number of deaths as are caused by lightning. Silicosis morbidity rates also have declined.

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Background – continued

Decline in Silicosis Deaths and Mortality Rates: 1968-2002



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Background – continued

- Two reasons for the decline in silica disease in the U.S. are the current exposure limit for silica – adopted in the early 1970s – and improvements in industrial practices.
- While isolated cases of silicosis still occur in the U.S. and must be prevented, they are attributable to widespread non-compliance with OSHA's existing PEL (0.1 mg/m³). OSHA data show that, year after year, an average of about 30% of the samples they take exceed the current PEL – many by a factor of 2, 3, or more.
- If the existing PEL were enforced and these exceedances were brought under control, the incidence of silicosis (which already has declined dramatically over the last half century) would largely disappear from American workplaces.
- OSHA has not examined this cost effective alternative to the pending proposed rule.

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Transparency and Timing

- OSHA refused our repeated requests (made both informally and through FOIA letters) to see and comment on its draft Health Risk Assessment and Preliminary Economic Impact Analysis.
- This was a retreat from prior commitments and is at odds with President Obama's promise to create "an unprecedented level of openness in Government."
- As a result, we now face the prospect of having just 90 or 120 days to review, analyze and develop comments on an enormous, technically complex record that likely will include:
 - An NPRM running several hundred pages in the Federal Register;
 - Risk Assessment and Technological/Economic Feasibility documents in excess of one thousand pages that we have never before seen even in draft form; and
 - A docket that we estimate already contains 25,000 – 50,000 pages of additional material placed there by OSHA alone.
- Transparency and fairness require an extended comment and hearing period.

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Significant Risk

- OSHA must show that the Standard is needed to address a significant risk of material health impairment that exists at the current PEL and that would be reduced substantially at the proposed PEL. We expect OSHA's significant risk analysis to focus on lung cancer, silicosis mortality and silicosis morbidity.
- OSHA likely will contend that silica exposure *per se* increases the risk of lung cancer. But the alleged association between silica exposure and lung cancer remains controversial for the following reasons, among others:

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Silica/Lung Cancer Association Remains Unproven

- Conflicting findings in epidemiological studies;
- Absence of clear dose-response relationships in many of the studies nominally viewed as positive;
- Difficulties in controlling for effects of possible confounders – like smoking, radon, arsenic, asbestos;
- Data suggesting that lung cancer risk is increased only among silicotics – so that a PEL protective against silicosis would prevent lung cancer risk as well; and
- Failure to find increased lung cancer risks in animal species other than rats (where a particle overload phenomenon may very likely be the causal factor).

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Threshold Phenomenon

- Moreover, the literature indicates that if silica exposure increases lung cancer risk at all, it does so through an inflammation-mediated mechanism having a threshold that is comparable to the threshold for the relation between silica exposure and the risk of non-malignant lung pathologies such as chronic inflammation, fibrosis and silicosis.
- This threshold is such that the risk of lung cancer and silicosis at the current PEL is negligible, if it exists at all.

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Evidence of the Threshold

- A recent study by Mundt *et al.* (2011) of almost 18,000 German porcelain industry workers with detailed work histories and about 8,000 industrial hygiene measurements found:
 - No association between exposure to crystalline silica and any cause of death, including lung cancer.
 - No statistically significant relationship between average exposures to respirable crystalline silica below 0.15 mg/m^3 and the development of silicosis.
- When dust controls were implemented in the Vermont granite industry beginning around 1940 (reducing average exposures from levels of $0.2 - 0.6 \text{ mg/m}^3$ to below 0.1 mg/m^3 with about 10% of the samples being above that level), cases of clinically relevant silicosis in workers first exposed after that date were virtually non-existent.
- The dramatic decline in silicosis mortality since 1968 (noted earlier) also is consistent with the existence of a threshold above the current PEL of 0.1 mg/m^3 .

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Technological Feasibility

- With approximately 30% of OSHA sampling results exceeding the current 0.1 mg/m^3 PEL (often by wide margins), massive new control technology would be needed to attempt to comply with a reduced PEL of 0.05 mg/m^3 .
- Meeting a PEL of 0.05 mg/m^3 is inconceivable in many settings.
- In exposure situations like construction, both equipment and constantly changing work environments pose countless insurmountable feasibility challenges.

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Economic Feasibility

- The Crystalline Silica Standard will affect a vast number of businesses and close to 2 million jobs.
- Among the general industries that would be most affected by the Standard are:
 - Foundries;
 - Industries with abrasive blasting operations (such as shipyards);
 - Paint manufacture;
 - Glass manufacture;
 - Concrete products manufacture;
 - Brick making;
 - China and pottery manufacture;
 - Plumbing fixture manufacture;
 - Structural clay and refractories; and
 - Cut stone industries.
- Construction will be severely impacted, including all segments of the housing industry.

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Economic Feasibility – continued

- While we have not seen the draft Economic Impact Analysis for Silica, experience in the SBREFA process leads us to expect that OSHA will greatly understate both the true costs of the proposed Standard and its likely impact on the economy and jobs. Some of the reasons for this are as follows:

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Developing/Interpreting the Silica Exposure Profile

- OSHA's approach to developing a silica exposure profile significantly underestimates the number of workers, processes, jobs and facilities requiring the implementation of new controls.
 - For example, if OSHA has 4 exposure samples for a production process, 3 of which are below the proposed PEL and one of which is above it, OSHA typically starts its cost analysis by assuming that only 25% of exposed workers in that process will need exposure-reducing controls.
 - That assumption is likely to be unjustified. Instead, the process likely will have to be subject to exposure-reducing controls 100% of the time.

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Unit Costs Underestimated

- Many of OSHA's unit cost values were wildly unrealistic in the SBREFA process. For example:
 - OSHA allowed only one hour of a consultant industrial hygienist's time to take a silica exposure sample. But consultants bill on a "door-to-door" basis and typically take two days to complete the process – so that OSHA's one hour estimate was off by more than an order of magnitude.
 - OSHA estimated the cost of establishing "regulated (restricted) areas" where exposures might exceed the PEL in construction by assuming an average crew size of four and a job length of five days. That ignores the many other impacted tasks undertaken concurrently at a construction site.

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Productivity Losses

- In its SBREFA analyses, OSHA assumed productivity losses associated with using wet methods and LEV/enclosures would not exceed a maximum of 5% of the base labor costs.
- In fact, the productivity penalty is likely to be far higher than that in many operations.
- This is very significant, because, even at the 5% figure, productivity losses constituted a large percentage of the total engineering costs estimated in OSHA's SBREFA documents.

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Conclusion

- We agree with the small business representatives on the 2003 SBREFA Panel: “OSHA's draft silica rules are not needed, will not provide real benefits, and if not withdrawn, will eliminate countless jobs and small businesses.”
- Silica-related diseases have declined dramatically over the past four decades under the existing PEL (even though it is exceeded >30% of the time); they can be eliminated entirely if full compliance with the current PEL is achieved.
- OSHA should help educate the workforce and enforce its current rules, rather than issuing a new standard that will eliminate countless jobs and small businesses at a time when our fragile economy is struggling with a 9% unemployment rate, an anemic housing market, and a manufacturing base increasingly being driven off-shore.

