BEFORE
ENVIRONMENT CANADA
and
HEALTH CANADA

Comments of the

Industrial Minerals Association - North America

National Industrial Sand Association

International Diatomite Producers Association

and

American Chemistry Council - Crystalline Silica Panel

on the

Draft Screening Assessment for the Challenge:

Quartz and Cristobalite

Communications Regarding These Comments Should Be Sent To:

Mark G. Ellis
President
Industrial Minerals Association - North America
2011 Pennsylvania Avenue, NW, Suite 301
Washington, DC 20006
(202) 457-0200 (Phone)
(202) 457-0287 (Fax)
markellis@ima-na.org

Jackson Morrill
Director
Chemical Products & Technology Division
American Chemistry Council
700 Second Street, NE
Washington, DC 20002
(202) 249-6712 (Phone)
jackson_morrill@americanchemistry.com

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Introduction

In December 2009, Environment Canada and Health Canada released Substance Profiles for Quartz and Cristobalite (two polymorphs of crystalline silica) in connection with the consideration – by the Ministers of Environment and Health – of whether to recommend the addition of quartz and cristobalite to the List of Toxic Substances in Schedule 1 of the Canadian Environmental Protection Act, 1999 ("CEPA 1999"). Public comments on the two Substance Profiles were invited – and, in January 2011, having considered the public comments, Environment Canada and Health Canada released a Draft Screening Assessment for the Challenge: Quartz and Cristobalite ("Draft Screening Assessment"). In that document, the two agencies – using a weight-of-evidence approach tempered by precaution, as required under CEPA 1999 – concluded that:

1. "[S]ufficient data exists to demonstrate that a threshold approach to risk characterization is appropriate" for evaluating the potential of quartz and cristobalite to induce lung tumors or other critical effects in humans; and

2. "[Q]uartz and cristobalite are not entering the environment in a quantity or concentration or under conditions"

    a) "that have or may have an immediate or long-term harmful effect on the environment or its biological diversity"; or

    b) "that constitute or may constitute a danger in Canada to human life or health."[1]

Based on those findings, Environment Canada and Health Canada have "proposed that quartz and cristobalite do not meet any of the criteria set out in section 64 of CEPA 1999" for inclusion on the List of Toxic Substances in Schedule 1 of that statute. See *id*.

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[1] Draft Screening Assessment at iii; see also *id*. at 51.

In these Comments, the Industrial Minerals Association - North America, the National Industrial Sand Association, the International Diatomite Producers Association, and the American Chemistry Council's Crystalline Silica Panel wish to express their support for the conclusions reached by Environment Canada and Health Canada in the Draft Screening Assessment. Those conclusions, we believe, are correct, as is the agencies' associated proposal to find that quartz and cristobalite do not meet any of the criteria for inclusion on the List of Toxic Substances in Schedule 1 of CEPA 1999. These conclusions and findings are the product of a careful and thorough analysis of available information, and they reflect a highly conservative approach to the estimation of concentrations of respirable quartz and cristobalite in the ambient air of Canada.

In the remainder of these Comments, we underscore two points: First, the use by Environment Canada and Health Canada of a threshold approach to risk characterization for quartz and cristobalite is indeed appropriate. Second, the approach used in the Draft Screening Assessment to assess ambient air concentrations of respirable quartz and cristobalite in Canada was even more conservative than the agencies may fully appreciate.

I. The Weight of Evidence Clearly Supports the Decision of Environment Canada and Health Canada To Use a Threshold Approach in Evaluating the Potential of Quartz and Cristobalite To Induce Lung Tumors or Other Critical Effects in Humans.

The weight of evidence clearly supports the decision of Environment Canada and Health Canada to use a threshold approach to characterizing potential health risks (including possible lung tumor induction) associated with exposure to quartz and cristobalite. As the agencies observe:

> Although the mechanism of induction for the lung tumours has not been fully elucidated, there is sufficient supportive

> mode of action evidence from the data presented to demonstrate that a threshold approach to risk assessment is appropriate based on an understanding of the key events in the pathogenesis of crystalline silica induced lung tumours.[2]

A paper by Dr. Louis Anthony Cox, Jr. that recently was accepted for publication in *Risk Analysis: An International Journal* elucidates this point from both biochemical and mathematical perspectives. A copy of that paper is submitted as Attachment 1 to these Comments. As Dr. Cox explains, there is a "tipping point" threshold for the relation between crystalline silica exposure and the risk of lung pathologies such as chronic inflammation, silicosis, fibrosis and lung cancer. That "tipping point" is not reached as a result of ambient air exposures to quartz and cristobalite in Canada.

II. Consistent With the Precepts of the Precautionary Principle, Environment Canada and Health Canada Followed an Approach To Assessing Concentrations of Respirable Quartz and Cristobalite in the Ambient Air that Was Even More Conservative Than the Agencies May Fully Appreciate.

To determine whether quartz and cristobalite meet the criteria for inclusion on the List of Toxic Substances under CEPA 1999, Environment Canada and Health Canada utilized what they characterize as a "conservative" approach to assessing concentrations of respirable quartz and cristobalite in the ambient air of Canada – with the result that the exposure values on which their determinations rest are overestimated.[3] In fact, for the reasons discussed below, the approach used by Environment Canada and Health Canada was even more conservative than the agencies may fully appreciate. This point can best be understood by considering the methodology the agencies employed.

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[2] *Id.* at 48.

[3] See Draft Screening Assessment at 33, 49.

Using measurements of $PM_{2.5}$, PM_{10} and the silicon ("Si") content of ambient air in 24 urban locations, Environment Canada and Health Canada calculated the median silica ("SiO_2") content of ambient particulate by multiplying the median % Si content of the $PM_{2.5}$ and PM_{10} fractions times the molar ratio of 2.14 – resulting in a median SiO_2 content of 2.52% for $PM_{2.5}$ and 5.22% for PM_{10}.[4] The fact that the silica content of PM_{10} was calculated to be twice as high as the silica content of $PM_{2.5}$ should not be surprising – because smaller size particulate fractions tend to have lower quartz content than larger size fractions. In part, this is because quartz is very refractory and more resistant to breaking down into smaller particles than most other constituents of particulate matter. Thus, this difference in the quartz content of the different particle size fractions is to be expected. Indeed, Davis et al. (1984) found that the median quartz percentage of PM_{15} in 22 U.S. urban areas was 5.58%, while the median quartz percentage of $PM_{2.5}$ was only 0.35%, more than an order of magnitude difference.[5]

One major reason why the Draft Screening Assessment is conservative is that Environment Canada and Health Canada used the SiO_2 content of 5.22% that they calculated for PM_{10} as a principal input to calculate ambient air concentrations of respirable quartz.[6] In fact, however, as the agencies acknowledge, the SiO_2 content of 5.22% for PM_{10} that they calculated represents *all* silicon-containing substances in ambient air particulate. Not only does it include crystalline silica in the form of quartz; it

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[4] See Draft Screening Assessment at 13, 34.

[5] See Draft Screening Assessment at 14, citing Davis BL, et al. 1984. The quartz content and elemental composition of aerosols from selected sites of the EPA inhalable particulate network. Atmos Environ 18(4): 771-782.

[6] See Draft Screening Assessment at 49.

also includes amorphous silica and other silicate minerals.[7] In effect, the concentrations of *silicon* in PM were used as a surrogate for the concentrations of *quartz*. See *id.* at 33. Consequently, treating 5.22% as the *quartz* content of PM_{10} clearly produces an exaggerated estimate of *quartz* concentrations in the PM_{10} fraction of ambient air particulate. As Environment Canada and Health Canada describe it, the resulting calculations yield "an upper bound for respirable quartz and cristobalite in ambient air." *Id.* at 34.

In fact, it is likely to be a highly exaggerated upper bound. Environment Canada and Health Canada themselves point to a study of 22 urban regions in the U.S. by Davis et al. (1984), which found that quartz comprises only a fraction (ranging from 2% to 70%) of the SiO_2 in PM_{15} (the median value being 31%). See *id.* at 13-14, 33, 35, 49. Davis et al. also determined that the median quartz percentage of PM_{15} was 5.58%, while the median quartz percentage of $PM_{2.5}$ was only 0.35%. This last value is almost an order of magnitude lower than the median SiO_2 content of 2.52% that Environment Canada and Health Canada calculated for $PM_{2.5}$. See *id.* at 14. Based on the measurements by Davis et al., the levels of quartz in ambient air calculated by Environment Canada and Health Canada could be overestimated by as much as a factor of 50 for this reason alone. Even if one uses the median figure of 31% quartz content of the SiO_2 in PM_{15}, the quartz exposure estimates of Environment Canada and Health Canada would be exaggerated by more than a factor of 3.

A second reason why the Draft Screening Assessment is conservative is that the exposure assessment values used by Environment Canada and Health Canada to evaluate

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[7] See Draft Screening Assessment at 13, 33, 34, 36.

ecological risk and risk to human health are based on calculated levels of quartz *in* PM_{10}. But the potential health risks of exposure to quartz and cristobalite are associated with inhalation of *respirable* size particles – largely the PM_4 and smaller size fractions. As noted above, these smaller (respirable) size fractions tend to have lower quartz content than the larger size fractions. For example, Davis et al. (1984) found that the median quartz percentage of PM_{15} in 22 U.S. urban areas was 5.58%, while the median quartz percentage of $PM_{2.5}$ was only 0.35%, more than an order of magnitude difference. Thus, by assuming a quartz content of 5.22% – which, as noted above, is conservative even for PM_{10} – Environment Canada and Health Canada have overstated the quartz content of respirable size particles in the PM_4 and smaller size fractions. And those smaller sized particles are the ones that are most relevant in assessing potential silica-related health risks. In addition to overstating the quartz content of the respirable size particles, the ambient quartz concentrations calculated by Environment Canada and Health Canada include the quartz content of particles in the PM_5 to PM_{10} size range that are less respirable and, therefore, less of a potential threat to human health than PM_4 size particles.

Finally, Environment Canada and Health Canada also have conservatively overestimated quartz and cristobalite exposures *indoors*, by assuming they are the same as outdoor levels – even though indoor levels of particulate matter generally are lower than outdoor levels. See Draft Screening Assessment at 35. This can be a significant overestimating factor, because people spend the majority of their time indoors.

Conclusion

As discussed above, the highly conservative approach that Environment Canada and Health Canada have taken in the Draft Screening Assessment more than amply supports their conclusion that quartz and cristobalite do not meet any of the section 64 criteria for inclusion on the List of Toxic Substances in Schedule 1 of CEPA 1999. The agencies are to be commended for their thorough analysis of the issues and of the underlying data upon which this sound conclusion is based.