Response to Public Comments Received on the June 2020 Silica, Crystalline Forms, 24-h Reference Value Development Support Document

CAS Registry Numbers:

14808-60-7 (quartz)
14464-46-1 (cristobalite)
1317-95-9 (tripoli)
15468-32-3 (tridymite)

Response to Comments

December 11, 2020

TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

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Silica, Crystalline Forms, 24-h Reference Value DSD Response to Comments

The public comment period for the June 2020 Proposed Development Support Document (DSD) for the 24-h Reference Value (ReV) for Silica, Crystalline Forms ended on August 28, 2020. The TCEQ received comments from Dr. Timothy Jarvis and Dr. Mary Jarvis, Environmental Toxicologist/Scientist, and from the Associated General Contractors of Texas. The TCEQ appreciates the effort put forth by these groups to provide technical comments on the proposed Silica 24-h ReV DSD. The goal of the TCEQ is to protect human health and welfare based on the most scientifically defensible approaches possible (as documented in the DSD), and evaluation of these comments furthered that goal. A summary of the comments received and the TCEQ responses are provided below. The full comments are provided in the Appendix. TCEQ responses indicate what changes, if any, were made to the DSD in response to the comments.

Comments received from Dr.'s Timothy and Mary Jarvis, Environmental Toxicologist/Scientist:

Comment 1:

Upon review, we conclude that the above-referenced document needs to be refocused and its regulatory underpinnings clarified. We think the document could be strengthened by addressing certain gaps and technical issues prior to the document moving forward. In our opinion, it was likely premature to release the document for external review and in its current form is not ready for publication by the State of Texas. Our review comments below identify what we view as the document's omission and technical concerns. Addressing the comments listed below will not serve to finalize the document. We believe it should be redrafted and submitted for rigorous peer review prior to its re-release for public comment. Our observations and comments are offered in a collegial spirit in anticipation of improving the text.

TCEQ Response:

Thank you for your comment.

In reference to your concerns about the validity and peer review of the DSD, as posted on the TCEQ website (https://www.tceq.texas.gov/toxicology/esl/guidelines/about) and mentioned on p. 1 of the proposed DSD, the 24-hour ReV was developed based on the TCEQ Guidelines to Develop Toxicity Factors (TCEQ 2015). These guidelines have been peer reviewed by external experts and have been used to develop reference values (ReVs) and effects screening levels (ESLs) for numerous constituents. The TCEQ Guidelines incorporate the use of nationally and internationally recognized guidelines and references including those used by the U.S. Environmental Protection Agency (EPA), Agency for Toxic Substances and Disease Registry (ATSDR), California Environmental Protection Agency (CalEPA), National Research Council (NRC), Health Canada, World Health Organization (WHO), and the International Agency for Research on Cancer (IARC) among others. Please refer to the 2015 TCEQ Guidelines to Develop Toxicity Factors (https://www.tceq.texas.gov/assets/public/comm_exec/pubs/rg/rg-442.pdf)

for more details regarding the guidelines, references and databases used to research substances.

When a DSD is developed, it undergoes internal peer review and is posted for public comment. For some constituents an external peer review is also conducted; however, an external peer review was not conducted for the DSD for the 24-hour ReV for crystalline silica.

Comment 2:

Some regulatory background and thinking is needed. Where does the State of Texas' 'reference value' fit into the universe of Federal Clean Air Act Programs, allowable quantities, and State of Texas air program numbers?

TCEQ Response:

Crystalline silica is not a National Ambient Air Quality Standards pollutant and is not included on the U.S. EPA's list of hazardous air pollutants. Therefore, crystalline silica is not specifically regulated under the Federal Clean Air Act. The TCEQ ReV is not a national or state standard. TCEQ ReVs are health-based toxicity factors used in the evaluation of ambient air monitoring data.

Comment 3:

Is the 'reference value' planned to be an enforceable numerical standard or a suggestion?

TCEQ Response:

ReVs are health- or welfare-based toxicity factors used in the evaluation of ambient air monitoring data (where they are called air monitoring comparison values, or AMCVs), as well as to derive effects screening levels (ESLs) for use in air permit reviews (TCEQ 2015). In the air permit review process, the TCEQ utilizes short- and long-term ESLs to evaluate proposed emissions for their potential to adversely affect human health and welfare. For evaluation of ambient air monitoring results, AMCVs are used to assess the potential for exposure to the measured concentrations to adversely affect human health and welfare.

Comment 4:

How should the 'reference value' be applied? Is it intended to an ambient air value? Is the thinking to require manufacturers to adhere to this level in of consumer products?

TCEQ Response:

TCEQ ReVs are used in the evaluation of ambient air; they do not pertain to consumer products.

Comment 5:

Missing is a discussion of the regulatory drivers require this document. Why is it necessary for the State of Texas to develop a 'reference value'? Please cite the law or regulations that require public monies be spent to develop a 'reference value'.

TCEQ Response:

TCEQ ReVs are not developed via rulemaking. ReVs are developed to evaluate ambient air data.

Please refer to Section 1.1, Legal Authority and Regulatory Use, in the in the 2015 TCEQ Guidelines to Develop Toxicity Factors (TCEQ 2015). The Texas Clean Air Act (Chapter 382 of the Texas Health and Safety Code (THSC)) authorizes the TCEQ to prevent and remedy conditions of air pollution. Sections 382.0518 and 382.085 of the THSC specifically mandate the TCEQ to conduct air permit reviews of all new and modified facilities to ensure that the operation of a proposed facility will not cause or contribute to a condition of air pollution (TCEQ 2015). Air permit reviews typically involve evaluations of best available control technology and predicted air concentrations related to proposed emissions from the new or modified facility. In the review of proposed emissions, federal/state standards and chemical-specific ESLs are used, respectively, for criteria and non-criteria pollutants. Health-based ESLs are calculated from ReV and unit risk factor (URF) toxicity factors. Welfare-based ESLs are set based on odor and vegetation effect threshold concentrations.

The TCEQ also relies upon this authority to evaluate air monitoring data. An AMCV is used to evaluate measured air toxics concentrations for their potential to cause health and welfare effects, as well as to help the agency prioritize its resources in the areas of permitting, compliance, and enforcement. Health-based AMCVs are based on ReV and URF toxicity factors whereas welfare-based AMCVs are equal to welfare-based ESLs.

The TCEQ selects substances for evaluation for one or more of the following reasons: 1) they have been detected in air monitoring, 2) permits are frequently issued for them, and/or 3) the public has expressed concerns about them (https://www.tceq.texas.gov/toxicology/esl/develop).

Comment 6:

The document is missing a meaningful discussion about how the ‘reference value’ is to be applied or in which circumstances the ‘reference values’ use is considered applicable.

TCEQ Response:

Please refer to the responses to Comments 3 and 4. The 24-h ReV may be used as the health-based 24-h AMCV for evaluation of ambient air data collected over a 24-h period. Ambient air refers to air to which the general public is exposed. It is common to collect ambient air particulate samples over a duration of 24-h and if TCEQ does analyze for crystalline silica, the 24-h ReV will be used as the air monitoring comparison value.

Comment 7:

The document is also missing a presentation on which Texas laws, regulations, guidance, permits or citation the ‘reference value’ is intended to be used to fulfill compliance expectations. For example, is the reference value intended to be used by a permit holder in

annual or periodic reporting or modeling? Or is the reference value intended to be used for land-use planning, business siting, or permitting evaluations?

TCEQ Response:

The 24-h crystalline silica ReV will be used in the evaluation of ambient air monitoring and will not be used for the purposes of air permitting, land-use planning, or business siting. The ESLs (used for air permit review and discussed in responses to comments 3 and 5) for crystalline silica are included in the 2009 DSD for Silica, Crystalline Forms (https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/final/october09/silica_crystalline_forms.pdf). The intended use for ReVs in general, and for the crystalline silica 24-hr ReV in particular, are discussed in responses to comments 3 and 4 above.

Comment 8:

The document would be strengthen by providing a comparison and technical discussion of similar 'reference values' used by other U.S. states (e.g. California, Washington state), the U.S. Federal government (EPA & CDC-ATSDR) Canada, England, and the European Union.

TCEQ Response:

Toxicity factors from other organizations (US EPA, ATSDR), other states (California, Washington), or countries or regions outside of the U.S. (Canada, England, European Union) are not in the DSD for the 24-h Reference Value for Crystalline Silica because these organizations, states, countries, and regions either do not have toxicity factors for crystalline silica, or do not have a toxicity factor relevant to the duration of sampling (24 h).

Comment 9:

The document is missing a discussion of why 'reference values' used by other U.S. states and/or other countries could not be adopted directly by the State of Texas and a justification for why public monies must be spent on the current, apparently Texas-specific effort.

TCEQ Response:

Please refer to responses to Comments 5 and 8.

Comment 10:

If the 'reference value' is to be a regulatory limit, then the cost to industry and/or the public to implement it should be approximated and presented in the background document.

TCEQ Response:

The ReV is not a regulatory limit.

Comment 11:

Excessive Use of Acronyms: We submit that the use of an acronym increases the probability of communication errors and misunderstandings. Even internal communication among peers

should contain as few acronyms as possible to avoid a misunderstanding. This is why most scientific articles tend to minimize the use of acronyms, frequently limiting to four (4) or five (5) per document. *Nota Bene*: System International and metric units of measurement are typically understood and are not considered acronyms. However, other units of measurement are more often than not considered acronyms.

The reviewed document has two (2) pages of acronyms! This huge number of acronyms is way too many for even an internal memo between or among peers in the same department, let alone a publication for public release. The document's extreme use of acronyms makes it a challenge to read and interpret. The reader/reviewer must rewrite each sentence filling in the acronyms and hope thy have captured the intent of the authors. In our experience, the number of acronyms in a document is directly proportional to the likelihood that the reader/reviewer will misinterpret the intent.

TCEQ Response:

Thank you for your comment. As per the format of the DSD, and in accordance with various style guidelines, we included the definition of all abbreviations and acronyms in a table at the beginning of the document. The table of abbreviations and acronyms is comprehensive and is intended to be an aid to the reader of the document. Additionally, the abbreviations and acronyms are ones that are commonly used in scientific journals, and regulatory documents and guidelines from other agencies, including the U.S. Environmental Protection Agency.

Comment 12:

The document's organization is in an atypical format; not what is routine for a regulatory document or a toxicological review article. Please see the "Gaps" section above. There are many style guides available for regulatory documents, toxicological documents, and/or data presentation documents. The authors would be well served to obtain and use these style guides.

TCEQ Response:

Although it may be different than a journal article, all of the TCEQ's DSDs use a similar outline to display information in a consistent manner. The DSD is a TCEQ publication designed to provide details on the derivation of toxicity factors. As noted in Section 1.8 Toxicity Factor Development Support Document in the 2015 TCEQ Guidelines to Develop Toxicity Factors, "The purpose of the DSD is to provide a summary of information on the toxicity factor development process and the key toxicity studies/information used to derive inhalation and oral toxicity factors." TCEQ DSDs are not toxicological review articles.

Comment 13:

Chapter 2 does not provide the reader with any context of background for development of a "reference value' or use of same.

TCEQ Response:

Information on the development of this reference value is noted in Chapter 2 of the DSD.

Additionally, please also refer to Section 4.6, 24-Hour AMCVs, in the 2015 TCEQ Guidelines to Develop Toxicity Factors (TCEQ 2015).

Comment 14:

The facts and assumptions associated with the toxicological evaluation of silica exposures to the general population are missing. For example, does the 'reference value' assume that the exposure is for 24- hours and ends abruptly? Or, is the assumed exposure for 24- hours a day continuously? Or, is the assumed exposure something novel, unique, and for some reason undiscussed in the document? What are the ages, occupations, and health conditions of the assumed exposed populations? What about sensitive subpopulations; are they considered? What groups to the authors consider sensitive subpopulations?

TCEQ Response:

Please refer to Section 4.6, 24-Hour AMCVs, in the 2015 TCEQ Guidelines to Develop Toxicity Factors and to section 3.2, Acute 24-H ReV for Air Monitoring Evaluation, in the DSD. The 24-h ReV may be used for the evaluation of ambient air data collected over a 24-h period. Ambient air refers to air to which the general public is exposed. Ambient air particulate samples are commonly collected over a duration of 24-h. The 24-h ReV is sufficiently conservative for the protection of public health for the general population, including potentially sensitive subpopulations (e.g., children, the elderly, those with pre-existing health conditions).

Comment 15:

The lack of exposure assumption makes the 'reference value' ineffectual because the circumstances needed for its use are not stated.

TCEQ Response:

Please refer to response to Comment 13.

Comment 16:

Chapter 3 makes the following bold, but untrue, statement: "There are no adequate studies evaluating the effects of acute exposure to crystalline silica in humans." Silica is a very well-studied chemical with studies dating back over one-hundred years. Such a statement has no place in a regulatory document or a toxicological review article.

TCEQ Response:

The statement "There are no adequate studies evaluating the effects of *acute* (emphasis added) exposure to crystalline silica in humans" is referring to the lack of acute, short-term inhalation studies in humans. There are numerous published studies of *chronic* exposures to crystalline silica in humans, but there are no relevant studies evaluating the effects of *acute* exposure to

crystalline silica in humans. Exposures to crystalline silica at levels that produce health effects have only been reported in workers who have been exposed by inhalation for a prolonged period of time in crystalline silica-generating industries (ATSDR 2019, Leung et al. 2012) (please refer to Section 3.1.1 of the DSD). Exposure to high occupational levels of crystalline silica for several years, up to a lifetime, may result in silicosis and lung cancer (ATSDR 2019, Leung et al. 2012). Additionally, the cumulative dose of respirable silica in exposed workers (respirable concentration multiplied by duration of exposure, mg/m^3-year) is the most important factor in the development of silicosis (ATSDR 2019, Leung et al. 2012).

Comment 17:

There are a plethora of published toxicological and epidemiological studies on the effects of silica exposure. The authors' insistence on using only select studies as a basis for the 'reference value', while disregarding many important studies, leaves the reader with the impression that the authors have purposefully 'cherry-picked' the toxicological studies on silica for their review. This document should be withdrawn until a comprehensive review of all relevant toxicological studies is undertaken and a full peer review conducted.

TCEQ Response:

A comprehensive review of the literature was performed prior to the derivation of the 24-h acute ReV. Based on this literature review, the key study was identified, and additional supporting studies were described (refer to section 3.1.1 of the DSD). TCEQ is not required to do an external peer review (2015 TCEQ Guidelines to Develop Toxicity Factors, Section 1.11 Public Comment and Peer Review of DSDs).

Comment 18:

The document proposes a 24 µg/m^3 'reference value' (presumably protective of public health). But, that value is much higher than the Canadian Ambient Air Quality Criteria of 5 µg/m^3. Similarly, the States of California, New Jersey, Washington State, and Minnesota all have Ambient Air Quality Criterial of 3 µg/m^3. Meanwhile, the EPA's Acceptable Source Impact Level is also 3 µg/m^3. The incongruity between established ambient air threshold values and the reviewed document's 'reference value' is not explored or explained in the text. A stark order-of-magnitude difference with other analogous regulatory values calls for the authors to address and justify the difference. Comparison to existing occupational values are also not addressed; such as to the American Conference of Governmental Industrial Hygienist (ACGIH) of 3 µg/m^3.

It is strongly advised that this document be withdrawn and its need re-evaluated. Unless there is some undisclosed and unique aspect to public exposure to silica in the Texas, the Canadian value or U.S. states' values would likely serve. Toxicological exposure values may have large public health impacts. Consequently, these values should be formulated by qualified toxicologists in a manner free from any political influences. And, the supporting document should be subjected to rigorous peer reviews prior to release for public comment.

TCEQ Response:

The referenced values from Ontario (Canada), California, New Jersey, Washington State, and Minnesota are all chronic values, intended to protect against health effects from lifetime exposure to crystalline silica. The TCEQ has also derived chronic toxicity factors for crystalline silica in 2009, as is noted in Chapter 2 of the 24-hr DSD.

The TCEQ ReV derived in this DSD is a 24-h value and is *not* a long-term value. The end of Chapter 2, Background, states: "Please refer to the crystalline silica Development Support Document (TCEQ 2009) for detailed information on human and animal studies used in the derivation of other health- and welfare-based values for crystalline silica." The reference for the 2009 DSD is included in the reference section (Chapter 4). The TCEQ 2009 DSD for crystalline silica may be accessed here: https://www.tceq.texas.gov/assets/public/implementation/tox/dsd/final/october09/silica_crystalline_forms.pdf. The 24-h reference value is protective of human health, including potentially sensitive subpopulations (e.g., children, the elderly, those with pre-existing health conditions), as it relates to a short-term 24-h exposure duration.

In the TCEQ 2009 DSD for crystalline silica, the chronic non-cancer (based on silicosis in miners) ReV is 2 µg/m^3 (respirable, ≤ 4 µm in diameter), and the chronic cancer (based on lung cancer mortality in silica-exposed workers) value is 0.27 µg/m^3 (respirable, ≤ 4 µm in diameter). Therefore, the TCEQ's long-term air monitoring comparison value (AMCV) for crystalline silica would be 0.27 µg/m^3, which is lower than the chronic values of other states and is one order of magnitude lower than chronic AMCVs of the other states mentioned in your comments. The states of California, Minnesota, New Jersey and Washington have state exposure limits of 3 µg/m^3 for respirable crystalline silica, which is slightly higher than the TCEQ's chronic non-cancer ReV of 2 µg/m^3. While the TCEQ non-cancer ReV of 2 µg/m^3 is slightly more conservative than the other state values, for long-term data evaluation, TCEQ would use the more conservative cancer value of 0.27 µg/m^3.

ReVs developed by the TCEQ are compared to concentrations measured in ambient air and are not intended to be applied to workplaces or compared to workplace standards (e.g. ACGIH).

Comments received from the Associated General Contractors of Texas:

Comment 1:

Please describe how the proposed Air Monitoring Comparison Value (AMCV) will be used? For example, will it be used for permitting or enforcement purposes?

TCEQ Response:

ReVs are health-based toxicity factors used in the evaluation of ambient air monitoring data (where they are called AMCVs), as well as to derive effects screening levels (ESLs) for use in air permit reviews (TCEQ 2015). In the air permit review process, the TCEQ utilizes short- and long-term ESLs to evaluate proposed emissions for their potential to adversely affect human health and welfare. For evaluation of ambient air monitoring results, AMCVs are used to assess the potential for exposure to the measured concentrations to adversely affect human health and welfare.

The 24-h ReV may be used as the health-based 24-h AMCV for evaluation of ambient air data collected over a 24-h period.

Comment 2:

Is the proposed AMCV only to be compared to Particulate Matter equal to or less than 4 microns in diameter (PM_4)?

TCEQ Response:

The proposed 24-h ReV was developed based on the respirable fraction of crystalline silica, which is ≤ 4 µm in diameter. The value reflects the crystalline silica content of PM_4 and may be used in the evaluation of measured 24-h ambient air crystalline silica data. Crystalline silica is typically measured using a modified inlet that allows for the collection of the PM_4 fraction.

Comment 3:

Given that PM_4 monitoring information is not readily available, can Particulate Matter equal to or less than 10 microns in diameter (PM_{10}) or Particulate Matter equal to or less than 2.5 microns in diameter ($PM_{2.5}$) data be used for a surrogate comparison? If so, please explain the process that will be used to conduct an accurate comparison.

TCEQ Response:

Crystalline silica is one of the many constituents of $PM_{2.5}$ and PM_{10}. Therefore, it is inappropriate to compare total $PM_{2.5}$ or PM_{10} measurements to the 24-h crystalline silica AMCV. In addition, the 24-hr AMCV is intended to be compared to crystalline silica measurements gathered using a PM_4 size cut-off, and TCEQ does not intend to compare the AMCV to crystalline silica measurements gathered using a different PM size cut-off.

If and when the TCEQ monitors specifically for crystalline silica, it will be typically measured using a modified inlet that allows for the collection of the PM_4 fraction. The proposed 24-h ReV may be used in the evaluation of measured 24-h ambient air crystalline silica data.

Comment 4:

How will the agency handle days where Saharan dust, smoke from Mexico or other natural events that cause high readings at particulate (PM) monitors? Will those days be flagged and invalidated for comparison to the new AMCV? If so, please explain that process.

TCEQ Response:

If PM_4 crystalline silica is measured on days where Saharan dust, smoke from Mexico or other natural events result in crystalline silica concentrations that are higher than the 24-h ReV (24 $\mu g/m^3$), the TCEQ may conduct a more in-depth review. The data will not be invalidated if the data collection and analysis methods are properly followed; therefore, the concentrations measured will be considered accurate for the period(s) sampled. Because PM_4 crystalline silica is only likely to be monitored on an as-needed basis (e.g. as part of special monitoring projects), then the team conducting the monitoring can ensure that samples are collected on days when there are no known non-anthropogenic sources causing silica emissions.

Comment 5:

Can monitoring periods less than 24 hours be used to compare to the AMCV? If so, how would this be done correctly?

TCEQ Response:

The 24-h ReV may be used for the evaluation of ambient air data collected over a 24-h period. Ambient air particulate samples are commonly collected over a duration of 24-h. Additionally, the TCEQ has previously derived a 1-hour ReV for crystalline silica (TCEQ 2009). If a sample were to be collected for a 1-hour duration, then the concentration would be compared to the 1-hour ReV.

Comment 6:

Can either PM property line monitoring or ambient air monitoring be used to compare to the AMCV?

TCEQ Response:

AMCVs are designed to protect public health and welfare; they are appropriate to compare to ambient air monitoring data. Ambient air monitoring is performed in areas to which the public may be exposed and can include the fenceline of a property, if that fenceline is accessible to the general public.

Comment 7:

Are short term exceedances of an AMCV (less than a 24-hour average) a concern? For example, if a PM monitor shows 1- or 2-hour spikes intermittently but the 24 hours average is below the AMCV can the air quality be considered protective of public health?

TCEQ Response:

The TCEQ has derived a 1-h reference value of 47 µg/m^3 for PM_4 crystalline silica. If 1-h or 2-h ambient air concentrations of PM_4 crystalline silica were intermittently higher than the 1-h AMCV of 47 µg/m^3, this may require a more in-depth review as to why this is occurring. The AMCVs are set sufficiently below a level expected to cause adverse health effects so that, even when concentrations are somewhat above the AMCV, adverse health effects are not expected but rather a more in-depth review would occur.

Comment 8:

If an AMCV exceedance is identified, what will the agency do to determine the cause of the exceedance?

TCEQ Response:

If an exceedance of the 24-hr crystalline silica ReV is measured, the TCEQ would conduct a more in-depth evaluation of the data and surrounding area (e.g., location of population, potential for exposure, and frequency and magnitude of detections and how do they compare to levels at which health effects would be anticipated?).

Comment 9:

Please describe a scenario under which TCEQ would utilize the AMCV. For example, if there was a complaint received.

TCEQ Response:

Please refer to the responses to Comments 1 and 2.

Comment 10:

AGC recommends and requests that in response to comments the TCEQ provide greater context to the issue being addressed by the proposed AMCV. To that end:

TCEQ has previously noted that *most* Particulate Matter emissions from aggregate production operations (APOs) are large dust particles (i.e. total suspended particulates, or TSP), that are much larger than 10 microns in diameter (PM10), are visible, and can be filtered by hair in a person's nose. Based on this does TCEQ agree that most PM emissions from aggregate production operations are TSP and for the reasons stated above do not constitute a health hazard?

TCEQ Response:

On a mass basis, most emissions from APOs may be TSP. Particles much larger than PM_{10} will not penetrate beyond the larynx (the lower part of the head airways region) and, therefore, will not penetrate the lungs. TSP samples are poor indicators of potential health effects and represent nuisance PM.

However, this DSD is not addressing general PM emissions from APOs, but rather PM_4 crystalline silica from any source. Therefore, discussions of TSP emissions from APOs are outside of the scope of the document. Respirable crystalline silica, as measured in PM_4 is a potential health concern, and APOs are a potential source (Richards et al. 2009, Minnesota Pollution Control Agency [MPCA] May 2015, MPCA Dec 2015, MPCA Jan 2018, Richards and Brozell 2015, Peters et al. 2017).

Comment 11:

Does TCEQ agree with the statement that most *silica* generated by APOs are large particles (TSP) and therefore cannot be inhaled into the lungs?

TCEQ Response:

Refer to response to Comment 10.

Comment 12:

Does TCEQ agree with the statement that while some mining operations can form smaller PM10 and PM2.5 particles very close to the source, the particles drop out of the air by the time they reach the fence line?

TCEQ Response:

The TCEQ does not agree that PM_{10} and $PM_{2.5}$ generated near a source will drop out of the air rapidly. $PM_{2.5}$ and PM_{10} can travel far from the source of generation, depending upon weather conditions and prevailing winds (US EPA 2019). Under the same conditions, larger particle sizes will drop out of the air faster than smaller particle sizes, such as $PM_{2.5}$ and PM_{10}. For example, as mentioned in Comment 4, weather patterns that result in the presence of Saharan dust, smoke from Mexico or other natural events (e.g., wildfires) may contribute to higher concentrations of $PM_{2.5}$ and PM_{10} in Texas even though they are generated hundreds and sometimes thousands of miles away.

Comment 13:

Please confirm that silicosis is an occupational disease (or associated with certain hobbies), is extremely rare in Texas, and that studies have shown that silica concentrations are lower or not detected at the fence line, and that concentrations are very low to not detected off-site; and that off-site concentrations were not of a health concern.

TCEQ Response:

Silicosis is a rare disease that is caused by occupational exposure to silica. Workers exposed daily for several years up to a lifetime to high occupational levels of fine respirable particles of crystalline silica may develop silicosis, an irreversible, progressive and fatal, but preventable lung disease (ATSDR 2019). The effects of inhaled crystalline silica are strictly associated with occupational exposure to particles that are of respirable size, which is particulate matter with an aerodynamic diameter of 4 µm or less (ACGIH 2019).

PM_4 crystalline silica has been monitored near APOs in a few other states (California, Minnesota, Wisconsin). Although crystalline silica monitoring is not required under U.S. regulations, monitoring has been periodically conducted in urban areas, including Dallas and El Paso, and near APOs. In ambient air of 22 U.S. cities, annual average $PM_{2.5}$ crystalline silica concentrations ranged from 0 to 1.9 µg/m^3 (Davis et al. 1984), while the estimated annual average PM_{10} crystalline silica concentrations of 17 U.S. cities ranged from 0.3 to 5.0 µg/m^3 (US EPA 1996). The range of respirable crystalline silica (PM_4) concentrations measured near APOs ranged from 0 (many samples were below the limit of detection) to 2.8 µg/m^3 (Richards et al. 2009, Minnesota Pollution Control Agency [MPCA] May 2015, MPCA Dec 2015, MPCA Jan 2018, Richards and Brozell 2015, Peters et al. 2017). The results of these monitoring studies indicate that the overall contribution of APOs to ambient air concentrations of crystalline silica is minimal or negligible. When compared to TCEQ's AMCVs for crystalline silica, the concentrations of crystalline silica near APOs are generally not likely to cause chronic adverse health effects and are not associated with silicosis (ATSDR 2019).

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Appendix – Official comments received from Dr. Timothy Jarvis and Dr. Mary Jarvis, Environmental Toxicologist/Scientist, and from the Associated General Contractors of Texas.

Subject: Review Comments

Reference: "24-h ReV (reference value) Development Support Document for Silica, Crystalline Forms," A State of Texas Commission on Environmental Quality, Proposed Document, released for Public Comment 10JUL2020.

By: Timothy T. Jarvis, PhD, CSP --- Environmental Toxicologist
Mary F. Jarvis, PhD. --- Environmental Scientist/Engineer

Date: 28 July 2020

Upon review, we conclude that the above-referenced document needs to be refocused and its regulatory underpinnings clarified. We think the document could be strengthened by addressing certain gaps and technical issues prior to the document moving forward. In our opinion, it was likely premature to release the document for external review and in its current form is not ready for publication by the State of Texas. Our review comments below identify what we view as the document's omissions and technical concerns. Addressing the comments listed below will not serve to finalize the document. We believe it should be redrafted and submitted for rigorous peer review prior to its re-release for public comment. Our observations and comments are offered in a collegial spirit in anticipation of improving the text.

Gaps:

- Some regulatory background and thinking is needed. Where does the State of Texas' 'reference value' fit into the universe of Federal Clean Air Act programs, allowable quantities, and State of Texas air program numbers?
- Is the 'reference value' planned to be an enforceable numerical standard or a suggestion?
- How should the 'reference value' be applied? Is it intended to an ambient air value? Is the thinking to require manufacturers to adhere to this level in of consumer products?
- Missing is a discussion of what regulatory drivers require this document. Why is it necessary for the State of Texas to develop a 'reference value'? Please cite the law or regulations that require public monies be spent to develop a 'reference value'?
- The document is missing a meaningful discussion about how the 'reference value' is to be applied or in which circumstances the 'reference values' use is considered applicable.
- The document is also missing a presentation on which Texas laws, regulations, guidance, permits, or citations the 'reference value' is intended to be used to fulfill compliance expectations. For example, is the reference value intended to be used by a permit holder in annual or periodic reporting or modeling? Or, is the reference value intended to be used for land-use planning, business siting, or permitting evaluations?

- The document would be strengthen by providing a comparison and technical discussion of similar 'reference values' used by other U.S. states (e.g. California, Washington State), the U.S. Federal government (EPA & CDC-ATSDR) Canada, England, and the European Union.
- The document is missing a discussion of why 'reference values' used by other U.S. states and/or other countries could not be adopted directly by the State of Texas and a justification for why public monies must be spent on the current, apparently Texas-specific effort.
- If the 'reference value' is to be a regulatory limit, then the cost to industry and/or the public to implement it should be approximated and presented in the background document.

Format and Style Issues

- Excessive Use of Acronyms: We submit that the use of an acronym increases the probability of communication errors and misunderstandings. Even internal communication among peers should contain as few acronyms as possible to avoid a misunderstanding. This is why most scientific articles tend to minimize the use of acronyms, frequently limiting them to four (4) or five (5) per document. *Nota Bene*: System International and metric units of measurement are typically universally understood and are not considered acronyms. However, other units of measurement are more often than not considered acronyms.

  The reviewed document has two (2) pages of acronyms! This huge number of acronyms is way too many for even an internal memo between or among peers in the same department, let alone a publication for public release. The document's extreme use of acronyms makes it a challenge to read and interpret. The reader/reviewer must rewrite each sentence filling in the acronyms and hope they have captured the intent of the authors. In our experience, the number of acronyms in a document is directly proportional to the likelihood that the reader/reviewer will misinterpret the intent.

- The document's organization is in an atypical format; not what is routine for a regulatory document or a toxicological review article. Please see the 'Gaps' section above. There are many style guides available for regulatory documents, toxicological documents, and/or data presentation documents. The authors would be well served to obtain and use these style guides.

Scientific and Technical Issues

- Chapter 2 does not provide the reader with any context or background for development of a 'reference value' or the use of same.

- The facts and assumptions associated with the toxicological evaluation of silica exposures to the general population are missing. For example, does the 'reference value' assume that the exposure is for 24- hours and ends abruptly? Or, is the assumed exposure for 24- hours a day continuously? Or, is the assumed exposure something novel, unique, and for some reason undiscussed in the document? What are the ages, occupations, and health conditions of the assumed exposed populations? What about sensitive subpopulations; are they considered? What groups do the authors consider sensitive subpopulations?
- The lack of exposure assumption makes the 'reference value' ineffectual because the circumstances needed for its use are not stated.
- Chapter 3 makes the following bold, but untrue, statement: "There are no adequate studies evaluating the effects of acute exposure to crystalline silica in humans." Silica is a very well-studied chemical with studies dating back over one-hundred years. Such a statement has no place in a regulatory document or a toxicological review article.
- There are a plethora of published toxicological and epidemiological studies on the effects of silica exposure. The authors' insistence on using only select studies as a basis for the 'reference value," while disregarding many important studies, leaves the reader with the impression that the authors have purposefully 'cherry-picked' the toxicological studies on silica for their review. This document should be withdrawn until a comprehensive review of all relevant toxicological studies is undertaken and a full peer review conducted.

Summary

The document proposes a 24 $\mu g/m^3$ 'reference value' (presumably protective of public health). But, that value is much higher than the Canadian Ambient Air Quality Criteria of 5 $\mu g/m^3$. Similarly, the States of California, New Jersey, Washington State, and Minnesota all have Ambient Air Quality Criteria of 3 $\mu g/m^3$. Meanwhile, the EPA's Acceptable Source Impact Level is also 3 $\mu g/m^3$. The incongruity between established ambient air threshold values and the reviewed document's 'reference value' is not explored or explained in the text. A stark order-of-magnitude difference with other analogous regulatory values calls for the authors to address and justify the difference. Comparison to existing occupational values are also not addressed; such as to the American Conference of Governmental Industrial Hygienist (ACGIH) of 3 $\mu g/m^3$.

It is strongly advised that this document be withdrawn and its need re-evaluated. Unless there is some undisclosed and unique aspect to public exposure to silica in the Texas, the Canadian value or U.S. states' values would likely serve. Toxicological exposure values may have large public health impacts. Consequently, these values should be formulated by qualified toxicologists in a manner free from any political influences. And, the supporting document should be subjected to rigorous peer reviews prior to release for public comment.

AGC of TEXAS
Highway, Heavy, Utilities & Industrial Branch
JENNIFER WOODARD, Executive Vice President

August 24, 2020

Dr. Michael Honeycutt, Director
Toxicology, Risk Assessment, and Research Division
P.O. Box 13087
Austin, Texas 78711-3087

RE: Silica, Crystalline Forms, Proposed 24-h ReV Development Support Document

Dear Dr. Honeycutt:

The AGC of Texas - Highway, Heavy, Utilities & Industrial Branch appreciates the opportunity to review and comment on the Silica, Crystalline Forms, 24-h ReV Development Support Document proposed on July 10, 2020. AGC of Texas' Environmental Committee members reviewed the document and have no specific comments.

We do have questions relating to how the 24-h ReV will be used. Those questions are attached for your consideration.

Please feel free to contact me or our consultant, Richard Hyde, if you have any questions or if we can be of assistance.

Respectfully,

Jennifer Woodard

Jennifer Woodard
Executive Vice President

AGC Questions
TCEQ AMCV Proposal - Silica, Crystalline

1. Please describe how the proposed Air Monitoring Comparison Value (AMCV) will be used? For example, will it be used for permitting or enforcement purposes?

2. Is the proposed AMCV only to be compared to Particulate Matter equal to or less than 4 microns in diameter (PM_4)?

3. Given that PM_4 monitoring information is not readily available, can Particulate Matter equal to or less than 10 microns in diameter (PM_{10}) or Particulate Matter equal to or less than 2.5 microns in diameter ($PM_{2.5}$) data be used to for a surrogate comparison? If so, please explain the process that will be used to conduct an accurate comparison.

4. How will the agency handle days where Saharan dust, smoke from Mexico or other natural events that cause high readings at particulate (PM) monitors? Will those days be flagged and invalidated for comparison to the new AMCV? If so, please explain that process.

5. Can monitoring periods less than 24 hours be used to compare to the AMCV? If so, how would this be done correctly?

6. Can either PM property line monitoring or ambient air monitoring be used to compare to the AMCV?

7. Are short term exceedances of an AMCV (less than a 24-hour average) a concern? For example, if a PM monitor shows 1- or 2-hour spikes intermittently but the 24 hours average is below the AMCV can the air quality be considered protective of public health?

8. If an AMCV exceedance is identified, what will the agency do to determine the cause of the exceedance?

9. Please describe a scenario under which TCEQ would utilize the AMCV. For example, if there was a complaint received.

10.. AGC recommends and requests that in the response to comments the TCEQ provide greater context to the issue being addressed by the proposed AMCV. To that end:

- TCEQ has previously noted that *most* Particulate Matter emissions from aggregate production operations (APOs) are large dust particles (i.e. total suspended particulates, or TSP), that are much larger than 10 microns in diameter (PM10), are visible, and can be filtered by hair in a person's nose. Based on this, does TCEQ agree that most PM emissions from aggregate production operations are TSP and for the reasons stated above do not constitute a health concern?
- Does TCEQ agree with the statement that most *silica* generated by APOs are large particles (TSP) and therefore cannot be inhaled into the lungs?
- Does TCEQ agree with the statement that while some mining operations can form smaller PM10 and PM2.5 particles very close to the source, the particles drop out of the air rapidly, and there are very few of these particles in the air by the time they reach the fence line?
- Please confirm that silicosis is an occupational disease (or associated with certain hobbies), is extremely rare in Texas, and that studies have shown that silica concentrations are lower or not detected at the fence line, and that concentrations are very low to not detected off-site; and that off-site concentrations were not of a health concern.