COMMENTS BY THE TEXAS COMMISSION ON ENVIRONMENTAL QUALITY REGARDING THE RISK AND EXPOSURE ASSESSMENT AND POLICY ASSESSMENT FOR THE REVIEW OF THE PRIMARY NATIONAL AMBIENT AIR QUALITY STANDARDS FOR SULFUR OXIDES

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I. Summary of Proposed Action

On September 19, 2017, the United States Environmental Protection Agency (EPA) published a notice in the *Federal Register* (82 FR 43756) that the draft *Risk and Exposure Assessment for the Primary National Ambient Air Quality Standards for Sulfur Oxides, External Review Draft* (draft REA) and the *Policy Assessment for the Primary National Ambient Air Quality Standards for Sulfur Oxides, External Review Draft* (draft PA) are available for public review and comment. On the day the public comment period was set to close, the EPA published a notice in the *Federal Register* (82 FR 48507) that the public comment period had been extended for an additional 30 days.

The REA presents the EPA's assessment of sulfur dioxide (SO_2) exposures and health risks as part of its current review of the National Ambient Air Quality Standard (NAAQS). The PA presents the EPA's evaluation of the policy implications of the technical information in the REA and Integrated Science Assessment (ISA). Under a proposed consent decree (82 FR 4866), the EPA will issue its Proposed Rule no later than May 25, 2018, and will finalize the review of the primary SO_2 NAAQS no later than January 28, 2019. The EPA last revised the primary SO_2 NAAQS in 2010 based on the available scientific literature.

II. Comments

A. General Comments

Although the TCEQ agrees with the EPA's preliminary conclusion that the current SO_2 NAAQS provides adequate protection of public health, the EPA should still work to resolve key issues with its risk assessment.

As further detailed in comments under Section B below, there are several scientific issues that have yet to be resolved with the EPA's evaluation of the risk that ambient SO_2 poses to public health. It is important to resolve these issues in the current review for many reasons. Most importantly, the science should be correct. A NAAQS should be the best reflection of the many scientists and vast resources that are devoted to its development. NAAQS are important; they provide a meaningful way for regulators to focus their regulatory strategies on key ambient air pollutants. Finally, NAAQS are important to the public, as most states' ambient air monitoring and communication strategies are built around criteria air pollutants and compliance with the NAAQS. Therefore, although the TCEQ agrees that the current standard provides adequate public health protection, the TCEQ strongly encourages the EPA to resolve these issues in the current review cycle.

The TCEQ agrees with the EPA's proposed conclusion to maintain the 1-hour duration of the current SO_2 standard.

The EPA states that the current 1-hour standard is adequate to protect against peak 5-minute exposures. The TCEQ supports this conclusion, based on available air quality data, as well as the lack of any new controlled human exposure studies that provide compelling evidence that the averaging time of the current 1-hour standard is inadequate.

The EPA should have initially provided for adequate notice for the public review and comment of the draft REA and draft PA.

The EPA originally provided the public only 30 days from the date of the *Federal Register* notice to inspect and comment on the combined 581 pages of assessment documents. On the day the original public comment period was set to close, the EPA announced a 30-day extension to the comment period. The original 30-day period was insufficient for regulatory agencies and others to provide meaningful comments. Although appreciated, the belated 30-day extension does not help organizations conduct a more thorough analysis. In order to meet the original deadline, organizations would have already shifted their focus to a few key issues, rather than critically reviewing the assessment documents. Waiting to extend the comment period until the last day leaves organizations with no time to restart the analysis in a more holistic fashion. The EPA should plan ahead for at least a 60-day public review and comment period that begins after stakeholders and the public are notified for documents that support the NAAQS.

B. Technical Comments Related to the SO_2 Risk and Exposure Assessment

Specific airway resistance (sRaw) is inappropriate for this analysis because of limited understanding of adversity and variability.

There is a noticeable lack of information in the scientific and medical literature regarding reliable benchmarks for adverse changes in sRaw, as well as normal inter- and intra-individual variability in sRaw. As noted in comments on previous assessment documents, there is similarly a noticeable lack of scientific references to serve as an appropriate rationale for why the EPA chose to select a change of 100% as moderate and 200% as severe adverse changes in sRaw. Upon further inspection, the EPA has selected sRaw not because it is a clinically meaningful health endpoint on its own, but because there were more data available on sRaw than on more meaningful clinical endpoints. Because there were no published benchmarks to determine the severity of changes in sRaw, the EPA developed a simple linear interpolation of data from between 52 and 61 subjects[1] from Linn et al. (1987, 1990) to correlate a 100% increase in sRaw to a 12-15% decrease in FEV_1 and a 200% increase in sRaw to a 25-30% decrease in FEV_1 (USEPA 1994). This interpolation is unsupported by any published literature and subsequent analyses have not been conducted to determine whether the simple relationship they calculated holds true for a broader population, particularly one that includes children, asthmatic children, unmedicated asthmatics[2], and the elderly.

The EPA's use of a surrogate (sRaw) that is of limited clinical use is inappropriate for an evaluation of this magnitude. At a minimum, the EPA should be able to justify the use of any health endpoint with published literature and use standard benchmarks to determine whether changes in that endpoint are outside of normal variation and are adverse. If the EPA insists on maintaining sRaw as an endpoint, a more thorough analysis of the relationship between sRaw and FEV_1 should be conducted and provided for public review. The resulting conclusions based

[1] Linn et al. (1990) indicates that nine subjects were participants in prior controlled exposure studies. It is unclear if these subjects provided data in Linn et al. (1987).
[2] All subjects in Linn et al. (1990) and three subjects from Linn et al. (1987) used asthma medication during the exposure study.

on sRaw should also be appropriately caveated and given less weight in the subsequent risk assessment.

At a minimum, the EPA should justify its use of a no-threshold model and conduct a sensitivity analysis that includes a threshold in the exposure-response curve.

As explained in TCEQ's comments on the draft REA Planning Document (and incorporated here by reference), it is entirely plausible that the exposure-response curve for SO_2-mediated increases in specific airway resistance (sRaw) includes a threshold (TCEQ 2017). It is well-established that a threshold exists in the mode of action for general biological reflexes (Holgate et al., 2015; Wong and Morice, 1999). Further, SO_2-induced bronchoconstriction, in particular, is reasonably explained with the threshold model. The National Academies of Science (2010) states that "the body of experimental data suggests that 0.25 ppm may be a threshold for bronchoconstriction in asthmatics" and "0.2 ppm may be a NOEL [No Observed Effect Level] for bronchoconstriction in exercising asthmatics."

Despite the presence of scientific data suggesting a threshold and the concurrence by other organizations, the EPA does not justify its decision to use a no-threshold model in any of its assessment documents beyond the rationale of using it as a default assumption. Important scientific analyses should not rely on defaults in the presence of data, particularly without further justification and appropriate limited weighting in the final analysis. If the EPA continues to advocate the use of a no-threshold model, it should explain that decision and support it with scientific data. Further, the EPA should conduct a sensitivity analysis to at least determine how much the no-threshold assumption could bias their results. While this exact sensitivity analysis was planned in the EPA's SO_2 REA Planning Document, it was not conducted in the actual REA.

The EPA should re-run their model using more appropriate exposure-response functions and exposure categories. The draft REA's current construction of exposure categories inappropriately suggests that effects can confidently be observed at concentrations below 100 and 200 ppb.

The selection of the exposure categories in the draft REA is inappropriate. The draft REA includes a 100 ppb benchmark concentration in its analysis, claiming that the four benchmark levels (e.g., 100, 200, 300, and 400 ppb) "are derived solely from the controlled human exposure studies" and that "health effects observed in such controlled studies can confidently be attributed to a defined exposure level of SO_2" (USEPA 2017b). However, as established in the ISA and draft REA, there is a well-established lack of free-breathing chamber studies in the peer-reviewed literature that have tested SO_2 concentrations below 200 ppb (USEPA 2016, USEPA 2017b). The 100 ppb benchmark is not based on a controlled human exposure study and there can be no confidence in any modeled health effects at this concentration level, as there are neither dose-response nor mode of action data to inform the shape of the curve. The presentation of the more detailed modeling results for mean SO_2-attributable increases in sRaw (Table J-28 in Appendix J) is especially suspect, as there are no data available to support exposure-response modeling at the 10 ppb resolution that is presented, particularly at concentrations below 200 ppb.

Further, the EPA's own REA Planning Document states that "there is uncertainty about whether SO_2 is causally related to lung function effects at exposure levels below 100 ppb" (EPA 2017a). Given this paucity of data and causal uncertainty, it is unclear why the EPA relies so heavily on risk estimates below 200 ppb in its quantification and discussion of risk in the draft REA and draft PA. Indeed, almost all of the risk in the Fall River area (the only area showing any incidence of at-risk individuals experiencing a day with at least a 100% increase in sRaw) was estimated to occur at concentrations below 100 ppb. The EPA needs to better justify how the vast majority of the risk of SO_2-mediated bronchoconstriction can occur at concentrations where

there is unlikely to be a causal relationship. If not, these data should either be omitted or included with an explicit caveat detailing the extreme uncertainty in the estimate.

The EPA should provide a rationale for why it did not follow its own REA Planning Document in the selection of study areas and description of their selection criteria.

The EPA released the SO_2 REA Planning Document for public comment in February 2017. That document detailed the preliminary selection of study areas that would be used to evaluate potential public health risk in the REA. Given that the REA was released just six months after the REA Planning Document, it is confusing why the EPA chose to change both the proposed study area selection criteria and the three study areas used in the REA. The table below provides a comparison of the selection criteria presented in the REA Planning Document and the draft REA. Such a large departure from the approach reviewed by the public seems to warrant at least a justification, if not a second draft planning document that is available for public review and comment.

	EPA's Risk and Exposure Assessment Planning Document (USEPA 2017a)	EPA's Risk and Exposure Assessment Document (USEPA 2017b)
Selection Criteria	• Three years of ambient monitoring data with at least one monitor reporting 5-minute data. • A design value near the NAAQS of 75 ppb. • A population of at least 100,000 within 10 km of the ambient monitors.	• Three years of ambient monitoring data with at least one monitor reporting 5-minute data. • A design value near the NAAQS of 75 ppb. • A population greater than 100,000 • Availability of existing air quality modeling datasets. • Presence of significant and diverse emissions sources.
Study Areas Selected	• Brown County, Wisconsin • Cuyahoga County, Ohio • Hillsborough County, Florida • Marion County, Indiana	• Fall River, Bristol County, Massachusetts • Indianapolis, Marion County, Indiana • Tulsa, Tulsa County, Oklahoma

The EPA should use a standard geographical reference for designating areas of the country.

The REA describes the selection of the three study areas as geographically diverse because the areas represent the New England (Fall River, Massachusetts), Ohio River Valley (Indianapolis, Indiana), and Midwest (Tulsa, Oklahoma) regions of the United States. These geographical designations are inaccurate. Oklahoma is not considered to be part of the Midwest by any major organization. Indianapolis is questionably part of the Ohio River Valley, although it is considered to be a part of the Midwest. Instead of arbitrarily assigning cities to these geographical regions, the EPA should use a standard reference, such as that used by the U.S. Census Bureau. This would allow for greater consistency and accuracy across documents. According to the U.S. Census Bureau, Oklahoma is part of the West South Central Division of the South Region. Indianapolis is part of the East North Central Division of the Midwest Region.

The EPA should provide additional rationale for creating artificially inflated design values for Fall River and Tulsa in order to just meet the current standard.

The 2011-2013 design values for the Fall River and Tulsa study areas are below the current NAAQS of 75 ppb. In order to conduct its risk assessment at the predetermined concentrations, the EPA created a model to increase the design values for these areas. However, it is not clear why this step was necessary and if the method for increasing these design values was appropriate. The EPA should provide additional support for its reasoning and method.

The EPA should provide additional analyses and justification for the disparity in risk estimates between the study areas and the representativeness of these results to the rest of the United States.

The draft REA details the EPA's modeling results for three study areas that were supposed to have been selected so that they represent the different ambient scenarios across the country. As explained above, the study areas were supposed to include different diverse and significant emission sources. However, even a preliminary review of the risk estimates causes concern.

The Fall River area appears to have been modeled differently than the other two areas. First, the EPA only modeled one source in the area, not the several sources that it intended with its selection criteria nor the number modeled in the other areas. In addition, the EPA used a broader grid (500 meters) in Fall River than in the other areas, which were modeled down to 100 meters.

Oddly, the resulting risk estimates for Fall River are more than 100-times higher than the estimates for Tulsa or Indianapolis. In fact, the Fall River area was the only area to show a single at-risk individual at risk for a day with a "moderate" SO_2-induced bronchoconstriction. While the draft REA does discuss the potential overlap of higher SO_2 exposure and higher population, this large risk difference still is not fully explained.

Finally, it is unclear how relevant the risk estimates are for evaluating the nation's current public health risk for SO_2. The Fall River area's only significant source, the Brayton Point Power Plant, was permanently decommissioned in July 2017. Therefore, the only location modeled to have an SO_2-mediated effect on the public now has no significant sources.

At a minimum, the EPA should provide an analysis of their modeling results and a reasoned justification for how well they represent current public risk. This discussion should include the necessary discussions of uncertainty, common quality assurance descriptors (e.g., accuracy, precision, and goodness of fit), and presentation of confidence intervals. As is, the draft REA's risk estimates look highly suspicious and only erode confidence in the assessment results.

The EPA should better attempt to quantitatively address the many uncertainties identified in the draft REA.

Table 6-3 of the draft REA details a significant list of remaining uncertainty in the risk analysis. Although the EPA adequately identifies and articulates relevant qualitative uncertainty factors, there is almost no quantitative consideration. The TCEQ encourages the EPA to consider the available quantitative methods that exist for dealing with this large amount of uncertainty.

The EPA should include uncertainty bounds in its presentation of risk assessment results to allow for more meaningful communication of risk.

The EPA habitually fails to present more than a point estimate in its presentation of risk assessment results from its Air Pollutants Exposure (APEX) model. Presenting a point estimate suggests an unfounded certainty in the results. As detailed above, the risk estimates reported by the EPA in the REA are highly uncertain, particularly below 200 ppb. However, the oversimplified presentation of results does not convey this uncertainty to the reader. The EPA

should present results from the published literature and its own risk analysis results with both point estimates *and* uncertainty bounds in order to allow for more accurate and meaningful communication of risk.

C. Technical Comments Related to the Policy Assessment

The EPA should provide a quantitative analysis and additional discussion to explain the relevance of modeled effect estimates in the three study areas to the ambient conditions found across the rest of the country.

As detailed in the draft REA and draft PA, the EPA estimates almost all risk of SO_2-mediated health effects to occur in Fall River, Massachusetts, to the almost exclusion of the other two areas. The EPA provides a map in Appendix F of the draft PA that overlays 2010 population density with point sources that reported emitting more than 1,000 tons per year SO_2 in the 2011 National Emission Inventory (NEI) to justify the relevance of the Fall River estimates to the rest of the country. However, the map does not provide fine enough resolution to allow the reader to understand the likelihood that point source emissions overlap with dense populations as they did in Fall River. Given the importance of the Fall River estimates (i.e., that this was the only study area that showed any measureable impact to receptors), the EPA should provide a quantitative evaluation of how likely the exposure circumstances represented in the Fall River study area are to occur elsewhere in the country. This evaluation should also include newer data from the more recent 2014 NEI.

To justify the current standard, the EPA inappropriately relies on highly uncertain modeled health effects below concentrations that cause effects in controlled human exposure studies.

In the draft REA, the EPA chose to model a health endpoint (changes in sRaw) that it has not proven to be adverse through independent study or through supporting scientific literature. Further, rather than relying on the exposure-response information available in controlled human exposure studies, the EPA has modeled effects down to 0 ppb, although results are combined for exposures less than 100 ppb. Even with these methodological decisions, Table 5-5 of the draft REA details that only one of the three study areas was anticipated to have any asthmatic individuals experiencing at least a moderate (100% increase) change in sRaw. Table 5-6 goes on to detail the distribution of risk estimates in the Fall River area. Specifically, 48.1% of the risk in 2011, 96.5% of the risk in 2012, and 70% of the risk in 2013 was estimated to occur following exposure to SO_2 concentrations below 100 ppb. At this 100 ppb benchmark, the EPA has determined that it is uncertain whether lung function effects are causally related to SO_2 exposure. However, it is these effects that drive the level of the standard. The EPA should re-evaluate the level of proof necessary to derive a NAAQS, as it appears that the standard is set to protect effects that may not be adverse at concentrations where they may not occur.

The EPA needs to more clearly discuss how uncertainties in the draft REA alter the current understanding of at-risk populations.

The EPA assumes that asthmatic children are at particularly high risk of asthma exacerbations due to SO_2-induced bronchoconstriction. However, the draft REA merely models sRaw changes in children by interpolating sRaw changes in adults. There is no scientific support for this method. Even in controlled human exposure studies in only one life stage, sRaw changes and physical symptoms were difficult to predict (USEPA 2016).

Further, the idea that severe asthmatics are more at risk to SO_2-mediated bronchoconstriction is not supported by the available literature. In the draft REA, the EPA notes that "there is no evidence to indicate that [individuals with severe asthma] would experience moderate or greater lung function decrements at lower SO_2 exposure concentrations than individuals with moderate

asthma." Further, the EPA states that "the limited data that are available indicate a similar magnitude SO_2-specific response (in sRaw) as that for individuals with less severe asthma" (pp. 4-24).

The risk assessment does not identify a public health risk with any scientific confidence.

The draft REA does an extensive analysis of potential risk posed by modeled SO_2 emissions from what the EPA deems to be representative sources in areas that are in close proximity to populations with at-risk children and adults. However, in the final analysis, only one of the three areas modeled shows a single day with one of these at-risk individuals having a moderate effect. This area (Fall River, Massachusetts) only shows these effects when its design value is artificially inflated to meet the current 75 ppb standard and when concentrations that are not likely to be causally related to SO_2-induced health outcomes are considered. In the end, using the analysis in the draft REA, the EPA cannot confidently determine that there is a public health risk at ambient SO_2 concentrations below 200 ppb.

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