BEFORE THE ADMINISTRATOR

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

IN RE: NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS: MISCELLANEOUS ORGANIC CHEMICAL MANUFACTURING RESIDUAL RISK AND TECHNOLOGY REVIEW 85 FED. REG. 49084 (AUG. 12, 2020)	))))))	DOCKET NO. EPA–HQ–OAR–2018–0746

PETITION FOR RECONSIDERATION

SUBMITTED BY

THE AMERICAN CHEMISTRY COUNCIL

Pursuant to Section 307(d)(7)(B) of the Clean Air Act (Act or CAA) the American Chemistry Council (ACC) hereby petitions the United States Environmental Protection Agency (EPA or the Agency) to convene a reconsideration proceeding for the final rule entitled *National Emission Standards for Hazardous Air Pollutants Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review,* 85 Fed. Reg. 49084 (Aug. 12, 2020) (Final Rule). For the reasons discussed below, EPA is required to convene such a proceeding because: 1) EPA has not considered the Texas Commission on Environmental Quality's (TCEQ's) peer reviewed assessment on ethylene oxide (EO); and 2) EPA committed to address ACC's Request for Correction under the Information Quality Act (IQA) related to the validity of the IRIS value, but decided not to do so prior to the issuance of the Final Rule. ACC further urges the Agency to comprehensively address the additional concerns with the validity of the IRIS value raised by ACC and TCEQ while conducting the necessary review.

ACC filed its Request for Correction in August 2018 and TCEQ first issued its draft EO assessment nine months later in June 2019. When EPA proposed the MON RTR six months later, it committed to address the concerns raised by ACC and TCEQ in the final rule: "[b]ecause of the robustness of the comments received and their relevance to this rulemaking, the Agency will consider those comments in the final rule for the Miscellaneous Organic Chemical Manufacturing source category." 84 Fed. Reg. 69218. EPA also responded to ACC's Request for Correction by committing to address the concerns ACC raised in the MON in a December 2019 response letter.

EPA reneged on this commitment. In the Final Rule, EPA declined to address the concerns raised in either the Request for Correction or the TCEQ analysis, stating that the rulemaking schedule did not provide sufficient time to address the issues raised by ACC's Request for Correction, and that the TCEQ analysis had not yet been peer reviewed. Rather, EPA committed to addressing ACC's IQA petition "in the near future" and committed to consider the TCEQ value or new dose response values as they "become available." 85 Fed. Reg. 49098.

While ACC believes that the timing and availability concerns that led EPA to defer consideration of these issues in the rulemaking process are not valid (and ACC has challenged the final rule in part on that basis), these concerns no longer apply. A Petition for Reconsideration is not subject to the same court schedule as the Final Rule was, and the TCEQ's peer review is now complete. Accordingly, EPA should address these matters now and do so expeditiously to ensure that the Final Rule is based on the best available science and accurately conveys the risks associated with low-level EO exposure.

As discussed below, CAA Section 307(d)(7)(B) requires EPA to convene a reconsideration proceeding where (1) it was either impractical to raise an objection during the comment period or new information becomes available after the close of the comment period; and (2) such information is of central relevance to the outcome of the rule. Both EPA's treatment of the IQA petition and the final peer review of the TCEQ value meet this test.

The IQA petition and the TCEQ study both meet the first requirement. With respect to the IQA petition, ACC could not have objected to EPA's failure to consider that petition in developing the MON, because the Agency had explicitly committed to do so in the proposed rule.[1] With respect to the TCEQ analysis, peer review was completed after the comment period closed; thus, as the Agency's sole justification for excluding the TCEQ analysis from consideration was the lack of peer review, the completion of that peer review represents new information that became available only after the close of the comment period.

With respect to the second prong, the analysis contained in the IQA petition and the release of TCEQ's final peer reviewed value are both of central relevance to the outcome of the rule—that is, they independently provide substantial support for the proposition that the regulation should be revised. If EPA had considered the information contained in the IQA petition and/or the information supporting the TCEQ alternative value, it would likely have found that another risk value (or an adjusted EO IRIS value) was more appropriate. As EPA acknowledged in the MON proposal, this modification would have significantly reduced the projected emissions risk level relied upon by EPA as a basis for the Final Rule and could have allowed EPA to reasonably conclude that additional EO controls were not needed to address residual risk. 84 Fed. Reg. 69218. Moreover, had EPA adopted the TCEQ value instead of the IRIS value, it would have found the source category risks were well below the presumptive excess risk threshold of 1-in-10,000 and indeed would have concluded that EO was not a risk-driver for the source category. Accordingly, there is a reasonable possibility that EPA would have concluded that EO-specific controls are unwarranted.

[1] Alternatively, EPA's response to the IQA petition constitutes arising after grounds as EPA's decision to not address the IQA petition did not occur until after the close of the comment period.

I. BACKGROUND

The CAA requires EPA to regulate hazardous air pollutants (HAP) from categories of industrial facilities in two phases. In the first "technology-based" phase, EPA develops standards for controlling the emissions of air toxics from a specific industry source category, or maximum achievable control technology (MACT) standards. MACT standards are based on emissions levels that are already being achieved by the lowest emitting sources in the category. Within eight years of setting these MACT standards, EPA must assess the remaining health risks from each source category to determine whether the existing MACT standards protect public health with an ample margin of safety and protect against adverse environmental effects. This is the risk-based "residual risk" phase where EPA must determine whether more stringent standards are necessary to ensure the protection of human health with an ample margin of safety.

EPA's effort to develop an EO IRIS value began in April 1984 with an EO health assessment document. The first draft EO IRIS assessment was released in September 2006, and a Science Advisory Board (SAB) review of this draft was conducted in 2007. The SAB report identified several shortcomings with EPA's draft IRIS assessment, including its selection of the linear regression modelling approach. EPA prepared revised drafts in July 2011, July 2013, and August 2014. ACC provided detailed comments on the review drafts published by EPA to highlight the lack of representativeness associated with the data used by EPA as well as the lack of proper "statistical fit" associated with the regression model.[2] The July 2013/August 2014 EPA drafts were reviewed by a second SAB, and the subsequent SAB review report was issued in August 2015. The August 2014 draft was again modified, based in part on the SAB report, but no public comment period or additional technical review was scheduled for this revised draft. The final EO IRIS assessment, introducing for the first time a 2-piece spline model, was published in December 2016 and established EPA's final EO IRIS value.

In August 2018, EPA first used the new EO IRIS value when EPA released the most recent National Air Toxics Assessment (NATA)[3] results. In the NATA, EPA evaluates emissions, ambient concentrations, and exposure estimates for CAA air toxics. The 2018 NATA was based on 2014 emissions data, and because EPA assessed the risk of EO emissions using the IRIS value for EO, the 2018 NATA greatly overestimated risks associated with EO exposure.

In September 2018, ACC filed an IQA Request for Correction (IQA petition) seeking correction of EPA's use of the EO IRIS value and noting the significant flaws associated with it. The IQA petition built upon and expanded the concerns that were raised by ACC in its comments submitted during the development of the IRIS value. These included flaws associated with supporting data and modeling as well as the procedural development of the value and EPA's lack of a robust response to the SAB review. As ACC noted in the IQA petition, EPA's reliance on

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[2] ACC Comments on the Revised External Review Draft Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide, Docket ID No. EPA-HQ-ORD-2006-0756. October 11, 2013.

[3] In each NATA, EPA estimates population exposures of emissions from sources based on census tracts and uses that information to model and ultimately characterize potential public health risks

the EO IRIS value in the NATA was inappropriate and exacerbated its significant flaws by overestimating exposure risks associated with EO emissions. As such and as requested in the petition, the "NATA risk estimates for EO should be withdrawn and corrected to reflect scientifically supportable risk values."[4] EPA has yet to fully respond to the ACC IQA Petition that has now been pending for over 2 years.

TCEQ has a long history of producing Development Support Documents (DSD) for chemicals to support screening levels used in air permitting programs. As part of one of these efforts, TCEQ issued an information request for EO in August 2017. ACC, in addition to a number of other sources, provided substantive information to TCEQ for their consideration regarding dose-response assessment and the issues associated with the EO IRIS value. Subsequently, TCEQ issued the first DSD draft for EO for public comment on June 28, 2019. Following the close of the comment period on September 26, 2019, TCEQ provided the revised draft EO DSD for review by six independent peer reviewers. The peer review was completed in April 2020. After TCEQ addressed the peer review comments, the final EO DSD was issued on May 15, 2020.

On December 17, 2019, EPA's proposed residual risk and technology review (RTR) for the Miscellaneous Organic Chemical Manufacturing (MON) source category was published in the Federal Register; the comment deadline was later extended to March 19, 2020. In its proposal, EPA proposed to find unacceptable risk from the source category due to EO emissions from two facilities. Indeed, EPA identified almost all the source category risk as being driven by EO. *See* 84 Fed. Reg. 69812, 69213 ("Based on the results of the risk assessment, we have identified ethylene oxide as the primary contributor to risks."); 85 Fed. Reg. 49084, 49093 ("[T]he MIR posed by the source category was 2,000-in-1 million driven by ethylene oxide emissions from storage tanks (75 percent), equipment leaks (15 percent), and process vents (8 percent).") As such, the Agency proposed to address this perceived residual risk by revising the MON pursuant to CAA section 112(f)(2) to require control of EO emissions from process vents, storage tanks, and equipment "in ethylene oxide service."[5]

The day following the proposal's Federal Register publication, EPA responded to ACC's IQA petition in a December 18, 2019 letter stating that the proper place to consider the issues raised in the petition was in the MON rulemaking process.[6] Specifically, EPA noted in the letter that because the EO IRIS value was already informing a number of RTRs, the Agency "believes it is appropriate to address this RFC as part of the MON RTR rulemaking."[7] EPA supported this decision by noting that because the MON was the first RTR in which EO was a regulated

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[4] ACC Request for Correction under the Information Quality Act: 2014 National Air Toxics Assessment (NATA). September 30, 2018.
[5] *See* proposed 40 CFR 63.2493. 84 Fed. Reg. at 69,248.
[6] *See* Letter from Anne L. Idsal, acting Assistant Administrator for Air and Radiation to William P. Gulledge, American Chemistry Council (December 18, 2019) (Idsal letter).
[7] *Id.*

pollutant, "the way to ensure full consideration of all the comments it has received, and is expected to receive, from numerous entities on the 2016 [EO] IRIS Assessment is to address them in that rulemaking."[8] EPA also mentioned the ability to respond to public comments in the final rule as another reason for addressing the issues with the EO IRIS values raised in the IQA through the MON RTR.

In the proposed rule, EPA noted that information previously submitted to the Agency in the form of ACC's IQA petition, comments on the hydrochloric acid RTR, as well as TCEQ's June 28, 2019 DSD, which included an effects screening level (ESL) for EO, all raised significant questions about the validity of the 2016 EO IRIS value. Nevertheless, EPA exclusively relied upon that very value in determining that risks were unreasonable absent control, and that a residual risk existed that must be addressed. EPA reached this conclusion despite its express recognition that it was "reasonable to assume that, allowing for the uncertainties in the URE, estimated risks for the [MON] could be lower, even potentially lower than the 100-in-1 million benchmark." 84 Fed. Reg. at 69218.

Both TCEQ and ACC submitted substantial technical comments demonstrating the significant errors in the IRIS value. TCEQ further clarified its use of biological mode of action, model fit criteria, and endogenous data to model the age dependent adjustment factor (ADAF)-unadjusted risk-based air concentration for EO at 4.0 ppb at the no significant excess risk level of 1 in 100,000. TCEQ then added the ADAF to account for exposure to children (ages 0 to 16) and determined the ADAF adjusted chronic no-threshold risk value of 2.4 ppb. The addition of the ADAF is consistent with EPA's cancer policy. ACC, in turn, submitted revised detailed comments addressing a number of priority issues and precedential concerns with EPA's proposal. ACC's comments provided a detailed technical analysis of EPA's risk modeling results and control requirements. Namely, ACC noted the precedential concerns associated with proposed emissions requirements based on the flawed IRIS value as well as the technical infeasibility associated with the operation of the proposed controls. In the comments, ACC presented alternative risk modeling that demonstrated the actual risks from the two identified facilities were significantly lower than EPA originally stated. This modeling presented multiple alternative scenarios, some of which were informed by TCEQ's proposed dose-response value and/or updated emissions information that better reflected actual emissions. The results from all alternative scenarios showed that the risks informed by the IRIS value were overstated.

On June 1, 2020, EPA released the signed pre-publication version of the final MON RTR (published in the August 12, 2020 Federal Register). In the risk review portion of the final MON RTR, EPA revised its modeling to account for updated emissions inputs from the two facilities with elevated risk. However, because it continued to use the 2016 EO IRIS value, EPA concluded that the risks prior to control remained unacceptable from one facility.

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[8] *Id.*

In the final rule analysis, EPA declined to use the TCEQ alternative value because the external scientific peer review (completed in an April 30, 2020 report) and revisions in response thereto were not completed until May 15, 2020, which was after the close of the comment period. Additionally, in the final MON RTR, EPA deferred providing a final response to ACC's IQA petition, noting that it was "under a court ordered deadline requiring signature of the final MON RTR" and it "determined that, given the time available and in light of other resource constraints, completing [EPA's] consideration of the Information Quality Act request for correction in conjunction with taking final action in this rulemaking is not practicable." 85 Fed. Reg. 49098. As such, it pushed taking final action on the petition to sometime "in the near future."

As a result of its decision not to consider the TCEQ value, or the information previously submitted by ACC, EPA concluded that it was required to impose controls to address residual risk. Consequently, in the rule, EPA finalized a number of its proposed changes, including a modified version of one of the emissions control options for EO emissions from equipment "in EO service" at 40 CFR 63.2493.

II. EPA is required to grant reconsideration as a result of the peer review of the TCEQ Value and the Agency's shift in position on the need to address the IQA Petition.

The standard for reconsideration is provided under section 307(d)(7)(B) of the Act, stating:

> one is entitled to reconsideration by the Administrator after the period for public comment has passed if that person can show: (1) "it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review)," and (2) "such objection is of central relevance to the outcome of the rule,"

Chesapeake Climate Action Net. v. EPA, 952 F.3d 310, 314(D.C. Cir. 2020) (*Chesapeake)* (quoting CAA sec. 307(d)(7)(B). The first prong of this test can be met either by demonstrating that the final rule is "not a logical outgrowth of the proposed rule", *Alon Refining Krotz Springs, Inc. v EPA*, 936 F.3d 628, 648 (D.C. Cir. 2019), *or* by demonstrating grounds "arising after" the close of the comment period, but before the time for seeking judicial review. *Chesapeake*, 952 F.3d at 319. The logical outgrowth test asks if "'interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period.'" *Id.* (quoting *Clean Air Council,* 862 F.3d 1at 10 (internal quotations omitted)). It extends not only to the final outcome of the rule but the analyses conducted to reach the result. *See id.* (finding lack of logical outgrowth where "[p]etitioners were not given the opportunity to comment on, propose revision to, or otherwise challenge the process for selecting the "best performers.").

The second prong, "central relevance, asks whether the objections provide substantial support for the argument that the regulation should be revised." *Id.* at 22 (*quoting* CAA Sec. 307(d)(7)(B)).

Where a petitioner makes this demonstration, the Agency is required to convene a notice and comment proceeding on such objection. CAA sec. 307(d)(7(B)("the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed.") As described below, both of these prongs have been met.

A. EPA's response to the IQA petition and the TCEQ final peer review meet the first prong of the CAA reconsideration standard.

1. In the final rule, EPA viewed the TCEQ value as not being available until after the close of the comment period.

Although the TCEQ value[9] was presented to EPA during the comment period, the value was not peer reviewed prior to the close of the comment and thus was not viewed by the Agency as an alternative value that it could use in conducting its risk analysis.[10] EPA made that clear in the preamble to the Final Rule:

> [t]hough the TCEQ submitted their draft cancer dose-response assessment for ethylene oxide to the EPA as part of the public comment process, the assessment had not yet undergone peer review, and the TCEQ dose-response value had not yet been finalized by the close of the public comment period for this rulemaking, which closed on March 19, 2020. Therefore, the TCEQ dose response value could not be considered for this rulemaking.

85 Fed. Reg. at 49098.

In short, EPA concluded that it could not consider the TCEQ value as an alternative because it was not peer reviewed. Regardless whether this view is correct, that determination was the basis for EPA's refusal to consider the TCEQ study. Accordingly, the completion of the TCEQ peer review on May 15, 2020 – after the close of the comment period and before the expiration of the time for seeking judicial review – satisfies the first criterion for mandatory reconsideration.

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[9] At the proposal, EPA noted that TCEQ had a value of 4 ppb (1 in 100,000 excess risk level). TCEQ subsequently made adjustments to reflect more sensitive populations (ADAF), resulting in an adjusted value of 2.4 ppb. This revised value was submitted by TCEQ in its initial set of comments and was thus in the docket during the extended comment period. EPA-HQ-OAR-2018-0746-0071.

2. It was impracticable to object to EPA's decision to not address ACC's IQA Petition.

In the MON proposal, EPA acknowledged receipt of the IQA petition and stated its intent to consider those comments in the final rule. The following day, EPA directly responded to the IQA petition, reiterating this commitment:

> As indicated in section 8.5 of EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of information Disseminated by the Environmental Protection Agency* (IQG), if a group or an individual raises a question regarding information supporting a proposed rule, EPA generally expects to treat it procedurally like a comment to the rulemaking addressing it in the response to comments rather than through a separate response mechanism.

Idsal letter at 2 (footnotes omitted). In other words, EPA refused to consider ACC's IQA petition directly, because the Agency concluded its guidelines required it to do so in the MON.

ACC took the Agency at its word and developed its comments on the MON based on the understanding that EPA would view its IQA petition as a comment on the MON rule, consider the issues raised in that petition while developing the final standards, and explain its decision on those issues in its response to comments document for the final rule.

ACC could not have known during the comment period that EPA would renege on its commitment. Given that the Agency had explicitly committed to address the IQA in the MON final rule, and indeed its insistence in its letter to ACC that the MON was the proper forum for doing so, ACC reasonably concluded that it did not need to resubmit the Petition to the MON docket as a comment.

Because the Agency did not announce its change of position on the IQA petition until it issued the final MON rule, ACC could not have commented on that change in position during the comment period, and thus the IQA petition satisfies the first reconsideration criterion.[11]

B. The peer reviewed TCEQ study and the Agency's response with respect to the IQA petition are of central relevance.

As noted above, the central relevance test asks "whether the objections provide substantial support for the argument that the regulation should be revised." *Chesapeake* at 322.

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[11] Furthermore, because EPA provided no prior indication before finalizing the MON RTR that it would not consider the IQA petition, its failure to do so cannot be considered a logical outgrowth of the proposal. *See*, e.g. Chesapeake, 952 F.3d at 320 ("Because nothing in the 2013 proposed Rule indicated EPA was setting it standards based on the best performing sources, the Final Rule's reliance on its newly selected 'best performers' cannot be considered a logical outgrowth."). As noted earlier, in the alternative, EPA's response constitutes grounds arising after because ACC did not have opportunity to comment on EPA's position that it could further defer consideration of the IQA petition based on a lack of time.

Accordingly, a petitioner need not demonstrate that the rule in fact would have changed but must only provide substantial support that it should be revised.

Here, both the IQA petition and the TCEQ study meet this test, because both identified significant scientific and technical flaws in the IRIS value, which directly affect the validity of EPA's determination that pre-control EO exposure risks were unacceptable. *See Kennecott Corp. v. EPA,* 684 F.2d 1007, 1019 (D.C. 1982) (finding central relevance test to have been met where "the reasonableness and accuracy of the forecast data [was] critical. . . [the] objections to that data, if well founded, would clearly have been 'of central relevance'").

Had EPA considered the TCEQ study or the value TCEQ determined to be more appropriate, or had it adjusted its pre-control risk analysis to take into consideration the issues identified in the IQA petition, there is substantial support for the proposition that EPA would have concluded: (1) that pre-control risks were acceptable – *i.e.* below 100-in-1-million – and (2) that the existing standards provided an "ample margin of safety." Accordingly, the finalization of the peer review of the TCEQ value after the close of the comment period, and the issues raised in the IQA petition, provide "substantial support for the argument that the regulation should be revised," *Chesapeake* at 322. Accordingly, the Agency must convene a reconsideration proceeding under CAA section 307 in order to take a hard look at the TCEQ study and ACC's IQA **petition.**

1. The Agency reasonably could have concluded that the TCEQ value constitutes a viable alternative value.

In the final rule, EPA made clear that it was open to alternative peer reviewed values, and indeed made clear that the only reason it had not given close consideration to the value or its accompanying analysis was because it had not been peer reviewed. Had the Agency considered it available and subsequently reviewed it, there is a reasonable likelihood that EPA would have recognized the robustness of the TCEQ process and the significant issues that it raised with the EO IRIS value. As a result of such a review, it is further likely that EPA would have adopted the alternative value.

a. In the final rule, EPA made clear that it viewed alternative peer reviewed values as being of central relevance.

In issuing the Final rule, EPA made clear that the only barrier it perceived to considering the TCEQ study was that the study had not completed peer review by the close of the comment period. EPA also made clear that it was willing to consider an alternative to the IRIS value; in fact, the Agency noted that had the TCEQ value been available, it may have used it rather than the IRIS value. As the Agency explained:

> Though the TCEQ submitted their draft cancer dose-response assessment for ethylene oxide to the EPA as part of the public comment process, the assessment had not yet undergone peer review, and the TCEQ dose-response value had not yet been finalized by the close of the public comment period for this rulemaking,

> which closed on March 19, 2020. Therefore, the TCEQ dose response value could not be considered for this rulemaking.
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> *For these reasons, we have decided to continue to use the EPA URE for ethylene oxide* for the risk analyses performed for this final rulemaking. As always, the EPA remains open to new and updated scientific information, as well as new dose response values such as the TCEQ value, as they become available.

85 Fed. Reg. at 49098 (emphasis added) (footnotes omitted). Accordingly, EPA's statements in the final MON RTR rule indicate a clear willingness to consider and "remain open" to alternative risk values as they become "available," or peer-reviewed and finalized.

EPA's willingness to consider a properly reviewed and scientifically robust alternative also reaffirms the role of such a risk value as of central relevance to the outcome of the rule. The TCEQ value for EO fits squarely into this description. As discussed below, the TCEQ value was subject to notice and comment and peer review, creating a fulsome record. Moreover, the record supporting the TCEQ final value raised significant questions regarding the IRIS value which a reasonable mind "might [have] accepted as adequate to support the conclusion" that the Agency should have used the TCEQ value, rather than the IRIS value, in calculating risks in the MON. *Consolidated Edison*, 305 U.S. at 229.

b. The TCEQ study involved a robust process and raised significant concerns about the validity of the IRIS value.

TCEQ's risk assessment and analysis was the result of a robust peer-reviewed process and identified critical flaws in the approach used by EPA to develop its EO IRIS value.[12] In the comments on the MON RTR proposal, TCEQ presented its analysis to the Agency for consideration. This assessment included significant new and additional information that was not considered, or not fully considered, in the IRIS process.

TCEQ released its draft DSD on EO on June 28, 2019. This analysis by TCEQ included an in-depth analysis of the EO IRIS value, which led TCEQ to conclude that:

> [t]he USEPA (2016) URF for [EO] is based on a scientifically unjustified, unconventional overall supra-linear dose-response model that has been demonstrated by the TCEQ to be (1) statistically significantly over-predictive; and *not* supported by: (2) carcinogenic mode of action (MOA); (3) data on endogenous levels normally produced within the human body; (4) reality checks

[12] TCEQ develops inhalation toxicity factors in order to fulfil its statutory duties related to the prevention and remediation of air pollution. *See* TCEQ, TCEQ Guidelines to Develop Toxicity Factors at 1 (Rev. Sept 2015) *available at* https://www.tceq.texas.gov/assets/public/comm_exec/pubs/rg/rg-442.pdf. The development of the Guidelines underwent two rounds of peer review and a response to comments. *See* https://www.tceq.texas.gov/toxicology/esl/guidelines/about.

> on population background incidence; or (5) even appropriate standard model fit criteria.

Scientific Issues in the Regulatory Assessment of Ethylene Oxide Cancer Risk at p21, Dec. 10-11, 2019.

After receiving comments, TCEQ revised the DSD in late January 2020 and submitted the revision to EPA as its comments on the proposed MON RTR. At the same time, TCEQ submitted its revised DSD to six peer reviewers for an independent review. The peer review comments and the final DSD were released in April and May 2020. In its response to comments, TCEQ noted that the peer review supported the linear model that TCEQ used to develop its value, and did *not* support the supra-linear model EPA used in the IRIS assessment. TCEQ also provided a detailed critique of EPA's EO IRIS value that includes mode of action considerations, model fit criteria, accuracy of model predictions, and consideration of endogenous/background of internal levels of EO. EPA did not address any of these issues in the final MON RTR.

Accordingly, the TCEQ analysis raises substantial questions about the validity of the EO IRIS value. These significant scientific issues raised by TCEQ include:

- Several issues associated with the NIOSH exposure analysis, including a limitation of the NIOSH cohort exposure regression models that only validated data between 1976 and 1985.
- TCEQ Section 3.1.1.1 Breast Cancer provides an analysis of the epidemiological evidence for EO and Breast Cancer. TCEQ (2020) included new analyses (some consistent with the ACC EO panel comments) that had not been considered previously by the EPA SAB or the IRIS (2016) assessment.
- TCEQ and USEPA acknowledge that human data are insufficient to establish that EO is a human breast cancer carcinogen. As a result, USEPA (2016) relies on support from EO induced mammary tumors in mice (but not rats) in classifying EO as carcinogenic to humans and for the human breast cancer endpoint. However, TCEQ determined that there is a lack of concordance between animals and humans for breast cancer based on IARC (2019) analysis.
- The TCEQ (2020) Appendix 6 Review of the USEPA (2016) Assessment provides a thorough detailed accurate explanation of the statistical analysis, and emphasizes the mode of action as the guiding principle together with correct statistics as the basis for selecting the standard Cox Proportional Hazards model. EPA's claim that it followed SAB's advice in selecting the spline models is incorrect. TCEQ provides a sophisticated detailed analysis and explanation of why and how its statistical model was implemented.
- TCEQ Appendix 3 provides a "reality check" by seeing how well the parametric models predict the number of lymphoid cancer deaths (the key cancer endpoint) versus the actual number of deaths observed in the key

NIOSH cohort. The standard Cox proportional hazards model accurately predicted the number of deaths compared to the IRIS (2016) 2-slope linear model not only for all exposures, but also at the lower exposure levels, indicating better fit. TCEQ uses this more objective analysis to counter the IRIS (2016) incorrect claim that the 2-slope spline model has superior visual local fit. TCEQ Appendix 6 provides a superior rigorous analysis of model selection that begins with MOA considerations but then addresses all the issues raised by EPA (2020) comments, which incorrectly claim that their analysis is supported by the SAB review.

- TCEQ Section 4.2.3 provides an in-depth analysis of model predictions versus observed as another more rigorous approach to assessing model accuracy and fit. The analysis concludes that the Cox proportional hazard model is statistically more accurate in predicting the NIOSH cohort lymphoid cancer mortalities than the IRIS (2016) 2-slope model.

Given the depth and scientific soundness of TCEQ's analysis, it is reasonable to conclude that had the Agency considered the TCEQ materials, it may well have concluded that the IRIS value did not accurately reflect the risks associated with EO – regardless of whether the Agency ultimately adopted the TCEQ value.

2. EPA's response to the IQA petition was of central relevance.

As discussed above, immediately after the MON was published in the Federal Register, the Agency notified ACC that it would be addressing ACC's IQA petition in the final MON rule. *See* Idsal letter at 2. Had EPA not issued this commitment, ACC likely would have resubmitted the scientific information and argumentation contained in its IQA petition to EPA as part of its comments on the MON. Moreover, had the Agency made ACC aware that it did not intend to address its petition in connection with the MON final rule, ACC would have explained that EPA was obligated to address the underlying scientific issues and arguments raised in the petition in the final MON RTR rule.

Both EPA and the D.C. Circuit have acknowledged that it is proper to question the scientific underpinning of an IRIS value in connection with the use of that value in a substantive rulemaking, and that the Agency is required to respond to comments questioning those scientific underpinnings. In *Chemical Mfrs. Ass'n v. EPA*, 28 F.3d 1259 (D.C. Cir. 1994), ACC[13] argued that prior to its use "EPA should have subjected . . . its IRIS database to notice and comment rulemaking." *Id.* at 1262. In response,

> the EPA argue[d] that it was not required to solicit comment on the [IRIS] database itself because any time the agency uses the data in it as part of a rulemaking, the scientific basis for, and the application of, those data are then subject to comment.

[13] At the time ACC was known as the Chemical Manufacturers Association.

Id. at 1263 The court agreed with EPA that it was not required to subject the database to notice and comment as "[t]he data in the database constrain no one until so applied in a particular rule." *Id.* The court then went on to reject ACC's claim since the reference concentration of the pollutant of interest had been subject to notice and comment and we had not "demonstrated the EPA, was, in fact, deaf to" our concerns." *Id.*

The instant case presents the opposite scenario: ACC's petition raised significant issues regarding the validity of the IRIS value; EPA expressly recognized that those issues were significant enough to require a response in the MON RTR; and EPA then failed to consider those concerns in the MON RTR, finding that it was "not practicable" to do so. 85 Fed. Reg. 49098. EPA "was, in fact, deaf to" ACC's concerns. Given that EPA itself has agreed that the concerns raised are significant to require the Agency's consideration and response, those concerns are of "central relevance" to the final decision on the EO risks that drove EPA's final decision.[14]

C. Had the Agency used an alternative value for EO, it could reasonably have concluded that EO-specific controls at 40 CFR 63.2493 were not necessary.

EPA's decision to use the EO IRIS value rather than an alternative value drove the Agency's decision to impose EO-specific controls. Specifically, EPA's use of the IRIS value led the Agency to conclude that residual risk, in the absence of additional controls, was unacceptable; this determination, in turn, obligated the Agency to require the installation of additional controls in order to reduce emissions to an acceptable level.

Had the Agency used the TCEQ value, or recognized the substantial flaws in the IRIS value raised in the IQA petition and used another, more appropriate approach to estimating low-level EO risks, EPA's decision-making process would have been entirely different. For example, the pre-control residual risk analysis using the TCEQ value would have demonstrated risks below the presumptive threshold, and so EPA would *not* have been required to impose additional controls. Similarly, had EPA agreed with ACC's IQA petition, it could also have concluded that the actual risk from the source category was below the presumptive threshold. While EPA could still have evaluated benefits of such controls, that analysis would have been governed by the more flexible "ample margin of safety" test – and given the significant difference between the EO IRIS value and the TCEQ value (or the value suggested in the IQA petition)[15], it is highly likely that EPA would have concluded that no additional controls were required. Accordingly,

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[14] To the extent that EPA views peer review as impacting its ability to consider information, or the weight it provides information, two articles, developed from the information submitted in the IQA petition have been published in peer reviewed journals, one of which was published after the close of the comment period. *See* Marsh, G.M., *et al.* Ethylene oxide and risk of lympho-hematopoietic cancer and breast cancer: a systematic literature review and meta-analysis. *Int Arch Occup Environ Health* 92, 919–939 (2019). https://doi.org/10.1007/s00420-019-01438-z; B. Gollapudi *et al.* Genotoxicity as a toxicologically relevant endpoint to inform risk assessment: A case study with ethylene oxide, Environmental and Molecular Mutagenesis, (Sept. 14, 2020) *available at https://onlinelibrary.wiley.com/doi/epdf/10.1002/em.22408*.

[15] Since ACC largely concurs with the TCEQ peer review final value we focus the remainder of our discussion on that value.

the selection of the IRIS value (rather than the TCEQ value) required a very different analysis, and led to a very different result.

As explained in the ACC and EO Panel comments, if EPA had selected the alternative risk value presented by TCEQ, it would have concluded that risks from the source category were acceptable with an ample margin of safety. The comments evaluated this claim and supported it through conducting risk modeling using TCEQ's alternative, which was substituted for the IRIS value in the human exposure model (HEM)-3 dose-response library. The risk model was then re-run for the two facilities with the highest category-specific cancer risk. The results are summarized below and in greater detail in both sets of comments.

For Huntsman Performance, if EPA had used the proposed TCEQ value, the maximum cancer risk for its facility site would have dropped to 1 in 1 million from the proposed 300 in 1 million with the IRIS value. This level is well below EPA's presumptive limit of acceptability. For Lanxess, selection of the TCEQ risk value would have reduced the cancer risk level to below 20 in 1 million, a significant reduction from the 2,000 in 1 million level initially calculated using the IRIS value and also significantly below the presumptive acceptability level. If EPA had used the TCEQ value in either modeling scenario, it would have found that both facilities are well within the acceptable risk range.

ACC's comments demonstrate the significant impact of alternative risk values, particularly the TCEQ value, on the estimated maximum cancer risks for the MON source category, as calculated by EPA. As described above, the reduced risk levels as a result of the revised final TCEQ value would have allowed EPA to conclude that overall source category risks are acceptable with an ample margin of safety, without requiring any additional controls. Further, ACC's risk modeling using the same inputs as EPA's HEM in the proposed and final MON rules indicate that the risk for the source category decreases significantly with the use of the revised TCEQ risk value. At proposal, the risk level for Huntsman would have been 1 in 1 million and the risk level for Lanxess would have been 20 in 1 million. In the final rule, the risk level for Huntsman would have been 0.5 in 1 million and the risk level for Lanxess would have been 10 in 1 million <u>without the imposition of additional controls</u>. These values are highlighted in the table below and compared against the actual values that EPA proposed and finalized.

Scenario		Facility	Category-Specific Cancer Maximum Individual Risk (MIR) (in 1 million)[16]	
			EO IRIS URE	Revised EO TCEQ URE
			URE = 5 x 10^{-3} per µg/m^3 (9.1 per ppm)	URE = 2.3 x 10^{-6} per µg/m^3 (4.2 x 10^{-3} per ppm)
1	EPA Emissions Engineering Calculations at Proposal (Baseline Risk Scenario)	Huntsman (EIS ID = 4945611) (Conroe, TX)	300	1
		Lanxess (EIS ID = 3965211) (Charleston, SC)	2,000	20
2	Updated Actual Emissions in Final Rule (Revised Risk Scenario)	Huntsman (EIS ID = 4945611) (Conroe, TX)	20	0.5
		Lanxess (EIS ID = 3965211) (Charleston, SC)	400	10

In addition to supporting a conclusion that risks were within the presumptively acceptable range, these values also provide substantial support for the argument that the additional controls specified in 40 CFR 63.2493 should not have been required to provide an ample margin of safety. The impact on risks are particularly critical considering that the basis for imposing these controls was to reduce EO emissions, which, when properly considered, is not a driver of risk.[17]

[16] The values expressed in these columns for the EO IRIS URE and the Revised EO TCEQ URE represent the increase in risk from inhalation exposure of one microgram per cubic meter. As defined by EPA: "Inhalation unit risk (IUR) is an estimate of the increased cancer risk from inhalation exposure to a concentration of 1 µg/m3 for a lifetime. The IUR can be multiplied by an estimate of lifetime exposure (in µg/m3) to estimate the lifetime cancer risk." The values in the table demonstrate that the increased cancer risk per 1 µg/m3 exposure of EO over a lifetime is 5 in 1,000 using EPA's estimate, but 2.3 in 1,000,000 based on TCEQ's estimate –a much smaller risk.

[17] ACC's risk modeling also found that using any combination of more appropriate dose-response risk values or more accurate emissions inputs indicates lowered risks both from EO as well as other risk drivers (e.g., ethylene dichloride), which are the primary source of risk after EO has been properly assessed.

As the modeling results above indicate and consistent with EPA's statements in the MON, an overwhelming portion of the source category modeled risk in the MON RTR is attributable to EO emissions informed by the inaccurate IRIS value. When those risks are properly assessed with a more appropriate value like that of TCEQ, the risk levels significantly decrease. Accordingly, there is ample support for the argument that EPA should have reasonably concluded that the imposition of additional emissions controls in §63.2492 and §63.2493 was not necessary to provide an ample margin of safety particularly given that their imposition would not have meaningfully reduced risks.

III. CONCLUSION

For the reasons stated above, EPA is required to convene a reconsideration proceeding regarding the need for any additional emission monitoring and controls for EO under CAA section 307(b)(7)(D).