Texas Commission on Environmental Quality (TCEQ) Responses to Public Comments Received on the Proposed Development Support Document for 2-Butene April 15, 2008

The public comment period for the proposed Development Support Document (DSD) for 2-butene ended in March 2008. The Texas Chemical Council (TCC) and ExxonMobil Refining & Supply Company submitted comments. The Toxicology Section (TS) of the TCEQ appreciates the effort put forth by TCC and ExxonMobil to provide technical comments on the proposed DSD for 2-butene. The goal of the Toxicology Section and 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 TCC and ExxonMobil comments are provided below, followed by TCEQ responses. The full comments of TCC and ExxonMobil are in Appendices 1 and 2, respectively. Comments on issues that suggest a change in the DSD are addressed whereas comments agreeing with TCEQ's approach are not. TCEQ responses indicate what changes, if any, were made to the DSD in response to the comment.

A new section entitled *Comparison of ^{acute}ESL to Generic ESL* was added to the DSD since the ESL Guidelines suggest that when a subacute study is used to derive the ^{acute}ESL, a comparison to a generic ESL should be made to determine whether the ^{acute}ESL based on the subacute study is too conservative.

Texas Chemical Council (TCC) Comments Regarding the 2-Butene DSD

1. **Comment:** TCEQ should consider a hazard quotient of 1.0 in developing an acute ESL for 2-butene. . . TCEQ incorporates an uncertainty factor of 300. Health protective assumptions have been considered and built into the derivation of the acute ReV for 2-butene, such that the available evidence does not support the need for additional factors for health protection.

   Response: The DSD was not revised based on this comment. The TCEQ applied a total uncertainty factor of 300 to account for uncertainties in using animal data to predict the human response, variability of the human response as well as to protect susceptible members of the population, and database uncertainties. In order to develop ESLs for use in air permitting that adequately consider the potential for cumulative and aggregate exposures, the TS continues to believe that it is prudent to use an HQ less than 1 for chemical effects whose dose-response relationship is known or assumed to be nonlinear (which generally consist of noncarcinogenic effects). Consideration of cumulative risk is required by the Texas Water Code Subchapter D Section 5.130. Consideration of cumulative and aggregate concerns is also consistent with empirical evidence such as ambient air monitoring data that demonstrate the presence of multiple chemicals in the air at the same time and the repeated presence of the same chemical(s) over time, as well as

the fact that multiple sources of the same chemical can contribute to the concentration of that chemical at a single location. At the same time, the TS recognizes that the choice of a specific HQ less than 1 is a policy decision. TCEQ Regulatory Guidance 442 Section 1.4 Specific Risk Management Objectives (No Significant Risk Levels) states: "In consideration of cumulative and aggregate exposure, the Toxicology Section (TS) uses an HQ of 0.3 to calculate short-term and long-term ESLs for chemicals with a nonlinear dose-response assessment."

2. **Comment:** TCEQ Should Reconsider the Appropriateness of Using 50% Odor Detection Thresholds in the Development of ESLs. . . . Often the test methods and conditions are not reported in detail making it difficult to choose the most reliable value. In the case of 2-butene, the TCEQ references the 50% odor threshold value reported by Katz and Talbert (1930 as reported in Van Gemert 2003) of 4.8 mg/m^3 for 2-butene. At the same time TCEQ references recognition odor thresholds for 28.5 and 2,700 mg/m^3 for cis-2-butene and trans-2-butene, respectively. While the 6-fold differences between 2-butene (mixed isomers) and cis-2-butene odor thresholds may be at least partially explained by the difference in recognition versus 50% threshold, the more than 500 fold difference between the trans-2-butene and 2-butene odor thresholds appear to be at odds with each other. This clearly demonstrates the lack of precision and thus reliability around reported odor thresholds.

   Response: The DSD was not revised based on this comment. We agree the more than 500-fold difference between the trans-2-butene and 2-butene odor thresholds appear to be at odds with each other, but the value for trans-2-butene of 2,700 mg/m^3 was obtained from Mullins (1955 in van Gemert 2003), which was not an approved odor detection source. 2-Butene's proposed odor-based ESL adheres to TCEQ's 2006 regulatory guidance document, *Guidelines to Develop Effects Screening Levels, Reference Values, and Unit Risk Factors* (RG-442), that underwent external scientific peer review and two rounds of public comment. Furthermore, development of 2-butene's odor-based ESL included a comprehensive literature search, consideration of all available 2-butene odor studies, and selection of the lowest 50% odor detection threshold among the approved studies that meet the American Industrial Hygiene Association and USEPA odor evaluation criteria. 2-Butene's odor-based ESL is considered a useful tool in the air permit review process, and addresses the Commission's mandate to protect public welfare and public enjoyment of air resources.

3. **Comment:** TCC believes that, if TCEQ continues to rely on odor thresholds as a basis for ESLs, it is extremely important to indicate that these values are not based on anticipated health effects but rather simply represent a conservative estimate of a "nuisance" level.

   Response: The DSD was not revised based on this comment. The fact that odor-based ESLs are not derived on anticipated health effects is clear in the DSD. ESLs, including odor-based ESLs, are intended to be guidelines and not strict standards. For example, when applying the odor-based ESL in an air permit application review, consideration of

the nature of the odor, the surrounding land use, the frequency of odor-based ESL exceedance, and the odor complaint history at the site, all play a role in allowing off-site concentrations that exceed the odor-based ESL. 2-Butene is odorous at a concentration much lower than the concentration which could cause an adverse health effect. Because of this, if the permit applicant's predicted or monitored 2-butene concentrations are allowable from an odor perspective, they are allowable from a health perspective as well.

ExxonMobil
Comments Regarding the 2-Butene DSD

4. **Comment:** It is clear that the RG-442 guidelines were fully implemented as designed by the TERA group.

   Response: It is unclear what ExxonMobil meant by the reference to the TERA group, although this acronym is used by Toxicology Excellency for Risk Assessment. Although TERA organized the peer-review of the ESL Guidelines, the Toxicology Section wrote the guidelines.

5. **Comment:** ExxonMobil's general comment on the 5 DSD documents (list above) pertains to the development and/or application of the odor threshold value as the basis of short-term ESL permit review values. . . ExxonMobil offers that the body of data and information surrounding the very important odor limit values are not very robust, and the primary documents from Katz and Talbert (1930's) with updates from Nagata (2002) should be investigated with more current and technically precise methods.

   Response: The DSD was not revised based on this comment. If more current and technically precise methods are developed, the Toxicology Section will consider the updated odor studies. Refer to Response to Comments # 2 and 3.

APPENDIX 1

Texas Chemical Council (TCC)
Comments on TCEQ's Proposed Developmental Support Document for 2-Butene dated January 2008

TEXAS CHEMICAL COUNCIL
1402 Nueces Street • Austin, Texas 78701-1586 • (512) 646-6400 • Fax (512) 646-6420

March 17, 2008

Toxicology Section, MC 168
Texas Commission on Environmental Quality
P.O. Box 13087
Austin, TX 78711-3087

Re: Texas Chemical Council Comments Regarding the 2-Butene Effects Screening Level Development Support Document

TCEQ Toxicology Section:

The Texas Chemical Council (TCC) submits these comments in response to the Texas Commission on Environmental Quality's (TCEQ) request for public comments on its Effects Screening Level (ESL) Development Support Document concerning 2-butene.

The Texas Chemical Council is a statewide trade association representing approximately 85 chemical manufacturers at over 200 Texas facilities. Our industry has invested more than $50 billion in physical assets in the State and pays over $1 billion annually in state and local taxes. TCC's members provide approximately 70,000 direct jobs and over 500,000 indirect jobs to Texans across the State.

TCC appreciates the opportunity to comment on the ESL values for 2-butene. TCC understands the importance of ESLs in providing TCEQ with guidance to protect human health and welfare regarding its authority for air permitting and air monitoring. Air quality is also important to the regulated community, particularly to members of TCC.

In general, TCC believes the Draft Development Support Document for 2-butene is scientifically sound and demonstrates the diligence of TCEQ in developing supportable values. The attached document discusses more fully TCC's specific comments, noted below:

- TCC agrees with TCEQ's selection of the study of Waalkens-Brendsen & Arts (1992) as the key study for developing a health-based acute ReV and ESL for 2-butene
- TCEQ should consider a hazard quotient of 1.0 in developing an acute ESL for 2-butene
- TCEQ should reconsider the appropriateness of using 50% odor detection thresholds in the development of ESLs.

By offering the attached comments, TCC hopes to provide scientific perspectives to enhance the basis of the ESL values for 2-butene.

Again, TCC appreciates the opportunity to comment on this important document and looks forward to future discussions with TCEQ.

Sincerely,

Michael McMullen
Director of Regulatory Affairs
Texas Chemical Council

Texas Chemical Council (TCC)

Comments on TCEQ's Proposed Developmental Support Document for 2-Butene dated January 2008

In general, TCC believes the Proposed Development Support Document for 2-Butene is scientifically sound and well presented. However, TCC believes that in some areas, TCEQ was overly conservative in its approach. TCC offers the comments below for TCEQ's consideration.

TCC Agrees with TCEQ's Selection of the Study of Waalkens-Brendsen & Arts (1992) as the Key Study for Developing a Health-Based Acute ReV and ESL for 2-Butene

The Waalkens-Brendsen & Arts (1992) study is a well-conducted, comprehensive study in which rats were exposed to 2-butene at concentrations up to 5,000 ppm, 7 days per week, for 39-46 days. The only significant finding was minimal body weight changes in female rats at the 5,000 ppm level. TCC agrees with TCEQs determination of 2,500 ppm as the NOAEL and 5,000 ppm as the LOAEL for this study. Furthermore, TCC supports TCEQ's use of 2,476 ppm as the point of departure in determining the acute ReV and ESL for 2-butene.

TCEQ Should Consider A Hazard Quotient of 1.0 in Developing an Acute ESL for 2-Butene

As stated in previous comments submitted to TCEQ, TCC continues to have strong reservations concerning the use of a hazard quotient (HQ) of less than 1.0 for noncarcinogenic effects for any purpose, including consideration of cumulative and aggregate exposures. In deriving the acute ReV for 2-butene, TCEQ incorporates an uncertainty factor of 300. Health protective assumptions have been considered and built into the derivation of the acute ReV for 2-butene, such that the available evidence does not support the need for additional factors for health protection. In the case of 2-butene, exposure to rats of 5,000 ppm, 6 hours per day, 7 days per week for a period of 39-46 days did not result in any significant systemic toxicity. Only minimal changes in female body weights were noted at the 5,000 ppm dose level. Based on consideration of all the data, it is, therefore, likely that a short-term (hourly average) ESL of 15 ppm would be appropriate in regard to any potential acute effects of short-term 2-butene exposures.

TCEQ Should Reconsider the Appropriateness of Using 50% Odor Detection Thresholds in the Development of ESLs.

TCC believes that it is inappropriate to use odor thresholds in the development of ESLs. Published odor thresholds for a given material can vary dramatically; in some cases by several orders of magnitude. This variability has been attributed to a number of factors including, but not limited to, reliance on different test methods, trained versus untrained test subjects or "sniffers", purity of the test sample, differences in test environment conditions such as temperature and humidity and human variability. Often the test methods and conditions are not reported in detail

making it difficult to choose the most reliable value. In the case of 2-butene, the TCEQ references the 50% odor threshold value reported by Katz and Talbert (1930 as reported in Van Gemert 2003) of 4.8 mg/m^3 for 2-butene. At the same time TCEQ references recognition odor thresholds for 28.5 and 2,700 mg/m^3 for cis-2-butene and trans-2-butene, respectively. While the 6-fold differences between 2-butene (mixed isomers) and cis-2-butene odor thresholds may be at least partially explained by the difference in recognition versus 50% threshold, the more than 500 fold difference between the trans-2-butene and 2-butene odor thresholds appear to be at odds with each other. This clearly demonstrates the lack of precision and thus reliability around reported odor thresholds. Simply relying on the lowest values without further justification is likely to result in an unnecessarily low and overly conservative ESL values. In summary, TCC believes that given the high variability of existing threshold values, and the apparent absence of a method capable of generating a reproducible result, TCEQ should not rely on odor thresholds in the development of ESLs for 2-butene.

TCC believes that if TCEQ continues to rely on odor thresholds as a basis for ESLs that it is extremely important to indicate that these values are not based on anticipated health effects but rather simply represent a conservative estimate of a "nuisance" level.

References

Waalkens-Brendsen, D.H. and Arts, J.H.E. (1992) Combined Short Term Inhalation and reproduction/developmental toxicity Screening Test with Butene-2 in Rats. Proj. # B91-8336 (Study # 1410).

Katz, SH and EJ Talbert. 1930. Intensities of odors and irritating effects of warming agents for inflammable and poisonous gases. Washington, D.C., U.S. Dept. of Commerce, Bureau of Mine. Technical Paper 480.

Van Gemert, LJ. 2003. Odour thresholds. Compilations of odour threshold values in air, water and other media. Oliemans Punter & Partners BV, The Netherlands.

Appendix B

ExxonMobil Comments on Proposed DSDs

From: <judy.m.bigon@exxonmobil.com>
To: <tox@tceq.state.tx.us>
Date: Mon, Mar 24, 2008 8:51 AM
Subject: ExxonMobil Comments on Proposed DSDs

ATTN: Dr. Michael Honeycutt and Roberta Grant

ExxonMobil Downstream & Chemical Safety Health and Environmental (SHE) submits comments on the latest list of Development Support Documents (DSD) for Effects Screening Level (ESL) development. The chemicals of interest to ExxonMobil are 1) Butene-1; 2) Butene-2; 3) Ethylene; 4) Isobutene; and 5) 1-butene. Our understanding is the DSD is the summary document of available technical health and environmental information and the DSD's were developed according to RG-442 Guidelines to Develop Effects Screening Levels, Reference Values and Unit Risk Factors.

ExxonMobil congratulates the TCEQ on the thorough and complete preparation of these DSD's, and it is clear that the RG-442 guidelines were fully implemented as designed by the TERA group. The RG-442 guidelines appear to be a significant procedure that allows the TCEQ to craft a whole, complete technical dossier on individual chemicals in order to arrive at technically sound and defensible Effects Screening Levels that are protective of public health and welfare. ExxonMobil especially applauds the TCEQ on the open and transparent processes that were used to develop the DSD's, to include the public discussions that TCEQ staff offered for individual DSD review as well as data solicitation early in the process. ExxonMobil provided information and data to the TCEQ staff early in the process, and was engaged as one of the many stakeholders in the ESL development. We want to encourage TCEQ to continue this progressive and open scientific development process, guided by RG-442 and a cooperative spirit.

ExxonMobil's general comment on the 5 DSD documents (list above) pertains to the development and/or application of the odor threshold value as the basis of short-term ESL permit review values. We believe that the TCEQ has essentially done its best with respect to evaluation and implementation of an odor threshold value to describe the short-term ESL permit targets, and those targets are uniformly lower than both Acute and Chronic health values such that the public can and should feel confident that TCEQ ESL values are conservative in a manner to protect against human health effects. As well, the information with respect to odor thresholds used to develop these latest DSD's allowed a general relaxation of earlier (i.e., 2003) acute odor limit values, which had obviously been set using quite conservative values and techniques. ExxonMobil offers that the body of data and information surrounding the very important odor limit values are not very robust, and the primary documents from Katz and Talbert (1930's) with

updates from Nagata (2003) should be investigated with more current and technically precise methods. Since these odor values essentially take precedence over all the very sophisticated acute/chronic ReV's and URF's, the TCEQ should encourage the more complete and accurate development of these values in the future.

A specific comment on the proposed odor ESL value for 1-butene, the selection of the lowest value of the three studies (i.e., 170 ppb from Hellman, 1974) over more recent values and those chosen as the basis for other chemicals (i.e., 330 ppb from Nagata, 2003) is tenuous, however it is consistent with the RG-442 guidelines to use the lowest value from an appropriate study as you explain in the DSD for 1-butene. We feel that TCEQ will be challenged in areas such as this, for example with respect to the chronic ESL/ReV values for both 1-butene and 2-butene. TCEQ carefully followed the guidelines laid out by TERA in the 2006 RG-442 document, and properly chose to not establish the chronic ReV as the minimum data sets were not met.

ExxonMobil supports the values developed by TCEQ with respect to Acute and Chronic ESL values for health and welfare for the 5 chemicals listed above. ExxonMobil wants to reiterate the significant effort and collegial approach that TCEQ has employed in this latest set of DSD's. Overall, the current Acute and Chronic ESL proposed values were developed in a documented scientific manner, with clear and transparent methods, and include the maximum amount of actual published data and methods to interpret those data based on the publically reviewed and agreed upon approaches laid out in RG-442. ExxonMobil would very much like to continue to be included in these processes and offer our technical services whenever TCEQ and the public feel they are necessary.

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