

# Texas Commission on Environmental Quality Response to Public Comments

## February 2014 White Paper

### TCEQ Guidelines to Develop 24-Hour Inhalation Reference Values

The Center for Advancing Risk Assessment Science and Policy (ARASP) submitted comments dated May 6, 2014 on the Proposed White Paper entitled *TCEQ Guidelines to Develop 24-Hour Inhalation Reference Values*. The Texas Commission on Environmental Quality (TCEQ) appreciates the effort put forth by ARASP to provide technical comments on the White Paper. The goal of the TCEQ is to protect human health and welfare based on the most scientifically-defensible approaches possible and evaluation of these comments furthered that goal. A summary of comments from ARASP is provided below, followed by TCEQ responses. The full comments are provided in Appendix 1. Comments on issues that suggest changes in the White Paper are addressed whereas comments agreeing with TCEQ's approach are not. TCEQ responses indicate what changes, if any, were made to the White Paper in response to the comment.

#### **Comment No. 1: Problem Formulation**

Problem Formulation - the whitepaper states that derivation of chemical specific 24-hour ReVs might be needed, specifically in the case of those chemicals where the duration of exposure is a contributing factor. TCEQ should consider adding language to the whitepaper noting that when a 1-hour ReV is adequate and scientifically justified, based on the mode of action, to account for effects elicited from a single 24-hour exposure then a 24-hour ReV should not be calculated.

#### **TCEQ Response:**

The White Paper was not revised based on this comment. The TCEQ recognizes that a 1-hour ReV may also be protective of a 24-hour exposure. In those cases, the TCEQ will set the 24-hour ReV equal to the 1-hour ReV, then provide documentation in the Development Support Document (DSD) on the scientific justification for the 1-hour and 24-hour ReV being the same. The White Paper already addresses this issue (bottom of Page 2 to top of Page 3):

*The following are some examples of toxicity studies that may be appropriate for derivation of a 24-h ReV: . . .*

- *studies using exposure durations of less than 6 h must be used cautiously, and may only be appropriate when available data indicate that the primary toxic effect induced by a chemical is irritation, the magnitude of which is generally determined by exposure concentration, and exposure to 24-h would not be expected to have additional adverse effects other than the irritation;*

**Comment No. 2 Mode of Action and Dose Metric**

Mode of Action and Dose Metric - in this section of the whitepaper TCEQ identifies some questions for consideration in the evaluation. Additional questions that TCEQ should consider including are: (1) Are the adverse effects seen relevant to humans? (2) Are the adverse effects reversible given the exposure duration? and (3) Are the adverse effects biologically plausible?

**TCEQ Response:**

The White Paper was revised to include the additional questions suggested by ARASP.

**APPENDIX 1**

**Center for Advancing Risk Assessment**

**Science and Policy (ARASP)**

**Comments**



May 6, 2014

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SUBMITTED VIA EMAIL: [tox@tceq.texas.gov](mailto:tox@tceq.texas.gov)

**RE: Request for Public Comment on the Whitepaper – TCEQ Guidelines to Develop 24-Hour Inhalation Reference Values**

Dear Sir or Madam:

The Center for Advancing Risk Assessment Science and Policy<sup>1</sup> (ARASP), which is managed by the American Chemistry Council<sup>2</sup> (ACC), welcomes the opportunity to provide comments on the Texas Commission on Environmental Quality's (TCEQ) whitepaper titled: "TCEQ Guidelines to Develop 24-Hour Inhalation Reference Values." ARASP fosters activities to promote the adoption of policies and practices that assure the most relevant science and methodologies are used as the foundation for assessing potential risks from chemical exposures.

We commend the TCEQ for recognizing the importance of appropriately evaluating and characterizing acute inhalation exposures. The whitepaper lays out a framework for how the TCEQ will determine the relevance for developing a 24-hour reference value (ReV), analyze the availability and utility of the information for derivation of the ReV and utilize mode of action information to inform the calculations. The whitepaper also highlights the importance of understanding how a chemical interacts with the body during exposure and what key events are necessary to induce effects. Additionally, the approach encourages the consideration of all data and acknowledges the need to carefully evaluate each step of a mode of action (MOA), when

<sup>1</sup> ARASP is a coalition of nineteen organizations focused on promoting the development and application of up-to-date, scientifically sound methods for conducting chemical assessments. ARASP members include: Acrylonitrile Group, ACC's Chlorine Chemistry Division, Ethylene Oxide Panel, Formaldehyde Panel, Hexavalent Chromium Panel, High Phthalates Panel, Hydrocarbon Solvents Panel, Olefins Panel, Oxo Process Panel, Propylene Oxide/Propylene Glycol Panel, Public Health and Science Policy Team, Silicones Environmental, Health and Safety Center of North America and Vinyl Chloride Health Committee, American Cleaning Institute, American Petroleum Institute, CropLife America, Halogenated Solvents Industry Alliance, Nickel Producers Environmental Research Association and Styrene Information and Research Center. More information can be found: <http://arasp.americanchemistry.com/>

<sup>2</sup> ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$770 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for 12 percent of U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.



known, to ensure that available relevant and reliable toxicokinetic and toxicodynamic information is considered. ARASP strongly supports the use of MOA in chemical assessments, and strongly supports the MOA approach put forward by TCEQ.

TCEQ has conducted several rounds of peer review on the proposed guidelines and revised them as appropriate based on those comments. Included here are two additional suggestions to help improve the clarity and implementation of the guidelines.

- **Problem Formulation** - the whitepaper states that derivation of chemical specific 24-hour ReVs might be needed, specifically in the case of those chemicals where the duration of exposure is a contributing factor. TCEQ should consider adding language to the whitepaper noting that when a 1-hour ReV is adequate and scientifically justified, based on the mode of action, to account for effects elicited from a single 24-hour exposure then a 24-hour ReV should not be calculated.
- **Mode of Action and Dose Metric** - in this section of the whitepaper TCEQ identifies some questions for consideration in the evaluation. Additional questions that TCEQ should consider including are: (1) Are the adverse effects seen relevant to humans? (2) Are the adverse effects reversible given the exposure duration? and (3) Are the adverse effects biologically plausible?

ARASP supports TCEQ's efforts to develop these guidelines and appreciates the opportunity to provide additional review and comment. If you have any questions or require further information please feel free to contact me by phone (202-246-7000) or by email [kimberly\\_wise@americanchemistry.com](mailto:kimberly_wise@americanchemistry.com).

Respectfully,

Kimberly Wise, Ph.D  
Senior Director  
Chemical Products & Technology Division  
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