Texas Commission on Environmental Quality Responses to Public Comments on the 2015 Guidelines Revision

September 28, 2015

Texas Commission on Environmental Quality Toxicology Division Office of the Executive Director

Prepared by:

Toxicology Division Office of the Executive Director

Comments from the Public

The Texas Commission on Environmental Quality (TCEQ) received one set of public comments from Kimberly White, Senior Director with the American Chemistry Council (ACC) dated July 17, 2015, on the 2015 updates to the 2012 *TCEQ Guidelines to Develop Toxicity Factors* (RG-442, hereafter referred to as the Guidelines). The TCEQ appreciates the effort put forth by ACC to provide comments on the 2015 Guidelines updates. Incorporation of suggested revisions is done for those comments which increase the scientific and technical merit of the Guidelines or clarity for agency staff. A summary of comments are provided below with the response, a full copy of the received comments are attached at the end.

ACC Comments

Comment 1

While TCEQ has indicated that the intent of the odor-based value is to prevent odor nuisance conditions, ARASP has previously noted there is considerable variability and uncertainty in the use of odor for ESL development. We continue to recommend that language be included in the current guidelines on the uncertainty with the odor based screening levels and we have also provided separate public comments on the TCEQ position paper titled: Approaches to Derive Odor-Based Values (Proposed April 2015).

Response: TCEQ appreciates the recommendation; however, at this time methods for deriving odor values may be found in the TCEQ position paper: *Approaches to Derive Odor-Based Values*.

Comment 2

We would also recommend that on future revisions to TCEQ Guidelines that the agency provide a summary response to the comments received on the Guidelines in addition to any record of change document.

Response: TCEQ appreciates the recommendation; however, a summary of comments received are always included with our responses for all documents that undergo a public comment period. The response to comment documents are provided publicly on our webpage.



July 17, 2015

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

Submitted Via Email: tox@tceq.texas.gov

RE: Request for Public Comment on the 2015 Revision of the TCEQ Guidelines to Develop Toxicity Factors

Dear Sir or Madam:

The American Chemistry Council's Center for Advancing Risk Assessment Science and Policy (ARASP), appreciates this additional opportunity to provide comments in response to the Texas Commission on Environmental Quality's (TCEQ) request for public comment on the 2015 revision of the Guidelines to Develop Toxicity Factors (Guidelines). ARASP is a coalition of twenty-two independent groups that promotes the development and application of up-to-date scientific methods for conducting chemical assessments. Previously, ARASP submitted comments on the 2012 revision to the Guidelines which focused on the: use of odor as a basis for an effect screening level; use of the shape of the dose-response curve in the selection of point of departures (POD); and consideration of uncertainty associated with the derivation of the effect levels.

We recognize the importance of developing objective and transparent guidelines for the generation of toxicity values. ARASP commends the TCEQ for seeking public engagement, undergoing considerable peer review and revising the Guidelines to reflect the scientific input received to strengthen the Guidelines. The revised Guidelines provide expanded discussion on: how the literature for identification of toxicity studies is considered and applied in the derivation of values; and it also presents an informative discussion on study quality considerations, the utilization of mode of action (MOA) and the key questions that should be evaluated when utilizing the available data to make decisions regarding toxicity. ARASP appreciates the TCEQ's review of our 2012 comments and the incorporation of our suggested edits to the acronyms lists, Table 5-4, as well as providing additional clarification on animal-to-human inhalation dosimetry, route-to-route extrapolation and selection of PODs in development of 24-h reference values.

The TCEQ has also recognized the importance of providing clarification regarding its use of odor as the basis to develop effect screening levels (ESLs) by releasing an additional document for public comment focused on this issue. While TCEQ has indicated that the intent of the odorbased value is to prevent odor nuisance conditions, ARASP has previously noted there is considerable variability and uncertainty in the use of odor for ESL development. We continue to recommend that language be included in the current guidelines on the uncertainty with the odor based screening levels and we have also provided separate public comments on the TCEQ position paper titled: Approaches to Derive Odor-Based Values (Proposed April 2015).

ARASP thanks TCEQ for the opportunity to review the revised guidelines prior to them being made final. We would also recommend that on future revisions to TCEQ Guidelines that the agency provide a summary response to the comments received on the Guidelines in addition to any record of change document.

Should you have any questions please contact me by phone at 202-249-6707 or via email at kimberly_white@americanchemistry.com.

Respectfully,

Kimberly Wise White, PhD American Chemistry Council (ACC) Senior Director Chemical Products & Technology Division

On Behalf of ARASP

ARASP members:

Acrylonitrile Group American Cleaning Institute American Composite Manufacturers Association American Forest and Paper Association American Petroleum Institute ACC Chlorine Chemistry Division ACC Ethylene Oxide Panel ACC Formaldehyde Panel ACC Hexavalent Chromium Panel ACC High Phthalates Panel ACC Hydrocarbon Solvents Panel **ACC** Olefins Panel **ACC Oxo Process** ACC Propylene Oxide/Propylene Glycol Panel ACC Health, Products, and Science Policy Committee ACC Silicones Environmental, Health and Safety Center of North America ACC Vinyl Chloride Health Committee CropLife America Halogenated Solvents Industry Alliance Nickel Producers Environmental Research Association Styrene Information and Research Center Wood Preservative Science Council