

Jon Niermann, *Chairman*
Emily Lindley, *Commissioner*
Toby Baker, *Executive Director*



TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

Protecting Texas by Reducing and Preventing Pollution

April 26, 2019

Sector Policies and Programs Division
Office of Air Quality Planning and Standards
United States Environmental Protection Agency
Mail Code: 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

Attn: Docket ID No. EPA-HQ-OAR-2018-0417

Re: National Emission Standards for Hazardous Air Pollutants: Hydrochloric Acid Production Residual Risk and Technology Review

To Whom it May Concern,

The Texas Commission on Environmental Quality (TCEQ) appreciates the opportunity to respond to the United States Environmental Protection Agency's (USEPA) request for public comments on their proposed amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Hydrochloric Acid (HCl) Production. The TCEQ's comments specifically address the USEPA's estimation of facility-wide risks due to ethylene oxide.

The TCEQ comments that the USEPA unit risk factor (URF) for ethylene oxide is not scientifically justified. More specifically, use of a supra-linear dose-response must be strongly supported by biological or mechanistic data, which the USEPA has not done for ethylene oxide. Ethylene oxide is produced endogenously by the body at doses that are above those that would be generated from exposure to typical ambient concentrations of this chemical, or by exposure to USEPA's acceptable air concentrations.

In their 2016 IRIS assessment, USEPA (2016)¹ indicates that sublinearity is highly plausible in this endogenous range, which is completely contrary to USEPA's use of an exceptionally high dose-response slope from the supra-linear model in this dose region where USEPA acknowledges that sublinearity is expected. The result is the estimation that unreasonably low air concentrations of 0.0001-0.01 ppb cause excess cancer risk in the range of 1E-06 to 1E-04. By comparison, continuous air concentrations of 0.56, 1.6, and 4.5 ppb correspond to the 5th percentile, median, and 95th percentile of the normal endogenous background concentrations in the unexposed general population (Table 4 of Kirman & Hays 2017²).

¹ USEPA, 2016. Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide: In Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-16/350Fa

² Kirman, C.R., Hays, S.M., 2017. Derivation of endogenous equivalent values to support risk assessment and risk management decisions for an endogenous carcinogen: ethylene oxide. *Regul. Toxicol. Pharmacol.* 91, 165-172.

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As a scientifically reasonable alternative, the TCEQ is in the process of deriving a URF for ethylene oxide based on the same underlying data as is used by USEPA, but with a different modeling approach that will consider biological and mechanistic data for extrapolation down to environmental concentrations (e.g. endogenous levels). A public draft of the TCEQ's assessment can be expected in a few short months for any who are interested in an ethylene oxide URF that is derived using a more biologically-plausible low-dose extrapolation method.

If there are any questions concerning the TCEQ's comments, please contact Ms. Allison Jenkins, Toxicology Division, at 512-239-0656 or allison.jenkins@tceq.texas.gov. We look forward to working with EPA throughout this process.

Sincerely,

A handwritten signature in black ink, appearing to read 'Toby Baker', written in a cursive style.

Toby Baker
Executive Director
Texas Commission on Environmental Quality

Enclosure