TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

News Release

After years of careful review and analysis, TCEQ updates ethylene oxide exposure limit

Chemical critical for sterilizing medical equipment safer than previously thought

For Immediate Release
Friday, May 15, 2020
Media Contact: Andrew Keese
Phone: 512-239-0060; Mobile: 512-695-8072

After years of extensive study, public input and peer review, TCEQ today finalized its updated safe exposure level for ethylene oxide.

The agency has established a long-term effects screening level of 2.4 parts per billion, which is the health-protective air concentration used to determine limits for proposed air permits in Texas. TCEQ's previous ethylene oxide ESL, a preliminary standard, was 1 ppb.

TCEQ's final ethylene oxide ESL comes during a unique period of strain on the nation's medical industry. TCEQ's ethylene oxide cancer dose-response assessment demonstrates that this chemical, which is used to sterilize half of the approximately 40 billion medical devices used in the United States every year, poses less risk than was previously thought.

Previous assessments of the chemical's risk by other agencies forced the closure of some ethylene oxide sterilization facilities in other parts of the country and threaten more closures. These closures have already caused a shortage of pediatric tracheostomy (breathing) tubes, and the U.S. Food and Drug Administration has issued an alert about possible additional disruptions in the supply of sterile medical devices.

While the agency's assessment is a purely scientific exercise and does not consider the implications for the supply of sutures, surgical kits, and other medical devices, TCEQ's final ESL for ethylene oxide may help mitigate these supply chain risks. Using the most current science, the new limit remains protective for people living near facilities that emit ethylene oxide while providing flexibility for the medical sterilization industry to continue its own critical role in patient care in the state of Texas.

TCEQ began its cancer dose-response assessment for ethylene oxide in 2017 and published a draft assessment for public comment in 2019. A revised assessment was then peer reviewed by an independent, external panel of scientific experts, who completed their work in early 2020. The resulting rigorous final assessment, responses to public and expert comments, and other information regarding ethylene oxide can be found at www.tceq.texas.gov/toxicology/ethylene-oxide.

xxx