



Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

May 20, 2021

Ms. Sandra Hart, Chair, Lake County Board
Mr. Tim Sashko, President, Lake County Board of Health
Lake County Board Office
18 North County Street, 10th Floor
Waukegan, Illinois 60085-4351

Dear Ms. Hart and Mr. Sashko:

Thank you for your April 14, 2021, letter to Dr. Patrick Breysse, Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (ATSDR). I am the Director of the Office of Community Health and Hazard Assessment, and Dr. Breysse has asked that I respond to your request.

In March 2019, ATSDR received a formal letter of petition from the Lake County Health Department (LCHD) requesting that the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (ATSDR) perform a health risk assessment based on ambient air monitoring for ethylene oxide (EtO) around two Lake County facilities—Vantage Specialty Chemicals and Medline Industries. The petition described EtO air quality sampling collection that was to begin June 2019 by a vendor to be hired by Lake County, City of Waukegan, and the Village of Gurnee. The petition stated that Lake County Health Department and Community Health Center (LCHD/CHC) would provide ATSDR with a draft sampling and analysis plan and quality assurance project plan for review.

On April 10, 2019, ATSDR responded to the petition and stated that “after the results of the EtO air monitoring program are available, ATSDR will then be able to determine what additional public health activities would be appropriate.” In addition to responding to the petition, ATSDR took action to assist LCHD with public health risk communication and healthcare provider education. On May 7, 2019, the Region 5 Pediatric Environmental Health Specialty Unit, ATSDR Region 5 staff, and the Illinois Department of Public Health conducted a Grand Rounds at the Advocate Condell Medical Center to educate physicians on health concerns related to EtO exposure. Additionally, ATSDR Region 5 staff presented about the public health evaluation of EtO emissions in Lake County at an October 2, 2019, town hall meeting.

Your April 14, 2021, letter referred to the issuance of an ATSDR Letter of Health Consultation to EPA regarding the Sterigenics facility in Willowbrook, IL on August 21, 2018. That document acknowledged that the available data were very limited and recommended additional air sampling to better characterize long-term exposure and associated potential health risks. The additional air sampling was eventually conducted over a 4- month period which is the basis of a more detailed health assessment. Based on that experience, ATSDR recommended that LCHD consider extending the initial 30-day sampling plan. Since the first phase of air monitoring was initiated by LCHD in June 2019, ATSDR has worked collaboratively with LCHD to provide guidance on the collection of EtO air monitoring data near the Medline and Vantage facilities.

After ATSDR began the review and analysis of the data that were provided in June 2020, EPA and LCHD informed ATSDR of a potential data quality concern with discrepancies in pressure readings in some sampling canisters used for the EtO air monitoring. ATSDR worked with LCHD to carefully evaluate all the canister pressure readings on field and lab reports to confirm which samples could provide a valid measurement of EtO concentration. That data review process took time and resulted in some samples being invalidated.

In October 2020, EPA notified ATSDR that their quality assurance testing of the standard EPA analytical method for monitoring EtO in the air discovered some canisters used to collect air samples cause EtO results to be positively biased, resulting in reported concentrations that are higher than the true amount of EtO in the air being sampled. Even though the impact of the positive bias on measured results is expected to be relatively small, it does result in significant uncertainty and less confidence in the accuracy of EtO concentrations that are near the method detection limit. EPA continues to investigate this issue and is identifying possible modifications to the analytical method to reduce of contribution of this positive bias. ATSDR is considering this positive bias issue in the evaluation of LCHD air monitoring samples.

These data quality issues have contributed to an unanticipated delay in completing the health consultation that ATSDR was asked to conduct for the Lake County community. However, ATSDR has now worked through those technical issues and is working to finalize the data analysis to support its evaluation.

ATSDR understands the concerns Lake County residents and officials have about EtO exposure and how it may affect their health, the health of their families, and the health of their community. ATSDR also understands that there are concerns that the process has taken much longer than expected. However, it is very important that the assessment of EtO exposure be as accurate as possible so that the evaluation of health risks from that exposure represent the best available science. ATSDR is committed to completing the health consultation report and to communicating its findings and any appropriate recommendations to the citizens of Lake County as soon as it is confident in the completeness of its assessment.

Thank you for your ongoing partnership and attention to addressing this important public health issue.

Sincerely,



Elizabeth Irvin-Barnwell, Ph.D.
Director, Office of Community Health and Hazard
Assessment
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention