



Willowbrook

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October 11, 2018

Mr. Michael Koerber, Associate Director of Policy
U.S. Environmental Protection Agency
Office of Air Quality
MC 1804A
RTP, NC 27711

Via email: Koerber.mike@epa.gov

Subject: Sterigenics and News Release from IEPA dated 10-2-2018

Dear Associate Director Koerber,

As you may be aware, the Village of Willowbrook has formed a Task Force to study and address the emissions of ethylene oxide (EtO) associated with the operations of the Sterigenics facilities located in our Village. This Task Force is composed of experts in the field of environmental regulation, air pollution technologies, ambient and source gas monitoring, and toxicology.

The Task Force is in possession of the News Release from IEPA dated Oct. 2, 2018 and has completed a review of the same. As we prepare for conducting our own monitoring, we have also reviewed the limited information available on U.S. EPA's own modeling and monitoring efforts. Although we have a Freedom of Information Act pending with U.S. EPA, we have not yet received a response. Because time is of the essence, on behalf of the Village, we present the following questions to the U.S. EPA:

Question #1: The news release from IEPA contained the following statement:

"In addition, the September 28, 2018 meeting increased that concern due to information discussed. In particular, the August 21 ATSDR report referenced a "30 -fold increase in cancer potency" but at the September 28 meeting, U.S. EPA referenced a 60-fold increase."

- I. We seek clarification regarding the inhalation unit risk (IUR) factor that EPA plans to use in its follow up evaluations of EtO concentrations near Sterigenics facility in Willowbrook.



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- II. Our information suggest that the 2016 IUR factors for EtO currently available on IRIS represents a 30-fold increase (by comparison to EPA'S 1985 IUR) if an age dependent adjustment factor (ADAF) is *not* incorporated (i.e., $[0.003 \text{ ug/m}^3]^{-1}$ vs $[0.0001 \text{ ug/m}^3]^{-1}$) and a 50-fold increase (over the 1985 IUR) if a.n ADAF *is* incorporated (i.e. $[0.005 \text{ ug/m}^3]^{-1}$ vs $[0.0001 \text{ ug/mg}^3]^{-1}$).
- III. What is the IUR factor mentioned in IEPA's press release that represents a 60-fold increase over previous IURs?

Question #2: The air concentration that corresponds to a 1-in-1,000,000 cancer risk using the IUR factor currently in IRIS that incorporates an ADAF is 0.0002 ug/m^3 and the air concentration that corresponds to a 1-in-10,000 cancer risk using the IUR factor as ADF is 0.02 ug/m^3 .

- a) Our information suggests that these air concentrations are well below method detection limits (MDL) that can be achieved using Summa® canisters.
 - I. We have been quoted a MDL of 0.1 ppb (0.18 ug/m^3)
 - II. This detection limit is 10x the air concentration corresponding to a 1-in-10,000 and 100x the air concentration corresponding to a 1-in-1,000,000 cancer risk.
 - III. We are concerned that elevated cancer risks will be estimated even if EtO is *not* detected at these levels if $\frac{1}{2}$ the MDL is used for non-detects in calculating exposures concentrations.
- b) Will EPA's updated risk assessment be based on long-term ambient EtO monitoring or short-term Summa® sampling results?
 - I. If it will be based on long-term ambient monitoring results, will the ambient monitoring method be capable of detecting EtO concentrations in the $0.02\text{-}0.0002\text{ug/m}^3$ range?
 1. What method will be used?
 2. What MDL is the monitoring method capable of achieving?
 3. How will non-detects be handled in the exposure calculations?
 4. When do you anticipate initiating the long-term monitoring?
 - II. If it will be based on short-term Summa® canister sampling results, how will EPA achieve MDLs that are capable of detecting the low air concentrations associated with elevated EtO cancer risk?

1. Does EPA plan to collect grab samples, 12-hour samples, and/or 24-hour samples?
2. What MDL is EPA's SUMMA canister method capable of achieving?
3. Will EPA calculate an annual average concentration from the short-term Summa® sampling results or use the unadjusted Summa® canister results as representative of long-term exposure concentrations, as was done in the ATSDR report?
 - a. If an annual average will be calculated from Summa® canister results:
 - i. What equation(s) and assumptions will be used?
 - ii. How will non-detects be handled in calculating exposure concentrations?

Question #3: How will EPA account for the fact that most people spend 85-90% of their time indoors, where EtO concentrations are presumably lower?

- a. Will EPA use a penetration factor that is specific to EtO to calculate indoor air concentrations or some other method?
- b. Will EPA do indoor air sampling?
 - i. If so, when?
 1. What method will EPA use?
 2. What MDL will be achieved?
 3. Will EPA use the indoor and outdoor monitoring results to develop a site-specific penetration factor for EtO?

Question #4: Will EPA use a 1-in-1,000,000 cancer risk, a 1-in-10,000 cancer risk, or some other target cancer risk as the "acceptable" cancer risk level for purposes of identifying an "acceptable" ambient air concentration (i.e., an "acceptable" air concentration of 0.02 or 0.0002 ug/m³) in evaluating future sampling results or some other approach to identifying the level of EtO in air that represents an "acceptable" concentration?

QUESTION #5: Will EPA identify an "action" level (i.e., an ambient air concentration above which it will demand some action by Sterigenics?

- a. If EPA plans to identify an "action" level, what will the "action" level be and what is the EPA's rationale for selecting that specific level?

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QUESTION #6: Will EPA use meteorological models as part of the air sampling protocols?

- a. If so, which model?
 - i. Will air dispersion modeling be performed?
 - ii. Will EPA account for environmental conditions when selecting sampling locations?

On behalf of the Willowbrook Environmental Task Force please know we appreciate all of the Agency's efforts. In order for the Task Force to make informed decisions, we need the additional information we have requested in this letter and in our Freedom of Information Act request dated September 21, 2018. In order to facilitate a response, the Village will be contacting Ms. Kelly Rimer to arrange a follow up phone call. Thank you again for your work and please do not hesitate to call should you have any questions in advance of our call to be scheduled next week.

Sincerely,

VILLAGE OF WILLOWBROOK



Gayle Neal, Village Trustee
Willowbrook Environmental Task Force Coordinator

Cc: Ms. Kelly Rimer
U.S. Environmental Protection Agency
MC C539-02
RTP, NC 27709

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