What is the current regulation for the emissions of ETO with regard to sterilization facilities?

Proposed Rule changes for sterilizations facilities are currently under review? what are those possible changes? and what is the process of final approval and when may that happen?

Is it true with respect to sterilizers that the EPA did nothing new in terms of ETO regulation in 2006?

Should the emissions control of ETO be increased from 99% to 99.9 %?

Commented [BM1]: OAQPS

Is Braun considered a small business? What is a small business in the eyes of the EPA?

Commented [BM2]: R3?

What controls are currently in place for sterilizers?

What known controls are in use now? How much do these cost?

You mention state of the art controls in GA, Missouri, and Illinois? What are those controls specifically?

Commented [BM3]: OAQPS

How does state law differ in those states compared to PA with regard to newest and best practices of control?

Commented [BM4]: R3?

Does that include fence line monitoring? Why isn't that required? Is that a possible rule change?

Commented [BM5]: OAQPS

For workers what does the interim decision entail for protective clothing?

Commented [BM6]: OCSPP

Workers exposed to EtO as a part of their jobs must wear specialized protective equipment where required by EPA and OSHA standards. You can learn more here: [HYPERLINK "https://www.epa.gov/ingredients-used-pesticide-products/ethylene-oxide-eto"]

How much ethylene Oxide is allowed to be emitted from a sterilization company? are there any proposed amounts? Do you foresee those amounts changing?

Commented [BM7]: ? OAQPS/OCSPP/R3?

A proposed rule was scheduled for 2021 with regard to ETO. Has that done?

Commented [BM8]: OAQPS (though I asked him what he was talking about, I suspect he means the MON)

What are background ETO levels? Is that naturally occurring? What could that be from?

Commented [BM9]: OAQPS

Is Braun and the ETO sterilization sector covered under TRI?

By law, only certain facilities are required to report to EPA's Toxics Release Inventory: those which meet all three reporting criteria (i.e., in a covered sector; have at least ten full-time employee-equivalents; and manufacture, process, or otherwise use a listed chemical above reporting thresholds). According to the 2017 NAICS Manual, facilities that primarily engage in contract sterilization fall under NAICS code 561910 ("Product sterilization and packaging services"), which isn't covered by TRI reporting criteria. Any facility not covered by all TRI reporting criteria is not required to report.

However, B Braun in Allentown, PA classifies itself as a "Surgical and Medical Instrument Manufacturing" facility (NAICS 339112), which *is* a NAICS code regulated by TRI. The facility has reported to TRI every year since 1987, and will be required to report as long as it meets all three TRI reporting criteria.

In addition to TRI, this facility reports to several other EPA programs. To see a summary of a facility's reporting or compliance history, search for the facility in EPA's Enforcement and Compliance History Online (ECHO) tool: [HYPERLINK "http://www.echo.epa.gov"].

IF so, where do we find those reports related to a specific facility?

You can search by facility name within the [HYPERLINK "https://edap.epa.gov/public/extensions/newTRISearch/newTRISearch.html"] or TRI Search Plus tools to find Braun's TRI data. To access all of Braun's reporting forms back to 1987, use Envirofacts: [HYPERLINK "https://enviro.epa.gov/enviro/trisquery.dcn_details?tris_id=18018BRRNM824TW"]

According to the TRI map, Braun released 10000-100000 lbs in 2019. What does that mean? Put that into perspective?

EPA is unsure of what specific TRI map you are referring to and how you arrived at 10000-100000 lbs of release quantities reported by Braun for 2019. For 2019, Braun reported releasing 2,791 pounds of ethylene oxide (EtO) into the air: 240 pounds were reported as fugitive or non-point air emissions, and the remaining 2,551 pounds were reported as stack or point air emissions. Braun also reported to TRI in 2019 for ethylene glycol, but no environmental release quantities were reported by the facility.

See [HYPERLINK "https://enviro.epa.gov/enviro/tri_formr_v2.fac_list?rptyear=2019&facopt=tris_id&fvalue=18018BRRNM824TW&fac_search=fac_equal&postal_code=&city_name=&county_name=&state_code=&industry_type=&bia_code=&tribe_Name=&tribe_search=fac_beginning"] to review Braun's ethylene oxide and ethylene glycol TRI reporting form submissions for 2019.

This facility ranks 17 out of the 111 facilities that reported air releases of ethylene oxide to TRI in 2019; 16 facilities reported releasing more pounds of EtO into the air than B Braun.

[HYPERLINK "https://www.epa.gov/toxics-release-inventory-tri-program/find-understand-and-use-tri"]