UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 1, 2021

Gary Cranston
President
Professional Contract Sterilization, Inc.
40 Myles Standish Blvd
Taunton, MA 02780

Subject: **EPCRA Section 313(b)(2) Notice**
FRS ID: 110000882466
TRI Facility Identification Number: 02780PRFSS40MYL
Chemicals: Ethylene Oxide and Ethylene Glycol

Dear Gary Cranston:

The U.S. Environmental Protection Agency (EPA) is sending this letter to provide notice of EPA's intent to apply reporting requirements under the Emergency Planning and Community Right-to-Know Act (EPCRA) section 313 to the facility listed above, and to provide an opportunity for the facility to respond before any final action is taken.

This action may be taken pursuant to EPCRA section 313(b)(2). EPCRA section 313 established a public database of chemical releases and other waste management activities from certain facilities; this is also known as the Toxics Release Inventory (TRI).

This notice is organized as follows:

I. Overview and Authority

Toxics Release Inventory

EPCRA Section 313 requires covered facilities to submit certain data to EPA's Toxics Release Inventory (TRI) on the releases and treatment of listed toxic chemicals annually. *See* EPCRA § 313, 42 U.S.C. § 11023; 40 C.F.R. pt. 372. For a general overview of TRI, please visit EPA's website (*See*: www.epa.gov/tri). The Pollution Prevention Act (PPA) of 1990 further requires TRI-covered facilities to also report on additional waste management (*i.e.*, recycling, treatment, and energy recovery) and source reduction activities for these toxic chemicals. *See* PPA § 6607, 42 U.S.C. § 13106. For the purposes of this notice, the terms "EPCRA section 313" and "TRI" are used interchangeably.

Application to Additional Facilities

EPCRA section 313(b)(2) provides EPA the authority to extend the reporting requirements of EPCRA section 313 to additional facilities per the Administrator's discretion:

> The Administrator, on their own motion . . . , may apply the requirements of [EPCRA Section 313] to the owners and operators of any particular facility that manufactures, processes, or otherwise uses a toxic chemical listed under [EPCRA Section 313(c)] if the Administrator determines that such action is warranted on the basis of toxicity of the toxic chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of releases of such chemical at such facility, or such other factors as the Administrator deems appropriate.

Using this authority, EPA may compel a facility to submit TRI reports for listed chemicals that it manufactures, processes, or otherwise uses above the chemical's respective threshold. *See* EPCRA § 313(a) ("[t]he owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under [EPCRA Section 313(g)] for each toxic chemical listed under [EPCRA Section 313(c)] that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by [EPCRA Section (f)] during the preceding calendar year at such facility."). A facility added by an order issued under EPCRA Section 313(b)(2) would be required to determine, each year, whether it meets the reporting thresholds for the chemical(s) identified by that order. Such a facility would be required to conduct a threshold analysis for each chemical(s) identified in the order and submit a TRI reporting form for an identified chemical should the reporting threshold be exceeded for the given chemical. The facility would be responsible for complying with TRI reporting requirements, regardless of its industry sector or number of full-time employee equivalents. *See* EPCRA § 313(a), (b)(2).

EPA is considering issuing an order applying TRI requirements to your facility for ethylene oxide (CASRN: 75-21-8) and ethylene glycol (CASRN: 107-21-1). EPA's expected rationale for the determination supporting this potential order is outlined in Unit III of this notice.

II. Reporting Required

EPCRA requires reporting to provide information on releases and other waste management of TRI chemicals. This information is used by the public and assists EPA and other regulatory agencies in determining whether future regulations are needed, among other uses.

Among other data elements, facilities must report (1) the quantities of routine and accidental releases, (2) releases resulting from catastrophic or other one-time events of TRI chemicals, (3) the maximum amount (in ranges) of the TRI chemical on-site during the calendar year, and (4) the amount contained in wastes managed on-site or transferred off-site. EPA provides replicas of Form R (*See*: https://ordspub.epa.gov/ords/guideme_ext/guideme/file/ry_2020_form_r.pdf) and Form A Certification Statement (*See*: https://ordspub.epa.gov/ords/guideme_ext/guideme/file/ry_2020_form_a.pdf) on its website. Form R is the standard TRI reporting form. Form A Certification Statement is a simplified certification form available to facilities to report on chemicals for which the facility neither (1) manufactures, processes, or otherwise uses above one million pounds, nor (2) exceeds 500 pounds for total quantities released or otherwise managed as waste on-site and quantities transferred off-site for waste management. For instructions on TRI reporting requirements, please visit EPA's website (*See*: www.epa.gov/tri/guideme).

If EPA issues its planned order, your facility would be required to submit TRI reporting forms for ethylene oxide and ethylene glycol if it manufactures, processes, or otherwise uses the chemical above the respective activity thresholds in 40 CFR 372.25. Reporting on ethylene oxide and ethylene glycol would begin with Reporting Year 2022, TRI reporting forms covering all releases and other waste management activities of ethylene oxide and ethylene glycol during the 2022 reporting year would be due to EPA by July 1, 2023. This reporting requirement would continue to apply for each subsequent reporting year where your facility's chemical activities meet or exceed the respective activity threshold.

If your facility is required to report to TRI, the annual public burden related to the Form R (approved under OMB Control No. 2070-0212) is estimated to average 35.71 hours per response for a facility filing a report on one chemical. The annual public burden related to the Form A (also approved under OMB Control No. 2070-0212) is estimated to average 21.96 hours per response for a facility filing a report on one chemical.

Regardless of any action EPA may take under EPCRA Section 313(b)(2) relating to your facility's reporting requirements on ethylene oxide and ethylene glycol, if your facility meets the generally applicable reporting requirements under 40 C.F.R. Part 372 now or in the future, then for any such year your facility would be responsible for reporting requirements for all chemicals listed under 40 C.F.R. § 372.65.

III. Bases for Applying Reporting Requirements to this Facility

Pursuant to EPCRA Section 313(b)(2), EPA is considering whether this facility's activities involving ethylene oxide and ethylene glycol warrant reporting to TRI based on: the toxicity of ethylene oxide and ethylene glycol, the facility's proximity to a population center, the history of releases of ethylene oxide at the facility (*e.g.*, from the facility's past reports to TRI), and other

factors the Administrator determines are appropriate (*e.g.,* environmental justice concerns, facility employee concerns).

Ethylene oxide's toxicity

Ethylene oxide is a flammable, colorless gas used to sterilize equipment, such as medical equipment, among other manufacturing applications, including the manufacture of ethylene glycol. In December 2016, EPA's Integrated Risk Information System (IRIS) Program (*See*: https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025) updated its cancer assessment for ethylene oxide and characterized the chemical as "carcinogenic to humans" by the inhalation route of exposure based on the total weight of evidence. Additionally, the IRIS assessment concludes that there is "clear evidence" of ethylene oxide's genotoxicity and a sufficient weight of evidence to support a mutagenic mode of action for carcinogenicity.

Ethylene oxide has been on the TRI toxic chemical list since its inception in 1987. *See* 40 C.F.R. § 372.65. EPA is considering whether the toxicity of ethylene oxide supports requiring this facility to report to the TRI program to provide exposure information and support community right-to-know.

Ethylene glycol's toxicity

Ethylene glycol is a clear, colorless liquid with many uses, including as antifreeze, in hydraulic brake fluids, and as a solvent. Ethylene glycol is produced using ethylene oxide. EPA's IRIS Program (*See*: https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=238) has found that acute exposure to ethylene glycol via the ingestion exposure route causes three stages of human health effects: central nervous system depression, cardiopulmonary effects, and renal damage. The National Institute for Occupational Safety and Health (*See*: https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750031.html) has also noted that "systemic ethylene glycol toxicity can occur through ingestion."

Ethylene glycol has been on the TRI toxic chemical list since its inception in 1987. *See* 40 C.F.R. § 372.65. EPA is considering whether the toxicity of ethylene glycol supports requiring this facility to report to the TRI program to provide exposure information and support community right-to-know.

Proximity to population centers

There is a population of approximately 69,653 within a five-mile radius of this facility. Additionally, there are approximately 3,483 children under five years living within a five-mile radius of the facility (as determined via EJSCREEN, www.epa.gov/ejscreen). EPA has also estimated there are at least 18 schools within a five-mile radius of the facility (determined using geospatial data from the National Center for Education Statistics, www.nces.ed.gov). Because EtO is mutagenic (i.e., it can change the DNA in a cell) and children may be more susceptible to the harmful effects of mutagenic substances, the proximity of young children to a facility using ethylene oxide concerns EPA.

EPA is considering whether this facility's proximity to the nearby community, including the number of children under five years of age living near the facility, supports requiring TRI reporting for ethylene oxide and ethylene glycol.

Past reports to TRI

This facility has previously reported ethylene oxide to TRI. The last reporting year the facility submitted such data was 1992. EPA understands that this facility may have determined it was not legally obligated to continue reporting to TRI after that time. However, these previous TRI reports indicate that this facility has a history of releases of ethylene oxide. Based on this facility's TRI reporting history, EPA is considering whether this facility's history of releases supports requiring TRI reporting for ethylene oxide.

Environmental justice concerns

EPA maintains an online environmental justice screening and mapping tool, EJSCREEN. (*See*: www.epa.gov/ejscreen.) This tool combines publicly available datasets representing both demographic and environmental indicators to produce environmental justice indices for a given geographic area. EJSCREEN provides a screening-level view of potential environmental justice concerns in a specific area, and EPA does not interpret these results as a risk assessment.

Because EPA lists ethylene oxide as "carcinogenic to humans" by the inhalation route of exposure, EPA focused its EJSCREEN screening of this facility to certain air-related environmental indicators. These environmental indicators produced the following EJSCREEN environmental justice indices for a five-mile radius surrounding this facility, when compared to all groups across the state, EPA region, or U.S.:

Environmental Justice Index	**Percentile in State**	**Percentile in EPA Region**	**Percentile in U.S.**
National-scale Air Toxics Assessment (NATA) air toxics cancer risk	40	39	28
NATA respiratory hazard index	41	39	31
NATA diesel particulate matter (PM)	43	37	27
PM 2.5	36	37	30
Ozone	37	38	24
Traffic proximity	57	44	25
Proximity to Risk Management Plan (RMP) sites	17	14	11

EPA is considering whether these environmental justice factors support requiring this facility to report to the TRI program to provide exposure information and support community right-to-know.

Facility employees

Some evidence—from historic occupational studies of workers at ethylene oxide facilities—indicates that exposure to high levels of ethylene oxide may cause adverse health effects on workers, including an increased rate of miscarriages in female workers. For more information, see https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/frequent-questions-health-information-about-ethylene-oxide. EPA is considering whether potential worker health concerns may support requiring TRI reporting of its ethylene oxide releases and waste management amounts.

Additionally, studies have suggested that dermal or inhalation exposure to workers in facilities that manufacture and/or use ethylene glycol may lead to chronic (non-cancer) effects, including throat and upper respiratory tract irritation. For more information, see EPA's IRIS page for ethylene glycol. EPA is considering whether potential worker health concerns may support requiring TRI reporting of its ethylene glycol releases and waste management amounts.

The purpose of TRI is to provide governments and the public, including residents of communities surrounding covered facilities, with information on the releases and other waste management activities of listed toxic chemicals. Based on the factors identified in this Unit, EPA may ultimately determine that applying TRI reporting requirements to this facility for ethylene oxide and ethylene glycol is warranted under EPCRA § 313(b)(2). EPA believes this facility may meet TRI reporting thresholds for on-site activities involving ethylene oxide and ethylene glycol, and the public would benefit from increased information disclosure related to those releases.

IV. Responding to this Notice

If the facility would like to respond to this notice, including with any additional information pertinent to EPA's considerations under EPCRA section 313(b)(2), please provide your written response and any supplemental information to: TRI_Discretionary_Authority@epa.gov.

Please submit any response to EPA within 30 days from the date of this letter. *Do not send any information you consider to be CBI or otherwise protected without notifying EPA first.* EPA will consider any information submitted by your facility during the 30-day response period before making a decision on applying TRI reporting requirements to your facility for ethylene oxide and ethylene glycol reporting. EPA will then notify the facility of its determination, issuing an order applying TRI requirements to your facility if appropriate.

V. For Further Information Contact

If you have questions related to this notice, please contact Stephanie Griffin, Data Collection Branch, Data Gathering and Analysis Division, Office of Pollution Prevention and Toxics, by email at griffin.stephanie@epa.gov.

Sincerely,

MICHAL FREEDHOFF Digitally signed by MICHAL FREEDHOFF
Date: 2021.10.02 09:48:08 -04'00'

Michal Freedhoff
Assistant Administrator