



South Coast Air Quality Management District

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Via Email and CERTIFIED RETURN RECEIPT to addressee

September 29, 2022

Kevin Wagner
VP Environmental Health & Safety
Sterigenics US, LLC
687 Wanamaker Avenue
Ontario, CA 91761

Subject: Notice of Designation of Sterigenics US, LLC (South Coast AQMD ID 126060) as a Potentially High Risk Level Facility

Dear Mr. Wagner:

Thank you for meeting with the South Coast Air Quality Management District (South Coast AQMD) staff on September 27, 2022, to discuss the possible designation of Sterigenics US, LLC (Sterigenics Ontario) as a Potentially High Risk Level Facility. Pursuant to South Coast AQMD Rule 1402, South Coast AQMD is now designating Sterigenics Ontario as a Potentially High Risk Level Facility.¹ Based on this designation, you are required to expeditiously reduce risks from your facility and provide reports on your toxic emissions and potential health risks to the surrounding community as detailed below.

A. Findings Substantiating Designation

Some information used to substantiate this designation was communicated to you in a letter dated September 7, 2022, and also discussed with you via videoconference on September 27, 2022. South Coast AQMD has collected additional monitoring data beyond that communicated in our September 7, 2022 letter that further corroborates designation as a Potentially High Risk Level Facility.²

¹ Pursuant to Rule 1402 (c)(14), a Potentially High Risk Level Facility is a facility for which the Executive Officer has determined that emissions data, ambient data, or data from a previously approved Health Risk Assessment indicate that the facility has a likely potential to either exceed or has exceeded a Significant Risk Level. A Significant Risk Level is a cancer risk to surrounding areas of greater than 100 chances in a million or a total acute or chronic hazard index of five (5.0) for any target organ system at any receptor location.

<http://www.aqmd.gov/docs/default-source/rule-book/reg-xiv/rule-1402.pdf>

² See Air Monitoring Efforts section:

<http://www.aqmd.gov/home/news-events/community-investigations/sterigenics-ontario>

A.1 Ambient Air Quality and Sampling Data

South Coast AQMD staff collected 24-hour air monitoring samples adjacent to and nearby Sterigenics Ontario beginning on June 16, 2022, and found elevated levels of ethylene oxide at these sampling sites. Figure 1 below shows the locations of the samplers positioned near Sterigenics Ontario. As seen in Table 1 and Figure 2, the levels that have been recorded near Sterigenics Ontario are substantially higher than the 2021 annual average ethylene oxide concentration from the South Coast AQMD Rubidoux regional monitoring station, which is 0.06 ppbv (with a max value of 0.14 ppbv).³ Over many years, these levels would present a cancer risk to off-site workers substantially higher than the Rule 1402 (c)(19) Significant Risk Level of 100 chances-in-one million. No additional sources of ethylene oxide near the monitored areas have been identified.

Figure 1 – Map of Monitoring Sites Near Sterigenics Ontario



³ See the average 2021 ethylene oxide concentration readings from the Rubidoux monitoring station: <https://www.epa.gov/outdoor-air-quality-data/monitor-values-report-hazardous-air-pollutants>

Figure 2 – Ethylene Oxide Air Monitoring Results

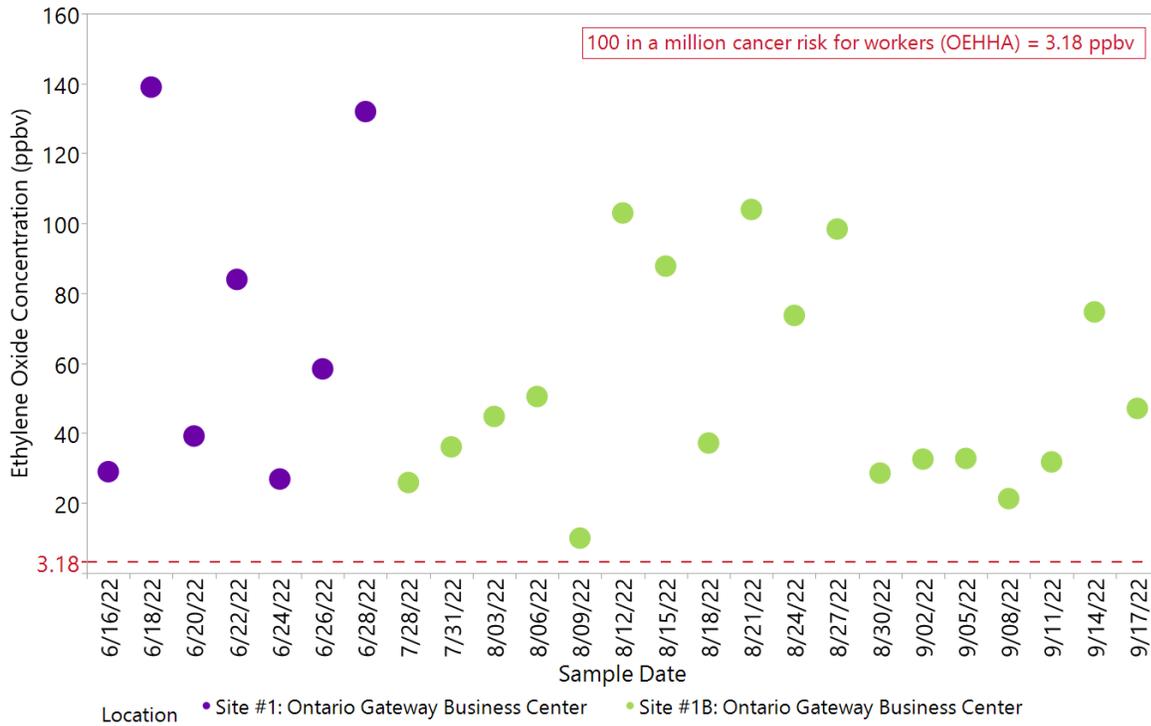


Table 1 – Measured Concentrations (ppbv) near Sterigenics Ontario

Sample Begin Time	Site #1 (Ontario Gateway Business Center)	Site #1B (Ontario Gateway Business Center)
06/16/2022 12:00	29.0	
06/18/2022 12:00	139	
06/20/2022 12:00	39.2	
06/22/2022 12:00	84.0	
06/24/2022 12:00	26.9	
06/26/2022 12:00	58.4	
06/28/2022 12:00	132	
07/28/2022 12:00		25.9
07/31/2022 12:00		36.1
08/03/2022 12:00		44.8
08/06/2022 12:00		50.5
08/09/2022 12:00		10.0
08/12/2022 12:00		103
08/15/2022 12:00		87.8
08/18/2022 12:00		37.2
08/21/2022 12:00		104
08/24/2022 12:00		73.7
08/27/2022 12:00		98.4
08/30/2022 12:00		28.6
09/02/2022 12:00		32.6
09/05/2022 12:00		32.8
09/08/2022 12:00		21.3
09/11/2022 12:00		31.8
09/14/2022 12:00		74.7
09/17/2022 12:00		47.1

A.2 Findings From Facility Site Visits

Based on numerous visits to Sterigenics Ontario since March 2022, South Coast AQMD staff identified several sources of ethylene oxide emissions. Additionally, data provided by Sterigenics of ethylene oxide concentrations from the facility's gas chromatographs located inside the buildings indicate that these sources are potentially contributing to elevated concentrations found in monitors off-site. Potential sources include:

- Direct emissions from control equipment and stacks venting sterilizing operations;
- Ventilation and air flow patterns indicating less than full capture within the controlled

- areas in the buildings;
- Cross drafts coming through open roll up doors that would allow for escape of ethylene oxide from the building; and
 - Continued off-gassing from materials removed from the aeration rooms.

B. Rule 1402 Requirements for Potentially High Risk Level Facilities

Sterigenics Ontario is required to submit an Early Action Reduction Plan, an Air Toxics Inventory Report (ATIR), a Health Risk Assessment (HRA), and a Risk Reduction Plan (RRP) based on the most current operating conditions and emission inventory for **calendar year 2021**. The aforementioned items are due no later than the timelines outlined below.

Deliverable	Due Date	Due Date	Rule Reference
Initial Information for ATIR	30 days	11/1/2022	1402 (d)(1)
Early Action Reduction Plan	90 days	12/28/2022	1402 (g)(2)
ATIR	150 days	02/28/2023	1402 (d)(2)
HRA	180 days	03/28/2023	1402 (g)(3)
RRP	180 days	03/28/2023	1402 (g)(4)

Further, Sterigenics Ontario will be required to conduct public notification within 30 days after the HRA is approved and will need to implement the RRP as quickly as feasible, but no later than two years after the RRP is approved. Sterigenics Ontario is strongly encouraged to aggressively reduce risks to off-site locations as quickly as possible and faster than the timeline provided above. In particular, given the lessons learned from the EARP prepared for the Sterigenics Vernon facility and the persistently elevated levels of ethylene oxide measured offsite, **we strongly encourage submittal of a draft EARP well before the 90-day timeline allowed within the rule**. A suggested target date is to submit the EARP within 30 days, and to expedite completion of early actions to reduce ethylene oxide emissions as quickly as feasible.

C. Guidelines for Preparing Rule 1402 Deliverables

Pursuant to Rule 1402 (d)(1), Sterigenics Ontario is required to submit the **Initial Information** for an ATIR to South Coast AQMD within thirty (30) days of the date of this letter, on or before **November 1, 2022**. The Initial Information should include a list of device(s) or process(es) to be included in the detailed ATIR and their corresponding toxic pollutants and Reference Sources for each emission factor.

Pursuant to Rule 1402 (g)(2), Sterigenics Ontario is required to submit an **Early Action Reduction Plan** to South Coast AQMD no later than 90 days of the date of this letter, on or before **December 28, 2022**. As indicated above, we encourage you to develop and implement this plan well before this timeline. The Early Action Reduction Plan should include a list of measures that can be implemented immediately or have recently been implemented to reduce the facility-wide health risk. The operator must identify risk reduction measure(s) that can be implemented that includes, but are not limited to, procedural changes, process changes, physical modifications, and curtailments.

Pursuant to Rule 1402 (d)(2), Sterigenics Ontario is required to submit a **detailed ATIR** within 150 days of the date of this letter, on or before **February 28, 2023**. In your detailed ATIR, you

must include all toxic air contaminant emissions from your facility that are listed in Appendix A of the *AB 2588 Air Toxics “Hot Spots” Emission Inventory Criteria and Guidelines Regulation* (effective March 21, 2022) which is available at:

<https://ww2.arb.ca.gov/our-work/programs/ab-2588-air-toxics-hot-spots/hot-spots-inventory-guidelines>

The ATIR must also be prepared in accordance with South Coast AQMD’s *AB 2588 and Rule 1402 Supplemental Guidelines* which are available at:

<http://www.aqmd.gov/docs/default-source/planning/risk-assessment/ab-2588-supplemental-guidelines.pdf>

Pursuant to Rule 1402 (g)(3), Sterigenics Ontario is required to submit an HRA within 180 days of the date of this letter, on or before **March 28, 2023**. The HRA must be prepared in accordance with *The Air Toxics Hot Spots Program Risk Assessments Guidelines (February 2015)* developed by the State of California Office of Environmental Health Hazard Assessment (OEHHA). Please follow the detailed outline for the HRA report, which is contained in Appendix C of the South Coast AQMD’s *AB 2588 and Rule 1402 Supplemental Guidelines* mentioned above. OEHHA’s guidelines can be accessed using the following link:

http://www.oehha.ca.gov/air/hot_spots/hotspots2015.html

Pursuant to Rule 1402 (g)(4), Sterigenics Ontario is required to submit a **Risk Reduction Plan** to South Coast AQMD within 180 days of the date of this letter, on or before **March 28, 2023**. Guidance for preparing a Risk Reduction Plan can also be found in the South Coast AQMD *AB 2588 and Rule 1402 Supplemental Guidelines* mentioned above.

Please include a signed copy of the AB 2588 Air Toxics Document Certification & Application Form along with your submittals. This form can be downloaded at:

<https://www.aqmd.gov/docs/default-source/aqmd-forms/AB2588/ab2588-certification-form.pdf>

D. Other Resources for Preparing Rule 1402 Deliverables

The California Air Resources Board (CARB) has developed the “Hot Spots” Analysis and Reporting Program (HARP) which includes the emissions inventory and risk assessment procedures of the “Hot Spots” Program into a set of program modules. Your ATIR must include an electronic file in the HARP Emission Inventory Module (EIM) format. You may obtain a free copy of the HARP software from the following link:

<http://www.arb.ca.gov/toxics/harp/harp.htm>

You are required to prepare and submit your HRA using the latest version of the HARP software, which includes the United States Environmental Protection Agency (USEPA) air quality dispersion model called AERMOD. Additional documentation is available at:

<https://www.epa.gov/scram/air-quality-dispersion-modeling-preferred-and-recommended-models>

South Coast AQMD provides meteorological data from multiple stations throughout South Coast Air Basin for use in HARP and AERMOD:

<http://www.aqmd.gov/home/air-quality/meteorological-data/data-for-aermod>

South Coast AQMD's guidance on using AERMOD is also available at:

<http://www.aqmd.gov/home/air-quality/meteorological-data/modeling-guidance>

You should also be aware that Sterigenics Ontario is subject to the fees shown in South Coast AQMD Rule 307.1 as a Potentially High Risk Level facility. Fees under this category are partially based on time and materials and are applicable while you remain under this program category.

Given the significant levels of ethylene oxide emitted by Sterigenics Ontario, we strongly encourage you to take all necessary steps to reduce these emissions as quickly as possible. If you have questions regarding the requirements detailed in this letter, please contact me at (909) 396-3244 or Victoria Moaveni, Program Supervisor at (909) 396-2455.

Sincerely,



Ian MacMillan
Assistant Deputy Executive Officer
Planning, Rule Development & Implementation

cc:

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IM:EK:VM:FC:TT:VT