



South Coast Air Quality Management District

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Via Email and CERTIFIED RETURN RECEIPT TO ADDRESSEE

June 7, 2022

Kevin Wagner
VP Environmental Health & Safety
Sterigenics US, Inc.
4801-63 E 50th St.
Los Angeles, CA 90058-2709

Sterigenics US, Inc.
4900 Gifford Ave.
Los Angeles, CA 90058-2785

Subject: Notice of Designation of **Sterigenics US, Inc. – Los Angeles Facility** (South Coast AQMD ID **126191 & 126197**) 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 May 26, 2022, to discuss the potential designation of your facility as a Potentially High Risk Level Facility. Pursuant to South Coast AQMD Rule 1402, South Coast AQMD is designating Sterigenics US, Inc. – Los Angeles Facility (Sterigenics LA Facility)¹ as a Potentially High Risk Level Facility.² 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 May 6, 2022, and also discussed with you via videoconference on May 26, 2022. South Coast

¹ The Sterigenics LA Facility - (South Coast AQMD IDs 126191 & 126197) is being designated as a single facility for Rule 1402 purposes based on site specific circumstances, including the Gifford Avenue fronting public right-of-way connection between the operationally-related buildings, which also aligns with federal requirements.

² 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>

AQMD has collected additional monitoring and other data beyond that communicated in our May 6, 2022 letter that further corroborates designation as a Potentially High Risk Level Facility.³

A.1 Ambient Air Quality and Sampling Data

South Coast AQMD staff collected 24-hour air monitoring samples adjacent to and nearby the Sterigenics LA Facility beginning on April 22, 2022, and found high levels of ethylene oxide at these monitors. Figure 1 below shows the locations of the monitors positioned near and around the Sterigenics LA Facility and near residents. As seen in Table 1 and Figure 2, the levels that have been recorded near your facility are substantially higher than average background levels of 0.07 ppb (range of 0.01 to 0.17 ppb) from South Coast AQMD's downtown Los Angeles regional monitoring station.⁴ Over many years, this level 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. Lower monitored levels have been found at monitors located upwind and downwind and farther from your facility, indicating that Sterigenics LA Facility is likely the source of ethylene oxide found in these areas. No additional sources of ethylene oxide near the monitored areas have been identified.

Figure 1 – Map of Monitoring Sites in Vernon



³ See Air Monitoring Efforts section:

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

⁴ See the 2021 average ethylene oxide background concentration readings from the Los Angeles monitoring station:

<https://www.epa.gov/outdoor-air-quality-data/monitor-values-report-hazardous-air-pollutants>

Figure 2 – Ethylene Oxide Air Monitoring Results

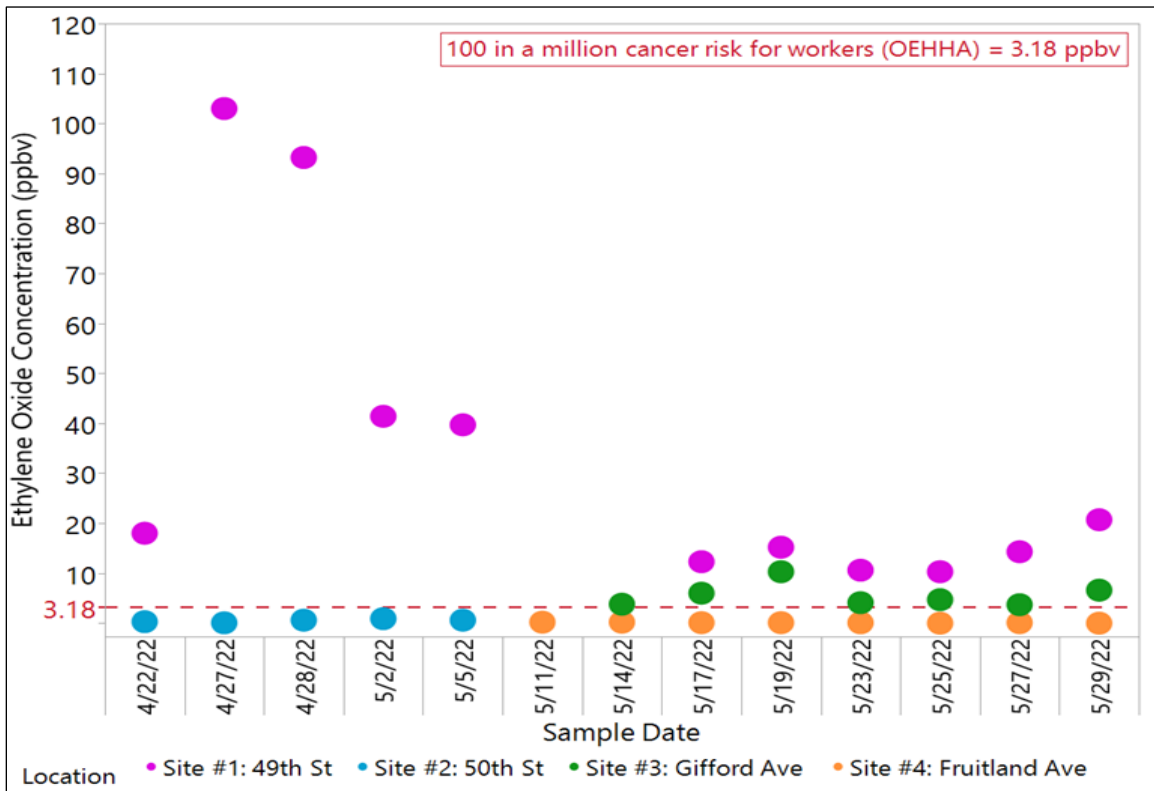


Table 1

24-hour Time-integrated Sample data (concentrations in ppbv)

Sample Begin Time	Site #1 (49th St.)	Site #2 (50th St.)*	Site #3 (Gifford Ave.)	Site #4 (Fruitland Ave.)
04/22/2022 12:00	18	0.3		
04/27/2022 00:00	103	0.07		
04/28/2022 12:00	93.2	0.6		
05/02/2022 00:00	41.4	0.9		
05/05/2022 00:01	39.7	0.6		
05/11/2022 00:01	Invalid		Invalid	0.2
05/14/2022 00:00	Invalid		3.8	0.2
05/17/2022 00:00	12.3		6.0	0.1
05/19/2022 00:00	15.2		10.3	0.1
05/23/2022 00:00	10.6		4.1	0.08
05/25/2022 00:00	10.3		4.7	ND
05/27/2022 00:00	14.3		3.7	0.1
05/29/2022 00:00	20.7		6.6	ND

*Discontinued sampling at Site 2

ND = Not Detected

A.2 Findings From Facility Site Visits

Based on numerous visits to your facility since March 2022, South Coast AQMD staff identified several sources of ethylene oxide emissions. Additionally, data provided by the facility 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 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 LA Facility 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 no later than the timelines outlined below.

Deliverable	Due Date	Due Date	Rule Reference
Initial Information for ATIR	30 days	07/07/2022	1402 (d)(1)
Early Action Reduction Plan	90 days	09/06/2022	1402 (g)(2)
ATIR	150 days	11/04/2022	1402 (d)(2)
HRA	180 days	12/06/2022	1402 (g)(3)
Risk Reduction Plan	180 days	12/06/2022	1402 (g)(4)

Further, Sterigenics LA Facility will be required to conduct public notification within 30 days after the HRA is approved and will need to implement the Risk Reduction Plan as quickly as feasible, but no later than two years after the Risk Reduction Plan is approved. Sterigenics LA Facility is strongly encouraged to aggressively reduce risks to off-site locations as quickly as possible and faster than the timeline provided above.

C. Guidelines for Preparing Rule 1402 Deliverables

In accordance with the State of California’s Air Toxics “Hot Spots” Information and Assessment Act (AB 2588) and Rule 1402, Sterigenics LA Facility is required to prepare a detailed ATIR for your facility based on your most current operating conditions and emission inventory for **calendar year 2021**.

Pursuant to Rule 1402 (d)(1), your facility 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 **July 7, 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. This should include the emission sources discussed above as well as any other potential sources of emissions.

Pursuant to Rule 1402 (g)(2), your facility is required to submit an **Early Action Reduction Plan** to South Coast AQMD within 90 days of the date of this letter, on or before **September 6, 2022**.

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), your facility is required to submit a **detailed ATIR** within 150 days of the date of this letter, on or before **November 4, 2022**. 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)*. The ATIR must also be prepared in accordance with South Coast AQMD’s *AB 2588 and Rule 1402 Supplemental Guidelines*.

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

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

Pursuant to Rule 1402 (g)(3), your facility is required to submit an HRA within 180 days of the date of this letter, on or before **December 6, 2022**. 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.

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

Pursuant to Rule 1402 (g)(4), your facility is required to submit a **Risk Reduction Plan** to South Coast AQMD within 180 days of the date of this letter, on or before **December 6, 2022**. 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.

<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 U.S. EPA air quality dispersion model called AERMOD. AERMOD 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.

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

You should also be aware that your facility 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 your facility, 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:

- Wayne Nastri
- Susan Nakamura
- Sarah Rees
- Jason Aspell
- Terrance Mann
- Jason Low
- Victor Yip
- Jillian Wong
- Barbara Baird
- Eugene Kang
- Victoria Moaveni
- (All with South Coast AQMD)

SR:IM:EK:VM:FC:VT:AS