Sterigenics.
A Sotera Health company

June 14, 2023

Submitted via OEHHA Website: https://oehha.ca.gov/comments

Esther Barajas-Ochoa
Office of Environmental Health Hazard Assessment
P. O. Box 4010
Sacramento, California 95812-4010

Re: Notice of Proposed Rulemaking Title 27, California Code of Regulations – Amendment to Section 25705 Specific Regulatory Levels Posing No Significant Risk: Ethylene Oxide.

On April 7, 2023, the Office of Environmental Health Hazard Assessment ("OEHHA") released a draft document for public review that summarizes the carcinogenicity data and derives an updated cancer inhalation unit risk factor ("IUR") for ethylene oxide ("EtO") and a proposed "Updated No Significant Risk Level for Ethylene Oxide," ("NSRL"). Sterigenics US, LLC ("Sterigenics") appreciates the opportunity to provide comments on the OEHHA's proposed Cancer IUR for EtO, its accompanying Draft Technical Support Document, and the proposed NSRL.

Sterigenics operates three facilities within California that sterilize medical devices with EtO utilizing a U.S. Food and Drug Administration ("FDA")-validated, non-invasive method to sterilize medical equipment prior to use. Sterilization using EtO is the only method available for sterilizing large quantities of packaged medical equipment. Sterilization prevents biological contamination in health care settings that can lead to patient infections, and in severe cases, deaths. The Sterigenics EtO facilities within California sterilize over 90 million essential medical devices and supplies each year, including surgical kits, catheters, cardiac implants, stents, IV sets and more. These products are supplied to nearly 100 healthcare product manufacturers as well as numerous hospitals throughout the state.

Sterigenics is concerned that the above referenced OEHHA proposals could result in temporary or permanent closure of some EtO sterilization facilities in California. As OEHHA considers its proposals, Sterigenics urges the agency to take into account the greater context within which Sterigenics' facilities operate. The national capacity for EtO sterilization is limited, and shortages of sterilized products and equipment can have – and have had – direct, significant health consequences. Sterigenics supports efforts to reduce EtO emissions to the extent feasible. Unfortunately, other methods of sterilization cannot replace the use of EtO for many devices. Consequently, we are concerned about the potential impact of shortages of sterilized medical devices that would result from disruptions in commercial sterilizer facility operations. Without adequate EtO sterilization, infection risks in healthcare would be meaningfully increased.

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We appreciate your time and consideration in reviewing these comments. Please contact us if you have any questions or require additional information.

Sincerely,

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Sterigenics U.S., LLC ("Sterigenics") is submitting these comments on two concurrent Office of Environmental Health Hazard Assessment ("OEHHA") regulatory activities concerning ethylene oxide ("EtO"):

(1) The proposed "Updated No Significant Risk Level for Ethylene Oxide," dated April 7, 2023; and

(2) The draft document for public review that summarizes the carcinogenicity data and derives an updated cancer inhalation unit risk factor ("IUR") for EtO, also released April 7, 2023.

While we recognize that the rulemaking activities of the No Significant Risk Level ("NSRL") and the updated cancer IUR for EtO are conducted pursuant to different statutory and regulatory mandates, with different purposes, OEHHA relies on common bases for both updates. Accordingly, Sterigenics' comments below, addressing the regulatory context and the underlying scientific studies purporting to support the updates, are applicable to the rulemaking for both the NSRL and the IUR.

I. COMPANY BACKGROUND AND OVERVIEW OF COMMENTS

Sterigenics is a leading provider of terminal sterilization for medical products in the United States. Sterigenics operates EtO and gamma processing facilities across the United States to provide contract sterilization services for critical medical products, ensuring that they are free from dangerous and potentially deadly organisms prior to patient use. As of May 31, 2023, Sterigenics employed approximately 800 individuals across 24 U.S. facilities – nine EtO facilities, 14 gamma facilities and its headquarters office, including 165 individuals at 7 facilities located in California.

Terminal sterilization is the process of sterilizing a product in its final packaging; it is an essential, and often government-mandated, last step in the manufacturing process of healthcare products before they are shipped to end-users. These products include surgical procedure kits and trays, implants, syringes, catheters, wound care products, medical protective barriers, including personal protective equipment ("PPE"), laboratory products and pharmaceuticals, as well as bioprocessing equipment used in the pharmaceutical industry for the production of vaccines and other prescription and over the counter treatment products.

The effective sterilization of medical devices is essential to public health. In 2007, the Centers for Disease Control ("CDC") calculated that there are 1.7 million healthcare-associated infections ("HAIs") and 99,000 HAI-related deaths each year

resulting therefrom, and these unfortunate circumstances occur even when the country is doing all it can to sterilize medical devices. HAIs are a particular concern during medical procedures where our bodies can be exposed to infection from microbes, bacteria, or viruses. Approximately 53 million such outpatient surgical procedures are performed in this country every year, and each of these procedures involves direct contact between human tissue and medical devices or surgical equipment. Each such contact poses a risk of infection.

Sterigenics sterilizes millions of medical devices and products each day using EtO according to specific processes validated by the U.S. Food and Drug Administration ("FDA"). Sterilization by EtO is the "method with the broadest application available for medical products due to its effectiveness at lower temperatures and its general compatibility with a diversity of materials, resins and product types."[1] FDA has explained that "ethylene oxide is the most common method of sterilization of medical devices in the U.S. and is a well-established and scientifically proven method of preventing harmful microorganisms from reproducing and causing infections."[2] "[M]ore than 20 billion devices sold in the United States every year are sterilized with [EtO], accounting for approximately 50% of devices that require sterilization."[3] EtO sterilization is the only viable sterilization method approved by the FDA for many delicate, complex, and sophisticated medical products. And, as the agency that requires and approves sterilization using EtO, the FDA has emphasized, "It's important to note at this time there are no readily available processes or facilities that can serve as viable alternatives to those that use ethylene oxide to sterilize these devices. In short: this method is critical to our health care system and to the continued availability of safe, effective, and high-quality medical devices."[4]

Sterigenics' EtO facilities consistently have operated in accordance with the applicable air quality permits issued by the relevant State permitting agencies pursuant to delegated authority under the federal Clean Air Act ("CAA"). Sterigenics operates three such facilities in California, two in Los Angeles and another in Ontario. Each of these facilities are operating in compliance with Early Action Reduction Plans approved by the South Coast Air Quality Management District

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[1] Medical Device Network, Sterigenics, Ethylene Oxide, https://www.medicaldevice-network.com/products/ethylene-oxide/ (last visited May 26, 2023).
[2] FDA, Press Announcement, Norman E. "Ned" Sharpless, MD, Acting Commissioner of Food and Drugs, Statement on Concerns with Medical Device Availability Due to Certain Sterilization Facility Closures (Oct. 25, 2019), https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures.
[3] FDA, Press Announcement, Jeffrey E. Shuren, MD, JD, Director – CDRH Offices, FDA Continues Efforts to Support Innovation in Medical Device Sterilization (Oct. 25, 2019), https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization.
[4] Sharpless Statement, *supra* note 2.

("South Coast AQMD") within the past year pursuant to District Rule 1402.[5] Sterigenics' facilities offer critical services needed for healthcare in California and across the U.S. For example, the Los Angeles facilities sterilize a wide variety of products for nearly 100 customers, over half of which are based in California. These customers range from large global medical device and pharmaceutical companies to small niche start-up companies as well as local hospitals and medical centers. All are dependent on the Los Angeles facilities to get their products sterilized and distributed to their customers. Sterigenics is committed to the continued operation of these facilities and the delivery of the critical services they provide in a manner that will protect the health of its workers and the communities in which the facilities are located.

Sterigenics offers these comments to address fundamental flaws in the proposed NSRL and IUR that could undermine public health on a much larger scale and lead to unwarranted public confusion about health risks in the vicinity of EtO sterilization facilities. OEHHA has proposed an NSRL and IUR based on flawed scientific analyses (discussed in detail in the following pages) that would result in public warning requirements in communities near EtO sterilization facilities at air concentrations that are below (and, in the case of OEHHA's parallel rulemaking on an updated cancer IUR for EtO, far below) background levels for EtO elsewhere in the State, including in numerous areas without any EtO sterilization facilities. In short, the proposed NSRL and IUR would provide misleading information that undermines continued EtO sterilization in California, without providing any meaningful health risk information to California residents.

II. BASIS FOR COMMENTS ON PROPOSED NSRL AND IUR

Sterigenics' comments are applicable to both OEHHA's amendment to the NSRL as well as the update to the IUR. While these activities are authorized under different regulatory programs, OEHHA's underlying justification for both activities relies generally on common studies and data. Sterigenics requests that OEHHA consider its comments for the updates of both the NSRL and IUR.

OEHHA is developing the subject NSRL on the basis that EtO is a chemical "known to the state to cause cancer" for purposes of Proposition 65.[6] The NSRL is

[5] Letter from Ian MacMillan, South Coast AQMD, to Kevin Wagner, Sterigenics (Sept. 9, 2022), *available at* https://www.aqmd.gov/docs/default-source/compliance/sterigenics/earp-approval-letter.pdf?sfvrsn=8 (Approving Rule 1402 Early Action Reduction Plan for Sterigenics US, Inc. – (Facility IDs 126191 & 126197)); Letter from Ian MacMillan, South Coast AQMD, to Kevin Wagner, Sterigenics (Apr. 7, 2023), *available at* https://www.aqmd.gov/docs/default-source/compliance/sterigenics/earp-approval-letter-ontario.pdf?sfvrsn=9 (Approving Rule 1402 Early Action Reduction Plan for Sterigenics US, Inc. – (Facility ID 126060)).

[6] The Safe Drinking Water and Toxic Enforcement Act of 1986 (codified at Health & Safety Code § 25249.5 et seq.) (hereinafter referred to as "Proposition 65" or "Prop 65").

generally defined in the Prop 65 regulations as "[the level] which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question."[7]

In establishing or updating the NSRL, OEHHA's assessment should not be limited to the specific studies used as the basis for listing the chemical, but instead OEHHA's "assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer."[8] The regulations prescribe the standards that must be met in establishing the NSRL, noting that "[n]othing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk."[9]

Accordingly, the information submitted here, as it relates to the NSRL, is based on the quality of evidence specified by the standards in the regulation. Moreover, while we recognize that the NSRL must be "based upon the results of the most sensitive scientific study deemed to be of sufficient quality,"[10] Sterigenics notes that the key term is "sufficient quality." When there is insufficient quality of data in the "most sensitive" studies, as we contend is the case here, OEHHA must draw from other information meeting the rigorous standards in the regulation, such as the information presented for OEHHA's consideration below.

While NSRLs are established for solely for purposes of identifying exemptions to the warning requirements of Prop 65,[11] and the regulations provide that the NSRLs shall not be construed to establish exposure or risk levels for other regulatory purposes,[12] the same scientific rationale forms the basis for OEHHA's proposed update of the IUR for EtO.

OEHHA is updating the IUR pursuant to its implementation of the Air Toxics Hot Spots Program, which includes the development of guidelines for conducting health risk assessments.[13] In implementing this requirement, OEHHA derives IUR factors for certain designated "Hot Spots" air pollutants,[14] and may do so based on technical documents that form the basis for cancer potency factors established by other regulatory regimes, including the U.S. Environmental Protection Agency

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[7] *See, e.g.,* 27 Cal. Code Regs. §§ 25703(b) and 25711(a)(1).
[8] *Id.* § 25703(a).
[9] *Id.* § 25701(a).
[10] *Id.* § 25703(a)(4).
[11] Cal. Health & Safety Code § 25249.10(c).
[12] 27 Cal. Code Regs. § 25701(d).
[13] Cal. Health & Safety Code § 44360(b)(2).
[14] Cal. Air Res. Bd., "Hot Spots" List of Substances, https://ww2.arb.ca.gov/hot-spots-list-substances (last visited June 13, 2023).

("EPA") and Prop 65.[15] By incorporating information that forms the basis for other programs' determination, OEHHA may avoid the effort of a *de novo* review while also benefiting from the rigor required to meet those agencies' standards.[16] Here, OEHHA is relying in large part for its updated EtO IUR on the work and documentation associated with the EPA Integrated Risk Information System ("IRIS") IUR and Prop 65 NSRL for that chemical.[17]

Sterigenics' comments on the proposed NSRL relate directly to studies relied upon in the IUR update. Accordingly, the comments set forth below relate to both the proposed NSRL and proposed IUR and their supporting documents and should be considered in those contexts.[18]

III. FUNDAMENTAL FLAWS IN OEHHA'S CALCULATION OF THE PROPOSED NSRL AND IUR

A. The Proposed NSRL and IUR Cannot Be Reconciled with the NIOSH Study.

As explained in its Initial Statement of Reasons, in developing the proposed updated NSRL and IUR for EtO, OEHHA relied on EPA's 2016 report entitled *"Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide" (CASRN 75-21-8) in support of Summary Information on the Integrated Risk Information System* ("IRIS"). The IRIS assessment analyzed epidemiologic data from a cohort of more than 18,000 sterilization facility workers with quantitative estimates of exposure to EtO, assembled by the National Institute for Occupational Safety and Health ("NIOSH"). Sterigenics is very familiar with the NIOSH study, having through its predecessor companies contributed data from thousands of the workers in the cohort and having received repeated updates and worker notifications from NIOSH regarding the study findings.

Given the central importance of the NIOSH study on the derivation of the proposed NSRL and IUR, it is worth reviewing what the NIOSH scientists stated about their study findings in the peer review publications themselves, as well as in a

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[15] *See, e.g.,* OEHHA, Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures, at 10 (May 2009), *available at* https://oehha.ca.gov/media/downloads/crnr/tsdcancerpotency.pdf.

[16] *Id.*

[17] Even to the extent OEHHA's updating of the IUR has any aspects of *de novo* assessment, it is still bound to the standards it sets in its 2009 Technical Support Document for Cancer Potency Factors, referenced above.

[18] Sterigenics also supports and reiterates the comments made by The American Chemistry Council on the EtO NSRL and IUR. Those comments highlight important concerns we also have with OEHHA's selection of NSRL and IUR; our comments here focus more narrowly on those issues more specifically applicable to the medical device sterilization industry.

contemporaneous worker notification that NIOSH sent to Sterigenics and other sterilization companies and required them to publish to their workers. Notably, rather than suggesting that EtO posed an excess cancer risk at the exceedingly low level proposed for the new NSRL and IUR, NIOSH's clear conclusion was that EtO concentrations at historical workplace exposure levels did not lead to any increase in cancer. These historical workplace levels are many orders of magnitude higher than OEHHA's proposed NSRL and proposed IUR.

In both its 2003 publication focused on breast cancer incidence and its 2004 publication on cancer mortality more broadly, NIOSH concluded that there was no overall excess incidence of cancer in the 18,000 sterilization facility workers with historically high EtO exposures:

- "Our data do not indicate any overall excess of breast cancer incidence among the cohort as a whole compared to the U.S. population."[19]

- "In conclusion, we found no overall evidence of excess cancer mortality in this cohort, with the exception of bone cancer based on small numbers."[20]

In its IRIS assessment, EPA sought to explain away these findings by contending that they were due to the "healthy worker" effect, i.e., that the working population might have lower cancer incidences than the general population. But the scientific literature does not support any such healthy worker effect for blood cancers or breast cancers.[21] Moreover, EPA ignores the fact that NIOSH specifically considered and rejected this argument in its 2004 publication, stating that the "healthy worker effect would seem an unlikely explanation for the lack of cancer excesses in exposed versus non-exposed comparisons."[22]

NIOSH provided further reassurance in its contemporaneous worker notification of its study findings, which is still posted on the CDC website.[23] As it had in its published studies, NIOSH assured sterilization facilities and their workers that its study found "[n]o overall elevated risk for any type of cancer or other disease as compared to the general U.S. population."[24] NIOSH noted moreover that "most workers in our studies were exposed years prior to 1985 when EtO exposures were

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[19] K. Steenland, et al., *Ethylene oxide and breast cancer incidence in a cohort of 7567 women (United States)*, 14 Cancer Causes & Control 531, 537 (2003), https://link.springer.com/article/10.1023/A:1024891529592.
[20] K. Steenland, et al., *Mortality analyses in a cohort of 18,235 ethylene oxide exposed workers: follow up extended from 1987 to 1998*, 61 Occup. Env't Med. 2, 7 (2004), *available at* https://oem.bmj.com/content/61/1/2.short.
[21] J. Kirkeleit, et al., *The Healthy Worker Effect in Cancer Incidence Studies*, 177(11) Am. J. Epidemiology 1218 (2013), *available at* https://academic.oup.com/aje/article/177/11/1218/95903.
[22] Steenland (2004), *supra* note 20, at 6.
[23] CDC, NIOSH, Worker Health Study Summaries – Ethylene Oxide, https://www.cdc.gov/niosh/pgms/worknotify/ethyleneoxide.html (last visited June 13, 2023).
[24] *Id.*

much higher than they are today," and that the average exposure level for workers in the NIOSH cohort (a group again that on average demonstrated no excess cancer risk) from 1976-1985 was 4.3 parts per million ("ppm") for sterilization workers and 2 ppm for other workers.[25] These exposure levels are many orders of magnitude higher than OEHHA's proposed NSRL and proposed IUR.

The EPA did not base its new conclusion on any new data or scientific measurements or other developments subsequent to the completion of the NIOSH study. Rather, the EPA reinterpreted the NIOSH data to reach conclusions contrary to those stated in the peer-reviewed NIOSH studies themselves. Further, EPA has only presented purported findings/outcomes of this reinterpretation of cancer risks from the NIOSH cohort in its IRIS documentation, without including the underlying data or modeling output in the document or an appendix. The OEHHA proposal does not acknowledge this omission from the IRIS documentation or explain how OEHHA verified the risk model and, accordingly, appears to adopt the EPA reinterpretation without having reviewed the underlying model and data inclusion and processing. The adoption of a NSRL and IUR requires a transparent derivation that can be independently verified by the Scientific Review Panel on Toxic Air Contaminants ("SRP") and adopting the IRIS reinterpretation without providing the underlying information to the SRP and the public does not satisfy the applicable statutory requirements.[26]

B. The Proposed NSRL and IUR Conflict with Several State-Sponsored Epidemiological Studies.

The disconnect between the EPA's IRIS assessment and the scientific evidence has become even more stark in the years following the 2016 release of the IRIS assessment, as state health agencies across the country have conducted investigations in communities surrounding EtO sterilization and manufacturing facilities in search of the purported increases in cancers associated with historic EtO facility emissions.[27] In considering these findings, it is worth recalling that many of

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[25] *Id.*

[26] The SRP is charged with evaluating the risk assessments of substances proposed for identification as toxic air contaminants, including updated risk assessments prepared by OEHHA to support changes to existing health reference values and guidelines for conducting air toxics health risk assessments, also prepared by OEHHA pursuant to Health and Safety Code sections 39660 and 44360, respectively. Health and Safety Code section 39661(b) requires the SRP to "review the scientific procedures and methods used to support the data, the data itself, and the conclusions and assessments on which the report is based." This subsection also requires the "scientific data on which [OEHHA's] report is based" to be made available to the public.

[27] In its Initial Statement of Reasons, OEHHA relies on four other studies that seek to similarly investigate associations between residential proximity to EtO emitting facilities and increased cancer risks, noting that "these community-based air pollutant studies can be useful for hazard identification." OEHHA, Initial Statement of Reasons at 9 (Apr. 2023), *available at* https://oehha.ca.gov/media/downloads/crnr/etonsrlisor040723.pdf. *See also* OEHHA, Air Toxics Hot Spots Program, Ethylene Oxide, Cancer Inhalation Unit Risk Factor, Technical Supporting Document

these facilities were in operation dating back to the early 1980s, before the existing NESHAP regulations came into effect. Given the long latency period for many cancers, emission levels during the relevant time period for potential cancer initiation in these communities were likely higher than they are today. Even with these potentially higher historic EtO emission levels though, the search for the IRIS-predicted excess cancers in these communities has come up empty:

- In Colorado, the "incidence of all cancers combined and five individual types of cancer in the community surrounding Terumo BCT were no different than expected based on cancer rates in the remainder of Colorado for the years 2000 through 2017."[28]

- In Illinois, the "two assessments [of communities surrounding ethylene oxide sterilization and manufacturing facilities] did not offer clear convergence of evidence in specific cancer elevations."[29]

- In Michigan, the "results of this analysis presented in this report do not suggest that further investigation is needed at this time."[30]

- In Pennsylvania, the "cancer analysis within a 2-mile radius of the site revealed no consistent pattern for adult lymphohematopoietic and female breast cancer rates between 1985-2017."[31]

- In Tennessee, a "cancer cluster investigation provided no evidence for the clustering of high numbers of leukemia, Non-Hodgkin Lymphoma, breast,

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for Cancer Potency Factors, App. B at 13 (Apr. 2023 draft), *available at* https://oehha.ca.gov/media/downloads/crnr/etocanceriurdraft040723.pdf. OEHHA failed, however, to discuss any of the studies conducted by its sister state health agencies. Initial Statement of Reasons at 9. The four studies that OEHHA did cite also reached inconsistent conclusions. *See, e.g.*, R. Jones, et al., *Ethylene Oxide emissions and incident breast cancer and non-Hodgkin lymphoma in a U.S. cohort*, 115(4) J. Nat'l Cancer Inst. 405 (2023), *available at* https://pubmed.ncbi.nlm.nih.gov/36633307/ (study of EPA Toxics Release Inventory data reporting a "novel, potential association" between EtO emissions and *in situ* breast cancer but no association between EtO emissions and invasive breast cancer or non-Hodgkin's Lymphoma).

[28] Colo. Dep't of Pub. Health & Env't, *Community risk assessment of ethylene oxide near Terumo BCT in Lakewood, Colorado* (Dec. 3, 2018), *available at* https://www.terumobct.com/Pages/Eto-FAQ.aspx.

[29] Ill. Dep't of Pub. Health, *Cancer Incidence near Two Facilities Utilizing Ethylene Oxide, Lake County, Ill. 1998-2017* (Nov. 19, 2021), *available at* https://dph.illinois.gov/data-statistics/epidemiology/cancer-registry/cancer-assessment-lake-county.html.

[30] Mich. Dep't of Health & Human Servs., *Cancer Incidence Data Review: Area Surrounding Viant Medical Inc., Grand Rapids, MI* (2019), *available at* https://www.michigan.gov/egle/about/organization/air-quality/facility-specific-info/viant-medical.

[31] Penn. Dep't of Health, *Community Cancer Incidence Data Review: B. Braun Medical Sterilization Facility, Allentown, Lehigh County, Pennsylvania* (May 2022), *available at* https://www.health.pa.gov/topics/Documents/Environmental%20Health/Community%20Cancer%20Incidence%20Data%20Review%20B.%20Braun%20Medical%20Sterilization%20Facility-Factsheet.pdf.

or stomach cancer near the facility when compared to a group away from the facility in 2000-2009 or 2010-2019."[32]

- In West Virginia, the "results show no evidence that cancer incidence is related to living near these facilities."[33]

C. The Proposed NSRL and UIR Ignore Background Levels

OEHHA's proposed NSRL and IUR also disregard newly emerging evidence regarding background levels of EtO in ambient air unrelated to sterilization facility emissions and exposures from endogenous production of EtO in the human body. These data show that the general population experiences background EtO exposure at levels far greater than the NSRL and IUR. As reported by OEHHA, the South Coast AQMD air monitoring for EtO has detected background levels of EtO ranging up to 0.17 parts per billion ("ppb") in the South Coast Air Basin for 2022-2023.[34] In its own ambient air monitoring, EPA has measured average ambient air background EtO concentrations of 0.297 μg/m^3, which translates to 0.165 ppb.[35] More recent EtO monitoring conducted by other state environmental regulators has resulted in similar findings.[36] In addition, the CDC, through its National Health and Nutrition Examination Survey ("NHANES") program, has measured endogenous average EtO levels (as reflected in hemoglobin adduct measurements) corresponding to ambient concentrations of 2.5 ppb.[37] EtO exposures to the public from sterilization facilities are indistinguishable from these background and naturally occurring levels.

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[32] Tenn. Dep't of Health, *Potential Cancer Cluster Investigation for Sterilization Services of Tennessee located in Memphis, TN* (Feb. 27, 2023), *available at* https://www.shelbytnhealth.com/571/Ethylene-Oxide-EtO.

[33] W. Va. Dep't of Env't Prot., *Evaluation of Ethylene Oxide-related Cancers in Kanawha County, West Virginia* (June 9, 2022), *available at* https://oeps.wv.gov/cancer/Documents/Data/Ethylene_Oxide_in_Kanawha_County.pdf.

[34] *See* OEHHA, Air Toxics Hot Spots Program: Cancer Inhalation Unit Risk (IUR), Ethylene Oxide, Public Workshop Presentation at 3 (May 5, 2023), *available at* https://oehha.ca.gov/media/downloads/crnr/etoiurpublicwkshppresentation.pdf.

[35] *See* EPA, Ethylene Oxide Data Summary from National Air Toxics Trends Stations and Urban Air Toxics Monitoring Program sites, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-data-summary-national-air-toxics-trends (last visited May 26, 2023).

[36] *See* Ga. Dep't of Nat. Res., Env't Prot. Div., Air Protection Branch, 2021 Air Quality Report (2022), https://storymaps.arcgis.com/stories/e30085ae1e5345b9bf18595ee0a713c6 (measuring background ambient concentration of 0.43 μ/m^3 or 0.24 ppb).

[37] *See* CDC, National Report on Human Exposure to Environmental Chemicals, https://www.cdc.gov/exposurereport/whats_new_060622_1.html (last visited May 26, 2023); I. Rietjens, et al., *The role of endogenous versus exogenous sources in the exposome of putative genotoxins and consequences for risk assessment*, 96(5) Arch. Toxicol. 1297 (2022), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9013691/.

IV. FAILURE TO ACCOUNT FOR BACKGROUND CONCENTRATIONS OF ETO IN CONNECTION WITH PUBLIC NOTICE REQUIREMENTS

As part of its regulatory oversight of Sterigenics' sterilization facilities in Los Angeles and Ontario, the South Coast AQMD has conducted air monitoring in the areas surrounding the facilities to determine whether their operations are generating excess levels of EtO in residential communities neighboring the plants. This monitoring has confirmed that there are no such excess levels. At the Ontario facility, the South Coast AQMD concluded that "concentrations decreased to near background levels approximately 1,000 ft downwind of the plant," while "[t]he nearest residential area is about 1.4 miles away and the nearest school is about 1.2 miles."[38] Likewise, air monitoring around the Los Angeles facilities "shows levels of EtO in the community to be within background levels."[39] Consistent with the South Coast AQMD's broader air monitoring data, these background levels ranged upwards of 0.2 ppb. Even if one were to accept the flawed science underlying the proposed NSRL and IUR – which, for the reasons stated above, Sterigenics believes would be improper – this monitoring data confirms that individuals living near these Sterigenics facilities would not be at any greater risk of cancer than the general population.

Notwithstanding this clear evidence, Sterigenics anticipates that the proposed IUR could trigger new, widespread public notifications around these facilities. If and where the air dispersion modeling predicts EtO concentrations from the facility exceeding a theoretical excess cancer risk of 10 in one million, residents would be notified that they were subject to excess cancer risks. Meanwhile, residents in neighboring communities *exposed to higher levels* of *ambient EtO from other sources or from varying background levels in their communities* would receive no such notices. Indeed, based on the South Coast AQMD monitoring data, the public in many areas of the State would have higher levels of exposure through ambient background EtO levels without any health risk disclosure.

Given this reality, establishing an IUR that would require public notification under state and local air toxics regulations solely to populations in areas surrounding sterilization facilities would not serve the public interest or provide any meaningful information to recipients. Rather, the result would be to mislead notice recipients and create an atmosphere of fear and anxiety in the communities around

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[38] South Coast AQMD, Sterigenics Emissions Investigation in Ontario, https://www.aqmd.gov/home/news-events/community-investigations/sterigenics-ontario (last visited June 8, 2023).

[39] South Coast AQMD, Sterigenics Emissions Investigation in Vernon, https://www.aqmd.gov/home/news-events/community-investigations/sterigenics (last visited June 13, 2023).

sterilization facilities. These outcomes would be detrimental to public health in the affected communities and in conflict with guidance from the California Air Pollution Control Officers Association on the importance of putting health risk estimates for stationary sources into perspective with risk from other directly comparable routine exposures.[40]

V. FAILURE TO EVALUATE RISKS OF POTENTIAL MEDICAL DEVICE SHORTAGES CAUSED BY ETO CAPACITY CONSTRAINTS

OEHHA has stated that the anticipated benefit in its proposed new NSRL for EtO is "to protect the health and welfare of the California public, in line with the public health goal of Proposition 65."[41] Similarly, OEHHA's goals updating the IUR is to advance the goals of the Air Toxics "Hot Spots" Act,[42] which are "to collect emission data, identify facilities having localized impacts, ascertain health risks posed by those facilities, notify nearby residents of significant risks and reduce emissions from significant sources,"[43] consistent with the Act's statutory declaration that "It is in the public interest to ascertain and measure the amounts and types of hazardous releases and potentially hazardous releases from specific sources that may be exposing people to those releases, and to assess the health risks to those who are exposed."[44] To properly weigh the anticipated benefit (or cost) of the NSRL and IUR in protecting the health and welfare of the California public, OEHHA should evaluate the non-air quality health impact of a diminished ability to sterilize medical equipment in the State.

As the United States emerges from the pandemic, FDA has focused its attention and resources on addressing potential shortages of medical devices critical to public health and safety. In 2020, Congress gave FDA new statutory authority under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") to help mitigate and prevent devices shortages in advance of a public health emergency ("PHE").

In a fact sheet entitled "Mitigating and Preventing Medical Device Shortages and Prioritizing Public Health," FDA highlights the fact that, during the pandemic, shortages hit hard for "such critical devices as ventilators, test supplies, and even

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[40] Cal. Air Pollution Control Officers Ass'n, Air Toxics "Hot Spots" Program, Public Notification Guidelines (Oct. 1992), *available at* https://ww2.arb.ca.gov/sites/default/files/2023-05/pubnotif.pdf.
[41] OEHHA, Notice of Proposed Rulemaking, Amendment to Section 25705, Specific Regulatory Levels Posing No Significant Risk: Ethylene Oxide at 4 (Apr. 7, 2023), *available at* https://oehha.ca.gov/media/downloads/crnr/ethyleneoxidensrlnprm040723.pdf.
[42] Cal. Health & Safety Code § 44300 et seq.
[43] Technical Support Document for Cancer Potency Factors, *supra* note 15, at 3.
[44] Cal. Health & Safety Code § 44301(h).

some of the equipment needed to administer vaccines."[45] FDA points out that COVID-19 exposed weaknesses in the U.S. supply chain and emphasizes the dependence on supply from China and other countries. In the context of proposed federal regulation likewise based on the EPA's 2016 IRIS Report, the FDA has notified EPA of the potential that its EtO rulemakings will "inadvertently contribute to significant medical device supply chain disruptions."[46] This is exactly the type of situation FDA has been working to address; as is stated in the fact sheet, "[d]ealing with medical device supply chain disruptions requires getting ahead of problems before they become serious shortages."[47]

In instances where the substance in question provides substantial public health benefits, those benefits must be weighed against potential health risks from exposure to the substance, both to inform effective risk management decisions and to avoid foreseeable adverse public health impacts. As in the case of fluoride, which has been an unqualified success in preventing tooth decay in the general population, and which the State's Qualified Experts unanimously declined to list as a Proposition 65 carcinogen,[48] the public health benefits of sterilizing medical devices outweigh the health risk from exposure to EtO emissions from sterilization facilities, regardless of how that risk is evaluated and characterized.

VI. CONCLUSION

OEHHA's proposed NSRL and IUR do not reflect the weight of the well-founded scientific and other evidence regarding the risks presented by EtO. The proposals are premised wholly on EPA's IRIS IUR for EtO and fail to account for the definitive NIOSH studies from which the IRIS IUR was purportedly derived or the subsequent State-conducted studies consistently finding no increased incidence of cancer in the vicinity of EtO sterilization facilities. The proposed NSRL and IUR would not serve the public interest or provide any meaningful information to residents of California, but the new standards very likely could limit EtO sterilization capacity in California and thereby lead to a shortage of sterilized medical devices in this and surrounding states.

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[45] FDA Fact Sheet, Mitigating and Preventing Medical Device Shortages and Prioritizing Public Health at 1 (2022), *available at* https://www.fda.gov/media/156980/download.

[46] 12866 Interagency Review Documentation - File Set 1 of 2: "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review," Att. 33 at 14 (Apr. 17, 2023), *available at* https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-0493 (Margin Comment [A2]).

[47] FDA Fact Sheet, *supra* note 42.

[48] *See* OEHHA, Meeting Synopsis and Slide Presentations Carcinogen Identification Committee Meeting Held on October 12, 2011 (Nov. 2, 2011), https://oehha.ca.gov/proposition-65/transcript-comment-presentation/meeting-synopsis-and-slide-presentations-carcinogen.