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Subject: Comments on OEHHA's Proposed Draft Cancer Potency Factor for Ethylene Oxide and Technical Support Document

South Coast Air Quality Management District (South Coast AQMD) staff appreciates the opportunity to provide comments on the Office of Environmental Health Hazard Assessment's (OEHHA) proposed revision to the inhalation cancer potency factor (CPF) for ethylene oxide (EtO) and technical support document (TSD) released on April 7, 2023. This proposed action is largely based on the 2016 evaluation by the Environmental Protection Agency (U.S. EPA) regarding the carcinogenicity of EtO. That review identified a unit risk estimate that is several times higher than currently used by OEHHA for health risk assessments (HRA) under the state's AB 2588 Hot Spots Program. According to the IRIS assessment and the draft OEHHA CPF, low concentrations of EtO can pose significant cancer risk to the public when exposed for many years.

We take the concerns raised regarding the revised health risks associated with EtO seriously. When the U.S.EPA notified us of the potential for elevated cancer risks associated with medical sterilizers, we started an extensive monitoring campaign to characterize EtO levels near these facilities. Our comments are informed by the results of this monitoring campaign, as well as our ongoing compliance activities, rulemaking, implementation of the AB 2588 program and subsequent permitting activities.

There are three main concerns detailed in the attachment to this letter. First, if EtO indeed has the cancer potency that OEHHA is proposing, there are significant consequences for all Californians. The potential cancer risk at background levels would be about 1,000 chances in-a-million, more than double the cancer risk from all other pollutants and sources combined in South Coast AQMD. It is currently unclear what sources are contributing to background levels of EtO – based on our monitoring data, it does not appear to be due to medical sterilizers. With population-wide risks of this level, we believe it is imperative that CalEPA take a much more active role in identifying the sources of the risk, as well as appropriate measures to reduce it. This effort will take significant coordination among the state, air districts, and others as well as substantial resources.

Second, additional clarity is needed for how the underlying data is being interpreted to derive the proposed CPF. It is unclear if the low exposure epidemiologic data supports the conclusion that

higher risks are experienced at background levels. For example, if the risks from background levels of EtO are persistently about 1,000 chances in-a-million, it is unclear how this risk is factored into the development of the CPF. Further, data in OEHHA's Technical Support Document (TSD) suggests that the relationship between relative risk and cumulative exposure is non-linear, with low level exposures seeming to have a protective effect. While we strongly support the adoption of a CPF based on best-available science, we ask that OEHHA clarify the assumptions and treatment of data in developing the revised CPF. This is particularly important given the implications of the high risks associated with low exposures that would be experienced everywhere given levels of background EtO.

Finally, although OEHHA appears to rely almost wholly on U.S. EPA's conclusions about the carcinogenicity of EtO, the resulting cancer risks in California's regulatory program are 60% higher than those using U.S. EPA methods. For example, under U.S. EPA's approach, 0.011 ppb = 100 chances in-a-million risk for residential exposure, whereas OEHHA's draft approach results in 0.007 ppb = 100 chances in-a-million. We are unaware of an epidemiologic basis to support this higher result by OEHHA. If this effect is unintended, then OEHHA should evaluate potential modifications to the draft CPF in consideration of how it is applied under the AB 2588 program.

Additional details are provided in the attachment. We request a meeting to discuss these comments and encourage OEHHA to finalize its statewide guidance in an expeditious manner. Please do not hesitate to contact either myself at (909) 396-3244 or imacmillan@aqmd.gov, or Eugene Kang at (909) 396-3524 or ekang@aqmd.gov.

Sincerely,

Ian MacMillan

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Attachment

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Attachment

EtO is used in certain chemical manufacturing processes and is also used for sterilization of medical equipment. Currently, there are 16 facilities subject to South Coast AQMD Proposed Amended Rule 1405 - Control of Ethylene Oxide and Chlorofluorocarbon Emissions from Sterilization or Fumigation Processes, of which 15 facilities use EtO for sterilization and the other remaining facility is an aeration-only facility receiving EtO sterilized materials from sterilizers outside of South Coast AQMD jurisdiction. Since notified by U.S. EPA of the potential for elevated cancer risks from these facilities, South Coast AQMD has undertaken an extensive study of these facilities. This work continues today through monitoring efforts both near and far from EtO emission sources, inspections and subsequent compliance activities, rulemaking, and implementation of the AB 2588 program and subsequent permitting activity (www.aqmd.gov/eto). The comments below are based on information gathered from this effort.

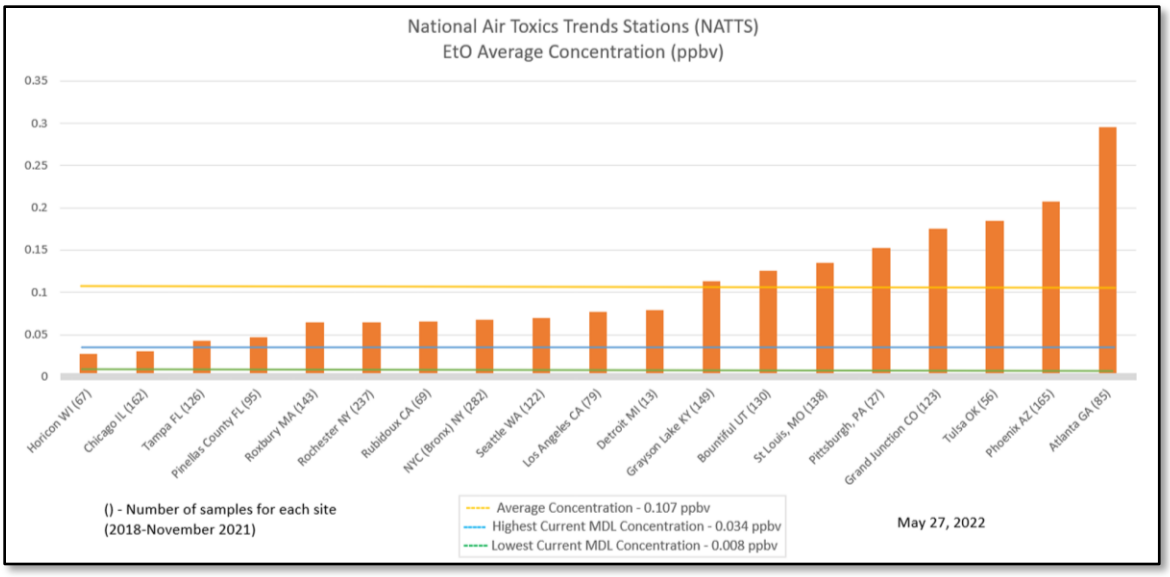
High Risks Associated with Background Levels of EtO

Beginning in 2020, South Coast AQMD began monitoring background levels of EtO at two sites in our jurisdiction under U.S. EPA's National Air Toxics Trends Stations (NATTS) program. Summary information for these two sites is shown in the table below for calendar year 2021.

Statistical Parameter	Ethylene Oxide Concentration (ppbv)	
	Downtown Los Angeles	*Rubidoux*
Average	0.07	0.06
Median	0.07	0.06
Maximum	0.17	0.14
Minimum	MDL	MDL

**Method Detection Limit (MDL) = ~0.02 ppb for more recent sampling. Earlier sampling had MDL = ~0.08 ppb*

The levels found at these sites are consistent with levels found at NATTS sites throughout the nation as shown in the figure below (copied from https://dep.wv.gov/key-issues/Documents/EtO/Final%20Report/Final%20Report%20Body%202-21-2023.pdf). These background levels are also consistent with monitored EtO levels found a few hundred feet from sterilization facilities in South Coast AQMD, indicating that the sterilization facilities are likely not the leading source of EtO emissions contributing to background levels found nearly everywhere throughout our region and the nation.



Using the draft CPF from OEHHA, the average background level of EtO at the downtown LA site would result in a residential cancer risk of about 1,000 chances in-a-million. As a point of comparison, the most recent MATES study from South Coast AQMD (that does not consider the new draft EtO CPF) found that the average air toxics cancer risk from all pollutants and all sources in the air basin is about 455 chances in-a-million, based on 2018 emissions (www.aqmd.gov/matesv). Thus, the potential adoption of this new CPF would result in a newly identified cancer risk in our region that is more than double the previously considered cancer risk from all other sources combined.

Given the high monitored background levels of EtO and its potential impact on public health, we are requesting assistance from OEHHA and CalEPA to identify, develop and implement appropriate risk management strategies similar to CARB's diesel risk reduction plan if OEHHA moves forward with the proposed CPF. For context, in 1998 CARB and OEHHA designated Diesel Particulate Matter (DPM) as a toxic air contaminant, and subsequently estimated a population-wide air toxics cancer risks throughout the state of 380 chances in-a-million.[1] In 2000, CARB committed to reducing diesel particulate matter (DPM) by 75% by year 2010 and by 85% by year 2020 due to this newly discovered elevated risk affecting large portions of the state.[2] We are concerned that OEHHA is identifying a similarly high risk, however there are no coordinated statewide actions to identify the sources of that risk, or feasible measures to reduce it.

Clarification of Potential Cancer Risks from Ethylene Oxide Exposure at Background Levels
Further clarification is needed regarding the interpretation of the data underlying the proposed CPF. We recognize the important studies that OEHHA is relying on its assessment. We request that OEHHA provide more clarification about the available data on low-level ethylene oxide exposure to support the assertion that higher risks are encountered at background levels. To understand the extent of the issue, it is important to investigate the modeling techniques employed

[1] ww2.arb.ca.gov/sites/default/files/classic/toxics/dieseltac/finexsum.pdf

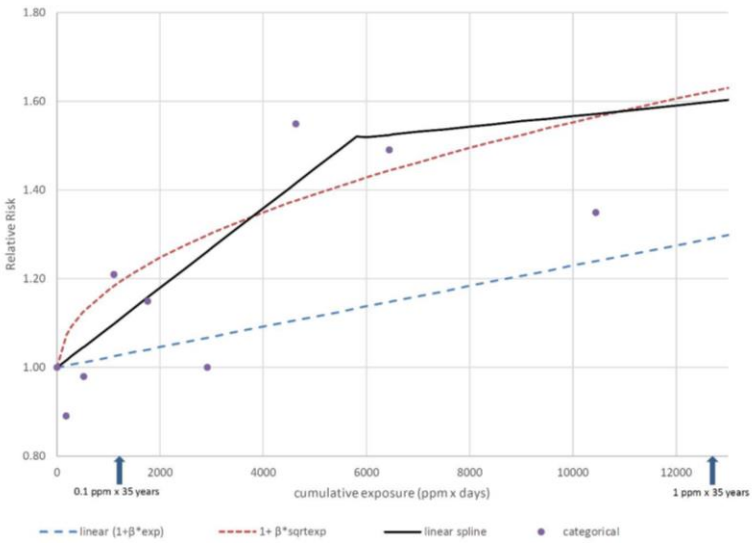
[2] ww2.arb.ca.gov/sites/default/files/classic/diesel/documents/rrpfinal.pdf

to assess the potential risks associated with low-level ethylene oxide exposures. It is unclear how much ethylene oxide found at background levels throughout the nation is naturally occurring and what are the key contributing man-made sources. Given its ubiquitous presence even in environments presumably far from any known man-made sources (such as background sites in Utah and in the middle of a state park in Kentucky),[3] an evaluation of the modeling methodologies and data interpretation at low exposures used in the risk assessment is essential. Additional analysis and explanation should be provided to help explain the factors considered and the underlying assumptions made when evaluating the carcinogenicity of ethylene oxide at low exposure levels.

In reference to relative risk estimates as presented in Figure 6 and 7 of the Ethylene Oxide Cancer Inhalation Unit Risk Factor Technical Support Document (TSD) for Cancer Potency Factors Appendix B April 2023 Draft, it is unclear how a relative risk of 1 at 'zero' exposure (the left side of the graph) corresponds to background EtO levels found everywhere. If EtO is found naturally in the human body, and potentially is persistent everywhere in ambient air, the final TSD should explain how the CPF considers these ubiquitous low-level exposures, and whether they pose an elevated cancer risk. Is the baseline level of ethylene oxide taken into account when determining if there is an increased risk at low exposure levels?

Further, based on the proposed model depicted in Figure 7 (copied below), there appears to be an observation that low-level exposure to ethylene oxide may be protective rather than posing an increased risk. The two categories with lowest exposure show a relative risk <1, while a third category at 'zero' exposure with a relative risk of exactly 1 appears to be an assumption rather than actual data. This observation adds complexity to the understanding of the potential carcinogenicity at low exposure levels and highlights the importance of thoroughly assessing the available data and modeling techniques to ensure accurate risk evaluation. We note that at a typical background level of ~0.1 ppb and a 70-year exposure for the general public, cumulative exposure would be about 3 on the graph below, within the category showing potentially protective effects.

Figure 7 from Draft OEHHA Technical Support Document for Ethylene Oxide



[3] See https://deq.utah.gov/air-quality/ethylene-oxide-study and data for Grayson Lake, KY in bar chart above

In light of the available evidence, an important question arises regarding the application of the CPF at low concentrations of ethylene oxide. Does the CPF hold true for lower exposure levels experienced by the general public based on the information currently accessible? It is crucial to evaluate the existing evidence to determine the applicability of the CPF at low ethylene oxide concentrations.

Use of Cancer Potency Factor Resulting from Draft OEHHA TSD

We also request OEHHA to confirm that estimating cancer risk using the CPF (once it has been made final), in conjunction with the methodology from OEHHA's 2015 Guideline is appropriate. OEHHA has provided guidance through the past several years to modify the risk assessment procedures for AB 2588. These changes include the adoption of age sensitivity factors and higher breathing rates, including those for lower age bins. Cumulatively, these changes have resulted in more conservative cancer risk estimates when compared to the previous use of inhalation unit risk factors in AB 2588 HRAs.

Although the draft unit risk factor from OEHHA's TSD is 10% higher than U.S. EPA's unit risk estimate, using the CPF in accordance with AB 2588 methodology (i.e., calculating dosages across all age bins) results in a cancer risk estimate that is more than 60% higher than results from U.S. EPA's unit risk estimate for full lifetime exposure. Staff requests OEHHA to confirm that this is the intended consequence from using the CPF as stated in the TSD and provide guidance on how it should be applied under the AB 2588 program. Some examples include:

- 0.0068 ppbv[4] of EtO would pose an excess cancer risk of 100 chances in-a-million at a residential receptor[5]; whereas using U.S. EPA's unit risk estimate, 0.011 ppbv[6] would pose the same risk for a full lifetime exposure.
- 0.082 ppbv of EtO would pose an excess cancer risk of 100 chances-in-a-million for worker receptors, whereas 0.169 ppbv[7] would pose the same excess cancer risk of 100 chances in-a-million using U.S. EPA's risk methodology.

[4] Note that these concentrations may be below the detection level for certain test methods.

[5] Using Risk Management Practice; OEHHA Derived Method would result in even higher risk values.

[6] https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=355443&Lab=CEMM

[7] Assuming exposure of 8 hrs/day, 240 day/yr for 35 years over a 70-year lifetime.