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EPA Should Revise Its Assessment of Medical Supply Sterilant

Faulty Science on Ethylene Oxide is Fueling Unfounded Health Scares, Plant Closures, and Medical Supply Shortages

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The COVID-19 crisis is a stark reminder of the importance of maintaining critical medical supplies. Not only must policy makers ensure that the market is free to serve normal medical supply needs, the market must also be positioned to fill increased demand related to potential pandemics. Unfortunately, the U.S. was not fully prepared in part because intrusive government policies had disrupted supplies long before COVID-19 became an issue. Several state and local governments had shut down a number of medical supply sterilization facilities during 2019 in response to a perceived health scare related to emissions of ethylene oxide (EtO), a gas used to sterilize medical supplies. The Food and Drug Administration (FDA) warned that the closures would produce medical supply shortages, which were compounded when COVID-19 emerged.[1]

A U.S. Environmental Protection Agency (EPA) toxicology information program known as the Integrated Risk Information System (IRIS) had triggered the health scare by releasing questionable information about EtO cancer risks. IRIS conducts hazard assessments of chemicals that other agency offices use to develop risk assessments and set regulations. Based on faulty and outdated science, the IRIS assessment for EtO vastly overstated its risks, generating unwarranted fears that the emissions could cause cancer within communities located near these facilities.

Although some of the facilities reopened during 2020 at the behest of the FDA to help address medical supply needs, their future remains uncertain. Unless it is corrected, the IRIS assessment will likely continue to misinform the public and alarm residents and businesses near facilities using EtO. Accordingly, the EPA should revisit and revise its flawed EtO hazard assessment to ensure it reflects the best available science on the topic.

This paper examines the science that IRIS used to develop its EtO assessment. Serious flaws in the exposure data of the underlying research led IRIS to vastly overstate cancer risks. However, this paper does not cover all the serious problems associated with the IRIS assessment. Other reviews have uncovered substantial issues related to scientific models the agency deployed in the assessment. Readers can get more information by reviewing those sources.[2]

Background. Ethylene oxide is a gas that naturally enters air from vegetation, manure, volcanic eruptions, waterlogged soil, and combustion related to traffic, smoking, fires, and

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many other sources. Humans inhale some, but it is also naturally formed inside the human body by our metabolic processes, and we release it as waste products. Moreover, according to the EPA, the human body is well equipped to safely manage EtO formed inside the body and inhaled from the environment, releasing it "fairly quickly," with levels falling by "50% every 42 minutes."[3]

EtO has been used for decades in many industrial processes and is used in the production of many consumer products such as personal care products, household cleaners, and antifreeze. It is also used to remove potentially dangerous pathogens from spices. A small percent of EtO is used for medical supply sterilization, which involves placing medical equipment and devices—everything from medical devices to bandages to disposable masks—in tightly sealed chambers. EtO gas is then pumped into the chamber, where it penetrates the equipment for hours until all is rendered sterile. The gas is then removed from the chamber and recycled for sterilization or used in other industrial applications. Only tiny traces may enter ambient air or are released as emissions.

For decades, regulators around the world have understood that trace emissions from these facilities were too low to pose significant risks. Public perception changed when the EPA released its Integrated Risk Information System assessment of EtO risks in 2016.[4] For each chemical it assesses, IRIS normally sets a reference concentration "of a continuous inhalation exposure" and a reference dose "of a daily oral exposure" at which the chemical is expected to pose no "appreciable risk of deleterious effects during a lifetime."[5] IRIS assessments also place chemicals expected to be carcinogens into one of various cancer categories ranging from "Carcinogenic to Humans" down to "Not Likely to Be Carcinogenic to Humans."

EPA officials created IRIS administratively as a research program in 1986, and there are no statutory guidelines for the science it produces. Its assessments have proven controversial, and concerns about the program have only grown over past decades. IRIS reform has long been the subject of Government Accountability Office reports, an Inspector General Report, and congressional hearings.[6] In 2011, a National Academies of Sciences panel report on IRIS' formaldehyde risk assessment criticized the program for "recurring methodologic problems," including repeated failures to provide "clarity and transparency of the methods," inconsistencies, poor research documentation, failure to follow EPA research guidelines, and other issues.[7]

Much of IRIS' functions could be better situated inside the EPA's Office of Chemical Safety and Pollution Prevention following the statutorily established scientific guidelines of the Toxics Substances Control Act. As detailed in this paper, IRIS' highly flawed EtO assessment underscores the need to take such actions.

IRIS released its assessment of EtO in 2016, setting an excessively stringent reference concentration at 0.1 parts *per trillion* or 100 parts per *quadrillion*. Supposedly, people exposed to EtO above this minuscule level could have elevated cancer risks, but as detailed in a subsequent section, that conclusion is implausible.

Nonetheless, another office at the EPA used the IRIS number when developing an air quality report known as the National Air Toxics Assessment (NATA), running models that estimated where air concentrations of EtO might have exceeded IRIS' reference concentration. In a fact sheet accompanying the report, released in 2018, NATA noted: "The 2014 NATA shows that several areas could have elevated cancer risks from long-term exposure to the chemical ethylene oxide. These elevated risks are largely driven by an EPA risk value that was updated in late 2016."[8]

Despite the fact that NATA reports are meant to be screening tools only, not indicators of actual risk, that NATA report set off a panic in communities located near medical equipment sterilization plants. Several even shut down in 2019 because of unfounded fears about the risks. These shutdowns contributed to medical supply shortages during the early part of the 2020 COVID-19 outbreak. All but one facility, which closed permanently, had reopened to help address supply shortages. Unfortunately, misinformation campaigns based on the faulty IRIS science continue to fuel efforts to close medical sterilization plants in the future. In addition, trial lawyers are trolling for clients, hoping to capitalize by tying unrelated cancers in these communities to EtO usage.[9]

The EPA Should Comply with ACC's Information Quality Act Petition. In September 2018, shortly after the NATA report was released, the American Chemistry Council (ACC) filed an Information Quality Act (IQA) petition with the EPA calling on the agency to correct both the NATA report and the IRIS assessment. The petition explained:

> ACC seeks the correction of EO information disseminated in the 2014 update to the National Air Toxics Assessment (NATA). … [T]he 2014 NATA does not meet the IQA's data quality requirements because the EO IRIS Assessment is not the best available science.
>
> Therefore, the 2014 NATA risk estimates for EO should be withdrawn and corrected to reflect scientifically-supportable risk values. … As producers and users of EO, ACC members are directly impacted by the errors in the 2014 NATA. The risk estimates based on the EO IRIS value have significant regulatory implications for ACC member companies who produce commercial products of value to consumers using EO. Correcting these deficiencies will result in more accurate estimates of potential risk that will lead to improved regulatory outcomes, the dissemination of more accurate information to the public, and overall reduced misconception.[10]

Ethylene oxide has critically important applications that benefit consumers. Accordingly, the EPA should revoke the NATA risk estimates and invalidate the IRIS assessment. A review of the science underlying IRIS' original assessment reveals serious flaws and assumptions that have misled the public and state and local regulators about EtO risks.

The IRIS Reference Concentration Does Not Reflect Reality. Considering both background concentrations and other natural exposures to EtO, the IRIS reference concentration makes no sense. The ACC petition explains that the IRIS figure supposedly "corresponds to a one-in-a-million increased cancer risk."[11] But considering exposures from

natural sources and background levels, the IRIS reference concentration is way off the mark. The human body produces EtO at a level that is 19,000 times *higher* than IRIS' reference concentration of 0.1 ppt, as much as 1,900 ppt (1.9 ppb) of EtO. IRIS' reference concentration is also 1,000 to 2,000 times lower than the background levels reportedly found in urban air around the nation, which EPA data indicate is about 0.1-0.2 ppb.[12] ACC explains: "Thus, if the EO IRIS Assessment is to be believed, normal human metabolism and/or breathing ambient air is sufficient to cause cancer."[13] In short, the incremental exposure to ethylene oxide that would occur at IRIS' reference concentration would be both negligible and undetectable against the background of ambient ethylene oxide concentrations.

Not surprisingly, the IRIS reference concentration is out of sync with government safety standards around the world. As toxicologist Gail Charnley points out, it is more than "5 million times more stringent than the scientific judgements underlying all other regulatory limits on ethylene oxide in the United States and worldwide."[14] For example, the Occupational Safety and Health Administration's (OSHA) safety standard for EtO is 1 part per million, which is *10 million times* higher than the EPA's IRIS reference concentration. And that is for workers exposed for hours a day for decades. This standard has been in place since 1984, and there is no compelling evidence demonstrating that workers have suffered ill effects at that level. Prior to 1984, the OSHA standard was 50 ppm.

In response to the unwarranted panic prompted by IRIS and NATA, the EPA took measurements of EtO in the air during 2018 and 2019 in and around medical sterilization plants, and the levels discovered are not alarming.[15] "No doubt, scientific truths are desperately needed in the public dialogue," Charnley explains. "The most important truth being, there is no cancer threat from the tiny amounts of ethylene oxide released from these sterilization plants."[16]

The EPA is also working on a rule that would potentially tighten regulations on medical sterilization facilities, which it is expected to finalize in 2021.[17] However, this new rule appears to be driven by politics rather than real concerns about public health. It is already clear that EtO emissions from these plants are so low that they do not pose any significant health risks. In an exercise of excessive caution, the EPA issued a rule in June 2020 that tightened emission standards for certain other industrial facilities that use or produce EtO.[18] However, the agency indicated that it was still considering the ACC petition under the Information Quality Act, which is a positive development. As the EPA develops a rule that will apply to medical sterilization facilities, the correction to the science that ACC requests is imperative.

Flaws in the Underlying Research Contributed to the Excessively Cautious Reference Concentration. Several studies that rely on both human exposures and rodent tests indicate that ethylene oxide may cause cancer in humans,[19] but some more recent research casts doubt on those findings.[20] In any case, the key question is at *what exposure level and duration* might the chemical pose a significant risk that warrants regulatory action. Regulatory bodies around the world have set safe exposure limits that are orders of magnitude higher than IRIS' reference concentration, which raises questions about the

scientific basis of the assessment. While many of the alternative exposure limits apply to occupational exposures, the striking difference between those limits and the IRIS value should not be so dramatic.

In developing its IRIS reference concentration, the EPA primarily relied on three studies conducted by researchers from the National Institute for Occupational Safety and Health (NIOSH). All three of these NIOSH studies focused on the same cohort of workers exposed to EtO between 1938 and 1985.[21] Yet, it disregarded other studies and data that could have proved valuable in its assessment (discussed in more detail below). The EPA's assessment explains that the agency relied on these studies alone because the cohort was large, tracking the cancer rates among 18,254 workers at 14 plants that used EtO to sterilize medical equipment or spices over a period of 16 years.[22] It also had fewer confounding factors than did other EtO worker studies, according to the EPA. However, none of the NIOSH studies found a statistically significant, causal relationship between EtO and cancer.

Overall, these three studies showed one thing: that cancer rates among workers exposed to EtO over several decades were *lower* than cancer rates within the general population. These studies also reported weak associations for a few rare cancers, but the researchers had to parse through the data to tease out those associations.

While it is plausible that EtO could cause cancer in cases of relatively high, long-term exposure, the NIOSH studies did not look at actual exposure measures for the workers. Instead, the 1991 study developed average exposure estimates based on data related to EtO measures at the facilities during a limited number of years. A review of the studies indicates that it is likely that they substantially underestimated exposures for a large portion of the cohort. Accordingly, by relying on these studies, which vastly underestimated exposures, without attempting to correct the data, IRIS staff assured that their assessment would vastly overstate EtO risks.

The first study, published in 1991, covered worker exposures that occurred between 1938 and 1985. No data on worker exposures existed prior to 1976, so the researchers developed estimates based on air samples collected between the years 1975 and 1984. Using this data, the final estimated exposure was quite low, at an average of 4.3 ppm for workers operating sterilization machines and a low of 2 ppm for other workers in the plants.[23]

However, it is likely that actual exposures were much higher for the years before 1975. For example, a study published in the *British Journal of Industrial Medicine* also examined the NIOSH cohort and developed its own estimated exposures for those workers. It contended these workers were regularly exposed to 16 ppm during the years before 1978 and 4 ppm to 5 ppm after 1978, although those numbers may be underestimates for the years before 1975. However, the EPA did not include these data in its analysis, relying solely on the three U.S. studies conducted by NIOSH researchers.

Moreover, other research reveals that common exposure levels in the industry at that time were much higher than estimated in the NIOSH studies. This research is summarized in a 1993 meta-analysis, which included a number of studies that provided actual measurements

of EtO exposures—rather than estimates—that occurred before 1978 in medical sterilization facilities. During the 1970s, the meta-analysis reports that at least some plants periodically exceeded the odor threshold of 400 parts per million, indicating exposures vastly higher than the NIOSH studies developed. A large number of workers were likely exposed to these much higher levels, which magnifies the impact of relying on underestimates. "About 86% of the workers had exposures before 1978, when the exposure levels were believed to have been higher," the meta-analysis explained.[24] Hence, the NIOSH studies likely *underestimated* exposures for a significant number of the cohorts in the study, and potentially by a large amount.[25]

Even though many workers in the cohort likely had exposures much higher than estimated, the NIOSH studies still failed to produce compelling evidence that EtO was responsible for cancer among medical sterilization plant workers. The 1991 study found no association between EtO and cancer in general. The authors report "slight but significant" levels of blood-related cancers, but only among men in the cohort, while women had a lower than average level of blood-related cancers. The authors acknowledge that this difference between the sexes is "inconsistent" with rodent EtO studies, and they grapple to find an explanation. They suggest that perhaps the men experienced higher exposures than the women, but that is no more than supposition. In fact, because these cancers are relatively rare, there is a reasonably high probability that the weak association found among men is nothing more than a statistical accident.[26] The authors admit as much in their conclusion:

> Although our study is the largest to date of workers exposed to ethylene oxide, the results for the relatively rare cancers of a priori interest are still limited by the small numbers of cases and perhaps limited by the short follow-up. Our findings are therefore not conclusive.[27]

The second study, published in 2003, found a weak association between breast cancer and EtO using a subset of the cohort, based on "7576 women employed for at least one year and exposed for an average 10.7 years while working in commercial sterilization facilities."[28] The association is limited to women who had *longer exposures*, which indicates they probably were among those with exposures well above the study estimates. Even then, the association proved weak and the causation questionable. The authors note:

> Our data suggest that ETO is associated with breast cancer, but a causal interpretation is weakened due to some inconsistencies in exposure–response trends and possible biases due to non-response and incomplete cancer ascertainment.[29]

The third study, published in 2004, did not find anything more compelling than the first or second study.[30] Yet again, the study reports there was no overall excess number of cancers compared to the general population. An editorial in the same publication and same issue regarding this study noted:

> However, the analyses show no clear excess mortality from cancer in comparison to expected numbers derived from the general population, except for bone cancer as represented by six cases only. The so called healthy worker effect that usually

> appears when the mortality experience of a worker cohort is compared to that of the general population comes through also in this study, and the mortality in both sexes from all causes was 90% of the expected, somewhat lower for women than for men. … The fact that this cohort has about the same cancer mortality experience as the general population could certainly be interpreted as suggesting a downgrading of ETO in the IARC [International Agency for Research on Cancer] classification, especially in view of the several such re-evaluations that have recently been made for other compounds.[31]

Nonetheless, the NIOSH researchers went to considerable lengths to tease out the possible cancer risk for "haematopoietic" (blood related, like lymphoma) cancers but, again, only for men. And these cancers were discovered mostly among those with the *longest exposures*. So, this weak association found between EtO and blood-related cancers in men appears largely among workers whose exposures were vastly underestimated. NIOSH researchers also teased out of the data a weak association with bone cancer, yet the rarity of this cancer, combined with the small number they found, means that the association could easily be a statistical accident.

The authors of the third study concluded:

> In conclusion, we found no overall evidence of excess cancer mortality in this cohort, with the exception of bone cancer based on small numbers. However, in exposure-response analyses we found evidence of an association between increased exposure and some types of haematopoietic cancer, particularly for males. There is also some evidence for a positive exposure-response for breast cancer mortality.[32]

IRIS Failed to Correct the Flawed Exposure Data, Leading to Faulty Conclusions about EtO Risk Levels. The NIOSH studies are important, particularly given the large cohort, so it is reasonable that IRIS would use them along with other research to develop its reference concentration. However, the program's failure to reassess the exposure levels to make them comply with more reasonable assumptions is a key reason why the reference concentration makes no sense, particularly when compared to natural exposures.

IRIS staff defended their reliance on the NIOSH exposure estimates, stating that the figures "were based on extensive sampling data and regression modeling." Even though this sampling data was taken during 1976-1984, IRIS staff insisted that it served as a good proxy for exposures between the late 1930s into the mid-1970s because "the sterilization processes used by the NIOSH cohort workers were fairly constant historically."[33]

ACC's petition rightly takes issue with this claim, pointing to concerns raised by the agency's Science Advisory Board (SAB).[34] According to the SAB, some of the data from the original NIOSH cohort presented to the panel was "surprising" because it indicated some estimated exposures were *lower* prior to 1975. The SAB report then noted that it "finds the surprising historical behavior to be unlikely" and then suggested to the EPA that it might explain such peculiar findings by addressing "changes in processes in specific plants, rather than some failure of the model to capture historically larger exposures."[35]

Apparently, the EPA followed that advice, attempting to explain the "surprising data" by suggesting changes in technology *increased* exposure in later years, but that assertion is out of line with the historical record for the industry.[36] All evidence points to the opposite conclusion: Worker exposure declined over time as control measures were implemented and technological development further reduced exposures.

Even the original NIOSH study itself noted that the introduction of technology in 1978 reduced exposures. It stated:

> Separate analyses were conducted for workers first exposed before 1978, when many companies began to install engineering controls to lower workers' level of exposure (for example, increased ventilation and better door seals), after the initial reports of the carcinogenicity of ethylene oxide.[37]

OSHA officials make similar observations in a 2005 "lookback" review of the OSHA EtO standard in 2005. They noted: "Based on exposure monitoring data from several sources indicating that occupational exposure to EtO has fallen markedly since the EtO standard went into effect, workers are being protected." The trending downward of exposures was common in developed nations. For example, a 2005 article published by the *British Medical Journal* notes:

> Environmental and personal monitoring carried out since 1977 indicated time weighted average exposures of less than 5 ppm in almost all jobs, but with occasional peaks of up to several hundred ppm because of operating difficulties in the chemical plants and when sterilizers were loaded and unloaded in hospitals. In earlier years, exposures were probably somewhat higher, and peak exposures above the odour threshold of 700 ppm were reported both at factories and hospitals.[38]

IRIS' assertion that technological changes increased worker exposures in the industry over time appears to be an attempt to rationalize the nonsensical exposure estimates found in the original NIOSH studies. Exposure data from the late 1970s and 1980s, after controls and improved technologies were in place, never should have served as a proxy for exposures between 1938 and 1975. Data from other studies and the historical record indicate the opposite was more likely the case.

IRIS Wrongly Dismissed Conflicting Research. Around the same time that the NIOSH studies were being produced, other researchers concluded that the small excess of blood-related cancers among men in the NIOSH cohort was not likely related to EtO exposure. However, while IRIS staff described some of these studies in their assessment, they refused to use any of them as a basis for the reference concentration, which was based solely on the NIOSH studies.

For example, the EPA disregarded the *British Journal of Industrial Medicin*e study that estimated the pre-1975 worker exposures among the NIOSH cohorts to be 16 ppb—about four times higher than the estimates found in the three NIOSH studies on which IRIS relied.

This *British Journal of Industrial Medicin*e study found no excess cancers related to EtO. It concluded:

> In conclusion, this cohort of workers potentially exposed to EO experienced a more favourable mortality than the general population. Their overall mortality was 27% less than the expected, primarily due to significant deficits in circulatory and other nonmalignant diseases. No excess mortality risk from leukemia was found, a major concern based on some of the previous studies. The absence of such risk was further supported by a lack of an upward trend based on an analysis of duration of employment. Similarly, there were no increases in mortality from cancers of the stomach, pancreas, or brain and central nervous system. There was an increased mortality from non-Hodgkin's lymphoma among the men but not among the women. Because of the lack of a dose-response relation and the inconsistency between the two sexes, the increase in non-Hodgkin's lymphoma among the men did not seem to be related to exposure to EO.[39]

IRIS also dismissed several studies that relied on data from about 2,000 workers employed at Union Carbide facilities in West Virginia, stating that the size of the cohort and inadequate exposure data undermined the value of this research. These studies by and large did not find the associations with cancers reported in the NIOSH studies. The Union Carbide Corporation (UCC) cohort data did include some uncertainties. As ACC points out, so did the NIOSH study. The ACC petition explains:

> Although the NIOSH exposure model was validated with data after 1978, there were no contemporary data between the late 1930s and mid-1970s to validate the final model. Thus, the UCC exposure assessment uncertainties are no greater than the NIOSH study uncertainties and, therefore, are not a valid reason to exclude the UCC cohort.[40]

After the EPA released its controversial IRIS assessment, the Texas Commission on Environmental Quality (TCEQ) launched its own scientific investigation to determine if it should revise its standard. In their review of the science, the TCEQ regulators determined that, although uncertainties remain, the Union Carbide data should be included in the state's assessment of EtO risks. Despite the uncertainties, TCEQ noted: "Nevertheless, this is an important cohort that contributes to the human EtO carcinogenicity database."[41] The final TCEQ report determined that EtO is even *less dangerous* than the state originally determined in its 2003 evaluation.[42] Accordingly, the TCEQ increased the acceptable level of background concentrations from 1 ppb to 2.5 ppb, which is many times higher than the EPA reference concentration of 0.1 part per trillion. The TCEQ's more reasonable standard partly resulted from the inclusion of this additional Union Carbide data and the fact that the agency relied on risk assessment models that it deemed more applicable than the one IRIS deployed.[43]

Finally, the EPA's Science Advisory Board review of the agency's 2006 draft also recommended including the Union Carbide data. Appendix H of the IRIS assessment notes:

> [T]he Panel encouraged the EPA to broadly consider all of the epidemiological data in developing its final Assessment. In particular, the Panel encourages the EPA to explore uses for the Greenberg et al. (1990) data including leukemia and pancreatic cancer mortality and EtO exposures for 2,174 Union Carbide workers from its two Kanawha Valley, West Virginia facilities.[44]

The final IRIS assessment expanded the discussion of this research but excluded the data for its analysis. As a result, IRIS staff disregarded useful data and research that might have at least tempered their overreliance on the NIOSH studies and the related faulty exposure assumptions.

Conclusion. The IRIS reference concentration for ethylene oxide is tens of thousands of times lower than levels found naturally in the human body and the environment. Therefore, it is an inappropriate measure to develop regulations. This examination of the underlying science explains how IRIS staff managed to develop such an unrealistic reference concentration, and it demonstrates the need for correction. The EPA should immediately render invalid both the IRIS assessment and the related NATA report. The agency's Office of Chemical Safety and Pollution Prevention should be placed in charge of any future EtO agency assessments, producing them under the statutorily approved, scientific guidelines of the Toxic Substances Control Act.

The faulty IRIS assessment's contribution to medical supply shortages during the COVID-19 pandemic underscores the need for swift action. Failure to correct the science threatens to undermine essential medical supply sterilization infrastructure. Pressure to close these facilities continues to mount around the nation because of misinformation campaigns driven by the IRIS and NATA reports. If EPA does not revise these assessments, some medical sterilization facilities may be forced to move overseas, and there may be fewer overall to manage the medical supply needs to address the current pandemic as well as potential future pandemics.

Notes

[1] For details on the problems related to these closures, particularly during the COVID-19 outbreak see Angela Logomasini, "Deploy Rational Science-Based Policies for Medical Plant Sterilization," *Web Memo* No. 52, Competitive Enterprise Institute, May 21, 2020, https://cei.org/content/deploy-rational-science-based-policies-medical-plant-sterilization.

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[4] Angela Logomasini, "EPA's Flawed IRIS Program Is Far from Gold Standard," *OnPoint* No. 251, Competitive Enterprise Institute, February 12, 2019, https://cei.org/onpoint/epas-flawed-iris-program-is-far-from-gold-standard/.

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[9] For example, see ClassAction.com webpage devoted to collecting potential plainiffs for EtO lawsuits at https://www.classaction.com/ethylene-oxide/exposure-lawsuit.
[10] American Chemistry Council, Request for Correction under the Information Quality Act: 2014 National Air Toxics Assessment (NATA), Addressed to the EPAs Information Quality Guidelines Staff, September 20, 2020, https://www.americanchemistry.com/EO/Request-for-Correction-under-the-Information-Quality-Act-2014-NATA.pdf, p. 2.
[11] American Chemistry Council, p. 1.
[12] Citing EPA data: Joseph T. Haney et al, Ethylene Oxide Carcinogenic Dose-Response Assessment, Development Support Document Final, CAS Registry Number: 75-21-8, Toxicology, Risk Assessment, and Research Division, Texas Commission on Environmental Quality. U.S. Environmental Protection Agency, Ethylene Oxide Ambient Concentrations at National Air Toxics Trends Stations and Urban Air Toxics Monitoring Program stations October 1, 2018–March 31, 2019, https://www.epa.gov/sites/production/files/2019-11/documents/data_summary_stations.pdf.

[13] American Chemistry Council, p. 3.
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[16] Ibid.
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