SB0916 - Ethylene Oxide - Favorable.pdf
Uploaded by: Dave Arndt
Position: FAV

Committee: Education, Energy, and the Environment

Testimony on: SB0916 - Ethylene Oxide – Prohibition Bill

Organization: Self

Submitting: March 14, 2023

Position: Favorable

Hearing Date: March 15, 2023

Dear Chair and Committee Members:

Hello, my name is Dave Arndt, a resident of Baltimore MD, an environmental advocate, a chemical engineer and retiree of The National Institutes of Health. Thank you for allowing our testimony today in support of SB0916. I urge you to vote favorably on SB0916.

Beginning July 1, 2023, the bill prohibits the use, manufacture, sale, offering for sale, or distribution of ethylene oxide in the State of Maryland.

There are a few fundamental chemicals that are the building blocks to most thing that we use, and one of them is ethylene oxide (EtO). EtO is used to make plastics, glycols, detergents, solvents, adhesives, and pharmaceuticals. It is also used by commercial sterilization companies to render medical devices free of germs, and as a pesticide to fumigate spices. Unfortunately, EtO is also a highly volatile chemical, and a known carcinogen. The reliance on EtO means that its ubiquity is disastrous.

Facilities sterilizing food or medical products emit EtO from chimneys and vents (stack emissions), but it also leaks from pumps, values, and pressurized connectors since it is such a volatile gas—a phenomenon called "fugitive emissions." Because EtO is cheap to produce, waste from fugitive emissions is not a cost issue for companies to resolve. And current EPA regulations for public health don't require facilities to account for fugitive emissions, meaning companies have no reason to rein them in.

Unfortunately, lifetime exposure rates to EtO have shown it to be carcinogenic. It is also tied to other health effects such as reproductive effects and learning disabilities. Exposure to EtO in and near these facilities is a dangerous reality for workers and adjacent communities across Maryland. Scientist have documented the associated health risks of EtO since the late 70's and in the last 5 years there have been more than 2600 studies on the negative health effects of EtO.

Maryland has four commercial sterilizers. More than 343,000 people live within five miles of at least one of these facilities. There are two sterilizers between Washington and Baltimore, in Hanover and Jessup, they are roughly three miles apart. They are used to sterilize spices and dehydrate vegetables. The EPA has identified both facilities as contributing to elevated cancer risks. According to the EPA's ECHO database, these facilities reported a combined 143 pounds of EtO releases and transfers in 2021. More than a quarter-million people and nearly 200 schools and childcare centers are within five miles of these facilities. Both of these communities have a disproportional higher concentration of people of color than the rest of the county they are in.

The other issue with these plants is that they are sterilizing food. EtO just doesn't magically disappear, residues of this cancer-causing substance remain. Unfortunately, processors don't have to tell

consumers about this. Safer alternatives, such as food irradiation or steam treatment are increasingly being used to replace fumigation with EtO. Europe has banned EtO sterilizers and prohibits the importation of EtO sterilized foods. Since 2003, Australia has banned the use of EtO for any foods that are sold in Australia. They cited the potential health risks to consumers for this decision.

To protect the health of the residents in Maryland, I support SB0916 and recommend a FAVORABLE report.

Lisa Snyder oral testimony SB 916.pdf
Uploaded by: Lisa Nurnberger Snyder
Position: FAV

My name is Lisa Nurnberger Snyder. I live about two miles from two Elite Spice plants that use ethylene oxide to sterilize spices and dehydrated vegetables. According to the EPA, ethylene oxide emissions from both plants exceed the federal cancer risk threshold and contribute to elevated cancer risks in the community.

I learned these plants were in my backyard when my organization, the Union of Concerned Scientist, released a report looking at communities impacted by ethylene oxide pollution from commercial sterilizers.

Baltimore is the only metro area in the country that has two sterilizer plants that each emit ethylene oxide at levels the EPA found contributes to elevated community cancer risks. Three of the 23 sterilizers on EPA's national list of high-risk facilities are in Maryland.

The cancer risk around the Jessup plant is 40 cases per one million people, twice the national average. Ethylene oxide makes up about one-third of the cancer risk from toxic air pollutants in Jessup.

The cancer risk around the Hanover plant is just slightly lower -- at 30 cases per one million people.

And these estimates do not account for other sources of pollution or stressors that can increase the risk of getting cancer.

Like me, the people who live or work around these plants had no idea the plants were releasing this cancer-causing gas. For the past 15 years I've been bike riding less than a mile from both plants.

Furthermore, workers at these facilities may face extremely dangerous occupational exposures if ethylene oxide continues to be used.

Elite Spice opened in 1988. They installed scrubbers in 2014 to reduce emissions. Yet there are still fugitive emissions being released from the facilities, as evidenced by EPA's 2022 assessment. My community has been subjected to enough ethylene oxide. Consider if you lived or worked next to one of these plants. Wouldn't you say, enough is enough?

It's time to protect the residents of this state who have been unknowingly living with this risk.

I urge the committee to vote FAVORABLE on Senate Bill 916.

Lisa Snyder written testimony SB 916.pdf
Uploaded by: Lisa Nurnberger Snyder
Position: FAV

My name is Lisa Nurnberger Snyder. I live about two miles from two Elite Spice plants that use ethylene oxide to sterilize spices and dehydrated vegetables. According to the EPA, ethylene oxide emissions from both plants exceed the federal cancer risk threshold and contribute to elevated cancer risks in the community.

Chronic exposure to this gas is associated with cancers of white blood cells, such as non-Hodgkin's lymphoma, as well as breast cancer in women. Children are especially vulnerable -- EtO exposure can make them susceptible to DNA mutations. EPA's own science confirms that ethylene oxide is extremely toxic to breathe.

I learned these plants were in my backyard when my organization, the Union of Concerned Scientist, released a report looking at communities impacted by ethylene oxide pollution from commercial sterilizers.

I learned that Baltimore is in fact the only metro area in the country that has **two** sterilizer plants that each emit ethylene oxide at levels that EPA found contributes to elevated community cancer risks. Three of the 23 sterilizers on EPA's national list of high-risk facilities are in Maryland.

The cancer risk around the Jessup plant is 40 cases per one million people, twice the national average. The area around the Hanover plant is 30 cases per one million people. Ethylene oxide makes up about one-third of the cancer risk from toxic air pollutants in Jessup. And these estimates do not account for other sources of pollution or stressors that can increase people's risk of developing cancer.

Like me, the people who live or work around these plants had no idea the plants were releasing this colorless, cancer-causing gas into the air we breathe. For the past 15 years I've been bike riding less than a mile from these plants.

Elite Spice opened in 1988. They installed scrubbers in 2014 to reduce emissions. Yet there are still fugitive emissions being released from the facilities, as evidenced by EPA's 2022 assessment. My community has been subjected to enough ethylene oxide. Consider if you worked or lived next to one of these plants. Especially if you had a child. Wouldn't you say, enough is enough?

The EPA is developing regulations to reduce these emissions, but there is no reason for these plants to be using ethylene oxide because alternatives exist. The European Union bans the importation of spices sterilized with ethylene oxide, primarily because the material can remain in the product. Meanwhile, McCormick uses steam to sterilize all of the spices we buy off the shelf here in the US. Furthermore, workers at these facilities may face extremely dangerous occupational exposures if ethylene oxide continues to be used.

It's time to protect the residents of this state who have had to unknowingly live with this risk for far too long.

As a result, I respectfully urge members of the committee to vote FAVORABLE on Senate Bill 916. Thank you for the opportunity to testify and thanks to Sen. Beidle for working to protect the people of Maryland.

SB916 Testimony.pdf
Uploaded by: Pamela Beidle
Position: FAV

PAMELA G. BEIDLE
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DEPUTY MAJORITY WHIP

Finance Committee
Chair, Executive Nominations Committee
Spending Affordability Committee

Joint Committee on Gaming Oversight
Joint Committee on Management of Public Funds

Chair, Anne Arundel County Senate Delegation

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THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

March 16, 2023

SB 916
Environment – Ethylene Oxide - Prohibition

Good afternoon, Chair Feldman, Vice Chair Kagan and Members of the Committee;

Thank you for the opportunity to present SB 916, Ethylene Oxide – Prohibition. Ethylene Oxide (EtO) is a chemical used for sterilization in certain medical equipment, some spices, and dried foods. It is a known carcinogen. Chronic exposure to this gas is associated with cancers of white blood cells, such as non-Hodgkin's lymphoma, as well as breast cancer in women. Children are especially vulnerable -- EtO exposure can make them susceptible to DNA mutations. EPA's own science confirms that ethylene oxide is extremely toxic to breathe.

The EPA has been reviewing the use of EtO and its emissions since 2004, in 2005 the EPA considered prohibiting its use at new facilities. It takes the EPA a long time to make a rule or prohibit the use of a chemical. Just look at lead paint:

- France, Belgium, and Austria prohibited lead in paint for interior painting in 1909,
- The European Union prohibited it for interior and exterior painting in 1940, and
- The United States finally prohibited it in 1978.

Just think of all the children that have been harmed needlessly by lead paint.

You will hear that hospitals use EtO to sterilize their equipment. The Hospital Association stated that their members do not use it in their facilities, including Johns Hopkins and the University of Maryland System. Here is quote from one hospital:

> *"We do not use Gas Sterilization (ETO) here and haven't since the 90s. The removal of Gas Sterilization was a safety decision for staff and patients for all hospitals. We use high temperature sterilization which is steam sterilization and we use low temperature sterilization which is vaporized hydrogen peroxide sterilization. High temperature sterilization is used for most surgical instrumentation and heat sensitive items such as cameras and endoscopes are sterilized using low temperature sterilization."*

Ethylene Oxide is also used to sterilize spices and dried foods. Two plants are located within a few miles of each other. One in Hanover, District 32, and one in Jessup, District 13. This is what EPA says about the Hanover plant:

> *"Elite Spice, Inc. is located at 1415 Magellan Drive, Hanover, MD. The facility uses ethylene oxide (EtO) to sterilize spices. EPA scientists and analysts recently completed a risk assessment to understand the impact of EtO emissions from the Elite Spice, Inc. facility. As part of this risk assessment, we used the most recent available information about how much EtO the company emits into the air, and we modeled estimated cancer risks to people living nearby. The risk assessment identified elevated cancer risk in the Hanover."*

The EPA is developing regulations to reduce these emissions, but there is no reason for these plants to be using ethylene oxide because alternatives exist. The European Union bans the importation of spices sterilized with ethylene oxide, primarily because the material can remain in the product. Meanwhile, McCormick uses steam to sterilize all of the spices we buy off the shelf here in the US.

In an article in "The Hill" from February 28, 2023:

> *"Last year, the EPA said that communities near 23 sterilization plants around the country have elevated cancer risks...Asked why these plants were still in operation EPA spokesperson said that its authority to shut down facilities is limited. But the spokesperson said the agency is working with state authorities to reduce emissions while developing new regulations."*

Due to its highly toxic nature, the European Union and much of the rest of the world, has banned the use of EtO for the fumigation of foods and food storage areas. The EU has also banned the use of ethylene oxide as a pesticide in 1991.

There are alternatives to the use of Ethylene Oxide. Why are we protecting businesses and not protecting people?

I respectfully request a favorable report on SB 916.

Fuchs Testimony.pdf
Uploaded by: Ashley Brooks
Position: UNF

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Senator Brian J. Feldman
Senate Committee on Education, Energy and the Environment
2 West Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

RE: SB 916 – UNFAVORABLE - Environment – Ethylene Oxide – Prohibition

Dear Chair Feldman and Members of the Committee:

Fuchs North America ("Fuchs") is a seasoning and spice company located in Hampstead, Maryland. Although we're part of the worldwide Fuchs Group, you may also know us as Baltimore Spice. That's because our company began as Baltimore Spice Company all the way back in 1939. At our Maryland location, we employ about 250 people.

Senate Bill 916 would ban the use, manufacture, sale, or distribution of ethylene oxide (EtO) in the state.

As part of our seasoning manufacturing process, Fuchs uses ethylene oxide ("EtO") as a fumigant to ensure that our spices meet Food and Drug Administration ("FDA") standards, 21 CFR 117. EtO is highly effective and validated to kill the pathogen, *Salmonella*. Fuchs's products are treated with EtO in an enclosed chamber using a programmed cycle of EtO treatment, followed by nitrogen and air washes that are intended to reduce the amount of EtO residual left on the product. Fuchs is compliant with all Federal and State requirements for the use of EtO on spices (FDA, EPA, OSHA and MDE). Fuchs is also in compliance with the Maryland air toxics requirements of COMAR 26.11.15.06 and the emissions limitations of 40 CFR 63.3629(c). Passage of this bill will cause irreparable damage to Fuchs business and negatively affect the food safety of our customers and consumers of food.

In summary,

- Fuchs use of EtO is safe for food, the environment, our employees and our community through following established use requirements already established by Federal and State agencies for the use of EtO on spices.
- Passage of this bill would result in insufficient capacity to sterilize our raw materials through alternative means, greatly affecting our ability to serve our customers and consumers.
- Passage of this bill would negatively affect the food safety and quality of the products that we produce.
- Passage of this bill would result in giving a significant commercial advantage to our competitors who operate outside of the state of Maryland.

We appreciate you taking the time to consider our request for an **UNFAVORABLE** report on Senate Bill 916.

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Fuchs requests an Unfavorable report on SB 916 as ethylene oxide is of critical importance for the spice industry for food safety purposes.

The human health benefits of using EtO to rid spices of dangerous pathogens greatly outweigh any exposure risk from the substance itself. Importantly, EtO allows for packaged spices to undergo treatment. This has significant food safety benefits, since it prevents the potential for post process contamination. Additionally, when treated spices require reconditioning due to a post-process contamination, EtO may be the only viable option available.

While alternative technologies are available for some applications of spices, EtO remains critical for the spice industry. Some spices are particularly vulnerable to alternative treatments due to having more delicate flavor and color. Steam is particularly challenging for use with low-density products such as herbs, and spice products with a high density, such as ground spices and cannot be used for pre-packaged spice. Steam treatment can also result in discoloration or loss of flavor, thus destroying certain spice products -- for which the main purpose is to add flavor to foods. Another potential alternative – gamma – comes with issues. Because of world-wide shortages of cobalt, there is very low availability.

Most likely, the result of banning EtO sterilization in Maryland will result in shutting down facilities operating in the state that are in compliance with all federal regulations. And could push much of the spice sterilization offshore to developing countries with far less sophisticated regulatory systems than the U.S., which presents both significant food safety and environmental risks.

Fuchs requests an Unfavorable report on SB 916 as it creates inconsistencies with pending federal regulations and other states.

The U.S. Environmental Protection Agency (EPA) regulates the use of EtO & requires emissions controls and worker protections. Fuchs and the spice industry have a long track record of working effectively with EPA to address concerns regarding the safety of ethylene oxide use on spices. EPA is working on several forthcoming regulations to further reduce air emissions of EtO. These actions will put in place extensive new protections for residents and workers as well as environmental controls, including emissions restrictions, limitations of non-critical uses, and equipment requirements. Fuchs and the spice industry has been actively and voluntarily pursuing ways to reduce EtO worker exposure and EtO emissions and will continue these efforts. The unintended consequences of SB 916 creates inconsistencies with pending federal regulations and other states.

Spice companies that use EtO have worked for the last 20 years to reduce residues and emissions to the lowest possible level, sometimes achieving undetectable emissions levels, while still ensuring spices are treated to control food safety hazards. In conclusion, concerns regarding EtO exposure risks should be balanced with critical benefits. Passage of SB 916 would unnecessarily pose health risks to Marylanders and irreparably harm Maryland businesses.

Thank you,

MD- EO Bill Comments- Mar 2023.pdf
Uploaded by: Bill Gulledge
Position: UNF

March 15, 2023

Submitted via: MGA website

The Senate of Maryland
Education, Energy, and The Environment Committee
Miller Senate Office Building
11 Bladen Street, Suite 2 West
Annapolis, Maryland 21401

Re: SB0916- Comments of the American Chemistry Council's Ethylene Oxide Panel

The Ethylene Oxide (EO) Panel of the American Chemistry Council (ACC), hereby submits comments on SB0916- prohibiting a person from using, manufacturing, selling, offering for sale, or distributing ethylene oxide (EO) in the State of Maryland. The EO Panel includes the major producers and users of EO in North America. ACC strongly opposes SB0916. The Bill is overreaching, premature, and should it be implemented, will severely restrict crucial uses and products of EO, especially if restrictions proposed by Maryland are widely adopted.

EO is a versatile building block of chemistry. It helps make many of the products we use every day, such as plastics, safety glass, adhesives, and textiles. In addition to EO's critical use in sterilizing medical products and spices, it is used as a building block chemical for producing active ingredients in pesticides and the production of bioethanol. As the US continues to grow, so do our nation's food needs. Overly conservative restrictions on the production, use, or distribution of ethylene oxide could put the needs of the agriculture sector and its derivatives at risk.

A family of EO derivatives -- ethanolamines are used to allow for cleaner burning fuels resulting in less air pollution. EO and its derivatives are used in natural gas purification to reduce corrosion and scale in oil and gas processing, freeze protection for finished goods, gas dehydration, and carbon capture in gas processing, which ultimately helps enable energy transition.

Additionally, ethylene oxide is also a critical chemistry in the production of electric vehicle battery electrolytes. Given Govern Moore's stated intent to transition the state to electric vehicles by 2035 and the intent of the Inflation Reduction Act to onshore battery production,

restrictions on EO could preclude Maryland from participating in industries that will drive this transition.

SB0916 is overreaching and premature. At the federal level, the US EPA is nearing the publication of proposed air toxics rules for EO that will impact commercial sterilizers and industrial manufacturers and users of EO. The proposals are scheduled for late March or April 2023, and are designed to tighten current regulations on EO air emissions. The rules may include requirements for additional monitoring of process and fugitive EO emissions, and ambient air monitoring. Even now, according to the EPA National Emissions Inventory, industrial EO emissions have already fallen nationwide by over 80% since 2002.

The heightened concern over EO emissions and perceived risk arose when EPA applied its IRIS risk value to the 2018 National Air Toxics Assessment. Updated modeling in 2022 again used theoretical calculations, not emissions measurements to identify "hot spots" of elevated cancer risk due to exposure to EO. The lifetime cancer risk modeling of 100 in a million for the spice treatment facilities in Hanover and Jessup and the medical sterilization facility in Salisbury were all benchmarked against the unrealistic EO IRIS value.

The IRIS value of 0.1 parts-per-trillion (ppt), which is used in modeling calculations, is unrealistic. Current measured background ambient EO air concentrations across a wide range of US geographies all exceed the IRIS value by orders of magnitude. Thus, if the EO IRIS Assessment is to be believed, breathing background ambient air alone should cause substantial concern for elevated cancer risks. Almost all states and localities that have been evaluated by states show no statistically significant increased cancer risk from just breathing EO in ambient air.

The problem presented by the EPA risk value is further emphasized by the fact that ambient air is not even the primary source of potential human background ethylene oxide exposures. Ethylene oxide is produced in our bodies as part of everyday normal metabolism (endogenously produced ethylene oxide). Endogenously produced ethylene oxide is equivalent to an external exposure to 1,900 ppt ethylene oxide, and is 19,000-times higher than the EPA-estimated 1 in a million cancer risk. The EPA EO IRIS value would lead one to conclude that the levels of ethylene oxide produced by normal human metabolism and/or breathing ambient air are sufficient to present an elevated cancer risk far in excess than the risks posed by industrial sources. This conclusion is non-sensical and raises questions about the use of the value for regulatory purposes.

Additional shortcomings of the EO IRIS value include the following issues:

I. The EO IRIS value (2016) used visual fit comparisons to categorical data, which misrepresents the individual data modeled. This flawed visual fit as the basis for the IRIS selection of a risk model leads to unrealistic inhalation risk estimates.

II. The IRIS modeling process did not make a simple correction in statistical analysis that led to an incorrect conclusion that the model (steep slope) used in the IRIS has a superior fit compared to the traditionally used Cox Proportional Hazard (CPH) model. The use of

the EPA model leads to incorrect conclusions of risk acceptability and uncertainty, especially at lower EO concentrations.

III. IRIS (2016) did not consider the biological plausibility of models based on biological mode of action and toxicological evidence, which support a shallow linear exposure-response at lower exposures. IRIS has not offered any biologically plausible mode of action analysis accounting for a steeper dose-response of EO in the low-exposure range. The IRIS risk specific concentration of 0.1 ppt is overly conservative to the point of lacking regulatory utility because it is 4 orders of magnitude lower than average human background (predominately endogenous) exposure levels and variability.

ACC urges that SB0916 be rejected. The State of Maryland should wait until the new federal air toxics regulations are promulgated and then reassess whether additional legislation is warranted. Thank you for your attention.

Sincerely,

William Gulledge

William P. Gulledge
Senior Director
Chemical Products & Technology Division
Manager, EO Panel

ESI Unfavorable SB 916.pdf
Uploaded by: Bob Cloney
Position: UNF

ELITE SPICE

Senator Brian J. Feldman
Senate Committee on Education, Energy, and the Environment
2 West Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

RE: SB 916 – UNFAVORABLE - Environment – Ethylene Oxide – Prohibition

Dear Chair Feldman and Members of the Committee:

Elite Spice is writing to express our vehement opposition to SB 916 which seeks to ban Ethylene Oxide (EtO) and abolish its use in controlling harmful pathogens. EtO is a critical tool used to ensure the safety of food products and to protect public health. For more than 70 years, EtO treatment has been used by the U.S. spice industry, and demanded by the commercial food manufacturing industry, to prevent countless instances of serious and sometimes deadly foodborne illness. The proposed EtO ban is an immediate threat to public health. Its impact will reach far beyond the Maryland companies this bill is targeting. Hundreds of millions of pounds of spice produced in Maryland are used as flavoring ingredients in tens of billions of pounds of commercially produced foods. The viability and adoption of alternative treatment methods has been impeded by serious process limitations and inadequacies; there are no immediate treatment remedies capable of supplanting the EtO treatment capacity eliminated by this bill. If SB 916 is ratified, the U.S. food supply chain will suffer consequential disruptions, food safety will be compromised, and public health will be threatened. We urge you to consider this request for an unfavorable report on SB 916.

Elite Spice is an American owned and operated spice and seasoning manufacturer headquartered in Jessup, Maryland. Elite employs 800 people nationwide; 610 of whom are working at our facilities in Maryland. For 35 years, Elite has specialized in producing pure, high-quality, and safe-to-consume food ingredients marketed to commercial food manufacturers. Our products provide flavor to a wide variety of meats, seafood, vegetables, dairy items, snacks, condiments, sauces, dressings, soups, seasonings, beverages, cereals, baked goods, and other food items produced by thousands of commercial food manufacturers across the country. This year alone, the essential flavoring components we produce are estimated to impact more than 10 billion pounds of consumer foods. Given the magnitude of the consequences, Elite's guiding principles have always been purity and safety. These principles are not limited to the products we produce; they extend to the air we breathe and the environment in which we work and live. We care deeply about the health and well-being of our workers, our communities, and the consumers of our products.

Spices, as raw agricultural products, may be imported from more than 4 dozen countries where foodborne hazards could be introduced by a variety of conditions, including farming and handling practices. Like many other raw agricultural commodities, spices are known to carry a significant risk of pathogenic contamination, such as *Salmonella*. Federal food regulations and commercial standards require the use of a scientifically validated process to mitigate the risk of identified microbial hazards.

Fumigation with EtO is recognized and approved as one of the most effective and viable treatment methods for eliminating pathogens in spice.

Elite Spice has been safely using EtO to ensure food safety since the inception of our business. Multiple federal and state agencies regulate the safe use of EtO, including the Environmental Protection Agency (EPA), Maryland Department of the Environment (MDE), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). Elite's use of EtO is fully permitted by law, and the agencies continue to approve its use to treat spice in order to protect public health. Most importantly, **Elite's facilities operate in full compliance with stringent EPA and FDA regulations** (and all other federal and state requirements).

In an unconventional manner and in advance of forthcoming proposed rulemaking, on August 3, 2022, EPA released information about facilities across the country that use EtO. The information released by EPA included allegations that EtO emissions from two of Elite Spice's facilities may create an elevated long-term cancer risk to nearby lifelong residents. The scientific basis for EPA's assessment of the long-term risk of EtO exposure has been harshly criticized by credible scientific authorities and state environmental agencies. Additionally, the Maryland Department of the Environment has publicly criticized EPA's process of communicating potential EtO risks without having detailed source specific analyses to support EPA's assertions.

Within the EPA's published risk information, EPA states, "We are continuing to collect and verify information about these facilities and its emissions." EPA also says, "If EPA receives new data, we will update this information." As MDE can attest, on October 14, 2022, Elite Spice submitted data and modeling to EPA for its Maryland facilities demonstrating that emissions are in fact substantially lower than the risk level that EPA deems as unacceptable. However, despite EPA's unequivocal commitment that it, "will update this information," it has not done so. Consequently, inaccurate information has not been updated, and egregious errors have not been corrected. We know EPA is busy drafting proposed rules which are intended to further reduce EtO emissions and offer enhanced protections for workers and communities. We fully support EPA's rulemaking efforts and anticipate the imminent publication of proposed rules.

In the meantime, non-governmental organizations have exploited EPA's inaccurate published information as part of a misguided campaign to draft myopic public policy in Maryland and subvert EPA's directive to promulgate appropriate nationwide regulations. They have disseminated mappings and information that are misaligned with the mappings and information published by EPA; their frightening and inflammatory rhetoric is often contradicted by credible scientific authorities and common sense.

In conclusion, SB 916 fails to recognize the critical role that EtO plays in preventing outbreaks of food borne illness by mitigating the known pathogenic risks in spice. The quantities of food affected by the proposed EtO ban are exponentially greater than the quantities of spice produced by the Maryland companies using EtO treatment. Absent immediately viable alternative treatment methods, nationwide food supply and public health will be jeopardized. We urge you to consider this request for an unfavorable report on SB 916 and work to protect public health and the environment by promoting policies based upon sound scientific evidence. Elite Spice will continue to work closely with all federal,

state, and local regulatory authorities to ensure its ongoing compliance with all environmental regulations. Above all, we will continue to operate in a manner that keeps our people, our products, and the public safe.

Respectfully,

Joseph Samuel
President
Elite Spice, Inc.

Maryland_EtO_SB 916_Testimony-AdvaMed_Final.pdf
Uploaded by: Bobby Patrick
Position: UNF

AdvaMed
Advanced Medical Technology Association

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March 14, 2023

Honorable Brian Feldman
Chair, Education, Energy, and the Environment Committee
Maryland State Senate
2 West
Miller Senate Office Building
Annapolis, MD 21401

RE: SB 916 (Beidle) – Opposed

Dear Senator Feldman:

AdvaMed, the Advanced Medical Technology Association, appreciates the opportunity to provide comments regarding SB 916 (Beidle).

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our more than 450 members range from small, emerging companies to large multinationals and include traditional device, diagnostic, and digital health technology companies.

AdvaMed respectfully opposes SB 916. This bill risks disrupting patient access to life-saving medical devices by banning the use of ethylene oxide (EtO) in Maryland. EtO sterilization of medical devices is crucial for preventing infection in patients undergoing surgical procedures and other medical treatments. Both the U.S. Food and Drug Administration (FDA), which regulates medical device safety and effectiveness, including sterility assurance, and the Environmental Protection Agency (EPA), which regulates EtO emissions in the air, agree EtO is a critical medical device sterilization method.[1,2] Notably, the U.S. EPA is finalizing regulations in the coming weeks on the emissions controls for, and use of, EtO by commercial sterilizers.[3]

We share the bill sponsor's commitment to mitigating any hazardous pollutants found to pose a threat to the community. Our industry is continually identifying how it can lessen its impact on the environment, including reducing its use of EtO and

[1] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[2] https://www.epa.gov/newsreleases/epa-launches-community-engagement-efforts-new-ethylene-oxide-risk-information
[3] https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/what-epa-doing-address-ethylene-oxide-and-learn-more-about

developing novel sterilization methods to replace it where appropriate.[4] However, according to the FDA, "other methods of sterilization cannot currently replace the use of EtO for many devices."[5]

EtO occurs naturally in addition to its commercial production and uses. There are several known emitters, including humans (from our breath), plants (living and decaying), school bus engines, and gas generators.[6] EtO has been detected at higher levels in a remote state park – far from any known commercial sterilizer facility – than just outside of a commercial sterilizer facility.[7] While using only half of one percent of all commercial EtO, commercial sterilizers have drawn more attention than other EtO users. Commercial sterilizers serving the medical device industry are governed by extensive regulatory obligations at every level of government. The new EPA regulation could preserve this critically important aspect of the health care system while reassuring community members of the safety of the facilities sterilizing medical devices with EtO.

EtO is used to sterilize approximately 50 percent of all medical devices – 20 billion – in the United States each year, including surgical kits, heart valves, and pacemakers, and is the only viable modality for many devices.[8] Other methods destroy or render these critical medical devices unusable. The appropriate sterilization method is determined during the concept and design phase of a device. Manufacturers opt to use the sterilization method for each device that meets design specifications, FDA requirements, patient safety, and the large-scale demand for devices, all without impacting device functionality.

Hundreds of thousands of medical, hospital, and laboratory processes rely on EtO-sterilized devices and equipment to protect millions of patients from the real risks of infection caused by bacteria, viruses, and fungi. For example, Maryland has 11,374 hospital beds and 26,201 professionally active physicians serving Marylanders.[9] When any of the 6.2 million residents of the Old Line State seek

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[4] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[5] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[6] https://www.advamed.org/industry-updates/policy-issues/sterilization-ethylene-oxide/
[7] https://epd.georgia.gov/document/document/eto-data-through-042821pdf/download
[8] https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization
[9] https://www.kff.org/statedata/custom-state-report/?i=458128%7C24284bec~32444%7C24284bec~32446%7C24284bec~32448%7C24284bec~32450%7C24284bec~32452%7C24284bec~459977%7C24284bec~32772%7C2d11dde6~32486%7C2d11dde6~32771%7C2d11dde6&g=md&view=3

health care treatment, they deserve and receive treatment with sterile medical equipment, achieved in large part through sterilization with ethylene oxide.[10]

Any disruption in the availability of sterile medical devices and supplies could lead to delays in patient care – an outcome disastrous to patient safety, the daily practice of medicine, and overall public health in the United States. According to Marcus Schabacker, MD, PhD, President and CEO at the ECRI Institute, "If there's an ubiquitous ban on ethylene oxide today, we're going to have a health crisis on our hands, because in very short time and order, sterile products won't be available, and we don't have an alternative to replace that today."[11]

EtO sterilization facilities are subject to comprehensive emissions control rules, including the federal Clean Air Act and other EPA-enforced laws on emissions. The U.S. EPA is finalizing regulations on the emission control for EtO pertaining to commercial sterilizers, as well as for its labeling and use. The EPA has conducted extensive stakeholder engagement and outreach, over the course of several years, in developing this rule. This rule will likely result in significant upgrades to commercial sterilizers, in addition to what has already been done in recent years. AdvaMed supports EPA in this effort.

EtO sterilization is a highly regulated process, and device manufacturers, hospitals and third-party sterilizers must follow rigorous controls established by EPA, OSHA and other government agencies (including state and local entities) to protect patients, workers and the environment.

Federal regulations and international guidance on emissions, residuals and worker safety allow for the safe and responsible use of EtO to sterilize medical products. Device manufacturers and sterilizers capture, remove, and destroy EtO. In a recent Modern Healthcare piece, Dr. Lucy Fraiser, a Board-Certified Toxicologist, said, "If every commercial sterilization facility closed tomorrow, the public wouldn't be appreciably safer from EtO emissions. The emissions from the facilities are that small and getting smaller all the time, as new capture technology becomes available, and facilities buy it and install it."[12]

In sum, SB 916 is unnecessary and could have the unintended effect of inhibiting medical care to Maryland patients.

---

[10] https://msa.maryland.gov/msa/mdmanual/01glance/html/pop.html
[11] https://www.advamed.org/industry-updates/policy-issues/sterilization-ethylene-oxide/
[12] https://www.modernhealthcare.com/opinion/feedback-medical-device-sterilization-ethylene-oxide-emissions

Some additional information is attached to this testimony, including:

- More information on the role of EtO sterilized devices in infection prevention;
- Additional detail on the types of medical devices sterilized on EtO; and
- Commentary from an expert providing context on EPA modeling and data.

Thank you for the opportunity to provide comments today.

Sincerely,

Bobby Patrick
Vice President, State Government and Regional Affairs
AdvaMed

cc: Senator Pam Beidle, Maryland State Senate

AdvaMed
Advanced Medical Technology Association

EtO Sterilization Prevents Infection

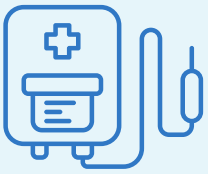
Americans are admitted to the hospital 33.4 million times[i] and visit doctors 1.0 billion times per year.[ii]

82.3 percent of adults and 91 percent of children see a health care professional each year.[ii]

That care requires billions of pieces of sterile medical equipment: syringes, catheters, and surgical tools.

33.4 M
hospital admissions

1.0 B
doctor visits



20 B
devices sterilized with EtO

Approximately half of those devices – 20 billion – are sterilized in the United States each year with ethylene oxide (EtO).[iii]

EtO is safe and proven effective to achieve FDA-required sterility.

AdvaMed
Advanced Medical Technology Association

- That millions of patients experience medical care without life-endangering infection is the product of modern science, including EtO.
- Infections that do occur can be extremely dangerous.
- Sepsis, for example, is "a medical emergency ... that can lead to tissue damage, organ failure, and death." [iv]

Sepsis causes the deaths of

350,000 adults

each year in the United States. [v]

For survivors, it can cause amputations or result from amputations. [vi]

Antimicrobial resistance is another compelling reason to fight infection.

More than 2.8 million antimicrobial-resistant infections occur in the United States each year, causing more than 35,000 deaths. [vii]

MRSA, or methicillin-resistant Staphylococcus aureus, is a bacteria that is resistant to several antibiotics. It can cause bloodstream infections, pneumonia, or surgical site infections.

> **If left untreated, MRSA infections can become severe and cause sepsis—the body's extreme response to an infection.** [viii]

The Bottom Line

Health care providers fight infection around the clock. Their challenge would be far steeper without EtO, carefully controlled and regulated and the only sterilization option for many medical devices. The need for sterile medical equipment will only increase as the population ages, antibiotic-resistant infections proliferate, and health care professionals seek to keep patients safe.

[i] http://bit.ly/3KdqP1B
[ii] http://bit.ly/3Is74lo
[iii] http://bit.ly/3xpiDDP
[iv] http://bit.ly/3KaDPF9
[v] http://bit.ly/40YZDJM
[vi] http://bit.ly/3I6qCdU
[vii] http://bit.ly/3YQByD0
[viii] http://bit.ly/3EdAbX0

Ethylene Oxide's Invaluable Role In Protecting Public Health

Ethylene Oxide (EtO or EO) is a colorless gas used commercially in a wide variety of ways, including the production of textiles, personal care items, and the sterilization of medical devices, cosmetics, and spices. EtO is one of the most common ways to sterilize medical devices, which is crucial for preventing infection in patients undergoing surgical procedures and other medical treatments.

Approximately 50 percent of all medical devices are sterilized with EtO, and for many of those, it is the only available option.

Hundreds of thousands of medical, hospital, and laboratory processes rely on EtO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. For the majority of these products, EtO sterilization is the most effective and efficient—and often the only viable—sterilization technology. The gentle yet thorough nature of EtO allows for the sterilization of many critical medical technologies and devices that would otherwise be destroyed and rendered unusable by other sterilization methods.

Many medical devices cannot be sterilized by methods other than EtO for the following reasons:

> Gamma and e-beam radiation can make plastics brittle, or cause certain non-woven materials to literally disintegrate

> Steam is high temperature and will melt plastics and/or damage products sensitive to heat and/or moisture

> Hydrogen peroxide and gas plasma are intended for small-scale, surface sterilization only and cannot penetrate devices that have interior chambers or two surfaces that are in contact with each other (e.g., piston and barrel of a syringe)

EtO also has the unique ability to penetrate packaging and plastic without damaging them and effecticely sterilize otherwise hard-to-sterilize product configurations (e.g., inside tubing, products that have two touching surfaces, connectors, etc.).

Medical Devices that Require EtO Sterilization:

> Fiberoptic endoscopes
> Specula
> Surgical kits
> Syringes
> Sutures
> Catheters
> IV sets
> Plastic tubing
> Inhalation therapy supplies
> Surgical telescopes
> Anesthesia masks and circuits
> Renal peritoneal dialysis sets
> Renal hemodialysis sets
> Tubing sets/bloodlines
> Gowns and drapes
> Heart valves
> Pacemakers
> Surgical drills
> Pumps
> Respirators
> Electrical equipment
> Uterine monitors
> Surgical staplers
> Diagnostic electrode catheters

Source: AdvaMed member companies

In addition to the high level of efficacy that EtO provides, it is highly compatible with a wide variety of medical device materials of construction, enabling medical device companies to manufacture many devices that would not be possible without EtO. The high level of performance and effectiveness of medical devices when sterilized by EtO is well understood. If EtO could not be used for sterilization of healthcare products, there would certinly be significant, and likely disastrous, adverse public health consequences. Elimination of this sterilization technology would introduce the real risks of increased morbidity and mortality.

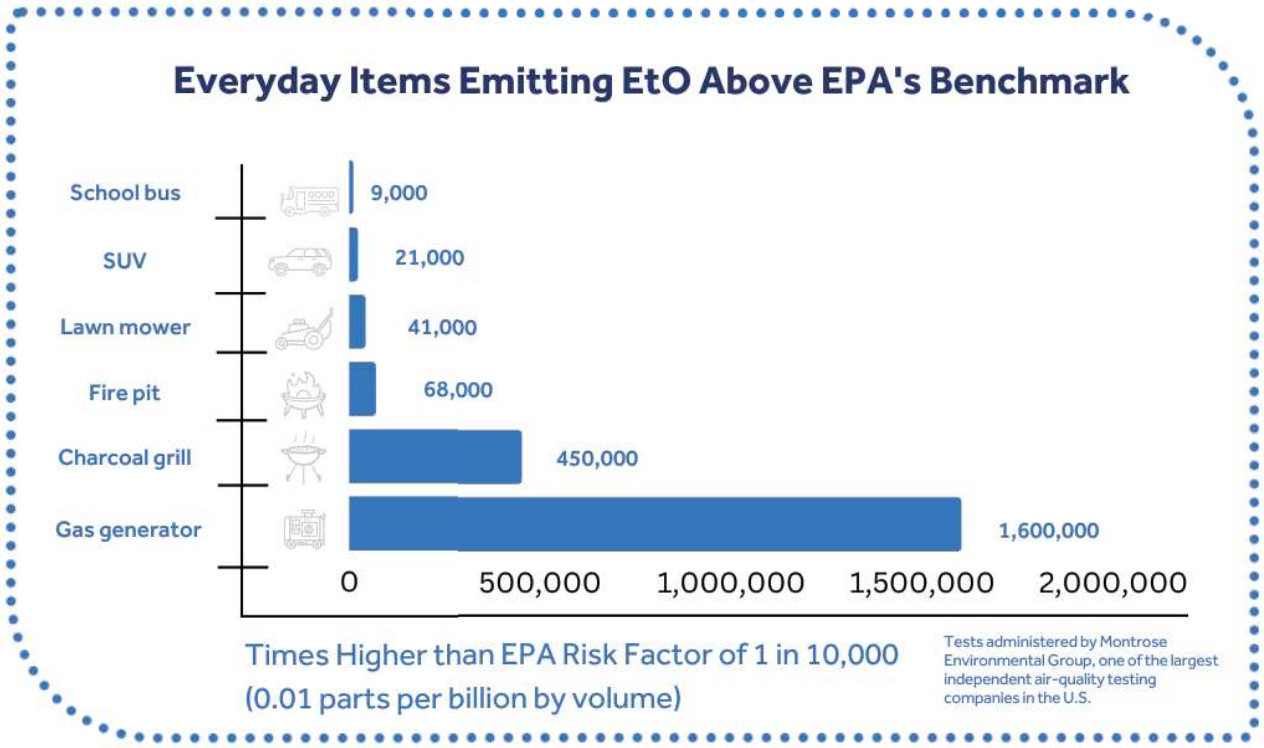
Strict government regulation controls EtO use in the U.S. FDA and other global regulators play an important role in ensuring that manufacturers' sterilization methods are properly validated. FDA regulations, guidance, and harmonized international standards include provisions that address the use of EtO and other sterilants for medical devices. Manufacturers must conduct exhaustive studies to demonstrate that the required sterility assurance levels are achieved by the process and to confirm that exposure to the sterilization process does not adversely affect the device's performance, safety, or effectiveness.

Manufacturers must comply with FDA's Quality Systems Regulation (QSR) relative to the methods used in, and facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices. This includes the use of contract sterilization firms, as the contract sterilizers are considered vendors and part of the regulated manufacturing process.

An international standard (ISO 11135:2014) specifies requirements for the development, validation, and routine control of an EtO sterilization process for medical devices in both the industrial and health care facility settings.

Under the Clean Air Act, the U.S. Environmental Protection Agency (EPA) sets limits on certain air pollutants. The EPA has set emission standards for EtO under the National Emission Standards for Hazardous Air Pollutants (NESHAP) rule, which applies to commercial sterilization operations. In addition, the U.S. Occupational Safety and Health Administration (OSHA) sets permissible EtO exposure limits for workers under the Toxic and Hazardous Substances rule. State permitting rules and enforcement also apply.

Manufacturers' finished products must meet global standards for device bicompatibility testing and assessment of EtO residuals remaining on the finished product post-sterilization. These requirements ensure patients and health care providers are not exposed to unacceptable levels of chemical residues from the sterilization process. Changing sterilization methods or making process changes requires manufacturers to reestablish product biocompatibility through repeat studies.



Modern Healthcare

Letter to the Editor: Article on device sterilization didn't provide the complete picture

LUCY FRAISER, PH.D | BOARD-CERTIFIED TOXICOLOGIST

OCTOBER 17, 2022

As a toxicologist, I have followed the Environmental Protection Agency's (EPA) work on ethylene oxide (EtO) closely, and I am concerned about how the recent article titled, "A Dirty Business: How the medical device sterilization process sickens some to heal others," portrays the EPA's findings on the sterilization of medical devices using EtO. Inaccurate, incomplete information about EtO can have dangerous repercussions for patient access to safe medical devices across the country. It can unnecessarily scare community members about their health.

This article fails to disclose that the EPA uses a "worst-case scenario," the agency's own phrase, of continuous exposure, for 70 years, 24 hours a day, a highly unlikely scenario, in its estimate of EtO's cancer risk.

The EPA emphasizes that its own models for estimating the safety of ethylene oxide are just that, models, not actual readings outside a commercial sterilization facility. The EPA also doesn't consider background air levels of EtO, so emissions from sources other than commercial sterilization facilities aren't a factor in its calculations, even though sterilization plants are far from being the largest source of EtO.

If every commercial sterilization facility closed tomorrow, the public wouldn't be appreciably safer from EtO emissions. The emissions from the facilities are that small and getting smaller all the time, as new capture technology becomes available, and facilities buy it and install it.

> **"If every commercial sterilization facility closed tomorrow, the public wouldn't be appreciably safer from EtO emissions."**

Modern Healthcare seeks to inform its readers but reporting without context or clarity is more harmful than useful. Your publication should present the full story on this issue going forward.

Lucy Fraiser is a board-certified toxicologist (Diplomate of the American Board of Toxicology) with over 30 years of experience.

Published in print on October 17, 2022; available online at t.ly/z3IC

Opposition of SB916.pdf
Uploaded by: Bunky Luffman
Position: UNF

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OFFICE OF THE COUNTY EXECUTIVE
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Julie M. Giordano
County Executive

Bunky Luffman
Director of Administration

March 14, 2023

Senate Education, Energy, and the Environment Committee
Attn: Hon. Senator / Chairman Brian J. Feldman
2 West
Miller Senate Office Building
Annapolis, MD 21401

Re: MD 2023 SB 916 Environment – Ethylene Oxide - Prohibition

Senator / Chairman Feldman & Senate Education, Energy, and the Environment Committee Members,

I respectfully write this letter of opposition for this bill which would prohibit the use of ethylene oxide as well as levy burdensome fines.
Ethylene oxide is used to sterilize medical equipment used extensively in hospitals and surgery centers throughout Maryland and the United States. The EPA has said that an abrupt ban could have an immediate disruption in sterilizer operations and cause significant shortages of various medical devices needed by patients and the Maryland and U.S. healthcare system.
Trinity Sterile, located in Wicomico County, currently employs 120 people with plans to increase employment to 180 people by the end of the year. Passage of this bill could eliminate these jobs and Wicomico and our region could lose millions of dollars in economic impact almost immediately.
Understanding the concerns of the use of ethylene oxide, this bill offers no alternative solutions. What could be done instead is for the industry to continue working with government regulators toward strengthened controls and processes to reduce emissions and thus, mitigate the potential devastating effects this bill would have on employers, employees and patients throughout local the healthcare system
For these reasons, I respectfully ask the committee for an unfavorable report for MD 2023 SB 916 Environment – Ethylene Oxide - Prohibition.

Respectfully,

Wicomico County, Maryland

Julie M. Giordano
County Executive

trinityeolegislationbillsb0916F.pdf
Uploaded by: David Ryan
Position: UNF

SALISBURY-WICOMICO ECONOMIC DEVELOPMENT

March 13, 2023

Senate Education, Energy, and the Environment Committee
Attn: Hon. Senator / Chairman Brian J. Feldman
2 West
Miller Senate Office Building
Annapolis, MD 21401

Re: MD 2023 SB 916 Environment – Ethylene Oxide - Prohibition

Dear Senator / Chairman Feldman & Senate Education, Energy, and the Environment Committee Members,

Please accept this letter in opposition of MD 2023 SB 916 Environment – Ethylene Oxide – Prohibition.

Understanding the concerns of the use of ethylene oxide, an outright prohibition would have an immediate disruption and could eliminate the one hundred twenty jobs Trinity Sterile has in Salisbury, Maryland. An outright ban could also cause significant shortages of various medical devices needed by patients and the Maryland and U.S. healthcare system. Perhaps what should be done instead is to continue working with government regulators toward strengthened controls and processes to reduce emissions and implementation of recommended courses of action over time, thus mitigating the disruptions this bill would most certainly cause.

For these reasons, we respectfully ask the committee for an unfavorable report for MD 2023 SB 916 Environment – Ethylene Oxide - Prohibition. Thank you.

Very Truly Yours,

David J. Ryan
Executive Director

ONE PLAZA EAST, SUITE 501 | P.O. BOX 4700 | SALISBURY, MD 21803
410.749.1251
SWED.ORG | INFO@SWED.ORG

SB0916_UNF_MTC_Environment - Ethlylene Oxide - Pro

Uploaded by: Drew Vetter

Position: UNF

MARYLAND TECH COUNCIL

TO: The Honorable Brian J. Feldman, Chair
Members, Senate Education, Energy, and the Environment Committee
The Honorable Pamela Beidle

FROM: Andrew G. Vetter
Pamela Metz Kasemeyer
J. Steven Wise
Danna L. Kauffman
Christine K. Krone
410-244-7000

DATE: March 15, 2023

RE: **OPPOSE** – Senate Bill 916 – *Environment – Ethylene Oxide – Prohibition*

The Maryland Tech Council (MTC) writes in **opposition** to *Senate Bill 916: Environment – Ethylene Oxide – Prohibition*. We are a community of over 700 Maryland member companies that span the full range of the technology sector. Our vision is to propel Maryland to become the number one innovation economy for life sciences and technology in the nation. We bring our members together and build Maryland's innovation economy through advocacy, networking, and education.

Senate Bill 916 prohibits the use, manufacture, sale, offering for sale, or distribution of ethylene oxide (EtO) in the State. EtO is a gas that is commonly used in the sterilization of medical devices. The sterilization of these devices is done in a safe, tightly controlled, and highly regulated manner to ensure medical devices prevent infection and lead to safe surgeries and medical treatments for patients. According to AdvaMed, the Advanced Medical Technology Association, approximately 50% of all medical devices are sterilized with EtO, and for many of those devices it is the only option for sterilization. If EtO could not be used for sterilization purposes, there could be significant disruptions in the medical device supply chain and adverse impacts to Maryland's health care system and patients.

EtO is already highly regulated at the Federal level. The Federal Food and Drug Administration (FDA) has regulations to ensure that manufacturers' sterilization methods are properly validated, and the Environmental Protection Agency (EPA) sets emissions standards for EtO under the National Emission Standards for Hazardous Air Pollutants rule, which applies to commercial sterilization operations. In addition, the Occupational Safety and Health Administration (OSHA) sets permissible EtO exposure limits for workers under the Toxic and Hazardous Substances rule.

Senate Bill 916 proposes a prohibition on EtO – as drafted, it would have a significant impact on several MTC member companies in the "Medtech" industry that manufacture medical devices which must be sterilized to be safely used. As such, the proposed prohibition could have a significant detrimental impact to those companies and their employees. Given that the use of EtO is already strictly regulated by the FDA and emissions controlled by the EPA, we request that the General Assembly take time to complete additional due diligence on this issue before taking the drastic step of imposing a prohibition.

In fact, Maryland would become the first state in the nation to impose such a prohibition. Before taking this step, we believe that additional examination and discussion is warranted. MTC would be pleased to serve as a convenor of our MedTech member companies to participate in a substantive discussion of appropriate regulatory steps at the State level moving forward.

For these reasons, MTC respectfully requests an unfavorable report.

MD 2023 SB 916 Environment Ethylene Oxide - Prohi

Uploaded by: Jonathan Bourne

Position: UNF

TRINITY STERILE
A Minority Business Enterprise

03/02/2023

Senate Education, Energy, and the Environment Committee
Attn: Hon. Senator / Chairman Brian J. Feldman
2 West
Miller Senate Office Building
Annapolis, MD 21401

Re: MD 2023 SB 916 Environment – Ethylene Oxide - Prohibition

Senator / Chairman Feldman & Senate Education, Energy, and the Environment Committee Members,

Please accept this as a letter of opposition for MD 2023 SB 916 Environment – Ethylene Oxide – Prohibition.

We respectfully write to the committee today asking It to oppose this proposed legislation of outright banning the use of ethylene oxide, and levying extreme fines on employers that use this compound. This bill seems heavy handed and offers no other solutions for employers that use ethylene oxide.

This compound is used to disinfect medical equipment in hospitals, it has been reported about half of the medical devices in the country are sterilized using ethylene oxide. The EPA has said that an abrupt stopping the use of this compound would have an immediate disruption in sterilizer operations.

Here in the state of Maryland there are three businesses located in Howard, Anne Arundel, and Wicomico County that use this compound to sterilize medical equipment. Trinity Sterile, which is in Wicomico County, currently employs 120 people and is looking to increase employment to 180 people by the end of the year. If this bill were to pass the negative economic impact this would have on Wicomico County and the surrounding region would be significant.

While we understand the concerns of the use of ethylene oxide, we hope the committee and its members understand what outright banning the use of this compound especially with offering no alternative solutions will do to the supply chain of sterilizing hospital equipment in the state, and the major economic, and health impact this would cause. Perhaps what should be done instead is a study of alternative solutions to replace the use of ethylene oxide and work to implement those changes gradually over time thus mitigating the disruptions this bill would most certainly cause.

For these reasons, we respectfully ask the committee for an unfavorable report for MD 2023 SB 916 Environment – Ethylene Oxide - Prohibition.

Sincerely,

Abrar Solatch

Abrar Solatch
President
Trinity Sterile Inc
Ph:610-659-9833
Email: Abrar.solatch@trinitysterile.com

ASTA Testimony MD SB 0916.pdf
Uploaded by: Laura Shumow
Position: UNF

AMERICAN SPICE TRADE ASSOCIATION, INC.

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Washington, DC 20036 USA
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Web: www.astaspice.org

March 14, 2023

Senator Brian J. Feldman
Senate Committee on Education, Energy and the Environment
2 West Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

RE: SB 916 – UNFAVORABLE - Environment – Ethylene Oxide – Prohibition

Dear Chair Feldman and Members of the Committee:

ASTA was established in 1907 and serves as the expert voice of the U.S. spice industry in the global market. Member companies are involved in all aspects of the spice trade: importing, growing, processing, and marketing at both the wholesale and retail levels. Approximately 200 companies are members of ASTA. ASTA members manufacture and market the majority of spices sold in the U.S. for industrial, food service, and consumer use. The highest priority of ASTA and our members is ensuring the supply of clean, safe spice to American consumers.

ASTA represents a number of companies based in Maryland that would be severely harmed if ethylene oxide is no longer able to be used on spices. Banning ethylene oxide as a pathogen control method would result in there not being sufficient capacity to treat spices to ensure their safety. Moreover, SB 916 would ban any sale or distribution of ethylene oxide, which would have far-reaching implications of prohibiting any product containing detectable levels of ethylene oxide from being sold in the state.

The spice industry recognizes and supports federal and state policymaker's goals of reasonably minimizing ethylene oxide emissions. To this end, ASTA and spice companies that use ethylene oxide have worked for the last twenty years to reduce residues and emissions, while still achieving the objective of ensuring spices are treated to control food safety hazards. We are continuing to work to identify alternatives and reduce emissions.

As explained in more detail below:

- Ethylene oxide is critical for ensuring the safety of spices and complying with Food and Drug Administration (FDA) regulations.
- There are not currently viable alternatives for all spice products and where alternatives exist, there are serious limitations.
- The Environmental Protection Agency (EPA) is in the process of proposing new regulations to put in place additional emissions controls to protect workers and communities.

We appreciate you taking the time to consider our request for an **UNFAVORABLE** report on **Senate Bill 916**.

AMERICAN SPICE TRADE ASSOCIATION, INC.

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Ethylene oxide is of critical importance for the spice industry for food safety purposes.
The most critical food safety issue for the spice industry is the need to manage potential contamination by microbial pathogens that cause foodborne illness that could result in serious illness or death. Spices are commonly exposed to conditions that could result in microbial contamination. *Salmonella*, in particular, is a pathogen that must be controlled by treatment.

Under the Federal, Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq, all food companies are required to develop a food safety plan that identifies microbiological hazards and create a validated treatment plan to address these hazards. Spice companies must comply with the Preventive Controls for Human Food rule under the FDA Food Safety Modernization Act regulations, 21 C.F.R. Part 117, which requires that processes to control hazards such as *Salmonella* must be validated to ensure that they are effective.

In FDA's risk profile for spices[1], the only wide-spread technologies available to achieve validated reduction of *Salmonella* in spices are steam, irradiation, and ethylene oxide treatment:

> The most common spice processing treatments that impact the viability of microorganisms, including human pathogens such as *Salmonella*, can generally be grouped into three categories: 1) steam treatment, 2) gamma radiation, and 3) fumigation with ethylene oxide (E.O.). These treatments are also commonly used for other materials such as pharmaceuticals and biologics as described by the U.S. Pharmacopeia (U.S.P., 2011). Other treatment options have been studied and are described in the scientific literature; however, they are not currently used or are only minimally used on a commercial basis for spice treatment.

Steam and irradiation are capable of performing the necessary microbial reduction for *Salmonella*, however, both have significant limitations and without the availability of ethylene oxide, there would not be sufficient total capacity to treat the entire spice supply.

Limitations of the use of steam on spices include cost, capacity, and quality degradation. Importantly, steam cannot be used to treat packaged products, which creates the potential for post-process contamination. Additionally, steam is not a suitable alternative for herbs or ground spices. Steam treatment can result in discoloration or loss of flavor, thus destroying certain spice products – for which the primary purpose is to add flavor to foods.

While irradiation is a valid pathogen control, there is limited capacity for spice irradiation due to shortages of cobalt-60. There are also a limited number of irradiation facilities currently available to treat spices. Further, labeling requirements limit the commercial viability of the technique in certain

[1] Center for Food Safety and Applied Nutrition Food and Drug Administration U.S. Department of Health and Human Services. FDA Risk Profile: Pathogens and Filth in Spices (2017). Available at https://www.fda.gov/media/108126/download

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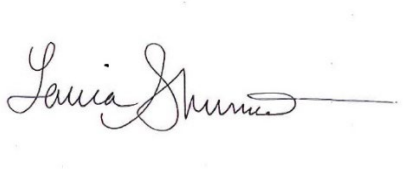
circumstances. There continues to be a substantial reluctance on the part of the customer in the U.S. to accept irradiated products, which is a concern that is not limited to spice products.

Forthcoming federal regulations will strengthen controls on emissions of ethylene oxide.
Ethylene oxide emissions are federally regulated by the EPA and the Maryland Department of Environment routinely enforces compliance with EPA's ethylene oxide regulations. EPA has announced that it will soon propose new requirements that will strengthen protections for workers and community members. In the meantime, EPA is planning to conduct community outreach events for facilities near ethylene oxide facilities in Maryland. Nonetheless, the industry has not waited for new regulations to make great strides in reducing emissions and companies are continuing to strive to minimize emissions every day.

In conclusion, ethylene oxide is essential for public health to prevent serious illness or death from harmful pathogenic bacteria. It remains an essential and necessary tool for the spice industry to comply with food safety requirements and to ensure a supply of clean, safe, spices. Moreover, **Senate Bill 916**, if passed, would create irreparable harm for Maryland businesses and create serious health consequences for Marylanders. For these reasons, ASTA respectfully requests an **UNFAVORABLE** report on **SB 916**.

Respectfully submitted,



Laura Shumow
Executive Director
American Spice Trade Association

MD 2023 SB 916 Environment Ethylene Oxide - Prohi

Uploaded by: Mark Gordon

Position: UNF

TRINITY STERILE
A Minority Business Enterprise

03/02/2023

Senate Education, Energy, and the Environment Committee
Attn: Hon. Senator / Chairman Brian J. Feldman
2 West
Miller Senate Office Building
Annapolis, MD 21401

Re: MD 2023 SB 916 Environment – Ethylene Oxide - Prohibition

Senator / Chairman Feldman & Senate Education, Energy, and the Environment Committee Members,

Please accept this as a letter of opposition for MD 2023 SB 916 Environment – Ethylene Oxide – Prohibition.

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This compound is used to disinfect medical equipment in hospitals, it has been reported about half of the medical devices in the country are sterilized using ethylene oxide. The EPA has said that an abrupt stopping the use of this compound would have an immediate disruption in sterilizer operations.

Here in the state of Maryland there are three businesses located in Howard, Anne Arundel, and Wicomico County that use this compound to sterilize medical equipment. Trinity Sterile, which is in Wicomico County, currently employs 120 people and is looking to increase employment to 180 people by the end of the year. If this bill were to pass the negative economic impact this would have on Wicomico County and the surrounding region would be significant.

While we understand the concerns of the use of ethylene oxide, we hope the committee and its members understand what outright banning the use of this compound especially with offering no alternative solutions will do to the supply chain of sterilizing hospital equipment in the state, and the major economic, and health impact this would cause. Perhaps what should be done instead is a study of alternative solutions to replace the use of ethylene oxide and work to implement those changes gradually over time thus mitigating the disruptions this bill would most certainly cause.

For these reasons, we respectfully ask the committee for an unfavorable report for MD 2023 SB 916 Environment – Ethylene Oxide - Prohibition.

Sincerely,

Abrar Solatch

Abrar Solatch
President
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00389308.pdf
Uploaded by: Meibao Zhuang
Position: UNF

EOSA **The Ethylene Oxide Sterilization Association, Inc.**
Managed by B&C® Consortia Management, L.L.C.

March 14, 2023

Senator Brian J. Feldman
Chair
Senate Committee on Education, Energy and the Environment
Miller Senate Office Building, 2 West Wing
11 Bladen Street
Annapolis, MD 21401

Re: **SB 0916 – Environment – Ethylene Oxide – Prohibition**

Dear Chair Feldman and Members of the Committee:

On behalf of its members, the Ethylene Oxide Sterilization Association, Inc. (EOSA) is submitting this letter to request for an **UNFAVORABLE** report on Senate Bill 0916. Senate Bill 0916 has the potential to devastate the medical device sterilization capacity and spice treatment/pathogen reduction capacity in Maryland and the United States. Given these serious negative impacts, it is imperative that the Senate Bill be stopped to avoid creating a crisis with respect to availability of medical devices and spices. This is also very important given that the data and science do not support the underlying basis for this Bill.

EOSA members represent a broad spectrum of the U.S. ethylene oxide (EtO) sterilization industry. EOSA is a nonprofit organization that represents EtO suppliers, spice processors, contract sterilizers, sterilization equipment manufacturers, medical device manufacturers, analytical equipment and systems suppliers, and laboratories. EOSA members work diligently to assist in providing life-saving sterile healthcare products around the world, over 50% of which are sterilized using EtO, and assist in providing safe and wholesome spices for consumers. EOSA works to educate industry, regulators, and the public on the essential uses and benefits of EtO sterilization, for which no direct replacement is currently, and not for the foreseeable future, available. EOSA also works to improve safety standards, foster industry communication, and provide a forum for many subjects related to EtO sterilization.

EOSA and its members believe that the safety of surrounding communities and workers in the EtO sterilization industry is critically important. The EtO sterilization industry has historically undertaken, and will continue to undertake, significant efforts to reduce the emissions and potential worker exposure of EtO utilizing the best available technologies and practices. EOSA is providing these comments to ensure that regulatory decisions reflect accurate facts, the best available science, and proven technologies and practices.

Some of the critical facts and information are:

- The critical and essential need for EtO sterilization capacity to ensure available and safe medical devices for the U.S. healthcare system, and the importance of this availability to public health must be carefully considered to ensure no adverse impacts to public health, including potential loss of life resulting from lack of availability of sterile medical devices. The loss of medical device sterilization capacity at even one facility creates a potential risk for medical device shortages due to the limited available capacity of other sterilization facilities to assume sterilization of the medical devices that were sterilized at a closed facility, in addition to lengthy sterilization process validation and regulatory approvals that would be required.

- Approximately 50% of medical products sterilized (U.S. ~20 billion/year) are sterilized using EtO, and currently there are no alternative methods that can replace it. Alternatives to industrial EtO sterilization are limited in material compatibility, penetration, and scalability. Use of other proven industrial sterilization methods, such as radiation and steam, are not compatible with the majority of products currently sterilized by EtO. Novel methods, such as vaporized hydrogen peroxide (VHP), chlorine dioxide (ClO_2), nitrogen dioxide (NO_2) and others, are very limited in terms of applicability. Even if viable alternatives could be developed in the future, it will take years, if not decades, to develop and acquire the required U.S. Food and Drug Administration (FDA) approval. The development of new life-saving, life-sustaining, and life-enhancing products, which could include new materials, new devices, combination devices, etc., can often only be accomplished using EtO as the sterilization modality.

- There are not currently any viable fumigation alternatives for spice products, and where alternatives exist for a limited number of products, there are serious limitations. Alternatives, including steam and irradiation, are limited by their capacity, quality, and/or degradation. EtO remains an essential and necessary tool for the spice industry to comply with food safety requirements and to ensure a supply of clean and safe spices.

- The U.S. Environmental Protection Agency's (EPA) 2016 Integrated Risk Information System (IRIS) value is scientifically flawed and should not be used in EtO risk assessment or regulatory decision making. Alternate risk values have been developed by credible regulatory bodies, such as the

Texas Commission on Environmental Quality (TCEQ), and the disparity between these assessments and the 2016 IRIS value (>2,000 fold) warrants significant concern in relying upon IRIS for a decision of this magnitude. According to IRIS, normal background concentrations of EtO (from automobile exhaust, decay of plant matter, etc.), as well as endogenous EtO (from naturally generated within our bodies and normal biological functions), would cause unacceptable bystander risk for everyone.

Thank you for your consideration of these comments. It is critical that federal and state agencies consider the information presented above since it is of paramount importance not to overestimate the potential risk of EtO from its critical sterilization use. EOSA urgently requests for an **UNFAVORABLE** report on Senate Bill 0916.

Sincerely,

Meibao Zhuang
Senior Manager
The Ethylene Oxide Sterilization Association, Inc.

SB0916_UNF_MedChi_Environment - Ethylene Oxide - P

Uploaded by: Pam Kasemeyer

Position: UNF

MedChi

The Maryland State Medical Society

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TO: The Honorable Brian J. Feldman, Chair
Members, Senate Education, Energy, and the Environment Committee
The Honorable Pamela Beidle

FROM: Pamela Metz Kasemeyer
J. Steven Wise
Danna L. Kauffman
Andrew G. Vetter
Christine K. Krone
410-244-7000

DATE: March 15, 2023

RE: **OPPOSE** – Senate Bill 916 – *Environment – Ethylene Oxide – Prohibition*

The Maryland State Medical Society (MedChi), the largest physician organization in Maryland, **opposes** Senate Bill 916.

Senate Bill 916 prohibits a person from using, manufacturing, selling, offering for sale, or distributing ethylene oxide (EtO) in the State. According to the U.S. Environmental Protection Agency (EPA), EtO is a colorless gas that is used by commercial sterilizers to sterilize devices that cannot be sterilized using steam or radiation, such as some medical and dental equipment.

MedChi recognizes that EtO is considered a toxic air pollutant. However, it is currently highly regulated at both the Federal and State level. It is not clear at this time how common the use of EtO is in the State or whether there are viable alternative sterilization options for medical and dental equipment if it is banned. Without a full understanding of the current use of EtO in Maryland, passage of Senate Bill 916 may have unintended consequences related to medical and dental equipment sterilization. For these reasons, MedChi urges an unfavorable report.

SB916_UNF_MRA.pdf
Uploaded by: Sarah Price
Position: UNF

SB916 Environment - Ethylene Oxide - Prohibition
Senate Education, Energy, and the Environment Committee
March 15, 2023

Position: Unfavorable

Background: SB916 would prohibit the use, manufacturing, distribution, and sale of ethylene oxide in Maryland.

Comments: The Maryland Retailers Association has serious concerns about the impact that a prohibition on ethylene oxide (EtO) could have on businesses in Maryland. EtO is a chemical compound used in a wide variety of manufacturing production and industries including the production of textiles, personal products like shampoo and laundry detergent, and automotive products like antifreeze and brake fluid, and the sterilization of spices and medical equipment. The Environmental Protection Agency (EPA) reports that "the use of EtO is the only sterilization method available for many medical devices and approximately 50 percent of all sterile medical devices in the United States are treated with EtO annually".[1]

EtO has been used as a sterilization agent since the mid-twentieth century, and Maryland is home to a variety of businesses that use the chemical to sterilize spices and medical equipment. Biotechnology companies, which can rely heavily on the use of or access to EtO, also make up a growing industry sector in the state. These industries would all be negatively impacted by a prohibition of EtO in Maryland.

The EPA is currently reviewing its registration of EtO and will issue mitigation measures for its use and potential exposures as part of the review process. The EPA is not alone in working to address any risks of using EtO; industries that use the chemical are also researching product stewardship technologies that can improve safety practices and procedures for EtO's use.

MRA would urge the Committee against the proposed restriction that would negatively impact a variety of businesses and industries in Maryland, and recommends an unfavorable report on SB916. Thank you for your consideration.

[1] Environmental Protection Agency. (2022, August). *Ethylene Oxide (EtO)*. EPA. https://www.epa.gov/ingredients-used-pesticide-products/ethylene-oxide-eto

SB 916 LOI 031523.docx.pdf
Uploaded by: Rachel Jones
Position: INFO

Maryland
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Office of the Secretary
Wes Moore, Governor
Aruna Miller, Lt. Governor
Kevin Atticks, Secretary
Steven A. Connelly, Deputy Secretary

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Maryland Department of Agriculture
Legislative Comment
Date: March 15, 2023

BILL NUMBER: Senate Bill 916

SHORT TITLE: Environment – Ethylene Oxide - Prohibition

MDA POSITION: INFORMATION

SB 916 would require the Secretary of the Maryland Department of Environment (MDE) to prohibit the use, manufacture, sale, offer for sale, or distribution of ethylene oxide in the state.

From a fiscal perspective, the bill would result in a loss of $1,210 in revenue per year. However, the impact on two industries in the state would be quite severe. The would be the spice industry and the medical kit/medical instrument sterilization.

Ethylene oxide (EtO) is used in several areas of industry, such as, spice manufacturing, healthcare (hospital, veterinary, dental, and medical), contract sterilization facilities, libraries, museums, cosmetics, clothing, and music industries. EtO is generally used in chambers to sterilize batches of spices, medical, veterinary, and dental instruments, books, artifacts, cosmetics, and musical instruments.

Spices: There are six major spice manufacturers in the state of Maryland: McCormick, JO Spice, Chesapeake Spice, Harbor Spice, Fuchs North America, and Elite Spice. The FDA will often hold products at a port without inspection depending on which country it comes from. If that is the case, the company that purchased the spice is responsible for the fumigation of the product before it is released from the quarantine. Fuchs NA in Hampstead MD uses EtO for this reason. It is a validated kill step sterilant for the control of *Salmonella sp.* This will have a large impact upon Fuchs. Elite Spice in Jessup also uses EtO as a sterilant. There are four companies that do not use EtO in the process.

If the bill is passed, this would require the two spice companies, Elite, and Fuchs, to source their spice sterilization to out of state companies. The other four companies are already doing this. The extra workload could potentially create a bottleneck in the supply chain of the spice industry in Maryland.

Healthcare Sterilant: EtO is used in specially designed chambers to sterilize medical instruments, and other medical devices before they are used. EtO is an effective sterilant for medical instruments. Although most hospitals have gravitated away from using EtO for on-site sterilization, commercial sterilization facilities still use EtO. About 50% of all medical devices, including catheters and surgical mesh, in the U.S. are sterilized using EtO. The types of devices that are sterilized with ethylene oxide range from devices used in general health care practices (for example, wound dressings) to more specialized devices used to treat specific areas of the body (for example, stents).

There is one commercial sterilization facility in Maryland, Trinity Sterile located in Salisbury MD. Trinity is a Certified Minority Business Enterprise serving the healthcare industry. They assemble and sell medical kits, procedure trays, and a wide range of disposable or reusable medical supplies. They also offer contract sterilization services for the medical field. It is used for custom medical kits and trays, catheters, esmark bandages, and surgical instruments.

The effect of the ban would be detrimental to their business in that the business is a contract sterilization facility and sells medical kits, surgical instruments, etc. Trinity would be forced to go out of business. They have been around for 30 years supporting the healthcare industry.

If you have additional questions, please contact Rachel Jones, MDA Director of Government Relations at Rachel.Jones2@maryland.gov or (410) 841-5886.

MDE LOI SB 916.docx.pdf
Uploaded by: Tyler Abbott
Position: INFO

March 15, 2023

The Honorable Brian Feldman, Chair
Education, Energy, and Environment Committee
Miller Senate Office Building, 2 West
Annapolis, Maryland 21401

Re: Senate Bill 916 – Ethylene Oxide – Prohibition

Dear Chair Feldman and Members of the Committee:

The Maryland Department of the Environment (the Department) has reviewed Senate Bill 916 and would like to provide the following information regarding this legislation. Senate Bill 916 would prohibit the use, manufacture, sale, or distribution of ethylene oxide in Maryland beginning July 2023.

For some background, ethylene oxide is a colorless gas. While effective in sterilization, ethylene oxide is a toxic air pollutant and has been connected to causing cancer. Maryland currently has four commercial sterilization facilities and seven medical institutions that use ethylene oxide. Of the four commercial facilities, three sterilize spices and the fourth sterilizes medical equipment.

Currently, both the EPA and the Department are using a risk management approach to address emissions of toxic and cancer-causing air pollutants, whether it is for ethylene oxide or numerous other toxic air pollutants. In doing so, a 70-year continuous exposure scenario is used in establishing an acceptable risk level.

Based on this risk-based approach, the EPA establishes technology standards that facilities need to meet to ensure emissions stay below a level that is protective of public health. The EPA had set an earlier technology standard and is poised to publish a rule that tightens up the earlier standard. This is expected to be released within the next few months. The Department supports EPA's efforts to impose stricter technology requirements to reduce risk to public health. Currently, the four commercial sterilization facilities are in compliance with the earlier standard and will need to meet the new standard upon it becoming final.

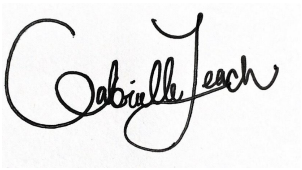
The Department is working with two of the three spice sterilization facilities to reduce their ethylene oxide usage by up to 20% through the use of a less toxic sterilization agent - propylene oxide. The Department is also in discussion with the medical sterilization facility to add equipment to further control emissions of ethylene oxide. These actions are under consideration in anticipation of the forthcoming federal rule. Again, the federal rule, once finalized, will govern the degree to which all four sterilization facilities in Maryland will further control ethylene oxide emissions to be protective of public health.

Finally, the Department would like to note that the new enforcement provisions under § 6-1703 in the bill do not authorize administrative penalties or corrective orders, nor do they provide any authority to seek injunctive relief. These authorities would be needed to ensure a prohibition could be legally sustained as a

practical matter.

Thank you for your consideration. We will continue to monitor SB 916 during the Committee's deliberations, and I am available to answer any questions you may have. Please feel free to contact me at 410-260-6301 or by e-mail at gabrielle.leach@maryland.gov.

Sincerely,



Gabrielle Leach

cc: The Honorable Pam Beidle
Christopher R. Hoagland, Air and Radiation Administration