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Andrew R. Wheeler, Administrator
U.S. Environmental Protection Agency
E.P.A. Docket Center
Docket ID No. E.P.A.–H.Q.–OAR–2019– 0178
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460.

RE: Docket ID No. E.P.A.–H.Q.– OAR–2019–0178

Dear Administrator Wheeler:

The American Spice Trade Association (ASTA) appreciates the opportunity to comment on the United States (U.S.) Environmental Protection Agency's (EPA's) advanced notice of proposed rulemaking on the *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*, 84 Fed. Reg. 67889-99, December 12, 2019, *Docket ID: No. E.P.A.–H.Q.– OAR–2019–0178*.

Background

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.

The spice industry is a part of the overall food and agricultural sectors, which account for about one-fifth of the U.S. economy. While ASTA's member companies include multinational corporations, the majority of its members are small businesses. Some long-standing, multi-generational, small business spice companies have invested in and operate ethylene oxide chambers at their facilities. These companies, several of whom have operated these facilities for over 50 years, are an integral part of the spice industry. These small businesses take sterilization and ethylene oxide use very seriously. They have worked for years with both the U.S. Food and Drug Administration (FDA) and the EPA to reduce emissions and the amount of ethylene oxide residue that remains on spices after sterilization.

Although several spice companies operate their own ethylene oxide chambers, there are many more spice companies whose products are treated by a commercial sterilizer. There are different types of

commercial sterilizers. Some of the larger sterilizers sterilize several different kinds of products, including medical devices, as well as small amounts of spices. However, these large sterilizers operate primarily as medical device sterilizers; spices represent an extremely small part of their business. In fact, the amount of ethylene oxide used for spice sterilization is minuscule. Ethylene oxide used for spices accounts for less than 1% of all total FIFRA use of the chemical. Although larger commercial sterilizers could function without the spice sterilization business, the opposite is not true. The spice industry cannot meet its regulatory requirements and global demand for spices without access to the large ethylene oxide sterilization facilities.

Ethylene oxide is critically vital to the spice industry, and for decades, the spice industry and ASTA worked to address ethylene oxide residues in spices. Concerns from the spice industry on ethylene oxide residues led to the development of an alternative ethylene oxide sterilization method, which lowered not only residual ethylene oxide residues on spices but also reduced fugitive air emissions to the lowest level possible. In fact, spice companies typically have nondetectable fugitive emissions levels.

For the reasons outlined below, ASTA urges E.P.A. to ensure any new emissions control requirements are not overly burdensome for the spice industry:

- Ethylene oxide is of critical importance for the spice industry for food safety purposes;
- Ethylene oxide is a necessary tool for compliance with the F.D.A.'s Food Safety Modernization Act (FSMA) regulations, 21 C.F.R. Part 117;
- The spice industry has already reduced residue levels of ethylene oxide on spices, which has, in turn, dramatically reduced fugitive air emissions.

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 the potential contamination by microbial pathogens that could result in foodborne illness. Like all agricultural products, spices are commonly exposed to conditions that could result in microbial contamination. Many spices are grown in tropical or subtropical climates, which means they are typically grown in developing countries where sanitation and food handling practices may not always be adequate. *Salmonella,* in particular, is a pathogen that must be controlled by treatment. As such, spices must undergo extensive cleaning, processing, and treatment for pathogens to ensure they are free of microbial contamination. The only wide-spread technologies available to achieve validated reduction of *Salmonella* in spices are steam, irradiation, ethylene oxide treatment, and to a lesser degree, propylene oxide treatment. FDA recognizes this in its risk profile for spices:

> 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.

While steam, irradiation and ethylene oxide technologies are all capable of performing the necessary microbial reduction for *Salmonella*, each has limitations. As such, the industry needs to continue to retain multiple available treatment methods. Some spice companies choose to rely solely on one

treatment method and do not use ethylene oxide to control *Salmonella*. However, in other instances, a company may determine that ethylene oxide is the best commercially viable tool that can deliver the necessary pathogen control without compromising the quality of the spice product in the process.

Limitations of the use of steam on spices can include cost, capacity, and quality degradation. The cost of steam can be up to two to three times higher than ethylene oxide, and there are a limited number of steam treatment facilities in the U.S. available to treat spices. Steam is not a suitable alternative for low-density products such as herbs, or spice products with a high density, such as ground spices. Steam treatment can also 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 works well for pathogen control, labeling requirements limit the commercial viability of the technique in certain 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. There are also a limited number of irradiation facilities currently available to treat spices. While irradiation is a valid pathogen control, there is limited capacity for spice irradiation due to shortages with medical device sterilization facilities.

The spice industry must work to maintain the flexibility to take advantage of different treatment options. While all three technologies-steam, irradiation, and ethylene oxide-are successfully used within the spice industry for pathogen control, the loss of one of these three processes would disrupt the entire spice industry. It could impact the global market and supply. Certain companies would be severely harmed if ethylene oxide is no longer able to be used on spices as a pathogen control. If ethylene oxide is removed as a pathogen control method, there would not be enough facilities in existence that have the capacity to treat products with steam or irradiation that are currently processed using ethylene oxide. If the spice industry is no longer able to use ethylene oxide, the entire industry will be upended, causing disruption and delay up and down the entire supply chain.

Ethylene oxide is a necessary tool for compliance with the FDA FSMA regulations.

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, including pathogens, and create a treatment plan to address these hazards. The treatment plan must also be validated to assure that it is successful. Spice companies must comply with the Preventive Controls for Human Food rule under FSMA regulations, 21 C.F.R. Part 117, which requires the control of all food safety hazards. Any processes to control hazards such as *Salmonella* must be validated to ensure that they are effective.

While there are emerging technologies that may eventually be available for pathogen control in spices, including infrared and other cutting-edge technologies, these methods are still new and not yet widely used. It takes a significant amount of time, money, effort, additional validation studies, and more to change the type of pathogen control for spices. Before adoption by the industry as a method to comply with preventive controls requirements, any new techniques must also undergo significant research to show the technology is capable of delivering a 5-log reduction of *Salmonella*. Additionally, a company must conduct tens of thousands of dollars in validation studies to ensure that any treatment method is effective, yet also capable of preserving the necessary quality attributes of the products. The industry continues to explore new advancements, but there are significant costs associated with changing to a new sterilization technology, and the required capital investment can be a significant barrier.

The spice industry has already reduced residue levels of ethylene oxide on spices, which has, in turn, dramatically reduced fugitive air emissions.

The spice industry recognizes and supports EPA's goal of minimizing ethylene oxide emissions resulting from the use of the chemical. To this end, spice companies that use ethylene oxide have worked for the last twenty years to reduce residues and emissions to the lowest possible level, sometimes achieving undetectable emissions levels, while still achieving the objective of ensuring spices are treated to control food safety hazards.

During the EPA's Office of Pesticide Programs re-registration process, ASTA members using ethylene oxide to sterilize spices undertook significant effort to reduce the residual levels of ethylene oxide. These efforts included reducing the potential residues of the byproducts of ethylene oxide, including ethylene glycol and ethylene chlorohydrin. In conjunction with EPA, ASTA and other industry experts participated in a project to reduce the ethylene oxide residue levels that remained on spices after sterilization. They developed what will be referred to in these comments as the "ASTA method." The results of the ASTA method supported the use of ethylene oxide as a tool for chemical sterilization of spices, while also reducing residue levels of ethylene oxide and the byproducts that remain on spices below established EPA tolerances. Due to the success of the ASTA method, the process continues to be used today, and spice companies and sterilizers continue to use ethylene oxide on spices safely.

An additional, unintended benefit of the processes developed under the ASTA method resulted in the reduction of emissions of ethylene oxide, both controlled and uncontrolled, from the sterilization facilities. The levels of emission reduction recorded have been at the lowest levels possible, with some facilities recording no emission levels. Essentially, this occurs because the spice product is not removed from the sterilization chamber until all of the ethylene oxide that can be removed from the chamber is removed.

Sterilization under the ASTA method dramatically reduced emissions. Under the previous conventional ethylene oxide sterilization process, two steps were associated with both controlled and fugitive emissions. The first one, when the ethylene oxide gas is removed from the sterilizer with the vacuum pump, was typically a short process, requiring additional aeration. The second step occurred when the product was unloaded and moved to aeration rooms, which was a potential source of fugitive air emissions. In the spice industry today, the vast majority of the ethylene oxide passes through the vacuum pump for capture. The additional aeration mandated for the treatment of spices passes the bulk of the ethylene oxide through a primary technology, which controls it to >99% under the technology mandated by National Emission Standards for Hazardous Air Pollutants (NESHAP). In many facilities, the control technology provides an even higher efficiency than 99% mandated. Spices remain in the sterilization chamber for the aeration process. Therefore, under the ASTA method, the sterilization chamber door is not opened, and ethylene oxide emissions, fugitive or otherwise, do not escape.

Under the ASTA method, the aeration takes place in the same chamber as sterilization, dramatically cutting down or eliminating the possibilities of fugitive emission since the spices remain in the same sealed chamber. After the spices are sterilized, fresh air flows into the room, while air contaminated with ethylene oxide is removed. This process accelerates the removal of residual ethylene oxide from the product, and controls emissions from the aeration room as the gas from the chamber is extracted with a blower. The rule of thumb is that about 1% of the ethylene oxide is removed in aeration, although it may be higher. Fugitive emission from the aeration room previously occurred as part of the

conventional process as the chamber doors were opened and closed or when the products were transferred into the aeration room from the sterilizer. Again, under the current ASTA method, the spices remain in the sterilization chamber, without opening the doors or moving the sterilized spices, so there are no emissions.

Previously, the conventional process removed ethylene oxide from the sterilizer utilizing a combination of vacuums followed by nitrogen or air pulses. Typically, this was repeated until the atmosphere in the sterilizer was not flammable and safe for human entry. However, the ASTA method uses a combination of vacuums to reduce pressure followed by steam injections and air injections in a series of pressure pulses. These pulses extract the ethylene oxide from deep within the product very efficiently. As a result of the effectiveness of the steam/air pulse and the number of pulses, the ethylene oxide residue levels in spices under the ASTA method are dramatically reduced following sterilization.

Because of the ASTA method, facilities that are sterilizing spices may either already meet, or could easily meet, dramatically reduced EPA air emissions requirements for ethylene oxide emissions. For these reasons, ASTA respectfully requests that any new or proposed air emissions requirements for the use of ethylene oxide in sterilization take into account the methods and work that the spice industry, along with EPA, has already undertaken.

Conclusion

The spice industry voluntarily demonstrated its commitment to lower ethylene oxide levels to the lowest possible amount for both residue levels on the finished product and fugitive air emissions and will continue to maintain its commitment. Ethylene oxide remains an essential and necessary tool for the spice industry to comply with FSMA requirements and to fulfill the ASTA members commitment to supplying consumers with clean, safe, spices.

For these reasons, we urge EPA to continue to permit the use of ethylene oxide on spices and to continue to be mindful of any burdens that emissions requirements would place on the spice industry and especially small businesses. Ethylene oxide plays a critical role in the protection of public health through the prevention of foodborne illness.

ASTA would be happy to answer any questions or to meet with the EPA regarding our comments or answer any additional questions that the EPA may have.

Respectfully submitted,

Laura Shumow
Executive Director
American Spice Trade Association