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Andrew R. Wheeler, Administrator

U.S. Environmental Protection Agency

EPA Docket Center

Docket ID No. EPA–HQ–OAR–2019– 0178

Mail Code 28221T

1200 Pennsylvania Avenue NW

Washington, DC 20460.

RE: Docket ID No. EPA–HQ– OAR–2019–0178 Comments of [Insert Company Name]

Dear Administrator Wheeler:

MY COMPANY HERE 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, Docket No. EPA–HQ–OAR–2019–0178. We are submitting this letter to express support for the continued availability of ethylene oxide for use on spices as a critical food safety tool to control microbial pathogens. We also endorse the comments submitted by the American Spice Trade Association (ASTA).

The spice industry recognizes and supports EPA’s goal of minimizing ethylene oxide emissions resulting from its use. To this end, the industry has worked over many years to reduce residues and emissions to the lowest level possible level while still achieving the objective of ensuring spices are treated to control food safety hazards.

The most important 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 under tropical or subtropical conditions, 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.

Ethylene oxide is a critical tool used by the spice industry for the control of *Salmonella*. The use of ethylene oxide is of paramount importance to the spice industry despite the fact that sterilization of spices accounts for less than 1% of the total FIFRA use of the chemical and only an infinitesimal portion of all uses of ethylene oxide. Although a minor user of this chemical, the spice industry relies on the ability to treat spices with ethylene oxide to protect the safety of consumers and meet U.S. Food and Drug Administration (FDA) regulatory requirements.

Spice companies must comply with the FDA’s Preventive Controls for Human Food rule under the Food Safety Modernization Act (21 CFR 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.

The only wide-spread technologies available to achieve validated reduction of *Salmonella* in spices are steam, irradiation and ethylene oxide treatment. While each of these technologies is capable of performing the necessary microbial reduction, each has limitations and as such, it is important for the industry to continue to retain multiple available treatment methods. Limitations on the use of steam on spices include discoloration or loss of flavor, thus destroying certain spice products, whose main purpose is to add flavor to foods. Additionally, while irradiation works well for pathogen control, labeling requirements limit the commercial viability of the technique in certain circumstances. Therefore, in some instances, ethylene oxide is the only commercially viable tool that can deliver the necessary pathogen control for spices without destroying the product in the process.

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. Prior to adoption by the industry as an effective pathogen control, any new methods must also undergo significant research to show the technology is capable of delivering a 5-log reduction of *Salmonella*. To this end, a company must invest 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 and uncertainties associated with changing to a new sterilization technology and the required capital investment can be a significant barrier.

For these reasons, we urge EPA to continue to permit the use of ethylene oxide on spices and to ensure any new emissions control requirements are not overly burdensome for the spice industry. Ethylene oxide plays a critical role in the protection of public health through the prevention of foodborne illness.

Regards,