ELITE SPICE

EPA originally proposed is insufficient to implement the changes needed to comply with the NESHAP. The NESHAP effectively forces the spice industry to cease using EO at the end of the implementation period. Additionally, several spice sterilizers have already left the industry due to these challenges.

These concerns are echoed in the comments submitted by the U.S. Office of Advocacy of the Small Business Administration (NESHAP Dock ID No. EPA-HQ-OPP-20130244 & Docket ID No. EPA-HQ-OAR-2019-0178). Specifically, issues have been raised regarding the unreasonable compliance period, the challenges posed by overlapping compliance regulations with the PID, and the difficulties associated with retrofitting facilities to accommodate total enclosures.

While not classified as a small business, we at Elite Spice handle spice sterilization as a small segment of our operations, primarily to ensure the safety of our customers and their consumers.

Explanation why an extension is in the national security interests of the United States: In 2013, the FDA published a Draft Risk Profile on the prevalence of pathogens and contaminants in spices, identifying significant microbial risks, particularly Salmonella. The FDA found that nearly 7% of examined spice shipments entering the U.S. were contaminated, and both the FDA and Elite Spice believe this rate is likely underestimated due to sampling methods. Effective microbial reduction treatments are essential to protect consumers from life-threatening foodborne pathogens.

The spice industry has relied on Ethylene Oxide for over 70 years as a primary means of mitigating pathogen contamination. Given the limited alternatives, it is critical that EO remains available to safeguard public health and meet FDA safety mandates. Without EO, the industry would struggle to ensure spice safety and would need significant time to evaluate and implement new, effective sterilization technologies.

Due to the anticipated challenges in complying with the new NESHAP standards, companies have invested considerable capital and time in researching and developing alternative sterilization technologies that meet food safety standards while reducing reliance on EO. However, the equipment required for these new technologies has long lead times—often taking 8 to 12 months to deliver as it is designed and manufactured overseas, an additional 4 to 6 months to install, and up to 16 months to validate. This timeline is insufficient to meet the compliance deadline, leaving little time to transition away from EO or fully implement other engineering controls.

With the lack of time to implement new controls required by NESHAP or alternative sterilization technologies, many companies may turn to outsourcing this critical function, often relying on overseas vendors to manage foodborne pathogen risks. While spices may seem minor in the food industry, their widespread use in flavoring a variety of food products means that insufficient treatment could result in large-scale foodborne illness outbreaks, posing a significant public health risk and even a national security threat.

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