



April 4, 2023

Via E-Mail

Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

RE: EPA's "Ethylene Oxide Risk from Commercial Sterilizers" Communications

Dear Administrator Regan,

The American Spice Trade Association (ASTA) is writing to express significant concerns regarding language on the EPA's website that misrepresents the risk from commercial sterilizers that process spices with ethylene oxide. We respectfully request that the agency immediately correct these inaccuracies, which are driving public confusion and harming the reputation of companies who are in compliance with EPA's current regulations on ethylene oxide emissions.

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, and these companies 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 recognizes and supports EPA's goals of protecting public health, and the spice industry further embraces the goal of reducing emissions, including ethylene oxide emissions. To this end, ASTA and spice companies that use ethylene oxide have worked for the last twenty years to reduce emissions, while still achieving the objective of ensuring spices are treated to control food safety hazards. Ethylene oxide remains critical for keeping spices safe and complying with Food and Drug Administration (FDA) regulations.¹ Importantly, there are not currently viable treatment alternatives for all spice products and, where alternatives exist for some spices, there are serious limitations.²

¹ 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 FSMA 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.

² Per FDA's Risk Profile: Pathogens and Filth in Spices (available at <https://www.fda.gov/media/108126/download>), the only wide-spread technologies available to achieve validated reduction of *Salmonella* in spices are steam, irradiation, and ethylene oxide 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.

On August 3, 2022, EPA published a list of the locations and names of commercial sterilizers that EPA determined presented an “elevated risk at or above 100/million to nearby communities.” ASTA represents a number of companies that were included on this list. Notably, this list did not highlight companies because they were in violation with EPA’s existing regulations. Instead, EPA named companies that it had determined exceeded its IRIS risk value based on modeling using theoretical calculations, rather than measured emissions.

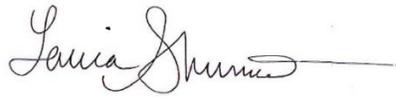
On the EPA’s website, the agency asserts that the “assessment is based on the most up-to-date information available from commercial sterilizers,” and if “EPA receives new data, we will update this information.” Further, when ASTA raised these concerns during a stakeholder meeting with EPA on August 9, 2022, officials reiterated that companies were encouraged to provide new information and assured that the agency’s website would be updated once new information was received. However, EPA has failed to follow through on this commitment. While companies in the spice industry submitted updated data months ago demonstrating that their facilities do not exceed EPA’s risk value, EPA has still not corrected outdated and misleading information on its website. ASTA urges EPA to immediately (1) remove facilities from the list if they have provided data to demonstrate that their facilities fall below the risk threshold and (2) reflect on EPA’s website accurate, up-to-date information.

This request is particularly urgent in advance of planned meetings in some communities that are located near spice facilities on EPA’s list, such as the April 12 meeting scheduled in Jessup, Maryland. Rather than holding meetings that will further spread confusion and alarmism in these communities, EPA should correct the inaccurate information on its website. If EPA proceeds with these meetings, then it should use the opportunity to share the corrected risk assessments based on the new data that spice companies have provided the agency. Importantly, updating the public orally in these community meetings is not sufficient; EPA should also update its website in advance of the meetings to provide clarity to consumers and other stakeholders.

Furthermore, the EPA’s publication of erroneous risk maps has led to widespread concern, development of [mapping tools](#) that further misrepresent the actual risk to communities, and the introduction of legislation in the state of Maryland that would to completely ban ethylene oxide. As such, the EPA’s risk communications approach on this issue has been criticized by industry and public health groups, alike. As I am sure you are aware, the National Association of Clean Air Agencies (NACAA) – a national, non-partisan, non-profit association of state and local air pollution control agencies – submitted a letter identifying concerns with both EPA’s risk communications approach and flawed assumptions with facility-specific analyses, emissions factors, and background levels of ethylene oxide.

In summary, ASTA urges EPA to immediately correct its website to reflect the most up to date information on commercial sterilizers it has received from facilities that the agency initially determined are at an “elevated risk at or above 100/million to nearby communities”. EPA’s swift attention to this matter is critical for both the U.S. consumers and the spice industry.

Respectfully submitted,

A handwritten signature in black ink, reading "Laura Shumow" with a long horizontal flourish extending to the right.

Laura Shumow
Executive Director
American Spice Trade Association

CC:

Alice Chow
Chief
Air Quality Analysis Branch

Jonathan Witt
PE Environmental Engineer
Office of Air Quality