AMERICAN SPICE TRADE ASSOCIATION, INC.

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May 9, 2024

Dr. K. G. Jagadeesha IAS
Secretary
Spices Board of India

Submitted via email to secy.kochi-sb@gov.in

CC: Dr. Remashree, Director Development, remashreeab.ab@gov.in

Re: Ethylene oxide usage in spices exported to the U.S.

Dear Dr. K. G. Jagadeesha IAS,

The American Spice Trade Association (ASTA) has become aware of recent media reports on the rejection of Indian spices from Singapore and Hong Kong due to the presence of ethylene oxide (EtO) residues. In light of these recent developments, we are reaching out to offer clarification on EtO and food safety regulations pertaining to spices imported into the United States. Ethylene oxide is currently permitted for use on spices in the U.S. and prohibiting this critical treatment method has the potential to result in serious unintended implications regarding compliance of Indian spices with U.S. food safety regulations.

ASTA was established in 1907 and is the voice of the U.S. spice industry in the global market. Our members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at 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.

Ethylene oxide is an approved antimicrobial fumigant in the U.S. and the tolerances (MRLs) for EtO and ethylene chlorohydrin/2-chloroethanol (ECH) are 7 ppm and 940 ppm respectively for herbs and spices (except basil).[i] Moreover, both the U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) have concluded that consumption of spices treated with EtO is safe.[ii]

The U.S. spice industry relies on EtO sterilization as one of the primary methods to comply with the FDA regulations under the Food Safety Modernization Act. Specifically, the Preventive Controls for Human Foods Final Rule requires that U.S. companies have in place a validated kill step to control the risk of foodborne pathogens known to occur on spices, including *Salmonella, E-Coli,* etc.[iii] Currently EtO is one of the primary methods that U.S. spice importers use to comply with these requirements, while maintaining high quality standards. Spices that do not undergo a validated kill step prior to import to the U.S. will be deemed "Not Ready-To-Eat" and are required to be labeled with a "Not Processed to Control Microbial Hazards" disclosure.[iv] Replacing EtO with alternative methods would require cost- and time- intensive validation studies needed to comply with FDA regulations while maintaining quality standards. More importantly, in the meantime, there may be an elevated risk of the presence of microbiological pathogens, resulting in foodborne illness and product recalls in the U.S.

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In conclusion, the U.S. imports more than 100,000 MT of spices from India valued at more than $360 million annually[v], all of which needs to be treated with a validated kill step, such as EtO, prior to being sold in the U.S. market. Current U.S. regulations permit the use of EtO treatment on imported spices and spice products as long as residues adhere to the prescribed tolerances. Moreover, without the use of EtO on spices, imported products are at a higher risk of the presence of pathogens and non-compliance with FDA food safety regulations.

ASTA remains at the disposal of the Spices Board of India to provide any additional information or respond to any questions regarding the U.S. EtO and food safety requirements. Any inquiries may be directed to laura.shumow@astaspice.org or +1-630-542-3482.

Warm regards,

Laura Shumow
Executive Director
American Spice Trade Association

[i]Per 40 CFR Part 180.151
[ii]FDA has indicated that there is not a cancer concern from exposures to EtO residues from the consumption of spices. In its 2017 Risk Profile on Pathogens and Filth in Spices, FDA states that *"an assessment of cancer risk (Fowles et al., 2001) from EO residues in spices concludes that 'risks are practically negligible' based on current understanding on exposure from concentrations of EO found in spices"* (FDA, 2017). Furthermore, EPA's Proposed Interim Decision (PID) for EtO, states that *"EPA has determined that there is no human dietary risk from registered uses of EtO…EPA concludes that there is a reasonable certainty that no harm will result from dietary exposure to EtO or ECH [ethyl chlorohydrin]. Therefore, EtO and ECH residues are safe"* (EPA, 2023).
[iii]Per 21 CFR Part 117
[iv]Per 21 CFR 117.3
[v]Per FAS - Global Agricultural Trade System (GATS) (usda.gov)