ASTA Responses to EPA Questions on Use of ETO for Reconditioning of Spices and Proposed Phase-Out on June 28, 2024

1. **EtO usage information for the commodities in Group 1 and what compliance timeline would be needed for the cancellation of these commodities.**

ASTA concurs with EPA's determination that continued use of EtO on Group 1 commodities is not critical for food safety. The spice industry can readily comply with the revocation of EtO use for these commodities.

2. **Information on how frequently reconditioning/retreatment occurs with EtO as a secondary treatment for human pathogens (if a primary treatment fails).**

The reconditioning and retreatment of spices may be necessary when an initial food safety intervention has failed or for which post-process contamination has occurred. Testing for bacterial pathogens such as *Salmonella* in spices is conducted by the Food and Drug Administration and spice companies alike to determine safety and compliance of spice product. During these screening processes, *Salmonella* or other pathogens may be detected, and thus the spice product must undergo additional microbial reduction treatment.

As noted, the reconditioning of spice products may be prompted by the regulatory screening of imports by FDA. Imported shipments of spices offered for entry to the U.S. may be sampled as part of FDA's Import Foods – General Compliance Program either as part of general surveillance or targeted sampling. In some cases, sampling may reveal that the product is non-compliant with regulatory standards, e.g., the spice product contains microbial pathogens, such as *Salmonella*. Per Section 801(b) of the Federal Food, Drug, and Cosmetics Act, importers on record may submit to FDA a written application requesting authorization to bring into compliance an article adulterated, misbranded, or in violation of Section 505 by relabeling or other action. When *Salmonella* is detected by FDA in a shipment of spice, the importer can therefore (1) export the product; (2) destroy the product; or (3) request permission from FDA to recondition the product to bring the product into compliance. Reconditioning proposals by the importer are reviewed and approved by FDA and if the reconditioning is successful in remedying the violation, FDA will release the product into U.S. commerce.

Additionally, FDA may place specific importers or origins on automatic detention without physical examination based on historical incidents of contamination. In these incidents, any product subject to the import alert must undergo reconditioning regardless of whether there is evidence of contamination in the specific shipment. For example, currently, all black and white peppercorn (whole and ground) imports from Brazil are subject to detention without physical examination due to historical evidence of *Salmonella* contamination. As such, all shipments of black and white peppercorn from Brazil require reconditioning to demonstrate compliance and have the product released from detention.

Based on FDA's publicly available Import Refusal Database, between fiscal years 2002 and 2024, 6,686 imports of spices and seasoning blends were rejected at import which listed *Salmonella* as a refusal charge. This represents 52.5% of all rejected imports for spices and seasonings during this time period (n=12,737). Based on FDA's Import Entry Dashboard, during this same time frame, over 1. 6 million imports of spices, seasonings, and flavors entered into the U.S. without refusal. Although ASTA was not

able to refine this number to exclude non-spice commodities (e.g., flavors, salt, etc.), it is estimated that less than 1% of all spice imports screened at the border are refused due to *Salmonella* contamination and thus require reconditioning.

EtO has historically been used as a tool to recondition spice shipments that have been refused at import. FDA reported in a presentation to ASTA at its 2023 Regulatory Workshop that between 2015-2019, 50% of reconditioning proposals submitted to FDA for imported spices and herbs were for EtO, while the remaining proposals were for alternative treatment methods such as irradiation, steam, and PPO. Between 2019-2022, approximately 36% of reconditioning proposals for spices and herbs were for EtO, while the remaining proposals were for steam, irradiation, and heat treatment.

Moreover, many spice companies conduct internal analyses for *Salmonella* as part of the verification of their respective food safety plans to ensure product safety and regulatory compliance. The proactive, internal screening of *Salmonella* in spices permits companies to retreat product before leaving the facility. The frequency of retreatment of spices by spice companies varies and is likely higher than the frequency at which the reconditioning of imports occurs. Some companies report that approximately 1% of spice products are retreated internally, with up 12-15% of spice commodities being treated in certain cases. Factors that contribute to this variation are spice type, as some spices are more resistant to treatment either due to their form, starting microbial load, or inherent chemical properties, as well as the efficacy of the initial microbial treatment method.

It is important to note that as the industry transitions away from EtO and implements novel treatment methods, different rates of reconditioning may be required. Increases in reconditioning treatments may be reported as alternative treatment methods may not yet be as efficacious as EtO. As such, ASTA supports the continued use of EtO as a reconditioning/retreatment method for all spices in Group 2.

3. Additional Comments on Group 2 Commodities

ASTA would like to use this opportunity to request that EPA consider the reassignment of the following commodities from Group 2 to Group 3:

- Saffron, Tarragon, Lavender, Marjoram/Oregano, Parsley, Rosemary, Savory, Sweet Bay, Thyme, Dill Weed, Coriander Leaves

As outlined in ASTA's initial comments, alternative microbial reduction treatments such as the steam treatment of flowers and leafy herbs can lead to detrimental effects on these commodities' organoleptic and visual properties. As such, spice companies using EtO on these commodities would need a transition timeline of at minimum 7 years to research, validate, and implement alternative treatment methods.

4. Information on the dried vegetables that are currently treated with EtO.

ASTA supports EPA's inclusion of capsicums, ginger, horseradish, paprika, garlic, onion, turmeric, and arrowroot within the category of "vegetable, dried." Although ASTA does not represent the dried vegetable industry more generally, it is important to note that other dehydrated vegetables exist, and some seasoning manufacturers may include additional dehydrated vegetables outside of the eight spice commodities, which EPA notes the category of dried vegetables including. Examples of other dehydrated vegetables used in seasoning blends that may be treated with EtO include asparagus,

artichoke, green bean, green bell pepper, red bell pepper, broccoli, cabbage, carrot, celery stalk, corn, kelp, leek, mushroom, tomato, and meleguenta.

Lastly, as EPA implements the phased cancellation of EtO on spices, ASTA would like to reiterate the critical importance of retaining import tolerances for EtO and ECH on all spices, since spices may be treated with EtO at origin prior to import into the U.S. Cancellation of EtO/ECH import tolerances would have the potential to be extremely disruptive to trade. Recent recalls of spices in Hong Kong and Singapore due to the presence of trace levels of EtO underscore the potential disruption to trade that could occur as a result of the loss of these import tolerances.