ASTA Responses to EPA Questions on ETO Concentration and Critical Food Safety Uses for Spices from Call on December 1, 2023

1. Is it possible to reduce the concentration of ETO use on spices to less than 500 mg/L?

The spice industry has been using all efforts to reduce EtO emissions, including exploring the potential to reduce concentrations of EtO where possible. EtO is used by both spice companies directly, as well as commercial sterilizers that offer services to the spice industry. Some commercial sterilizers that treat spices with EtO have been able to successfully use a concentration of 400 mg/L to obtain the desired food safety effect in certain spices, though some spices are more challenging to treat. Furthermore, treatment at these lower concentrations may be effective because another form of treatment was previously applied to reduce the microbial load (e.g., steam wash prior to import).

All spice companies that have validated their processes have done so at 500 mg/L. As such, in order to reduce the concentration of EtO applied, these spice companies would need to conduct validation studies at lower concentration for all of their spice products to ensure that an appropriate log reduction can be achieved and validated. While some commercial sterilizers have indicated that they are using lower concentrations, it is unclear if these processes can be validated for all spices. The spice industry is willing to work with EPA on a reduced concentration. However, this will take several years.

Validation studies must be conducted to comply with the Preventive Controls for Human Food rule under the Food Safety Modernization Act (FSMA), 21 C.F.R. 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 and are capable of delivering a scientifically appropriate reduction of *Salmonella*, which is typically understood to be a 5-log reduction. These validation studies must be conducted on up to hundreds of botanical products which include many different forms, including powders, pieces, seeds, leaves, and bark, which all present unique challenges and may respond differently to the application of EtO at different concentrations.

Although ASTA has published guidance on how to group spice commodities in validation studies to streamline the validation process, given the vast array of different products that would need to be studied, it would take a number of years to design, conduct, and analyze the results of the studies for all spices.

These validation studies are time and resource intensive. Validating new processes, while at the same time having to change operations, where even feasible, to address new requirements in the anticipated NESHAP, the timeline provided for continued use of EtO in spices published in the PID, and other external pressures such as state legislation and litigation will create severe operational and resource challenges and may not be possible. If sufficient time is permitted to continue the use of EtO on spices, the industry is committed to supporting the additional research needed to reduce EtO levels.

It is also noteworthy that in order to reduce EtO concentration levels, a longer dwell time may be necessary to achieve the appropriate food safety effect. ASTA questions if EPA would be open to considering a longer dwell time at the lower concentration, recognizing the label would also need to be changed to address this.

2. How much time would the spice industry need to transition away from ETO?

At this time, EtO remains critical to food safety for the spice industry due to limitations of alternative methods. If EPA decides to phase out the authorization for EtO to be used on spices, sufficient time would be required to transition away from EtO to prevent unintended consequences, including food safety incidents and outbreaks. EtO especially remains critical for the reconditioning of spices for which an alternative food safety intervention has failed, as well as the treatment of packaged spices to prevent post-process contamination.

The use of multiple treatment methods within the same company creates inefficiencies in the process. Therefore, most companies choose to use a narrow set of treatment methods (1 or 2). Since spice companies treat dozens of products, it is cost prohibitive to install specific equipment for each type of spice. As such, methods must be able to treat a wide variety of products.

Spice companies using EtO would need a transition timeline of a minimum of 7 years, and in some instances longer, to ensure that they can properly research, validate, and install alternative treatment methods within their facilities. Companies that have transitioned away from EtO in the past have reported that it took up to a decade to successfully implement alternative treatment methods. Although this timeframe may seem to be lengthy, it is important to consider the many steps companies will need to take to identify, acquire, install, test, and implement alternatives.

Moreover, this timeline will allow for companies to continue treatment domestically, which provides the most significant level of protection to U.S. consumers. If the transition away from EtO is rushed, companies may elect to move the treatment of spices with EtO overseas, which increases the risk of post-process contamination and resulting risk of food safety incidents.

A detailed breakdown of the anticipated timeline required to transition away from EtO is included below:

<u>Researching Viable Alternatives [1-3 years]</u>

In considering the viability of alternative systems, spice companies need to ensure that the treatment method meets a number of essential criteria:

- Safe
- Adaptable to many products
- Long history of successful use
- Safe harbor process that doesn't require individual validations
- Retains quality and characteristics of product
- Cost effective
- Accessible
- Minimizes opportunity for recontamination
- Regulatory authorization

A variety of factors influence the selection of a treatment method, including the effects of the method on product attributes, product labeling requirements, customer performance criteria, consumer preferences, scalability of the method, cost, and regulatory acceptance.

Beyond the conventional treatment methods, a number of alternative treatment options have been studied for many years and reviewed in the scientific literature; however, these technologies are currently not widely used due to commercial limitations, and/or lack of widespread applicability and/or evidence on efficacy. Due to the lack of research available on these alternative methods in spice matrices, companies will either have to undertake their own research or commission external groups to evaluate the impact of these methods on spice products. Given the number of spices which will need to be tested, these studies may take several years.

Acquiring New Equipment [1-2 years]

Once a new treatment system has been selected and purchased, it can take more than a year for the equipment to arrive at the facility since the equipment is typically custom built. The acquisition of this equipment may also be affected by global supply chain challenges and limitations in the number of equipment manufacturers. All of these issues are heightened if everyone in the industry is attempting to secure the equipment at the same time.

Installing New Equipment [6 months – 1 year]

It may take up to one year for the new treatment system to be installed in a spice company's facility. New equipment may require the factory to redesign their process and/or layout to ensure sufficient flow of the product or to meet local and state building codes. Furthermore, existing equipment will need to be relocated or removed.

Hygienic design considerations must also be taken into account, as the hygienic design of equipment is essential in controlling the microbiological safety and quality of products treated. Hygienic design has a significant impact on food safety, as food processing equipment itself can be a vector for cross contamination from biological, chemical, and physical contaminants. As both legal regulations and third-party certification programs evaluate hygienic design, this is a particularly important step.

Additionally, EtO is currently the only widespread technology available for use in spice facilities that can be used to treat packaged spice products. Upon the installation of alternative treatment systems which will be used to treat unpackaged products, companies may have to implement new processes and equipment to allow for the post-treatment packaging of spices.

Testing the Efficacy and Quality Implications of Alternative Methods [1-3 years]

Testing of treatment methods is not simply a question of whether a method is effective, but how best to optimize the method to ensure that it is effective, consistent, and least damaging to the product. Treatment systems can be operated with a variety of parameters; each company must identify which parameters are most appropriate to ensure the food safety effect and quality impacts to their products within their specific facility.

Efficacy Testing

New treatment systems will need to be validated to ensure that they provide a sufficient log reduction in pathogens, such as *Salmonella*, per FSMA requirements (21 C.F.R. Part 117). As these validation studies will need to be completed on all of the products within a company's portfolio, the validation process may take several years. There are typically six phases to validating microbial reduction processes:

1) Phase 1: Assemble a multi-disciplinary team to plan and oversee validation activities
    - A team approach ensures that processes, protocols, and timelines are realistic and that relevant considerations are not overlooked. The validation team is responsible for all aspects of the project, and must gain the support of stakeholders who can provide the internal manpower and financial support necessary to complete it. The team is typically comprised of members with expertise in quality assurance, process engineering, food safety, maintenance, microbiology, purchasing, data analysis, project management, and regulatory affairs.
    - It should be noted that the validation team may need to include external consultants if the appropriate qualifications and experience does not exist internally. Manufacturers of equipment may be able to offer advice on how to confirm that their products are functioning as intended. Scientific organizations, competent authorities, process control experts, or universities may also serve as resources that may also be consulted in design and evaluation of validation studies.

2) Phase 2: Develop a master validation plan
    - A master validation plan is a strategic document that guides the validation project from start to finish. Its development is paramount to building consensus and gaining required approvals.
    - The master plan gives structure to the validation project, and specifies individual responsibilities, project phases, benchmarks, timelines, and budget. It also specifies parameters and decision criteria that will demonstrate that a control measure or combination of control measures, if properly implemented, is capable of consistently controlling the hazard to the specified outcome.

3) Phase 3: Identify sources of product and process variability
    - In order to successfully control a process, one must know the process, understand the limitations of the process, and remove (or reduce) variability. Sources of variability may be evident in defect complaints, batch records, in-coming spice product records, and adverse event reports. In-plant processing staff and quality assurance staff may also provide insights into process variability and should be queried during this phase of the validation project. Preliminary trials may also be necessary to gain a complete understanding of sources of process and product variability and their impact on the process and product.

4) Phase 4: Develop and test validation protocols
    - Protocol development is likely the lengthiest, most work-intensive phase of a successful validation. Whereas the master plan is a strategic document, validation protocols are tactical and very detailed. Validation protocols are designed to confirm process control.
    - The three main protocols used to validate a microbial reduction process are:
        i. The “installation qualification” (IQ) protocol, which confirms that the equipment is installed correctly.
        ii. The “operational qualification” (OQ) protocol, which confirms that the lethality step delivers the critical limits required for the target log reduction. What to measure, how to measure, and where to measure should all be considered.
        iii. The “performance qualification” (PQ) protocol, or inoculation challenge, which determines the extent to which the process inactivates the target organism or a surrogate organism (ie, a non-pathogen used in place of the target organism if validation is performed in a food processing facility).

- Once the data from protocol-based validation testing has been generated, it must be analyzed for patterns and trends. Statistical process control techniques and the application of control charts are useful for this type of analysis. Involvement of a skilled statistician is essential to verifying assumptions about the applicability of the analysis method and ensuring the appropriate statistical software is employed. Based on the analysis of the experimental data collected, the process may need to be adjusted or new process controls established. The testing and adjusting should be repeated until repeatability and predictability for the process can be established. Only then should the validation protocols be finalized.

5) Phase 5: Prepare a validation report
    - This report will aid future validation studies and may be requested by internal stakeholders, public health organizations, industry groups, or regulatory authorities. The validation team must ensure that the reporting mechanism is compatible with applicable regulatory requirements.
6) Phase 6: Perform continuing process verification
    - Once a process is validated, systems must be established to assure that the process remains in a state of control during full-scale commercial operation. These systems include continuous monitoring of critical control points, periodic microbial testing of finished product, facility and equipment maintenance, cleaning and calibration schedules, adherence to prerequisite programs, and comprehensive staff training.

Validation involves demonstrating that a process, when operated within specified limits, will consistently produce a product meeting predetermined specifications. A successful validation requires diverse expertise, detailed planning, and a keen eye for sources of process variability.

As alluded to, validation studies are incredibly complex. A variety of factors including product and process variability can slow down the validation process. Pre-process product variability may affect the ability of a treatment process to achieve the target lethality in validation studies, such as formulation and form, density, degree of air flow, in-going product temperature, moisture content, and origin. There may also be a variety of sources of process variability, including atmospheric conditions, size of load and load pattern, depth of the product, type and placement of calibrated monitoring/recording devices, and changes in operating conditions and personnel from day to day or shift to shift. Additional sources of variability that may affect microbial challenge studies include conditions under which the surrogate microorganism culture is grown, inoculum preparation, product preparation prior to inoculation, incubation duration and conditions, post-process sampling, and duration of studies. Because all of these factors must be considered, the validation process is extremely laborious and time consuming. However, this step is essential to ensure efficacy of the equipment and product safety.

Quality Testing & Assurance

Spices and herbs are used in food products for flavor and aroma, which come from volatile components that are heat sensitive. Therefore, quality considerations are essential to the commercial viability of an alternative method. Companies must conduct quality testing including impact to volatile oil, sensory, color, and other key attributes.

<u>Implementing New Processes [6 months – 1 year]</u>

Following installation and validation of the equipment, new processes will be implemented with the facility and existing processes may be altered. Should longer dwell times be necessary following

treatment, subsequent processes such as packaging and distribution may be delayed. As such, new training and schedules may need to be created and implemented.

Additionally, the company will need to design and administer training to employees on how to use the equipment, ensure equipment function and safety, and verify the continued efficacy of the treatment.

In summary, the spice industry will require a transition timeline of at minimum 7 years to identify and implement alternative treatment systems to treat spices and ensure food safety. A longer timeline will be needed for the most difficult to transition spices.

3. Are there spices that are particularly challenging to transition away from EtO?

There are several categories of commodities that are particularly challenging to treat because of their inherent physiochemical properties. The industry would require additional time to identify alternative treatment methods for these sensitive commodities.

Leafy Green Herbs

Leafy herbs such as parsley, sage, oregano, cilantro, and basil are particularly delicate and difficult to treat. The flavor, aroma, volatile oil, and color of these products is impacted by heat treatment. Additionally, because of the low density of the product, specific treatments may result in clumping.

Sensitive Seeds

Some seeds, such as cumin, clove, sesame, and poppy are particularly sensitive to treatment. For example, heat treatment may negatively impact the volatile oil content of cumin and clove. In sesame and poppy, heat treatment results in the formation of rancid flavors. Additionally, PPO is not authorized to be used on sesame.

Capsicums

Capsicum spices, such as red pepper, chili, and paprika, can be difficult to treat. Depending on the method employed, the spices may suffer from a loss of color and uniformity. Additionally, heat treatment may caramelize the product, impacting the flavor profile.

It is notable that PPO is not authorized for this category.

Others

It is also particularly difficult to treat cinnamon and mace products due to loss of volatile oil and lack of uniformity. It is also noteworthy that PPO is not authorized for use on ginger and turmeric.

Powdered Spices

Any spice in a powdered form is particularly challenging to treat because of the risk of clumping.

Reconditioned Spices

Finally, EtO especially remains critical for the reconditioning of spices for which an alternative food safety intervention has failed as well as the treatment of packaged spices to prevent post-process

contamination. Reconditioning proposals must be submitted to FDA for review; FDA has the ultimate authority to approve which methods are permissible to recondition products for which previous food safety inventions were ineffective.

4. What would be the impact of EPA authorizing the expanded use of PPO on spices?

The spice industry believes that the transition to PPO represents the most rapid and accessible pathway away from its reliance on EtO. Similar to EtO, PPO can be used to treat spices in their final packaging, reducing the risk of post-process contamination. Furthermore, current EtO treatment chambers can be repurposed for PPO treatment fairly quickly.

However, because of current label limitations for PPO, the chemical cannot be used as an alternative for several key spice commodities for which EtO is currently used, including turmeric, capsicums, ginger, and sesame seeds. ASTA submitted a ChemSAC proposal in December 2023 proposing to translate existing residue data for various spice commodities to establish tolerances for residues of PPO and its metabolites and degradates on these commodities.

The expanded use of PPO to these missing commodities would aid in the industry's transition away from EtO and grant additional time for the industry to identify and evaluate the viability of other alternative treatment methods. However, it may take several years for EPA to authorize PPO for these commodities. ASTA anticipates that it will receive an indication from ChemSAC on if existing residue data may be used to establish PPO tolerances for these commodities. If the determination is not favorable, the industry will need to conduct residue trial studies on these spices which will take 6 months-1 year. The petition process will take approximately 2 years between the development of the petition and the PRIA timeline. Then, industry will need to conduct validation studies, which will take several years as outlined above.