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**Re: Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide; Notice of Availability. (Docket EPA-HQ-OPP-2013-0244)**

To Whom it May Concern,

The American Spice Trade Association (ASTA) appreciates the opportunity to submit comments on the Environmental Protection Agency's (EPA) proposed interim decision (PID) for ethylene oxide (EtO) and associated draft risk assessment addendum.

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 commercial food manufacturing, food service, and consumer use. The highest priority of ASTA and our members is ensuring the supply of clean, safe spices to American consumers.

The spice industry recognizes and supports EPA's goal of lowering emissions of EtO from sterilization facilities and protecting public health. To this end, ASTA wishes to highlight the spice industry's history of collaborating with regulatory authorities to reduce EtO emissions while maintaining its rigorous commitment to ensuring food safety by reducing microbiological contamination in spice products. The spice industry has taken steps to move away from its reliance on EtO when effective alternatives are available. However, there are currently no effective alternatives for certain spices and spice-related categories. EtO's use is needed until effective alternatives are developed.

The PID proposes several actions that are either not achievable or that would significantly impact the industry's ability to supply safe, clean spices to the U.S. population and to U.S. commercial food manufacturers. It is noteworthy that the vast majority of packaged food products sold at retail contain some spices or flavorings derived from spices (including prepared meals, meat products, soups, sauces, beverages, etc.). As such, this proposal has the potential to impact the entire food sector. Through these comments, ASTA endeavors to emphasize the following:

- While ASTA recognizes EPA's goal of narrowing the registration for use of EtO to only the most critical uses, the subsequent revocation of tolerances is unnecessary and would significantly impact global trade and food supply chains, as well as create potential for compliance issues for years to come.
- Under the Federal, Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 301 et seq, all food companies are required to develop a food safety plan that identifies microbiological hazards, including pathogens, and create a treatment plan to address these hazards. The treatment plan must also be validated to assure that it is successful. Spice companies must comply with the Preventive Controls for Human Food rule under FSMA regulations, 21 C.F.R. Part 117, which requires the control of all food safety hazards. Any processes to control hazards such as *Salmonella*, including alternative treatment methods, must be validated to ensure that they are effective and are capable of delivering a 5-log reduction of *Salmonella*.
- The spice industry has not had sufficient time to identify and evaluate the viability of alternative treatment methods for all spice products within the "dried herbs, spices, dried vegetables, and seasoning" materials categories.
- The industry has identified a list of spices, dried herbs, and dehydrated vegetables for which EtO use remains critical and for which there are no viable alternatives. However, it is important to recognize that treatment is situationally dependent. Many factors influence the selection and ability to leverage a treatment at any given time.
- In the event that EPA determines the use of EtO will be phased out, the industry will require many years to transition their operations to include alternative technologies.
- The spice industry welcomes the opportunity to work with EPA on lowering the concentration limit of EtO for spice treatment methods.
- The spice industry has been subject to a limit on gas concentration and has been using all-in-one processing since 2008. The EPA recognizes the benefits of the processing technologies that were developed and introduced by ASTA in regulations that were recently proposed. We are proud of the fact that the commercial sterilization of spices has been at the forefront of compliance by minimizing worker exposure, primary emissions, fugitive emissions, and residues of ethylene oxide on spices for the last 15 years.
- Proposed automation requirements, particularly requiring covered conveyors, are unnecessarily burdensome and will require not only the purchasing of new equipment, but for entire facilities to be redesigned.
- Real time monitoring at 10 ppb is not achievable.

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## **1. Tolerances should not be revoked for herbs, spices, and dried vegetables.**

*Exposure to EtO and ECH residues from the consumption of spices does not pose a public health risk; therefore, it is unnecessary to revoke tolerances. Moreover, the PID is intended to reduce emissions of EtO, not reduce dietary exposure to EtO and ECH.*

The PID proposes to consider future actions revoking tolerances on commodities for which uses of EtO are cancelled. However, there is no public health justification for this proposal.

In its 2020 Draft Risk Assessment for EtO, the U.S. Environmental Protection Agency (EPA) noted that sterilization studies demonstrate that although low levels of EtO residues may be present on commodities after the fumigation process (e.g., 24 hours), residues are anticipated to completely dissipate by the time the commodity is available for consumers (EPA, 2020). After treatment, the EtO reacts with natural bromides and chlorides present in the food to form ethylene bromohydrin (EBH), ethylene chlorohydrin (ECH), and ethylene glycol (EG). Low levels of EtO may be detected in spice products depending on the time of testing, while ECH residues remain present on treated commodities when they are available for consumption. ECH is non-volatile and will remain on the commodity; as such, the only relevant exposure pathway is through dietary sources.

The U.S. Food and Drug Administration (FDA) has indicated that there is not a cancer concern from exposures to EtO or ECH residues from the consumption of spices. In its 2017 Risk Profile on Pathogens and Filth in Spices, FDA states that “while toxic residues of EO [ethylene oxide] in treated materials remains a concern, 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, 2017a). Furthermore, EPA’s PID for EtO, states that “EPA has determined that there is no human dietary risk from registered uses of EtO that is inconsistent with the FFDCA [Federal Food, Drug, and Cosmetic Act] safety standard...EPA concludes that there is a reasonable certainty that no harm will result from dietary exposure to EtO or ECH. Therefore, EtO and ECH residues are safe” (EPA, 2023).

As outlined in the FD&C Act 408(b)(2)(D), EPA may only consider the following factors in the revocation of a tolerance for a pesticide chemical residue:

“...available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources.”

As such, it would be inappropriate for EPA to propose the revocation of tolerances as it has determined that dietary exposures from EtO and ECH residues are safe. Rather, EPA is proposing action based on the occupational risks associated with EtO, which is not an appropriate basis for a tolerance revocation.

*Tolerances are essential to facilitate global trade.*

The existing tolerance of 7 ppm (EtO) and 940 ppm (ECH) for Crop Group 19, sesame seeds, and dried vegetables should not be revised to exclude commodities where uses of EtO are cancelled. These

tolerances function as a critical import tolerance for spices and as such, the cancellation of these tolerances would disrupt global trade.

U.S. law does not specifically differentiate a tolerance as an “import” tolerance or a “domestic” tolerance. Regardless, the concept of import tolerances has been recognized and promulgated by the EPA for years. The agency has established numerous tolerances for chemicals in/on imported commodities for which there is not a risk for dietary exposure and for which there is no corresponding domestic registration for the chemical. As stated by EPA, “When no U.S. registration exists, interested persons may submit a petition requesting that EPA establish an import tolerance (or tolerance exemption) for a pesticide residue on a food or feed commodity, which will allow the food or feed treated with the pesticide in foreign countries to be lawfully imported into the United States.”

These import tolerances are established for the purpose of facilitating trade. Examples of this include import tolerances established for metalaxyl and difenoconazole in or on spices, as well as teflubenzuron in or on grapes and raisins.

Generally, the lack of domestic registration for the chemical in the U.S. is not reflective of a lack of safety. Section 408 of the FD&C Act requires that to establish a tolerance, EPA must determine that the levels of the chemical proposed in the tolerance are “safe.”

The EPA’s EtO and ECH tolerances are essential to support global trade as the majority of spices are imported from foreign countries where the treatment of spices with EtO is permitted. In 2022, the U.S. imported approximately 12 times the weight of spices as it exported (497,209 tons imported versus 40,846 tons exported) (ITC, 2023). In the appended document, ASTA has compiled permissible global maximum residue limits (MRLs) for EtO in spices, herbs, and dried vegetables (Appendix 1). Many countries, including critical source countries for spices, permit residues of EtO in these agricultural products.

As referenced, the revocation of tolerances for EtO and ECH residues on spices and dried vegetables will create massive supply chain and compliance challenges for the entirety of the food industry. Moreover, it may result in an increase in food safety incidences related to microbiological contamination of spices, as evidenced by trends observed in the European Union. EtO is not permitted for use as a pesticide in the EU under Regulation (EC) 1107/2009, however MRLs are established that permit low levels of residues of EtO on imported commodities per Regulation (EU) 2015/868. In 2020, a large number of imported sesame seed and other spice shipments with EtO residues above the established MRLs were detained upon entry. In 2020, almost 300 RASFF notifications were issued for EtO residues in sesame seeds. Following this crackdown, importers made an effort to ensure that EtO residues on spices did not exceed the MRLs, and the EU subsequently reported that pathogen contamination in spices nearly doubled from 8.7% to 16%. It is notable that this is substantially higher than current reported instances of pathogen contamination in the U.S., which dropped from 3.5% to 1.5% in the same timeframe. Table 1 summarizes the comparative pathogen contamination as listed in HorizonScan between the two regions.

**Table 1.** Food Safety Alert Trends (2020-2022).

Year	Total Food Safety Alerts	EU Food Safety Alerts	% of Total	US Food Safety Alerts	% of Total
2020	115	10	8.7%	4	3.5%
2021	298	29	9.7%	5	1.7%
2022	131	21	16.0%	2	1.5%

Notable detentions of spice products due to pathogen contamination in the EU include the presence of *Salmonella* spp. in ground ginger, *Bacillus cereus* in paprika powder, *Salmonella* spp. in cumin powder, and *Clostridium perfringens* in ground cinnamon (RASFF 2017, 2020, 2021, 2022).

*Spices may contain low levels of EtO due to the chemical's natural occurrence and cross-contact with EtO-treated materials.*

EtO is naturally occurring, meaning that residues may be found in/on spices that have not been treated with EtO for sterilization purposes. For example, EtO has been reported to be found by certain plants when ethylene, a natural plant growth regulator, is metabolized to EtO (Abeles and Dunn, 1985; Jerie and Hall, 1978; Dodds et al, 1979). Other studies have shown that it is produced through ethylene catabolism in certain microorganisms (De Bont and Albers, 1976). Additionally, spices may come into contact with materials treated with EtO, resulting in low concentrations of EtO or ECH residues.

Resultingly, spices and herbs may contain low levels of EtO or ECH even if they have not undergone fumigation with the gas. If the tolerances for EtO and ECH are revoked, these commodities may be unjustly identified as non-compliant. This is particularly notable given that if the tolerances are revoked, the tolerance will be interpreted as zero, creating an unachievable standard for the industry.

**2. The spice industry has not had sufficient time to identify and evaluate the viability of alternative treatment methods for all spice products within the “dried herbs, dried spices, vegetables, and seasoning materials” categories.**

The spice industry requested an additional 90 days to develop comments, but only a very short extension of 15 days was granted. As noted in our response to EPA’s extension, the time provided was insufficient, and industry requires more time to further evaluate the broad sweeping implications of the potential phased cancellation of uses in this category. We stand ready to work with EPA on following the comment period on this issue considering that insufficient time was provided.

- 3. As a starting point, the industry has identified the following commodities for which the use of EtO remains critical for food safety and for which it will take industry many years to complete testing for validations as well as identify the quality implications and commercial viability for alternatives.**

*The sterilization of spices and dried herbs is required by U.S. regulations to reduce microbiological hazards that may pose a public health concern. The availability of EtO is critical to overall treatment capacity in the U.S.*

Many spices are grown in tropical climates where they are subjected to excess heat, humidity, and minimal good agricultural practices. These conditions may lead to contamination by microorganisms and their subsequent growth. Therefore, raw unprocessed spices commonly harbor large numbers of bacteria and fungi, including organisms that cause spoilage and food borne pathogens such as *Salmonella*, *E-coli*, *C. perfringens*, and *B. cereus*. Fortunately, the total number of outbreaks attributed to contaminated spices in the last 30 years is low. However, EPA notes in its Use, Usage, Benefits, and Impacts of Cancellation document that there have been 60 recalls of herbs and spices due to contamination with pathogenic bacteria (*Salmonella* or *Listeria monocytogenes*) over the last five years (2016-2022) (EPA, 2022). EPA also states:

“...spices were imported from 79 countries and *Salmonella*-contaminated shipments arrived from 37 countries (FDA, 2017a). Previously, the FDA found that from 2007 to 2009, spices imported into the U.S. had a prevalence of *Salmonella* that was 4.4 times greater than any other FDA-regulated food import (FDA, 2017a), and the Agency anticipates a similar prevalence in current imports.”

Due to the prevalence of pathogenic bacteria in spices, FDA has identified contamination with pathogenic bacteria as a risk that may require preventive control in its guidance document: Hazard and Risk-Based Preventive Controls for Human Food - Appendix 1: Potential Hazards for Foods and Processes.

As such, under the FD&C Act 21 U.S.C. 301 et seq, all food companies are required to develop a food safety plan that identifies microbiological hazards, including pathogens, and create a treatment plan to address these hazards. The treatment plan must also be validated to assure that it is successful. Spice companies must comply with the Preventive Controls for Human Food rule under FSMA regulations, 21 C.F.R. Part 117, which requires the control of all food safety hazards. Any processes to control hazards such as *Salmonella*, including alternative treatment methods, must be validated to ensure that they are effective and are capable of delivering a 5-log reduction of *Salmonella*.

EtO is one of the technologies that has been validated in spices to meet these requirements. EtO is leveraged by the spice industry during the processing and reconditioning of dried herbs and spices to control pathogens and reduce microbial activity. Beyond *Salmonella*, EtO treatment has been shown to be effective against other microorganisms such as *Bacillus cereus* and *Clostridium perfringens*, which may be pathogenic above certain concentrations and contribute to spoilage, as well as yeasts and molds. Additionally, EtO may be used to fumigate spices in their final packaging material, reducing the possibility of post-process contamination.

### *Overview of Alternative Treatment Methods.*

EtO fumigation is one of three conventional treatment technologies available to the spice industry, as summarized by FDA's 2017 Risk Profile: Pathogen and Filth in Spices (FDA, 2017a). Conventional alternatives to EtO include steam, irradiation, and fumigation with PPO. However, these alternative methods have varying impacts on product quality (e.g., aromatics, color, flavor, texture), applicability, and degrees of consumer acceptance.

**Steam.** Steam treatment is a well-characterized treatment technology that has been reviewed extensively in the literature and by FDA (FDA, 2017a). Traditional steam treatments expose spice particles to steam consisting of vaporized steam and saturated steam at a pressure. Although steam treatments can effectively reduce microbial populations in some spices and dried herbs, the technology has been reported to negatively impact the quality parameters of a spice, including mouthfeel, color, texture, or aromatics.

In its review of the scientific literature, FDA found that the reductions in total aerobic plate count ranged from 1.3 log for a 16-minute continuous process at 100°C at atmospheric pressure to 7.9 log for an autoclave process in saturated steam at 121°C for 15 minutes when spices were treated with steam (FDA, 2017a). In a study on steam treatment of dried whole red peppers, bacterial loads were reported to decrease by less than 2 logs, with significant impacts to the physiochemical properties of the commodity (Rico et al., 2010). Another study with black pepper yielded similar results (Waje et al., 2008). APC, coliform, and yeast/mold counts were reduced by 2.6 log, 4.2 log, and 2.3 log respectively, with significant impact to quality parameters (color and flavor). However, FDA notes that there is very little scientific literature available on the reduction of *Salmonella* specifically in spices by steam sterilization (FDA, 2017a). As such, the companies themselves must conduct time-intensive and costly studies to comply with FDA's preventative controls requirements demonstrating the effectiveness of the process on all of the spices that are treated.

The varying effectiveness of the treatment is the result of many factors, including that microorganisms have varying levels of thermal resistances, as well as factors such as environmental influences during cells growth and environmental influences during the heating cycle (FDA, 2017a). Furthermore, the efficacy of steam treatment is highly dependent on the density of the commodity being treated. Steam treatment is not suitable for low-density products such as herbs, or spice products with a high density, such as ground spices. Additionally, steam treatment may cause clumping, which impacts the marketability of the commodity.

Moreover, steam treatment can be incompatible with packaging materials used for spices and dried herbs. These materials may be damaged after exposure to steam, which impacts the integrity of the product and renders it vulnerable to post-process contamination. As such, spices must be packaged after treatment, which creates a risk for post-process contamination.

**Irradiation:** Non-thermal treatments, such as irradiation, are also conventionally used to decontaminate spices and dried vegetables. Irradiation treatment may use Cobalt-60 or cesium-137 as a source of gamma rays for application to pre-packaged foods to achieve microbial lethality.



According to section 201(s) of the FD&C Act, sources of irradiation used on food are contained under the definition of food additives. Per 21 CFR 179.26, “dry or dehydrated aromatic vegetable substances when used as ingredients in small amounts solely for flavoring or aroma: culinary herbs, seeds, spices, vegetable seasonings that are used to impart flavor but that are not either represented as, or appear to be, a vegetable” may be irradiated with a maximum absorbed dose of 30 kGy. These ingredients are subsequently required to be labeled with the phrase “treated with radiation” or “treated by irradiation.”

Studies on the efficacy of gamma radiation are summarized in FDA’s 2017 Risk Profile on Pathogens and Filth in Spices. The studies suggest that gamma radiation is an efficient method of pathogen elimination while resulting in few changes in physiochemical quality parameters of spices. ASTA has prepared a literature review on inactivation of microorganisms in spices by ionizing radiation that is available on the association’s website (ASTA, 2021). Although irradiation treatment is highly effective at sterilizing spices and dried herbs, the technology is not compatible with certain food packaging materials, including polypropylene bags or plastic bags. Additionally, the size and configuration of the packaging that can be used in the treatment chamber is extremely limited as to ensure effective penetration depth of the radiation into the product.

Furthermore, there are limitations on the ability to expand irradiation treatment beyond its current capacity for spices and dried herbs as only a very limited number of facilities irradiate spices, and many of these facilities also treat medical equipment. During the height of the COVID-19 pandemic, when most irradiation capacity needed to be diverted to treatment of medical supplies, spice companies needed to find alternative methods. While some suppliers offering irradiation services are now reporting that some of the capacity that had been diverted during the height of the pandemic is opening up, the locations of these facilities may not be logistically practical for many spice companies.

Moreover, there is a lack of consumer acceptance for irradiated food products due to fears of food being rendered radioactive (Eustice and Bruhn, 2012; Duncan et al., 2017; Castell-Perez and Moreira, 2021). Additionally, there have been calls for the Cobalt-60 radioisotope to be phased out (Comben, 2021; Zimmerman, 2020; Chou et al., 2018; Lieberman et al., 2020) by consumer groups and regulatory authorities, which would further exacerbate capacity challenges.

**Propylene oxide (PPO):** To a lesser extent, PPO is used as a fumigant and sterilant in/on spices and dried herbs. It is used to control bacteria, fungi, and mold. At this time, PPO does not presently have widespread applicability due to numerous limitations of this technology. However, EPA could easily alleviate several of these key limitations that would allow this chemical to be a more viable alternative for EtO.

For example, the current PPO label limits the application of the gas to only Crop Group 19 materials, which excludes several key spices for which EtO currently serves as an important treatment. Excluded commodities under the current label include ginger, turmeric, and red pepper, which is the most commercially traded spice worldwide.

However, this was not always the case. Prior to 2006, the PPO label authorized application of the gas to spices and seasonings more broadly. Then, following EPA’s reregistration review of 2005, the label was changed to cover Crop Group 19 commodities in an effort to provide more specificity. However, due to a lack of alignment between Crop Group 19, FDA’s definition of spices, and ASTA’s definition of spices, key

commodities were excluded, including dried vegetables. In response, Keller and Heckman LLP submitted a public comment stating that “vegetables, dried” be added to the tolerance expression in addition to “herbs and spices, group 19, dried.” In EPA’s response, labeled “HED Response to Public Comments on the Propylene Oxide (PPO) Reregistration Eligibility Decision (RED) PC Code 042501; DP Barcode D334250”, EPA states that “HED agrees with this comment and will revise the proposed tolerance expression accordingly” (EPA, 2006).

Despite EPA’s indication that the label would be amended to include dried vegetables, subsequently aligning the label with FDA’s and ASTA’s definition of spices, this action was never executed. Resultingly, the industry lost its ability to treat these key commodities with the chemical despite the fact it was never the agency’s intention to formally revoke these applications.

Moreover, PPO is not as effective as EtO. The fumigation process takes more time than EtO and requires a higher volume of gas to be applied to the commodity being treated. ASTA members have reported that efficacy of the gas could be increased if the permissible temperature on the label were raised by 25°C from 125°C to 150°C.

ASTA urges EPA to correct the administrative mistake that excluded key spices from the tolerance definition during the reregistration process in 2006, and expand the chemical’s registration to cover all spices, including those beyond Crop Group 19, so that PPO may have more applicability as a replacement for EtO and to establish a higher temperature allowance during treatment.

However, it is important to recognize that requiring the industry to undergo a fulsome petition process to correct this previous administrative mistake that excluded these spices should not be necessary and could take several years, which further limits the ability of the industry to meaningfully transition treatment away from EtO. It would be extremely burdensome to require the industry to undergo a new registration petition for PPO at the same time that a significant financial burden has been placed on the spice sector to transition away from EtO. To support the goal of reducing the reliance on EtO, EPA should be promoting alternative tools that are effective and safe. One easy way that EPA can do this is through assisting the industry in reducing the regulatory burden of this process to re-expand the authorization to the spices that were inadvertently excluded in the 2006 reregistration review process.

Although PPO is considered the closest alternative to EtO treatment, widespread use of PPO would require additional FDA validation testing to determine if the use of the gas consistently results in a 5-log reduction of pathogens to ensure food safety. At this time, PPO does not have the same widespread acceptance for the purpose of reconditioning spices. Spice shipments may be refused for import on the basis of microbial hazards, requiring a reconditioning treatment to be accepted for entry. Of the 50 reconditioning proposals for spices accepted by FDA’s Center of Food Safety and Applied Nutrition (CFSAN) between January 2007 and December 2012, irradiation and EtO fumigation were the most common type of reconditioning treatment (23/50 irradiation, 8/50 EtO) (FDA, 2017a). Several reconditioning proposals with PPO were also approved, and ASTA members have attempted to leverage PPO as a reconditioning treatment over the past decade in place of these technologies.

However, ASTA members anecdotally report that reconditioning proposals with PPO that have been submitted to FDA Center for Food Safety and Applied Nutrition (CFSAN) have been subject to increased scrutiny and delays for approval. Members indicate that despite providing full validation reports relevant

to the treatment of the refused commodity, CFSAN officers have questioned the use of surrogates, operation parameters, and validation tools. Although some of the questions raised by CFSAN offices are relevant, others demonstrate that the reconditioning proposals and provided documents have not been reviewed. After undergoing several rounds of questioning, ASTA members report submitting EtO reconditioning proposals instead in order to release the held commodity without further delays.

**Emerging Treatment Methods.** A number of other treatment options have been identified, including ultrasonication, pulsed energies, ohmic heating, microwave radiation, radiofrequency heating, infrared radiation, and non-thermal technologies. However, these technologies are currently not widely used due to commercial limitations, a lack of widespread applicability, and/or a lack of evidence of efficacy. As such, many years of research, as well as quality and validation testing would be required to determine efficacy and commercial viability before they could be implemented widely.

*Spices and herbs for which EtO use remains critical for food safety.*

The following list is comprised of spices and herbs for which EtO use remains critical to food safety and for which there are not viable alternatives. Importantly, the following list also contains several commodities that are not in Crop Group 19, but rather that are considered by EPA to be “dried vegetables,” including onion, garlic, turmeric, ginger, pepper, and capsicums spp. ASTA considers these commodities to be spices and has previously asked EPA to include them in the expanded crop group for spices due to their commercial relevance in the spice industry. EtO remains critical for the safety of these commodities, and they must be included in any updates EPA makes to the EtO label and/or tolerance definition. These commodities are currently covered under the “vegetable, dried” tolerance.

Additionally, ASTA’s list includes “sesame, seed” which is an oilseed that is commonly used in spice and seasoning blends and is covered by its own current tolerance. Likewise, ASTA’s list includes peppermint and spearmint, which are currently covered by their own tolerances, but are considered to be spices by the industry.

A number of other dehydrated vegetables are commonly used for seasoning purposes by the spice industry. Examples include pumpkin flakes, diced tomato, dried bell peppers, etc. While these commodities are not considered to be spices and therefore not represented on the list below, they are also critical for the spice and seasoning industries and are often handled within the same facilities as other spices and herbs.

**Table 2.** List of spices, herbs, and dried vegetables for which EtO use remains critical for food safety and no viable alternatives exist.

Allspice ( <i>Pimenta dioica</i> )	Hyssop ( <i>Hyssopus officinalis</i> )
Anise (anise seed) ( <i>Pimpinella anisum</i> )	Juniper berry ( <i>Juniperus communis</i> )
Anise, star ( <i>Illicium verum</i> )	Lavender ( <i>Lavandula officinalis</i> )
Annatto (seed)	Lemongrass ( <i>Cymbopogon citratus</i> )
Balm (lemon balm) ( <i>Melissa officinalis</i> )	Mace ( <i>Myristica fragrans</i> )
Camomile ( <i>Anthemis nobilis</i> )	Marjoram ( <i>Origanum spp.</i> ) (includes sweet or annual marjoram, wild marjoram or oregano, and pot marjoram)
Caper buds ( <i>Capparis spinosa</i> )	Mustard (seed) ( <i>Brassica juncea</i> , <i>B. hirta</i> , <i>B. nigra</i> )
Caraway ( <i>Carum carvi</i> )	Nutmeg ( <i>Myristica fragrans</i> )
Caraway, black ( <i>Nigella sativa</i> )	Onion ( <i>Allium cepa</i> L. var. <i>cepa</i> )
Cardamom ( <i>Elettaria cardamomum</i> )	Oregano, Mediterranean ( <i>Origanum vulgare</i> )
Cassia bark ( <i>Cinnamomum burmannii</i> )	Oregano, Mexican ( <i>Lippia graveolens</i> )
Cassia buds ( <i>Cinnamomum aromaticum</i> )	Parsley (dried) ( <i>Petroselinum crispum</i> )
Celery seed ( <i>Apicum graveolens</i> )	Pepper ( <i>Capsicum spp.</i> )
Chervil (dried) ( <i>Anthriscus cerefolium</i> )	Pepper, black ( <i>Piper nigrum</i> )
Chive ( <i>Allium schoenoprasum</i> )	Pepper, green ( <i>Piper nigrum</i> )
Chive, Chinese ( <i>Allium tuberosum</i> )	Pepper, pink ( <i>Schinus terebinthifolius</i> )
Cinnamon ( <i>Cinnamomum verum</i> )	Pepper, white ( <i>Piper nigrum</i> )
Clary ( <i>Salvia sclarea</i> )	Peppermint ( <i>Mentha piperita</i> )
Clove buds ( <i>Eugenia caryophyllata</i> )	Poppy (seed) ( <i>Papaver somniferum</i> )
Coriander (cilantro or Chinese parsley) (leaf) ( <i>Coriandrum sativum</i> )	Rosemary ( <i>Rosemarinus officinalis</i> )
Coriander (cilantro) (seed) ( <i>Coriandrum sativum</i> )	Saffron ( <i>Crocus sativus</i> )
Cumin ( <i>Cuminum cyminum</i> )	Sage ( <i>Salvia officinalis</i> )
Dill (seed) ( <i>Anethum graveolens</i> )	Sassafras
Dill (dillweed) ( <i>Anethum graveolens</i> )	Savory, summer and winter ( <i>Satureja spp.</i> )
Fennel (common) ( <i>Foeniculum vulgare</i> )	Sesame ( <i>Sesamum indicum</i> L., <i>S. radiatum</i> Schumach. & honn)
Fennel, Florence (seed) ( <i>Foeniculum vulgare</i> Azoricum Group)	Spearmint ( <i>Mentha spicata</i> )
Fenugreek ( <i>Trigonella foenumgraecum</i> )	Sweet bay (bay leaf) ( <i>Laurus nobilis</i> )
Galangal ( <i>Alpinia officinarum</i> Hance)	Tarragon ( <i>Artemisia dracunculus</i> )
Garlic ( <i>Alium sativum</i> )	Thyme ( <i>Thymus spp.</i> )
Grains of paradise ( <i>Aframomum melegueta</i> )	Turmeric ( <i>Curcuma longa</i> )
Ginger ( <i>Zingiber officinale</i> )	Vanilla ( <i>Vanilla planifolia</i> )
Horehound ( <i>Marrubium vulgare</i> )	

Summarized below are considerations relevant to available treatment methods for each of the spices and dried herbs for which ASTA has identified that the continued use of EtO is critical for food safety.

<p>Allspice</p>	<p>Allspice is the berry of a tree that is native to the Caribbean. The unique flavor is often described as a blend of cloves, juniper, pepper, and cinnamon. It is usually used in a ground form in such blends as pumpkin pie spice, apple pie spice, seafood seasoning and curry powder, and is present in many formulations for sausage and pickled meats and fish products. It is also often used in sweet goods baking, puddings and fruit preparations. The essential oil content of allspice is critical to the flavor and commercial viability of this spice.</p> <p>Allspice has been associated with pathogens, including <i>Salmonella</i> and <i>Bacillus</i> (FDA, 2017a), and has caused recent recalls for <i>Salmonella</i> (FSAI,2022). Allspice is known to have antimicrobial properties, however, this is insufficient to prevent the risk of pathogens.</p> <p>According to FDA’s 2017 Risk Profile for Spices: “The relatively large Salmonella prevalence found by FDA for shipments of oregano and ...allspice offered for import to the United States during FY2007-FY2009 demonstrates that the antimicrobial activity against Salmonella is not sufficient to eliminate Salmonella contamination from shipments of these types of spices.”</p> <p>In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p>
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	<p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Annatto (seed)	<p>Annatto is the seed of a tree native to South and Central America with a sweet, spicy, and earthy flavor. It is used in both its whole and ground form in a variety of culinary applications, including as a natural food colorant and to flavor cheese, butter custards, cakes, and baked goods.</p> <p>According to FDA’s 2017 Risk Profile for Spices, <i>Salmonella</i> species have been detected in annatto seed in the U.S. (FDA, 2017a). In 2014, a recall was initiated for ground annatto due to possible contamination with <i>Salmonella</i> (Food Safety News, 2014).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>

Anise (seed)	<p>Anise is the seed of an annual herb of the parsley family with a sweet and spicy licorice flavor. It is used in both the whole and ground form in a variety of applications in sweet and savory products, including pastries, candies, meat dishes, vegetables, and also to flavor teas and alcoholic beverages.</p> <p>A microbiological link between anise seed and <i>Salmonella</i> illness has been established (FDA, 2017a). <i>Salmonella</i> has been implicated in illnesses in infants (&lt;13 mo) following consumption of baby tea containing anise seed (Koch et al., 2005; Rabsch et al., 2005; Ilic et al., 2010). Additionally, anise seed is associated with other pathogens, including <i>Clostridium perfringens</i> and <i>Cronobacter</i>.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Anise, star	<p>Star anise is a star-shaped fruit of an evergreen shrub that is native to Asia. Although unrelated to anise seed, these spices contain the same flavoring compound, and are used in similar applications. Star anise is used in both the whole and ground form. Ground star anise has been implicated in a number of recalls for <i>Salmonella</i> (NBC, 2009; Whole Foods Magazine, 2016).</p>

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Balm (lemon balm)	<p>Lemon balm is an herb in the mint family with a lemon-like flavor. It is used in herbal teas and culinary applications. There is limited evidence on the food safety treatments available for this herb in the scientific literature.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. Commodities in the mint family are leafy green herbs. Steam is particularly damaging to herbs due to their delicate nature. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60</p>



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Camomile	<p>Chamomile is a dried flower used predominantly in herbal tea products. Studies have confirmed that <i>Salmonella</i> can survive on chamomile in brewed tea, following the brewing process, indicating a thermal resistance of the pathogen in this herb (Keller et al., 2015). There was also a melioidiosis outbreak associated with an aromatherapy spray containing chamomile oil (CDC, 2021).</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p>

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Caper buds	<p>Capers are unripened buds from a bush native to the Mediterranean. They have a lemony/briny flavor and are used as a garnish/condiment and in dressings and sauces.</p> <p>There is limited literature on microbiological pathogens associated with capers. However under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>Given the lack of scientific literature on effective treatment methods for this commodity, EtO is needed until additional research can be conducted.</p>

Caraway	<p>Caraway seed is the fruit of an herb that grows in both Northern temperate and tropical climates. The seeds taste simultaneously warm, sweet, biting and acrid, and are a classic ingredient of rye breads. They are also used to flavor cakes, cookies, biscuits, cheese, and applesauce. The flavor and quality are dependent on the volatile oil content. The seeds may be used in either the whole or ground form.</p> <p>A microbiological link between caraway seed and <i>Salmonella</i> illness has been established (FDA, 2017a). <i>Clostridium botulinum</i> and <i>C. perfringens</i> have also been detected in caraway seeds.</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Caraway, black	<p>Black caraway (also known as black cumin) is the seed of a flowering plant native to Eastern Europe. The seeds have a distinct smokey, pungent flavor often described as herby/oniony and can be used in a variety of culinary applications including breads, rice dishes, and to season vegetables and meats.</p>

	<p>There is limited literature on microbiological pathogens associated with black caraway. However, under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>Given the lack of scientific literature on effective treatment methods for this commodity, EtO is needed until additional research can be conducted.</p>
Cardamom	<p>Cardamom comes from a seed pod that grows on a shade plant. It has a unique sweet flavor and is predominantly used in tea and baking applications. It is often used in the ground form.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Salmonella</i>, <i>Staphylococcus aureus</i>, and <i>Bacillus spp</i>, have been detected in cardamom. (FDA, 2017a). Cardamom has also been the subject of recalls due to possible <i>Salmonella</i> contamination (FDA, 2018).</p>

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Cassia bark	<p>The term cassia is used to distinguish between the three Southeast Asian types of cinnamon and the Ceylon type of cinnamon. Cinnamon/cassia is the dried bark of trees in the evergreen family of the genus <i>Cinnamomum</i>. Cassia is native to China, Indonesia and Vietnam, which produce what most Americans recognize as cinnamon: a reddish brown powder with a strong sweet and pungent aroma and flavor. It is often used in a ground form in baking applications and is also used in a variety of other applications.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Salmonella</i>, <i>Staphylococcus aureus</i>, <i>Clostridium perfringens</i> and <i>Bacillus</i> spp., have been detected in cinnamon (FDA, 2017a). Cinnamon has also been the subject of recalls due to possible <i>Salmonella</i> contamination, as well as a recent outbreak due to <i>Clostridium perfringens</i> in Spain (Food Safety News, 2023a).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high</p>

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Cassia buds	<p>Cassia buds are the dried unopened flower of the cinnamon tree. It has a floral cinnamon-like flavor and is used in pickling and marinades. Cassia buds may be used in a whole or ground format.</p> <p>Like cassia bark, cassia buds have potential to be contaminated with microbiological hazards. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p>

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Celery seed	<p>Celery seeds are the dried fruit of a biennial herb. The seeds are light brown to brown-colored and have a characteristic celery aroma and a warm, bitter taste. The quality characteristics are measured by its volatile oil, non-volatile ether extract, total and acid insoluble ash. Celery seeds are used in the whole or ground form in a variety of savory dishes and beverages.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Salmonella</i> and <i>Bacillus</i> spp. have been detected in celery seeds (FDA, 2017a). Furthermore, celery seeds have been recalled due to <i>Salmonella</i> contamination (Reuters, 2011).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p>

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Chervil	<p>Chervil is an herb in the parsley family. It is similar in appearance to parsley, but sweeter and more aromatic. It has an anise-like fragrance with a slight hint of pepper flavor. Chervil is often used in herb blends and often used on egg/poultry dishes.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Bacillus</i> spp. have been detected in chervil (FDA, 2017a).</p> <p><b>Steam:</b> Steam treatment is not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p>



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Chive	<p>Chives are a flowering herb that produces edible leaves and flowers with a garlicky/oniony flavor, Chives are a commonly used as an ingredient for egg and poultry dishes, potatoes, soups, and many other dishes. The edible flowers can be used in salads.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Bacillus</i> spp. and <i>Clostridium perfringens</i> have been detected in chives (FDA, 2017a). Furthermore, chives have been recalled due to contamination with <i>Listeria monocytogenes</i> (CBS, 2011).</p> <p><b>Steam:</b> Steam treatment is not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature.</p> <p>Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>

Chive, Chinese	<p>Chinese chives, also known as garlic chives, are related to regular chives, but are flatter and wider, with a more garlicky flavor. Since they are less common, limited research has been conducted on Chinese chives. However, they are used in a similar fashion as regular chives and would be assumed to have a similar food safety risk profile.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the lack of evidence on viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Cinnamon	<p>Cinnamon is the dried bark derived from several varieties of <i>Cinnamomum</i> trees. It is brown to reddish-brown in color. The principal active ingredient in the volatile oil is cinnamaldehyde, which is responsible for the characteristic odor. The quality attributes are measured by volatile oil, aldehyde content of the volatile oil, non-volatile ether extract, total and acid insoluble ash, and moisture.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Salmonella</i>, <i>Staphylococcus aureus</i>, <i>Clostridium perfringens</i> and <i>Bacillus</i> spp., have been detected in cinnamon (FDA, 2017a). Cinnamon has also been the subject of recalls due to possible</p>

	<p><i>Salmonella</i> contamination, as well as a recent outbreak due to <i>Clostridium perfringens</i> in Spain (Food Safety News, 2023a).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Clary	<p>Clary is an aromatic herbaceous plant of the mint family, which is used as a culinary and medicinal herb. It has a mild sweet floral flavor and is related to culinary sage and used in a similar way in foods. It is used as an ingredient in certain alcoholic beverages.</p> <p>Due to the less common nature of this herb, there is limited literature on microbiological pathogens associated with it. However, under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p>

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Clove buds	<p>Cloves are dried unopened flowers from an Evergreen tree. They are dark reddish-brown in color, have a strong aromatic odor, and a hot pungent, aromatic taste. They are used in their whole and ground form in countless spicing and seasoning combinations for sweet baked goods, sausages, luncheon meats and spreads, soups, salad dressings, relishes and casserole-type preparations, from baked beans to pot roast. In addition, substantial quantities of clove oil are used in consumer products, such as perfumes, cosmetics, medicines, mouthwashes and toothpastes.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Bacillus</i> spp. have been detected in cloves (FDA, 2017a). Additionally, cloves have been recalled due to the potential presence of <i>Salmonella</i> (FDA, 2020).</p> <p>The principal active ingredient in the volatile oil is eugenol. This compound has antimicrobial properties; however this is not sufficient to eliminate the risk of pathogenic bacteria. Further, this property complicates conducting validation studies of microbial treatment methods on the product.</p>

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Coriander	<p>Coriander is an annual herb of the parsley family and is related to other herbs such as anise, caraway, cumin and fennel. Coriander leaves are often called cilantro. The leaves are finely divided and flat with a unique bright pungent flavor. Cilantro is often used in Mexican and other Latin American dishes and in Chinese cookery, and it is also frequently found in recipes from the Middle East, India, and Southeast Asia (Indonesia, Thailand and Vietnam). On the spice shelf, coriander appears in either dried or freeze-dried form.</p> <p>FDA published findings on the prevalence of <i>Salmonella</i> in imported ground coriander its Risk Profile: Pathogens and Filth in Spices (FDA, 2017a). The findings demonstrated that the prevalence of Salmonella in this study was 18%. In addition, FDA summarized data from scientific literature that showed that <i>Salmonella</i>, <i>Bacillus spp.</i>, and <i>Clostridium perfringens</i> have been found on coriander. Furthermore, there have been recalls of coriander due to the risk of <i>Salmonella</i> contamination.</p>

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Coriander seed	<p>Coriander seed is the fruit of the coriander plant. Whole or ground coriander seed is used in a variety of spice blends for curries, stews, soups, and stir fries. It has a flavor that seems to be a blend of lemon and sage, with a sweet note as well.</p> <p>As stated above, coriander is associated with a variety of food safety risks, including <i>Salmonella</i>, <i>Bacillus</i> spp., and <i>Clostridium perfringens</i>.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p>

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Cumin	<p>Cumin seed is the dried fruit of an herbaceous annual of the parsley family. The yellowish-brown seeds have a strong, distinctive aromatic odor and a warm, aromatic taste. Cumin is the essential flavoring and aromatic factor in chili powder and an important ingredient in curry powder. It is used in a wide variety of savory applications in both the ground and whole form, including curries, barbeque sauces, rice dishes, stews/soups, meat dishes, and more.</p> <p>FDA published findings on the prevalence of <i>Salmonella</i> in imported ground cumin in its Risk Profile: Pathogens and Filth in Spices (FDA, 2017a). The findings demonstrated that the prevalence of <i>Salmonella</i> in this study was 8.5%. In addition, FDA summarized data from scientific literature that showed that <i>Salmonella</i>, <i>Bacillus</i> spp, and <i>Clostridium perfringens</i> have been found on cumin. Furthermore, there have been recalls of cumin due to the risk of <i>Salmonella</i> contamination.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination. Research has shown quality degradation, particularly of the color of cumin treated with steam (Duncan et al., 2017).</p>

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Dill (seed)	<p>Dill is an annual herb of the parsley family. Dill seed is the dried, ripe fruit of the herb. The pickle industry is the largest user of dill. Whole and ground dill seed are used commercially in a wide variety of products, including sausages, baked goods, condiments, cheese, curry powder and dry mixes for sauces and dressings.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Salmonella</i> has been reported on dill seed (FDA, 2017a).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p>



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Dillweed	<p>Dill is an annual herb of the parsley family. The pickle industry is the largest user of dill. Dill weed is used in salads, sauces, breads, egg and seafood dishes.</p> <p>According to the FDA Draft Risk Profile for Spices, <i>Bacillus</i> spp. have been detected in dill (FDA, 2017a). Furthermore, dill has been recalled due to contamination with <i>Listeria monocytogenes</i> (Food Safety News, 2022a).</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p>

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Fennel	<p>Fennel is a large, aromatic herb indigenous to the Mediterranean. It has a mild, sweet flavor with hints of licorice. Fennel is used in salads, sauces, marinades, and soups.</p> <p>There is limited literature on microbiological pathogens associated with this herb. However, under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Fennel, Florence	<p>Fennel seeds are the dried fruit of the fennel plant, a vegetable that is related to parsley. Fennel is used in the whole, cracked and ground forms and has a pleasant,</p>

	<p>sweet anise-like flavor. In the U.S., it is predominantly used to flavor meats, such as sausages and pepperoni.</p> <p>A microbiological link between fennel seed and <i>Salmonella</i> illness has been established (FDA, 2017a). <i>Salmonella</i> has been implicated in illnesses in infants (&lt;13 mo) following consumption of baby tea containing fennel seed (Koch et al., 2005; Rabsch et al., 2005; Ilic et al., 2010). Fennel seeds have been recalled due to <i>Salmonella</i> (Food Safety News, 2019). Additionally, fennel seed is associated with other pathogens, including <i>Bacillus spp.</i></p> <p>Florence fennel is one variety of fennel used in a similar way as common fennel, described above.</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Fenugreek	Fenugreek is an herb similar to clover. Both the dried leaves and seeds are used in culinary applications and have a similar, although distinct flavor and can be used in

	<p>curries, vegetables, sauces, and soups. The leaves have a pleasant, sweet flavor and the seeds are more bitter.</p> <p>Fenugreek is associated with a number of pathogens. The FDA Risk Profile: Pathogens and Filth reported that <i>Salmonella</i>, <i>Bacillus</i> spp. and <i>Clostridium perfringens</i> have been found on fenugreek (FDA, 2017a). Moreover, a large-scale outbreak of Shiga-toxin producing <i>Escherichia coli</i> serotype O104:H4 in Germany and France was traced to contaminated fenugreek seeds (EFSA, 2011c).</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Fenugreek seeds are often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Galangal	<p>Galangal is an aromatic rhizome/root plant commonly used in Southeast Asian cuisine. It is used in the dried and powdered form and has a piney flavor.</p> <p>There is limited literature on microbiological pathogens associated with this spice. However, under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered</p>

	<p>for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination. Steam is not compatible with the dense nature of galangal powder.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is not currently permitted for use in this commodity. However, ASTA encourages EPA to assist the industry in reducing the regulatory burden to re-expand the authorization of this chemical.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>Given the lack of scientific literature on effective treatment methods for this commodity, EtO is needed until additional research can be conducted.</p>
Garlic	<p>Garlic powder is made from the dehydrated bulb from a plant in the <i>Allium</i> genus. It has a long history of use as a seasoning worldwide in a variety of culinary applications.</p> <p>FDA published findings on the prevalence of <i>Salmonella</i> in ground, dehydrated garlic in its Risk Profile: Pathogens and Filth in Spices (FDA, 2017a). The findings demonstrated that the prevalence of <i>Salmonella</i> in retail samples of ground, dehydrated garlic was 0.49% between 2013 and 2015. Meanwhile, the prevalence of <i>Salmonella</i> in shipments of ground, dehydrated garlic offered for entry to the U.S. was 1.7% between 2012 and 2015. In addition, FDA summarized data from scientific literature that show that <i>Salmonella</i>, <i>Bacillus</i> spp., <i>Clostridium perfringens</i>, and <i>Staphylococcus aureus</i> have been found in garlic.</p> <p>FDA has also summarized data which indicate that garlic exhibits antimicrobial properties. However, this is insufficient to prevent the risk of pathogens. In fact, this</p>

	<p>property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination. Steam is not compatible with the dense natural of garlic powder.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is not currently permitted for use in this commodity. However, ASTA encourages EPA to assist the industry in reducing the regulatory burden to re-expand the authorization of this chemical.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>Given the lack of scientific literature on effective treatment methods for this commodity, EtO is needed until additional research can be conducted.</p>
Grains of paradise	<p>Grains of paradise is an aromatic spice that is similar in appearance to peppercorns. Its flavor is characterized by notes of cardamom, pepper, and citrus. The spice is commonly paired with other spices such as allspice, cinnamon, and cloves in the preparation of spice cakes, soups, and braises.</p> <p>Although there is limited literature on microbiological pathogens associated with grains of paradise, FDA considers this commodity to be a spice. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this</p>

	<p>commodity, rendering it potentially unmarketable. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Due to the density and form of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>Given the lack of scientific literature on effective treatment methods for this commodity, EtO is needed until additional research can be conducted.</p>
Ginger	<p>Ginger powder is made from the dehydrated rhizome of a flowering plant. It has been used in herbal tonics and to impart flavor to food items such as vegetables, candy, soda, and alcoholic beverages.</p> <p>FDA has summarized data from scientific literature in its Risk Profile: Pathogens and Filth in Spice that show that <i>Salmonella</i>, <i>Bacillus</i> spp., <i>Clostridium perfringens</i>, and <i>Staphylococcus aureus</i> have been found in ginger (FDA, 2017a). Furthermore, ginger powder has been recalled due to contamination with <i>Salmonella</i> (Food Safety News, 2017).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged</p>

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Horehound	<p>Horehound is an herb native to Europe, northern Africa, and Asia. The herb is used in hard candies, teas, beer, and other alcoholic beverages. Its flavor has been described as similar to those of licorice and root beer.</p> <p>Although there is limited literature on microbiological pathogens associated with horehound, FDA considers this commodity to be a spice. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is not compatible with this commodity, as it is a leafy green herb in the mint family. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation</p>



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<p>Hyssop</p>	<p>Hyssop is an herb from a plant native to the Mediterranean region. It is characterized by its minty, floral, and bitter flavors. The herb is used in culinary applications in salads, pastas, teas, and soups.</p> <p>Although there is limited literature on microbiological pathogens associated with hyssop, FDA considers this commodity to be a spice. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is not compatible with this commodity, as it is a leafy green herb in the mint family. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the low density of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p>

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Juniper berries	<p>Juniper berries are seed cones typically used to flavor meat dishes and gin products. The berries have piney and citrus notes.</p> <p>In its scientific opinion on the risk posed by pathogens in berries (including juniper berry), the European Food Safety Authority’s (EFSA) Panel on Biological Hazards (BIOHAZ) described that although berries and their juices generally have a low pH and the potential to contain antimicrobial phenolic compounds, there is still risk for contamination and cross-contamination of berries with <i>Salmonella</i> via equipment, water, and processing (EFSA, 2014). Evidence shows that <i>Salmonella</i> persists on the surface of whole, cut, and frozen strawberries and raspberries. However, there is limited data on the persistence of pathogens on the surfaces of other species of berry, such as juniper berry. Furthermore, the panel notes that although treatment are available to reduce the surface contamination of <i>Salmonella</i> on berries, studies demonstrate that the extent of this reduction is highly dependent on berry size, the site of contamination on the berry, and that treatment may impact berry quality.</p> <p>Although there is limited literature on microbiological pathogens associated with juniper berry specifically, FDA considers this commodity to be a spice. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p>

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Lavender	<p>Lavender is a flower characterized by its unique, sweet fragrance with lemon and citrus notes. It is used as a culinary spice in pastas, salads and dressings, desserts, and teas. The essential oil content of lavender is critical to the flavor and commercial viability of this herb.</p> <p>Although there is limited literature on microbiological pathogens associated with lavender, FDA considers this commodity to be a spice. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p>Lavender essential oil has been reported to exhibit antimicrobial activity, including against <i>E. coli</i> (Predoi et al., 2018; Moon et al., 2006). However, this is insufficient to prevent the risk of pathogens, such as <i>Salmonella</i>. In fact, this property may make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is not compatible with this commodity, as it is a delicate herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p>

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Lemongrass	<p>Lemongrass is an herb derived from grass plants native to Southeast Asia that possess a distinct lemon scent with mint and ginger tones. The herb can be used in its whole or ground form to flavor soups, salads, curries, and roasted meats. The outer leaves can be used to flavor teas and alcoholic beverages.</p> <p>Lemongrass oil and its bioactive component citral have been shown to exhibit antimicrobial properties, including against pathogenic strains such as <i>E. coli</i>, <i>B. cereus</i>, and <i>Salmonella</i> (Vazirian et al., 2012). However, this property is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p>Although there is limited literature on microbiological pathogens associated with lemongrass, FDA considers this commodity to be a spice. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final</p>

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Mace	<p>Mace is a spice derived from the aril (coating) of the nutmeg seed. The spice is available in its ground and whole form. The spice can range in color from orange-red to orange-yellow depending on origin. The flavor of mace has been described as a combination of cinnamon and pepper, characterized by its woody notes with a pungent kick. The spice is used in savory dishes like soups, sauces, and poultry and fish recipes.</p> <p>The presence of pathogens, including <i>Salmonella</i>, <i>Bacillus</i>, and <i>Clostridium perfringens</i>, has been detected in mace samples between 1985-2012 (FDA, 2017a). Although mace is known to have antimicrobial properties, this is insufficient to prevent the risk of pathogens as evidenced by FDA’s review of pathogen detection in the spice. Furthermore, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged</p>

	<p>after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Marjoram	<p>Marjoram is an herb indigenous to the Mediterranean, Western Asia, and the Arabian Peninsula. The flavor of marjoram is often likened to that of oregano; however, it is sweeter and more delicate. It is used to season soups, salad dressing, sauces, and to flavor herbal teas. The volatile oil content of marjoram is critical to the flavor and commercial viability of this spice.</p> <p>Marjoram has been associated with pathogens, including <i>Bacillus</i> (FDA, 2017a). Marjoram is known to have antimicrobial properties, however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. One study reported a 49% loss of total volatiles in marjoram samples after treatment with steam sterilization technologies, as well as significant changes in aroma (Wojtowicz et al., 2007). Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p>

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Mustard (seed)	<p>Mustard seeds are derived from various mustard plants are used as a spice in either their whole or powdered form. The seeds vary in flavor depending on the species, but flavors range from mild and nutty to hot and bitter. Mustard seeds are used in a variety of culinary applications, including to flavor meat, sauces, or curies.</p> <p>The presence of pathogens, including <i>Salmonella</i>, <i>Bacillus</i>, and <i>Clostridium perfringens</i>, was detected in mustard seed samples between 1985-2012 (FDA, 2017a). Although mustard seed essential oil is known to have antimicrobial properties, particularly against certain strains of <i>E. coli</i> and <i>Salmonella</i> (Turgis et al., 2009), this is insufficient to prevent the risk of pathogens as evidenced by FDA’s review of pathogen detection in the spice. Furthermore, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial</p>

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Nutmeg	<p>Nutmeg is the inner brown kernel of the fruit of the nutmeg tree. The spice is characterized by its nutty, earthy, woody flavors and is used in both desserts and savory dishes alike. Nutmeg is available in both whole and powdered forms.</p> <p>The presence of pathogens, including <i>Salmonella</i>, <i>Bacillus</i>, and <i>Clostridium perfringens</i>, was detected in nutmeg samples between 1985-2012 (FDA, 2017a). Although nutmeg is known to have antimicrobial properties (Gupta &amp; Rajpurohit, 2011), this is insufficient to prevent the risk of pathogens as evidenced by FDA’s review of pathogen detection in the spice. Furthermore, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to</p>



	<p>expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices. (FDA, 2017a)</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Onion	<p>Powdered, dehydrated onion is often used like a spice for the purpose of seasoning.</p> <p>Onion has been associated with pathogens, including <i>Salmonella</i>, <i>Bacillus</i>, and <i>Clostridium perfringens</i> (FDA, 2017a). In 2023, 21 tons of onion powder were recalled in the U.S. due to possible <i>Salmonella</i> contamination (Food Safety News, 2023b). In 2009, onion powder was one of the nine seasoning ingredients recalled due to a <i>Salmonella</i> outbreak which affected 42 people around the world, 33 of which were in California (Schnirring, 2009).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is not currently permitted for use in this commodity. However, ASTA encourages EPA to assist the industry in reducing the regulatory burden to re-expand the authorization of this chemical.</p>

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Oregano, Mediterranean	<p>Oregano, Mediterranean is an herb indigenous to the Mediterranean and southwestern Eurasia. It is characterized by a woody, peppery flavor and is commonly used to season soups, pastas, salad dressing, and sauces. The volatile oil content of marjoram is critical to the flavor and commercial viability of this spice.</p> <p>Oregano has been associated with pathogens, including <i>Salmonella</i>, <i>Bacillus</i>, and <i>Clostridium perfringens</i> (FDA, 2017a). Oregano is known to have antimicrobial properties, however, this is insufficient to prevent the risk of pathogens. According to FDA’s 2017 Risk Profile for Spices: “The relatively large <i>Salmonella</i> prevalence found by FDA for shipments of oregano and allspice offered for import to the United States during FY2007-FY2009 demonstrates that the antimicrobial activity against <i>Salmonella</i> is not sufficient to eliminate <i>Salmonella</i> contamination from shipments of these types of spices.”</p> <p>In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p>FDA published findings on the prevalence of <i>Salmonella</i> in imported oregano in its Risk Profile: Pathogens and Filth in Spices (FDA, 2017a). The findings demonstrated that the prevalence of <i>Salmonella</i> between 2012-2015 was 10%. In addition, FDA summarized findings on the prevalence of <i>Salmonella</i> in retail oregano between 2013-2015. The FDA concluded that the prevalence in retail oregano samples was 0.15% (FDA, 2017a).</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the density and form of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to</p>

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<p>Oregano, Mexican</p>	<p>Mexican oregano is an herb native to Mexico, Central America, and the southwest U.S. The herb is characterized by lemon and citrus flavors, with tones of licorice. Its unique flavor profile makes it popular for use in chili, soup, salsa, and meat dishes.</p> <p>Mexican oregano is known to have antimicrobial properties, however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the density and form of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher</p>

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<p>Parsley</p>	<p>Parsley is an herb derived from a flowering plant native to Greece and Morocco that is characterized by its clean, peppery taste. Parsley is used to impart flavor in a variety of dishes and as a garnish.</p> <p>A microbiological link between parsley and <i>Salmonella</i> illness has been established (FDA, 2017a). <i>Salmonella</i> has been implicated in the illness of 69 persons (96% of ill persons were children under 6 years old) following consumption of a seasoning mix consisting of broccoli powder, parsley powder, and other spices to coat a snack puff (Sotir et al., 2009). <i>Clostridium perfringens</i> has also been detected in parsley (FDA, 2017a).</p> <p>Parsley is known to have antimicrobial properties, however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices. Moreover, although one study reports a 5-log reduction in total plate count in parsley samples irradiated with a dose of 2.7 kGy, one third of evaluators subsequently reported off-flavors for parsley samples irradiated with this dosage (Cățunescu et al., 2019). It was also concluded that the application of irradiation at doses greater than 1.4 kGy resulted in aroma defects in the parsley samples.</p>

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Pepper (Capsicums)	<p>Red pepper (capsicum) is the highest traded spice by volume worldwide. It is used in a variety of culinary applications in both their fresh and dried forms to achieve a characteristically hot flavor. Red pepper spices vary in their heat intensity (as expressed through Scoville values) and includes a variety of common spices, including cayenne pepper, paprika, chipotle pepper, jalapeno, and serrano pepper.</p> <p>A microbiological link between red pepper and <i>Salmonella</i> illness has been established (FDA, 2017a). Between July 2009 and April 2010, 272 cases of illness were linked to <i>Salmonella</i> Montevideo and a further 11 cases of illness were linked to <i>Salmonella</i> Seftenberg contamination in black and red pepper on a salami product (CDC, 2010; Gieraltowski et al., 2012; DuVernoy, 2012). The outbreak resulted in 234,686 pounds of salami products being recovered from the marketplace (FDA, 2017a). Additionally, ~1000 cases of illness were linked to <i>Salmonella</i> contamination in paprika and paprika-containing spice mixes (Lehmacher et al., 1995).</p> <p>FDA has published findings on the prevalence of <i>Salmonella</i> in pepper in its Risk Profile: Pathogens and Filth in Spices (FDA, 2017a). It demonstrated that the prevalence of <i>Salmonella</i> in retail samples of pepper was 0.64%, while the prevalence of <i>Salmonella</i> in imported shipments of pepper was 11%.</p> <p>Global retail surveillance has also demonstrated the prevalence of <i>Salmonella</i> in red pepper products in Japan and Turkey (FDA, 2017a).</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Due to the density and form of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination. One study</p>

	<p>determined that atmospheric steam treatment (16 min, 100°C) of dried whole red peppers prior to grinding resulted in a &lt;2-log reduction in total aerobic plate count, as well as greater negative impacts to the physiochemical properties of the spice compared to gamma radiation (Rico et al., 2010).</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices. In a study of the effect of gamma irradiation on the physiochemical qualities of red pepper powder, it was noted that although there were no significant differences found in the pungent odor of color between irradiated and non-irradiated red pepper powder samples, an off-flavor was detected by most panelists in the irradiated samples (Jung et al., 2015).</p> <p><b>PPO:</b> PPO is not currently permitted for use in this commodity. However, ASTA encourages EPA to assist the industry in reducing the regulatory burden to re-expand the authorization of this chemical.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Pepper, black	<p>Black pepper is derived from the partially ripe berries of a climbing vine. It is a staple spice in most households and restaurants. The volatile oil content of black pepper is critical to the flavor and commercial viability of this spice.</p> <p>A microbiological link between black pepper and <i>Salmonella</i> illness has been established (FDA, 2017a). Between July 2009 and April 2010, 272 cases of illness were linked to <i>Salmonella</i> Montevideo and a further 11 cases of illness were linked to <i>Salmonella</i> Seftenberg contamination in black and red pepper on a salami product (CDC, 2010; Gieraltowski et al., 2012; DuVernoy, 2012). The outbreak resulted in 234,686 pounds of salami products being recovered from the marketplace (FDA, 2017a). Other outbreaks linked to <i>Salmonella</i> contamination in black pepper include:</p> <ul style="list-style-type: none"> <li>• Canada (1973-1974) 17 persons affected (Laidley et al., 1974; WHO, 1974)</li> <li>• Norway (1981-1982) 126 persons affected (Gustavsen and Breen, 1984)</li> <li>• United Kingdom (1996) 8 persons affected (Little et al., 2003; Little, 2012, Health Protection Agency, 2011)</li> </ul> <p>FDA has published findings on the prevalence of <i>Salmonella</i> in imported and domestic black pepper in its Risk Profile: Pathogens and Filth in Spices (FDA, 2017a). The findings demonstrated that the prevalence of <i>Salmonella</i> in imported black pepper was 6.7%, while the prevalence in retail black pepper was 0.24%.</p>

	<p>Black pepper has been associated with other pathogens as well, including <i>Bacillus</i>, <i>Clostridium perfringens</i>, and <i>Staphylococcus aureus</i> (FDA, 2017a).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. One study determined that the atmospheric steam treatment (16 min, 100°C) of black pepper yielded aerobic plate count, coliform and yeast/mold count reductions of 2.6 log, 4.2 log, and 2.3, respectively (Waje et al., 2008). However, a significant loss of color and flavor were reported for the black pepper product as a result of the steam treatment due to reductions in piperine content. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices. One study demonstrated that applications of 5.0 and 10kGy of gamma irradiation to powdered black pepper significantly decreased the concentration of key constituents relevant to the flavor and aroma quality of the spice (Emam et al., 1995).</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Pepper, green	<p>Green pepper is a spice derived from berries plucked from the <i>Piper nigrum</i> vine before they are ripe. Green pepper has a fresh and slightly fruity flavor that pairs well with tropical seafood. As with all spices, there is potential for pathogenic bacteria to occur on this product. There is limited evidence on the food safety treatments available for this spice in the scientific literature.</p>

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Pepper, pink	<p>Pink peppercorns are derived from the berries of a flowering plant in the cashew family. It has a unique flavor profile characterized by floral, camphor, and peppery notes. As with all spices, there is potential for pathogenic bacteria to occur on this product. There is limited evidence on the food safety treatments available for this spice in the scientific literature.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p>



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Pepper, white	<p>White pepper is made from the fully ripe berries of the <i>Piper nigrum</i> vine. Its flavor is often described as grassy and musty with notes of ginger. White pepper is used to flavor soups, marinades, and other savory dishes.</p> <p>A microbiological link between white pepper and <i>Salmonella</i> illness has been established (FDA, 2017a). In 2008-2009, a <i>Salmonella</i> outbreak associated was ground white pepper affected 87 persons in the U.S. White pepper has also been associated with other pathogens, such as <i>Bacillus cereus</i>. In 2010, <i>Bacillus</i> was implicated in illness in 112 persons following the consumption of stew containing white pepper (EFSA, 2013; EFSA, 2011). Other pathogens associated with white pepper include <i>Clostridium perfringens</i> and <i>Staphylococcus aureus</i> (FDA, 2017a).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p>

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Peppermint	<p>Peppermint is a hybrid species of watermint and spearmint. The leaves are used in a variety of applications, including to flavor desserts, chewing gum, alcoholic beverages, herbal teas, toothpaste, and as a garnish. The essential oil content of peppermint is critical to the flavor and commercial viability of this herb.</p> <p>Studies have confirmed that <i>Salmonella</i> can survive on peppermint in brewed tea, following the brewing process, indicating a thermal resistance of the pathogen in this herb (Keller et al., 2015). <i>Salmonella</i>-related recalls have been linked to peppermint teas. In 2011, a recall of 2,700 pounds of peppermint organic tea was initiated due to potential <i>Salmonella</i> contamination, although no illnesses were reported (Booth, 2011).</p> <p>Peppermint is known to have antimicrobial properties, however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb in the mint family. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p>

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Poppy	<p>Poppy seed is an oilseed that is commonly used in pastries and bread.</p> <p>Poppy has been associated with pathogens, including <i>Salmonella</i> and <i>Bacillus</i> (FDA, 2017a). In 2022, several recalls of poppy seed were initiated in Canada due to possible <i>Salmonella</i> contamination (Food Safety News, 2022b).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>

Rosemary	<p>Rosemary is an aromatic herb used to flavor meats, desserts, alcoholic beverages, soups, casseroles, and other savory dishes. The essential oil content of rosemary is critical to the flavor and commercial viability of this spice.</p> <p>Rosemary has been associated with pathogens, including <i>Cronobacter</i> and <i>Bacillus</i> (FDA, 2017a). Rosemary is known to have antimicrobial properties, however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Saffron	<p>Saffron is a spice derived stigma of a flower grown most commonly in Iran, Greece, Morocco, and India. The flavor of saffron has been described as earthy-sweet, with bitter, floral, and honey notes. The cultivation of saffron is laborious - it takes 75,000 saffron flowers to produce one pound of saffron spice. The spice is used in curries and desserts.</p>

	<p>Saffron has been associated with pathogens, including <i>Clostridium perfringens</i>, <i>Salmonella</i>, and <i>Bacillus</i> (FDA, 2017a). Saffron is known to have antimicrobial properties (Pintado et al., 2011), however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Sage	<p>Sage is an herb in the mint family that is commonly used in stuffings, soups, sausages, and meat dishes. It is characterized by an herbaceous and savory flavor with hints of pine, mint, and citrus.</p> <p>Sage has been associated with <i>Salmonella</i> (FDA, 2017a). According to FDA’s Import Alert database, there have been over 25 distinct shipments of sage from 18 companies detained without physical examination at the border due to the presence of <i>Salmonella</i> since 2009 (FDA, 2023).</p> <p>Sage is known to have antimicrobial properties (FDA, 2017a), however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties</p>

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Sassafras	<p>Sassafras is an herb native to North America. Its flavor is likened to those of licorice or anise. Ground sassafras is commonly used as a thickening agent in gumbo, but is also used in teas, meats, and salads. As with all herbs, there is potential for pathogenic bacteria to occur on this product. There is limited evidence on the food safety treatments available for this herb in the scientific literature.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising</p>

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Savory, summer and winter	<p>Summer savory and winter savory are herbs that are most commonly used to impart flavor to poultry and meat dishes. Although both have notes of marjoram, thyme, and mint, summer savory has a distinct peppery character, while winter savory has an earthier character.</p> <p>The essential oils of savory are known to have antimicrobial properties, however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p>As with all herbal products, there is potential for pathogenic bacteria to occur on this product. There is limited evidence on the food safety treatments available for this herb in the scientific literature.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial</p>

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Sesame	<p>Sesame seed is an oilseed that has one of the highest oil contents of any seed. Sesame seed is a common ingredient in breads, crackers, stir fries, and soups due to its rich, nutty flavor.</p> <p>In 2010, FDA conducted a study titled “Prevalence, level and distribution of <i>Salmonella</i> in shipments of imported capsicum and sesame seed spice offered for entry to the United States: Observations and modeling results” (Van Doren et al., 2013). Between August and December 2010, 23 out of 233 shipments sampled were found to be contaminated with <i>Salmonella</i> (<i>Salmonella</i> prevalence = 9.9%). Approximately 22% of the contaminated shipments were packaged for retail sale in their final packaging.</p> <p>According to FDA’s Risk Profile: Pathogens and Filth in Spices, <i>Salmonella</i> prevalence in imported sesame shipments offered for entry to the U.S. during 2007 and 2009 was 11% (20/177) (FDA, 2017a). Between 2012 and 2015, <i>Salmonella</i> prevalence in sesame shipments offered for entry to the U.S. was 7.7% (12/155). However, domestic retail sampling conducted in 2013, 2014, and 2015 indicated that no samples of sesame seeds tested were contaminated with <i>Salmonella</i> (n=526) (FDA, 2017a).</p> <p><b>Steam:</b> Steam treatment is not always compatible with this commodity. Steam treatment negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it potentially unmarketable. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Due to the density and form of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging</p>



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Spearmint	<p>Spearmint is a species of mint native to Europe and southern Asia. The leaves are used in a variety of applications, including to flavor desserts, chewing gum, alcoholic beverages, herbal teas, toothpaste, and as a garnish. The essential oil content of spearmint is critical to the flavor and commercial viability of this herb.</p> <p>Although there is limited literature on microbiological pathogens associated with spearmint, FDA considers this commodity to be a spice. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p>Spearmint is known to have antimicrobial properties (Imai et al., 2001), however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb in the mint family. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam,</p>

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Sweet bay	<p>Sweet bay an is herb that is used to flavor soups, stews, vegetables, and meats. Its flavor is described as sweet and pungent, with hints of nutmeg, vanilla, and pine.</p> <p>Sweet bay has been associated with pathogens, including <i>Salmonella</i>, <i>Clostridium perfringens</i>, <i>Shigella</i>, and <i>Bacillus</i> (FDA, 2017a). Sweet bay is known to have antimicrobial properties (FDA, 2017a), however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the density and form of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to</p>

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Tarragon	<p>Tarragon is an herb with a distinct licorice flavor that is used in soups, meat dishes, sauces, and soft drinks.</p> <p>In 2017, a recall of organic tarragon leaves was initiated in the U.S. due to the presence of <i>Salmonella</i> (FDA, 2017b). Although there is limited literature on microbiological pathogens associated with tarragon, FDA considers this commodity to be a spice. Under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve</p>

	<p>adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Thyme	<p>Thyme is an herb whose flowers, leaves, and oil are used to flavor soups, sauces, vegetables, and meat dishes. Thyme is characterized by a minty, lemony flavor.</p> <p>Thyme has been associated with pathogens, including <i>Salmonella</i> and <i>Bacillus</i> (FDA, 2017a). Thyme is known to have antimicrobial properties (FDA, 2017a), however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p><b>Steam:</b> Steam treatment is likely not compatible with this commodity, as it is a leafy green herb. Steam treatment severely negatively impacts the organoleptic, color, and quality parameters of this commodity, rendering it unmarketable. Steam is particularly damaging to herbs due to their delicate nature. Due to the density and form of this product, steam treatment may not be as effective. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p>

	<p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
Turmeric	<p>Turmeric comes from the roots of a perennial plant native to southern Asia. When the root is dried and ground, the color of the powder is yellow with an orange tinge. Turmeric is characterized by a peppery, earthy odor and a slightly aromatic, somewhat bitter taste, with gingery and nut-like undertones. It is commonly used as a colorant in a broad array of products, as well as a seasoning in curry powders, prepared mustard, and soups.</p> <p>Turmeric contaminated with <i>Bacillus subtilis</i> and <i>Bacillus pumilus</i> was implicated in two incidents of illness reported in the United Kingdom in 1995 (FDA, 2017a). Additionally, turmeric is associated with <i>Salmonella</i> (FDA, 2017a). <i>Salmonella</i> prevalence in imported turmeric shipments offered for entry to the U.S. between 2007 and 2009 was 7% (8/118 samples) (FDA, 2017a).</p> <p>Although curcumin, a major component of turmeric, is known to have antimicrobial properties, it has also been suggested to increase the pathogenicity of <i>Salmonella</i> (Marathe et al., 2016).</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. This commodity is often treated in its ground or powdered form, which is not compatible with steam treatment due to its high density. Moreover, steam treatment may result in clumping of the product, affecting its marketability. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is not currently permitted for use in this commodity. However, ASTA encourages EPA to assist the industry in reducing the regulatory burden to re-expand the authorization of this chemical.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p>

	<p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>
<p>Vanilla</p>	<p>Vanilla is a spice from the long black pods of a flower with a distinctively sweet flavor that is quintessential to modern baking and cooking. It is commonly used in custards, creams, cakes, beverages, and other baked goods.</p> <p>Vanilla is known to have antimicrobial properties (Fitzgerald et al., 2004; Maisch et al., 2022), however, this is insufficient to prevent the risk of pathogens. In fact, this property can make it more difficult to conduct validation studies on the spice. The antimicrobial properties complicate the selection of the surrogate used and other design elements of validation studies.</p> <p>There is limited literature on microbiological pathogens associated with this spice. However under Appendix 1: Potential Hazards for Foods and Processes, FDA identifies a number of potential microbiological hazards that should be considered for spice and seasoning ingredients, including <i>Salmonella</i>. FDA classifies this commodity as a seasoning/spice and therefore the risk must be evaluated to determine whether management steps are required.</p> <p><b>Steam:</b> Steam treatment has the potential to affect the organoleptic, color, and quality parameters of this commodity. Further, steam treatment is incompatible with certain food packaging materials, such as paper, propylene, or plastic bags, meaning that the product cannot be treated in its final packaging. This packaging may be damaged after exposure to steam, compromising the integrity of the product and introducing the possibility for post-process contamination.</p> <p><b>Irradiation:</b> Although irradiation treatment is permitted for use in this commodity, a lack of consumer acceptance and fears of “radioactive food” limit the commercial viability of this technology. Growing calls for the phase out of the Cobalt-60 radioisotope threaten the continued availability of the material to irradiation facilities. There may be limited ability for the irradiation of spices and dried herbs to expand beyond its current capacity as only a subset of irradiation facilities treat spices, and many of these facilities prioritize the treatment of medical devices.</p> <p><b>PPO:</b> PPO is permitted for use in this commodity. However, a longer throughput time and greater concentration of the gas are required compared to EtO to achieve adequate lethality. Amendment of the label to allow for application at a higher temperature would improve the efficacy of this treatment, but additional validation and quality testing would still be required to ensure efficacy of the treatment to consistently achieve lethality in relevant commodities.</p> <p><b>Emerging Alternatives:</b> The industry has not had sufficient time to perform necessary quality and validation tests to demonstrate that these technologies are able to consistently achieve lethality in this commodity.</p> <p>As such, due to the food safety risks and lack of viable alternatives for this commodity, the use of EtO remains critical for the food safety of this product.</p>

**4. In the event that EPA determines that the use of EtO will be phased out, the industry will require many years to transition their operations.**

*It will take many years for the industry to properly identify, research, and validate alternative treatment methods.*

As noted previously, under the FD&C Act, all food companies are required to develop a food safety plan that identifies microbiological hazards, including pathogens, and create a treatment plan to address these hazards. The treatment plan must also be validated to assure that it is successful. Spice companies must comply with the Preventive Controls for Human Food rule under FSMA regulations, 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.

While there are emerging technologies that may eventually be available for pathogen control in spices, including infrared and other cutting-edge technologies, these methods are still new and not yet widely used. It will take a significant amount of time, money, effort, additional validation studies, and more research for companies to change the type of pathogen control being used for spices. Before adoption by the industry as a method to comply with preventive controls requirements, any new techniques must also undergo significant research to show the technology is capable of delivering a 5-log reduction of *Salmonella*. Additionally, a company must conduct tens of thousands of dollars in validation studies to ensure that any treatment method is effective, yet also capable of preserving the necessary quality attributes of the products. The industry continues to explore new advancements, but there are significant costs associated with changing to a new sterilization technology, and the required capital investment can be a significant barrier. Even upon the identification of a potential alternative treatment method, it may take months to years to purchase, acquire, and install necessary equipment into treatment facilities.

Additionally, it would be remiss not to acknowledge that if there is insufficient time for U.S. companies to transition their operations, unfair competitive advantages may be granted to corporations overseas who continue to leverage EtO as a treatment procedure. If insufficient treatment capacity is available in the U.S. to treat the total spice volume, many companies may opt to have their international partners treat product at the country of origin. However, this transition to overseas treatment increases the risk of post-process contamination with pathogenic bacteria such as *Salmonella*. Moreover, it would result in an increase in EtO emissions in origin countries, for which regional regulations do not require the same extent of emissions control measures as are required in the U.S.

**5. The spice industry supports collaborating with EPA to lower the concentration limit of EtO for spice treatment methods.**

*The spice industry welcomes opportunities to collaborate with EPA to lower the concentration limit of EtO for spice treatment methods.*

Many spice companies have indicated that it is possible and efficacious to treat spices at levels lower than the 500 mg/L limit currently permitted. However, it will take time to identify and validate treatment with a lower concentration of EtO. Many companies have validated their current treatment operations at 500 mg/L. Although a reduction in the concentration limit of EtO is possible, the industry would require time to conduct validation studies and submit these proposals to FDA for review per its legal obligations under FSMA.

*The spice industry has worked for the last twenty years to reduce residues and emissions to the lowest level possible while still achieving the objective of ensuring spices are treated to control food safety hazards.*

The spice industry recognizes and supports EPA's goal of minimizing EtO emissions resulting from the use of the chemical. To this end, spice companies that use EtO have worked for the last twenty years to reduce residues and emissions to the lowest level possible while still achieving the objective of ensuring spices are treated to control food safety hazards.

During the EPA's Office of Pesticide Programs re-registration process, ASTA members using EtO to sterilize spices undertook significant effort to reduce the residual levels of EtO and its byproducts in spices. In conjunction with EPA, ASTA and other industry experts participated in a project to reduce the EtO and byproduct residue levels that remained on spices after sterilization. They developed what will be referred to in these comments as the "ASTA method." The results of the ASTA method supported the use of EtO as a tool for chemical sterilization of spices, while also reducing residue levels of EtO and the byproducts that remain on spices below established EPA tolerances. Due to the success of the ASTA method, the process continues to be used today by spice companies. An additional, unintended benefit of the processes developed under the ASTA method resulted in the reduction of emissions of EtO, both controlled and uncontrolled, from the sterilization facilities.

The ASTA method has been explicitly described and mandated by the direction for use since 2008. The language of the label follows:

"Place spices in the treatment chamber. Assure that the mixture of ethylene oxide and air is compatible with the chamber design, then, introduce into the chamber a concentration of Ethylene Oxide not to exceed 500 mg/L, with a dwell time not to exceed 6 hours. Then evacuate the gas from the chamber using a sequence of not less than 21 steam washes (injections and evacuations) between 1.5 PSIA (27" Hg) and 5.0 PSIA (20"Hg) while maintaining a minimum chamber temperature of 115°F."

It is noteworthy that:



- The label sets a limit for gas concentration at 500 mg/L. While the EPA is contemplating limits in the proposed NESHAP and PID, no other approved use of EtO has been subject to such a limit to date.
- The label also describes an all-in-one process that ensures that the product remains in the sterilizer until aeration of the product achieves the mandated residue tolerances. The PID contemplates a requirement for all-in-one processing for any company that does not run “soft cycles.”
- The label requires a minimum temperature which enhances the lethality of the process and also assists in the removal of EtO during the aeration portion of the process.

The spice industry has been subject to a limit on gas concentration and has been using all-in-one processing since 2008. The EPA recognizes the benefits of the processing technologies that were developed and introduced by ASTA in regulations that were recently proposed. We are proud of the fact that the commercial sterilization of spices has been at the forefront of compliance by minimizing worker exposure, primary emissions, fugitive emissions, and residues of ethylene oxide on spices for the last 15 years.

**6. Proposed automation requirements, particularly requiring covered conveyors are unnecessarily burdensome and will require not only the purchasing of new equipment, but entire facilities to be redesigned.**

*Due to the all-in-one process employed by facilities to treat spices, the call for covered conveyor systems is redundant and unnecessarily burdensome.*

For all-in-one systems, EPA is proposing “automation via covered conveyor from the aeration area to the shipping and storage area.” As explained above, the ASTA method dictates that aeration and sterilization of herbs and spices are performed in the same chamber, which significantly reduces the likelihood of fugitive emissions post-process. As such, the requirement of a covered conveyor system is unnecessarily burdensome and redundant given the current mitigation measures employed by the spice industry.

*Proposed automation requirements would require that entire facilities are reconstructed or replaced, and do not account for local building, fire, and electrical codes.*

Presently, spice companies store treated products in open warehouses. In order to comply with EPA’s proposal of a covered conveyor system from the aeration area to the shipping and storage areas, entire facilities would need to be retrofitted with a complex system of covered conveyors spanning the entirety of the warehouse. Transferring product via enclosed conveyor from the sterilizer to a post processing or shipping warehouse is illogical. The post processing warehouse is usually at or near the unloading door of the sterilizer. Transferring product through a warehouse in an enclosed conveyor and then placing the product in that same warehouse yields little or no benefit. Furthermore, the installation of this equipment would not be possible given the current layout and design of these facilities, meaning that these facilities would need to be demolished, reconstructed or replaced to accommodate this conveyor system.

Moreover, conveyor systems for spices are problematic due to the manner that spice pallets are configured. Sacks of spices are stacked in blocks. These stacks tend to be loose and have overhangs, while bags often slip and move on the pallet. If conveyors are required, personnel would need to reenter the enclosed areas frequently to restack the bags.

Provided that spices are stored throughout the facility at multiple points, the conveyor system would need to be designed in a manner that is compliant with local building, fire, and electrical codes to allow for adequate evacuation procedures, worker safety, and freedom of movement.

At minimum, the implementation of these proposed automation requirements would take years to implement assuming that the required technology is currently available. However, it is important to note that covered conveyor systems consistent with EPA's proposal are not currently available.

#### **7. Real time monitoring at 10 ppb is not achievable.**

EPA requests comments on the feasibility of real time monitoring to a 10 ppb level. At this time, ASTA is not aware of technology that can reliably detect in real time to the 10 ppb limit of quantification. Currently, individual worker exposure is monitored via badges worn by employees in the breathing zone. There are not continuous monitoring technologies available for individual workers that can measure to such low concentrations. Additionally, it is problematic to establish an action level that is at the limit of current technology. The establishment of action levels at the limit of current technology can lead to issues with reading accuracy and interference, especially related to the ubiquitous background levels of EtO from other sources that already exceed this level.

Furthermore, there are challenges with requiring self-contained breathing apparatus (SCBA) use by all employees throughout the entire facility when EtO concentration exceeds 10 ppb, particularly if these levels are only observed in specific locations within the site. In facilities with combined functions, it is possible to foresee a situation where all employees in a facility – administrative, maintenance, production, quality – must wear SCBAs at certain times to perform their job functions. This is neither feasible nor safe.

#### **8. Conclusion**

The spice industry recognizes and supports EPA's goal of lowering emissions of EtO from sterilization facilities and ensuring public health. Recognizing that high emissions of EtO may impact public health, the spice industry has taken steps to move away from its reliance on EtO when effective alternatives are available. However, as summarized in this comment letter, there are currently no effective alternatives for certain spices and spice-related categories. As such, use of EtO is needed until effective alternatives are developed to ensure food safety.

As outlined in these comments:

- The continuance of tolerances is critical to maintain global trade, protect the food supply chain, and prevent compliance issues downstream.

- The spice industry requires additional time to identify and evaluate the viability and efficacy of alternative treatment methods for all spice products within the “dried herbs, spices, dried vegetables, and seasoning” materials categories.
- Although the industry has identified a variety of commodities in this letter for which EtO use remains critical for food safety and for which there are no viable alternatives, treatment is situationally dependent. Many factors influence the selection and ability to leverage a treatment at any given time. The industry has worked effortlessly over the past two decades in tandem with FDA to study and validate the treatment options currently available. Many more years will be required to identify, study, and validate emerging and alternative treatment methods to meet current regulatory requirements under FSMA.
- The spice industry welcomes the opportunity to work with EPA on lowering the concentration limit of EtO for spice treatment methods, recognizing that time would be needed for the industry to conduct scientific studies to validate the efficacy of treatment on various spice commodities, pursuant to FSMA regulations.
- Proposed automation requirements, particularly requiring covered conveyors, are unnecessarily burdensome and will require not only the purchasing of new equipment, but for entire facilities to be redesigned.
- Real time monitoring at 10 ppb is not achievable.

ASTA thanks EPA for the opportunity to comment on its proposed interim decision for EtO. Please do not hesitate to contact us if you have any questions regarding our comments.

Sincerely,



Laura Shumow  
Executive Director  
American Spice Trade Association

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