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P. O. Box 4010
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Re: Notice of Proposed Rulemaking Title 27, California Code of Regulations – Amendment to Section 25705 Specific Regulatory Levels Posing No Significant Risk: Ethylene Oxide.

To Whom it May Concern,

The American Spice Trade Association (ASTA) appreciates the opportunity to submit comments regarding the California Office of Environmental Health Hazard Assessment's (OEHHA) proposed changes to Section 25705, revising the safe harbor No Significant Risk Level (NSRL) for ethylene oxide (EtO) from 2 µg/day to 0.058 µg/day.

ASTA was established in 1907 and is the voice of the U.S. spice industry in the global market. Our members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. Approximately 200 companies are members of ASTA, and these companies manufacture and market the majority of spices sold in the U.S. for industrial, food service, and consumer use. The highest priority of ASTA and our members is ensuring the supply of clean, safe spices to American consumers.

The spice industry recognizes and supports OEHHA's goals of protecting public health. To this end, ASTA wishes to highlight the critical role of EtO in ensuring food safety by reducing microbiological contamination in spice products and requests that OEHHA consider the importance of EtO to food safety as it considers changes to the safe harbor NSRL for EtO under Proposition 65.

Moreover, ASTA wishes to note that although the proposed safe harbor NSRL value is derived from inhalation toxicity data, the primary route of exposure to EtO residues from spices is through dietary consumption. As such, the proposed safe harbor NSRL is not appropriate for calculating cancer risk from the consumption of spices. Furthermore, key federal agencies, including the U.S. Food and Drug Administration (FDA) and U.S. Environmental Protection Agency (EPA) have concluded that exposure to EtO residues from spice consumption do not pose a public health risk.



The use of EtO fumigation in spices supports public health by ensuring that spices are treated to control food safety hazards.

Current federal regulations permit the application of EtO to spices for the purpose of food safety under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Spices may be treated with EtO consistent with the U.S. Environmental Protection Agency's (EPA) regulation under 40 C.F.R. 180.151.

A number of pathogens that pose a risk to human health, including *Salmonella*, *Escherichia coli*, *Clostridium perfringens* and *Bacillus cereus* may be found on spices. Although production and processing controls in the form of Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) may be implemented to reduce filth and possible sources of pathogenic bacteria, microorganisms may still contaminate spices during cultivation, harvest, and storage (ASTA, 2020; ASTA, 2023).

Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq, all food companies are required to develop a food safety plan that identifies microbiological hazards and create a validated treatment plan to address these hazards. Spice companies must comply with Preventive Controls for Human Food rule under FSMA regulations, 21 C.F.R. Part 117, which requires that processes to control hazards such as *Salmonella* must be validated to ensure that they are effective.

As such, the spice industry implements treatment procedures, including fumigation with EtO, to inactivate pathogens and ensure spice safety. Per FDA's 2017 Risk Profile: Pathogens and Filth in Spices, the only wide-spread technologies available to achieve validated reduction of *Salmonella* in spices are steam, irradiation, and EtO treatment. Steam and irradiation are capable of performing the necessary microbial reduction for *Salmonella*. However, both have significant limitations and without the availability of EtO, there would not be sufficient total capacity to treat the entire spice supply. Furthermore, unlike other conventional sterilization methods, EtO treatment is compatible with packaging materials, meaning that spices can be treated while in their final packaging. Thus, EtO treatment offers the unique benefit of reducing the likelihood of post-process contamination in spices.

Exposure to EtO residues from the consumption of spices does not pose a public health risk.

The proposed safe harbor NSRL of 0.058 µg/day has been derived from several inhalation studies in humans and animals and no studies involving ingestion. This value would therefore not be applicable to calculated risk from dietary exposure, which would be a consumer's primary route of exposure to EtO residues from the consumption of spice products.

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). However, low levels of EtO may be detected in spice products depending on the time of testing.



Nevertheless, the U.S. Food and Drug Administration has indicated that there is not a cancer concern from exposures to EtO residues from the consumption of spices. In its 2017 Risk Profile on Pathogens and Filth in Spices, FDA states that “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, 2017). Furthermore, EPA’s Proposed Interim Decision (PID) for EtO, states that “EPA has determined that there is no human dietary risk from registered uses of EtO that is inconsistent with the FFDCSA safety standard...EPA concludes that there is a reasonable certainty that no harm will result from dietary exposure to EtO or ECH [ethyl chlorohydrin]. Therefore, EtO and ECH residues are safe” (EPA, 2023).

The effects of a chemical can be significantly different between exposure routes, as evidenced by both FDA’s and EPA’s analyses of dietary exposure data for EtO residues compared to OEHHA’s analysis of inhalation toxicity data. As such, it would be remiss to correlate an NSRL value for EtO derived from inhalation toxicity studies to the calculated dietary exposure levels from the consumption of spices, as the value is not representative of the cancer risk associated with this route of exposure at the levels observed in spice products. Indeed, because there is no evidence that EtO exposures by the route of ingestion pose any significant risk of cancer, OEHHA should amend its regulation at Section 25707 of Title 27, California Code of Regulations, to add ethylene oxide to the list of chemicals that present no significant risk of cancer by the route of ingestion.

OEHHA should adopt a higher safe harbor NSRL for EtO residues in food based on “sound considerations of public health.”

Under its regulation at Section 25721(b) of Title 27, California Code of Regulations, OEHHA recognizes that “sound considerations of public health” support an alternative NSRL that is based on a different measure from the standard 1 in 100,000 excess lifetime cancer risk. Indeed, the regulation notes that that the impact of “cooking or similar preparation of food or beverage components necessary to render the food or beverage palatable or to avoid microbiological contamination” is one such “sound consideration[] of public health” that should be considered in setting the NSRL for the chemical. Similarly, it is essential that OEHHA consider the importance of EtO in the disinfection of spice products to prevent and/or reduce microbiological contamination for the purpose of ensuring food safety and not discouraging consumers from using spices that have been treated with EtO due to the presence of a Proposition 65 warning. We believe that, in light of the determinations of FDA as well as the relatively small mass of spices consumed by Californians on a daily basis, sound considerations of public health support a safe harbor NSRL for EtO exposure as a carcinogen in species that is two orders of magnitude higher than the safe harbor level proposed by OEHHA, i.e., 5.8 µg/day. We also note that this level is in the same order of magnitude as the 2 µg/day safe harbor MADL for exposures to EtO as a reproductive toxicant (male, female, or developmental toxicity).



OEHHA is required to consider the economic impacts of this proposed regulation and has not done so.

Reducing the safe harbor level for EtO to less than 34 times the established level that businesses have been abiding by since 1988 also risks imposing significant costs on California businesses. OEHHA must carefully consider these costs before it sets a new standard that will have ripple effects throughout the food industry. Indeed, under Section 11346.3 of the California Government Code, agencies are obligated to “assess the potential for adverse economic impact on California business enterprises.” OEHHA’s brief dismissal of such costs in its Initial Statement of Reasons, together with no underlying data in the administrative record, suggests that OEHHA has incorrectly assumed that there are no such adverse economic impacts on California businesses. OEHHA cannot rely on this unwarranted assumption, and instead must complete this analysis with data before proceeding.

If OEHHA lowers the safe harbor NSRL for EtO, it will require companies who produce, distribute, and sell spices in California to reevaluate the potential for EtO exposure from their products. The proposed level is so low as to challenge existing analytical methods, meaning that new methods may need to be established, or else companies may be incentivized to provide unnecessary warnings by the risk of litigation. Given the uncertainties of Proposition 65 enforcement litigation as well as the highly active enforcement environment among private enforcers, many companies will consider abandoning EtO treatment or placing a warning on their products. Both alternatives, as well as the required analysis, will result in “adverse economic impact[s] on California business enterprises.” Cal. Gov’t Code section 11346.3.

In the three-and-a-half decades that the present NSRL for EtO has existed, manufacturers and importers of spices have invested enormous resources in developing and improving their food safety plans and implementing specific sterilization techniques that are most suitable for a particular spice commodity. The proposed regulatory change would require businesses to revamp their food safety plans, involving time- and cost-intensive validation studies to gather efficacy data and assure the safety of spices using techniques other than EtO, or else face risky and expensive litigation. Additionally, because most spices in California originate from or are shipped through less developed countries where different standards in sanitation and food handling practices may pose heightened risk of pathogens, raising the barriers of entry through burdensome EtO limits could have widespread economic consequences. Substantially lowering the safe harbor, as OEHHA proposes, could increase both monitoring costs and rejection of imported spices out of fears of liability for inconsequential levels of EtO. This in turn would disrupt the availability of spice commodities and raise prices, which would harm the tens of thousands of food manufacturers, retailers, distributors, and restaurants that rely on imported spices and do business in California.

As explained, there are only three viable sterilization methods for treating spices: steam treatment, irradiation, and fumigation (primarily, EtO). Businesses must have the latitude to utilize all three options in order to meet their specific needs, particularly given the diversity of variables that influence the



commercial decision to use one method over another. And although there is presently no one-size-fits-all approach to sterilizing spices, in many circumstances, EtO is the best commercially viable tool to deliver the necessary pathogen control without compromising the quality of the spice product in the process. For instance, steam is an unsuitable treatment for spices that are sensitive to heat and moisture; it can result in degradation of flavor, texture, and aromatic qualities of certain spices. Moreover, considering the limited capacity of irradiation facilities to treat spices and the reluctance in some consumer markets to buy irradiated food products, many businesses are left with EtO as their most viable choice. The spice industry has taken steps to move away from 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 proposed regulation could pressure businesses to hastily alter their existing EtO regimen or rely on other sterilization methods that may be less effective and more expensive overall, thus increasing the risk of bacterial foodborne illnesses, product recalls, and costly litigation. In short, flexibility to take advantage of different microbiological treatment options is essential. Severely discouraging a common, safely used treatment method would not only immediately raise manufacturers' costs of safely and efficiently processing spices, it would also inflict costs that reverberate throughout California's commercial food sector.¹

Finally, although our comments are focused on the spice industry, OEHHA of course must consider the economic impacts of its proposed regulation on all California business entities.

Conclusion

In summary, the use of EtO is critical to achieve the objective of ensuring that spices are treated to control food safety hazards, while also complying with FDA food safety regulations. Further, dietary exposure to residues of EtO in spice commodities has been concluded to pose no public health concern by both FDA and EPA. As such, ASTA requests that OEHHA consider the food safety importance of EtO and the lack of public health concern from dietary exposure to EtO in its determination of Proposition 65 labeling requirements for the chemical. OEHHA should (1) adopt a regulation declaring that there is no significant risk of cancer from ingestion of EtO; (2) set an alternate safe harbor NSRL for EtO of 5.8 µg/day based on sound considerations of public health; and (3) at the very least comply with the Administrative Procedure Act requirement to assess the economic impact of the proposed regulation on California business enterprises.

Please do not hesitate to contact us if you have any additional questions. Thank you for your consideration.

¹ In addition to the costs described, retailers in California may have to begin posting signage in spice aisles, while manufacturers would face pressures to devise warning labels that can fit on small jars and packets of spices. These carry material compliance costs that OEHHA cannot overlook.



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Sincerely,



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