AMERICAN SPICE TRADE ASSOCIATION, INC.
1101 17th Street, N.W. • Suite 700
Washington, DC 20036 USA
Tel: 202-331-2460 • Fax: 202-463-8998
E-mail: info@astaspice.org
Web: www.astaspice.org

Via Submission on Regulations.gov

September 30, 2022

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: American Spice Trade Association's Input on FDA's Preventive Controls for Human Foods "Appendix 1: Potential Hazards for Foods and Processes" Guidance (Docket No. FDA-2016-D-2343)

To Whom It May Concern,

The American Spice Trade Association (ASTA) appreciates the opportunity to submit comments regarding the U.S. Food and Drug Administration's (FDA) "Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry," which was published on August 24, 2016. Specifically, our focus is on the section of this document entitled "Appendix 1: Potential Hazards for Foods and Processes" (referred to herein as "Appendix 1"). During the several years since this Draft Guidance was issued, the challenges presented by Appendix 1 have become increasingly apparent. The Food and Beverage Issues Alliance (FBIA) met with FDA on June 3, 2022 to raise industry concerns. During this meeting, FDA requested industry follow up to provide written comments on these issues. ASTA is submitting these comments in response to this request.

Introduction

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. We represent our members' U.S. interests by supporting regulatory compliance and maintaining relationships with U.S. agencies. ASTA shares FDA's commitment to food safety. Our highest priority is ensuring the supply of pure, safe spices to American consumers. Additionally, ASTA has consistently advocated to ensure that FDA is adequately resourced and are a member of the Alliance for a Stronger FDA.

ASTA has a long history of working cooperatively with food regulatory authorities, including FDA. We are pleased to provide the following comments on Appendix 1, which is a document intended to assist industry in preparing hazard analyses for their Food Safety Plans by presenting potential hazards for foods and processes. Although this document is only draft guidance and not binding, industry's experience is that Appendix 1 is being enforced as a rule. Our members have faced challenges from FDA Investigators when reaching alternative conclusions to those presented in the document. ASTA supports establishing a science-based framework to systematically analyze food safety hazards to ensure food safety through the development and implementation of risk-based preventive controls. However, we are concerned that the analysis used in and conclusions reached by Appendix 1 are not scientifically grounded and present significant inconsistencies. Additionally, including an overly broad scope of potential hazards in Appendix 1 forces industry to focus resources on preparing justifications of why these hazards are not hazards requiring preventive controls, which is not an exercise that adds value for food safety. This draft guidance has resulted in confusion for ASTA members regarding the incorporation of certain potential hazards into their Food Safety Plans, as well as regarding the level of scientific support needed to reach a conclusion that differs from that in Appendix 1.

Through these comments, we aim to identify for FDA certain Appendix 1 concerns related to spices and herbs and provide corresponding scientific support for our reasoning. Specifically, our comments focus on the following four issues:

- First, Appendix 1 identifies spore-forming bacteria, such as *C. botulinum, C. perfringens,* and *B. cereus* as potential risks in spices, herbs, and seasonings. Although these bacteria may be present in dried spices and herbs, spores require appropriate environmental conditions to germinate and grow. The limited water activity of dried spices and herbs are not conducive to the germination of spores, and thus the presence of these spore-forming bacteria is unlikely to present a potential hazard to consumers.
- Second, Appendix 1 incorrectly and inconsistently identifies pesticides as potential hazards requiring preventive controls in spices and herbs. Based on limited evidence of adverse health incidents, and the very small volume of spices and herbs consumed, pesticide residues on spices are unlikely to present a potential hazard.
- Third, Appendix 1 identifies "recontamination with environmental pathogens" as a potential hazard for "untreated, raw herbs and spices." This point presents confusion since untreated spices are typically considered to be not ready-to-eat and will subsequently undergo a kill step. It would be more appropriate to clarify that this hazard applies to spices that are considered to be ready-to-eat.
- Finally, members of ASTA and affiliated industries have experienced Appendix 1 being applied by FDA Investigators as a "checklist" of mandatory hazards requiring preventive controls, rather than as guidance for identifying potential hazards. ASTA requests additional training of inspection staff to promote the use of Appendix 1 as guidance that can be leveraged as a tool for industry members to conduct internal hazard analyses, not as a checklist of mandatory requirements.

ASTA requests that FDA revise Appendix 1 to address these comments in its next revision of the document. Further, ASTA requests that FDA ensures that the revised guidance is issued in draft form to allow for additional industry input prior to the publication of the final guidance.

Food-related biological hazards for spices and herbs (Table 1P)

Appendix 1 Table 1P identifies a number of biological hazards in the spices and herbs categories, including *Salmonella* spp., *Escherichia coli*, *Clostridium botulinum, Clostridium perfringens,* and *Bacillus cereus*. While these pathogenic bacteria may be found on raw spices, due to the low water activity of spices, *Salmonella* spp. present the greatest risk from a public health standpoint. The spore-forming bacteria *B. cereus, C. botulinum,* and *C. perfringens* require high numbers to be present in the food in order to cause illness (>10^5 CFU/g) and their presence in foods at low levels is not normally a health concern. As such, although *B. cereus, C. botulinum,* and *C. perfringens* may be present in spices, they should not be considered hazards requiring a preventive control in spices.

In the Bad Bug Book (2022), FDA outlines that spore-forming bacteria such as *C. botulinum* require that certain food processing conditions are met to promote spore overgrowth and toxin production, such as adequate water activity in the surrounding food matrix. Spices and dried herbs are classified as low-moisture foods, which are defined as having a water activity of less than 0.85 (FAO/WHO, 2014; FDA, 2022). Generally, the minimum available water activity required to facilitate growth of most bacteria is 0.87. *Clostridium*, for example, requires a minimum water activity of ~0.89 for spore germination (Ayerst, 1969). As shown in Table 1, typical water activities in spices range from 0.3 to 0.65, which is below the threshold required to facilitate spore growth. Therefore, conditions in dried spices are not conducive to germination.

Table 1. Typical water activities of spices (Based on Voelker et al., 2020).

Water Activity (a_w)	**Spices**
0.3 to 0.4	Cumin, coriander, oregano powder, parsley leaves
0.4 to 0.5	Basil leaves, basil powder, rosemary powder, chili powder, mustard, paprika, curry powder, allspice, oregano powder
0.5 to 0.6	Black pepper, cinnamon, nutmeg, cayenne, oregano leaves, mace, turmeric, ginger
0.6 to 0.65	Cloves

It is possible that spices used as ingredients in a moisture-rich matrix (e.g., mixed with a dairy-based cream to form a dip) may result in conditions that are conducive to germination of spore-forming bacteria. However, provided that the dried spice and herb matrices are not themselves conducive to the growth of these spore-forming bacteria, and that the risk is instead associated with the application of these commodities into a moisture-risk matrix, spore-forming bacteria should not be considered a hazard in the spice itself. Commercial users of dried spices should consider the risks of these microorganisms and have appropriate preventive controls articulated in their Food Safety Plans when needed.

ASTA requests that in its revision of Appendix 1, FDA remove *Clostridium botulinum, Clostridium perfringens,* and *Bacillus cereus* as hazards from the spices, seasonings, and herbs categories. Alternatively, the revision could indicate that these hazards are ***only*** associated with the use of spice and seasoning blends in a high moisture application that could promote their growth.

Food-related chemical hazards for spices and herbs (Table 2P)

Pesticides are identified as a hazard in Table 2P, in the category "untreated, raw herbs and spices," subcategory 2 "dried, whole." Pesticides should only be considered a hazard if there is a reasonable probability that their presence in a product could cause serious adverse health risks. Evidence does not support that the pesticide residues in spices and herbs are likely to pose a risk to consumers when considering exposure assessments, illness reports, recalls, and other data.

In FDA's Pesticide Monitoring Report for 2020, only 4 samples of spices were tested, two of which had no detectable pesticide residues and none of the samples exceeded established pesticide tolerances. Although one sample of carom seeds did have two residues detected for profenofos and dimethoate, which do not have established tolerances, the levels detected were extremely low - 0.02 ppm and 0.04 ppm, respectively. Further, there have not been any reports of consumer illness or recalls associated with the presence of pesticides on spices. Between 2019-2022, 434 notifications were issued for pesticide residues detected in spice products globally (including through FDA's pesticide monitoring program and the EU Rapid Alert System for Food and Feed), comprising only 0.05% of all notifications issued for pesticide residues in food commodities[1].

According to FDA's "Refence Amounts Customarily Consumed: List of Products for Each Product Category: Reference Guidance for Industry (RACC)" (2018), the amount of spices and herbs customarily consumed per eating occasion is 0.5g. Based on FDA's Pesticide Monitoring report, pesticide residue levels in spices tend to be low (<0.04 ppm). Although safety thresholds vary by pesticide, total daily exposure to pesticide residues from spices do not exceed safety thresholds. Pesticide residues that are compliant with EPA tolerances are thus able to be consumed with "reasonable certainty of no harm" (EPA, 2022).

Given the lack of evidence of pesticide residues presenting a health risk in spices, it may be reasonable for a company to conclude that pesticides are not a hazard requiring a preventive control. Instead, these companies may ensure that pesticide residues are in compliance with regulatory requirements through the implementation of a range of measures across the supply chain including Good Manufacturing Practices (GMPs), such as supply chain surveillance testing, supplier verification programs that include on-site audits, product specifications, and ingredient testing requirements, depending on the likelihood of occurrence in a company's specific portfolio and supply chain.

By definition, a substance is not a "hazard" if it does not have the "potential to cause illness or injury."[2] Further, even if illegal pesticide residues are present on a spice and this render the food per se adulterated, this does not mean that they also are a "hazard" under the PCHF rule. If pesticides are not included as a potential hazard in Appendix 1, companies are not precluded from identifying and evaluating the risk of pesticides in their own hazard analysis (e.g., in the event that there is evidence of adverse events related to the consumption of a spice). However, including them in Appendix 1 will cause every spice company to document their conclusion that any potential presence of pesticide

[1] Based on data available within HorizonScan. Total pesticide reports for all commodities – 8,358. Pesticide reports for spices = 434.
[2] 21 CFR § 117.3.

residues does not have the potential to cause illness or injury and therefore is not a hazard, let alone a hazard requiring a preventive control.

As such, ASTA requests that pesticides be removed as a hazard requiring a preventive control from the category "untreated, raw herbs and spices," subcategory 2 "dried, whole in Table 2P. Alternatively, in the revision of Appendix 1, it could be clarified that pesticides should only be considered a hazard in the event that there is evidence of adverse events or violations related to pesticide residue violations observed in specific spices.

Process-related biological, chemical, and physical hazards for spices and herbs (Table 3P)

Table 3P identifies "recontamination with environmental pathogens" as a potential hazard for "untreated, raw herbs and spices" that are "dried, ground or cracked." In many instances, untreated spices will subsequently undergo a validated kill step to control biological hazards and are thus considered to be not ready to eat (NRTE). Although facilities have GMPs and environmental pathogen controls, the areas where an NRTE spice may come into contact with the environment do not need be controlled to the same extent as areas where there could be environmental contact with a ready-to-eat spice. "Recontamination with an environmental pathogen" should not be considered a potential hazard in a NRTE spice, as these products will be subject to treatment downstream (ASTA, 2018). Therefore, we request that FDA revise Appendix 1 to specify that this potential hazard is only associated with RTE spices that will not undergo a subsequent kill step.

Appendix 1 is a non-binding guidance document for industry and inspection staff, not a checklist of mandatory requirements

As stated by FDA, Appendix 1 is intended to provide a list of "non-binding recommendations"[3] concerning potential hazards to help support industry efforts "to identify food-related and process-related hazards" across a variety of food categories within their food safety plans. However, various members of ASTA and affiliated industries have reported that FDA Investigators sometimes leverage Appendix 1 as a checklist of mandatory hazards requiring a preventive control that must be identified in a food safety plan, even if the company concluded otherwise in their own hazard analysis. This has resulted in confusion, frustration, and caused a number of companies to implement unnecessary preventive controls for potential hazards that are not true food safety risks, resulting in resources being focused away from core food safety issues. ASTA requests that additional training be provided to inspectors to ensure the appropriate use of Appendix 1 during inspections.

Conclusion

ASTA appreciates the opportunity to submit comments to FDA on Appendix 1 to the "Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry." In summary, ASTA supports FDA's efforts to assist industry in conducting hazard analyses but is concerned that certain issues in Appendix 1 are incorrectly identified as potential hazards. We request that FDA amend

[3] FDA. 2016. Appendix 1: Pontenital Hazards for Foods and Processes. https://www.fda.gov/media/99581/download

Appendix 1 to address these issues, which will reduce confusion and facilitate companies' efforts to focus their resources on the truly essential issues for food safety and public health.

Please feel free to contact ASTA with any questions or if we can be of assistance to the agency on this or other matters.

Sincerely,

Laura Shumow
Executive Director
American Spice Trade Association

cc: Jenny Scott, Senior Advisor to the Director, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration

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