

**Docket No. FDA-2016-D-2343**

**BEFORE**  
**THE UNITED STATES OF AMERICA**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**FOOD AND DRUG ADMINISTRATION**

**COMMENTS OF THE**  
**AMERICAN HERBAL PRODUCTS ASSOCIATION**

**ON THE**

**Hazard Analysis and Risk-Based Preventive Controls for Human Food**  
**Draft Guidance for Industry**

**August 2, 2024**

## **Prefatory remarks**

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as manufacturers and marketers of herbs and herbal products, including conventional foods and dietary supplements.

On February 2, 2024, the U.S. Food and Drug Administration (FDA or the “agency”) published a notice in the Federal Register<sup>1</sup> announcing the availability of revisions to parts of the draft guidance “Hazard Analysis and Risk-based Preventive Controls for Human Food” (the “Draft Guidance”). The specific proposed revisions include a significant expansion of content in the introduction of the Draft Guidance and a major reorganization of and revision to the material at Appendix 1 of the Draft Guidance, entitled “Known or Reasonably Foreseeable Hazards (‘Potential Hazards’)” (hereinafter “Appendix 1” or “the Appendix”). The comment period for these revisions was initially set to close on June 3, 2024, but was extended to August 2, 2024<sup>2</sup>.

AHPA’s members are engaged in the commerce of herbs and herbal products in the United States and in other countries, including the supply, manufacture, and sale of conventional foods using herbal and other commodities within the scope of the Draft Guidance. These comments are submitted on behalf of AHPA’s members.

AHPA’s comments solely address certain proposed changes to Appendix 1. The absence of comments on proposed revisions to any other element or section of the introduction or Appendix 1 of the Draft Guidance should not be taken to mean that AHPA agrees with such element or section, unless such agreement is specifically stated.

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<sup>1</sup> Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability, 89 Fed. Reg. 7,315 (February 2, 2024).

<sup>2</sup> Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Appendix 1; Extension of Comment Period, 89 Fed. Reg. 47,108 (May 31, 2024).

## 1. The purpose and history sections should clarify the limitations of the Appendix

AHPA greatly appreciates the addition of sections A.1.1, “Purpose of Appendix 1,” and A1.4, “How We Developed Appendix 1.” These sections greatly clarify the intended purpose and scope of coverage provided by the document. AHPA also appreciates the statement in section A1.4 that, “[a]lthough Appendix 1 is comprehensive, it is not exhaustive...” and the clarifying statement at the end of section A1.4 (also reflected in the discussion at section A1.8.3) that

...each facility has the ultimate responsibility to identify the hazards relevant to food manufactured, processed, packed, or held at that facility, such as hazards that are associated with its facility-specific history even though they are not identified as known or reasonably foreseeable (“potential”) hazards in the tables.

However, AHPA members are concerned that FDA investigators may inappropriately rely upon Appendix 1, or upon other third-party standards, as a presumptive or absolute substitute for the direct analysis of potential hazards identifiable in foods at any particular food facility. While we agree that the potential hazards and product categories identified in the Appendix may serve as a “comprehensive starting point,” as the Appendix is admittedly not exhaustive, its scope of identified known or reasonably foreseeable hazards may be both over- and under-inclusive depending on the food and food facility at issue. We are particularly concerned with overreliance on Appendix 1 for some highly diverse product categories, such as products containing herbal ingredients, because they lack a uniform set of known or reasonably foreseeable biological hazards.

For these reasons AHPA requests that FDA revise this final paragraph of section A1.4 to read as follows (changes in bold):

...each facility has the ultimate responsibility to identify the hazards relevant to food manufactured, processed, packed, or held at that facility, such as hazards that are associated with its facility-specific history **whether or not they are** identified as known or reasonably foreseeable (“potential”) hazards in the tables.

AHPA also requests the inclusion of language in section A1.1 to (i) explicitly state that tables in the Appendix do not serve as a substitute for the facility's implementation of its responsibility to identify known or reasonably foreseeable hazards and (ii) clarify that the tables used in the Appendix are not intended to supplant FDA's evaluation of whether a facility is in compliance with FDA requirements with respect to identifying potential hazards during inspection.

## **2. The “How to Use the Tables in Appendix 1” instructions should emphasize potential hazard diversity**

At section A1.8.2, the Appendix notes that some known or reasonably foreseeable hazards identified in the tables are not applicable to all products in a food subcategory. For instance, the Appendix provides by way of example that the identification of *Cyclospora* in Table 1O for two herb subcategories is overinclusive because it is a potential hazard for some, but not all, herbs in those subcategories<sup>3</sup>. However, this clarification is not included in the discussion of facility responsibility at section A1.8.3, which identifies examples of circumstances where a hazard identified in the tables may not require preventive controls. While the examples provided in this section of the Appendix are not exhaustive, the diversity of hazards within some product subcategories can lead to misunderstandings in applying the hazard analysis requirements to particular food products.

AHPA therefore requests that, in addition to the bulleted list at section A1.8.3 noting instances in which a hazard marked with an X in the tables does not require a preventive control if it has a low probability of occurring in a food product, FDA revise this section to clarify that a potential hazard marked with an X in the tables also does not require a preventive control where the potential hazard does not apply at all to the specific food product in question.

## **3. Table 1B: Greater differentiation is needed within the “tea and tea substitutes” category of beverage products**

AHPA appreciates that FDA has amended the identified biological hazards for tea and tea substitutes in Table 1B by removing the identification of *Bacillus cereus*, *C.*

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<sup>3</sup> These comments use entries from the Spices and Herbs biological hazards table (Table 1O, moved from Table 1P in the prior version) for the purpose of illustration. AHPA acknowledges and appreciates revisions made to this table and its citations, which better reflect available information and uncertainties regarding the identification of hazards in the diverse herb and spice food categories.

*perfringens*, and *S. aureus* as known or reasonably foreseeable hazards. As with other categories that include herbal products, the tea and tea substitute category includes a particularly broad range of diverse botanical ingredients that do not share the same potential hazards. Specifically, this category includes a wide range of herbal ingredients produced using entirely different growth, cultivation, and intermediate processing methods as compared to teas made from *Camellia sinensis*.

For this reason, AHPA requests the division of the tea and tea substitutes category to distinguish “tea” from “herbal tea,” at either the category or subcategory level, and further examination and justification of the evidentiary basis for foreseeable hazards specifically associated with each of these groups.

#### **4. Greater specificity and consistency is needed in “Comments”**

Tables in the current draft Appendix replace the “Example Products” column found in previous versions with a “Comments” column. Per the introductory material at section A1.5.3, the purpose of this column is to provide product examples “that may not obviously fall into” a particular subcategory. AHPA appreciates this direct statement of purpose; AHPA also greatly appreciates the immediately following paragraphs, which, again, state directly that recommendations in the tables are not universally applicable and that facilities are ultimately responsible for the identification of applicable hazards requiring preventive control. However, the comments column is not consistently used this way in the body of Appendix 1, which may lead to confusion about its purpose and subsequent misapplication.

To illustrate this issue using examples from Table 1O, the comments cell for the dried, ground, cracked, or whole spices subcategory states that it “includes” a list of 22 foods, including a number that are unambiguously spices (e.g., pepper, cayenne powder, and allspice). “Includes” comments such as these, which do not identify their contents as non-exhaustive examples, are at odds with the stated purpose of the comments field, and may open the category to a range of misinterpretations, e.g. that the list of foods in the comments column is exhaustive of the subcategory, that the listed commodities are the sole spices to which the listed foreseeable hazards apply, or that the stated spices were specifically analyzed to determine the listed potential hazards, among others.

Conversely, comments to other subcategories do not provide examples at all, instead making broad or universal statements about the group's inclusivity. For example, the pastes subcategory of seasonings includes the comment that it "Includes varieties made from a single spice or herb or from multiple spices or herbs" where it had previously listed three specific pastes as examples. 27 entries in the draft Appendix include comments that simply say the subcategory includes "all varieties." Such universal statements provide no useful information about what foods are covered by particular categories, and by their inclusion feed the perception that other comment cells providing specific examples or guidance are intended to be exhaustive. These entries further undercut the intended purpose of the column to provide examples of nonobvious foods included in particular food subcategories.

For these reasons AHPA requests the revision of entries in the comments column to better align with its intended purpose and avoid any impression of exhaustive description. Entries naming or listing any foods should state that they are examples, such as by beginning with "examples include" rather than simply "includes." Where universal statements such as "includes all varieties" are currently employed, the cell should be left blank or occupied by text signifying a lack of comments such as "None applicable."

## **5. Table 1O: References to "kaffir lime" should be updated**

AHPA notes that among the examples of products in the dried or fresh herbs subcategories of Table 1O, the draft Appendix refers to "kaffir lime," referring to the fruit of *Citrus hystrix*. The name "kaffir lime" has seen a reduction in common use over time, in part due to sensitivities regarding the etymological root and meaning of the term "kaffir" in a number of cultural contexts. AHPA therefore recommends replacing both references to "kaffir lime" in Table 1O with "makrut lime," a well-recognized common name for the same species.

## Summary

AHPA greatly appreciates the opportunity to provide comments on the proposed revisions to the Hazard Analysis and Risk-based Preventive Controls for Human Food Draft Guidance, and AHPA looks forward to its continued growth and improvement. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

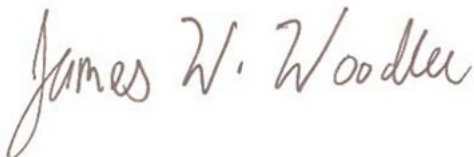
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