COVINGTON & BURLING LLP

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Memorandum

To: Food and Beverage Issue Alliance Regulatory Working Group

From: Jessica O'Connell and Sophie DeBode

Re: Revisions to Appendix 1: Known or reasonably foreseeable hazards

I. Background

On January 30, 2024, the U.S. Food and Drug Administration ("FDA") released a revised draft of Appendix 1: Known or reasonably foreseeable hazards ("potential hazards")[1], to the multi-chapter draft guidance for industry titled "Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry" ("PCHF Draft Guidance").[2]

In 2022, the Food and Beverage Issue Alliance ("FBIA") Regulatory Working Group compiled written comments and feedback for FDA regarding the 2016 Draft of Appendix 1. Members raised a variety of concerns with both the substance of Appendix 1 and the manner in which it was being used by FDA during facility inspections. The comments supplemented the original written comments submitted by FBIA and its members during the 2016 public comment period.

The revised draft of Appendix 1 incorporates certain changes in response to comments the agency received on the original draft made available in 2016,[3] including: (1) significantly revising product categories (which emphasize ingredients that go into foods rather than finished foods that can be formulated with many variations of such ingredients); (2) replacing a series of tables listing known or reasonably foreseeable process-related hazards with a discussion of such hazards; (3) providing a general discussion of food allergen hazards rather than identifying known or reasonably foreseeable food allergen hazards that could apply to multiple product categories; and (4) identifying scientific, technical, or regulatory information that the agency considered when identifying some hazards that are known or reasonably foreseeable, but less common, hazards in some food categories. It also addresses, at least partially, much of the feedback FBIA provided in its comments.

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[1] FDA, Draft Guidance for Industry Hazard Analysis and Risk-Based Preventive Controls for Human Food: Appendix 1 (January 2024) (hereafter "Appendix 1 (2024)").

[2] FDA, Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (January 2024).

[3] FDA, Draft Guidance for Industry Hazard Analysis and Risk-Based Preventive Controls for Human Food: Appendix 1 (2016).

In the sections below we describe the newly added introductory sections of Appendix 1, identify FBIA's suggestions that FDA has addressed and explain how FDA has addressed the suggestions, and then identify the suggestions FBIA provided that the agency did not incorporate.

II. Appendix 1 Introductory Sections

The updated draft of Appendix 1 includes new introductory sections which address the purpose of Appendix 1; describe terms, abbreviations, and resources; discuss the requirements for a hazard analysis; explain the agency's process for developing Appendix 1; and outline the organization of Appendix 1.[4]

a. Introductory Sections on Purpose; Terms, Abbreviations, and Resources; Requirements for a Hazard Analysis; and Development of Appendix 1

Section A1.1 explains that Appendix 1 is intended to help industry "identify known or reasonably foreseeable biological, chemical, and physical hazards for each type of food manufactured, processed, packed, or held at [a] facility" in order to determine which hazards will require a preventive control.[5]

Section A1.2 refers readers to other sections throughout the introduction to the PCHF Draft Guidance which provide information on Terms (Section III.A and III.B), Abbreviations (Section IV), and Resources (Section VI).[6]

Section A1.3 describes the requirements for a hazard analysis.[7] Briefly, it explains that to conduct a hazard analysis a firm should (1) start with the universe of all hazards that are relevant to food safety; (2) narrow this universe to the biological, chemical, and physical hazards that are known to be, or have the potential to be, associated with a facility or a type of food manufactured, processed, packed, or held at a firm's facility—the known or reasonably foreseeable hazards; and (3) through a "hazard evaluation" determine the subset of those known or reasonably foreseeable hazards that are hazards requiring a preventive control to minimize or prevent the hazard in a food and components to manage those controls as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.[8] Additional information on conducting a hazard analysis is available in Chapter 2 and Chapter 3 of the PCHF Draft Guidance.

Section A1.4 describes how the agency developed Appendix 1. This section first explains how FDA developed the food groups (and categories and subcategories within each food group). FDA consulted with subject matter experts ("SMEs") within the Center for Food Safety and Applied Nutrition ("CFSAN") as well as with SMEs within the food industry and academia.[9] These

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[4] Appendix 1 (2024) at 5-29.
[5] *Id.* at 5.
[6] *Id.* at 5-6.
[7] *Id. at 6-8.*
[8] *Id.*
[9] *Id.* at 8.

experts relied on scientific publications; published data from the FDA Recalls, Market Withdrawals, & Safety Alerts Website; published FDA databases; and unpublished FDA databases available to CFSAN SMEs. Through consultations with these experts, the agency identified 16 food groups as well as food categories and subcategories within each food group.

Section A1.4 goes on to describe the process of amending the initial draft guidance released in 2016. The agency explains that after considering public comments, it amended Appendix 1 by limiting the tables of known or reasonably foreseeable hazards to biological hazards and chemical hazards.[10] The agency removed the tables for process-related biological, chemical, and physical hazards "because process-related hazards generally are unique to each facility based on its operations and processes" and instead recommends that each facility identify known or reasonably foreseeable process related hazards for its products based on its knowledge, experience, and history of hazards associated with its operations.

FDA also flagged the limitations of Appendix 1, noting that "[a]lthough Appendix 1 is comprehensive, it is not exhaustive and only reflects data and information available as of 2022" and "Appendix 1 does not address specialty ingredients such as seaweed."[11] Further, FDA explained that "[w]hile Appendix 1 is a comprehensive starting point, 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 hazards in the tables."[12]

b. Organization of Appendix 1

Section A1.5 explains that Appendix 1 is organized around 16 food groups—Food Groups A through P.[13] Tables 1A through 1P list the most relevant food-related biological hazards in food subcategories for each food group. Tables 2B, 2C, 2D, 2E, 2G, 2H, 2I, 2J, 2K, 2L, 2O, and 2P list the most relevant food-related chemical hazards in food subcategories for specified food groups. Tables 2A, 2F, 2M, and 2N describe the most relevant food-related chemical hazards for the respective food group depending on the ingredients used.

Subsections A1.5.3, A1.5.4, A1.5.5, and A1.5.6 provide additional detail on the organization of each table, the food subcategories addressed in the tables, food categories and food subcategories that are Low-Acid Foods Packaged in Hermetically Sealed Containers ("LACF"), and infant formula and other foods for infants/toddlers.[14]

c. Background on Tables of Known or Reasonably Foreseeable Hazards

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[10] *Id.*

[11] *Id.* at 9.

[12] *Id.*

[13] *Id.* at 9-10. Food Group A: Bakery Items; Food Group B: Beverage items; Food Group C: Food Additives, Color Additives, and GRAS Substances; Food Group D: Chocolate and Candy; Food Group E: Dairy; Food Group F: Dressings, Condiments, and Dips; Food Group G: Egg and Egg Products; Food Group H: Fruits and Vegetables; Food Group I: Game Meat Product; Food Group J: Grains, Pulses, Flours, and Starches; Food Group K: Nuts and Seeds; Food Group L: Oils and Oil Products; Food Group M: Snack Foods; Food Group N: Soups and Sauces; Food Group O: Spices and Herbs; Food Group P: Food Sweeteners (Nutritive and Non-Nutritive).

[14] *Id.* at 11-13.

i. Biological Hazards

Section A1.6 provides background on the food-related biological hazards FDA assessed in Appendix 1. FDA explains that the most relevant food-related biological hazards are *Bacillus cereus, Clostridium botulinum, Clostridium perfringens, Brucella spp., Campylobacter spp., Pathogenic E. coli, Salmonella spp., Listeria monocytogenes, Shigella spp., Staphylococcus aureus*, Parasites, and Viruses.[15]

FDA notes that while many raw agricultural commodities ("RACs") that are raw materials or ingredients in food products could be contaminated with multiple known or reasonably foreseeable biological hazards, in many cases the processing for common biological hazards will also control for less common biological hazards.[16] Where this is the case, the tables only identify the more common biological hazards.

Section A1.6 then provides information on more detailed considerations regarding viruses, parasites, and Shigella spp. (A1.6.1.2); biological hazards in food subcategories manufactured using exceptionally lethal processes (A1.6.1.3); biological hazards in products produced in establishments that are under the jurisdiction of USDA (A1.6.1.4); biological hazards in infant formula and other foods for infants and toddlers (A1.6.1.5); biological hazards in food products produced using ingredients that are pasteurized or otherwise treated to control biological hazards (A1.6.1.6); and biological hazards in food products that consumers cook (A1.6.1.7).

ii. Chemical Hazards

Section A1.6 also addresses food-related chemical hazards that are most relevant to food safety: drug residues in milk, honey, and game meat; environmental contaminants (e.g., dioxins and PCBs); food allergens and substances associated with a food intolerance or food-related disease (e.g., sulfites, gluten); toxic elements in or on produce ingredients; mycotoxins in commodities such as grains, apples, peanuts, and tree nuts; natural toxins (such as hypoglycin A in ackee and cyanogenic glycosides in cassava (yuca)); pesticides in or on produce RACs; radiological hazards; and unapproved food or color additives. FDA notes that the tables address drug residues, toxic elements, mycotoxins/natural toxins, and pesticides; but do not address food allergens, substances associated with a food intolerance or food-related disease, radiological hazards, dioxins, and unapproved food or color additives.[17]

Section A1.6 then provides information on more detailed considerations regarding food allergen hazards and substances associated with a food intolerance or food-related disease (A1.6.2.2); radiological hazards, dioxins, PCBs, and toxic elements (A1.6.2.3); unapproved food and color additives (A1.6.2.4); toxic element hazards in foods for infants and toddlers, including infant formula (A1.6.2.5); and mycotoxin hazards (A1.6.2.6).

d. Process-Related Hazards and Facility-Related Hazards

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[15] This is a non-exhaustive list of known or reasonably foreseeable biological hazards.
[16] *Id.* at 14.
[17] *Id.* at 19.

FDA recognizes that because each facility is unique, process-related hazards and facility-related hazards are specific to each facility. Consequently, the agency does not include known or reasonably foreseeable process-related hazards or facility-related hazards in Appendix 1 and instead recommends that each facility identify these hazards based on its knowledge, experience, and history of hazards associated with its operations.[18] The remainder of section A1.7 lists the most relevant process-related or facility related biological (A1.7.1), chemical (A.1.7.2), and physical hazards (A.1.7.3).

III. FBIA Comments Addressed

a. FBIA Request for Inspector Training and Clarification on the Purpose of Appendix 1

FBIA suggested that FDA train inspection staff on the purpose of Appendix 1 and provide supplemental training through the Food Safety Preventive Controls Alliance ("FSPCA")[19] to further communicate to inspectors that the guidance is intended to be used as a tool for industry members to conduct their ingredient hazard analysis rather than as a checklist for FDA inspections. Similarly, FBIA also requested "that FDA emphasize the purpose of Appendix 1 guidance is to serve as a resource for industry, and not a checklist for inspectors to use. If inspectors have a separate checklist of hazards, they are seeking during inspection that must be included in a food safety plan then that should be communicated to industry in a separate document."

FDA's updates to Appendix 1 partially addresses these comments. Specifically, the introductory sections, described above, explain that the purpose of the document is for use by industry members. Section A1.1, titled "Purpose of Appendix 1," states "[t]he guidance in Appendix 1 is intended to help you identify known or reasonably foreseeable biological, chemical, and physical hazards for each type of food manufactured, processed, packed, or held at your facility. Identifying known or reasonably foreseeable hazards is one step in determining, through your hazard analysis, which hazards require a preventive control."[20] While it doesn't explicitly state that the guidance is not for inspector use, it does indicate that it is for industry use.

Appendix 1 does not mention the suggested supplemental training through the FSPCA; therefore, these suggestions were only partially addressed.

b. FBIA Request for Clarification Regarding Hazards

FBIA recommended "that the agency clarify in Appendix 1 and in inspector training that the hazards in the tables are guidelines at a category level and may not necessarily apply to every specific ingredient in that category due to differences in composition, purity, or processing within a category." Further, FBIA suggested that "the guidance should explicitly acknowledge this limitation of hazard assignment at a category level and allow for provision of an acceptable justification as to why a specific ingredient varies from the guidance."

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[18] *Id.* AT 24.
[19] FDA, *Food Safety Preventive Controls Alliance,* https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-preventive-controls-alliance (last visited May 3, 2025).
[20] Appendix 1 (2024) at 5.

FDA incorporated this suggestion into the updated Appendix 1. Section A1.8, "How to Use the Tables in Appendix 1," includes a subsection, A1.8.2, which addresses "Hazards that SMEs Recommended Be Identified as Known or Reasonably Foreseeable Hazards ('Potential Hazards') Might Not Apply to All Food Products in a Food Subcategory."[21] In this subsection, FDA recognizes that the food products in a food subcategory, and the sources of food ingredients in the food subcategories, are diverse, and that as a result, the recommendations of SMEs in the Tables in Appendix 1 may not always apply to all food products in that food subcategory.[22] FDA explains that even when a hazard evaluation leads to the conclusion that a certain hazard is not present, a firm "may find it useful to take a conservative approach" and explain the reasons for concluding that a hazard is not present as this can be useful during a firm's review of its own food safety plan or a review conducted by an inspector or auditor who may inquire as to whether a particular hazard was considered.[23]

c. FBIA Request for a Discussion of a Broader Range of Hazards

FBIA requested "that Appendix 1 acknowledge that a firm may consider a broader range of hazards than those listed in Appendix 1 to encompass all potential uses of an ingredient and that inspectors be trained that consideration and control of additional hazards is not incorrect."

The updated Appendix 1 partially addresses this comment. While it does not provide for training of inspectors to consider that there may be a broader range of hazards, it does acknowledge that the hazards identified in the document are not exhaustive. Specifically, introductory section A1.4 on "How We Developed Appendix 1" states "although Appendix 1 is comprehensive, it is not exhaustive and only reflects data and information available as of 2022. New information about hazards that could be associated with certain types of food products could become available in the future."[24]

d. FBIA Request for a Digital Interface

FBIA stated that "to be a truly useful tool in the New Era of Food Safety, we believe the hazard characterizations of Appendix 1 should be made available via a digital, online interface which enables users to search and find specific information readily. The hazard characterizations should be updated continually based on recent scientific or published sources which support the hazard rationale."

The recently released draft of Appendix 1 does not include a discussion of a digital, online interface; however, FDA does acknowledge that there may be updates needed and notes, in section A1.2, "Terms, Abbreviations, and Resources," that "the policies, recommendations, and information in these resources can change over time."[25] Additionally, FDA recommends that firms "periodically review websites listing FDA's CPGs, FDA's Guidance for Industry, FDA's

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[21] *Id.* at 27.
[22] *Id.*
[23] *Id.* at 28.
[24] *Id.* at 9.
[25] *Id.* at 5-6.

Compliance Programs and Import Alerts, and Codex Standards, Codes of Practice, and Guidelines for new or modified policies, recommendations, and information."[26]

e. FBIA Request for Rationale Statements

FBIA requested the agency "make a rationale statement available with each recommendation in Appendix 1. Where the FDA's rationale for identifying potential hazards is based on sources of qualitative or quantitative surveillance testing data, those sources should be cited and be made available to industry."

FDA partially addressed this request. Though FDA did not include rationale statements for each recommendation that it makes in Appendix 1, the agency did include a section on how the document was developed which explains more generally how the recommendations were developed.[27] This section notes that to develop the guidance the agency consulted "subject matter experts (SMEs) within CFSAN" and with a "third-party consultant tasked to identify and retain recognized SMEs within the food industry and academia to provide input during this process." Throughout Appendix 1 FDA also cites to findings and opinions of the SMEs, but does not provide specific data for every conclusion and does not further identify the SMEs or their qualifications.

f. FBIA Request Regarding *Bacillus Cereus (B. Cereus) in Corn*

FBIA noted that Table 1J, which included information to consider for potential ingredient or other food-related biological hazards for Grains, Beans and Grain Products, of the 2016 draft of Appendix 1, identifies *B. Cereus* as a potential hazard in raw grain, with corn listed as an example product.[28] FBIA asked for clarification "as to the rationale for including this hazard."

FDA did not provide a rationale, however, this concern seems to have been partially addressed as Table IJ, now titled "Known or reasonably foreseeable ("potential") food-related biological hazards for Grains, Pulses, Flours, and Starches," does not include a food category for "raw grains." However, corn is still listed with a *B. Cereus* risk for "grains, milled product." FDA did not provide any expanded rationale for identifying *B. Cereus* as a potential hazard for corn.

g. FBIA Request Regarding Flavored-Teas

FBIA noted that, in the 2016 draft of Appendix 1, Table 3B, which included "Information that you should consider for potential process-related biological, chemical, and physical hazards for Beverage Items," included a "ready-to-drink" category, Category 7b (Flavored Tea).[29] This category listed "Undeclared allergens – incorrect label" and "Undeclared allergens-cross contact" as potential hazards. FBIA requested that FDA provide a "clarification and rationale as to why this has been identified as a hazard for flavored tea, but not for other beverages in the

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[26] *Id.* at 5-6.
[27] *Id.* at 8-9 (Section A1.4).
[28] FDA, Draft Guidance for Industry Hazard Analysis and Risk-Based Preventive Controls for Human Food: Appendix 1 (2016) at 46.
[29] FDA, Draft Guidance for Industry Hazard Analysis and Risk-Based Preventive Controls for Human Food: Appendix 1 (2016) at 158.

product category" as "these hazards are not identified for a variety of other beverage categories (*e.g.*, 8a and 8b Juice-Based Ready-To-Drink)."

While FDA did not explicitly address this suggestion, the issue seems to have been addressed as Table 3B has been removed and there are no longer tables addressing process-related hazards. Additionally, a new note on food allergen hazards has been included at A1.6.2.2 which clarifies the need to identify undeclared allergen hazards across categories.[30]

h. FBIA Request Regarding Mycotoxins

FBIA members from the baking sector, citing confusion and inconsistent requests from inspectors, requested clarification on mycotoxin requirements and risks.

FDA addressed this point by adding a "note about mycotoxin hazards" at A1.6.2.6.[31] This note addresses specific mycotoxins (including deoxynivalenol) and the commodities that they are associated with. While the previous version of Appendix 1 identified mycotoxins in the food-related chemical hazards tables, the new version provides additional detail and explanation on these potential hazards while also identifying where mycotoxins present a known or reasonably foreseeable food-related chemical hazard in the relevant tables.

i. FBIA Request Regarding *Clostridium botulinum* in Fresh Cut Vegetables

FBIA Members from the fresh produce industry requested FDA amend Table 1H, which "identifies *Clostridium botulinum* as a potential hazard in fresh-cut vegetables, listing a variety of fresh-cut vegetable examples that have very different production practices associated with them and thus unique hazard and risk profiles."

FDA amended Table 1H—FDA reorganized the chart and removed certain specifications. Specifically, FDA now addresses four categories: fruits, processed fruits, vegetables, and processed vegetables, rather than 14 as in the original version of Appendix 1. Table 1H no longer addresses RTE produce products. However, the *Clostridium botulinum* identification for fresh-cut vegetables in Table 1H remains the same and does not distinguish between production practices as requested.

IV. Comments Not Addressed at All

a. FBIA Request for Suggested Controls

FBIA requested FDA develop suggested controls for recommended hazards and where applicable, suggestions on where in the supply chain the control should be implemented. This request was not addressed in the updated Appendix 1 document. However, FDA refers readers to Chapter 2 of the guidance which "briefly discusses the types of preventive controls (e.g., process controls, food allergen controls, sanitation controls, and supply-chain controls) that

[30] Appendix 1 (2024) at 20.
[31] *Id.* at 23.

could be applied when the outcome of the hazard evaluation phase of the hazard analysis is that a known or reasonably foreseeable hazard requires a preventive control."[32]

b. FBIA Request for Increased Specificity in Hazard Tables

FBIA noted that in the chemical hazard tables broad categories of contaminants are noted. FBIA stated that "more specificity is needed to determine what chemical hazards are specifically associated with a material" and requested that "FDA cite any recommendation and provide the underlying data used to make such a determination." FDA did not address this request in the updated draft. The chemical hazard tables (2B, 2D, 2E, 2G, 2H, 2I, 2J, 2K, 2L, 2O, and 2P) still list broad categories of contaminants and do not provide underlying data for the determinations.

V. FDA Request for Comments

This draft version of Appendix 1 is available for public comment. FDA encourages comments to be submitted to regulations.gov under Docket No. FDA-2016-D-2343 by June 3, 2024 (within 120 days of publication in the Federal Register) but will accept comments on guidance documents at any time.

[32] *Id.* at 7.