

August 2, 2024

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-D-2343

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Appendix 1

Dear Sir or Madam:

The undersigned members of the Food & Beverage Issue Alliance (FBIA) appreciate the opportunity to provide comments on the Food and Drug Administration's (FDA's) Draft Guidance for Industry on Hazard Analysis and Risk-Based Preventive Controls for Human Food; Appendix 1 ("the revised Appendix 1") published January 30, 2024. FBIA represents over forty allied U.S.-based food and beverage trade associations representing various parts of the supply chain, from farmers and agricultural processors, to packaged goods and retail.

On June 3, 2022, members of the FBIA Regulatory Working Group met with representatives from the Center for Food Safety & Applied Nutrition (CFSAN), the Office of Food Policy and Response (OFPR), and the Office of Regulatory Affairs (ORA) to provide input regarding the substance of the 2016 Draft Appendix 1 and the manner in which it was being utilized by FDA investigators during facility inspections. Following the meeting, FBIA and its member associations submitted written feedback providing additional information and recommendations to supplement the meeting discussion and comments submitted by FBIA members to the Agency during the 2016 public comment period.

We appreciate the substantial changes the Agency made to the revised Appendix 1 and the extent to which the Agency addressed certain of FBIA members' comments. However, we believe that revisiting and revising a few aspects of the revised draft would further strengthen Appendix 1 and more fully address industry concerns which were not addressed in previous iterations of Appendix 1. Below are specific suggestions that FBIA members have previously shared with the Agency and would like to reiterate to be considered for review.

- **Supplemental Appendix 1 Training for FDA Investigators.** The updated introductory sections of the revised Appendix 1 provide significant background on the purpose of the Draft Guidance and how it is intended to be used. The undersigned organizations support the addition of these descriptive introductory sections. However, we encourage FDA to provide additional training to inspection staff on the purpose of Appendix 1 and to provide supplemental training through the Food Safety Preventive

Controls Alliance (“FSPCA”)¹ to clarify to investigators that the Draft 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. Additionally, in such training or otherwise, we suggest FDA should clarify to investigators that a firm may consider a broader range of hazards than those listed in Appendix 1 and that consideration and control of additional hazards is consistent with the Draft Guidance.

- **Digital, Online Interface for Hazard Characterizations.** We appreciate that FDA resources are periodically updated to reflect modified policies, recommendations, and information², however, 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 would enable 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 recommendation to ensure industry has access to the most relevant, up-to-date information.
- **Provide Rationale Statements for Each Recommendation:** The revised Appendix 1 explains the Agency’s recommendation development process at a high level. It states that 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.”³ However, we request FDA provide additional information and make a rationale statement available for each recommendation in Appendix 1 in order to ensure understanding of the Agency’s positions. Further, where FDA’s rationale for identifying potential hazards is based on sources of qualitative or quantitative surveillance testing data, the undersigned organizations requests that those sources be cited and be made available to industry. For example, Table 1J, “Known or reasonably foreseeable (“potential”) food-related biological hazards for Grains, Pulses, Flours, and Starches,” lists a *B. Cereus* risk for corn in the form of “grains, milled product.” However, FDA does not provide any expanded rationale for identifying *B. Cereus* as a potential hazard for corn. The undersigned organizations request that the Agency provide clarification as to the rationale for listing this hazard because members are not aware of any historic association of *B. Cereus* with corn, and similarly for other hazards the Agency has identified.
- **Standardize Subcategory Name and Comments Across Tables.** The undersigned organizations request that FDA review subcategory naming and comments in tables 1 and 2 and ensure they are aligned across tables to avoid confusion. For example, in Table 1J – Known or reasonably foreseeable (“potential”) food-related biological hazards

¹ 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).

² FDA, *Draft Guidance for Industry Hazard Analysis and Risk-Based Preventive Controls for Human Food: Appendix 1* (January 2024) at 5-6.

³ *Id.* at 8-9 (Section A1.4).

for Grains, Pulses, Flours, and Starches – Category 6a is described as “Pulses, whole, dried” and “Includes all pulses.” While in Table 2J - Known or reasonably foreseeable (“potential”) food-related chemical hazards for Grains, Pulses, Flours, and Starches – Category 6a is described as “Pulses, Whole (dried) or processed” and “Soybean, Kidney, Pinto...” This discrepancy creates confusion for the industry about how to classify its products.

- **Specify Chemical Hazards.** As currently drafted, the Chemical Hazard Tables in Appendix 1 (Tables 2B, 2D, 2E, 2G, 2H, 2I, 2J, 2K, 2L, 2O, and 2P) identify broad categories of contaminants. FBIA members respectfully request that the Agency include additional specificity to assist industry in determining which chemical hazards are specifically associated with a material and that the Agency provide citations and the underlying data to support any such recommendation.

In conclusion, we appreciate the Agency’s significant revisions to the 2016 Draft of Appendix 1, particularly the extent to which the Agency addressed certain FBIA comments. We thank FDA for the additional opportunity to comment on the revised Appendix 1. Please do not hesitate to contact our organizations if we can provide further information in support of these comments.

Sincerely,

Alliance for Chemical Distribution
Association for Dressings & Sauces
American Bakers Association
American Frozen Food Institute
American Herbal Products Association
American Spice Trade Association
Calorie Control Council
Can Manufacturers Institute
Edible Oil Producers Association
FMI – The Food Industry Association
Independent Bakers Association
International Food Additives Council
Juice Products Association
National Confectioners Association
National Seasoning Manufacturers Association
North American Millers' Association
Peanut and Tree Nut Processors Association
Refrigerated Foods Association