Updates
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Food Safety Focus: FDA Updates Draft HARPC Guidance for Human Food

The U.S. Food and Drug Administration (FDA) recently published revisions to its multichapter draft guidance for industry on Hazard Analysis and Risk-Based Preventive Controls (HARPC) for Human Food (the Draft Guidance). 89 Fed. Reg. 7315.

More specifically, FDA revised the draft Introduction, as well as draft Appendix 1: *Known or Reasonably Foreseeable Hazards (Potential Hazards)*, to address stakeholder comments submitted on prior drafts made available in 2016. In these revisions, FDA shares additional context and information on hazards in food categories of current interest in an effort to ensure that the Draft Guidance adequately reflects FDA's current thinking on the most relevant food safety hazards.

**How HARPC Fits Into FDA Requirements**

Stemming from the Food Safety Modernization Act (FSMA), FDA's HARPC requirements are codified at 21 C.F.R. Part 117, Subpart C. To facilitate compliance with these requirements, FDA first released draft chapters of its HARPC Draft Guidance beginning in 2016. FDA ultimately intends this Draft Guidance to include the 16 chapters listed in the Table of Contents.

**FDA's Revisions to the Introduction**

FDA revised the Introduction to add new sections on trainings, resources, and references, and to expand the glossary.

- **Training.** Although specific chapters originally contained some training recommendations (such as Section 11.10 on Food Allergen Program training), the 2024 Draft Guidance now contains more robust HARPC training recommendations within the Introduction. For example, the revised Introduction now

cites FDA regulations covering required trainings and qualifications for specific food safety personnel (21 C.F.R. §§ 117.4, 117.180) and references the Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls for Human Food training curriculum, in particular. FDA emphasizes that training topics must be appropriately tailored to a food safety professional's assigned duties.
- **Resources.** FDA added a resources section listing numerous FDA Compliance Policy Guides, FDA Guidance documents, Compliance Programs, Import Alerts, Codex standards, and resources for designing validation studies, among other helpful information.
- **References.** The 2016 Draft Guidance provided separate references sections for each chapter. For the 2024 Draft Guidance, FDA has added a references section containing sources cited in all Draft Guidance chapters, along with references that FDA anticipates it will include in future chapters. References for Appendix 3, however, are not included in the Introduction and remain within that Appendix.

**FDA's Revisions to Appendix 1**

FDA intends Appendix 1 to help stakeholders identify known or reasonably foreseeable biological, chemical, and physical hazards for each type of food manufactured, processed, packed, or held at a food facility. Appendix 1 in the 2016 Draft Guidance, however, contained only tables of potential hazards related to 16 food groups with little guidance on how to consider these tables in relation to other parts of the Draft Guidance.

FDA therefore revised Appendix 1 to clarify the purpose of the Appendix in relation to HARPC requirements and address stakeholder concerns regarding specific hazard-commodity associations and FDA's use of the Appendix during inspections. The Appendix now explains that FDA developed its comprehensive, but not exhaustive, list of potential hazards after consulting FDA subject matter experts who relied on scientific publications and other published resources that FDA has made available in the Introduction of the Draft Guidance. Additional revisions include:

- Explaining the purposes, terminology, and hazard identification/evaluation recommendations related to Appendix 1. For example, FDA recommends in Section A1.3 ("Requirement for a Hazard Analysis") that manufacturers use Chapters 2 ("Conducting a Hazard Analysis") and 3 ("Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food") to narrow down the potential hazards—related to the manufacturer's food as categorized by Appendix 1—to hazards that require a preventive control.
- Clarifying the most relevant hazards and analyzing specific concerns or subjects (e.g., *Shigella* spp., exceptionally lethal processes, USDA's jurisdiction, pasteurization, radiological hazards) before providing tables of potential hazards for each of the 16 food groups. For the process-related hazards, however, FDA removed the tables discussing food group-specific hazards entirely, opting for only a general discussion of the most relevant process-related hazards.
- Tailoring potential chemical hazards to the varying ingredients that could be used within certain food categories (i.e., bakery items; dressings, condiments, and dips; snack foods; and soups and sauces). For example, if your bakery item contains chocolate and wheat flour, FDA directs you to Table 2D and 2J, respectively.
- Providing a general discussion on food allergen hazards along with other relevant process-related chemical hazards (Appendix 1 of the 2016 Draft Guidance did not provide tables dedicated to allergens).
- Citing various scientific and regulatory sources, including for less commonly known hazards identified for a range of food categories.

Appendix 1 merits a careful review and contains many additional helpful insights for industry regarding HARPC requirements.

**What's Next?**

FDA welcomes stakeholder comments regarding the revised Draft Guidance by June 3, 2024. While comments can be submitted at any time, FDA has designated this 120-day deadline so that comments may be incorporated prior to the agency beginning work to finalize the Draft Guidance.



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