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FDA Publishes List of 2023 Priority Guidance Topics

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- FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Office of Food Policy and Response (OFPR) routinely publish a list of possible new topics for guidance documents or revisions to existing guidance documents that will be a priority during the next 12 months. Guidance documents on the list are characterized as "Level 1," meaning they involve FDA's thoughts on significant new regulatory requirements or substantial changes to an earlier regulatory interpretation or policy, and complex scientific or highly controversial issues.

- On February 23, 2023, FDA released the list of draft and final guidance topics that are a priority for possible action before January 2024. FDA's 2023 list includes categories of food topics and items for prioritization as follows:

- **Allergens** – following the addition of sesame to the list of major food allergens, effective January 1, 2023, as a result of the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021, FDA may:

    - Finalize "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 5),"released November 2022;

    - Finalize "Draft Guidance on Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act," released April 2022;

    - Add additional draft guidance to the existing "Compliance Policy Guide Sec. 555.250 Major Food Allergen Labeling and Cross-contact;"

- **Dietary Supplements** – FDA may:

    - Update the existing draft guidance, "New Dietary Ingredient (NDI) Notifications and Related Issues," released October 2016, with new information on "NDI Notification and Timeframes;"

- **Food Additives** – FDA may:

- Issue draft guidance for industry on “Premarket Consultation on Cultured Animal Cell Foods,” following the November 16, 2022 completion of its first pre-market consultation for a human food made from cultured animal cells, discussed here.

- **Food Safety** – FDA may:

  - Issue draft guidance for industry on “Foods Derived from Plants Produced Using Genome Editing;”

  - Finalize industry guidance on “Inorganic Arsenic in Apple Juice: Action Level,” released July 2013;

  - Issue draft guidance for industry on “Detention Without Physical Examination (DWPE) of Fish and Fishery Products Due to the Appearance of Adulteration by Bacterial Pathogens, Unlawful Animal Drugs, Scombrotoxin (Histamine), or Decomposition – Evidence Recommended for Release of Goods Subject to DWPE and Removal of a Foreign Manufacturer’s Goods from DWPE;”

  - Finalize “Compliance Policy Guide Sec. 555.320 Listeria monocytogenes in Human Food,” released as draft guidance on February 2008;

- **Food Safety Modernization Act (FSMA)** – FDA may:

  - Update its draft guidance on “Hazard Analysis and Risk-Based Preventive Controls for Human Food; Appendix 1: Potential Hazards for Foods and Processes” at Appendix 1: Potential Hazards for Foods and Processes, Chapter 11: Food Allergen Controls, Chapter 16: Validation of Process Controls, Chapter 17: Classifying Food as Ready-To-Eat or Not Ready- to-Eat, and Chapter 18: Acidified Foods; and

  - Finalize “Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations,” released as draft guidance in January 2017.

- **Labeling** – FDA may:

  - Finalize guidance for industry on “Labeling of Plant-Based Alternatives to Animal-Derived Foods,” released in draft in February 2023, as discussed here;

  - Issue draft guidance for industry on “Questions and Answers About Dietary Guidance Statements in Food Labeling.”

  - Issue draft guidance for industry on “Use of Nutrient Content Claims for Added Sugars in the Labeling of Human Food Products,” following FDA’s September 28, 2022 announcement that it had issued a proposed rule for when foods can be labeled with the claim “healthy” that includes limits for added sugar, as discussed here.

- Other potential action items on FDA’s 2023 list are draft guidances for industry on “Insanitary Conditions at Tattoo Ink Manufacturing and Distribution Facilities” and “Preparation of Premarket Submission for Food Contact Substances (Chemistry Recommendations).”

- FDA’s plans to publish all draft and final guidance topics on the 2023 list of priorities before January 2024 are, of course, subject to change. Public comments on the list, including suggestions for alternatives or recommendations on the topics FDA is considering, be submitted to www.regulations.gov in Docket FDA-2022-D-2088. Please feel free to contact Keller and Heckman at fooddrug@khlaw.com for assistance providing FDA comments.

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