

## FDA's New Hazard Analysis Impacts Food Safety Plans

*With FDA's release of draft guidance on potential hazards, many food processors will need to update their Food Safety Plans.*

March 12, 2024 - In a much awaited federal action, the FDA released an update of its [draft guidance](#) for the Preventive Controls/Human Foods (PCHF) Rule, including the highly anticipated revised draft of [Appendix 1: Known or reasonably foreseeable hazards \(potential hazards\)](#). To comply with the new guidance, to which FDA will be inspecting, food processors will need to review and, likely, update their PCHF Food Safety Plan.

[Of particular note](#) are the listings of potential biological, chemical, and physical hazards for 16 commodity types to be assessed, as opposed to the 17 of the previous version. The 17<sup>th</sup> category, "multi-component foods," was dropped because of the complexity of food types and to stress the need to *separately* consider the ingredients in each product to determine potential hazards, rather than assessing multi-component food as a single entity.

"This will be a game changer for some food companies," said Dr. David Acheson, President and CEO of The Acheson Group (TAG). "Determining, and mitigating, the potential hazards of each ingredient of a multi-component food can be significantly more challenging and time-consuming than looking at the product as a whole, particularly when focused on FDA's updates on the process-related biological, chemical, and physical hazard analysis for each."

That updated process-related hazard guidance provides 14 specific biological, chemical and physical process-related hazards that should be considered for all foods, and controlled if identified as being reasonably foreseeable:

- **Biological.** Bacterial pathogens: presence/growth/toxin production due to survival of a lethal treatment; growth and/or toxin production due to poor time/temperature control, poor formulation control, and reduced oxygen packaging; presence due to ingredients added after process controls; and presence, growth, or growth with toxin production due to recontamination due to lack of container integrity. Environmental pathogens: presence due to recontamination from the processing environment.
- **Chemical.** Undeclared food allergens due to incorrect labelling, unintended food allergen presence caused by cross-contact, chemical hazards due to mis-formulation (e.g., sulfites, yellow #5), and process-contaminant hazards in certain plant-based foods (e.g., acrylamide).
- **Physical.** Metal, glass, hard plastic

Additionally, food processors need to be aware that there may be other process-related hazards that need to be considered for their particular foods and manufacturing setting.

Even while the guidance is in draft mode, the new approaches are being incorporated into the revised FSPCA training curriculum, and FDA will begin referencing the new guidance in inspections. "So processors should review their Food Safety Plan hazard analysis to determine if it is on track with the new guidance or needs adjustments," said Dr. Acheson, adding, "The Acheson Group (TAG) has representation on the FSPCA Training Curriculum Revision Team, along with certified PCHF Lead Instructors, so we can assist in your hazard analysis and PCHF compliance."

For more information on the guidance, read "[How the New PCHF Hazard Analysis Guidance Will Impact Your Food Safety Plan](#)," view "[Understanding the New PCHF Analysis Guidance](#)," or [contact TAG](#).

**About The Acheson Group (TAG).** Led by former FDA Associate Commissioner for Foods Dr. David Acheson, The Acheson Group (TAG) is a global food safety and public health consulting group that helps companies assess their unique situation, address gaps, and deploy best practices for operational, regulatory, and reputational risk mitigation. With in-depth industry knowledge and real-world experience, TAG's experts provide remote or onsite assistance in Recall and Crisis Management, EMP & ECP, Food Defense, Supply Chain Management, Public Health, Food Safety Culture, Infectious Disease Protections, Toxicology, and Training, to help businesses mitigate risks, improve operational efficiencies, and protect your brand. Visit TAG at [www.AchesonGroup.com](http://www.AchesonGroup.com) or call 800.401.2239

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