

**For immediate release**

## **FSMA Appendix 1 Draft Guidance to Significantly Impact Industry**

*With FDA's new release of draft guidance for "known or reasonably foreseeable hazards" which food processors must consider, many will need to update their Food Safety Plans.*

In a much awaited federal action, the FDA released an update of its draft guidance for the Preventive Controls/Human Foods (PCHF) Rule on January 30, 2024, which includes a revised draft of [Appendix 1: Known or reasonably foreseeable hazards \(potential hazards\)](#). A key component of the release is the enhanced focus on food ingredients rather than finished products. As an example, FDA removed "multi-component foods" as a commodity category, to emphasize the need to separately consider the ingredients in each of these products (e.g., sandwiches, entrees, etc.) to determine potential hazards.

The draft guidance also simplifies the process-related hazard information. Rather than dividing the biological, chemical, and physical hazards by commodity type, FDA provides a list of 14 process hazards to be considered for all foods, and controlled if identified as being reasonably foreseeable. FDA also notes that Appendix 1 is just a starting point, each facility must identify the hazards relevant to its products and processes.

"So, it is important that facilities be aware that there may be other process-related hazards that need to be considered for their particular foods and manufacturing setting," said Dr. David Acheson, president and CEO of The Acheson Group (TAG). "We recommend that you take the time to review your hazard analysis and make sure it is on track with the new guidance – and if not make adjustments."

Even while the guidance is in draft mode, the new approaches are being incorporated into the revised FSPCA training curriculum, and facilities should expect that FDA will begin referencing the new guidance in inspections.

TAG has representation on the FSPCA Training Curriculum Revision Team, along with a number of certified PCHF Lead Instructors, so can assist facilities in their hazard analysis and general PCHF compliance.

### **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, Training, and COVID-19 protections to help businesses mitigate risks, improve operational efficiencies, and protect their brand. Visit TAG at [www.achesongroup.com](http://www.achesongroup.com).