

FDA INSPECTION CHECKLIST

What to Expect When They're Inspecting

Food Industry Counsel, LLC is pleased to provide you with the most comprehensive and useful FDA Inspection Checklist available. With the passage of the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) was given the mission of overhauling the safety of the nation's food supply. The new FSMA regulations written by FDA are now coming into effect, and the agency is now aggressively enforcing its new rules during routine inspections. Within the coming years, FDA investigators will conduct an onsite inspection of every food facility in the U.S.¹

Here are FDA's new enforcement priorities during routine unannounced inspections:

- 1** | To carefully critique each company's written food safety programs and verification records to ensure they are compliant with the new FSMA requirements;
- 2** | To conduct extensive Zone 1, Zone 2, Zone 3 and Zone 4 microbiological sampling inside all food facilities to find evidence of pathogenic contamination;
- 3** | To require recalls if the percentage of FDA samples testing positive for *Listeria Monocytogenes*, *Salmonella* or other pathogens exceeds FDA thresholds;
- 4** | To compare the DNA fingerprints of any pathogens found in the facility against the >1,000,000 human isolates stored in the CDC's PulseNet database to identify any matches, and then require food product recalls if any matches are found;
- 5** | To initiate broader investigations, including criminal investigations, against food companies whose products are found to have caused human illness.

Against this backdrop, all companies should begin taking steps to prepare for their next FDA inspection. Companies can use the following checklists to ensure that they have completed the needed preparations before the FDA investigators arrive, to help effectively navigate the inspection process once the inspection is underway, and to appropriately respond to any FDA criticisms once the FDA inspection concludes.

¹ The FDA employees performing these routine onsite inspections are not referred to as "FDA inspectors," but rather as "FDA investigators." The concern with this terminology is that some FDA investigators may be more inclined to find violations since their title presumes, in advance of any facility visit, that violations have already occurred.

Pass Fda Inspection Food Guide

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