

Preventive Controls for Human Food

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Keystone Foods



Preventive Controls for Human Food

- Overview of what may be required for a facility that is currently operating under the Food Safety and Inspection Service (FSIS) regulations to meet the regulatory provisions of the Food and Drug Administration's (FDA) Preventive Controls for Human Foods (PC) regulations
 - *PC rules (including updated GMP requirements) contained in [21 CFR Part 117](#).*

Preventive Controls for Human Food

- First step towards compliance with the FDA's requirements would be to [register the facility](#)
- At least one employee trained as a Preventive Controls Qualified Individual (PCQI).
 - A list of courses meeting the requirements is available on the [Food Safety Preventive Controls Alliance](#) website.

Steps to Compliance

- PCQI would be responsible for conducting or overseeing the development of a hazard analysis for the FDA-regulated process.
 - Based on the hazard analysis, preventive controls would be identified for process controls (similar to existing CCPs on FSIS-regulated lines), sanitation controls, allergen controls and supply-chain controls.
 - GMPs during time FDA-regulated products are produced

Environmental Testing for RTE

- Regulations requires that ready-to-eat products exposed to the environment after lethality include environmental sampling as part of the preventive control program.
 - recommend adoption of the FSIS Listeria Control Program for these products as well.

Supply Chain

- If any hazards that can not be controlled by the facility are identified then these must be controlled by the supplier or producer (e.g., pesticides in agricultural crops)
 - will be required to be addressed in a Supply Chain program (Subpart G of the final rule).
 - It should be noted that this may include annual supplier audits as well as an audit prior to initial use.
 - There is no comparable component in an FSIS HACCP plan.

Foreign Supplier Verification Program

- If the facility imports any ingredients as the “importer of record,” the facility will need to address these under the [Foreign Supplier Verification Program](#) regulation.
 - In essence, the facility will need to either conduct a hazard analysis on the incoming ingredients or verify the hazard analysis conducted by the foreign supplier.
 - Additionally, there are on-going verification requirements, including audits to ensure the foreign entity maintains an equivalent level of public health protection.

Training

- All employees in the facility will require documented training that is appropriate for the job they are performing.
- This includes temporary and seasonal employees.

Records Requirements

- The preventive control program will be required to be available on-site
- All records available upon verbal or written request to the FDA within 24-hours for viewing and/or copying (very similar to FSIS records access).

By-products for Animal Food

- Human food by-products sent to animal food use must comply with GMPs during holding and distribution; e.g.
 - Must be held under conditions that will protect against contamination
 - Ensure the safety of containers
 - Avoid contamination from trash or garbage (e.g., wood from pallets, gloves, dirt from floor sweeping)
 - Identify the material through labeling(e.g., product for inedible or pet food)

Summary Of PC Requirements

- Registration of the facility;
- Training of a PCQI;
- Documented training of all employees appropriate to jobs performed;
- Hazard analysis;
- Preventive Controls Plan (including environmental monitoring program, allergen cross-contact, sanitation, and processing preventive controls);
- Supply Chain Programs, including Foreign Supplier Verification Programs, as applicable; and
- Records.

Sanitary Transportation Rule

- Preamble... while the product is on the FSIS establishment site – it is exempt, but FDA believes that once it leaves the establishment grounds, it is subject to the regulation.
- FDA said that “FSIS does not have requirements that directly address transportation operations for these foods once they leave FSIS-inspected facilities. However, FSIS has regulations that require that FSIS-regulated establishments to address sanitation during transportation, e.g., 9 CFR 416.4(d) and 9 CFR 417.2(a)(1), and this rulemaking will complement FSIS’s efforts to promote the application of sanitary food transportation practices for FSIS-regulated meat, poultry, and egg products.” (81 Fed. Reg. 20099)

Questions