FSMA
Readiness Checklist

Since signed into law on January 4, 2011, the FDA Food Safety Modernization Act (FSMA) has been the largest food policy reform focused on preventive responses to food-borne illness in recent decades. FSMA has six mandatory rules, all specifying actions that must be taken to prevent contamination at each point of the human and animal food supply chain.

The Produce Safety rule was the last rule published— in January 2022. This checklist maps out the criteria needed to be compliant. For an exhaustive timeline, click here to view the FDA's official compliance date schedule.

The following is a summary of all the rules, along with an in-depth checklist to help you ensure you are prepared for this final hurdle.

Preventive Controls for Human Foods

Preventive Controls for Animal Foods

Food facilities now need to have a written food safety plan that includes a hazard(s) analysis and associated risk-based preventive control(s) to minimize or prevent them.

There are three major requirements:

1. Adhering to HARPC
2. Adhering to CGMP updates
3. Implementing a flexible, risk-based supply chain program if the hazard analysis identifies a hazard

Hazard Analysis and Risk-Based Preventive Controls (HARPC) have replaced the traditional Hazard Analysis and Critical Control Points (HACCP) system. HARPC requires a written food safety plan that includes a vulnerability assessment, preventive controls for said hazards, and complete oversight and management of the preventive measures.

While this can be viewed as the animal food equivalent of Part 117, this is still a change to the old status quo that is worthy of note.

For the first time, animal food processors are required to comply with CGMP standards.

This rule requires animal food facilities to have a food safety plan in place that includes an analysis of hazards to determine which ones need control and risk-based preventive controls to minimize or prevent those hazards.

Standards for Produce Safety

For the first time, science-based standards are being enforced for the safe growing, harvesting, packing, and holding of fruits and vegetables. The final rule was published on November 27, 2015.

To reduce the risk of produce contamination, there are six major requirements:

1. Meeting criteria for agricultural water quality and guidance for water testing
2. Mitigating risk associated with contamination associated with raw manure and stabilized compost
3. Mitigating risks associated with sprouts, which are especially vulnerable
4. Preventing contamination of produce by domesticated and wild animal activities
5. Training farm workers and their supervisors who handle covered produce and/or food-contact surfaces on health and hygiene, as well as training related to their assigned duties
6. Meeting standards for cleaning and sanitation of physical structures and facilities

Foreign Supplier Verification

With the final rule published on November 27, 2015, the responsibility for ensuring food safety was also put on importers. The main goal here is consistency, safeguarding that foreign suppliers meet the same HARPC standards as domestic suppliers.

The rule requires importers to perform risk-based foreign supplier verification activities to verify that:

1. The food is produced in a manner that provides the same level of public health protection concerning hazard analysis and risk-based preventive controls
2. The food is not adulterated
3. The human food is not misbranded concerning ingredients and allergens

The final rule requires that an importer provide its name, electronic mail address, and unique facility identifier (UFI) recognized as acceptable by the FDA for each line entry of food product offered for importation into the United States.

Sanitary Transportation

Intentional Adulteration

The final rule on the Sanitary Transportation of Human and Animal Food was published on April 6, 2016. The rule established requirements for shippers, loaders, carriers, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of that food.

There are four major requirements:

1. Maintaining vehicles and transportation equipment
2. Adhering to transportation operations standards
3. Training carrier personnel on sanitary transportation practices
4. Maintaining records of written procedures, agreements, and training

For the first time in the U.S., the Mitigation Strategies to Protect Food Against Intentional Adulteration rule required facilities to develop a defense plan against intentional contamination of the food supply, whether by terrorism or acts committed by insiders with legitimate access, that may cause wide-scale public health harm.

All food facilities must prepare and implement a written food defense plan that includes:

1. A vulnerability assessment, including the potential impact on public health, the degree of physical access to the product, and the ability to successfully contaminate said product
2. Mitigation strategies to reduce or prevent vulnerabilities at each stage
3. Management components, including monitoring, corrective actions, and verification
4. Training and documentation

Your Company's Checklist

Logistics

Documentations required throughout the process:

- ☐ Employee training
- ☐ Hazard analysis
- ☐ Established preventive controls
- ☐ Food safety plan
- ☐ Monitoring/verification procedures
- ☐ Supply chain program
- ☐ Recall plan

What should be in your Food Safety Plan:

- ☐ Hazard analysis
- ☐ Preventive controls
- ☐ Monitoring procedures
- ☐ Corrective action procedures
- ☐ Validation and verification
- ☐ Supply chain program
- ☐ Recall plan
- ☐ Recordkeeping

Determine which FSMA requirements apply:

- ☐ Justify N/A sections in your food safety plan
- ☐ Assign a Preventive Controls Qualified Individual to oversee the plan

Hazard Analysis

Identify both known and probable hazards for each different product and process

Hazards include but are not limited to:

- ☐ Allergens – cross-contamination
- ☐ Labeling – missing/mislabeled
- ☐ Personnel – sanitation
- ☐ Storage
- ☐ Facility design
- ☐ Transportation

Determine which hazards require a preventive control

Preventive Controls

Identify critical points where contamination can be stopped at its source:

- ☐ Implement preventative controls for these points
- ☐ Create oversight procedures to ensure the Food Safety Plan is followed at these points

Schedule routine product testing to verify the effectiveness of controls

Constantly monitor the cleanliness of your facility

Checklist Continuted

Monitoring & Verification

Verify that every step in Food Safety Plan is being implemented and that frequency is being met:

- ☐ Monitor preventive controls with adequate frequency
- ☐ Confirm preventive controls are mitigating hazards
- ☐ Create KPIs to measure changes

Corrective Actions

Outline correct food safety procedures once preventive controls are defined:

- ☐ Monitor Food Safety Plan based on unanticipated problems that occur
- ☐ Update Food Safety Plan to mitigate incoming problems

Supply Chain

- ☐ Create a routine audit schedule for your suppliers
- ☐ Review the preventive controls of your suppliers
  - Construct supervisory measures to prevent and detect contamination
  - Take action if a supplier fails to meet your standards

Recall Plan

Document a step-by-step plan describing how a recall will take place:

- ☐ Alert distributors
- ☐ Assess whether you can quickly locate the source of contamination
- ☐ Create a disposal procedure

Reanalysis

- ☐ Reanalyze Food Safety Plan at a minimum every 3 years
- ☐ Adapt the plan to every new production process
- ☐ Research food safety standards for continuous updates

Centralized Database

Eliminate the need for scattered systems and paper-based processes by having leave request, scheduling, and qualification information for each employee all in one place. With everything in the cloud, valuable employee information won't get misplaced (or thrown away).