

FSMA 2019 READINESS CHECKLIST



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Since being 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 foodborne 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 Intentional Adulteration (Food Defense) rule was the last rule published—the first deadline looms in July 2019. For each rule, the compliance deadlines vary based on considerations like business size, extension allowances, and supplier category. This checklist maps out the deadlines that need to be hit in 2019. 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 Food

The Story

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule was finalized September 17, 2015 along with the Preventive Controls for Animal Food. A major shift began in the way the industry recognized food safety, transforming practices from reactive to proactive. With nearly 48 million people per year getting sick from contaminated food, it was a long time coming!

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 to said hazards, and complete oversight and management of the preventive measures.

There are also a few updates to the Current Good Manufacturing Practices (CGMPs), where some provisions that used to be nonbinding—namely education and training—are now binding. It's about holding everyone in the organization accountable. Management has to guarantee all employees who manufacture, process, pack, or hold food are qualified to perform assigned duties; despite seniority, managers are not exempt in the health and hygiene training.

Upcoming Deadlines

This was the first rule issued, so the last compliance date was **September 17, 2018**.

Dates are extended for approximately 16 months for certain facilities that: only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells; would qualify as a secondary activities farm except that they do not meet the ownership criterion; or color raw agricultural commodities.

Preventive Controls for Animal Food

The Story

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.

Upcoming Deadlines

Qualified facilities (including Very Small Businesses) need to have their preventive controls in order by **September 17, 2019**.

Dates are extended for approximately 16 months for certain facilities that: only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells; would qualify as a secondary activities farm except that they do not meet the ownership criterion; or solely engage in the ginning of cotton.



Standards for Produce Safety

The Story

For the first time, science-based standards for the safe growing, harvesting, packing, and holding of fruits and vegetables are being enforced. The final rule was published 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 trainings related to their assigned duties
6. meeting standards for cleaning and sanitation of physical structures and facilities

Upcoming Deadlines

Very Small Farms with sprouts and Small Farms with other produce are required to comply by **January 28, 2019**.

Compliance dates for certain provisions that concern written customer assurances are extended for 2 years.

Foreign Supplier Verification

The Story

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.

Upcoming Deadlines

The following are expected to comply by **March 18, 2019**:

- Importer of animal food whose Small Business foreign supplier is subject to the preventive controls (PC) requirements, but not the CGMP requirements
- Importer of human food Grade “A” milk and milk products whose foreign supplier is subject to pasteurized milk ordinance (PMO) requirements
- Importer of human food whose foreign supplier is a qualified facility (including Very Small Businesses)
- Importer of animal food whose foreign supplier is a qualified facility (including Very Small Businesses) subject to CGMP requirements

The following are expected to comply by July 29, 2019:

- Importer whose Very Small Business foreign supplier is a farm producing sprouts and eligible for qualified exemption under the Produce Safety (PS) rule
- Importer whose Small Business foreign supplier is required to comply with the PS rule
- Importer whose Small Business foreign supplier is subject to the PS Rule and eligible for qualified exemption
- Importer whose Very Small Business foreign supplier is required to comply with sprout requirements of PS rule

Compliance dates are extended for 2 years for (1) certain provisions that concern written customer assurances and (2) meeting FSVP requirements for the importation of food contact substances.

Sanitary Transportation

The Story

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

Upcoming Deadlines

There are no upcoming deadlines. The last compliance date was **April 6, 2018**.

Intentional Adulteration

The Story

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.

The last of the FSMA ordinances, the Intentional Adulteration (IA) rule was published on May 27, 2016. 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

Upcoming Deadlines

This is the big one for 2019, as it is the first compliance milestone.

Since IA was established to cover companies whose products reach many people, Large Businesses are expected to comply with the IA rule first—by **July 26, 2019**. Small Businesses are expected to follow in 2020.



Your Company's Checklist

Logistics & Scope

- Documentations required throughout the process:
 - Employee training
 - Hazard analysis
 - Established (and not 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 non-applicable sections in your Food Safety Plan
- Assign a Preventive Controls Qualified Individual with the proper food safety training/education to oversee and analyze the Food Safety Plan and the validation of preventive controls

Hazard / Vulnerability 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
- Write your Food Safety Plan, which the hazard analysis and associated risk-based preventive control(s) to minimize or prevent them

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

Monitoring & Verification

- Verify that every step in Food Safety Plan is being implemented and that frequency is being met
- Monitor preventive controls with adequate enough frequency to ensure that they are consistently being performed
- Confirm that preventive controls are actually mitigating hazards
 - Create KPIs for demonstrating that hazards have been reduced or eliminated

Corrective Actions

- Outline procedures to correct a food safety issue once preventive controls are defined
- Monitor and update Food Safety Plan as needed based on unanticipated problems that occur

Supply Chain

- Create a routine audit schedule for your suppliers
- Review the preventive controls of your suppliers to make sure the organization is in sync
- Put supervisory measures in place to prevent and detect intentional contamination
- Take action if a supplier fails to conform to 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 plan with every introduction of a new production process
- Research food safety standards for continuous updates

Final Thoughts

With the July 26 deadline for the IA rule, the cloud is your best solution for keeping a centralized system of record.

With paper, you do not get the luxury of real-time information that can help your facility prevent problems and miscommunications, exposing your organization to risk. But with cloud-based systems, you can easily audit an employee's every keystroke and movement.

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).

Enter Workloud

Workloud is our workforce management SaaS solution which offers clients an end-to-end, cloud-based employee scheduling, time & attendance, and absence management system. Workloud integrates with your human capital management and enterprise resource planning systems to create a robust platform that provides you with real-time employee data. Our qualification management system automatically generates a skills matrix to ensure that you only assign qualified workers to each position.

We can help protect your food processing facilities through transparency and skills auditing.

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